

340B – Do the Evolution A Program in Transition

Presenter: Daniel Neal

Employer: Cardinal Health

Program Length: 1 Hour

Disclosure Information

Daniel Neal

I have the following financial relationships to disclose:

Employee of: Cardinal Health

AND

I will not discuss off label use and/or investigational use in my presentation.

Disclaimer

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.

I am not an attorney, and none of the content in this presentation is intended as legal advice. 340B covered entities and other stakeholders are encouraged to work with counsel on legal questions.

Introduction

- Presenter: Daniel Neal
- Biography:

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 Outline

- **340B Program History**
- **Covered Entities**
- **Program Mechanics**
- **Patient Definition**
- **340B Stakeholders**
- **340B Technology Vendors**
- **340B Contract Pharmacy Basics**
- **Audit and Oversight**
- **What's Next?**
- **Closing Thoughts**

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)
 - ADAP exception
- 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.)

- Original scope: limit the cost of covered outpatient drugs to certain federal grantees and designees
- However, shortly before the final bill passed, disproportionate share hospitals (DSH) meeting certain criteria were added to 340B
- Today - majority of 340B purchases are made by hospital entities, though many other types of entities participate in the program
 - Over 16,000 total covered entities
 - Over 2,000 of those are hospitals
 - 340B purchases in 2015 - \$12B; 2016 – est. \$16B

340B Program History (Cont.)

- 340B limits the cost of covered outpatient drugs sold to 340B covered entities by defining a ‘ceiling price’ for these 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)

340B Program History (cont.)

- In 2010, 340B was expanded:
 - Section 7101 of the 2010 Affordable Care Act (ACA) modified 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
 - Medicaid expansion – how does this affect 340B?
 - '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 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 and designees
- ACA added additional hospital types
- CEs may also enroll eligible “child sites”

Who is Eligible – DSH Hospital

- In order to be eligible for enrollment, DSH entities must have a DSH adjustment percentage greater than 11.75% on most recently filed Medicare Cost Report (MCR)
 - Value is result of formulaic adjustment to Disproportionate Patient Percentage (DPP)
 - Allowance for “pickle” hospitals
- In addition, DSH hospitals must be either:
 - State or local government-owned
 - Private, non-profit with state or local government contract
 - Private, non-profit formally granted governmental powers
- Provider-based clinics w/ costs and charges on right areas of MCR may also qualify under “parent” DSH
- 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 definition of a patient
- Restrictions apply:
 - IP vs. OP
 - GPO Exclusion
 - Prohibition against duplicate discount (Medicaid Carve-out)
 - Orphan drugs covered

340B Rules - Grantees and Others

- There is typically no additional criteria for eligibility; receipt of specific grant dollars is sufficient to allow enrollment in 340B for these entities
- Main restriction is that 340B-priced drugs must be dispensed only to those who meet the definition of a patient
- 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 questioned
 - Children's hospitals subsequently allowed to purchase Orphan Drugs (original exclusion called 'a mistake')
- Oncology hospitals still disallowed from purchasing 340B-priced Orphan drugs
- Recent Orphan Drug developments covered later in 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 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

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

HRSA/OPA website/database

- The HRSA OPA website is www.hrsa/opa.gov:



U.S. Department of Health and Human Services

HRSA Health Resources and Services Administration

Advanced Search

A-Z Index

HRSA Home Get Health Care Grants Loan & Scholarships Data Statistics Public Health

340B Drug Pricing Program & Pharmacy Affairs

Share | Print | Email | Facebook | Twitter | RSS | 1

- [Home](#)
- [Eligibility & Registration](#)
- [340B Implementation](#)
- [Program Requirements](#)
- [Medicaid Exclusion](#)
- [Program Integrity](#)
- [Manufacturers](#)
- [340B Database](#)
- [FAQs](#)

340B Drug Pricing Program & Pharmacy Affairs

[IPSEN Important Supply Interruption Information](#) (PDF - 46 KB)

[Covered Entity Qualifications for 340B Under Section 318](#) (04/12/2013)

[Deadline Extended to August 7 for Compliance with Prohibition on Group Purchasing Organization Participation](#) (04/05/2013)

The 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly

Bay
Apr
Lea
We
Rec
340
/20
New
/20
Poli
Cla
The
Op
(PC
Cla
Exc

340B Pricing

- Government and independent studies have estimate 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 patients (for example – inpatients)

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
 - Note – material breach thresholds
- 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 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.)

- The definition of a patient does not include payer status or income level
- The definition of a patient is crucial in determining eligibility for 340B-priced replenishment, especially in a CP setting
- The definition of a patient is currently under review, and a revised version is expected in “Mega Guidance”
 - More on Mega Guidance later in presentation

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

Role of Covered Entities and Manufacturers

- Covered entities purchase, track, and administer 340B-priced medications 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

340B Technology Vendors

Split-billing and contract pharmacy 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, Talyst, MacroHelix, eAudit Solutions, Integrated Informatics, 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
- Some companies operate exclusively in this market; others also offer other 340B technologies and services
- Example vendors: Sentry Data Systems, Talyst, MacroHelix, CaptureRx, Wellpartner, SunRx, etc.

340B Contract Pharmacy Introduction

Definition and history of 340B contract pharmacy

340B Contract Pharmacy - Basics

- As first created, the 340B program allowed covered entities (CE) to partner with a single contract pharmacy (CP)
- Use of multiple CPs was limited to participants in the Alternative Methods Demonstration Project (AMDP)
- 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 patient definition under 340B
- CPs continue to conduct their retail business, while including the 340B component

CP Model – Complete Flow

- Example of common 340B CP cash and product flow:

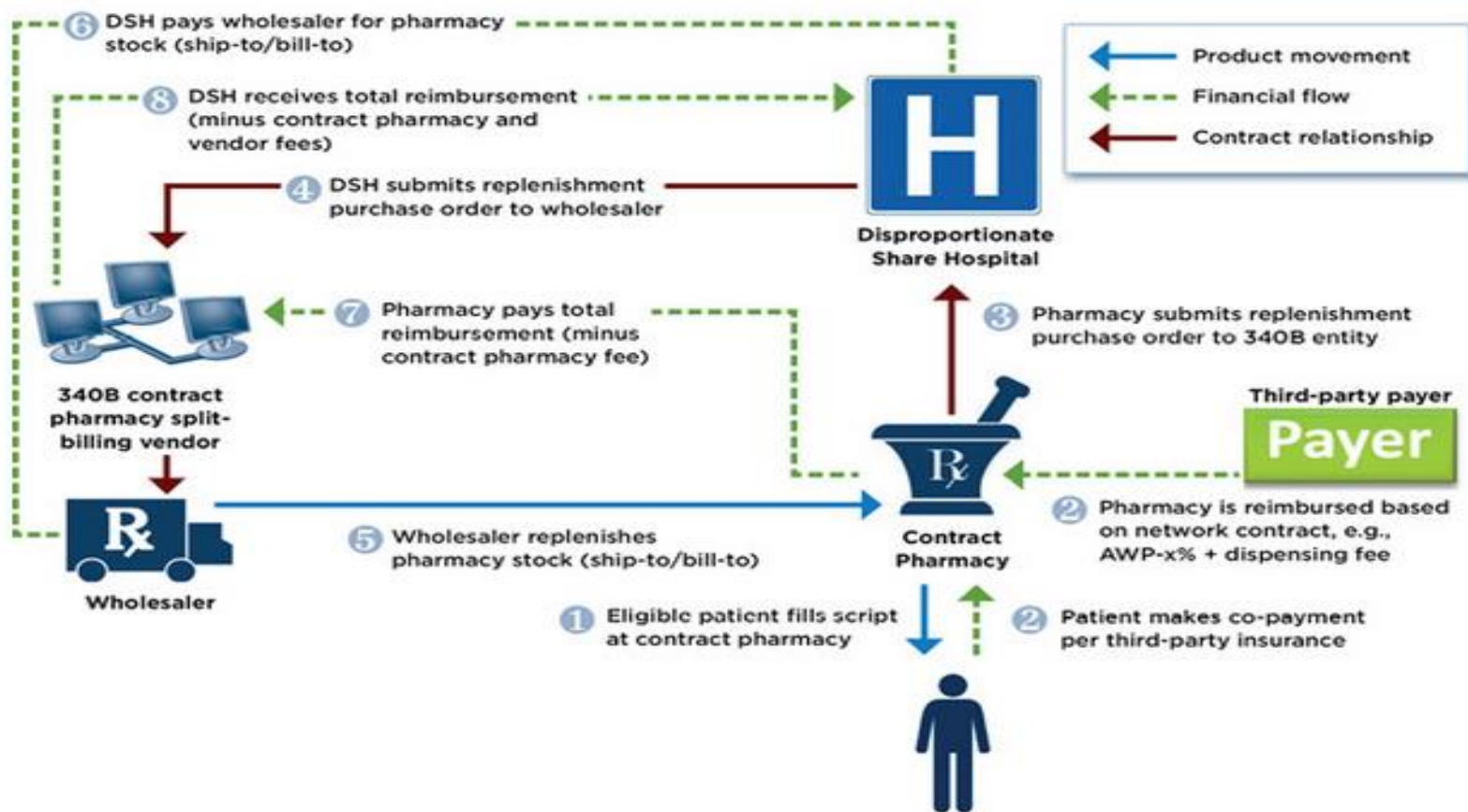


Figure. Flow of funds and product for 340B contract pharmacy network

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.

340B Audit and Oversight

Role of HRSA/OPA, Manufacturers, and self-audit

HRSA Audits

- HRSA can and does audit covered entities
- Target of 200 unique parent covered entities per fiscal year
 - Includes all child sites, entity owned pharmacies and contract pharmacies attached to each parent covered entity
- Audit findings can lead to:
 - Repayment obligation
 - Removal of some or all of a covered entity's 340B program

HRSA Audit Process

- CE receives notification from HRSA (or HRSA's sub-contracted audit agent, The Bizzell Group)
- Data request included in notification – new expectation is to return data within 2-3 weeks of notification
- After data returned, expect site visit from auditor(s) within roughly 2 weeks
 - Note – HRSA has started doing “desk audits” – these are mostly the same as on-site audits, minus the site visit

HRSA Audit Process, cont.

- Auditors obtain and review select 340B Program data and internal controls.
- Audit procedures include, at a minimum:
 - review of relevant policies and procedures and how they are operationalized;
 - verification of eligibility, including GPO and outpatient clinic eligibility;
 - verification of internal controls to prevent diversion and duplicate discounts, including how the covered entity defines whether a patient is considered inpatient or outpatient, HRSA Medicaid Exclusion File designations, and accuracy of covered entity's 340B database record;
 - review of 340B Program compliance at covered entity, outpatient or associated facilities, and contract pharmacies; and
 - testing of 340B drug transaction records on a sample basis.
- Auditors collect the facts throughout the audit but are not authorized to summarize any findings to the entity. Report goes to OPA.

HRSA Audit Process, cont.

- After HRSA issues a Final Report, the covered entity has 30 calendar days from the date of the HRSA Final Report to review findings noted in the HRSA Final Report, and to review HRSA's request for a CAP related to the findings noted.
- If a covered entity agrees with the Final Report, a covered entity must submit a CAP to HRSA within 60 calendar days for HRSA's approval.
- If a covered entity disagrees with the Final Report, it shall notify HRSA in writing within 30 calendar days with appropriate supporting documentation of the covered entity's disagreement. OPA reviews the covered entity's response and, if appropriate, may reissue the Final Report if changes are made based on documentation submitted.
- If an entity fails to submit a CAP, it may be removed from the 340B Program.
- Once an audit report is finalized by OPA, the findings and any associated corrective action will be summarized on the OPA public website.

Manufacturer Audit

- Manufacturers can audit CEs – process is broadly similar, but with key differences:
 - Must use outside audit firm with appropriate qualifications
 - Must submit a plan to OPA for review
 - Cannot audit same some areas of 340B compliance (notably the GPO prohibition)
- In addition, HRSA can audit manufacturers for instances of overcharging or any other failures to meet 340B obligations
 - Based on recently finalized rule, such audits could lead not only to repayments, but also civil monetary penalties

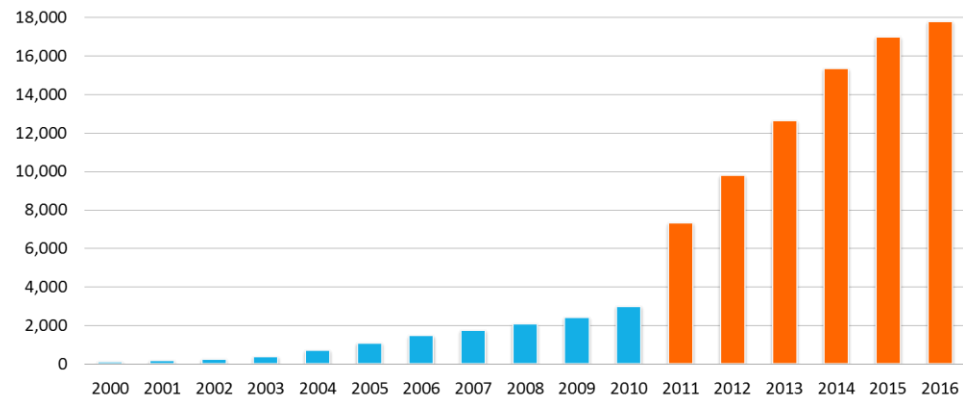
340B – What's Next?

Program growth, recent actions, and the future

340B – A Growing Program

- 340B sales were estimated at \$16B for 2016; some estimates see program exceeding \$21B during next 4-5 years
- Over 2,000 hospitals participate; thousands of other entity types
- Contract pharmacy registration continues to grow:

340B Contract Pharmacy Locations, 2000-2016



For 2000-2016, data show number of unique contract pharmacy locations as of July of each year. Data include a small number of locations that operate as central product distribution centers.

Sources: Avalere Health (2000-2012); Pembroke Consulting analysis of OPA Daily Contract Pharmacy Database (2013-2016)

Published on Drug Channels (www.DrugChannels.net) on August 9, 2016.

340B – Orphan Drugs

- ACA added new hospital types for 340B, but restricted most on use of 340B for drugs w/ orphan designation from FDA
 - Orphan Drugs – indicated for treatment of rare diseases; designation from FDA that grants sponsoring manufacturer certain benefits
- HRSA interpretation allowed for use of 340B in some circumstances
 - Could use 340B when drug used for 340B patients and not for orphan indication
 - Key question – what, exactly, is scope of HRSA’s rulemaking authority vis a vis 340B program?

340B – Orphan Drugs, cont.

- HRSA issued their interpretation first as a series of public statements, and then as a substantive rule
- Rule successfully challenged by PhRMA in federal court
- Rule withdrawn by HRSA; interpretative rule issued
- Interpretative rule also successfully challenged by PhRMA in federal court
- Result – HRSA considers orphan-designated drugs to not be 340B “covered outpatient drugs” for the affected entities
 - Manufacturers not obliged to offer 340B pricing; some voluntarily extend 340B-like pricing to these entities
 - Reminder – this all only affect certain CE types – most CE types are NOT affected at all!

HRSA 340B Regulatory Actions

- Omnibus Guidance (Mega Guidance) – interpretative rule in Final form pending OMB review
 - Growing consensus that, due to election results, we may never see this
 - Rule was expected to contain sweeping language affecting numerous aspects of the 340B program, including:
 - Patient definition
 - Medicaid MCO and duplicate discount prevention
 - Prescription eligibility for referrals, discharges, and certain “mixed-use” areas
 - 340B accumulator/software
 - Self-reporting and repayment obligations

HRSA 340B Regulatory Actions

- Published Final Rule for Manufacturer Price Calculations and Civil Monetary Penalties
- Published January, 2017; enforcement April 1, 2017
- Key provisions:
 - the requirement that a manufacturer calculate the 340B ceiling price on a quarterly basis; **(also that it will be “published” by HRSA)**
 - the requirement that a manufacturer charge \$0.01 per unit of measure if the 340B ceiling price calculation results in a ceiling price that equals zero (penny pricing);
 - the methodology manufacturers must use when estimating the ceiling price for a new covered outpatient drug;
 - an explanation of how a civil monetary penalty (CMP) would be imposed on a manufacturer that knowingly and intentionally overcharges a covered entity; and
 - an explanation of what would constitute an instance of overcharging to trigger a CMP.

HRSA 340B Regulatory Actions

- Published proposed rule in Federal Register for Dispute Resolution Process in August, 2016.
- Defines processes to resolve disputes regarding 340B, particularly between CEs and manufacturers
- HRSA describes self-disclosure obligations on their website
- Non-regulatory: HRSA's appointed Prime Vendor, Apexus, launches a 340B Advanced Operations Certification program

340B and CMS Provider-Based Reimbursement Rules

- Bipartisan Budget Act of 2015 (section 603)
- Changes to requirements for Provider-Based Clinics
- Intent is to move to “site-neutral” payment; not intended to affect 340B, but..
- Child-site eligibility could be affected for hospitals
 - Provider-based status
 - Reimbursable cost center on MCR w/ costs and charges

Site-neutrality and 340B

- Child sites:
 - Provider based clinics
 - Reimbursable (above the line) on parent entity's MCR
 - Outside four walls of covered entity
 - Outpatient charges and costs
- Site-neutrality in payments from CMS:
 - Result of budget bill
 - Moves certain hospital-owned clinics from hospital fee schedule to private practice fee schedule

Site-neutrality and 340B

- Question: for facilities/departments that under Section 603 are no longer eligible for provider-based reimbursement, will they still qualify for enrollment as 340B child sites?
- Examples – PT/OT/SLP are not paid under OPPIs, no decision made on PB status by CMS, but still “reimbursable” on MCR
- CMS vs. HRSA – who needs to clarify?
- Pre-amble to CMS “interim” final rule seems to clear concern during CY 2017, but still uncertainty for years beyond
 - Unique ID for billing will allow for lower payments, but still reported in way needed for current 340B child site qualification

Medicaid MCO and Billing

- Pressure increasing for identification of 340B claims:
 - CMS AMP Final Rule provisions
 - States Medicaid MCOs want claims identified (NY, MN, AZ, OR examples)
 - “Consistency” requirements
 - Mandatory “carve-out”
 - Retrospective data exchange models
 - POS claims ID models
 - CMS AMP Final Rule provisions
 - National Council for Prescription Drug Programs (NCPDP) standard in place
- Nothing in legislation appears to prevent PBMs and other payers from seeking reduced reimbursement rates for 340B pharmacies

“Repeal and Replace”

- Fate of ACA and 340B in general uncertain due to election results
- Some elements of 340B found in ACA, but would those elements be totally repealed?
 - New hospital types
 - New ceiling formulae (due to new Medicaid DR formulae)
 - Program integrity provisions
 - CHC/FQHC funding
 - Medicaid expansion and MCO rebate eligibility
- Core law is from early 1990’s – would there be an attempt to modify that language?
- “War of the words” – Critics and advocates of 340B in media, Congress, and beyond

Closing Thoughts

340B Q & A

Presentation End

Thank you for attending!