340B Program Audits: HSRA and Manufacturer Audits of Covered Entities
Preparing for Audits and Ensuring Compliance with 340B Discount Drug Program

WEDNESDAY, APRIL 10, 2013
1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today’s faculty features:

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340B Program Audits: HRSA and Manufacturer Audits of Covered Entities

Presentation for Strafford Publications

Bill von Oehsen, Founder and Outside Counsel

April 10, 2013
1:00-2:30 PM (Eastern)
Disclaimer

This presentation is not to be construed or relied upon as legal advice.
Overview

- Intro to SNHPA and 340B
- Audits
  - Background
  - Diversion
  - Duplicate discounts
  - Penalties
- Manufacturer audits
- Audit process
- Covered entity protections
- What SNHPA has learned
Who is SNHPA?

- Represents nearly 1000 hospitals in the 340B program – all hospital types
- At the table since inception of program in 1992
- The only exclusive advocate for 340B hospitals
- Provides valuable technical support and critical information on all aspects of 340B
20 Years of 340B!

- By supporting safety net providers, the program improves access and care for uninsured, underinsured and other vulnerable patient populations
- Examples of how SNHPA members use 340B to benefit patients:
  - Enhance affordability of both pharmacy and non-pharmacy services
  - Serve more indigent patients
  - Maintain or open up new clinics needed by the community
  - Avoid restrictive formularies and increase drug choice
  - Reduce patient wait times
  - Extend pharmacy hours
Audits: Background

- Both HRSA and manufacturers are authorized to perform audits
- HRSA audits began in January of 2012
- Audits cover diversion and duplicate discount violations
  - Prohibition against group purchasing is being audited as well (only applies to disproportionate share, children’s, and cancer hospitals)
- Covered entity is responsible for compliance status of itself and its contract pharmacies
  - Special compliance requirements apply to contract pharmacy arrangements
Audits: Background (cont’d)

- Up to 300 government audits expected in 2013, up from 51 last year
- Sixteen out of the 18 audits completed to date found no violations of program requirements
- Two audits required corrective action for unspecified inaccuracies in the providers' entries in the 340B covered entity database
- Audits are now also being conducted by manufacturers; one final audit report being reviewed by OPA
Audits are both randomly selected and targeted at suspected violators

Random selection process is weighted towards hospitals being audited more frequently

HRSA’s Office of Regional Operations (ORO) is conducting the audits
  - ORO located in all 10 HRSA regions
  - Both CPAs and pharmacists on staff
Audits: Diversion

- Controlling HRSA guidelines:
  - 1996 guidance on the definition of patient (61 Fed. Reg. 55156); and
- These guidelines are broad and subject to various interpretations
- HRSA proposed changes to patient definition in 2007 (72 Fed. Reg. 1543), but HRSA plans to withdraw the changes
Audits: Duplicate Discounts

- Controlling HRSA guidelines:
  - 1993 guidance on preventing duplicate discounts (58 Fed. Reg. 30458); and
  - 2000 guidance clarifying duplicate discount billing requirement (65 Fed. Reg. 13983)
- Requires covered entities to submit to HRSA the Medicaid billing or NPI numbers of their main facilities and clinics that use 340B (i.e., those that “carve-in”)
  - Must inform HRSA of changes in entity’s policy
  - May also look at whether covered entity is billing Medicaid appropriate rate, e.g., actual acquisition cost (AAC) in states that require AAC
Audits: Potential Penalties

- Corrective action – fixing the problem going forward
- Repay manufacturer the 340B discount
- If violation is “knowing and intentional,” covered entity also pays interest
- If violation is also “systemic and egregious,” covered entity is removed from 340B program and banned from re-entry for a reasonable period
Manufacturer Audits

- Manufacturer informs covered entity in writing of violation of law
  - Must have reasonable cause to believe a violation occurred
  - “Significant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity may be a basis for establishing reasonable cause”
- Parties have 30 days to resolve in good faith
- Manufacturer may proceed to voluntary dispute resolution without audit, OR file audit workplan with HRSA at least 45 days before audit
Manufacturer Audits (cont’d)

- 15 days after submission of workplan -
  - HRSA decides that government will conduct the audit, or
  - HRSA works with manufacturer to “incorporate mutually agreed upon revisions”
  - Per recent program notice - HRSA approves or denies audit plan
  - No opportunity for covered entity to review/comment on workplan
- Covered entity informed 15 days before audit to take place
Audit Process

- Neither HRSA nor manufacturers are subject to a limit on amount of time for audit
  - Covered entity may contact HRSA if manufacturer audit is unreasonably long
- Oral briefing by manufacturer or government at end of audit
- Written report by manufacturer or government at end of audit
  - Report will be shared with the Office of the Inspector General (OIG)
Audit Process (cont’d)

- Covered entity has 30 days to respond:
  - Steps it will take to address findings, or
  - Rationale for disagreement with findings
- Covered entity may challenge findings using voluntary dispute resolution procedures
  - Mandatory dispute resolution procedures under health reform?
- Hearing by HRSA prior to determining penalty
- Covered entity has right to appeal HRSA decision to federal court per Administrative Procedure Act
Audit Protections for Covered Entities

- Government bound by Government Auditing Standards
- Manufacturer bound by Government Auditing Standards and standards in 1996 guidance
- Government will follow 1996 guidance (61 Fed Reg. 65406) regarding scope of audits and auditing protocols
- Manufacturers must use an independent public accountant
- Covered entities may be subject to only 1 audit at a time
- Audit period can be no more than one year
Audit Protections for Covered Entities (cont’d)

- Manufacturers must continue to provide 340B discount during audit
- Records that may be reviewed are limited to covered entity records and records of organizations that work with covered entities to buy, dispense, and obtain Medicaid reimbursement for outpatient drugs that directly pertain to potential 340B violations
  - Ensure that HIPAA privacy rule is followed regarding records shared with manufacturers
What SNHPA Has Learned

- What we have learned so far:
  - Initially focused on physician administered drugs, now expanded to retail and contract pharmacy drugs
  - Important to have written policies and procedures
  - Looked at use in non-acute care settings, duplicate discounts, discharge prescriptions, and use of GPO
  - HRSA acknowledges patient definition is difficult to apply
  - SNHPA provides valuable assistance in preparing for audits
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340B Program Audits: HRSA and Manufacturer Audits of Covered Entities

William A. Sarraille
April 10, 2013
Agenda

- Overview of audit requirements
- Key manufacturer concerns about covered entity conduct
  - Diversion
  - Duplicate discounts
  - GPO violations
- Audit requirement: reasonable cause
- Audit requirement: good faith resolution
- Other challenges to conducting audit process
- Issues uncovered in audits & best practices
Manufacturer Audits

- 1996 audit guidelines:
  - Reasonable cause to believe the covered entity is in violation of the diversion and/or duplicate discount prohibitions;
    - *E.g.*, significant changes in order quantities.
  - Written notification of the suspected violation(s) provided to the covered entity and completion of a 30-day, good faith resolution period;
  - Engagement of independent public accountant to perform the audit in accordance with Government Accounting Standards (“GAS”);
  - Submission of audit plan to OPA prior to implementation; and
  - Covered entity is not the subject of another audit during the same time.
    - *The concern here: a war story*
Manufacturer Concerns

- Diversion
  - 340B-priced drugs dispensed to ineligible patients
  - Inpatient/outpatient diversion
  - Manipulation of patient clinical care pathways
  - Misuses and abuses of the “patient” definition (e.g., employees)

- Duplicate Discounts
  - Mounting evidence that duplicate discounts are happening with disturbing frequency
  - OIG report; audits
  - HRSA Policy Release 2013-2 addresses use of the Medicaid Exclusion File and the need to prevent duplicate discounts
  - Added complexities with 340B exclusion for now-required rebates on Medicaid managed care utilization

- Only two issues to be addressed in manufacturer audits, but, as discussed in next slides, not the only concerns.
GPO Violations

- In OPA’s view, an eligibility issue
  - HRSA’s Position
    - “Since the beginning of the 340B Program, HRSA has addressed violations of this prohibition in guidelines published in the Federal Register, stating that if a covered entity subject to this prohibition participates in a GPO, the covered entity ‘will no longer be an eligible covered entity and cannot purchase covered outpatient drugs at the section 340B discount prices.’ 59 FR 25113 (May 13, 1994)” (emphasis added).
    - “It is HRSA’s longstanding position that a covered entity enrolled in the 340B Program subject to the GPO prohibition and listed on the OPA 340B database may not use a GPO for covered outpatient drugs at any point in time” (emphasis added).

- August 7, 2013 date
GPO Violations: HRSA Policy Release 2013-1 (cont’d)

- Scope of the Prohibition
  - A hospital subject to the GPO prohibition “may not purchase covered outpatient drugs through a GPO for any of its clinics/departments within the four walls of the hospital (same physical address) under any circumstance” and this is true “even if the drugs are dispensed at a contract pharmacy” (emphasis added).
  - Established as a requirement more than 20 years ago

- Consequences of Violations:
  - Removal from the program
  - Repayment to manufacturers
GPO Violations: HRSA Policy Release 2013-1 (cont’d)

- Rejection of Retrospective Replenishment / Reclassification
  - The release directly addresses, and rejects, some hospitals’ practice of purchasing covered outpatient drugs through a GPO and then retrospectively either:
    - (1) “replenishing” through accounting by “replacing” the GPO purchased drug with a drug purchased under 340B; or
    - (2) “otherwise reclassifying the method of purchase after dispensing”.
  - “HRSA has not authorized this GPO replenishment model”.
  - HRSA states that the “GPO prohibition is violated upon use of a GPO to obtain covered outpatient drugs and cannot be fixed or cured by subsequently changing the characterization through accounting or other methods”.
  - HRSA directs hospitals using such models to “immediately cease this practice or be found in violation of the GPO prohibition”.

(Emphases added)
Medicaid Drug Rebate Program Proposed Rule

- Violations of GPO prohibitions by covered entities may have important price reporting implications for manufacturers.
  - CMS has proposed that manufacturers be able to exclude from Best Price drugs purchased under the 340B program only where the covered entity meets the conditions set by the PHSA.
    - Reflects trend of heightened sensitivity of policymakers and regulators to 340B compliance issues among all stakeholders, including covered entities.
    - But, an unclear and troubling proposal: Must manufacturers be “guarantors” of 340B entity compliance with all program requirements to secure BP exemption?
  - Troubling for manufacturers and 340B entities alike, if this is CMS’ meaning.
    - BP exemption is a foundational component of discounts provided to 340B entities.
    - Fundamental Catch-22 for manufacturers; harmful to providers
Other Concerns About Covered Entities

- Spread thinking and activity
- Hoarding activity or outsized orders
- Co-payment waivers without financial need
- Higher co-payments to beneficiaries
- Beneficiaries lacking “qualifying stays”
Reasonable Cause

- The current “reasonable cause” standard requires that a manufacturer must present evidence of diversion before it can be permitted by OPA to proceed with an audit.

- This requirement imposes an unrealistically high standard for manufacturer audits.
  - Manipulation may not be so readily-apparent unless that there are specific clinical realities of the particular drugs that make them generally inappropriate for outpatient use.

- In the commercial sector, contracts as a matter of course provide for random auditing so the party owing rebates/discounts can determine the other party’s compliance with the terms of the agreement.
Other Challenges

- Manufacturers also run into other significant challenges in conducting audits.
- The audit process can be lengthy and resource-intensive.
- Significant costs incurred through recoupment and collection efforts.
- Business concerns
  - Picking customers that minimize that concern.
- But many reasons to be positive about this option:
  - More manufacturers considering/doing these.
  - As audit firms gain experience, costs are going down.
  - Have been open to flat fee arrangements.
  - Careful analytics on the front end can identify particularly attractive candidates.
  - Audit results can have a significant impact beyond the targeted entity:
    - Deterrence and policy impact.
Issues Uncovered in Audit Process

- Several manufacturer audits conducted to date have found significant violations by covered entities.
- Lack of policies, procedures, and controls
  - No policies and procedures at all
  - Many employees never trained on 340B program.
  - No monitoring efforts/self-audits at the entity
    - Misleading self-audits (worth progressing to a manufacturer audit)
  - Inventory records were inadequate and often did not match providers’ notes.
  - One manufacturer’s auditor observed claims for 340B chargebacks from the manufacturer where the hospital had actually used a different product from a different manufacturer.
  - One covered entity did not track drugs by NDC, making it impossible to determine whether the claims for 340B chargebacks were proper because no records supported the use of a branded (versus a generic) drug.
Issues Uncovered in Audit Process

- Split billing software
  - Disturbing pattern of incorrect 340B purchasing due to several different types of third-party consultants’ split-billing software used by a number of the manufacturer’s 340B customers.
    - 340B entities often naming this as at least a reason for their non-compliance.
Issues Uncovered in Audit Process

- Manipulation of patient clinical care pathways
  - Many covered entities communicated to a manufacturer that they were entitled to 340B pricing because the patient received services in an area of their facility that was deemed “outpatient” at the time of service even though the patient at issue may have been a registered inpatient at the time.
  - One 340B provider explained that, after attending a 340B conference and implementing a consultant-designed 340B split-billing software program, its new position was that 100% of its patients received the product as “outpatients”. Previously, it had classified only 20% of its patients receiving this product as “outpatients”.
  - Suspected manipulation of patient clinical care pathways has led some manufacturers to identify covered entities for audits.
Problems Discovered in Audits (Cont’d)

- Duplicate discounts
  - Manufacturers have recently found significant duplicate discount violations based on reviews of State Medicaid Rebate Program invoices.
  - Based on one manufacturer review, the percentage of possible duplicate discounts ranged from 3% to 50% of all the product units for which the manufacturer paid a Medicaid rebate (with an average of 18%).
  - More than a decade long failure to identify covered entities: a final war story
Questions?

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340B Covered Entity Audits: The Auditors Perspective

340B(a)(5)(A) & 340B(a)(5)(B) of the Public Health Service Act

April 10, 2013

Clarissa Crain
Agenda

- Requirements of an Independent Audit Organization
- Audit Approach
- Generalized Covered Entity Audit Results
Independent Audit Organization

• Independent audit organization
  – Trained to perform performance audits in accordance with GAGAS
    ▪ Understanding and adherence to GAGAS
    ▪ Appropriate training on GAGAS
  – No conflict of interest with Covered Entity to be audited
  – Ability to uphold independence in performance of audit
  – Dedicated adherence to HIPAA and HITECH compliance

• 340B subject matter expertise
  – Understanding of program requirements
  – Understanding of processes employed within Covered Entities to maintain compliance with the 340B Program

• Other Considerations
  – Ability to perform audit work with limited disruption to Covered Entity’s day to day activities
Audit Approach
Audit Approach

1. Notification by Mfg to Covered Entity

2. Audit Organization Communicate Intent to Audit

3. Schedule Covered Entity Review of Audit Letter

4. Onsite Visit Agenda and Issue Request List

5. Data and Document Review

6. Onsite Testing Procedures

7. Reporting
Step 1 – Notification to Covered Entity

• Email or letter from the Manufacturer notifying the Covered Entity that the Manufacturer will be exercising its audit rights

• Notification includes naming of the third party audit organization that will be performing audit work on the manufacturer’s behalf
Step 2 – Letter Communicating Audit Intent

Communication of approval from OPA based on reasonable cause and audit work plan

Scope Overview
- Periods
- Products
- Processes to review

Requested Audit Start Date

High Level Onsite Needs
- Proposed interviews
- Logistics
- Data availability

Data and Document Request referenced (attached or forthcoming depending on timing)
- Requested timing of provision/cut-off date

Request Covered Entity Point Of Contact

Identify Auditor Point Of Contact
- Communicate Option for pre-onsite call to answer questions, etc

Commitment to limiting interruption and ensuring privacy requirements upheld

Request written confirmation of receipt and audit start date within 15 days
### Step 3 – Schedule Review of Notification Letter

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<th>Review Audit Notification Letter</th>
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<tr>
<td><strong>Scope</strong></td>
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<tr>
<td><strong>Timelines: Data and Document Provision, Onsite, Follow-up</strong></td>
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#### Discuss Questions from Covered Entity

#### Confirm Covered Entity Point of Contact, if not previously provided
1. **Policies and Procedures**
   related to the activities and processes impacting compliance with the PHSA. This will include activities related to:
   I. Procurement;
   II. Inventory management;
   III. Distribution/dispensing;
   IV. Billing of drug(s) purchased under the 340B program;
   V. Care pathways, or;
   VI. Policies and procedures related to patient status and handling where the relevant drug(s) is administered/dispensed; and,
   VII. Admissions handling (e.g., status, definitions).

2. **Previous Audit Outcomes**
   I. Internal
   II. External

3. To the extent that data requests are known based on the audit work plan approved (e.g. a listing of patients, product purchase prices, billing records, admission status), *incorporate data requests*, otherwise communicate future need for this information dependant on policy and procedure review.
## Step 5 – Data and Document Review

### Identify
- Process Documentation
  - Control points
  - Key process steps
  - Potential gaps
- Interviews (not previously identified)
  - Draft interview Questions
- Key Risks and Controls

### Prepare for On-Site Testing
- Sample selection
- Develop test scripts and reference to test procedures outlined in Audit Work Plan

### Update Audit Work Plan
- Interviews
- Test procedures
- Review with Manufacturer
- Submit, as courtesy, to HRSA
Step 6 – Onsite Testing Procedures

• Perform process walkthroughs for adherence to policies and procedures (e.g. product procurement, inventory, dispensing, billing, patient admission status)

• Review the Covered Entity’s split-billing software business rules, if applicable

• Test 340B product fulfilled prescriptions for adherence to auditable provisions
  – Test samples may be targeted depending on the approved audit work plan scope
    ▪ Duplicate Discount
    ▪ Diversion

• Quantify financial impact of any identified diversion or duplicate discounts in accordance with the approach outlined in the Audit Work Plan
### Step 7 – Reporting

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<th>Procedure</th>
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<td>1.</td>
<td>Document preliminary findings based upon audit procedures performed. Discuss all findings with the Covered Entity.</td>
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<td>2.</td>
<td>Develop a draft Performance Audit Report in accordance with GAS, orally communicate audit findings to Covered Entity, present the draft report to appropriate Manufacturer management, and incorporate feedback from the Covered Entity and the Manufacturer, as deemed appropriate by the independent auditor. Ensure all protected health information is redacted from the draft and final Audit Reports.</td>
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<td>3.</td>
<td>Finalize the Audit Report and present it to the Covered Entity for its response to all findings and plans for resolving any issues identified. The Covered Entity has thirty (30) days to provide its response(s).</td>
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<td>4.</td>
<td>Review Covered Entity response(s) and seek clarification, as necessary, on responses.</td>
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<td>5.</td>
<td>Incorporate the Covered Entity’s response(s) and issue the report to the Manufacturer, providing a copy of the final report to both the Health Resources and Services Administration, Healthcare Systems Bureau, Office of Pharmacy Affairs, and the Office of Inspector General, Office of Audit Services, PHS Audits Division.</td>
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<td>6.</td>
<td>Perform final review of the audit work papers, ensuring that all protected health information is redacted. Archive the work papers in accordance with document retention requirements. Ensure availability of report and work papers for peer review/audit within three (3) years.</td>
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Generalized Covered Entity Audit Results
Generalized Entity Reaction

• Receptive and collaborative
• Ability to articulate their organizations dependency on the program
• Willingness to assist auditors in interpreting information and data necessary to complete testing
• At time of audit notification, entities have performed analytics to independently quantify potential non-compliance
Generalized Findings

- Lack of a 340B Compliance Program and internal controls to ensure that program requirements are understood, adhered to, and monitored within the Covered Entity
Factors for Success

- Audit Work Plan:
  - Have a strong understanding of the set of facts supporting the reasonable cause argument presented in the Audit Work Plan.
  - Develop an Audit Work Plan with appropriate and sufficient testing procedures to appropriately vet compliance.
  - Once an Audit Plan is ‘approved,’ the audit team must have open dialog with the Covered Entity regarding scope of work, data requests, and other dependencies of the Plan’s execution.
Thank You

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