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340B Programs and Disproportionate Share Hospitals

What to Expect and How to Cope with Inquires from HRSA, Manufacturers, and Senator Grassley

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Welcome

- Download the slides for today's program by clicking the PDF link in the upper left corner of your screen.

- Also on the left is a Q&A box where you may type your questions. We'll look at those questions at the end of the program and answer as many as we can.

Session Overview

- 340B Program Key Features
- DSH Requirements
- Contract Pharmacy Arrangements
- HRSA and Manufacturer Audits
- Grassley Inquiries
- Preparing for an Audit
- GPO Participation
- Self-Reporting
- Certification and Registration
- Potential Penalties

340B Program Key Features

- Enacted in 1992 - Section 340B of the Public Health Services Act (42 U.S.C. 256b)
- Oversight by the Health Resources and Services Administration, Office of Pharmacy Affairs: www.hrsa.gov/opa/
- Establishes Ceiling Price on "Covered Outpatient Drugs" (25% to 50%, according to HRSA).

340B Program Key Features

- 340B Discount is Available Only to Covered Entities
  - Certain HRSA Grantees
  - Certain Hospitals Meeting Eligibility Criteria
    - Disproportionate Share Hospitals
    - Critical Access Hospitals
    - Rural Referral Centers
    - Sole Community Hospitals
    - Children's Hospitals
    - Free Standing Cancer Hospitals

DSH Requirements

- DSH Eligibility Requirements
  - DSH percentage > 11.75%
  - Must be:
    - (i) Owned or Operated by a State or Local Government,
    - (ii) a Public or Private non-profit hospital granted government powers, or
    - (iii) a private non-profit hospital under contract with a state or local government to provide "indigent care."
  - Must certify that it will not obtain covered outpatient drugs through a GPO or other group purchasing arrangement.

DSH Requirements

- Other 340B Compliance Requirements for DSH Hospitals
  - Diversion Prohibited - 340B Drugs may be dispensed only to a "patient" of a CE and may not be resold.
  - Duplicate Discounts Prohibited – CE may not request payment under Medicaid for a 340B drug if the drug is subject to the payment of a rebate to a state Medicaid agency

DSH Requirements

- Patient Definition for DSH
  - 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.

DSH Requirements

- "Child Sites" Must be Separately Enrolled
  - Applies to Off-Site Facilities (outside the "four walls" of the hospital).
  - The Off-Site Facility must be included in the most recently filed cost report.
  - May enroll at initial 340B enrollment or during quarterly enrollment periods.

Contract Pharmacy Arrangements

- HRSA issues revised guidance in 2010
  - Allows contracting with multiple pharmacies (previous 1996 guidance only allowed one contract pharmacy per delivery site).
  - Requires written agreement between CE and Contract Pharmacy.
  - Contract must address HRSA's "Essential Elements."
  - CE must conduct annual independent audits.
  - CE retains ultimate responsibility for compliance.

Contract Pharmacy Arrangements

- Operational Features
  - Enroll at initial enrollment or quarterly enrollment periods.
  - "Ship to" "bill to" drug purchasing.
  - Virtual inventory/replenishment models not contemplated by statute are widely utilized.
  - Contract Pharmacies are typically (but not always) paid a flat dispensing fee.

Contract Pharmacy Arrangements

- Contract Pharmacy Compliance Concerns
  - Diversion
  - Duplicate Discounts – CE's contract pharmacy may not dispense drugs purchased at 340B price to Medicaid FFS patients unless the contract pharmacy has established "an arrangement" to prevent duplicate discounts
  - Anti-Kickback Law
  - Federal and State Privacy
  - Need for Change of Law Provisions

Growth and Scrutiny

- ACA and Sub-regulatory Guidance Have Resulted in Exponential Growth
- Congressional and Industry Scrutiny
  - Questions Concerning Original Intent of Program
  - Lack of Oversight
  - Lack of Specific Guidance
  - Senator Grassley's letter to HRSA citing the three N.C. hospitals

What types of Audits/Inquiries are 340B Hospitals Subject To?

- HRSA/OPA Audit
- Manufacturer Audit
- Grassley Letter

HRSA Audits

- Recent Development in Program
- 50+ audits conducted in 2012
- Up to 300 expected in 2013

Manufacturer Audits

- Authorized by the Program
- Must have reasonable cause to believe there is non-compliance
- Must file an audit workplan with HRSA prior to audit
- Covered entities are given 15 days notice prior to audit

Manufacturer Audits

- Records reviewed limited to:
  - Covered entity records
  - Contract pharmacy records
  - Other vendors that assist covered entity in program
- Post-audit meeting
- Results in provided in written report
- Covered entity has 30 days to respond
  - May challenge results

Grassley Letter

- Initial letter inquiries sent out in September 28, 2012 to three North Carolina Hospitals
- Hospitals have responded
- Fourth Letter sent to Georgia Hospital

Grassley Letter

- Letter to HRSA March 27, 2013
  - Reported on responses from hospitals
  - Focused on how hospitals are using funds
  - Questions re HRSA's oversight of covered entities
    - Focus on how funds are used
- HRSA's response April 17, 2013
  - Statue does not limit the manner in which covered entities utilize the savings from discounts provided through the 340B Program

Who is more likely to be audited by HRSA and/or Manufacturers?

- Disproportionate Share Hospitals are by far the most common covered entity type
- HRSA audits are both random and targeted
  - Suspected violators
- Manufacturers more likely to target DSH with higher volume purchases
  - Will look at trends in purchases
    - Identifying increase purchases of certain drugs
    - Purchases of drugs that are generally used for inpatients

Grassley Letters

- DSH Hospitals with
  - high visibility
  - high volume purchases
- Unclear where focus will be placed in the future

Audit Focus: HRSA and Manufacturers

- Eligibility:
  - Annual Certification
  - Registration of contract pharmacies and child site clinics
- Diversion
- Duplicate Discounts
- GPO Participation

Audit Focus: Senator Grassley

- Diversion
- Duplicate Discounts
- Does the covered entity pass the discount on to under or un-insured patients?
- How does the covered entity use the savings realized through 340B purchasing?
  - Charitable care policies

Preparing for an Audit

- Documentation
- Education and Training
- Written Policies and Procedures

Common Issues that Arise During Audits

- Diversion: Who is an Eligible Patient?
  - Inpatient v. outpatient
    - Multiple use settings, non-acute care settings
    - Discharge prescriptions
  - Provider-based Clinics (child sites)
  - Employees
  - HRSA's guidance
    - Reverting to 1996 Guidance

Common Issues that Arise During Audits

- Duplicate Discounts
  - Medicaid Carve-In v. Carve-Out
  - Requirement to submit to OPA the Medicaid billing numbers for entities that "carve-in" Medicaid
  - Billing Medicaid appropriately

GPO Participation

- Newest "Clarification" by HRSA
- DSH covered entities only
  - May not use GPO for "covered outpatient drugs"
    - Exclusion applies even if outpatient drugs are not 340B eligible *e.g.*, Medicaid carve-out, in-house pharmacy open to public, etc.
  - Okay to use GPO for inpatient and non-covered drugs
- Vendor services offering split-billing systems

Certification and Registration

- Initial and Annual Certification
  - Eligibility dependent on being listed on OPA's list of covered entities
  - Information must be kept up to date
  - For DSH covered entities, this includes the qualifying DSH percentage of 11.75% on most recently-filed cost report

Certification and Registration

- Registration of Contract Pharmacies
  - Pharmacies are not covered entities and should not have a 340B ID
  - Covered entities must submit contract pharmacy registrations during open registration period (first two weeks of each quarter) to be eligible for the participation in the following quarter
- Registration of Child Site/Provider-based clinics
  - Quarterly Enrollment

Self-Reporting

- Eligibility:
  - "immediately inform" HRSA of any change in eligibility status
  - stop purchasing
- Other non-compliance
  - Report non-compliance
  - Repay amounts to manufacturers
    - Difference between discounted price and non-340B purchase price

Penalties for Non-Compliance: Diversion

- Refund discount to Manufacturers
- Interest penalty where diversion is "knowing and intentional"
- Removal from 340B program if diversion is also "systematic and egregious"
- Possible referral to OIG or FDA

Penalties for Non-Compliance: Duplicate Discounts

- Refund of discount to manufacturer
- Possible referral to OIG or FDA

Penalties for Non-Compliance: Prohibition on GPO Participation

- Removal from 340B Program
- Repayment to manufacturers

Questions?

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