



Institutional Handbook of Operating Procedures Policy 09.14.10	
Section: Clinical Policies	Responsible Vice President: Executive Vice President and CEO Health System
Subject: Pharmacy	Responsible Entity: Pharmacy Services

I. Title

Noncompliance and Material Breach in the 340B Drug Pricing Program

II. Policy

Covered entities are responsible for contacting Health Resources and Services Administration (HRSA) as soon as reasonably possible if there is any material breach by the covered entity, or any instance of noncompliance with any of the 340B Program requirements.

III. Purpose

To define UTMB's process for determining a material breach of 340B compliance and self-disclosure protocol.

IV. Procedures

- A. UTMB establishes a threshold of what constitutes a material breach for all of its 340B settings including contract pharmacies to increase program transparency among all stakeholders and to ensure that UTMB relies on a reasonable threshold to guide consistent and effective self-disclosure decision-making.
- B. A material breach refers to an instance of noncompliance with any of the 340B program requirements including diversion and/or duplicate discounts that exceeds 5% of total 340B program savings for the corresponding time period.
$$(\text{WAC Price} - 340 \text{ Price}) \div \text{Total 340B Savings} > 5\%$$
- C. UTMB assesses materiality. The materiality assessment will be performed by the UTMB Office of Institutional Compliance in conjunction with the Associate Vice President of Pharmacy Services.
- D. UTMB will develop a corrective action plan for areas of noncompliance as soon as reasonably possible. The corrective action plan will include the materiality assessment and will be reviewed by the 340B Compliance Committee.
 1. Instances of noncompliance with 340B program requirements that do not meet the threshold of materiality, will be addressed with applicable manufacturers. In these instances, UTMB will work with manufacturers to determine a mutually agreed upon plan to address noncompliance and how adjustments and/or repayments will be made.
 2. Instances of noncompliance with 340B program requirements that do meet the threshold of materiality, will be reported to HRSA and applicable manufactures as soon as reasonably possible.

- a. Compliance violations that meet the threshold of material breach will be disclosed to HRSA (340Bselfdisclosure@hrsa) using the 340B Prime Vendor Program self-disclosure tool.
- b. If applicable, UTMB will work with manufacturers to determine a mutually agreed upon plan to address material breach of compliance and how adjustments and/or repayments will be made.

3. Records will be maintained including manufacturer resolution and correspondence.

- E. The definition and procedure concerning material breach will be updated and approved whenever there is a clarification, or change, in the rules, regulations, or guidelines of the 340B Program.

V. Additional References

[Apexus. 340B University Tools. Establishing Material Breach Threshold Tool](#)
[HRSA. Self-Disclosure Process](#)

VI. Dates Approved or Amended

<i>Originated: 04/25/2019</i>	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
10/16/2020	02/21/2023

VII. Contact Information

Pharmacy Services
(936) 494-4188