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.

\[(WAC \text{ Price} - 340 \text{ Price}) ÷ \text{Total 340B Savings} > 5\%\]

C. UTMB assesses materiality.

1. The initial materiality assessment will be performed by the UTMB Office of Institutional Compliance in conjunction with the Associate Vice President of Pharmacy Services.

2. The UTMB 340B Compliance Committee oversees this process, reviews potential violations, and performs the final materiality assessment to determine if a material breach has occurred.

D. UTMB will develop a corrective action plan for areas of noncompliance as soon as reasonably possible.

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.

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
| Originated: 04/25/2019 |
| Reviewed with Changes | Reviewed without Changes |

VII. Contact Information
    Pharmacy Services
    (936) 494-4188