

Institutional Handbook of Operating Procedures Policy 09.14.01	
Section: Clinical Policies	Responsible Vice President: Executive Vice President and CEO Health System
Subject: Pharmacy	Responsible Entity: Pharmacy Services

I. Title

Covered Entity Eligibility in the 340B Drug Pricing Program

II. Purpose

To ensure UTMB's eligibility to participate in the 340B Program.

III. Policy

UTMB must meet the requirements of 42 USC §256b(a)(4)(L) to be eligible for enrollment in and the purchase of drugs throughout the 340B Program.

IV. Procedures

- A. UTMB qualifies for the 340B Drug Pricing Program as a [disproportionate share hospital](#) (DSH). Specifically, UTMB is owned and operated by the State of Texas and has a disproportionate share adjustment percentage greater than 11.75% as outlined in the most recently filed Medicare Cost Report maintained by UTMB's Office of Government Reimbursement.
 1. UTMB's Galveston Campus is the parent site for the purposes of the 340B Program.
 2. All other registered locations including Angleton Danbury Campus, League City Campus, Clear Lake Campus, outpatient clinics, and Correctional Managed Care (CMC) are child sites of UTMB.
- B. UTMB has identified 340B eligible locations that are 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) where UTMB prescribes, administers, or dispenses 340B drugs
 1. Within the four walls of the parent site (i.e., Galveston Campus)
 2. Within off-site outpatient locations that are registered on HRSA's Office of Pharmacy Affairs Information System (OPAIS) including the hospitals of Angleton Danbury Campus, Clear Lake Campus and League City Campus.
 3. Within a new location within the four walls of the parent hospital or unregistered offsite location (i.e., clinic, department or service) that has not yet appeared on a filed Medicare cost report because it was not operational when the most recent cost report was filed but uses 340B drugs for individuals that meet HRSA's definition of a patient
 4. UTMB-owned and operated outpatient pharmacies.

5. Contract Pharmacies which are non-UTMB owned or operated pharmacies within the community (Walgreens, CVS, etc.) with whom UTMB has entered into a contractual relationship to dispense 340B drugs to eligible UTMB patients.
 6. UTMB has observation beds located in child site hospital locations. HRSA does not require a child site hospital location to register inpatient locations with observation beds.
- C. UTMB uses 340B outpatient covered drugs for patients who receive outpatient health care services delivered using a variety of telehealth technology platforms such as telephones or televideo to deliver care to new or existing patients.
- D. UTMB ensures that the HRSA 340B OPAIS is complete, accurate, and correct for all 340B eligible locations including the parent entity, off-site locations, and contract pharmacies.
1. All 340B eligible off-site locations that appear on UTMB's most recently filed Medicare cost report will be registered on the HRSA 340B OPAIS.
 2. All main addresses, billing and shipping addresses, the Authorizing Official, and the primary contact information are correct and up to date.
 3. UTMB reviews its 340B OPAIS records quarterly and informs HRSA within two weeks of completing its review of any changes to its information by updating 340B OPAIS and/or the Medicaid Exclusion File.
 4. UTMB annually recertifies information on 340B OPAIS as required by HRSA.
 5. UTMB will notify HRSA immediately of any changes to UTMB's Medicare disproportionate share adjustment percentage resulting in a disproportionate share percentage less than 11.75%.
 6. UTMB will maintain a listing of 340B eligible locations (i.e., clinics, departments, and services) that have not yet appeared on a filed Medicare cost report because they were not operational when the most recent cost report was filed.
- E. UTMB does not obtain covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement, except in accordance with HRSA's GPO Policy Release.
1. UTMB interprets the term covered outpatient drug in Section 1927(k)(2) of the Social Security Act to include FDA-approved prescription drugs, an over-the-counter drug that is written on a prescription or electronically prescribed, a biological product that can be dispensed only by a prescription other than a vaccine, or FDA-approved insulin.
 2. UTMB has identified exclusions to the definition of covered outpatient drugs. These exclusions are generally billed and reimbursed as part of a service, therefore, they are not considered covered outpatient drugs and may be purchased through UTMB's GPO accounts.
 - a. Intravenous solutions without additives
 - b. Contrast agents
 - c. Anesthesia gases
 - d. Radiopharmaceuticals
 - e. Compounded products purchased from 503A or 503B pharmacies

- f. Sodium Chloride, Sterile Water, and Bacteriostatic Water for Injection
 - g. Irrigation Solutions
 - h. Vaccines
 - i. Although vaccines are not covered outpatient drugs per statute, UTMB has vaccine set up in the split-bill software to split to the lowest price (GPO, WAC, or 340B) to take advantage of any voluntary or value-added discounts offered on vaccines such as Apexus contracts.
3. UTMB is part of the University of Texas (UT) System and as such works closely with the UT System Supply Chain Alliance. The UT System Supply Chain Alliance was created to leverage the collective size and strength of the UT System institutions through cooperative purchasing. To ensure compliance with the GPO prohibition, contracts negotiated by the UT System Supply Chain Alliance are not used for outpatient covered drugs.
4. UTMB has tracking systems and safeguards in place to prevent GPO prohibition violations.
- a. UTMB uses a replenishment model with a neutral inventory in areas where 340B eligibility is not easily identified prior to the point of drug administration, because the areas serve both inpatients and outpatients. These areas are known as mixed-use areas (e.g., Galveston Campus, League City Campus, Clear Lake Campus, and Angleton Danbury Campus).
 - b. The physical inventory is considered to be neutral and is replenished only after the appropriate number of eligible dispensations have accumulated.
 - c. The neutral inventory is managed through the use of split-billing software.
 - i. The software is used to track and separate the 340B-eligible dispensations from the non-340B dispensations.
 - ii. The software builds and splits purchase orders based upon data feeds to help determine 340B eligibility after drugs have been dispensed or administered to patients. Data is obtained from the electronic medical record (EPIC) and hospital's admission, discharges, and transfers (ADT) and includes information on the patient, encounter location, and provider.
 - iii. The 11-digit NDC matching from EPIC is used for tracking and audit purposes. Billing units ensure accuracy of the amount of drug accumulated each time a drug is dispensed or administered to a patient.
 - iv. Data is then sent to UTMB's wholesaler purchasing accounts. Multiple accounts are used.
 - i. Inpatient GPO account is used to replenish drugs for eligible inpatient encounters. GPO pricing and/or individual hospital agreements are loaded to this account.
 - ii. Non-GPO (WAC) account is the terminal account used to purchase drugs for non-340B eligible outpatients, to increase inventory due to a new NDC being purchased, or when adequate accumulations are lacking. WAC pricing, Apexus PVP sub-WAC, Apexus

generic portfolio, Apexus value-added contracts, and/or individual hospital agreements are loaded to this account.

- iii. Outpatient 340B account is used to replenish drugs for eligible outpatient encounters. 340B pricing, Apexus sub-340B contracts, Apexus generic portfolio, Apexus value-added contracts, and/or individual hospital agreements are loaded to this account.

- v. The accuracy of contract loads are verified during routine self-audits.

- d. Separate records for GPO, non-GPO, and 340B accounts are maintained.

- e. The accuracy of wholesaler accounts and records are verified during routine self-audits.

F. UTMB Record Retention:

1. UTMB is responsible for ensuring that auditable records are maintained that demonstrate that only eligible patients receive 340B drugs, a Medicaid rebate is not paid on a 340B drug, and all other eligibility criteria are met.
2. UTMB maintains records per *IHOP 06.1.05 Records and Information Management and Retention* and the institutional Records Retention Schedule as approved by the Texas State Library and Archives Commission and the Texas State Auditor's Office in compliance with Texas Government Code, Chapter 441.
3. Official records may be paper, microfilm, electronic, or other media.
4. Record retention period varies based upon the type of record and follows the UTMB record retention schedule.

V. Related Federal and State Statutes

[Tex. Educ. Code § 74.001](#)

VI. Related UTMB Policies and Procedures

[IHOP - 06.1.05 - Records and Information Management and Retention](#)

VII. Additional References

[Disproportionate Share Hospitals](#)

[Statutory Prohibition on Group Purchasing Organization Participation. HRSA 340B Drug Pricing Program Notice. Release No. 2013-1.](#)

VIII. Dates Approved or Amended

<i>Originated: 04/09/2019</i>	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
10/15/2020	
04/14/2021	
02/01/2023	

IX. Contact Information

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