

NCPA's 113th Annual Convention
and Trade Exposition
Nashville, October 8-12



INDEPENDENT COMMUNITY PHARMACY: OPPORTUNITIES WITH THE 340B PROGRAM

Drug
Discount Monitor


Bill von Oehsen

President and General Counsel, SNHPA

Editor-In-Chief, Drug Discount Monitor

william.vonoehsen@snhpa.org



NCPA 
MEET. LEARN. SUCCEED

DISCLOSURE

Bill von Oehsen does not have any actual or potential conflicts of interest in relation to this program.

LEARNING OBJECTIVES

1. Discuss the 340B program and the potential role for the community pharmacy.
2. List key aspects of a 340B relationship between the entity and pharmacy.
3. Identify two potential barriers to providing for 340B and possible strategies to overcome these barriers.

ABOUT SNHPA & DRUG DISCOUNT MONITOR

- ✘ Represents over 700 hospitals in the 340B program – all hospital types
- ✘ At the table since inception of program in 1992
- ✘ Collaborating with NCPA and other pharmacy groups to promote 340B contract pharmacy arrangements
- ✘ Publishes the Drug Discount Monitor:
www.drugdiscountmonitor.com
 - + Comprehensive coverage of 340B, Medicaid rebates, Part D, PAPs, drug pricing litigation & investigations

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

CONGRESSIONAL INTENT

- ✘ Program was created for entities that serve a high proportion of indigent patients
- ✘ Program applies to all patients regardless of payer status
- ✘ “[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)
- ✘ Program would not survive if limited to uninsured and Medicaid patients

Congressional Intent (cont'd)

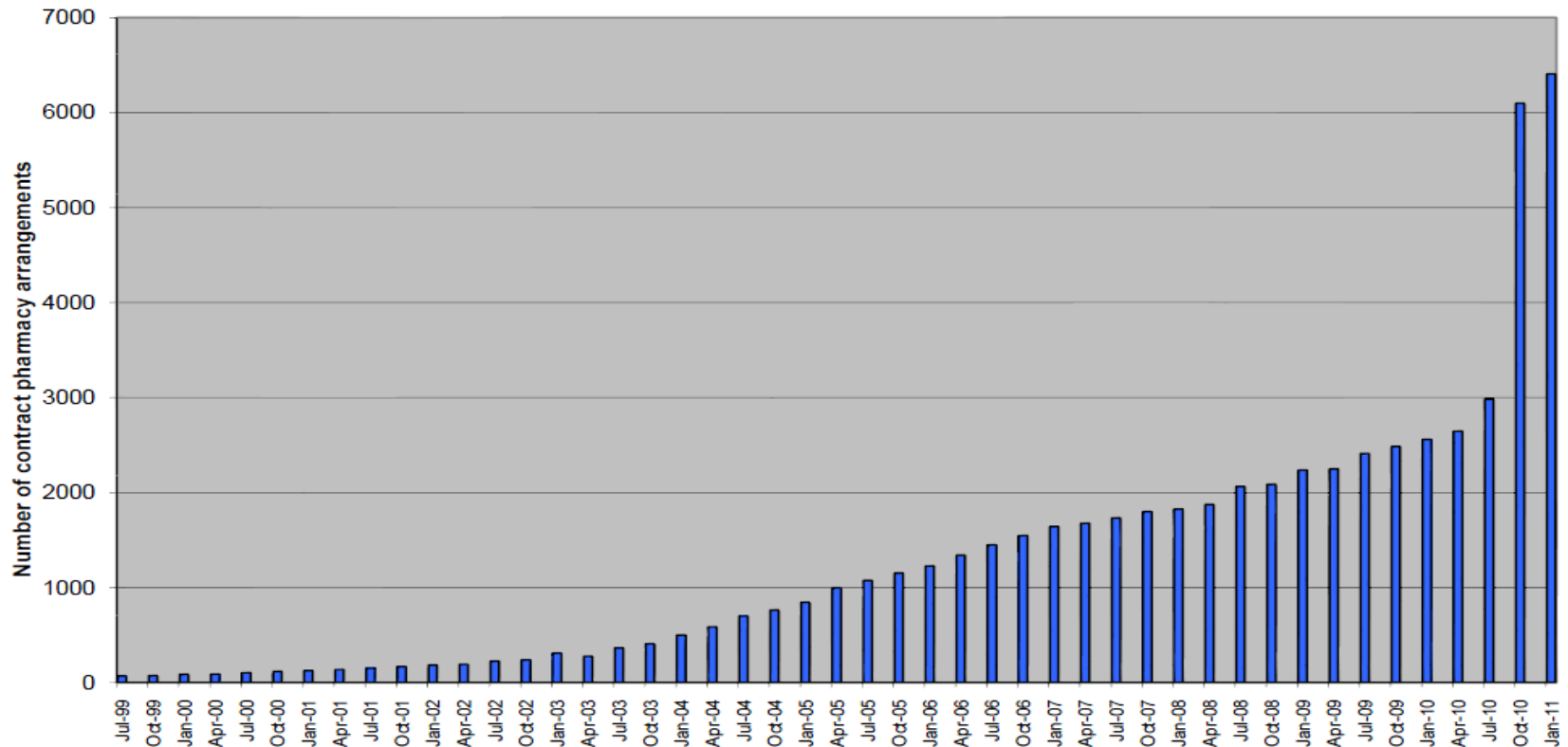
- ✘ Safety net hospitals face serious economic challenges
- ✘ Shrinking number of non-profit hospitals
 - + Hospitals are closing or are being forced to sell to for-profits
- ✘ Hospitals continue to struggle despite health reform
 - + Uncompensated care costs and percentage of uninsured patients still on the rise
 - + Reimbursement still insufficient despite Medicaid expansion and creation of health exchanges
- ✘ Contract pharmacy arrangements can help ensure survival for both independent pharmacies and hospitals

OPPORTUNITIES FOR COMMUNITY PHARMACIES

- Contract pharmacy model: pharmacy serves as dispensing and billing agent of covered entity
- Limitation of one contract pharmacy per covered entity was removed in 2010
- Most contracts are with community pharmacies – but pharmacy chains are aggressively pursuing such arrangements
- 340B providers are willing to pay for medication therapy management, formulary management, and increased inventory management responsibilities

CONTRACT PHARMACY ARRANGEMENTS CONTINUE TO INCREASE

Growth of 340B Contract Pharmacy Arrangements



Prepared: 1/01/2011

Source : 340B database

340B CONTRACT PHARMACY ARRANGEMENTS: KEY CONTRACTING ISSUES

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

340B CONTRACT PHARMACY ARRANGEMENTS: GETTING STARTED

- ✘ Who will be the parties?
 - + Rely on contract pharmacy management company?
- ✘ What will be the scope of services?
- ✘ What will be the base agreement?
 - + Pharmacy's?
 - + Management company's?
 - + SNHPA's model agreement?
- ✘ 340B replenishment or point-of-sale dispensing?
- ✘ 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)
- ✘ 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
 - + Parties should feel free to develop alternative patient verification systems

340B CONTRACT PHARMACY ARRANGEMENTS: PROTECTING AGAINST LIABILITY

- ✘ 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
- ✘ 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
- ✘ Be prepared for inventory swells caused by replenishment model

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
- ✘ Program 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?

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
- ✘ NCPDP developed standards to identify 340B claims at both point of sale and retrospectively as part of NCPDP Telecommunication Standard
- ✘ SNHPA and the 340B provider community view these efforts as undermining the purpose of the 340B program

CONTACTS

Bill von Oehsen

President/General Counsel
(202) 872-6765

william.vonoehsen@snhpa.org

Ted Slafsky

Executive Director
(202) 552-5860

ted.slafsky@snhpa.org

Tom Mirga

Editor, Drug Discount Monitor
(202) 552-5853

Tom.mirga@drugdiscountmonitor.com

Kara Stencil

Director of Government Relations
(202)552-5852

Kara.stencil@snhpa.org

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340B CONTRACT PHARMACIES: A HEALTH-SYSTEM LEADER'S PERSPECTIVE AND EXPERIENCE

Clint Peevy, Pharm.D.
System Director of Pharmacy Services
Baptist Health
Montgomery, Alabama

DISCLOSURE

Clint Peevy does not have any actual or potential conflicts of interest in relation to this program.

BAPTIST HEALTH: BACKGROUND

- ✘ A three-hospital system serving patients in south central Alabama
- ✘ Two system hospitals are enrolled in 340B:
 - + Baptist Medical Center-South (BMCS)
 - + Baptist Medical Center-East (BMCE)
- ✘ Current arrangements:
 - + BMCS: Contracted with Baptist Tower Pharmacy, a retail pharmacy owned by the for-profit branch of the system
 - + BMCE: Contracted with Adams Drugs, a 9-store independent pharmacy chain located in Autauga, Elmore, and Montgomery counties

BAPTIST HEALTH: 340B PROGRAM MANAGEMENT AND COMPLIANCE

- Baptist Health utilizes an external vendor's software to manage our 340B program and monitor for program compliance
- Chose one of this vendor's programs to manage contract pharmacy
- The vendor provided templates we used to craft the agreements

BAPTIST HEALTH: PHARMACY SELECTION CRITERIA

- ✘ Why did we select these pharmacies?
 - + BMCS has had a contract with Baptist Tower Pharmacy for 2 ½ years
 - + BMCE: Selected Adams Drugs because:
 - ✘ Relationship with pharmacy manager: I was friends with and a former pharmacy school classmate of the pharmacist
 - ✘ Independent pharmacy versus national chain: The independent pharmacy is easier to navigate as there is less bureaucracy.
 - ✘ Local firm: Easier to negotiate with a local pharmacy, and desirable to contract with a pharmacy that would keep its “dollars” in our communities and provide patient care opportunities in a potentially unique manner

BAPTIST HEALTH: FEE ARRANGEMENTS

- The vendor's software is used to manage the entire contract pharmacy process, from prescription fill to invoice generation
- Contract pharmacies are paid a fair fee for their dispensing services and receive medications via a ship to/bill to arrangement with our pharmaceutical distributor
- Software fees are managed via invoices they generate
 - Pharmacies are invoiced by - and pay - the vendor
 - Invoicing process is transparent
 - Exclusive account manager helps troubleshoot
- Pharmacies' fees are structured to help them realize a better-than-average prescription payment rate and cover any rebate monies they may lose by no longer purchasing from their pharmaceutical distributor

BAPTIST HEALTH: OUTCOMES

- ✘ These contracts have enabled Baptist to:
 - ✘ Provide a structured care program for employees with diabetes
 - ✘ Continue Baptist's Care Advisor program which provides free medical care, tests, and medications to indigent patients
 - ✘ Work with local community pharmacies to improve the care and access of our region's patients
- ✘ Creates new revenue streams for the covered entities, providing essential funds to allow us to expand hospital pharmacy services, add pharmacist FTEs, and purchase programs to enhance patient safety and improve patient outcomes.

BAPTIST HEALTH: NEXT STEPS

- ✘ Within the next month or so, we will:
 - + Add the remaining Adams Drugs locations, based on geographic proximity to our hospitals (all Adams Drugs pharmacies are within < 10 miles from one of our hospitals; two located across the street from one of our hospitals).
 - + Add Parks Drugs, an independent pharmacy with two locations near BMCS, providing services to rural areas and towns and disadvantaged areas of Montgomery
 - + Launch a marketing campaign to increase the use of contract pharmacy for employees (already underway with employee diabetes care program)

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340B OPPORTUNITY KNOCKS – SHOULD YOU ANSWER?

Shelley Bailey
Central Drugs

DISCLOSURE

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CENTRAL DRUGS AND 340B

- Who Are We?
 - 108-year-old retail pharmacy with a focus on serving individuals living with HIV
- Who We Serve?
 - Persons living with HIV
- 340B Start
 - 2002 contract pharmacy for a local FQHC
- Outcome
 - Poorly managed by both Central Drugs and FQHC



*Image courtesy of Gary D. Lundgren

340B WITH AIDS DRUG ASSISTANCE PROGRAM (ADAP)

- ✘ 2009 State ADAP decided to move to mail-order 340B solution
 - Prior to one-to-many 340B options
 - ADAP clients as a percent of Central Drugs revenue ~ 40%



*Image courtesy of Central Drugs

GRASSROOTS POLITICS

- Clients
- Local AIDS Service Providers
- NCPA
- Lobbyist
- Legal Council

 **THE LUND REPORT**
Unlocking Oregon's Healthcare System

CAREAssist Turns to Mail Order to Reduce Deficit

The program, which provides medications to HIV positive patients, faces a \$2.1 million budget hole this biennium
By: Diane Lund-Muzikant

 July 7, 2010 -- As the state deficit spirals out of control, a program that provides medications to HIV positive patients is the latest to take a hit. With a \$2.1 million budget hole looming, at least a portion of that money could be saved if people are willing to receive their prescription medication in the mail, rather than going to a pharmacy.

<http://www.thelundreport.com> 7/7/2010

340B FACT FINDING

- NCPA
- Pharmacy Buying Group (legislative assistance)
- Interviews colleagues in industry
 - Desired outcome to determine appropriate dispensing fee
- Pharmacy Services Support Center Consultants (PSSC)
 - 800-628-6297 <http://pssc.aphanet.org> (program has changed since dates of use)

340B CONTRACT RESPONSE WORK

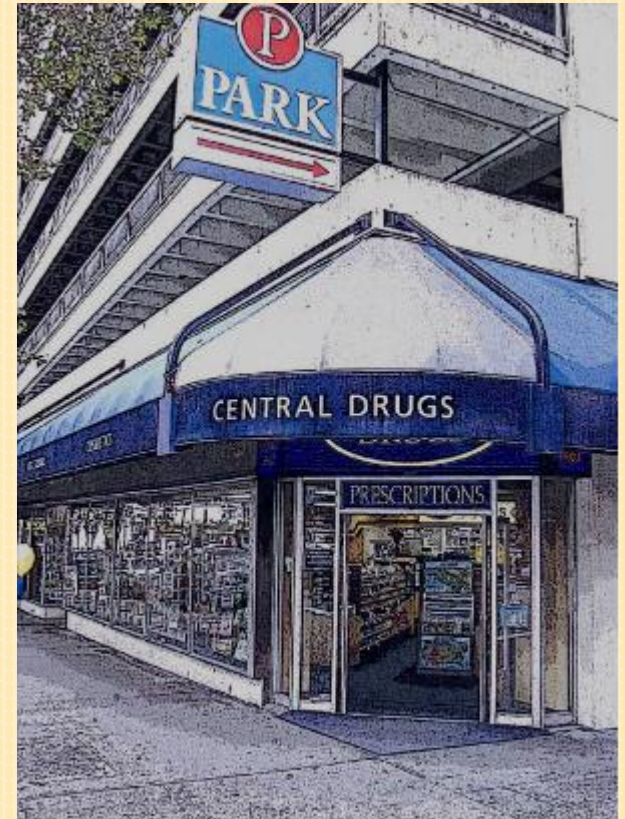
- Each Contracting experience will be different
- RFP completion took four months
 - Cost to Dispense critical component of RFP
- 340B Work and Time Management
 - Pharmacy Remodel & New Pharmacy System installation



*Image courtesy of Shelley Bailey

JUNE 2011 “GO LIVE” CHALLENGES

- State added additional 35 pharmacies
- Cannibalization of profit of existing client base
- Impacts of “Virtual Replenishment” on Cash Flow
 - Weekly Replenishment Challenges
- Working with a 340B Administrator
- Impact of Acquisition Pricing on non-340B portions of business with Wholesaler



*Image courtesy of Central Drugs

JUNE 2011 “GO LIVE” ADVANTAGES

- Achieved goal of keeping clients at pharmacy
- Assist State and Agency achieve goal of operating a 340B direct purchase program
- New Clients ~ 1 per day
- New Clients who are “carved out” of 340B Program
 - Medicaid Fee-for-Service and Medicaid Managed Care
- Increase pass-through revenue for pharmacy
- Increase 340B knowledge & awareness for future opportunities

FUTURE OPPORTUNITIES

- HRSA Office of Pharmacy Affairs (OPA) to search covered entities in your area
- <http://opanet.hrsa.gov/opa/CESearch.aspx>
- Increased interest in 340B by payers such as Managed Medicaid
- Statewide and National level 340B contracts being signed by PSAOs



*Image Courtesy of Central Drugs

DO YOU ANSWER THE DOOR? *IT DEPENDS*

- Know your business
 - Third-Party and Cash average dollar profit
 - Estimate average amount of new clients
- Know your cost-to-dispense
- Negotiate pre-plenishment of inventory or frequent replenishment for virtual 340B models
- Anticipate how 340B program will impact your existing wholesaler purchases
- Proactively look for opportunities



THANK YOU

Shelley J. Bailey

shelley@centraldrugspdx.com
503-780-8303



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340B Opportunity Knocks – Should You Answer?

Susan Sumrell

Assistant Director, Regulatory Affairs
National Association of
Community Health Centers

DISCLOSURE

Susan Sumrell does not have any actual or potential conflicts of interest in relation to this program.

America's Voice for Community Health Care

The NACHC Mission

To promote the provision of high quality, comprehensive and affordable health care that is coordinated, culturally and linguistically competent, and community directed for all medically underserved people.

HISTORY OF COMMUNITY HEALTH CENTERS

- Roots in Civil Rights Movement
- Unique Public Private Partnership
- Health Centers serve a two fold purpose
 - To be ***agents of care*** to communities with too little of the same
 - To be ***agents of change*** and give communities control of their health care

WHAT IS A COMMUNITY HEALTH CENTER?

- Five basic characteristics
 - Located in **high need** areas
 - Provide **comprehensive** health and related services
 - Open to all, **regardless of ability to pay** with charges based on income
 - Governed by **community boards** to assure responsiveness to local needs
 - Held to strict **performance and accountability standards** for administration, clinical, and financial operations

Who Do Health Centers Serve?

- × Health Care Home for over 20 Million Americans
- 1 of 4 low income uninsured persons (7.8 million)
- 1 of 8 Medicaid/CHIP recipients (7.1 million)
- 1 of 4 low income children (7.3 million)
- 1 of 4 low income births (500,000)
- 1 of 7 rural Americans (8.8 million)
- 1 of 4 low income people of color (12.8 million)
- 900,000 farmworkers and 1 million homeless

HEALTH CENTERS AND 340B

- FQHCs are “covered entities”
- Majority of health centers participate in 340B Program
- Provides increased access to prescription drugs for health center patients
- Must comply with both 340B and Section 330 requirements



WHAT ARE HEALTH CENTERS LOOKING FOR?

- ✘ Understand, and preferably embrace, the health center's mission
- ✘ Understand that the pharmacy is working as the agent of the health center, and that the health center has final say regarding pricing and service delivery issues
- ✘ Understand that the health center has ultimate responsibility for compliance

WHAT ARE HEALTH CENTERS LOOKING FOR?

- ✘ Understand federal health center requirements under federal procurement standards
- ✘ Understand that both health center and pharmacy must operate under HRSA contract pharmacy guidelines
- ✘ Be willing to provide services for a fair and reasonable price, taking into consideration all services provided. Revenue sharing/percentage compensation arrangements are not favored.

NACHC 340B RESOURCES

Understanding the 340B Program:
A Primer for Health Centers (May 2011)

NACHC Study: Benefits of the 340B Drug Pricing
Program for Health Centers (May 2011)

www.nachc.org

THANK YOU!

Any
Questions?



CONTACT INFORMATION

Susan Sumrell

NACHC

ssumrell@nachc.org

202.997.5922

Roger Schwartz

NACHC

rschwartz@nachc.org

202.296.3800

QUESTIONS TO ASK CONSIDER RE:340B:

- ✘ 1) How much am I currently making on this book of business (if the 340B relationships you are pursuing will mainly impact your current clients)?
- ✘ 2) How many new clients will I approximately gain through this relationship?
- ✘ 3) What dollar amount of dispensing fee will I accept?

-
- ✘ 4) Will I accept a flat rate dispensing fee for all medications or will brand and generic be paid at different dispensing fee amounts?
 - ✘ 5) Will there be a generic carve-out in this 340B program?
 - ✘ 6) How will inventory be handled?
 - + Do I have to store it separately or is it virtually replenished?

-
- ✘ Will I be pre-plenished with inventory or replenished after I have sold through a complete bottle of the NDC?
 - ✘ If I am being virtually replenished, how frequently?

-
- ✘ 7) How frequently are true-ups handled (the term for paying pharmacies for products that they have sold under a 340B program but where the usage of the product does not reach a complete package size and accordingly cannot be virtually replenished)?
 - ✘ At what rate will I be paid per unit for the items that I am “trued up.”?

-
- ✘ 8) Does my staff have to COB bill eligible transactions or are these transactions handled at the pharmacy switch level? Do I have to pay a second switching fee for these COB claims?
 - ✘ 9) How will my 340B sales impact my relationship with my wholesaler?

-
- ✘ 10) If you are buying from a wholesaler who uses a tiered volume system to determine pricing, will your overall book of business (non-340B) shrink, increasing your acquisition pricing of your non-340B PRODUCT?
 - ✘ 11) How will the 340B program impact the Brand or Generic Purchasing requirements, if you purchase from a wholesaler who uses this type of pricing strategy