

# 340B Update: Trends and Potential Future Changes

Douglas Wong, Pharm.D.

April 21, 2018

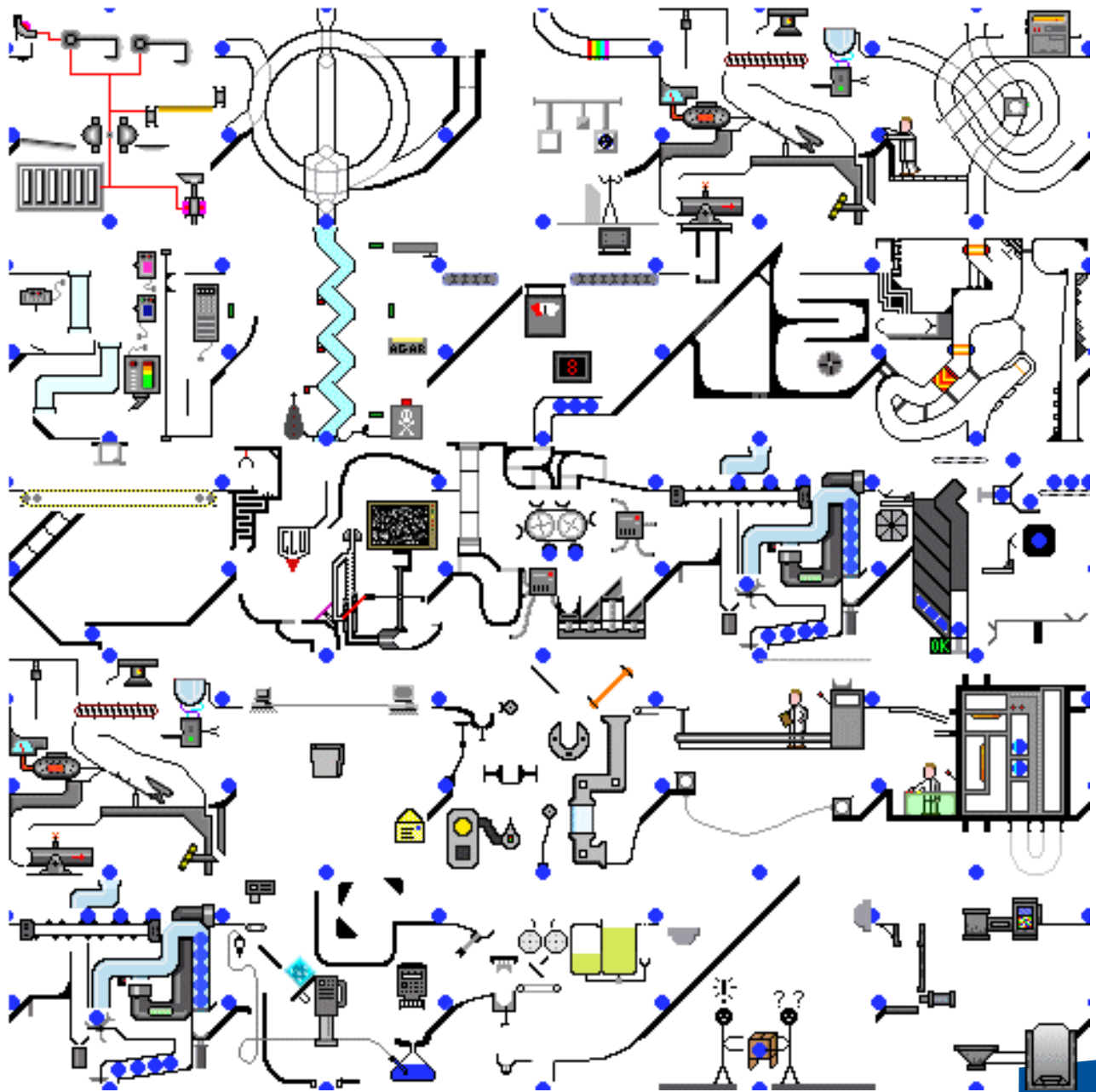


# Disclaimer

- The speaker is an associate of Pharmacy Healthcare Solutions, a wholly owned subsidiary of AmerisourceBergen Corporation
- Pharmacy Healthcare Solutions is a pharmacy centric consulting organization.
- This presentation is not to be construed or relied upon as legal advice

# Learning Objectives

1. Understand the current HRSA audit process and areas of increased focus
2. Understand the 2018 Medicare Outpatient Prospective Payment System
3. Identify possible 340B changes that may challenge your organization in 2018 and beyond
4. Assess how your team can manage the changes and compliance efforts.



# 340B Program

What is it?

- A drug discount program created in 1992 by the U.S. Federal government that requires drug manufacturers who participate in the Medicaid program to provide outpatient drugs to eligible healthcare organizations or covered entities (CEs) at significantly reduced prices.
- The 340B drug discount program allows CEs to stretch scarce federal resources as far as possible, enabling them to reach more eligible patients and provide more comprehensive care.

# 340B Program

- The Office of Pharmacy Affairs (OPA) branch, Health Resources and Services Administration (HRSA) is responsible for Program oversight and ensuring compliance.

## Federal Grantees/Designees

- Federally qualified health center
- Federally qualified health center look-alikes
- Title X family planning grantees
- State AIDS drug assistance programs
- Ryan White Care Act grantees (A,B,C,D,F)
- Black lung clinics
- Hemophilia treatment centers
- Native Hawaiian health centers
- Urban Indian organizations
- Sexually transmitted disease grantees
- Tuberculosis grantees

## Certain Hospitals

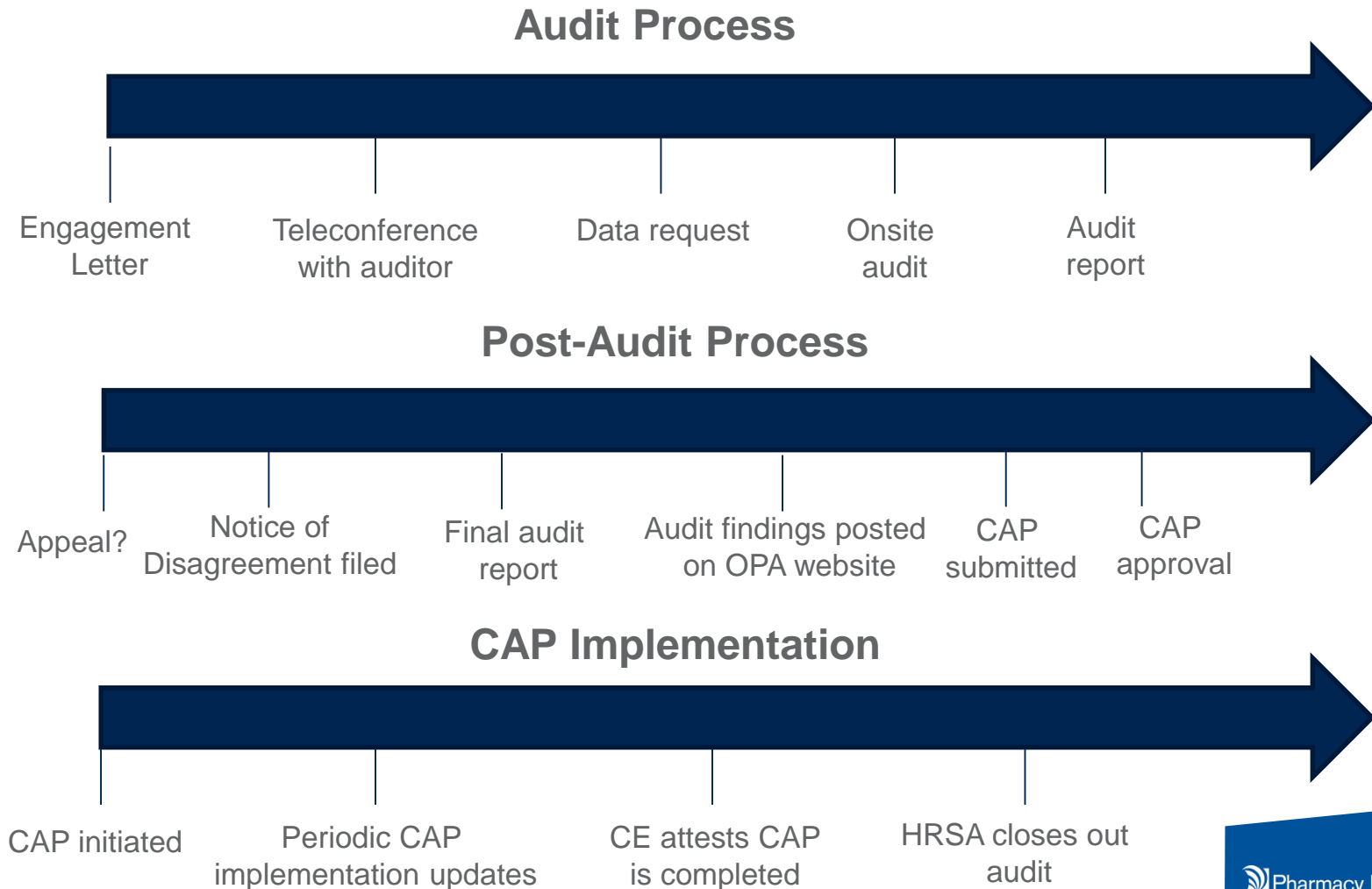
- Disproportionate share hospitals
- Children's hospitals
- Critical access hospitals
- Free-standing cancer hospitals
- Rural referral centers
- Sole community hospitals

# 340B Audits

- HRSA ensures compliance by performing CE audits
  - Audits began in 2012, and currently performing > 200 audits per year
  - Audit procedures
    - > **Database accuracy:** All entity eligibility requirements are met.
    - > **Diversion:** Hospitals must ensure that 340B drugs are not resold or otherwise transferred to anyone other than their eligible patients.
    - > **Medicaid Duplicate Discount:** Hospitals are obligated to ensure that Medicaid does not claim rebates from manufacturers on drugs purchased by the hospital through the 340B program
    - > **GPO exclusion:** Disproportionate share hospitals and children's and cancer hospitals are prohibited from obtaining covered outpatient drugs through group purchasing organizations ("GPOs") or other group purchasing arrangements.
    - > **Orphan drug exclusion:** Free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals

# HRSA Audit Process

- In 2016, HRSA awarded The Bizzell Group as the contracted auditor





# 340B Audits

## On site

- Typically onsite 1-3 days
- Procedures normally include:
  - Confirming CE has a 340B policy/procedures and ongoing monitoring program
  - Confirming CE information within the OPA database is accurate
  - Onsite testing of a sample of 340B dispenses to validate:
    - > Eligible patient
    - > Eligible provider
    - > Eligible location
    - > Absence of duplicate discounts

# HRSA Audits –Current Hot Topics

- GPO Prohibition –Single violation can result in removal from the program
- Program oversight (especially contract pharmacies)
- Contract with State/Local Govt
- Time period of non-compliance
- Split-billing access/documentation requests

# 340B Audits

## ■ Manufacturers

- Advanced analytics used to identify outliers and/or red flags that may indicate compliance issues
- CE inquiries (and audits) have increased in recent months
- Lack of adequate response may result in a full audit
- Kalderos working with manufacturers regarding duplicate discounts

# 2018 Medicare Outpatient Prospective Payment System

What is it?

- Centers for Medicare and Medicaid Services (CMS) was granted authority in 1998 to establish a prospective payment system for hospital outpatient services.
  - Drugs are reimbursed under a HCPC code (J-codes)
- Basis for change:
  - CMS utilized past GAO, MEDPAC and OIG audits as support for the Final Rule
  - Concern that current Medicare payments far exceed the overhead and acquisition costs for 340B drugs
- In November 2017, CMS released the 2018 Medicare Outpatient Prospective Payment System rule, which finalized the proposal:
  - Payment to certain 340B hospitals 22.5 percent less than the average sales price (ASP) for certain drugs purchased through the 340B program compared to ASP + 6% for non-340B purchases
  - Use of Billing Modifiers (JG or TB) to identify if a drug was purchased on 340B
- This rule went into effect January 1, 2018

# 2018 Medicare Outpatient Prospective Payment System

Who is affected with the reduced payment?

- Affected entities that are designated as:
  - Disproportionate Share Hospitals (DSH),
  - Urban Sole Community Hospitals (SCH), and
  - Rural Referral Centers (RRC)
- Exempted entities are:
  - Rural Sole Community Hospitals,
  - Children's hospitals, and
  - PPS-exempt cancer hospitals
- Unaffected hospitals are Critical Access Hospitals, Maryland hospitals, and non-excepted off campus hospital outpatient departments.

# 2018 Medicare Outpatient Prospective Payment System

Required Modifiers if billing for 340B drugs

- CMS is requiring the use of two new modifiers on claims for 340B Drugs.
  - JG and TB dependent on type of entity and the drug
- What if the modifiers are not applied?
  - Medicare Fraud
    - > Medicare can recover its erroneous payments.
    - > Fines
- Removal from the program

# 2018 Medicare Outpatient Prospective Payment System

## Litigation

- **Early Dec 2017:** American Hospital Association, America's Essential Hospitals and Association of American Medical Colleges sued HHS to halt the payment cuts
  - joined by three health systems: Brewer, Maine-based Eastern Maine Healthcare Systems; Detroit-based Henry Ford Health System; and Hendersonville, N.C.-based Park Ridge Health
  - Argued the 340B provisions of the OPPTS final rule violate the Social Security Act and should be set aside. Lawsuit further alleged the 340B provisions are outside of the HHS secretary's statutory authority
- **Dec 29, 2017:** a federal judge dismissed the lawsuit, allowing CMS to proceed with the cuts. The judge said the lawsuit was premature, but he did not rule on the merits of the case.
- **Jan 9, 2018:** lead plaintiff hospitals and trade organizations appealed Judge Contreras's decision dismissing their lawsuit.
- **Jan 30, 2018:** U.S. Court of Appeals for the District of Columbia Circuit granted a motion to expedite consideration of the suit, with Final briefs due in early April

# 2018 Medicare Outpatient Prospective Payment System

Current Congressional activity

- H.R.4392 - To provide that the provision of the Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs final regulation relating to changes in the payment amount for certain drugs and biologicals purchased under the 340B drug discount program shall have no force or effect, and for other purposes.

<https://www.congress.gov/bill/115th-congress/house-bill/4392?q=%7B%22search%22%3A%5B%22340B%22%5D%7D&r=2>



# 340B Challenges related to Hospitals

# H.R.4710 - 340B PAUSE Act

## 340B Protecting Access for the Underserved and Safety-net Entities Act

<https://www.congress.gov/bill/115th-congress/house-bill/4710?q=%7B%22search%22%3A%5B%22340B%22%5D%7D&r=1>

- To amend the Public Health Service Act to establish a moratorium on the registration of certain new 340B hospitals and new child sites, and for other purposes.
  - The 340B PAUSE Act pauses new enrollment of Disproportionate Share Hospitals into the 340B discount drug program.
    - > Two-year moratorium on new DSH parent registrations and new child sites for currently registered DSH entities
  - Critical access hospitals, sole community hospitals and rural referral centers would not be affected by this legislation.

# H.R.4710 - 340B PAUSE Act

## 340B Protecting Access for the Underserved and Safety-net Entities Act

- Imposes new reporting requirements on DSH hospitals and free-standing children's and cancer hospitals, requiring them to collect and report data on:
  - patients receiving 340B drugs broken down by payer mix, for hospitals and their child sites
  - total costs and total charity care costs incurred by each child site
  - total 340B drug reimbursement and acquisition costs for each hospital
  - contracts with state or local government for nonprofit hospitals required to have such contracts
  - the names of all third-party vendors providing 340B services for each hospital and child site

# S.2312 - HELP Act

Helping Ensure Low-income Patients have Access to Care and Treatment

<https://www.congress.gov/bill/115th-congress/senate-bill/2312?q=%7B%22search%22%3A%5B%22340B%22%5D%7D&r=4>

- To provide a moratorium on registration of new non-rural section 340B hospitals and associated sites, and for other purposes.

# S.2312 - HELP Act

## Helping Ensure Low-income Patients have Access to Care and Treatment

- Change eligibility requirements for DSH, children's, and cancer hospitals, as well as new eligibility requirements for their child sites.
  - Listed on the hospital's most recently filed Medicare cost report on a Medicare-reimbursable line;
  - Services provided at the location have reported Medicare costs and charges;
  - Location is wholly owned by the hospital;
  - Location meets Medicare provider-based rules, as demonstrated through an approved Medicare provider-based attestation;
  - Location provides "a full range of outpatient services," in addition to drugs; and
  - Location adheres to the charity care policy and any sliding fee scale policy of the hospital.
- Impose a two-year freeze on new hospital participants in 340B and establish a number of reporting requirements under the broad rubric of "transparency."

# What's next?

- HRSA to require Increased Transparency
  - > documenting where your entity is utilizing 340B savings
- HRSA expects entities to have Internal Monitoring Procedures
  - > Establish a 340B oversight/steering committee
  - > Ensure policy aligns with actual operation
  - > Perform splitter maintenance daily
  - > Perform periodic internal audits (across all settings and arrangements)
  - > Consider independent audits (another set of eyes on the program)

## What's next?

- Audits will likely continue to increase as HRSA increases oversight efforts.
- Congress will likely have more hearings in the investigation of the 340B program. It is likely to have more oversight and limit potential growth in the coming year.
- There are likely to be regulations put in place that require tracking of 340B savings and transparency in how these savings are used.
- Periodically review your internal monitoring strategy and validate alignment with recent HRSA audit focus areas.







■ Questions? Contact:

Doug Wong ([Dwong@pharmhs.com](mailto:Dwong@pharmhs.com))

215-353-6490

