Overview

- Planning Ahead
  - 340B Compliance “tool kit”
- Testing the Plan
  - Evaluating the tools
- Ready for Action
  - Identification of potential non-compliance
- Go Time!
  - Submitting self-disclosures and manufacturer notices
- Victory Lap
  - Follow-up and close out

Preparing

Make sure your Entity understands the purpose of 340B:

“The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”
Preparing

Understand your Entity’s 340B Program

- How are you eligible? Understand the implications, for example:
  - GPO Prohibition — DSH, children’s, free-standing cancer center
  - Orphan Drug Exclusion — CAH, RRC, SCH
  - Parent, child sites? Contract Pharmacy

- What are your State’s Medicaid requirements for 340B?
  - Carve in or carve out status
  - Billing or identifying 340B drug claims
  - Medicaid Exclusion File? Modifiers?

Preparing

- Who and what are your entity’s 340B Program Operators and influences?
  - Authorizing Official – assess understanding of program and role
  - Registration and recertification on HRSA 340B database
  - Pharmacy – purchasing, splitting software; replenishment processes
  - Ordering providers and settings
  - Vendors, consultants, informal guides
  - Professional Organization Conferences, articles

Planning Ahead

- Review Policies and Procedures, Program Activities
  - P&P updates needed?
  - Auditing or monitoring with effective CAPs?

- Ascertaining key stakeholders, staff, and program champions
  - Learn their goals for the program
  - Assess their understanding of the program
Planning Ahead

- Educate staff beyond their focused duty
  - Help operators understand constraints on program activity and their effect on others
    - Eligible patient
    - Outpatient only
    - Purchasing/replenishing

- Define Material Breach
  - Guidance available
  - Consider legal counsel

Planning Ahead

- Anticipate Audits – HRSA, Manufacturer
- Gather, Memorialize, Refine-
  - Patient Eligibility Process
  - Document Government Ownership or Control
  - Inventory Management
  - Duplicate Discount Prevention
  - Vendor Change Process
- Identify how Entity structures its program to align with 340B program intent
  - How is the Entity using the Savings that result?
    - Investing in mission, enhancements, etc.

Testing the Plan

- Test what you have memorialized-
  - Patient Eligibility Process
    - Pull a 340B replenishment and trace to Entity patient on order of provider with ongoing relationships with the entity?
  - Inventory Management
    - Show replenishments only of 340B drugs administered to an eligible Entity outpatient?
  - Material Breach
    - Does the definition yield reasonable results when used to calculate hypothetical breaches?
Testing the Plan

- **Duplicate Discount Prevention**
  - Pull 340B Medicaid patient bill and consistently find State requirements met?

- **340B Manufacturer or Vendor Information**
  - How are orders, records, contact information retained?
  - How are contact information monitored to ensure it is kept current?
  - How is a manufacturer or vendor change or termination processed?

Ready for Action

- How is potential non-compliance discovered?
- What are the next steps to determine if there is a real issue?
- When to handle internally and when to retain outside help
Example: 340B Governance Model (illustrative)

Covered entities should establish a governance framework that supports the 340B operations across the system. Establishing a program that integrates hospital leadership and operations will help prioritize compliance as a focal point.

**Governing Committee**
- Financial management guidance on 340B Program
- Ensure pharmacy data are integrated across the system to monitor and report on 340B
- Monitor programs on 340B initiatives and trends in the market
- Identify and implement opportunities to improve operational effectiveness
- Monitor monitoring and audit results

**Program Management**
- Develop system-wide SOPs
- Establish and maintain a 340B program that is integrated into the operational framework of all hospital teams
- Ensure monitoring and audit results
- Establish accountability with critical stakeholders
- Fulfill 340B program objectives

**Hospital Teams**
- Acute, Retail, and Retail verticals
- Ambulatory care
- Program strategy initiatives and advises on compliance matters
- Address 340B operations and initiatives taken across the system

**Monitoring Activities for 340B Program (illustrative)**

<table>
<thead>
<tr>
<th>Monitoring Activities</th>
<th>Frequency</th>
<th>Method</th>
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</thead>
<tbody>
<tr>
<td>Split Billing Software</td>
<td>Monthly</td>
<td>Review daily 340B claims per active pharmacy dispensing provider and identify the following:</td>
</tr>
<tr>
<td></td>
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<td>1. High drug spend claims</td>
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<td>2. High drug cost claims</td>
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<tr>
<td></td>
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<td>3. Opioid and controlled substances claims</td>
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<td>4. Vendor claims</td>
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<td>5. CII controlled substances claims</td>
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<td>Assess the following elements for the selected 340B claims:</td>
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<td>- Briefly assess the drug for each claim</td>
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<td>- Identify the primary wholesaler and the corresponding wholesaler, additional high drug spend, high drug cost, and random selections can be made</td>
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<td>Purchasing outside of</td>
<td>Monthly</td>
<td>Identify total number of packages for each drug product that were purchased outside of the split billing software, excluding CII controlled substances. Furthermore, identify any of the corresponding audiences are categorized:</td>
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<td>split billing software</td>
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<td>- Analyze all claims for each drug product and identify if the claim was made for a drug that does not utilize CII controlled substances, additional high drug spend, high drug cost, and random selections can be made</td>
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<td>Medical billing</td>
<td>Monthly</td>
<td>Identify total number of packages for each drug product that were purchased outside of the split billing software, excluding CII controlled substances. Furthermore, identify any of the corresponding audiences are categorized:</td>
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<td>Medication exclusion file</td>
<td>Monthly</td>
<td>Identify total number of packages for each drug product that were purchased outside of the split billing software, excluding CII controlled substances. Furthermore, identify any of the corresponding audiences are categorized:</td>
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<td>Purchasing volume</td>
<td>Monthly</td>
<td>Identify total number of packages for each drug product that were purchased outside of the split billing software, excluding CII controlled substances. Furthermore, identify any of the corresponding audiences are categorized:</td>
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**Example:**

1. Review daily 340B claims per active pharmacy dispensing provider and identify the following:
   - High drug spend claims
   - High drug cost claims
   - Opioid and controlled substances claims
   - Vendor claims
   - CII controlled substances claims

2. Assess the following elements for the selected 340B claims:
   - Briefly assess the drug for each claim
   - Identify the primary wholesaler and the corresponding wholesaler, additional high drug spend, high drug cost, and random selections can be made

3. Identify total number of packages for each drug product that were purchased outside of the split billing software, excluding CII controlled substances. Furthermore, identify any of the corresponding audiences are categorized:
   - Analyze all claims for each drug product and identify if the claim was made for a drug that does not utilize CII controlled substances, additional high drug spend, high drug cost, and random selections can be made

4. Identify total number of packages for each drug product that were purchased outside of the split billing software, excluding CII controlled substances. Furthermore, identify any of the corresponding audiences are categorized:
   - Analyze all claims for each drug product and identify if the claim was made for a drug that does not utilize CII controlled substances, additional high drug spend, high drug cost, and random selections can be made

5. Identify total number of packages for each drug product that were purchased outside of the split billing software, excluding CII controlled substances. Furthermore, identify any of the corresponding audiences are categorized:
   - Analyze all claims for each drug product and identify if the claim was made for a drug that does not utilize CII controlled substances, additional high drug spend, high drug cost, and random selections can be made
HRSA Requirements - Oversight of 340B Contract Pharmacies

HRSA requires that covered entities conduct the following oversight activities for their contracted pharmacies.

**Contract Pharmacy Oversight Requirements**

1. Conduct independent annual audits and/or adequate oversight mechanism.

2. Documentation requirements:
   a. Develop written 340B Program policies and procedures involving contract pharmacy oversight.
   b. Maintain auditable records at both covered entity and contract pharmacy.
   c. Ensure written contract pharmacy agreement lists each contract pharmacy individually and is in place before registering contract pharmacy in 340B Program.
   d. Contract pharmacy may not be utilized for purposes of the 340B Program until it has been registered, certified, and pharmacy is listed on the covered entity’s 340B database record.

3. Ensure that 340B drugs are only provided to 340B-eligible patients.

4. Carve-out Medicaid at contract pharmacies – or develop an alternative arrangement to work in collaboration with the state Medicaid agency to ensure duplicate discounts do not occur and report this to HRSA.

5. Maintain accurate information in the HRSA 340B database, including covered entity contact information, contract pharmacy information, and Medicaid billing information.

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**Example: Threshold Indicators**

What are the next steps to determine if there is a real issue?

- **Percent** of noncompliant claims, to total 340B purchases or to any one manufacturer
- **A fixed dollar amount of noncompliant claims, based upon total outpatient/340B spend**
- **Percent** of noncompliant claims, to total 340B inventory (units)
- **Percent** of noncompliant claims, to total review sample
- **Percent** of noncompliant claims, to total prescription volume/prescription sample
- Noncompliant claims will not self-correct within “X” months
- Total amount of refund due to manufacturers exceeding 1% of total 340B spend for the parent and all child sites
- Greater than or equal to 3% of total number of approved claims in the same period as the violation.

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Next Steps: Determining Severity of Noncompliance

As potential noncompliance issues are identified, covered entities should have a process in place to identify the impact to their program, and how to remedy the potential issues.

<table>
<thead>
<tr>
<th>Material Breach Definition</th>
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<td>It is recommended that covered entities define &quot;material breach&quot; for their organizations and establish a process for self-disclosure in their policies.</td>
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<th>Perform Assessment</th>
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<td>In addition to defining &quot;material breach&quot; covered entities should develop thresholds of noncompliance that require a disclosure.</td>
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<th>Threshold Requirements</th>
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<td>Any assistance analysis of potential noncompliance should consider the potential severity of the issue at hand.</td>
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<th>Disclose?</th>
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<td>An assessment will help identify the severity of the issue at hand.</td>
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- Quantify the seriousness of the issue (e.g., % of claims impacted compared to total 340B dispensations).
- Covered entities may want to notify the 340B Steering Committee at this time.
- Compare assessment results to covered entities material breach threshold requirements.
- Are there other factors to be considered (e.g., whether a refund is owed to the manufacturer and amount of the refund, pervasiveness of non-compliance, whether the non-compliance was knowing and intentional).

- Prepare summary of assessment results and report to 340B Steering Committee (e.g., Summary of Non-compliance, impacted internal and external parties, proposed Corrective Action Plan, Request for Manufacturer Action (if applicable)).
- Consult with outside resources including reputable consultants and attorneys about reporting obligations to manufacturers and OPA.


When To Retain Outside Help

A covered entity may consider retaining outside help to address noncompliance for a number of reasons.

- A covered entity may retain external assistance to perform independent assessment or analysis.
- Independent audits can help validate or quantify the potential noncompliance.
- An independent audit can help identify the potential severity of noncompliance.
- Prior to self-disclosure to HRSA covered entities should receive external assistance.
- Material breach has exceeded the covered entities threshold requirements.
- After a disclosure to HRSA and a Corrective Action Plan (CAP) has been developed.
- After a disclosure to HRSA and a Corrective Action Plan (CAP) has been developed and a final settlement agreement is reached.

- External assistance can independently assess the potential noncompliance.
- External assistance can independently assess the material breach threshold requirements.
Go Time!

- Emily Cook
- Next steps after confirming non-compliance
  - Disclosures to manufacturers, HRSA or other entities
    - Requirements and processes

Next Steps

- Process may vary depending on the nature of the non-compliance
- Refer to internal processes
  - Follow established organization reporting procedures
  - Involve appropriate compliance and legal staff
- Significant or novel issues may require involvement of outside legal counsel

Next Steps

- Refer to 340B Policies and Procedures
  - Policies should include material breach reporting threshold
- Determine whether non-compliance required reporting to HRSA, manufacturer, state or other entity
- Most confirmed non-compliance will require reporting to one or more entities
- “Self-help” corrections require risk analysis and should involve consultation with legal counsel
**Written Disclosures**
- Material breach requires reporting to HRSA and other affected entities.
- Non-material non-compliance may also require reporting depending on the nature of the non-compliance.
- Evaluate appropriate timing of notices to different affected entities.
- Determine appropriate level of detail to include in disclosure letter.

**Victory Lap**
- HRSA oversight of disclosures to manufacturers.
- Obligations for resolving non-compliance.
- Non-responsive manufacturers.
- Disagreements regarding resolution.

**HRSA Oversight**
- HRSA will monitor corrective actions taken following disclosure of material breach.
- Be prepared to make at least two notices to affected manufacturers.
- Retain documentation of notices sent, responses received and dates of all communications.
- HRSA will request periodic updates until satisfied that the issue is resolved as to manufacturers requesting repayments.
- Note: self-disclosures following an audit notice are likely to result in adverse audit findings.
Obligations for Corrective Action

- Expectation of “good faith” efforts by covered entity and manufacturer to resolve non-compliance
- Typically reasonable process, although can be lengthy
- No required time frame for resolution
  - Although updates required to HRSA for self-disclosed non-compliance

Non-responsive manufacturers

- Two frequent scenarios for non-responsive manufacturers
  - No response to notices
  - Become unresponsive after initial contact
- Expectation of two notices
- HRSA has indicated that it is willing to close self-disclosures if covered entity can document that manufacturer has been non-responsive
  - HRSA currently requires covered entities to agree to work with late-responding manufacturers

Disagreements Regarding Resolution

- Disputes as to the appropriate corrective action are unusual, but do occur
- Path forward is not clear
- To-date, HRSA has instructed the covered entity and manufacturer to continue “good faith” efforts
- HRSA has closed self-disclosures with open disputes between covered entities and manufacturers