

Institutional Handbook of Operating Procedures Policy 09.14.09	
Section: Clinical Policies	Responsible Vice President: Executive Vice President and CEO Health System
Subject: Pharmacy	Responsible Entity: Pharmacy Services

I. Title

Contract Pharmacy Oversight in the 340B Drug Pricing Program

II. Policy

UTMB is required to provide oversight of its contract pharmacy arrangements to ensure ongoing compliance. UTMB has full accountability for compliance with all requirements to ensure eligibility and to prevent diversion and duplicate discounts. Auditable records must be maintained to demonstrate compliance with those requirements.

III. Purpose

To ensure that UTMB maintains 340B Program integrity and compliance at its contract pharmacies.

IV. Procedures

- A. UTMB routinely conducts internal reviews of each registered contract pharmacy for compliance with 340B Program requirements (see policy [IHOP – 09.14.11 – Compliance, Monitoring, and Reporting in the 340B Drug Pricing Program](#)). The following elements will be included when conducting self-audits of contract pharmacies to ensure program compliance:
 1. Location eligibility:
 - a. Prescription is written from a site of care that is registered on the HRSA 340B OPAIS and included as a reimbursed outpatient service cost center on the most recently filed Medicare Cost Report.
 - b. Prescription is written from an unregistered 340B eligible location that is an integral part of the 340B eligible hospital as evidenced by the fact that it 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 the most recently filed Medicare cost report.
 2. Patient eligibility: The episode of care that resulted in the 340B prescription is supported in the patient's medical record.
 3. Provider eligibility: The prescribing provider is employed, contracted, or under another arrangement with UTMB at the time of writing the prescription so that the UTMB maintains responsibility for the care.
 4. An 11-digit NDC match can be documented for accumulation and/or replenishment of a 340B dispensation.
 5. UTMB documents that no prescriptions were billed to Medicaid unless the contract pharmacy is listed as a carve-in contract pharmacy on the HRSA 340B OPAIS.

- B. UTMB engages an external independent auditor to review UTMB’s compliance with 340B Program requirements.
- C. UTMB’s 340B Compliance Committee reviews audit results.
- D. UTMB follows all State practices consistent with State guidance on the prevention of duplicate discounts.
 - 1. UTMB Medicaid billing numbers/NPI numbers are properly reflected in the Medicaid Exclusion File.
 - 2. UTMB has mechanisms in place to demonstrate compliance with all state Medicaid billing requirements to prevent duplicate discounts at all sites, including off-site outpatient facilities.

V. Relevant Federal and State Statutes

[Federal Register. Vol. 75. No. 43. March 5, 2010.](#) Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services.

VI. Relevant UTMB Policies and Procedures

[IHOP – 09.14.08 – Contract Pharmacy Operations in the 340B Drug Pricing Program](#)

[IHOP – 09.14.11 – Compliance, Monitoring, and Reporting in the 340B Drug Pricing Program](#)

VII. 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

VIII. Contact Information

Pharmacy Services
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