



340B University Tools

Establishing Material Breach Threshold Tool

Purpose: This tool is designed to provide entity leaders with a framework to guide the written documentation of the entity’s definition of a material breach of compliance and the development of a process to determine materiality that requires self-disclosure, based on leading practices. Note: Materiality is commonly regarded as a convention within auditing/accounting pertaining to the importance/significance of an amount, transaction, or discrepancy.

Background: Upon annual recertification, each covered entity’s authorizing official must attest that “the covered entity acknowledges its responsibility to contact HRSA as soon as reasonably possible if there is any ... material breach by the covered entity of any of the foregoing [aspects of 340B compliance].” In this context, "material breach" refers to an instance of noncompliance with any of the 340B program requirements. To increase program transparency among all stakeholders and ensure that covered entities can rely on a reasonable threshold to guide consistent and effective self-disclosure decision-making, it is recommended that covered entities define “material breach” for their organizations and establish a process for self-disclosure in their policies and procedures.

A breach of 340B compliance requirements include any adverse event that results in diversion and/or duplicate discounts. For example, the following events are considered adverse: a facility that uses the 340B Program while not being eligible, a facility providing 340B drugs to ineligible patients, 340B drugs go missing in a facility's inventory, and a facility billing for 340B drugs contrary to an organization’s MEF status.

Action	Action Taken
Instructions	
1. Identify staff to perform assessment and documentation.	
2. Obtain current Policy & Procedure Manual.	
3. Refer to the table below to determine if existing material breach threshold policy and procedure adequately address each item.	
4. Follow the “recommended steps” in the left-hand column of the table below with a written response in the right-hand column.	
5. Read the sample material breach definition statement (see below) intended for various covered entity types.	
6. Engage with IT/Purchasing/Billing/Pharmacy to obtain data element(s) selected for decision-making.	
7. Draft your own statement for your organizations material breach definition.	



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Recommended Steps	Response
1. Establish a threshold for what would constitute a material breach of compliance that would require self-disclosure. <i>Ensure identification of any threshold variations among 340B settings (e.g., contract pharmacies).</i>	
2. Determine and articulate when, how, and by whom (e.g., 340B task force, compliance officer): <ul style="list-style-type: none"> a. <i>materiality would be assessed;</i> b. <i>self-disclosure to HRSA and/or manufacturers accomplished, and;</i> c. <i>corrective action plans submitted, approved and completed in the organization's standard operating procedures.</i> 	
3. Describe the maintenance of records of materiality assessments and of threshold and sub-threshold violations that led to manufacturer correspondence and/or formal self-disclosure process through HRSA, corrective action plans and incident resolution in the organization's policy and procedures.	
4. Determine how often and by whom the organization's standard operating procedures concerning material breach are to be reviewed. <i>Consider:</i> <ul style="list-style-type: none"> a. <i>date of policy origination and;</i> b. <i>date of last review/revision/approval, ensuring that the date of last review/revision/approval aligns with the organization's established policy and procedure process.</i> 	

Sample Statement: [Entity Name] defines a material breach of compliance as a violation(s) that exceeds [threshold indicator – see examples below*]. Such violations require self-disclosure. Violations identified through internal self-audits, independent external audits, or otherwise that [meet or] exceed this threshold, and that remain non-correctable within the entity-defined period timeframe of review, will be immediately reported to HRSA (at 340Bselfdisclosure@hrsa.gov) and applicable manufacturers using the following self-disclosure report template:

https://docs.340bpvp.com/documents/public/resourcecenter/ALL_Entities_Self_Reporting_340B_Non_Compliance.docx

[Entity Name] has a [340B committee] that oversees this process, reviews potential violations, performs materiality assessment, and determines if a material breach has occurred. The committee identifies to whom to self-disclose the breach dependent on that materiality determination and the corrective action plan resolution.

On behalf of [Entity Name] the [340B committee] reviews this policy [annually], makes decisions about the material breach definition and self-disclosure and submits any changes to the [Board] for approval.

[Entity Name] maintains records (including all internal or external correspondence and corrective action plans) of violations, materiality assessment, and resolution of manufacturer self-disclosure and/or formal self-disclosure to HRSA.



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*Examples of threshold indicators (use one or more in each definition to be applied within entity-defined review period timeframe of review):

1. X% of total 340B purchases or impact to any one manufacturer
2. \$X (fixed amount), based upon total outpatient or 340B spend, or impact to any one manufacturer
3. X% of total 340B inventory (units)
4. X% of audit sample
5. X% of prescription volume/prescription sample
6. Will not self-correct within x months

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.



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