Institutional Handbook of Operating Procedures Policy 09.14.05	
Section: Clinical Policies	Responsible Vice President: Executive Vice President and CEO Health System
Subject: Pharmacy	Responsible Entity: Pharmacy Services

I. Title

Roles and Responsibilities in 340B Drug Pricing Program

II. Policy

Covered entities participating in the 340B Program must ensure program integrity and compliance with 340B Program requirements.

III. Purpose

To identify UTMB key stakeholders and determine their roles and responsibilities in maintaining 340B Program integrity and compliance.

IV. Procedures

A. UTMB's key stakeholders involved with the 340B program and their roles and responsibilities

1. VP Legal Affairs and Interim Chief Legal Officer
    a. Serves as the 340B Authorizing Official.

    b. Responsible for completing the registration process and attesting to the compliance of the program through recertification.

2. Executive Vice President & CEO and Vice President Academic Medical Center Galveston
    a. Provides leadership and oversight of the 340B Program.

3. Associate Vice President & Deputy Chief Compliance Officer Office of Institutional Compliance
    a. Serves as the 340B Compliance Committee chair.

    b. Works in conjunction with key stakeholders to maintain a compliant internal audit plan for the 340B Program.

    c. Must maintain knowledge of the policy changes that affect the 340B Program, including, but not limited to, Health Resources and Services Administration (HRSA) rules and Medicaid changes.

4. Vice President and Chief Audit Executive
    a. Provides guidance on audit plan and approach to internal audits

5. Associate Vice President Finance- Government Reimbursement
    a. Responsible for providing the required Medicare cost report and supporting documentation.

b. Must maintain knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA rules and Medicaid changes.

6. Vice President & CFO Health System
    a. Accounts for 340B Program savings and use of funds to stretch resources to provide care to more eligible patients and/or provide more comprehensive services.

7. Associate Vice President Pharmacy Services
    a. Agent of the CEO responsible to administer the 340B Program to ensure that current policy statements and procedures are in place to maintain program compliance.

    b. Maintains knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA rules and Medicaid changes.

    c. Services as Primary Contact for Correctional Managed Care clinics.

8. Directors Pharmacy Services
    a. Agent of the Associate Vice President Pharmacy Services responsible for administering the 340B Program to ensure that current policy statements and procedures are in place to maintain program compliance in their respective areas.

    b. Responsible for informing employees of compliance policies and procedures specifically related to their job function and appropriately monitoring employees to help ensure adherence to 340B policies and procedures.

    c. Maintains knowledge of the 340B Program and policies and procedures.

9. 340B Program Director
    a. Accountable agent for 340B compliance and day-to-day manager of the 340B Program.

    b. Ensures compliance with 340B Program requirements for qualified patients, drugs, providers, vendors, payers, and locations.

    c. Ensures appropriate safeguards and system integrity.

    d. Responsible for documentation of policies and procedures.

    e. Supports the pharmacy software selection of tracking software to manage the 340B Program.

    f. Responsible for maintenance and testing of tracking software.

    g. Coordinates any change in clinic eligibility/information.

    h. Maintains system database configurations of contract pharmacy vendor.

i. Reviews and refines 340B cost savings report

j. Manages contracts and payments for contract pharmacies.

k. Serves as the Primary Contact for parent and departments within the walls of the hospitals.

l. Serves as the Primary Contact for contract pharmacies.

m. Must maintain knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA rules and Medicaid changes.

10. Senior Pharmacy Manager
    a. Manages purchasing, receiving, and inventory control processes and ensures appropriate safeguards are instituted.

    b. Monitors ordering processes, product inventory levels, and analyzes invoices, shipping, and inventory processes.

    c. Responsible for annual physical inventory and cycle counts of pharmacy items.

    d. Responsible for establishing three distribution accounts and maintaining those accounts: Group Purchasing Organization (GPO) account, non-GPO account, and 340B account.

    e. Responsible for establishing and maintaining direct accounts for GPO ("own use") class of trade, as well as direct 340B accounts.

    f. Responsible for ordering all drugs from the specific accounts as specified by the process employed.

    g. Responsible for segregation, removal, and/or return of 340B drugs, including reverse distributor transactions.

    h. Responsible for reconciliation of lend and borrow transactions.

    i. Must maintain knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA rules and Medicaid changes.

11. Director of Operations, Ambulatory Support Services
    a. Accountable agent for 340B compliance for Ambulatory Operations and day-to-day clinic operations.

    b. Ensures compliance with 340B Program requirements for qualified patients, drugs, and providers for Ambulatory Operations.

    c. Communicates any change in clinic eligibility/information.

    d. Serves as Primary Contact for outpatient clinics.

e. Must maintain knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA rules and Medicaid changes.

12. Sr. Business Operations Manager
    a. Manages purchasing, receiving, and inventory control processes of ambulatory operations and ensures appropriate safeguards are instituted.

    b. Responsible for establishing three distribution accounts and maintaining those accounts: GPO account, non-GPO account, and 340B account.

    c. Responsible for establishing and maintaining direct accounts for GPO ("own use") class of trade, as well as direct 340B accounts.

    d. Must maintain knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA rules and Medicaid changes.

B. 340B Compliance Committee
1. UTMB's 340B Compliance Committee is approved by the Executive Institutional Compliance Committee (EICC) which is comprised of the President, Chief of Staff, Executive Vice Presidents, Chief Legal Officer, and Chief Compliance Officer. The EICC relies on the 340B Compliance Committee to provide oversight and leadership regarding UTMB's 340B Program and initiatives.

2. The 340B Compliance Committee will address issues and/or concerns and promulgate policies and procedures where necessary to maintain compliance with 340B program rules and guidance. The 340B Compliance Committee will recommend strategic direction on institutional usage of the 340B Program to ensure it supports the intent of the program and supports UTMB's mission and is appropriately supported and implemented within UTMB's Health System. Specifically, the 340B Compliance Committee
    a. Communicates regularly with EICC on new and emerging legislation, issues and/or policies and related materials.

    b. Meets on a quarterly basis.

    c. Reviews 340B rules, regulations, and guidance to ensure consistent policies, procedures, and oversight exist throughout the organization.

    d. Identifies activities necessary to conduct comprehensive reviews of 340B Compliance.
        i. Ensure that the organization meets compliance requirements of program eligibility, patient definition, 340B drug diversion, and duplicate discounts via ongoing self-audits.

        ii. Ensures multidisciplinary teamwork with departments such as health systems operations, information technology, legal, pharmacy, compliance, government reimbursement, ambulatory services, purchasing, supply chain management, and patient financial services to develop standard processes that are compliant.

e. Oversees the review process of compliance activities (e.g., self-audits), as well as taking corrective actions based upon findings. If necessary, assesses whether self-audit results are indicative of a material breach requiring manufacturer repayment and/or self-disclosure to HRSA. 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.

f. Reviews and approves work group recommendations such as process changes, self-monitoring outcomes, and resolutions.

g. Recommends the creation and/or revision of current 340B policies and procedures.

h. Recommends 340B training for employees as directed by the Chief Compliance Officer.

C. Membership includes

1. Associate Vice President & Deputy Chief Compliance Officer
2. Legal Officer Institutional Compliance
3. Assistant Vice President Legal Affairs
4. Vice President and Chief Audit Executive
5. Associate Vice President Finance-Government Reimbursement
6. Vice President & CFO Health System
7. Vice President Academic Medical Center Galveston
8. Administrative Director Health System Pharmacy Services
9. Clinical Resource Manager
10. Associate Vice President Pharmacy Services
11. Director Pharmacy Services CMC
12. 340B Program Director
13. Senior Pharmacy Manager
14. Administrative Director Regional Maternal Child Health Program (RMCHP)
15. Director of Operations, Ambulatory Support Services
16. Vice President Ambulatory Operations
17. Associate Vice President Finance Correctional Managed Care

V. Related UTMB Policies and Procedures

IHOP – 06.00.00 – Institutional Compliance Plan

VI. Dates Approved or Amended

Originated: 04/10/2019	
Reviewed with Changes	*Reviewed without Changes*
10/15/2020	
03/02/2023	

VII. Contact Information

Pharmacy Services
(936) 494-4188