

Institutional Handbook of Operating Procedures Policy 09.14.08	
Section: Clinical Policies	Responsible Vice President: Executive Vice President and CEO Health System
Subject: Pharmacy	Responsible Entity: Pharmacy Services

I. Title

Contract Pharmacy Operations in the 340B Drug Pricing Program

II. Policy

UTMB is responsible for ensuring that its contract pharmacies' operations comply with all 340B Program requirements, such that UTMB remains responsible for the 340B drugs it purchases and dispenses through its contract pharmacies.

III. Purpose

To ensure that UTMB maintains responsibility for all 340B drugs used by its contract pharmacies.

IV. Procedures

- A. UTMB uses contract pharmacy services in accordance with Health Resources and Services Administration (HRSA) requirements and guidelines and has obtained sufficient information from the 340B Third Party Administrator(s) (TPA) to ensure compliance with applicable policy and legal requirements.
- B. UTMB has a signed contract pharmacy services agreement, containing the 12 essential compliance elements as best practice, in place between UTMB and contract pharmacy prior to registration on the HRSA 340B OPAIS.
- C. 340B drugs are not used at contract pharmacy locations until the contract pharmacy is registered on the HRSA 340B OPAIS.
- D. UTMB contracts with 340B TPA to facilitate the design and implementation of the 340B contract pharmacy program. UTMB is responsible for 340B compliance.
- E. 340B eligible prescriptions are presented to contract pharmacies via hard copy prescription, telephone, facsimile, e-prescribing, or other electronic means.
 1. TPA's software system verifies eligibility of claims.
 2. UTMB eligibility data is updated in the TPA's software as follows: billing data is a daily FTP from Revenue Cycle Operations, ADTs are real time based on patient registration events and the eligible provider file is uploaded daily.
- F. Contract Pharmacies use a replenishment model. The patient will be dispensed a non-340B drug from the pharmacy's inventory and then subsequently it will be replenished with a drug purchased at 340B pricing.
- G. Replenishment, Receiving, and Billing of 340B-Eligible Drug Products

1. UTMB, and its TPA where applicable, will use the following processes to manage inventory replenishment to contract pharmacies.
 - a. Wholesaler accounts are established for each contract pharmacy using a “ship to-bill to” arrangement between the wholesaler, contract pharmacy, and UTMB.
 - b. The dispensed quantities for all claims classified as 340B-eligible are placed in the accumulator. Total units available for replenishment are calculated using the 11-digit NDC number for each drug product. Replenishment will only occur at the 11-digit NDC level.
 - c. Replenishment will occur after a defined number of days have passed since the prescription was dispensed. This delay allows all required claims reversals (insurance changes, returns to stock, etc.) to be completed before replenishment is made. Time period may vary depending on the standard operating procedures used by the dispensing contract pharmacy.
 - d. At the time of replenishment, the total quantities of each 11-digit NDC in the accumulator are divided by the manufacturer package size quantity for that NDC. The number of available packages is recorded as replenishable. No partial packages may be replenished. For replenishment, the following steps will be used:
 - i. Invoices are billed to UTMB.
 - ii. Contract pharmacies receive shipment per the procedures outlined by the contract pharmacy.
 - iii. Contract pharmacies notify UTMB or the pharmacy vendor, who in turn, contacts UTMB if the contract pharmacy does not receive the 11-digit NDC replenishment order.
 - iv. Contract pharmacies verify the quantity received with the quantity ordered and are expected to identify inaccuracies, resolve inaccuracies, and document resolution of inaccuracies.
 - v. UTMB reimburses the contract pharmacies at pre-negotiated rates for such drugs.
 - vi. UTMB receives and reviews the invoices for drugs shipped to its contract pharmacies.
 - vii. UTMB pays the invoices to the wholesaler for all 340B drugs.
2. Contract pharmacies may adjust claims when a variance or discrepancy has occurred per the procedures outlined in the contract.
3. UTMB and its contract pharmacies will follow the agreed to procedure for inventory reconciliation if either party terminates the relationship.
 - a. Auditable records will be maintained to ensure the process is transparent to manufacturers and wholesalers.
 - b. For virtual inventories, UTMB pays un-replenished accumulations to the contract pharmacy as specified in contract.
 - c. The procedure may include transfer of virtual inventory to an associated pharmacy location that is still 340B registered, credit/rebill, return, or destruction according to state law.

4. Contract pharmacies will not use 340B drugs for Medicaid patients (carve-out).
 - a. UTMB carves out all Medicaid fee for service and Medicaid managed care organization claims for contract pharmacies through the TPA software.
 - b. The carve-out list is updated as needed when changes are made to the Texas Medicaid Pharmacy MCO Assistance Chart.

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. Additional References

[Texas Health and Human Services.](#) Vendor Drug Program. Managed Care. Pharmacy Resources. Pharmacy MCO Assistance Chart

VII. Dates Approved or Amended

<i>Originated: 04/24/2019</i>	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
10/16/2020	03/02/2023

VIII. Contact Information

Pharmacy Services
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