Tips for Optimizing 340B Programs and Finding the Profit for Your Pharmacy

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Disclosure Information

Continuing Education : 340B Daniel Neal

Daniel Neal is an employee of Cardinal Health. The conflict of interest was resolved by peer review of the slide content.

Learning Objectives

- Discuss the basics of 340B for the pharmacy and how to determine contract “fit.”
- Explain the importance of a contract pharmacy to 340B hospitals and their patients.
- Describe the flow of patients and product through the 340B system.

Disclaimer

Continuing Education : 340B Daniel Neal

The views expressed in this presentation are those of the speaker, and not necessarily those of Cardinal Health or any other entity, group, or individual.

Introduction

Daniel Neal is 340B Product Leader for Cardinal Health. In this role, Mr. Neal is responsible for development of Cardinal Health's 340B marketing strategies, market analysis, and solutions. In addition, he oversees Cardinal Health's 340B Consulting practice.

Mr. Neal has spoken at numerous trade shows, industry events and educational settings and published articles on 340B compliance and regulatory change impact.

Mr. Neal joined Cardinal Health in 2009. Since then, he has worked in the areas of 340B operations and implementations, as well as managing 340b remediation projects.

Course Purpose

A survey of the 340B program, beginning with the history of the program and a review of its current scope. The roles of the numerous governmental and non-governmental stakeholders will be discussed, along with definitions of key program concepts and terms. A substantial portion of the time will be spent in detailed analysis of how 340B fits into the retail pharmacy setting through "contract pharmacy" arrangements. The course ends with discussion regarding current and likely future political, regulatory and industry activities affecting the program.

Course Outline

- Review the history and scope of the 340B program
- Explain basic program mechanics, including pricing calculations, duplicate discounts, covered entities, patients, and drugs
- Explain role of stakeholders, include Apexus (PVP) and HRSA/OPA
- Define ‘contract pharmacy’ and list drivers of recent program growth
- Describe HRSA/OPA role and registration process and how to use database to find entities
- Explain key decision in process: self-management or 3rd-party management
- Articulate role of technology vendors and administrators
- Discuss operational, financial, and regulatory compliance approaches
- Explore key financial risk factors for retail pharmacies
- Describe growing trend to pursue “non-retail” contract pharmacy models
- Analyze current and future political, regulatory, and systemic issues impacting contract pharmacy

340B Program History

Definition, history and intent of the 340B drug pricing program

What is 340B?

- 340B is federally-administered drug pricing program for so-called "covered entities" (CE)
- 340B allows for purchase of drugs at or below a statutorily-defined "ceiling price"
  - This pricing is realized at the time of purchase

- 340B is **not** a rebate program (i.e., Medicaid drug rebate)
- 340B is **not** the same as a Patient Assistance Program (PAP)
- 340B is **not** an insurance program

340B Program History

- 340B was enacted in 1992 as part of Public Law 102-585, the Veterans Health Care Act (VHCA)
- The program is named for Section 340B of the VHCA
- 340B is managed by the Office of Pharmacy Affairs (OPA), which is part of the Health Resources and Services Administration (HRSA)
- Manufacturers participating in the Medicaid program must also offer 340B pricing
  - Pharmaceutical Pricing Agreement (PPA)

340B Program History (Cont.)

- The 340B program's original scope was to limit the cost of covered outpatient drugs to certain federal grantees and designees
- Before the final bill passed, disproportionate share hospitals (DSH) meeting certain criteria were added to 340B
- Today, the majority of 340B purchases are made by hospital entities, though many other types of entities participate in the program

340B Program History (Cont.)

- 340B limits the cost of covered outpatient drugs sold to 340B covered entities by defining a so-called 'ceiling price' for covered drugs
- Acknowledging that many of the grantees and designees had limited or no pharmacy services, contract pharmacy (CP) arrangements were permitted under HRSA guidance, but only on one-to-one basis
  - Note - CP arrangements are NOT addressed in the 340B statutory language – governance issued through guidance, rather than law/formal regulation
  - On a restricted basis, pilot programs for multiple CP arrangements were tested under Alternative Methods Demonstration Projects (AMDP)

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340B Program History (Cont.)

- The 340B statute also called for the creation of a Prime Vendor Program (PVP)
- While the original vision for this program may have been similar to that for the DoD Prime Vendor, today's 340B PVP functions most similarly to a GPO, though there are important differences
- As of June, 2013, Apexus holds the federal contract to administer the 340B PVP
  - Apexus is a non-profit founded in 2007 and located in Irving, Texas

340B Program History (cont.)

- In 2010, 340B was expanded:
  - Section 7101 of the 2010 Affordable Care Act (ACA) significantly expanded the 340B program
    - New entity types were added
      - Rural Hospitals
      - Children's Hospitals
      - Free-Standing Oncology Hospitals
    - Pricing calculations were altered
    - Expectations for regulatory and oversight action from HRSA defined
  - 'One-to-many' contract pharmacy relationships were allowed for all 340B enrollees (previously limited to AMDP)
    - Again – not part of law or formal regulation; this was managed through guidance

Intent of 340B Program

- The purpose of the 340B program is to stretch the power of scarce federal dollars flowing to entities that form a health care 'safety net' for some of the most vulnerable patient groups
- There is no required use of program savings, but uses can include:
  - Reduce price of medications for patients (pass-through)
  - Expand drug formularies
  - Increase number of indigent patients served
  - Expand other patient services offered by the entity

340B Program Mechanics

Enrollment, pricing, purchasing and remedies

340B Enrollment

- To receive 340B pricing, qualifying covered entities must enroll in 340B
- Enrollment for covered entities, child sites, and contract pharmacies now occurs during quarterly enrollment windows
  - Windows are from the 1st through 15th day of the first month of each quarter
    - Example: Jan 1st to 15th is an enrollment window
  - Enrollments received during an enrollment window are posted (effective) the 1st day of the quarter following the enrollment quarter
    - Example: Enrollment submitted Jan 4th results in posting on Apr 1st

340B Pricing

- Government and independent studies have estimated that 340B saves approximately 20% off of GPO pricing, and 50% off of average wholesaler pricing
- Specific pricing detail is not publically available information
- The 340B ceiling price:
  - …for brand products must be discounted the greater of 23.1% from AMP or the difference between AMP and Best Price (BP)
  - …for certain branded clotting factors must be discounted the greater of 17.1% from AMP or the difference between AMP and BP
  - …for generic products must be discounted the greater of 13% from AMP or the difference between AMP and BP
- For drugs increasing in price faster than the rate of inflation, an additional discount is calculated. This can lead to so-called 'penny pricing'.
- Manufacturers may also voluntarily offer sub-ceiling prices, or they may extend 340B pricing to non-covered patient categories (for example – inpatients)

340B & Medicaid

- Manufacturers protected against Duplicate Discounts:
  - Drug purchased at 340B price (discount #1)
  - Drug given to Medicaid patient
  - Medicaid agency seeks rebate on drug from manufacturer (discount #2)
- Risk exists for all CE types and for CPs
- Risk exists for both Medicaid FFS and Medicaid MCO
  - MCO rebates added in PPACA in 2010
- Most HRSA tools and policy directed towards FFS only
- States working on revised policies for FFS and/or MCO

340B & Medicaid (cont.)

- Complex issue because Medicaid itself complex (and growing):
  - Fee-for-Service (FFS) vs. Managed Care (MCO)
    - Plans and PBMs for Medicaid MCO often also support commercial and Medicare benefits – hard to tell them apart without BIN/PCN/GRP
  - Medical vs. Pharmacy benefits
  - Different states have different rules
    - Sometimes ambiguous or not comprehensive
    - Varying degrees of perceived favorability for CEs
    - Changing rapidly, due to pressure from CMS and others
    - Key ideas:
      - Retrospective vs. point of sale
      - Mandatory vs. voluntary “carve-out”
      - Actual-acquisition cost billing
      - Claims tagging/identification
      - Individual claims vs. bulk files

340B Purchasing and Remedies

- 340B covered entities may purchase 340B products through a traditional wholesaler, specialty channels, or directly from a manufacturer
- If 340B covered entities purchase 340B-priced products in error, they should notify OPA and work directly with manufacturers to arrive at a mutually agreeable settlement process
  - "Material Breach" thresholds for self-reporting
- Manufacturers have several means of reimbursing 340B covered entities that have been overcharged for 340B products
  - Apexus offers a program to facilitate this process

340B Covered Entities

Hospitals, grantees and designees

Who is Eligible for 340B Discount?

- Only covered entities (CEs) that actively enroll in the 340B program are eligible to purchase 340B drugs
- CEs originally fell into several categories:
  - Disproportionate Share Hospitals (DSH)
  - Federal Grantees
  - FQHC-look-alikes
- For-profit entities are never eligible for 340B pricing
- Enrollment with the OPA is a prerequisite to receiving 340B pricing; being one of the above types is not sufficient

Who is Eligible – DSH Hospital

- By purchasing volume, DSH hospitals continue to be the largest component of the 340B program
- In order to be eligible for enrollment, DSH hospitals must have a DSH adjustment percentage greater than 11.75%
- In addition, DSH hospitals must be either:
  - State or local government-owned
  - Private, non-profit with state or local government contract to provide indigent care
- For-profit hospitals are not eligible, regardless of other factors

340B Rules - DSH

- Enrolled DSH Hospitals may purchase 340B-priced drugs for outpatients who meet the 340B patient definition
- Restrictions apply:
  - IP vs. OP
  - GPO exclusion
  - Prohibition against duplicate discount (Medicaid Carve-out)
  - Orphan drugs covered

Who is Eligible – Grantees and Others

- Many federal grantees and designees are eligible. Examples include:
  - FQHCs (and FQHC-look-alikes)
  - Ryan-White funded entities (including state ADAP)
  - Section 318 and 317 STD sites
  - Urban Indian organizations
  - Black Lung clinics
  - Many others
- A complete list is maintained at the HRSA/OPA website
- The common thread here is receipt of federal grant dollars from specifics Acts of Congress
  - Look-alikes do not receive federal grant dollars, but in all other respects meet the criteria for FQHC status
- There is typically no additional criteria for eligibility; participation in a specified program is sufficient to allow enrollment in 340B for these entities

340B Rules - Grantees and Others

- Other entity types must use drugs only for patients in keeping with reasons for which the entities were granted federal dollars
  - Example: Ryan White entity uses 340B only for HIV/AIDS and related medications
- Use only for patients meeting 340B patient definition
- Avoid duplicate discount (Medicaid)
- Note that many of these 'clinic' entity types have limited or no pharmacy facilities
- As a result, the program may have limited value for these entities, unless they partner with a contract pharmacy

Who is Eligible – ACA Additions

- The 2010 ACA expanded eligibility to include the following:
  - Certain Children's Hospitals (11.75% or alternate formula)
  - Certain Free-Standing Oncology Hospitals (11.75%)
  - Certain Rural Hospitals
    - Critical Access Hospitals (no minimum)
    - Rural Referral Centers (8%)
    - Sole-Community Hospitals (8%)
- Note that each of these new entity types has its own eligibility criteria that must be met, prior to enrollment in 340B
- DSH adjustment percentage minimums are shown above
- Details for each type can be found at the HRSA/OPA website

340B Rules - PED and CAN Hospitals

- Similar rules to DSH hospitals
- Original ACA language excluded Orphan Drugs
  - Potential negative financial impact when combined with GPO Exclusion rule
  - Exclusion for PED hospitals politically difficult position
  - Children's hospitals subsequently allowed to purchase Orphan Drugs (original exclusion called 'a mistake')
- Oncology hospitals still not entitled to 340B pricing on Orphan Drugs
- Orphan Drugs restrictions were subject of lengthy regulatory and judicial saga – details are beyond scope of this presentation

340B Rules - Rural Hospital Types

- Critical Access Hospital, Sole Community Hospital, and Rural Referral Center have unique set of rules
- As with all entities: outpatient-only for 340B purchases
- Not subject to GPO exclusion (can 'pick and choose')
- Subject to duplicate discount prohibition (Medicaid Carve-out)
- Subject to Orphan Drug exclusion

Who is Eligible – Retail?

- Retail pharmacies generally are not eligible to purchase drugs at 340B price
- 340B-priced drugs can never be dispensed to non-patients of a covered entity
- Some pharmacy sites that are owned and operated by a covered entity and have a retail component may be eligible to purchase 340B drugs, but restrictions may apply
  - Must dispense 340B only to patients of CE
- Retail pharmacies participate in the 340B program primarily through the Contract Pharmacy (CP) model

340B Patient Definition

Who is a 340B patient?

Patient Eligibility

- 340B drugs can only be dispensed to those who meet the definition of a patient, under 340B guidelines:
  - the covered entity has established a relationship with the individual, such that the covered entity 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 covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
  - the individual receives a health care service or range of services from the covered entity 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. Disproportionate share hospitals are exempt from this requirement.

Patient Eligibility (cont.)

- Note – The definition of a patient does not include payer status or income level
- Note – The definition of a patient is crucial in determining eligibility for 340B-priced replenishment, especially in a CP setting
- Note – The definition of a patient was a key topic for clarification in the now-withdrawn “Mega Guidance”
  - Patient definition once again under review, per recent comments from HRSA

340B Stakeholders

Role of OPA, Apexus, manufacturers and covered entities

Role of HRSA/OPA

- OPA, a part of HRSA, has responsibility for administering the 340B program
- Among other things, HRSA/OPA:
  - Manage the enrollment process
  - Administer the 340B database of covered entities and contract pharmacies
  - Maintain an informational website available to the public
  - Work with Apexus and other stakeholders to share information
  - Conduct 340B audits
  - Manage recertification process

OPA Statement of Purpose

- The OPA published a statement of purpose, including the following objectives:
  - managing drug manufacturers' involvement in 340B,
  - maintaining the covered entity database,
  - publishing guidelines and regulations,
  - maintaining the 340B Prime Vendor Program (PVP),
  - maintaining the Pharmacy Services Support Center (PSSC),
  - fostering relationships with other federal agencies and the private sector,
  - coordinating and developing pharmacy services best practices,
  - promoting safe and effective medication use, and
  - managing the Patient Safety and Clinical Pharmacy Services Collaborative (PSPC) and other quality improvement initiatives.

Role of Apexus

- Apexus is the current holder of the federal contract to administer the 340B Prime Vendor Program (PVP)
- As the 340B PVP administrator, Apexus performs many functions, including:
  - Negotiate sub-ceiling and value-add pricing on behalf of 340B covered entities
  - Maintain extensive online FAQs
  - Host the 340B University event
  - Support other program integrity initiatives (sample P&P, email/phone support, etc.)

Role of Covered Entities and Manufacturers

- Covered entities purchase and track 340B-priced medications dispensed or administered to qualified patients
  - CEs are responsible for complying with all applicable rules and regulations, such as the Duplicate Discount Prohibition
- Manufacturers calculate 340B prices and offer them to 340B covered entities
  - Manufacturers must adhere to several rules and regulations, such as non-discrimination against 340B covered entities

Discussion topic

- How do you think 340B helps patients and covered entities? Do you have any first-hand experience with this?
- What differences are there in terms of 340B when it comes to insured versus uninsured patients?
- How might 340B be implemented differently for different entity types?

340B Technology Vendors

Split-billing and contract pharmacy tools

340B Technology

- The complexity and growth of 340B have encouraged many companies to offer solutions for 340B participants
- Solutions range from “bare bones” tools to robust, “fully managed” programs that outsource nearly all aspects of 340B management
- Companies target hospitals, clinics, or both
- Companies offer one or both of the following solution types:
  - Split-billing technology
  - Contract pharmacy technology/administration
- Some companies may offer other technologies and services, such as “gateway/backbone” models, consulting, and Medicaid billing tools

340B Technology – Split-billing

- Split-billing technology helps 340B covered entities order their items on the right cost-basis
- Most commonly used by hospitals
- Typically allows a buyer to build one order list and “split” the order into two or more components
- Split portions are then billed against the right wholesaler accounts
- Example vendors: Sentry Data Systems, Verity, MacroHelix, RxStrategies, PSG

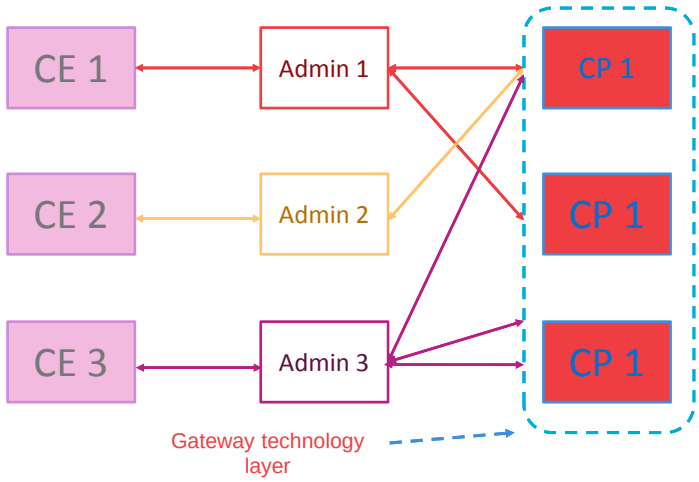
340B Technology – CP

- Typically a combination of technology and administration
- Program tracks and qualifies claims
- Manages inventory ordering/replenishment
- Manages pass-through billing processes
- May manage a cash-pay program for uninsured patients
- Many companies play exclusively in this market
- Example vendors: Sentry Data Systems, Verity, MacroHelix, RxStrategies, CaptureRx, Wellpartner, SunRx, etc.

340B Technology – Backbone/Gateway

- Relatively new idea – streamline and enhance management of multiple CP/CE arrangements
- Typically sold to the CP, most likely a large national chain, grocer, SP, etc.
- Intended to improve program efficiency, outcomes and compliance

340B Technology – Backbone/Gateway



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340B Contract Pharmacy Introduction

Definition and history of 340B contract pharmacy

340B Contract Pharmacy - Basics

- Early years of 340B - covered entities (CEs) can partner with a single contract pharmacy (CP)
- Use of multiple CPs was limited to participants in the Alternative Methods Demonstration Project (AMDP)
- The 2010 guidance allowed all CEs to partner with many CPs
- This is the so-called ‘one to many’ rule

340B Contract Pharmacy - Basics

- Under a CP arrangement, 340B-priced products are purchased by the 340B covered entity
- The 340B-priced drugs are shipped to, stocked at, and dispensed by the CP
  - Can only be dispensed to patients of the covered entity that meet the 340B patient definition
- CPs continue to conduct their retail business, while including the 340B component

Growth drivers

- 340B CP has grown steadily since 2011
- Major drivers of growth since 2010 include ACA expansion and new CP HRSA guidance:
  - More covered entities
    - Rural hospitals
    - Cancer and Children's hospitals
  - **Provision for one-to-many contract pharmacy model**
- Other drivers of growth:
  - **Increase in number of technology/administration providers**
  - Entry of major retail chains into market (Walgreens, etc.)
  - **Entry of PBM mail order and specialty pharmacies**
  - Provider consolidation
  - Reimbursement pressure

Getting started

Role of HRSA/OPA, 340B database, and registration process

Getting started – CP

- To start a CP program, the pharmacy and CE must first contact one another
  - Pharmacy owner may be able to leverage existing relationships:
    - Board member or other involvement with CE
    - Pharmacy is already serving large number of CE patients
  - HRSA/OPA website maintains searchable online database of CEs and CPs
  - A written contract must be in place between CE and CP to register with OPA!
- Note: A pharmacy is **not** required by law to act as a CP, even if approached directly by a current CE

340B Enrollment

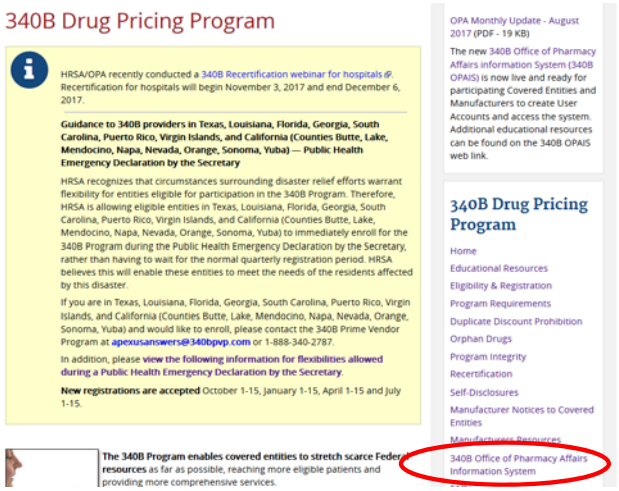
- To begin CP program, CE must register CP with OPA
  - Note – CE must be registered (or registering) itself!
- Enrollment for contract pharmacies occurs during quarterly enrollment windows
  - Windows are from the 1st through 15th day of the first month of each quarter
    - Example: Jan 1st to 15th is an enrollment window
  - Enrollments received during an enrollment window are posted (effective) the 1st day of the quarter following the enrollment quarter
    - Example: Enrollment submitted Jan 4th results in posting on Apr 1st

Registration Window	Posting (Effective) Date
Jan 1st – 15th	Apr 1st
Apr 1st – 15th	Jul 1st
Jul 1st – 15th	Oct 1st
Oct 1st – 15th	Jan 1st

Role of HRSA/OPA

- The Office of Pharmacy Affairs (OPA), a part of HRSA, has responsibility for administering the 340B program
- Among other things, HRSA/OPA:
  - Manage the enrollment process
  - **Administer the 340B database of covered entities and contract pharmacies**
  - Maintain an informational website available to the public
  - Work with Apexus and other stakeholders to share information
  - Conduct 340B audits
  - Manage recertification process

HRSA/OPA website/database



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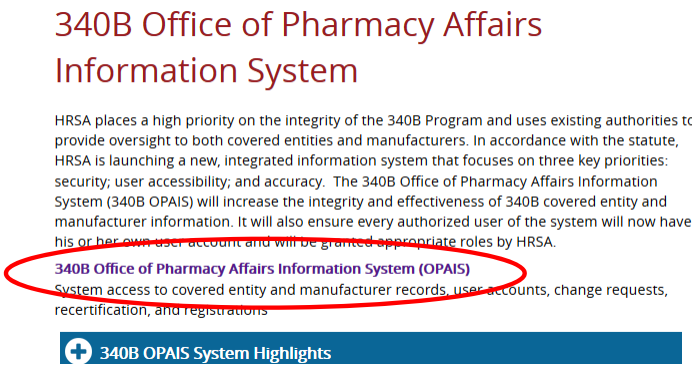

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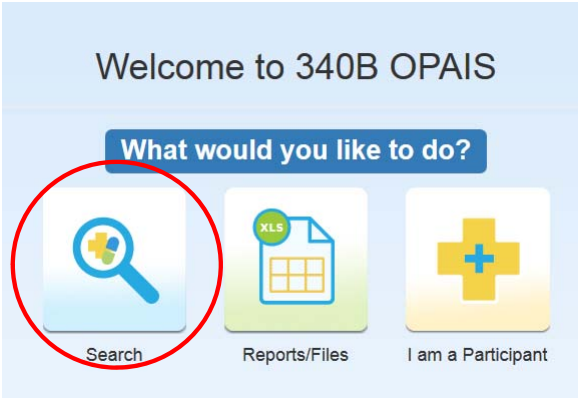

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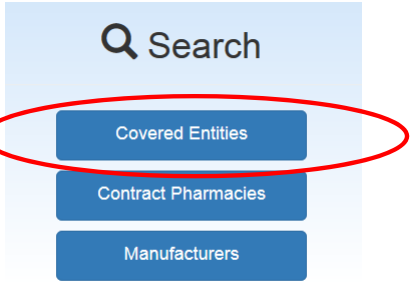

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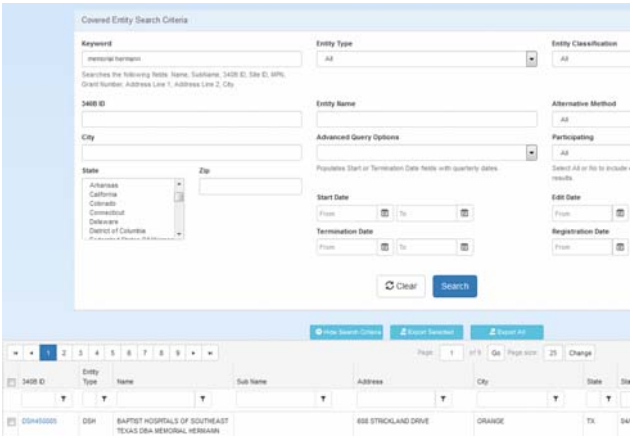

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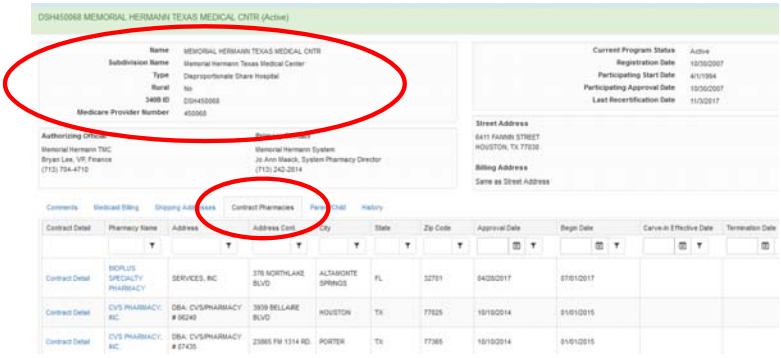


Who's running this thing?

Review of key decision point: self-management vs. 3rd-party administration

Choosing a management approach

- CP is a complex business opportunity that can create numerous regulatory, operational, and financial challenges
- CE and CP need to decide at the outset whether they prefer to self-manage the program or outsource management to a 3rd-party administrator (3PA)
- This decision should be made prior to contract/registration

Two choices

Due to practical considerations around self-management and the generally similar structure of most 3PA programs, the choice between these models largely dictates most aspects of the CP program:

Program Feature	Self-Management	3PA
Contracting & Registration	CE & CP draft contract; CE completes OPA registration process for CP	3PA provides standard agreement and facilitates negotiation of details; 3PA guides CE on reg. process
Fees	Negotiated; CP may collect both admin & dispensing fees	3PA defines standard fees; negotiated; 3PA collects admin fee & CP collects dispense fee
Qualification	CE & CP qualify scripts, usually at the point of sale	3PA qualifies scripts, usually retrospectively using switch data
Inventory	340B product ordered prospectively and tracked as separate inventory	No front-loaded product; single inventory; replenishment model
Ordering	CP sends order list to CE; CE orders from wholesaler	3PA automatically generates orders, usually via EDI
Billing	CE & CP manage process	3PA generates invoices; may facilitate funds transfer
Reporting	CP generates reports from pharmacy system	3PA generates reports; manages recon process; may provide audit support

What's right for me?

- There are pros and cons to both approaches
- In general, self-management fits well when formulary is small, one CE per CP, CE can afford to buy an initial stock, claims can easily be qualified at POS, and the retail owner is looking to do move into an administrator capacity (i.e., more than just pharmacy activities)
- 3PA works well when CE and CP want to minimize their labor commitment, formulary is large/changing, diversion/qualification are challenges, and cash may not be available for initial stock

Nuts & Bolts – How CP works

Contractual, regulatory, financial, and operational approaches and decisions

Implementing a CP program in your retail pharmacy – How it works

- There are many unique aspects of the 340B CP program
- This presentation will focus on six major aspects of the program:
  - Contracting
  - Wholesaler Choice
  - Inventory Model
  - Dispensing and Claims Qualification
  - Fees and Cash Flow
  - Ordering

CP Model – Complete Flow

Example of common 340B CP cash and product flow:

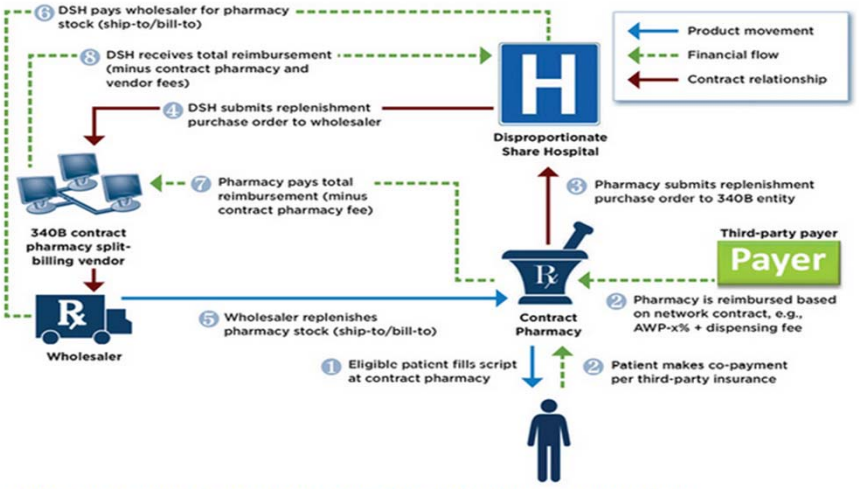


Figure. Flow of funds and product for 340B contract pharmacy network

AWP, average wholesale price; DSH, disproportionate share hospital

Source: Fein AJ. *2012-13 Economic Report on Retail, Mail and Specialty Pharmacies*. Drug Channels Institute; January 2013.

Contracting for 340B CP

- Building a strong contract is vital to a successful CP business model
- OPA no longer offers model agreement, but “essential elements” found in Federal Register Notices
- Apexus resources?
- CE may have access to peer-to-peer network
- Aside from retaining legal counsel, CPs may find support in the contracting process from:
  - Consulting companies specializing in healthcare
  - Wholesalers that offer consulting services
  - 340B software solution vendors
  - Pharmacy trade organizations

Contracting (Cont.)

- The following is **not intended as legal advice**, but a CP might consider including these elements in a contract:
  - Dispensing Fee structure
  - Cash-flow structure
    - Remittance pass-through (3rd-party payers, etc.)
    - Cash-pay and/or charity patients (if applicable)
    - Co-pay (if applicable)
    - Employee scripts (if applicable)
    - Dispensing Fee
    - Admin Fee (if applicable)
  - Inventory model
  - Formulary (if applicable)
  - True-up process and frequency
  - Program administrator (3rd Party, 'homegrown', etc.)
  - **Medicaid MCO claim identification requirements, if any**
  - **DIR fee process**
- In general, a contract should also address the essential elements described in HRSA guidance, as found in the Federal Register Notices

Getting Started – Wholesaler

- It is not required to purchase 340B drugs through a wholesaler, but most CEs will do so
- Federal 340B regulations do not restrict choice of wholesaler
- Some buying groups (TACHC, MMCAP, etc.) may have wholesaler restrictions
- Wholesaler for 340B business does not have to be the same as wholesaler for retail business
- Regulations do not preclude multiple wholesalers for CE business
  - For example: hospital might be primary with wholesaler A, but buy some 340B CP replenishment drugs from wholesaler B

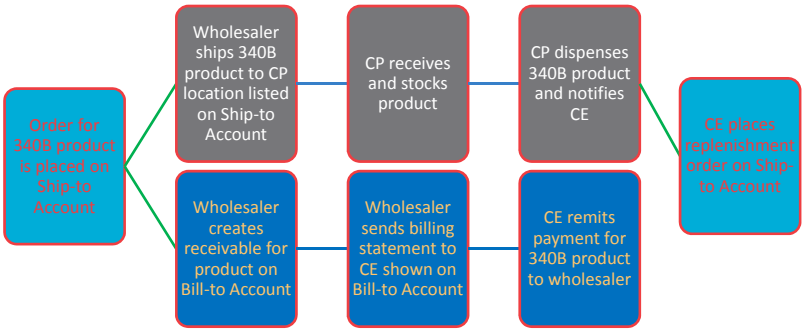
Getting Started – Wholesaler

- Once wholesaler is chosen, 'on-boarding' can begin
- Wholesaler may need to conduct on-boarding process for CE, if CE is not an existing customer of wholesaler
  - Process can include credit, contracting, and information gathering
- Wholesaler may need to conduct partial on-boarding process for CP, if CP is not a retail customer of wholesaler
  - Process can include site visit by wholesaler rep, license gathering, information gathering, and pictures of pharmacy
- Wholesaler will create new accounts (Bill-to/Ship-to)

Wholesaler – Bill-to/Ship-to Accounts

- Most wholesalers treat a CP set-up as a Bill-to/Ship-to (BT/ST) relationship
- A BT account is created with the CE's information
  - No shipping set-up is done for the BT
  - Credit terms and other factors relating to payment are loaded to the BT
- A ST account is created with the CP's information
  - Shipping set-up is completed for the ST
  - Licenses for ST are usually loaded to account
  - Billing linkage to BT account is created for ST account

Bill-to / Ship-to Basic Process Flow



Note: this is from a wholesaler perspective. Depending on inventory model chosen, the start point of the process may vary for your CP.

CP Operations – Inventory Models

Segregated	Replenishment

• Separate inventory (electronic or physical) maintained in CP
• Inventory is typically owned by CE and valued at 340B price
• Inventory purchased prospectively
  • This requires extra care to prevent diversion
• CP maintains regular retail inventory in separate area
• Tracking and accounting generally simpler
• Up-front and on-going capital costs can be significant
• Consumes additional shelf/floor space in CP
	• Uses existing retail inventory
	• Initial inventory is owned by the CP and 'borrowed' by the CE, until replenishment can occur
	• Inventory usually is purchased on a retrospective (replenishment) model
	  • This prevents potential diversion
	• Retail and 340B dispensation occur from the same physical inventory
	• Tracking and accounting can be more challenging
	• Lower capital and operational costs, as existing inventory is leveraged
	• Lower chance for diversion
	• Cash-flow is greater concern

Discussion topic

- Do you have experience with self-management or 3rd-party administration?
- What has worked well for you? What has not gone so well?
- Or, if you have not…what do you expect might be good or bad about these options?

CP Operations – Inventory (Cont.)

- Choice of inventory model should be made based on specific needs of CP and CE
- Reality – inventory model almost always follows from management choice:
  - Self-managed = segregated inventory
  - 3PA = replenishment inventory

CP Operations - Dispensing

- Under segregated model, eligible patients would typically be identified at time of script fill, and dispensation would occur from the appropriate inventory:
  - 340B-eligible patient – Dispense from CE's inventory
  - Non-340B-eligible patient – Dispense from retail inventory
- Under virtual model, all dispensations occur from the main inventory
  - Patient eligibility typically is determined after the fact
  - Cash-pay, charity, and/or employee scripts may be identified 'up front', depending on program needs
    - ***Up-front ID may becoming more of a challenge due to state- and plan-level requirements, especially for Managed Medicaid***

CP Operations – Dispensing (Cont.)

- Current federal law does not require identification of 340B (vs. Retail) claims as they pass through the switch
- Your administrator, state, and/or payer agreements may require flagging of 340B claims, so refer to the relevant contract language
- Medicaid MCO moving strongly in this direction
- NCPDP standard (D.0) creates reporting procedure in 'Basis of Cost' and 'Submission Clarification Code' fields
  - Standard covers POS and retrospective identification
  - Expect more payer contracts to require compliance w/ this standard

CP Operations – Dispensing (Cont.)

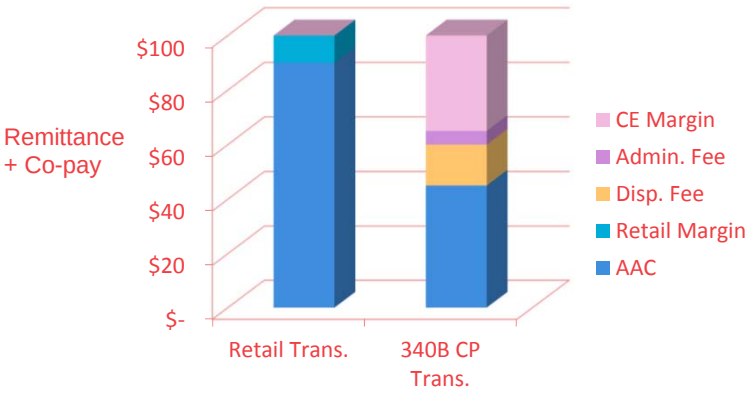
- 340B allows for 'carve out' of Medicaid scripts
- This means that, from a federal perspective, Medicaid may be excluded from the 340B program
- Each state has its own guidelines regarding Medicaid and 340B, so refer to the appropriate state agency website
- General practice and recommendation is to exclude fee-for-service Medicaid, unless arrangement is made with state Medicaid agency
  - Medicaid MCO patient claims should be managed on a state-by-state basis – *some states now moving to also mandate carve-out of these claims*

CP Operations – Cash Flow

- Cash flow is one of the most important operational considerations, when engaging in the 340B CP program
- A properly structured 340B CP program can provide enhanced pharmaceutical access to patients, savings that a CE can reinvest in their safety-net mission, and benefits for the CP
- On the other hand – a poorly structured CP program can cause financial harm to the retail pharmacy

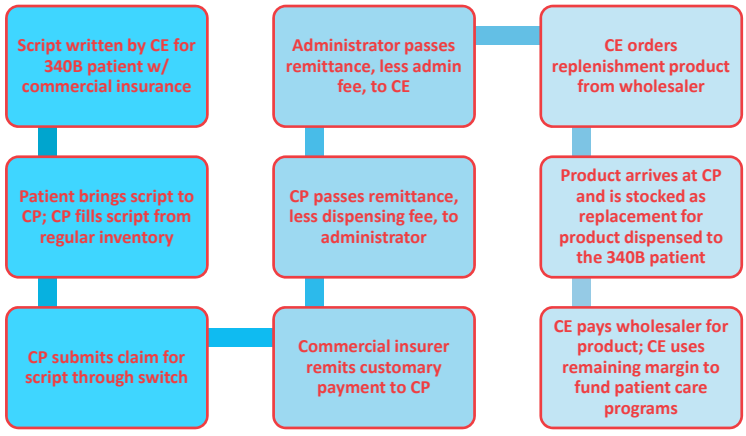
CP Operations – Cash Flow (cont.)

Example of retail vs. 340B economics in CP setting for insured patient qualified for 340B:



CP Operations – Cash Flow (Cont.)

Below is an example of a possible cash flow for a 340B CP using the replenishment inventory model:



CP Operations – Cash Flow (Cont.)

- Cash flow is absolutely critical in replenishment inventory models, as CEs are often counting on the remittance from their claims to pay their wholesaler bill, which in turn guarantees delivery of replenishment product to the CP
- CP and CE should ensure that any contract language governing cash flow actually meets the business needs of both parties
- Recognize that monies collected by CP, either from patient or 3rd-party payers, typically need to be 'passed through' to the CE

CP Operations – Cash Flow (Cont.)

- The dispensing fee is the CPs primary revenue source from the 340B program
  - Self-managed programs may also realize revenue through an administrative fee
- It is essential to do the necessary analysis to ensure that the dispensing fee is adequate to the CP's business needs
- Because 340B patients may have insurance, it is common for the dispensing fees to be very different for uninsured (cash or charity) vs. insured claims

CP Operations – Cash Flow (Cont.)

- Dispensing fee structures vary widely:
  - Cash/Charity/LIHP – typically a single fixed fee, usually between $6 - $12 per script
  - Insured – can take many forms:
    - Single fixed fee (no economic filter)
    - Single fixed fee (economic filter)
    - Multiple fixed fees (brand/generic, tiered to drug cost ranges, etc)
    - Percentage fee (percent of retail cost, percent of reimbursement, percent of "spread", etc)
    - Hybrid – fixed fee + percentage component
    - "Minimum wage" – percentage with a minimum fixed fee per script as a "floor" for the pharmacy

CP Operations – Cash Flow (Cont.)

- **A common feature of 3PA agreements is an "economic filter" or "financial edit"**
- This means that claims that are otherwise qualified as 340B will be excluded (treated as retail) when the dispensing fee + admin fee + 340B drug cost exceed the total amount of reimbursement
- In practice, this skews the program towards higher cost branded/specialty products, and away from the low cost generics that often constitute the majority of scripts
  - Note: this does not directly affect what drugs are actually written and dispensed, but rather what prescriptions are finally captured for 340B purposes

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CP Operations - Ordering

- Ordering in a CP environment is another potential operational challenge
- The federal register notice governing contract pharmacy, as well as several OPA resources, indicate that 340B CP orders should originate from the CE, and not from the CP
- In a non-automated CP arrangement, this means that it may be necessary to report the day's 340B dispensations, so that the CE can place a replenishment order
  - Note – purchasing agent arrangements are permitted
- Automation, via a 340B software solution, usually removes this challenge, as the solution vendor acts as an agent of the CE, captures eligibility, and places orders on the CE's behalf.

CP Operations – Ordering (Cont.)

- Regardless of inventory model or management method, orders placed through wholesaler are typically placed on the Ship-to (ST) wholesaler account number
- These orders are invoiced on the ST account number, but billing flows to the Bill-to (BT) account number
- Product will be shipped to the CP
- Billing statements will be sent to the CE
- Most wholesalers and 340B solution providers can provide reporting support for different aspects of the CP/CE relationship

Discussion topic

- Let's review and make sure we understand the flow of product and funds through a 340B CP model
- As we discuss, share parts of the process where you foresee or have experienced challenges

CP Model – Complete Flow

Example of common 340B CP cash and product flow:

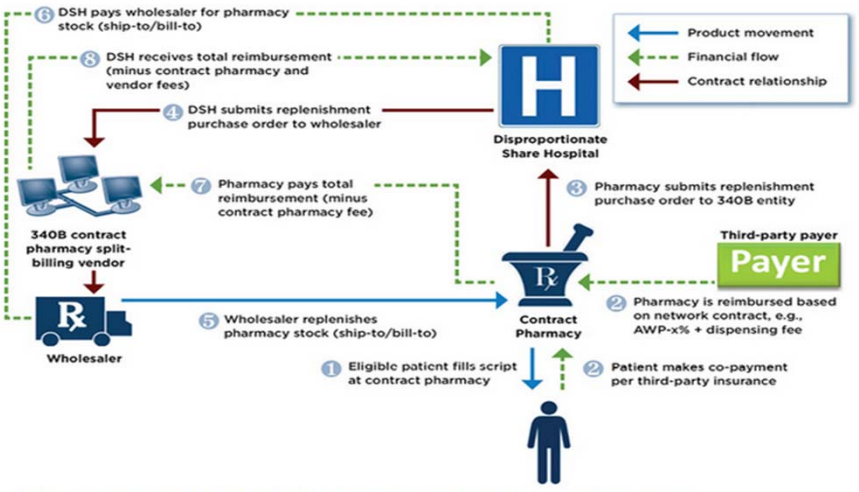


Figure. Flow of funds and product for 340B contract pharmacy network

AWP, average wholesale price; **DSH**, disproportionate share hospital

Source: Fein AJ. *2012-13 Economic Report on Retail, Mail and Specialty Pharmacies.* Drug Channels Institute; January 2013.

Risk factors for retail pharmacies

Financial and other types of risk

CP risk factors - financial

- The top financial risk for CP stores is **the opportunity cost associated with "conversion" of insured patients from retail claims to 340B claims**
- This occurs when patients with insurance, who would have filled their prescription at the retail store regardless, have their claim "captured" through 340B
- This usually results in the retail pharmacy **ultimately foregoing their gross profit on the script**
- As a result, it is **critical** to properly set the dispensing fee(s) for insured claims under 340B

CP risk factors – impact analysis

- To mitigate risks, retail stores should try to model the likely number and value of scripts that would convert to 340B
  - Focus on non-Medicaid insured scripts written by providers at the CE
  - What was the average gross profit on those scripts?
  - How many brand vs. generic?
- Understand the implications of an “economic filter” (if applicable)
  - Will mean most conversions are high-cost scripts
  - Likely means a higher fee or a percentage fee is appropriate to offset lost retail gross profit
- Emerging financial model - “cost” pass-through versus a “sales” pass-through
  - Can this address much of the above risk for the pharmacy?

CP risk factors - financial

- Other financial risk factors for the retail store:
  - Pass-through billing before replacement product has been received
  - Pass-through billing before store has been paid by PBM
  - Mismatch between billed amount and collected amount
  - CE credit issues (can’t buy replacement product)
  - Labor associated w/ program
  - Decrease in purchase volume –
    - Impact on wholesaler COGS
    - Impact on wholesaler generic rebate

CP risk factors - other

- Additional risk factors:
- Failure to join network causes competitive threat
  - Other retail independents and/or chains join
  - CE opens their own pharmacy
- Program changes due to legislation and/or regulation
- Compliance responsibility resides w/ CE, but…CP could still get "caught up" in any audit process
- DIR fees:
  - Claim-specific vs – non-specific
  - Impact on 340B revenue pass-through and calculations
  - Different philosophies

Non-retail models

340B contract pharmacy beyond traditional retail

Non-retail models

- Traditional, open-door retail pharmacies are by far the most common type of 340B contract pharmacy
- Other types of CP arrangements are growing:
  - Specialty pharmacy
  - Home infusion
  - Mail-order
  - LTC
  - Others?

Non-retail models

- While most considerations are similar, there are some special aspects that come into play with these alternative models:
  - Claims qualification when scripts dispensed through mail, administered in patient's home, etc.
  - High-cost therapies and dispensing fees – what is fair?
  - Limited-distribution drugs, REMS, payer restrictions, etc.
  - For LTC, what patients and facilities truly qualify for 340B?
    - Note – some nursing homes registered with OPA, but geographically concentrated

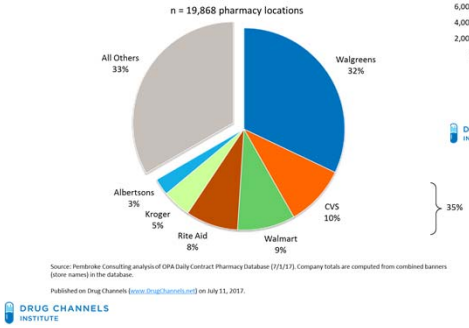
340B Program Trends

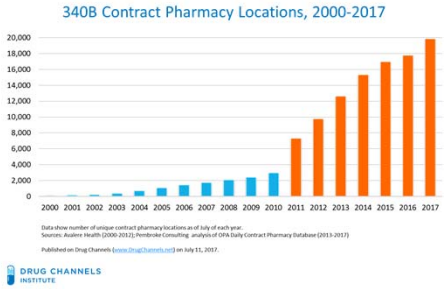
Program growth and political/regulatory/industry trends

Growth Drivers

- 340B program has grown steadily over last eight years, though speed of growth has slowed
- Major driver of growth was 2010 ACA:
  - Addition of Children's and Oncology hospitals
  - Addition of Rural hospitals
  - Provision for one-to-many contract pharmacy model (guidance, not ACA language)
- Current health care trends point towards continued growth:
  - Healthcare provider consolidation
  - Providers pressured to reduce costs and find new revenue streams
  - Growth in share and cost of specialty drugs
  - Expansion of Medicaid coverage under ACA
- But…pressure to restrict program is also increasing

Growth Drivers - CP





340B – Current Events and Trends

Calls to restrict scope of program from drug industry, consultants, PBMs, political figures, etc., claiming 340B is growing beyond original intent and even being abused

The Washington Times

EDITORIAL: The profitable abuse of drugs spawned by government
Compassionate discounts on medicines create the expected boondoggle

Forbes

Drug Discount Program Drives up Costs, Discounts the Poor

Bloomberg BNA

Study Raises Concerns About 340B Hospitals Acquiring Physician-Based Oncology Practices

Source – Safety Net Hospitals for Pharmaceutical Access

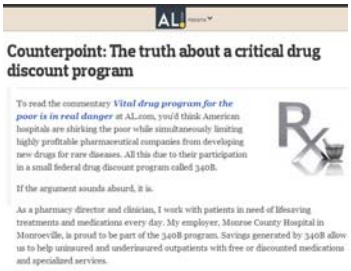
340B – Current Events and Trends

Program advocates speak out, claiming 340B serves vital need

Times Free Press

published Sunday, May 11th, 2014

Spiegel: Preserving a safety net for needy patients



Counterpoint: The truth about a critical drug discount program

To read the commentary *Vital drug program for the poor is in real danger* at AL.com, you'd think American hospitals are shirking the poor while simultaneously limiting highly profitable pharmaceutical companies from developing new drugs for rare diseases. All this due to their participation in a small federal drug discount program called 340B.

If the argument sounds absurd, it is.

As a pharmacy director and clinician, I work with patients in need of lifesaving treatments and medications every day. My employer, Monroe County Hospital in Monroeville, is proud to be part of the 340B program. Savings generated by 340B allow us to help uninsured and underinsured outpatients with free or discounted medications and specialized services.

CRAIN'S CHICAGO BUSINESS

Pharma's war on a drug program would hurt city's underserved

Source – Safety Net Hospitals for Pharmaceutical Access

340B – Current Events and Trends

- HRSA continues auditing 340B-participating entities, including those with CP programs – roughly 200 / yr.
  - New contractor to conduct audits – Bizzell Group
  - Manufacturer-driven audits as well
- HRSA attempts formal rulemaking – mixed results
  - Orphan Drug rule overturned – potential impact of ruling on future regulatory action
  - **Proposed "Mega Guidance" – withdrawn January 2017**
    - Included many changes to program elements, including **patient definition**
    - What happened to the "Mega Reg"?
    - **Some recent confusion on potential return of Mega Guidance**
    - **New HHS Secretary Azar signals willingness to address patient definition**
  - Other regulations:
    - Dispute resolution process – submitted to OMB, no final publication
    - Civil monetary penalties – final publication; **effective date delayed multiple times**
    - Establishment of price catalogue – **HRSA working on this, but may be tied to effective date of CMP rule**
- Core question - how broad is HRSA/HHS regulatory authority around 340B?

340B – Current Events and Trends

- Pressure increasing for identification of 340B claims:
  - States Medicaid MCOs want claims identified (NY, MN examples)
    - Trend to mandatory "carve out", especially in CP setting
  - Some PBM's and 3rd-party payers also want this
  - CMS AMP Final Rule provisions
  - National Council for Prescription Drug Programs (NCPDP) standard in place
  - California budget proposal – full carve-out
- Nothing in legislation appears to prevent PBMs and other payers from seeking reduced reimbursement rates for 340B pharmacies

Legislative Update

- House bill introduced to reverse CMS cuts; stalled at present
  - 194 co-sponsors at last count; bipartisan support
  - No further progress
- **PAUSE and HELP bills in House and Senate** – still in committee
  - Moratorium on CE enrollments
  - Numerous new reporting and data sharing requirements
  - OIG and GAO reports
- Orphan Drug bill
- H.R.5498 - Rural Hospital Frontier Fairness Act (4/12)
  - Would add certain hospitals with sole community hospital designations and within or near frontier states to 340B
    - Note – based on CMS designation, not HRSA registration type
    - SCH entities are already eligible at 8% DSH percentage; presumably this subset would become eligible even below 8%
  - Includes non-340B changes as well

Regulatory Update

- **CMS enacts lower reimbursement for 340B drugs:**
  - ASP+6% vs. ASP-22.5%
  - Part B – OPPS payments only
  - Budget neutral – savings to CMS would be redistributed via other Part B payments
    - Redistribution will include non-340B entities and for-profit entities
  - Requires claims to be tagged (see below on FAQ)
  - DSH and RRC only…for now
    - Note – Rural Sole Community Hospitals exempted (regardless of registration type - confirmed
- **Effective January 1, 2018**
- **Lawsuit filed** by three hospitals associations and health systems November 13, 2017. Key arguments:
  - CMS used "adjustment" versus "survey of costs", but adjust is for overhead
  - CMS is confounding Congressional intent by depriving CEs of 340B benefit
- Lawsuit asks for immediate injunction (or summary ruling of CMS rule's being impermissible)
  - Judge rules in favor of HHS – hospital groups confirm they will **appeal**
  - Decision did not directly address merits of either side's arguments
  - Oral arguments on May 4, 2018

Regulatory Update – CMS Rule

- Winners and losers:
  - Winners – Medicare Part B beneficiaries; non-DSH/RRC hospitals and providers paid under Part B OPPS; drug manufacturers; maybe GPOs?
  - Losers – DSH and RRC hospitals, patients, employees; wholesalers (?); maybe 340B "ecosystem"? (tech vendors, consultants, Apexus, etc.)
- Stated motivations:
  - Reduce costs for Medicare beneficiaries on co-insurance
  - Eliminate any incentive to use more costly drug regimens
  - Align payment rates with true acquisition costs
- CMS posts FAQ with extensive detailed information
  - FAQ updated with clarification regarding impact of cuts on Medicare Advantage
    - Contracted versus non-contracted

Administrative Update

- Registration window closed; next registration window July 1-15
- Civil Monetary Penalty and Price Ceiling regulation from HRSA sees yet another delay in enforcement
  - Had been July 1, 2018 – new date to be announced
  - Covered entities express frustration on this continued delay in enforcement of the rule
  - Rule covers CMP for overcharging by manufacturers and certain price calculation scenarios, including "penny pricing"
  - HRSA has now publicly stated that delays on this rule are impacting deployment of the 340B price verification database

Administrative Update

- President Trump comments on drug pricing not necessarily favorable to 340B
- Trump administration released two documents on subject:
  - FY19 Budget Blueprint
    - Link here: https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf
    - Mentions 340B several times – "…improve 340B Program integrity and ensure that the benefits of the program are used to help low-income and uninsured patients rather than subsidize providers or cross-subsidize the care they provide."
    - Familiar calls for more reporting on savings use, accountability and transparency for CEs
    - Calls out CMS rule and anticipated savings for beneficiaries on co-insurance
    - Would change reallocation scheme to make return of savings driven by "charity" or "uncompensated" care figures – both terms are used, though they have different meanings
    - User fees of $16M annually – similar to Obama administration proposals
  - White Paper – Reforming Biopharmaceutical Pricing at Home and Abroad
    - Link here: https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf
    - Report makes strange claim about 340B as a source of "profits for provider shareholders"
    - Suggests limiting drug reimbursement to 340B providers so that it covers only "uses the purchased drugs are intended to treat."
    - Restricting ability to use 340B drugs to "the intended poor patient populations."
    - Creating more "precise eligibility criteria [to] help meet the primary goals of the program in the future."
    - Allowing a single agency to "set prices at which the eligible providers can buy drugs."

HRSA 2019 priorities

- **HRSA said its priorities for fiscal year 2019 include:**
  - Price Verification – In addition to computing 340B ceiling prices, conducting "random spot checks of these prices with information submitted voluntarily by a small group of manufacturers."
  - Price Submission – "Maintain a secure system for all manufacturers to submit 340B price information, allowing regular spot checks of prices and any necessary follow up on pricing errors."
  - Refunds and Credits – "Facilitate refunds and credits to entities that are overcharged by participating manufacturers."
  - Pricing System – "Continue to develop a system whereby covered entities can access 340B ceiling price information via a secure website. Implementation is expected once the Civil Monetary Penalty and Ceiling Price calculation regulation has been finalized and any necessary changes to the system have been implemented."
  - HRSA gave these examples of how it currently ensures provider and manufacturer compliance with program requirements:
    - Initial eligibility checks of providers seeking to register
    - Annual recertification of provider eligibility
    - Provider audits
    - Reviewing all allegations of non-compliance and conducting audits if necessary
    - Manufacturer audits
    - Helping providers with self-disclosure
    - "Supporting an integrated system of compliance tracking" for providers and manufacturers

Comment on program's original intent

- Program critics often describe 340B CEs buying 340B drugs and then charging payers their standard rates as "abuse" or "misuse" of the 340B program
- However, the program has always allowed for this practice
- Marsha Simon, healthcare lobbyist, published the following powerful defense of this concept on her blog:

"The law specifically allows safety-net hospitals to dispense discounted medicines to eligible patients and to sell them at negotiated rates to insured patients. Congress intended for these savings to stretch financial resources by augmenting low reimbursement levels from the Medicare and Medicaid programs to fund the services required to treat the underserved. This mechanism is hardly abuse — it is exactly the way the program was designed.

I should know. I helped write the law for Sen. Edward Kennedy two decades ago."

Closing Thoughts

Is Contract Pharmacy right for my store?

Q & A

340B – Is it an opportunity?

- We've talked about risks, but 340B can represent a great opportunity:
  - Alternative revenue stream
  - Enhanced patient access and pharmacy reputation
  - Closer ties w/ key providers in area
  - Potential to participate in LIHP that require 340B
  - Positioned for the future of healthcare?

340B – Is It Right for My Store?

- While this presentation is intended to cover basic facts and processes relating to 340B, here are a few questions you might ask, as a starting point when considering the CP opportunity:
  - Do I have the data and analysis to determine exactly my business needs for a dispensing fee, or would I be guessing?
  - Am I confident in this CE as a business partner, and do we have a strong contract?
  - If I don't act as a CP, will my competitors do so? If so, how will that impact my business?
  - Can we build a limited formulary that maximizes 340B opportunity, without encroaching on aspects of my business that may be better handled as retail transactions?
  - Will 340B integrate with other aspects of my pharmacy (Inv. Mgmt., POS, etc.)?
  - Am I satisfied with the true-up processes presented in the contract, and am I confident that I will be 'made whole', should the need arise?

Q & A