

<b>Institutional Handbook of Operating Procedures Policy 09.14.11</b>	
Section: Clinical Policies	Responsible Vice President: Executive Vice President and CEO Health System
Subject: Pharmacy	Responsible Entity: Pharmacy Services

**I. Title**

*Compliance, Monitoring, and Reporting in the 340B Drug Pricing Program*

**II. Policy**

Covered entities are required to maintain auditable records demonstrating compliance with the 340B Program requirements.

**III. Purpose**

To provide an internal monitoring program to ensure comprehensive compliance with the 340B Program.

**IV. Procedures**

- A. UTMB is required to maintain auditable records demonstrating compliance with the 340B Program requirements.
- B. UTMB develops an annual internal audit plan approved by the Associate Vice President & Deputy Chief Compliance Officer and the 340B Compliance Committee.
- C. UTMB reviews the Health Resources & Services Administration (HRSA) 340B Office of Pharmacy Affairs Information System (OPAIS) quarterly to ensure the accuracy of the information for the parent site, child sites, and contract pharmacies.
- D. UTMB reviews the Medicaid Exclusion File (MEF) annually, or more frequently if needed, to ensure the accuracy of the information for the parent site, child sites, and contract pharmacies.
- E. UTMB ensures compliance with 340B Program requirements by conducting routine self-audits.
  - 1. UTMB ensures compliance with Group Purchasing Organization (GPO) prohibition.
  - 2. UTMB reconciles purchasing records and dispensing records to ensure that covered outpatient drugs purchased through the 340B Program are dispensed or administered only to patients eligible to receive 340B drugs and that any variances are not the result of diversion.
  - 3. UTMB reconciles administration and dispensing records to patients' health care records to ensure that all medications dispensed were provided to patients eligible to receive 340B drugs.
  - 4. UTMB reconciles administration and dispensing records and Medicaid billing practices to demonstrate that UTMB's practice is following the guidance listed on the HRSA 340B OPAIS.

5. Location eligibility: UTMB verifies that the prescription/order is written from a site of care that is registered on the HRSA 340B OPAIS, within the four walls of the parent site, or is an unregistered 340B eligible location that is reimbursable under Medicare cost reporting rules (i.e., meets the provider-based requirements of the Centers for Medicare & Medicaid Services) but has not yet appeared on a filed Medicare cost report.
6. Patient eligibility: UTMB verifies that the episode of care that resulted in the 340B prescription is supported in the patient’s medical record.
7. Provider eligibility: UTMB verifies that the prescribing provider is employed, contracted, or under another arrangement with UTMB at the time of writing the prescription/order so that UTMB maintains responsibility for the care.
8. An 11-digit NDC match can be documented for accumulation and/or replenishment of a 340B dispensation in locations using a virtual inventory.

F. Health System Self-Audits

1. Schedule

Audit Date Range	Fiscal Year Quarter	
September 1 - November 30	1st	
December 1 - February 28	2nd	
March 1 - May 31	3rd	
June 1 - August 31	4th	

2. Sample size of prescription/order audit

Location & System	Setting	# 340B Transactions	# GPO Transactions
Galveston Campus Cervey 340B Split Bill Software	Mixed-use	30	30
Angleton Danbury Campus Cervey 340B Split Bill Software	Mixed-use	20	20
League City Campus Cervey 340B Split Bill Software	Mixed-use	20	20
Clear Lake Campus Cervey 340B Split Bill Software	Mixed-use	20	20
Third Party Administrator Accumulator	Contract Pharmacies	40	NA
EPIC Willow Accumulator	UTMB-owned Pharmacies	15	NA

3. Audit components

Component	Description	Frequency
Inventory Audit	Includes a review of the setup and appropriate accrual of drugs within accumulators, reconciliation of orders upon receipt, process for direct purchases, and review of purchasing and	Each quarter

	dispensation records.	
Prescription/Order Audit	Includes a review of administration and dispensing records to patients' health care records to ensure that all medications dispensed were provided to eligible patients.	Each quarter
Account Audit	Includes a review of purchases made from UTMB Supply Chain Operations and the university's medical/surgical supply distributor used by clinics to ensure drugs are not purchased on these accounts and verification (n=2) that accounts used for direct purchases have the correct contracts/pricing loaded (e.g., GPO, WAC, 340B).	1 <sup>st</sup> and 3 <sup>rd</sup> quarters
Account Audit	Includes a review of the primary wholesaler accounts to ensure the correct contracts/pricing (e.g., GPO, WAC, 340B) are loaded and assigned the correct 340B ID # if applicable	4 <sup>th</sup> quarter
Entity Eligibility Audit	Includes review of: <ul style="list-style-type: none"> <li>• Most recently filed Medicare Cost Report</li> <li>• Eligibility as state government agency</li> <li>• Data policies for vendor software</li> <li>• Medicaid Exclusion File</li> <li>• 340B contracts with pharmacies and/or other 340B service providers</li> <li>• Policies related to 340B are current</li> <li>• Data on 340B OPAIS</li> <li>• Provider eligibility</li> <li>• 340B training</li> <li>• Cross-walk of EPIC location eligibility</li> </ul>	4 <sup>th</sup> quarter

#### G. UTMB CMC Self-Audits

1. Pharmacy staff completes random weekly audits of shipments to ensure accuracy and to monitor 340B inventory compliance.
2. Pharmacy staff completes monthly audits of the maintenance and segregation of pharmacy inventory (340B versus non-340B drugs) to ensure inventory controls are being followed. Monthly audits will include physical observation of the areas where inventory is stored to verify that 340B and non-340B inventory are kept separate and marked appropriately.
3. Semi-annual 340B integrity audits are conducted to ensure internal controls are in compliance with 340B Program requirements. Audit procedures include:
  - a. Semi-annual audits
    - i. Review of a sample of 50 prescriptions (twenty-five 340B and twenty-five non-340B prescriptions) covering the preceding six-month period.
    - ii. The review includes whether the relationship between UTMB and the individual met HRSA's patient definition standards (i.e., verification of clinic and patient eligibility).

- iii. Verification that weekly sorter audits, monthly inventory audits, and semi-annual sorter maintenance is completed.
- b. Once a year the semi-annual audit also includes:
  - i. Review of relevant policies and procedures and how they are operationalized.
  - ii. Review of the maintenance and segregation of pharmacy inventory (340B versus non-340B drugs) and evidence of compliance with the required GPO exclusion for covered entities by testing a random sample of 340B inventory transaction records. The review includes 10 medications in 340B inventory and 10 medications in non-340B inventory including beginning inventory balance, purchases, sales, and returns.
  - iii. Interviews of key staff members to ensure understanding of Program and requirements.
  - iv. Verification that separate wholesaler accounts are maintained and correct contracts/pricing (e.g., WAC, 340B) are loaded.
- H. UTMB contracts with an external auditor to conduct annual 340B compliance audits on its behalf to promote program integrity.
  - 1. Audits focus on identifying all potential 340B compliance gaps within the hospitals, departments, clinics, contract pharmacies, UTMB-owned pharmacies, and 340B software vendor.
  - 2. Audit components:
    - a. Overall program review
    - b. Diversion prohibition
    - c. Duplicate discounts prohibition
    - d. GPO purchase prohibition
    - e. Auditable records review
    - f. OPA database registration accuracy
    - g. Provider-based (i.e., hospital-based) setting generated prescriptions
    - h. Policy & procedures review
    - i. Compliance best-practices
- I. UTMB’s 340B Compliance Committee reviews audit results.

**V. Related UTMB Policies and Procedures**  
[IHOP - 06.01.05 - Records and Information Management and Retention](#)  
[UTMB CMC Pharmacy policy 30.55 340B Program Compliance](#)

**VI. Dates Approved or Amended**

<i>Originated: 04/25/2019</i>	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
10/16/2020	
01/11/2022	03/02/2023

**VII. Contact Information**

Pharmacy Services

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