**Purpose:** This tool is designed to provide 340B covered entity leaders with a framework to guide the definition of a material breach of compliance and the process for self-disclosure to HRSA, based on leading practices. *Note*: Materiality is commonly regarded as a convention within auditing/accounting pertaining to the significance of an amount, transaction, or discrepancy.

**Background:** 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. **Table 1** provides instructions as to how to do so.

A breach of 340B compliance requirements includes 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 missing from a facility's inventory, and a facility billing for 340B drugs contrary to an organization’s Medicaid Exclusion File status on 340B OPAIS.

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| --- | --- |
| **Table 1 – General Overview****Recommended Steps** | **Action Taken** |
| **Table 1a – Tool Instructions** |
| 1. Identify staff to perform assessment of current 340B policies and procedures.
 |  |
| 1. Determine whether existing policies/procedures adequately address criteria listed in **Table 2** and provide a follow-up action in the right-hand column (if applicable).
 |  |
| 1. Read the sample material breach definition statement intended for various covered entity types (bottom of page 2).
 |  |
| 1. Engage with IT/purchasing/billing/pharmacy to obtain data element(s) selected for decision making.
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| 1. Draft your new/updated statement for your organization’s material breach definition.
 |  |
| **Table 1b – Example Threshold Indicators** Use one or more in each definition within the entity-defined review period. |
| 1. X% of total 340B purchases or impact to any one manufacturer
2. X$ (fixed amount), based on 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
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| **Table 2 – Material Breach Policy/Procedure Criteria****Recommended Steps** | **Action Taken** |
| 1. Establish a threshold for what would constitute a material breach of compliance requiring self-disclosure (see **Table 1b** for example threshold indicators). Identify any threshold variations among 340B settings (e.g., contract pharmacies).
 |  |
| 1. Within the organization’s standard operating procedures, determine and articulate when, how, and by whom (e.g., 340B oversight committee, compliance officer):
* Materiality would be assessed
* Self-disclosure to HRSA and/or manufacturers is accomplished
* Corrective action plans are submitted, approved, and completed
 |  |
| 1. Describe the maintenance of materiality assessment records 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.
 |  |
| 1. Determine how often and by whom the organization’s standard operating procedures concerning material breach are to be reviewed.

Consider:* Date of policy origination
* Date of last review/revision/approval, ensuring that the date of last review/revision/approval aligns with the organization’s established policy
 |  |

**Sample Statement:**

[Entity Name] defines a material breach of compliance as a violation(s) that exceed(s) [threshold indicator – see examples in Table 1b]. 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 timeframe of review, will be immediately reported to HRSA (at 340Bselfdisclosure@hrsa.gov) and applicable manufacturers using the [Self-Disclosure to HRSA and Manufacturer Template](https://www.340bpvp.com/Documents/Public/340B%20Tools/self-disclosure-to-hrsa-and-manufacturer-template.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 depending on the materiality determination and corrective action plan resolution.

On behalf of [Entity Name], the [340B committee] reviews this policy [timeframe - e.g., 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/external communication and corrective action plans) of violations, materiality assessment, and resolution to the manufacturer and/or HRSA.

*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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