



# pharmacy & 2011 technology conference

August 27 - 30, 2011 ■ Boston Convention & Exhibition Center ■ Boston, MA

**Date:** Monday, August 29, 2011

**Time:** 10:15 a.m. – 11:15 a.m.

**Location:** Boston Convention & Exhibition Center, Meeting Level 2, Room 254 AB

**Title:** **340B and Contract Pharmacies: Past, Present and Future**  
ACPE # 0206-0000-11-515-L04-P (0.1 CEU)

**Speaker:** William von Oehsen, Safety Net Hospitals for Pharmaceutical Access

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## **Learning Objectives:**

At the conclusion of this knowledge-based program, participants will be better able to:

- Explain the history of the 340B drug discount program
- List how the government and stakeholders are responding to 340B program growth
- Identify opportunities and challenges for retail pharmacies unique to the 340B contract pharmacy program

Don't forget to obtain continuing education credit for your participation in this session. Instructions for processing your statement of credit online are included in your registration bag.

## 340B and Contract Pharmacies: Past, Present and Future

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2011 NACDS PHARMACY & TECHNOLOGY CONFERENCE

AUGUST 29, 2011  
BOSTON, MA

### Overview

- 340B Basics
- History of 340B
- 340B Program Growth
- Implications for Patient Definition
- 340B Reimbursement
- 340B Contract Pharmacy Arrangements
- SNHPA Information

### 340B Basics

- Created by Congress in 1992 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 determined by statutory formulas
- Covered entity types include, among others: hospitals, federally qualified community health centers, and hemophilia treatment centers and Ryan White clinics

### History of 340B: Pre-1992

- Medicaid rebate program was just established
- Double digit inflation of drug prices
- Congressional mentality: taxpayers should not have to pay more than “best price” in private market
- Congress created two federal drug discount programs: (1) 340B and (2) Federal Ceiling Price (FCP) program
- 340B legislative intent: to enable covered entities “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services” House Report No. 102-384(II) (Sept. 22, 1992)

## History of 340B: 1992-2000

- **Implementation challenges:**

- less than 30 days to implement
- duplicate discount mechanism
- identifying covered entities
- executing pharmaceutical pricing agreements
- lack of pricing transparency
- no funding for OPA
- what about covered entities without pharmacies?

## History of 340B: 1992-2000 (cont'd)

- **340B under attack (1994-1996):**

- link between Medicaid and 340B participation by manufacturers would be severed
- all 340B drugs would be billed at actual acquisition cost (AAC)
- 340B Coalition formed

## History of 340B: 1992-2000 (cont'd)

- **Emerging solutions:**

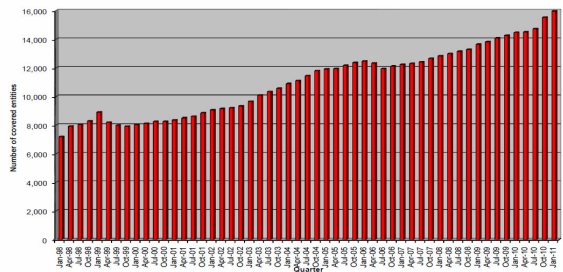
- HRSA guidances on patient definition
- contract pharmacies
- dispute resolution/audits, etc.
- Medicaid AAC billing standard revisited
- improvement of covered entity database

## History of 340B: 2000-2011

- Prime vendor program and Pharmacy Services Support Center (PSSC) established by HRSA
- Efforts to narrow patient definition
- Issuance of multiple contract pharmacy guidelines
- Passage of Affordable Care Act expanded the program and established numerous integrity measures
- Growth in number of entities
- Significant growth in 340B vendors

## History of 340B: 2000-2011 (cont'd)

Growth of 340B Covered Entity Sites (All Types)

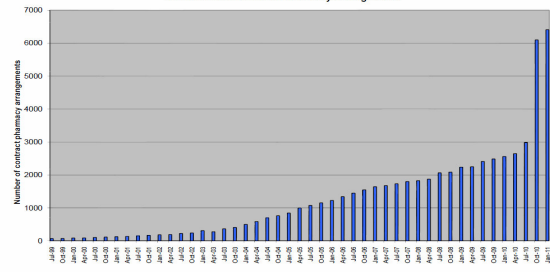


Prepared: 1/01/2011

Source: 340B database

## History of 340B: 2000-2011 (cont'd)

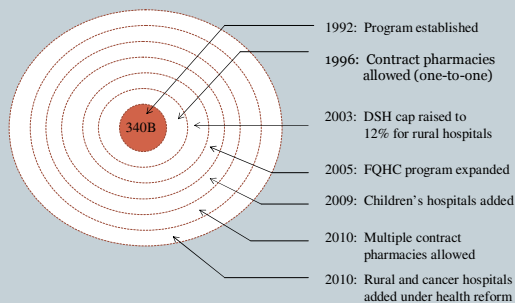
Growth of 340B Contract Pharmacy Arrangements



Prepared: 1/01/2011

Source: 340B database

## 340B Program Growth



## 340B Program Growth: Signs of Backlash

- Increased scrutiny by Congress
- Efforts to sunset program under health reform
- Exclusion of orphan drugs for newly eligible hospitals
- Government Accountability Office (GAO) asked to study whether program should be expanded
- Pharmaceutical industry and National Community Pharmacists Association (NCPA) raising questions about 340B
- Third party payers are ratcheting down reimbursement for 340B drugs

## Implications for Patient Definition

- Battleground likely to shift to definition of patient
- GAO report could be influential
- Lessons from HRSA's proposed changes in 2007
- Allegations of diversion are weak in the absence of concrete evidence based on audits

## Implications for Patient Definition: SNHPA's Position

- 340B can be used to fill prescriptions written within the walls of the hospital
- Prescriptions written outside walls of the hospital should not be filled with 340B drugs unless they fall within two limited exceptions
  1. follow-up care
  2. contractual care
- Available on SNHPA's website for both members and non-members are a set of "Principles" that SNHPA developed to assist with complying with patient definition requirements

## 340B Reimbursement: Duplicate Discounts

- Federal law protects manufacturers from being subjected to both a 340B discount and Medicaid rebate on the same drug
- No similar legal protection outside of Medicaid
- Manufacturers pay rebates to third-party payers and pharmacy benefit managers (PBMs) in exchange for the manufacturers' drugs being placed on the payers and PBMs' formularies
- Payment of a PBM rebate on a 340B drug may appear like a duplicate discount from a business perspective, but manufacturers have no legal protection against such risks

## 340B Reimbursement: Declining Rates

- Increasing number of Medicare Part D plans, Medicaid managed care organizations, commercial payers, and their PBMs are lowering payments to 340B provider-owned pharmacies and contract pharmacies
  - Some require providers to pass along entire 340B savings
- According to the Hemophilia Alliance, TRICARE has excluded hemophilia treatment centers from its provider network

## 340B Reimbursement: NCPDP's Role

- NCPDP develops standards and guidance for electronic exchange of pharmacy information
- NCPDP developed the means to identify 340B claims at both point of sale and retrospectively as part of NCPDP Telecommunication Standard
  - Voluntary for PBMs and pharmacies
  - Intended to enable payers and PBMs to exclude 340B claims from rebate requests
- SNHPA and other 340B provider organizations have requested temporary suspension of NCPDP's 340B transparency standards

## 340B Reimbursement: Impact

- **SNHPA's Position:** Below-market rates undermine the purpose of the 340B program except when paid by state Medicaid agencies
- **Congressional Intent:** "[T]o enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. 102-384, pt.2, at 12 (1992)
- **HRSA's Perspective:** "[If providers] were not able to access resources freed up by the drug discounts when they . . . bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them" to enroll or remain in the program. HRSA, Hemophilia Treatment Center Manual (July 2005)

## 340B Reimbursement: Additional Concerns

- Federal law prohibits community health centers (CHCs) from providing discounts to entities, including private payers, that are able to pay a CHC's full fee schedule price
- PBMs' reductions of 340B reimbursement rates are far in excess of the manufacturer rebates that PBMs are not receiving for 340B claims
- Skeptical that lower rates are resulting in reduced premiums for the insured
- Rates should not be unilaterally reduced. There should be negotiation between the parties.

## 340B Reimbursement: Solutions

- **Legislative options**
  - Enact an anti-discrimination law protecting reimbursement for 340B pharmacies
  - Give 340B pharmacies an antitrust exception that would allow them to collectively bargain
- **Non-legislative options**
  - Request Congressional investigations of payers and PBMs' reimbursement practices
  - Send letters to payers and PBMs
  - Form pharmacy services administrative organization that could negotiate contracts on behalf of 340B pharmacies
  - Educate entities on their right to negotiate contracts

### 340B Contract Pharmacy Arrangements: Key Issues

- Pre-contracting tasks
- Getting started with the contract
- 340B requirements
- Protecting against liability
- Replenishment
- Fee structure
- Indigent patients

### 340B Contract Pharmacy Arrangements: Pre- Contracting Tasks

- Multiple contract pharmacies and/or supplementing in-house pharmacy?
- What kind of contract pharmacy arrangement?
  - Network of multiple pharmacies?
  - On-site pharmacy?
  - Mail order?
  - Exclusive arrangement or will competing pharmacies be included?
- Rely on contract pharmacy management company?
- 340B replenishment or point-of-sale dispensing?

### 340B Contract Pharmacy Arrangements: Pre- Contracting Tasks (cont'd)

- Factors to consider
  - Where do entity's patients get their prescriptions filled?
  - Are your pharmacy sites convenient?
  - Consider covered entity's 340B experience and interest
  - Integrity issues
  - Potential liability
  - Future of 340B program
- Encourage covered entity partner to establish internal work group
- Schedule regular calls with work group
- Whose wholesaler will be used?
- Implementation timeline

### 340B Contract Pharmacy Arrangements: Getting Started

- Who will be the parties?
  - Three-party agreement if administrator is involved?
- What will be the scope of services?
- What will be the base agreement?
  - Pharmacy's?
  - Management company's?
  - SNHPA's model agreement?
- Does agreement comply with basic 340B requirements?
- What does the pharmacy and administrator expect to be paid?

### 340B Contract Pharmacy Arrangements: 340B Requirements

- Governing guidelines published by HRSA on March 5, 2010 (75 Fed. Reg. 10272)
- Specification of contract pharmacy arrangement
  - Multiple contract pharmacies, and/or
  - Supplementing in-house pharmacy
- 12 essential compliance elements
- Covered entity oversight
  - Independent audits
  - Self-report when violation discovered
- HRSA's "model contract" appendix
  - Beware that some provisions should be modified

### 340B Contract Pharmacy Arrangements: 340B Requirements (cont'd)

- HRSA's model language about covered entity maintaining title to 340B drugs is inconsistent with replenishment model
- Covered entity should feel free to develop patient verification systems other than those described in model contract
- Relying on a list of prescribers is risky if they prescribe for non-hospital patients
- Most contract pharmacies carve out Medicaid prescriptions to avoid duplicate discounts

### 340B Contract Pharmacy Arrangements: Protecting Against Liability

- Indemnification
  - In case of pharmacy mistake or negligence
- Specific refund provisions
  - Pharmacy can be contractually required to issue refunds if at fault
- Fraudulent billing
  - Billing 340B drugs under pharmacy's billing number raises fraud issues
  - HRSA condones this practice as long as it doesn't breach payer contract
- Part D true out-of-pocket (TrOOP) issues
  - Waiver of co-pay may count towards TrOOP if by pharmacy but not if by covered entity

### 340B Contract Pharmacy Arrangements: Replenishment

- NDC replenishment process should be described
  - 100% or selective replenishment?
  - Provide initial 340B stock for pharmacy?
- Set limits on replenishment wait times for drugs that are slow-moving, discontinued or on back order
- Periodic reconciliation
  - Quarterly or every 6 months
- Chain drug stores have advantage over independent pharmacies because they can aggregate volume across pharmacies to minimize problem of slow-moving drugs for covered entities

### 340B Contract Pharmacy Arrangements: Fee Structure

- Dispensing fee and/or admin fee
- Flat fee versus percentage-based fee
- **Must comply with anti-kickback laws**
  - OIG Advisory Opinion No. 98-15 (12/2/98)
  - Percentage-based fees are higher risk
  - Consider placing a cap on such arrangements
  - May need fair market value analysis
- PSSC guidance raises concerns that percentage-based arrangements may divert benefit to non-340B entities

### 340B Contract Pharmacy Arrangements: Indigent Patients

- Will contract pharmacy be required to fill prescriptions for indigent patients?
- Will pharmacy be required to apply sliding fee schedule?
- Refer patient back to covered entity for enrollment in patient assistance program (PAP)?
- Will covered entity issue indigent patient a card or voucher?
- Ask prescriber to order a less expensive drug?
- Other options?

### SNHPA: Become Corporate Partner

- Regular updates on key 340B issues
- Complimentary technical assistance on business opportunities and compliance
- Invitations to regional roundtables
- Significant discounts on conference exhibiting
- Drug Discount Monitor [www.drugdiscountmonitor.com](http://www.drugdiscountmonitor.com)
  - Discounted rates for corporate partners
- For more details, contact Lee-Anne Gabrielli at [lee-anne.gabrielli@snhpa.org](mailto:lee-anne.gabrielli@snhpa.org) or (202) 552-5856

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