Apexus

340B Drug Pricing Program; Transitioning from Access to Integrity

Arkansas Association of Health-system Pharmacists
47th Annual Fall Seminar
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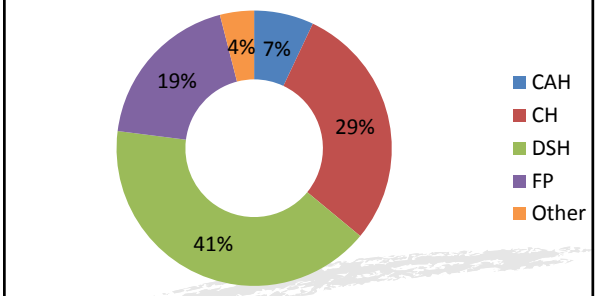
Objectives

- Describe the role and benefits of Apexus, HRSA's 340B Prime Vendor Program
- Discuss program integrity updates in the 340B environment
- Describe strategies for compliance with the GPO Prohibition
- Describe details of the orphan drug rule as it applies to rural hospitals

340B Stats, Arkansas

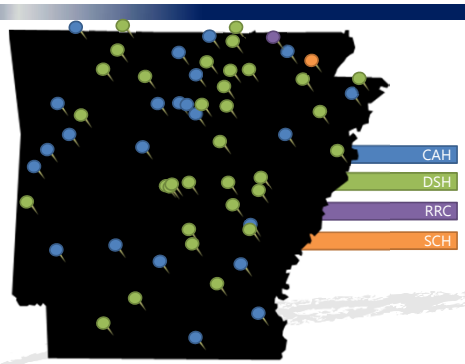
- 349 registered 340B entity sites
- 266 registered contract pharmacies
- 68% of all registered sites are hospitals, 40% of the hospital sites have contract pharmacies
- 67% of all hospital sites carve-out Medicaid
- 28 rural hospitals (primarily CAH); 18% opt-in for orphan drugs

340B Participating Entities, AR



Source: HRSA 340B Database as of 9/26/13

Arkansas 340B Hospitals by Zip Codes



Apexus Primary Roles

- Negotiates sub-ceiling 340B pricing on branded and generic pharmaceuticals
- Establishes distribution solutions and networks that improve access to affordable medications
- Provides other value-added pharmacy related products and services
- Provides support and education services to improve program compliance for all stakeholders
  - 340B University (sessions, tools, and resources)
  - Apexus Answers Call Center

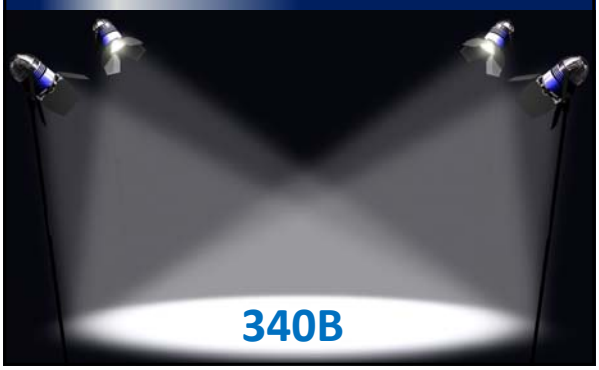
PVP Participant Benefits

- Free, federal benefit to covered entities electing to participate
- Exclusive access to:
  - Sub-340B pricing on pharmaceuticals
  - Discount pricing for Non-GPO WAC accounts (entities subject to GPO Prohibition)
  - Discounts on value added products, services, and supplies
- Pricing transparency
- Reports and tools
- 340B University
- Apexus Answers Call Center

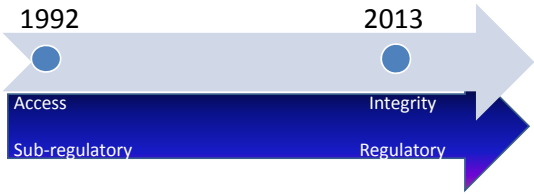
GAO Report 2011

- 340B Program allowed entities to support their missions by maintaining services and lowering medication costs, which the GAO found to be consistent with the intent of the program
  - 340B savings used to offset losses incurred from other patients, which helped support the financial stability of the organization and allowed them to maintain services
  - 340B savings were passed on to patients by providing lower-cost drugs to uninsured patients
- 340B statute does not define how covered entities must use the savings generated from the 340B discounts
- **Lack of oversight** by HRSA and need for implementing integrity initiatives

Political Landscape…



Program Evolution



Program Integrity - Ongoing Activities

- Determination of eligibility
- Annual Recertification
- Quarterly checks of FQHC status, DSH % and for hospital ownership status
- Quarterly calculations of 340B prices
- Maintenance of Medicaid Exclusion File
- Investigations/resolutions of alleged drug diversion and incorrect pricing/inappropriate limits on drug access
- Technical Assistance, webinars, FAQs, guidances
- Audits

HRSA Integrity Initiative - Audits

Manufacturer	Entity
Calculate and charge a correct 340B price	Comply with 340B statute and guidelines
Subject to HRSA audits	Subject to HRSA and manufacturer audits

- OPA Program Integrity Page: http://www.hrsa.gov/opa/programintegrity/index.html

Audits of Covered Entities

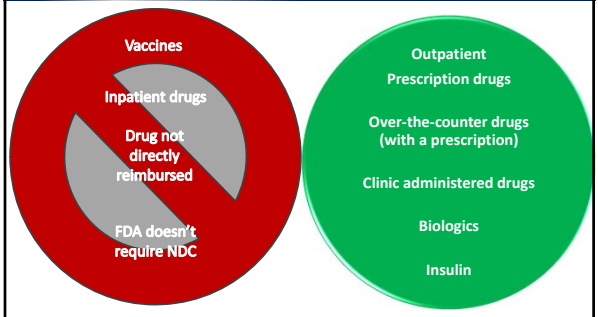
Entity shall permit manufacturer/government to audit records that directly pertain to entity compliance:

HRSA	Manufacturers
Duplicate Discounts Diversion Eligibility/GPO Prohibition Orphan Drug Exclusion	Duplicate Discounts Diversion Orphan Drug Exclusion

Major 340B Compliance Areas

1. Duplicate Discount Prohibition
2. No Diversion (Patient Definition)
3. Certain Hospitals Only
   - Group Purchasing Organization (GPO) Prohibition*
   - Orphan Drug Exclusion

340B Covered Outpatient Drugs



http://www.ssa.gov/OP_Home/ssact/title19/1927.htm

GPO Prohibition

- Applies to:
  - Disproportionate Share
  - Children's Hospitals
  - Free Standing Cancer Hospitals
- Such hospitals:

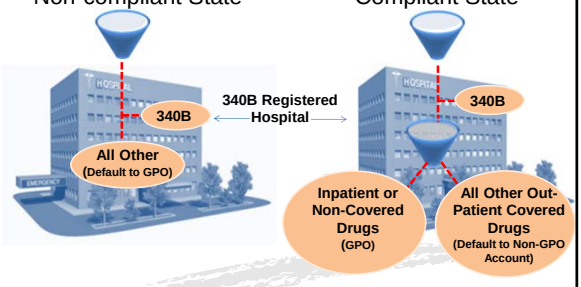
  "...will not participate in a group purchasing organization or group purchasing arrangement for **covered outpatient drugs as of the date of this listing on the OPA website.**" OPA GPO Certification Form
- Release clarifying OPA Policy
  - Effective August 7, 2013

Importance of HRSA's Clarification of the GPO Prohibition

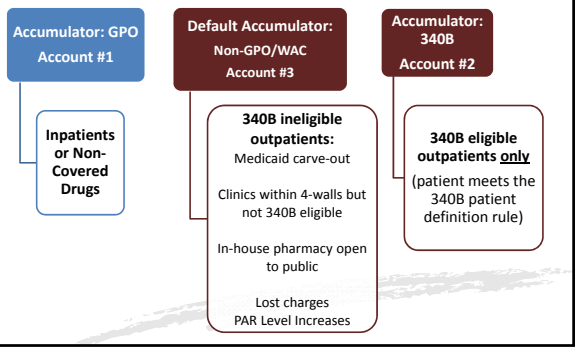
- Many stakeholders misinterpreted
- Many covered entities, wholesalers, and 340B solution vendors required to make system modifications to comply
- Demonstrated a need for more education in the marketplace
- All stakeholders will need to work in unison to support 340B compliant operations

GPO Prohibition Clarification – Purchase Flow for Some Hospitals

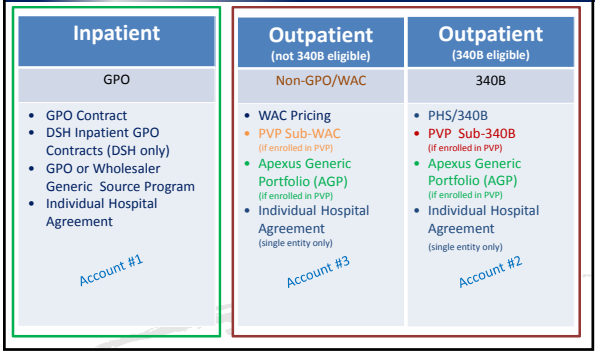
- Non-compliant State
- Compliant State



Mixed-Use Setting Accumulators and Eligibility



Wholesaler Account Setup -DSH/PED/CAN with GPO Prohibition



GPO: Special Situations

- GPO private label products
- IVIG
- Drug shortages
- Non-covered outpatient drugs
- IV Solutions
- Individual contracts
- Lost charges

FAQ: Apexus Role

Q: Why is it permissible for Apexus to establish contracts for the non-GPO account for hospitals subject to the GPO prohibition?

A: Apexus, as HRSA's contracted 340B Prime Vendor, is permitted to perform group purchasing functions within the scope of the 340B program on behalf of all entities who voluntarily participate in the prime vendor. The HRSA agreement enables Apexus to contract for outpatient covered drugs and other value added products on behalf of participating covered entities and does not restrict this contracting activity to the 340B class of trade. In this situation, Apexus is classified as the 340B Prime Vendor and **not considered as a GPO or group purchasing arrangement and therefore would not violate the GPO prohibition.**

FAQ: Contracting

Q: What are some examples of contracting approaches that are potential violations of the GPO Prohibition?

A: The following situations are **not** GPO-compliant contracting practices:

- An individual DSH accessing contracts executed by an IDN, in which it is a member
- A wholesaler's generic source program (unless offered as a subcontracted solution to the Apexus Generics Source portfolio)
- A manufacturer extending a discounted price to a group of covered entities (subject to the GPO prohibition) through a wholesaler, other third party or group purchasing arrangement that is not supported by an individual contract between the 340B covered entity and the manufacturer. Such agreements should be reproducible for review during an audit of compliant 340B operations.

FAQ: Covered Outpatient Drug

Q: Can a hospital subject to the GPO prohibition use a GPO to purchase drugs that do not meet the definition of covered outpatient drug (as defined by section 1927(k) of the Social Security Act)?

A:Yes. Entities should have clear documentation demonstrating how the entity applies the definition of covered outpatient drug with respect to GPO use.

FAQ: Entity-Owned Pharmacy

Q: Does the GPO Prohibition apply to covered entity owned pharmacies?

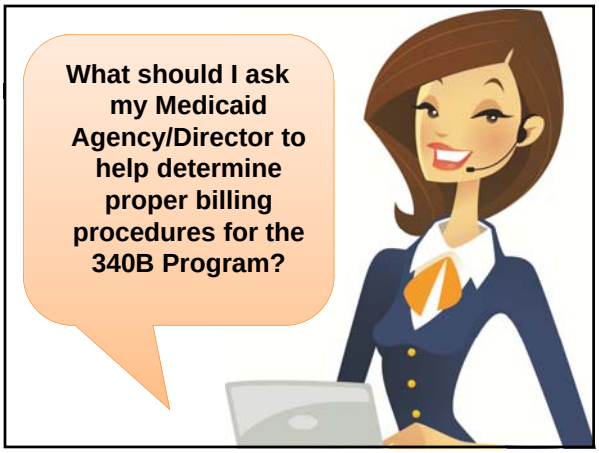
A: The GPO Prohibition applies to OPA registered covered entities. Covered entities have to determine how to apply the GPO Prohibition to their pharmacy locations. **Typically, entity-owned pharmacies purchase and manage drug inventory as part of the covered entity.** The entity is expected to have written policies and procedures and maintain auditable records. The entity should not try to circumvent the GPO Prohibition by accessing GPO purchased drugs via an entity-owned pharmacy. If a GPO is used, the entity is required to purchase through a separate pharmacy wholesaler account since the 340B pricing and GPO pricing cannot be co-mingled in the same account for program integrity reasons. For additional information, please review: The Statutory Prohibition on Group Purchasing Organization Participation Policy Release http://www.hrsa.gov/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf

Duplicate Discount Prohibition

Preventing Duplicate Discounts

Arkansas 340B/Medicaid Information

- 340B entities must bill Medicaid FFS: AAC + dispensing fee
- Use NCPDP value of "08" to indicate 340B retail prescriptions
- 67% of AR 340B hospital sites carve-out Medicaid
  - Impact on WAC purchases due to GPO Prohibition



Duplicate Discounts

- What is the state's general policy on Medicaid rebates on 340B drugs (for example, does the Medicaid Agency use the OPA Exclusion File?)
- If our entity uses 340B for Medicaid, what procedure should we use to notify the state Medicaid agency that a 340B drug was unavailable?
- Does the State Medicaid Agency seek a Medicaid Rebate on claims from patients:
  1. That are "Dual Eligible" (Medicaid/Medicare)
  2. That received physician administered Drugs
  3. That are billed from Medicaid Managed Care
  4. In any other circumstance?

Supporting 340B and Medicaid Programs

- CMS is strongly encouraging state Medicaid agencies to develop 340B policy (access and rebate related issues)
- Apexus is facilitating education of entities and state Medicaid agencies by assisting with the development of win-win reimbursement strategies
- Key areas for the use of 340B drugs for Medicaid recipients
  - Outpatient Fee-for-service programs
  - Outpatient managed care programs
  - Outpatient physician and clinic 340B drug use on procedure based services
- Medicaid resource database

Orphan Drug Exclusion

- Final Rule
  - Published July 23, 2013
  - Effective October 1, 2013
- Free-standing cancer hospitals, Rural Referral Centers, Sole Community Hospitals, and Critical Access Hospitals
- Excluded from 340B: drugs used for the indication for which they received an orphan designation but not when the drug is used for indications independent of that designation
- Both HRSA and manufacturers may audit this exclusion

Orphan Drug Incentives

- Orphan Drug Act allows for defraying the costs of qualified clinical testing expenses incurred in connection with the development of drugs for rare diseases and conditions
  - Grants
  - Research design support
  - FDA fee waivers
  - Tax incentives
  - Orphan drug market exclusivity are the main incentives for orphan drug R&D.

Orphan Drug List

- OPA published the orphan drug list here in 9/2013: http://www.hrsa.gov/opa/programrequirements/orphandrugexclusion/index.html
- List to be updated quarterly
- Work in progress
- Opportunities (NDC)

Opt-in OR Opt-out

- Covered entities (parent and child sites) are required to inform HRSA if they will opt in or opt out
  - **Opt In:** The hospital will purchase orphan drugs under the 340B Program, can track by indication and will maintain auditable records to demonstrate compliance
  - **Opt Out:** The hospital cannot or does not wish to maintain auditable records regarding compliance with the orphan drug exclusion and will purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used

Auditable Records

- Records need to contain the following:
  - Patient Name
  - Date of Service
  - Payer - exclude Medicaid if Carve In)
  - Site of Care – exclude inpatient activity or locations not on the cost report
  - Provider – exclude any provider not under contact with the Covered Entity
  - Drug Indication – exclude any use to treat an diagnosis linked to the orphan drug indication

About 340B University™

Apexus offers 340B University, an in-depth educational program designed for all 340B stakeholders to learn 340B compliance from industry experts. Topics covered in the training include fundamentals in implementing a compliant pharmacy program from basics to drug pricing and hands on training with tools and resources available to assist with program integrity.

340B U Supports Compliance

- Self-Assessment Tools:
  https://www.340bpvp.com/resource-center/other-resources/compliance-self-assessment/
- Sample Standard Operating Procedures:
  https://www.340bpvp.com/resource-center/other-resources/standard-operating-procedures/
- Educational:
  https://www.340bpvp.com/resource-center/other-resources/other-tools/
- FAQs:
  https://www.340bpvp.com/resource-center/faqs/

Apexus Contact Information

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Questions

Options by Covered Entity Type