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. Senior Vice President & General Counsel
         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 Health System Operations
         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. Designs the annual plan to cover all changes in the 340B Program from the preceding year.
         d. 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 Audit Services
         a. Provides guidance on annual audit plan and approach to internal audits
      5. Associate Vice President Office of 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 Finance 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.

9. 340B Program Manager
   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. Responsible for documentation of policies and procedures.

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

   e. Responsible for maintenance and testing of tracking software.

   f. Coordinates any change in clinic eligibility/information.

   g. Maintains system database configurations of contract pharmacy vendor.

   h. Serves as the Primary Contact for parent and departments within the walls of the hospitals.
i. Must maintain knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA rules and Medicaid changes.

10. Pharmacy Purchasing 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 semi-annual physical inventory of pharmacy items.
   d. Reviews and refines 340B cost savings report, detailing purchasing, and replacement practices as well as dispensing patterns.
   e. Responsible for establishing three distribution accounts and maintaining those accounts: Group Purchasing Organization (GPO) account, non-GPO account, and 340B account.
   f. Responsible for establishing and maintaining direct accounts for GPO (“own use”) class of trade, as well as direct 340B accounts.
   g. Responsible for ordering all drugs from the specific accounts as specified by the process employed.
   h. Responsible for segregation, removal, and/or return of 340B drugs, including reverse distributor transactions.
   i. Responsible for reconciliation of lend and borrow transactions.
   j. Manages contracts & payments for contract pharmacies.
   k. Serves as the Primary Contact for contract pharmacies.
   l. Must maintain knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA rules and Medicaid changes.

11. Senior Manager Ambulatory Operations
   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. Ambulatory Operations Senior Supply Coordinator
   a. Manages purchasing, receiving, and inventory control processes 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, Senior Vice President & General Counsel, 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. Legal Officer Legal Affairs
   4. Vice President Audit Services
   5. Associate Vice President Government Reimbursement
   6. Vice President Finance Health System
   7. Vice President Health System Operations
   8. Administrative Director Health System Pharmacy Services
   9. Associate Vice President Supply Chain Management
  10. Associate Vice President Pharmacy Services
  11. Director CMC Pharmacy Services
  12. 340B Program Manager
  13. Pharmacy Purchasing Manager
  14. Administrative Director Regional Maternal Child Health Program (RMCHP)
  15. Senior Clinical Staff Pharmacist RMCHP
  16. Senior Manager Ambulatory Operations
  17. Director Ambulatory Operations
  18. 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

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