



Institutional Handbook of Operating Procedures
Policy 09.14.02

Section: Clinical Policies	Responsible Vice President: EVP & COO Clinical Enterprise
Subject: Pharmacy	Responsible Entity: Pharmacy Services

I. Title

Enrollment, Recertification, and Change Requests in the 340B Drug Pricing Program

II. Policy

A. Purpose

To ensure UTMB is registered appropriately on the Health Resources & Services Administration (HRSA) 340B Office of Pharmacy Affairs Information System (OPAIS).

B. UTMB parent and eligible child sites that appear on UTMB’s most recently filed Medicare cost report must be registered on the HRSA 340B OPAIS to participate in the 340B Program. This information must remain accurate and up to date and changed when clinics, services or departments open, change locations, or close.

III. Procedures

A. Enrollment

1. UTMB is eligible to participate in the 340B Program as a disproportionate share hospital.
2. UTMB identifies upcoming registration dates and deadlines and submits registrations and/or change requests as needed. Registration dates:
 - a. January 1–January 15 for an effective start date of April 1
 - b. April 1–April 15 for an effective start date of July 1
 - c. July 1–July 15 for an effective start date of October 1
 - d. October 1–October 15 for an effective start date of January 1
3. UTMB identifies the institutional Authorizing Official for its program.
4. UTMB identifies the Primary Contacts for its program.
5. UTMB has the documents required for participation in the 340B Program including Medicare Cost Report Worksheet S, S-2, S-3 and Worksheet E, part A and for outpatient facilities Worksheet C, Worksheet A, and Working trial balance.
6. UTMB completes all registrations on HRSA 340B OPAIS.

B. Recertification

1. The Authorizing Official annually recertifies information on the HRSA 340B OPAIS by following the directions provided by HRSA prior to the stated deadline.
2. Any specific recertification questions are submitted to 340b.recertification@hrsa.gov

- C. Enrollment Procedure for New Offsite 340B Eligible Locations (i.e., clinics, departments, and services)
1. Offsite 340B eligible locations will be separately registered as a child site with HRSA once they appear on UTMB's most recently filed cost report as a reimbursable line with associated outpatient costs and charges.
 2. The UTMB 340B Program Director in conjunction with the Office of Government Reimbursement, Office of Institutional Compliance, Associate Vice President of Pharmacy Services, and area operational leaders are responsible for evaluating if a new offsite location is eligible for registration in the 340B Program.
 - a. Criteria used include that the outpatient service/clinic is an integral part of UTMB and appears as a reimbursable service or clinic on the most recently filed cost report, has outpatient drug use, and has patients who meet the 340B patient definition.
 - b. Upon completion and analysis of the annual Medicare Cost Report, the UTMB Office of Government Reimbursement will forward the report and suggestions to the 340B Program Director.
 - c. The 340B Program Director will map out all eligible locations and review the suggestions.
 3. Final recommendations for enrollment are made to the Authorizing Official by the Office of Institutional Compliance, 340B Program Director, and Associate Vice President of Pharmacy Services.
 4. If the new outpatient service or facility meets criteria, the UTMB Authorizing Official completes the online registration process during the registration window and will submit any updated Medicare Cost Report information as required by HRSA.
 5. If review of the latest filed cost report identifies any outpatient service/clinic that does not show outpatient revenue and expenses, this service/clinic will be de-registered and removed from OPAIS. The 340B grouper will be removed in Epic; the service/clinic will be removed from the 340B Universe; and will be updated as non-340B in the contract pharmacy software.
- D. Enrollment Procedure for New Contract Pharmacies
1. UTMB will have a signed contract pharmacy services agreement, containing the essential compliance elements in the Contract Pharmacy Guidance, in place between the entity and contract pharmacy prior to registration on the HRSA 340B OPAIS. Any contract renewals or new contract pharmacy agreements must be reviewed by UTMB Sourcing and Value Analysis and Legal Affairs to ensure all federal, state, and local requirements are met.
 - a. UTMB purchases replenishment drugs and may use:
 - i. a "ship to, bill to" procedure in which UTMB purchases the drug and the manufacturer/wholesaler bills UTMB for the drug that it purchased, but ships the drug directly to the contract pharmacy, or
 - ii. a direct replenishment model in which UTMB purchases the drug and then ships the drug directly to the contract pharmacy.

- b. The agreement will specify the responsibility of the parties to provide comprehensive pharmacy services (e.g., dispensing, record keeping, and patient counseling).
 - c. The patient has the freedom to choose a pharmacy provider.
 - d. The agreement will list other services provided to UTMB or its eligible patients (e.g., delivery).
 - e. The agreement will state that the contract pharmacy and UTMB will adhere to all Federal, State, and local laws and requirements.
 - f. The contract pharmacy will make available to UTMB reports consistent with customary business practices.
 - g. The contract pharmacy, with the assistance of UTMB, will establish and maintain a tracking system and controls suitable to prevent diversion of 340B drugs to individuals who are not patients of UTMB.
 - h. UTMB and the contract pharmacy will use a system to verify patient eligibility, as defined by HRSA guidelines.
 - i. Medicaid FFS, MCO, and MMP will be carved out of the UTMB 340B program for contract pharmacies.
 - j. UTMB and the contract pharmacy will establish mechanisms to ensure availability of information for periodic independent audits performed by UTMB.
 - k. Both parties are subject to audits by outside parties related to records that directly pertain to UTMB's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts.
 - l. Upon written request, a copy of the contract pharmacy service agreement will be provided to the HRSA Office of Pharmacy Affairs.
2. UTMB Sourcing and Value Analysis manages the contract pharmacy agreement. UTMB Legal Affairs reviews the contract pharmacy services agreement and verifies that all Federal, State, and local requirements have been met.
 3. UTMB has contract pharmacy oversight and a monitoring policy and procedure must be developed, approved, and implemented.
 4. The Authorizing Official or designee completes the online registration during one of four registration windows. Within 15 days from the date of the online registration, the Authorizing Official attests online that the contract pharmacy registration request was completed.
 5. UTMB begins using the contract pharmacy services arrangement only on, or after, the effective date shown on the HRSA 340B OPAIS.

E. Changes to UTMB information in HRSA 340B OPAIS

1. The Primary Contact or Authorizing Official will complete the online change request and the Authorizing Official will attest to the task as soon as a change in eligibility is identified.
2. 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%.
 - a. UTMB will stop the purchase of 340B drugs as soon as UTMB files its cost report with a disproportionate share percentage of less than 11.75%.
 - b. UTMB’s Authorizing Official will complete the online change request as soon as a change in eligibility is identified. UTMB will make changes to be reflected within approximately two weeks of submission of the changes.
3. UTMB will notify HRSA of any changes to UTMB’s information on its HRSA 340B OPAIS. UTMB will make changes to be reflected within approximately two weeks of submission of the changes.

IV. **Additional References**

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

V. **Dates Approved or Amended**

<i>Originated: 04/09/2019</i>	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
10/15/2020	03/02/2023
01/28/25	

VI. **Contact Information**

Pharmacy Services 340B Program
 340Bteam@utmb.edu