Preparing for Enforcement of the Complex 340B Pricing Program Requirements - An Integrated Compliance Effort

SESSION 207
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Introductions

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Session Objectives

• Present an overview of the HRSA OPA 340B Pricing Program.
• Identify requirements and areas of concern for 340B Compliance.
• Integrate the 340B Program into operations.
• Develop 340B self-audit programs and incorporate monitoring.
• Plan for 340B Audits by HRSA and drug manufacturers.
340B Pricing Program Overview

• Deeply discounts drugs 25-50% from typical market prices.
• Federally-mandates a discount for institutions that serve a high number of Medicare, Medicaid and uninsured patients.
• Enables covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

The 340B Pricing Program

• Health Centers - Federally Qualified Health Centers
  - Federally Qualified Health Center Look-Alikes
  - Native Hawaiian Health Centers
  - Tribal / Urban Indian Health Centers
  - Ryan White-HIV/AIDS Program Grantees

• Hospitals - Children’s Hospitals
  - Critical Access Hospitals
  - Disproportionate Share Hospitals
  - Free Standing Cancer Hospitals
  - Rural Referral Centers
  - Sole Community Hospitals

• Specialized Clinics - Black Lung Clinics
  - Comprehensive Hemophilia Diagnostic Treatment Centers
  - Title X Family Planning Clinics
  - Sexually Transmitted Disease Clinics
  - Tuberculosis Clinics

Covered Entities
Eligible Patients

340B acquired medications and supplies are to be used only for eligible patients.

- 1996 Patient Definition Regulations:
  - 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.

Eligible Drugs

The 340B Program generally covers the following OUTPATIENT drugs:

- FDA-approved prescription drugs;
- Over-the-counter (OTC) drugs written on a prescription;
- Biological products that can be dispensed only by a prescription (other than vaccines); or
- FDA-approved insulin.
Ongoing Requirements
To participate in the Program a covered entity must:

- Keep 340B database information accurate and up to date;
- Recertify eligibility every year;
- Prevent duplicate discounts;
- Prevent diversion to ineligible patients; and
- Prepare for program audits.

GPO Participation Prohibition
There is a statutory prohibition on Group Purchasing Organization Participation.

The prohibition applies to
- Disproportionate share hospitals,
- children’s hospitals, and
- freestanding cancer centers.

These entities may not
- "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement."

Non-Compliance: Termination
- GPOs cannot be used for “covered outpatient drugs” within the 4-walls of hospital “under any circumstance.”
  - Includes drugs for ineligible patients.
- An off-site facility can use a GPO for covered outpatient drugs if the following criteria are met:
  - Located at a different physical address than the parent;
  - Not registered on the OPA 340B database;
  - Purchase drugs through a separate pharmacy wholesaler account than the 340B participating parent; and
  - Hospital maintains records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the hospital or child sites.

AREAS OF CONCERN FOR COMPLIANCE

HRSA Registration

- Accurate registration with HRSA’s Office of Pharmacy Affairs (OPA) is **critical**:
  - Official record of where 340B drugs are maintained/340B prescriptions originate.
  - Manufacturers rely on database to track discounted drugs and honor wholesaler chargebacks.
- Registration is required for Parent Site (e.g. DSH).
- Also required for Child Sites and Contract Pharmacy relationships.
  - Child sites need to be listed as reimbursable above line 119 of the most recently filed cost report and require Outpatient Facility Registration.

Contract Pharmacies

- Contract pharmacies serve as an additional dispensing and billing agent of a hospital to increase qualified patients’ access to 340B.
- HRSA does not allow one 340B site to transfer medication to another 340B site.
- Complex systems may wish to seek approval of a HRSA Alternate Methods Demonstration Project to operate outside 340B Drug Pricing Program guidelines.
Medicaid Exclusion File

- During OPA registration, hospitals must answer the following: “Will you bill Medicaid for drug purchased at 340B drug price?”
  - Carve-In: List Medicaid provider numbers and NPI.
    - Pass through 340B price.
  - Carve-Out: Do not list Medicaid provider numbers/NPI.
    - Bill according to hospital standards.
- This information is maintained on the OPA Medicaid Exclusion File.

Other Areas of Concern

- Up to date registration on HRSA website.
  - Communication with state drug rebate unit regarding NPI numbers.
- Bill-to, ship-to arrangements across contract pharmacies and tracking systems.
  - Very challenging given current patient access/service issues.
- Applying state and federal regulatory criteria.
- Managing the high number of current accounts takes planning and stringent controls.

Inventory Issues

- Virtual inventory helps tracks utilization of 340B, GPO and WAC purchases.
- 11-digit NDC replenishment.
  - Shortages, auto-replace, discontinuation, NDC change.
- CDM to NDC cross-walk.
  - Correct NDC need to ensure 11-digit NDC replenishment and Medicaid pass-through.
  - Ability to purchase at 340B and not default to WAC.
- Unit of measure issues.
  - Impacts correct accumulation at NDC package level
  - Both compliance and efficiency issues.
Compliance is Critical

• Sanctions for non-compliance are real.
  ▫ They include removal from the 340B program and/or repayment to manufacturers for drugs purchased using 340B pricing during the time period for which the violation occurred.

• The “Authorizing Official” is a significant role.
  ▫ They certify compliance with the 340B Program during the annual recertification process.

Self-Disclosure

• Covered Entities must disclose violations of the 340B Program to HRSA.
• Timing is essential.
  ▫ A covered entity should self-disclose as soon as reasonably possible after a violation and at any given point prior to the recertification process.
• Process includes:
  1. Covered entity disclosure;
  2. Covered entity - Manufacturer communication;
  3. HRSA review of disclosure; and
  4. HRSA closure of issue
• Self Disclosure reporting tool available on Apexus website.

AN INTEGRATED 340B PROGRAM
It’s Not Only Pharmacy

- Participation in the program offers most entities significant savings.
- Management of 340B is complex and detailed.
- 340B entities are under significant government and industry scrutiny.
- Coordination across all departments is critical to successful administration of the Program.
- Involve a cross-functional executive team.
  - This demonstrates the commitment to compliance with the Program at a high level within the organization.

Why Executive Involvement?

- A cross-functional executive team,
  - Provides overarching oversight.
  - Ensures covered entities and child sites are properly registered.
  - Communicates any impending changes to existing infrastructure (i.e., adding new sites, changing existing site status) are identified, discussed and addressed properly in the HRSA database.
  - Assesses 340B billing practices meet state Medicaid laws and HRSA requirements (e.g., use of modifiers; split billing)
  - Provides independent monitoring of self-audit findings.

Set the Standard through Policy

- Entities should develop policies that address processes for 340B program compliance; include language to:
  - Ensure covered entities and child sites are properly registered and maintain and recertify 340B program eligibility.
  - Address changes to existing infrastructure (i.e., adding new sites, changing existing site status) and properly accounted for in the HRSA database.
  - Assess 340B billing practices to comply with state Medicaid laws and HRSA requirements (e.g., use of modifiers; split billing).
  - Monitor 340B inventory is properly managed.
  - Incorporate monitoring and reporting of self-audit findings.
Include Exclusions

- The policy should also address the purchase of drugs which do not meet the definition of “covered outpatient drugs.”
  - Example: If a drug is (1) part of or incident to another service, (2) used in the same setting as that service and (3) is paid as part of that service (instead of the drug being reimbursed directly), then the drug is not considered to be a covered outpatient drug for 340B purposes, and will be purchased through the GPO.
  - This consideration shall be applied to anesthetic gases, contrast media, crash cart trays and IV solutions.

Train on the Policy

- Training should be ongoing.
  - Deliver to everyone involved in 340B program operations (e.g., pharmacy, finance, etc.) and the 340B executive team.
  - Training should:
    - Outline pertinent 340B program rules and regulations, on state and federal level
    - Discuss the process for addressing 340B policy and the maintenance of integrity of the 340B Program participation.
    - Describe the role of the entity in 340B pricing integrity.
    - Identify the roles and responsibilities of 340B program implementation and monitoring.

Review, Review, Review

- Monitoring Activities
  - Regular 340B Program Team update meetings
  - Communications with contract pharmacies to ensure compliance
- Self Audits
  - Covered entities are expected to maintain auditable records of its 340B participation
  - HRSA recommends conducting self-audits as a means by which entities can detect and resolve any compliance issues.
- External Audits
  - HRSA OPA has a peer to peer program that has identified leading practice sites – reach out!
  - If you can, access industry experts to further identify and mitigate detected compliance issues.
SELF-AUDITS AND PROGRAM MONITORING

Program Expectation: Self Audits

- Develop a process that includes:
  - Interviews with key organizational leaders involved in 340B program operations (e.g., Pharmacy Director, Purchasing Coordinators, Finance Director responsible for cost report)
  - Performance of assessments of compliance with 340B policy(ies), entity eligibility criteria and up to date entries in the OPA Database
  - Audit samples of 340B drug transactions.

Keep HRSA OPA Top of Mind

- Covered entities are expected to maintain auditable records of its 340B participation.
- HRSA recommends conducting self-audits as a means by which entities can detect and resolve any compliance issues.
- The process for conducting self audits should be outlined in organizational policies and procedures.
- Self audit process should involve multiple departments – Pharmacy, Finance, Internal Audit and/or Compliance.
- Remember to keep all records of audits.
Self Audit Tools

340B Compliance Self-Assessment: Policy
A Quick Self-Assessment for DISH Leaders

Purpose:
The purpose of this self-assessment is to help participating DISH Leaders to assess their current level of compliance in their pharmaceutical operations.

Instructions:
1. Identify all staff responsible for the self-assessment.
2. Complete the attached self-assessment form.
3. Submit the completed form to your supervisor.
4. Use the guidance provided in the attached form for self-assessment.

PREPARING FOR 340B AUDITS BY HRSA AND DRUG MANUFACTURERS
**HRSA OPA Audits are Here!**

- HRSA has the authority to audit covered entities for compliance with 340B Drug Pricing Program requirements (42 USC 256b(a)(5)(C)).
- HRSA’s 340B Program audits review covered entity compliance with respect to eligibility status, including compliance with the GPO prohibition as applicable, duplicate discounts, and diversion.
- Failure to comply may make the 340B covered entity liable to manufacturers for refunds of discounts or cause the covered entity to be removed from the 340B Program.

**What to Expect**

- Audit consists of pre-audit interactions, an onsite audit and audit close out process.
- Audit procedures consist at least the following:
  - 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.

**How to Learn More**

- Summary results of past audits are found at: http://www.hrsa.gov/opa/programintegrity/index.html
- Samples address issues related to:
  - Diversion,
  - Failure to follow GPO Exclusion,
  - Incorrect 340B Database Record
Manufacturers Can Audit Too!

- Pharmaceutical manufacturers enter into a pharmaceutical pricing agreement or PPA with the Secretary of HHS.
- Under the PPA, a manufacturer agrees to provide discounts and otherwise comply with 340B requirements.
- Manufacturers are advised to monitor 340B customer purchasing trends to protect against overutilization of discounted drugs.
- HRSA has launched a audit of a manufacturer for compliance with 340B pricing requirements.

Manufacturer Audit Guidelines

- Guidelines are published in the Federal Register.
  - 61 FR 65406 (December 12, 1996)
- An audit may be conducted “only when it has documentation which indicates that there is reasonable cause.”
- Prior to conducting an audit, manufacturers must submit audit work plans to HRSA for review.
  - HRSA reviews for reasonable purpose and scope.
- The audit is to determine compliance with the following:
  - Section 340B(a)(5)(A) of the PHS Act – Prohibiting Duplicate Discounts or Rebates; and
  - Section 340B(a)(5)(B) of the PHS Act – Prohibiting Resale of Drugs.

Prepare

- Be always at the ready!
- Develop your 340B policy to incorporate procedures in the event of a HRSA OPA or manufacturer audit.
Resources

- HRSA OPA Website
  http://www.hrsa.gov/opa/

- Apexus Prime Vendor Website
  https://www.340bpvp.com/controller.html

- Safety Net Hospitals for Pharmaceutical Access (SNHAPA)
  http://www.snhpa.org/

WRAP UP & QUESTIONS

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