W03 -340B Drug Pricing Self-Disclosures and Repayments: Success Stories and Lessons Learned

Anne Daly
Karolyn Woo-Miles
Emily Cook

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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?
- Ascertain 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 is 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

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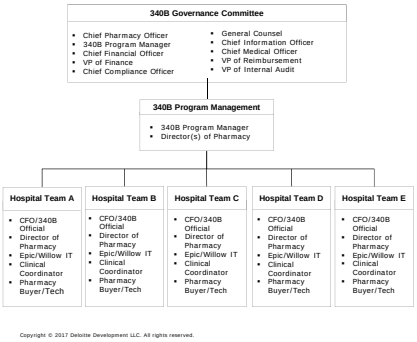
Example: 340B Governance Model *(illustrative)*

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.



Governance Committee

- Delivers strategic guidance on 340B Program
- Ensures necessary steps are taken across the system to address 340B operations and compliance matters
- Reviews progress on 340B initiatives and advises on program strategy
- Identifies interdependencies across Acute, Ambulatory, and Retail verticals

Program Management

- Coordinates system-wide 340B Program operations
- Develops system level SOPs
- Engages with hospital staff to fulfill 340B program objectives
- Established accountability with critical stakeholders
- Reviews monitoring and audit results

Hospital Teams

- Executes day-to-day 340B operations
- Operationalizes system SOPs
- Initiates and drives 340B improvement and compliance opportunities.
- Monitors 340B compliance and self-audits
- Escalates significant concerns to 340B Program Manager

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Monitoring Activities for 340B Program *(illustrative)*

Monitoring	Frequency	Method	Owner
Split-billing software claims	Monthly	Review twenty (20) 340B claims per active pharmacy dispensing location at Hospital based upon the following criteria: • 5 high drug spend claims • 5 high drug cost claims • 5 CII controlled substances claims • 5 random In cases where a pharmacy ID does not utilize CII controlled substances, additional high drug spend, high drug cost, and random selections can be made. Assess the following elements for the selected 340B claims: • Billed/accumulated quantity of the drug • Patient status • Location • Authorizing/Ordering provider is 340B-eligible	Pharmacy Technician
Purchases outside of split billing software	Monthly	Identify total number of packages by NDC/drug product that were purchased outside of the split billing software, excluding CII controlled substances. Furthermore, identify if any of the corresponding accumulations are negative.	Pharmacy Technician
Medicaid billing	Monthly	Review 10 Medicaid outpatient drug claims per facility to assess whether Medicaid claims meet 340B/state requirements, including the appropriate price and modifiers are utilized for billing.	Pharmacy Technician
GPO exclusion file	Monthly	Identify all drugs listed on the GPO Exclusion File in the split billing software. Furthermore, identify any drugs not listed on the standard GPO Exclusion Items report found within the split billing software.	Pharmacy Technician
Purchasing volume	Monthly	Identify significant changes in drug purchasing volume for each account (340B, GPO, and WAC). Significant changes in purchase volume should be noted for further investigation.	Pharmacy Technician

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Monitoring Activities for 340B Program *(illustrative)*

Monitoring	Frequency	Method	Owner
Direct purchases and their accumulations in split billing software	Monthly	Review "Direct Purchases" made from vendors outside of primary wholesaler have been adjusted in the split billing software	Pharmacy Technician
OPA Database information	Annual	Confirm presence of all Covered Entities and accuracy of information; verify contact information including phone and e-mail information, Medicaid exclusion information, ship to/bill to information, and contract pharmacy information. www.opanet.hrsa.gov/opa/CESearch.aspx	Pharmacy Technician
Eligible providers for split billing software	Quarterly	Assess available master data within the split billing software, including the list of eligible providers, locations, etc.	Pharmacy Technician
340B contract pharmacy claims	Monthly	Review 20 340B contract pharmacy claims per facility to confirm compliance with 340B Program requirements. Validate the following elements for the selected 340B claims: • Patient eligibility • Billed/accumulated quantity of the drug • Location • Authorizing/Ordering provider is 340B-eligible • Pharmacy invoices to validate payments to pharmacy wholesaler	Pharmacy Technician

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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.

Source: https://www.hrsa.gov/opa/updates/contractpharmacy02052014.html

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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 X %** of monthly 340B drug spend for the parent and all child sites	**Greater than or equal to X %** of total number of approved claims in the same period as the violation	

Source: https://docs.340bpvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf

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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

Material Breach Definition	• "It is recommended that covered entities define 'material breach' for their organizations and establish a process for self-disclosure in their policies and procedures."[1] • In addition to defining "material breach" covered entities should develop thresholds of noncompliance that require a disclosure
Perform Assessment	• An assessment will help identify the severity of the issue at hand • 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
Threshold Requirements	• 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)
Disclose?	• 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 Manufacture Action (if applicable)) • Consult with outside resources including reputable consultants and attorneys about reporting obligations to manufacturers and OPA

1) Source: https://docs.340bpvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf

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When To Retain Outside Help

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

Covered entities may retain external assistance to perform independent assessment or analysis.
- Independent audits can help validate or quantify the potential noncompliance

After a covered entity has identified a material breach and it is unable to internally assess the level of severity for noncompliant 340B prescriptions.

Material breach has exceeded the covered entities threshold requirements.
- Prior to self disclosure to HRSA covered entities should retain outside assistance

After a disclosure to HRSA and a Corrective Action Plan (CAP) has been developed.
- External assistance can independently assess that the CAP has been properly addressed.

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
  - Polices 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