340B Compliance

Presenters:
• Barbara Williams, Principal, Powers Pyles Sutter & Verville
• Cindy Bartlett, Compliance Officer
• Scott Ponaman, President, Ponaman Healthcare Consulting
• Coley Deal, 340B Program Manager, Bon Secours Mercy Health System

Presenters and Today’s Agenda

• The Legal Approach Compliance
  • Barbara Williams, Principal, Powers Pyles Sutter & Verville
• A System Wide Approach to 340B Compliance
  • Cindy Bartlett, Compliance Officer
• Current Climate of Compliance
  • Scott Ponaman, President, Ponaman Healthcare Consulting
• Monitoring and Auditing
  • Coley Deal, 340B Program Manager, Bon Secours Mercy Health System
Audience Poll #1

I would describe my level of knowledge of 340B as:

• Minimal (just beginning to learn about 340B)
• Average (deal with 340B matters occasionally)
• Expert (routinely advise on 340B compliance matters)

Audience Poll #2

I am employed by a/an:

• Hospital or health system
• 340B grantee
• Consulting organization
• Law firm
• Government entity
• Other
History/Purpose:

• Section 340B of the Public Health Service Act (42 U.S.C. §256b) was implemented by Congress in 1992 of Public Law 102-585, Section 602.

• The 340B statute requires pharmaceutical manufacturers to enter into an agreement with HHS to provide discounts on “covered outpatient drugs”, purchased by certain providers called “covered entities” that serve the nation’s vulnerable patient populations as a condition of the manufacturer’s drugs being reimbursable under Medicaid and Medicare Part B.

• Participation in the 340B program provides covered entities with access to significant pricing discounts on covered outpatient drugs.
340B Compliance
The Legal Approach

Principal Compliance Issues for Providers:

1. Anti-Diversion/Patient Eligibility
2. Duplicate Discounts
3. Group Purchasing Organization (GPO) Restriction (applicable to 11.75% DSH, Children’s and Cancer Hospitals)
4. Orphan Drug Restriction (applicable to RRCs, SCHs, CAHs, and Cancer Hospitals)
5. OPA Database Errors
6. Maintain Auditable Records

OPA Sanction Authority for Diversion and Duplicate Discount Issues:

• Repayment to manufacturers.
• Interest on repayments for knowing and intentional violations.
• Removal from 340B for violations that are systematic, egregious, knowing and intentional. 42 USC§256b (a)(5)(c),(d)(v)(I),(II).
• HRSA Notice: “A finding of non-compliance in two or more audits, depending on the type of violation, may be considered systematic and egregious, as well as knowing and intentional, which may result in the CE being removed from the 340B Program…”

OPA Sanction Authority for GPO Violation:

• Removal from 340B program
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The Legal Approach

Anti-Diversion/Patient Eligibility:
Definition of “patient” for 340B includes three criteria:

1. **Record Maintenance Test** - The covered entity maintains records of the individual’s health care.

2. **Professional Care** - The individual must be under the care of a physician or other health care professional who is employed by, under contract with, or in a referral relationship to the covered entity such that **responsibility for the individual’s care remains with the covered entity**.

3. **Qualified health care service/range of services** - The individual must receive a range of health care services that are consistent with the services for which grant funding or FQHC look-alike status has been provided to the covered entity. (This requirement is not applicable to hospitals.)

   • An individual will NOT be considered a patient of the covered entity if the ONLY health care service received is the dispensing of a drug or drugs for self-administration in the home setting.

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The Legal Approach

Anti-Diversion/Patient Eligibility: Eligible Facility

• Only provider-based outpatient departments may dispense 340B drugs. HRSA guidance states that, “[o]utpatient facilities which are an integral component of the DSH will be included on the DSH Medicare cost report, and only those facilities will be eligible for PHS [3408] discount pricing.”

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The Legal Approach

Duplicate Discount Prohibition:

• Drug manufacturers are required to give rebates to State Medicaid programs on drugs reimbursed under State Medicaid programs, either FFS or managed care, but are protected from giving both a 340B discount and a Medicaid rebate on the same drug.
• Covered entities may elect to use 340B drugs for Medicaid patients ("carve-in") or may elect not to use 340B for Medicaid patients ("carve-out"). May make different election for each Medicaid billing number.
• Medicaid programs submit for rebates on carve-out 340B drugs, but forgo rebates for entities that carve-in.
• Covered entities notify OPA of their election and OPA maintains an "exclusion file" for State Medicaid to determine if an entity has carved-in. State may also require billing modifier to identify 340B drugs.

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The Legal Approach

State Medicaid Billing Requirements for 340B Drugs:

• States may require 340B claims to be flagged (e.g. UD modifier for physician administered drugs; “20”; “08” and/or “05” for retail claims).
• Recent state initiatives to require covered entities to carve out to avoid disputes on duplicate discounts.
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The Legal Approach

GPO Restriction:

• Certain hospitals (acute care with DSH > 11.75%, children’s and cancer) may not purchase any covered outpatient drugs through a GPO. Exception: Prime Vendor Program (Apexus).

• Provider-based departments of a hospital may elect not to participate in 340B if they meet four requirements:
  • Are located at a different physical address than the parent;
  • Are not registered on the OPA 340B database as participating in the 340B Program;
  • 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 parent hospital or any outpatient facilities registered on the OPA 340B database.
340B Compliance
System Wide Approach

Best Practice
• Goal 1: Proactive Approach to 340B Compliance
• Goal 2: Decrease Variations to achieve compliance and efficiencies
• Core Leadership:
  • System 340B Expert
  • System Compliance Officer (340B Experience and Knowledge)
  • System Legal Counsel (In-house or External with 340B Knowledge)
  • 340B External consultants/auditors (Proven Experts)
• Focus
  • Policies
  • Monitoring (Internal)
  • Auditing (Independent and External)

340B Compliance
System Wide Approach

• Program Focus:
  • Compliance vs. monitoring
  • System Level 340B Policy
    • Each facility will adopt policy and modifications may only be made by Core Leadership
  • Flowcharts and Procedures
  • On-going Education
  • Be Prepared for HRSA Audit 24/7/365

• Focus Monitoring: (Handout)
  • Eligibility
  • Diversion
  • Duplicate Discounts
  • GPO Exclusions
  • Database Accuracy
  • Expert external auditors
340B Compliance
System Wide Approach

- HRSA 340B Audit Statistics
  - HRSA OPA Conducts 200 audits annually
    - 1.6% of 340B Covered entities
  - Entities are selected randomly using risk-based criteria
    - Volume of 340B purchases
    - Number of contract pharmacies
    - Complexity of 340B program
    - History of noncompliance
  - 10% of audited entities are targeted based on information from stakeholders, or they are selected as a follow-up from a previous audit

340B Compliance
System Wide Approach

- Corrective Action Plans (CAP)
  - Developed, monitored, and report (Compliance Committee) under the direction of the 340B Core Leadership team for the following:
    - HRSA Audit Preparations
    - HRSA Audit Findings
    - External Annual Audits at each location
    - Non-compliance with purchasing, eligibility, diversion, duplicate discounts, GPO prohibitions, etc.
    - Proposed new Regulations
    - Changes in any and all federal and state guidelines
340B Compliance
Current Climate

Scott Ponaman
President
Ponaman Healthcare Consulting

340B Compliance
Current Climate

• Ponaman has assisted with over 65 HRSA audits
• Audits have shifted focus to the following areas of compliance:
  • Tracer samples
    • From dispensation/administration to replenishment over time
  • Targeted Medicaid billing
  • Sample validation
  • Coding sampling
  • Medicaid billing review
  • Review purchasing history and accumulation reporting
  • Impact on covered entity outside of 6 month audit timeframe
340B Compliance
Current Climate

- Most recent changes to HRSA final reports
  - Controls for the procurement of 340B drugs including for replenishment
  - Accumulation and reconciliation
  - Material breach disclosure to OPA
  - Policies and procedures around
    - record keeping 340B drug waste
    - monitoring inventories
  - Prevention of duplicate discounts on covered outpatient drugs reimbursed through Medicaid managed care organizations (MCOs)

340B Compliance
Current Climate

- Areas of preparation to focus on:
  - 340B team organization and defined staff roles
  - Keep items from the data request readily available, up-to-date and accurate
  - Keep a folder with all items that are submitted on the NIH portal
  - Review Policies and Procedures and compare them to your processes to make sure that your procedures follow your policies exactly
  - Maintain clear communication with your retail/contract pharmacy prior to audit and during the audit for quick access to sampling
  - Check OPAIS to ensure information is accurate
  - Keep Pharmacy Service Agreements available, up-to-date and accurate
  - Ensure contract between state/local government and covered entity is up-to-date and available
340B Compliance Monitoring and Auditing

Coley Deal
340B Program Manager
Bon Secours Mercy Health System

340B Compliance Monitoring and Auditing

• Focus Monitoring: (Handout)
  • Eligibility
    • Compare Medicare Cost Reports to Database
    • Review OPA for program changes
    • Validate DSH percentage
  • Diversion
    • Validate DEA provider list
    • Review and reconcile inventory
  • Duplicate Discounts
    • Validate NPI (provider numbers) on database
    • Validate status with on-going monitoring (Carve In or Out and State Rules)
    • Use of billing modifiers
340B Compliance Monitoring and Auditing

- **GPO Exclusions** — Non compliance risk may include
  - Exclusion from the program
  - Repayments to manufacturers for 100% of what was purchased during the time of non compliance.
- **Database Accuracy** — Review accuracy including parent and all child sites.
  - Review Addresses, suite numbers, names
  - Compare to Medicare Cost Reports
- Review of 340B only inventories
- Eligible provider review
- **External auditors**
  - Independent from internal auditors or monitoring staff
  - Proven track record
  - Annually complete a "mock HRSA audit" at each parent site which will include child sites

Questions?
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