

Institutional Handbook of Operating Procedures Policy 09.14.07	
Section: Clinical Policies	Responsible Vice President: Executive Vice President and CEO Health System
Subject: Pharmacy	Responsible Entity: Pharmacy Services

I. Title

Inventory Management in the 340B Drug Pricing Program

II. Policy

Covered entities must be able to track and account for all 340B drugs to ensure the prevention of diversion.

III. Purpose

Ensure the proper procurement and inventory management of 340B drugs.

IV. Procedures

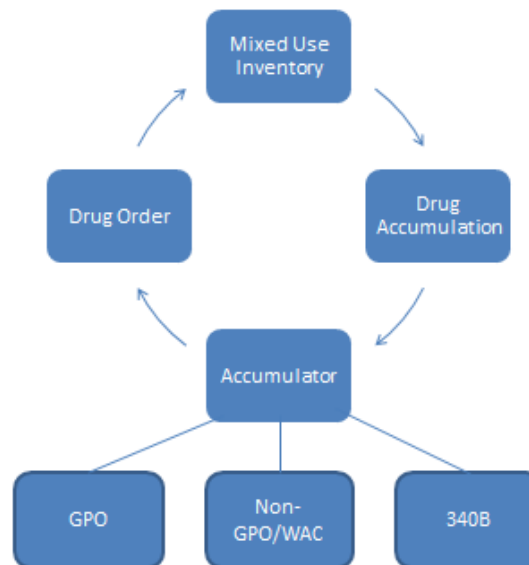
- A. UTMB tracks and accounts for all 340B drugs to prevent drug diversion. 340B inventory is procured and managed in several settings.
 1. Mixed-use areas
 2. UTMB-owned pharmacies
 3. Off campus provider-based (i.e., hospital-based) clinics
 4. Contract pharmacies
 5. Correctional Managed Care (CMC)
- B. Pharmacists and technicians dispense 340B drugs only to patients meeting all of the criteria in UTMB's policy on Patient Eligibility.
- C. UTMB has tracking systems and safeguards in place to prevent diversion.
- D. UTMB identifies all pharmaceutical purchasing accounts.
- E. UTMB identifies which accounts are used to purchase 340B drugs for each 340B-eligible location.
- F. UTMB reconciles purchasing records with dispensing records during self-audits to ensure that covered outpatient drugs purchased through the 340B Program are used only for 340B-eligible patients.
- G. UTMB uses a hybrid (physical and virtual) approach to inventory management that varies based on setting.
 1. Mixed-use areas
 - a. UTMB administers 340B purchased drugs to outpatients including Medicaid patients AND subsequently bills Medicaid for those 340B drugs (carve-in).
 - b. UTMB uses a replenishment model with a neutral inventory for mixed-use areas within the hospitals (e.g., observation) where 340B eligibility is not easily

identified prior to the point of drug administration because the areas serve both inpatients and outpatients.

- c. The physical inventory is considered to be neutral and is replenished only after the appropriate number of eligible dispensations have accumulated.
- d. Staff perform inventory reviews and shelf inspections to determine purchase order.
 - i. The neutral inventory is managed through the use of 340B split-billing software. The user manual may be found online at <https://www.mdwebportal.net/mdwp/Manuals/340B.User.Guide.pdf>
 - ii. The software is used to track and separate the 340B-eligible dispensations from the non-340B dispensations. The process used to determine how accumulations are identified as 340B-eligible is outlined in the policy on Patient Eligibility (i.e., meets the definition of a patient).
 - iii. The software builds and splits purchase orders (340B, GPO, and WAC) 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 includes information on the patient status and encounter location based on eligible dispense pharmacy.
 - iv. Eligibility of a transaction follows a charge on administration model for accumulation. Dispensations are date and time stamped within EPIC.
 - v. Accumulation occurs at the 11-digit NDC level and a full package size is accumulated before replenishment.
 - vi. Pharmacist Informatics Specialists update the NDC to CDM crosswalk in EPIC when new drugs are purchased and/or quarterly if needed when HCPCS changes are made.
 - vii. The EPIC NDC administered exports to the accumulator. If that EPIC NDC does not match to an NDC number in the accumulator, then the NDC will fall into the exceptions list to be appropriately linked. The drug will not accumulate as long as it remains in the exception list.
 - a) User can link the exception to the correct NDC (e.g., outer and inner packaging NDC are different).
 - b) User can ignore the exception and it will not accumulate and will be removed from the exception list (e.g., discontinued NDC).
 - viii. If an exact 11-digit to 11-digit NDC match is not made, accumulations are not earned.
 - ix. In certain circumstances the 11-digit NDC in the electronic medical record may not be representative of what was actually dispensed to the patient. When this occurs, UTMB maps the incorrect NDC from the electronic

medical record to the correct NDC for purchasing in the split billing vendor.

- x. Data is sent daily to UTMB's purchasing accounts according to eligible accumulations. Multiple accounts are used.
 - a) Inpatient GPO account is used to replenish drugs for eligible inpatient encounters. GPO pricing and/or individual hospital agreements are loaded to this account.
 - b) 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, when products are not available (e.g., drug shortages), for eligible outpatients when WAC pricing is equal to or less than 340B pricing, and for inpatients when WAC pricing is equal to or less than GPO pricing such that an 11-digit NDC match is not available, 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.
 - c) 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.

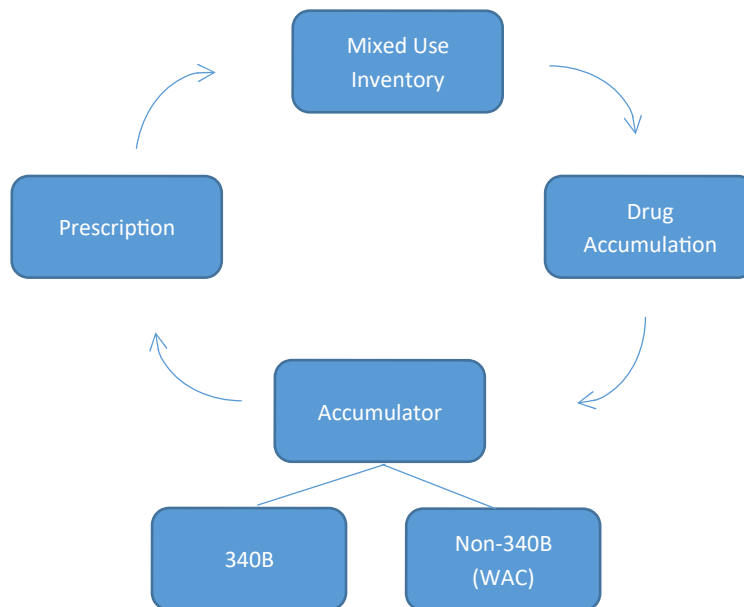


- xi. Accumulations are manually adjusted/decremented or through the EDI process if available for direct purchases.
- xii. UTMB documents manual manipulations to the 340B split-billing accumulator, including reason for manual manipulation.
- xiii. Appropriate processes are in place to ensure proper ordering, tracking, and adjusting of accumulators for CII controlled substances.

- xiv. Two options may be used when ordering CII controlled substances.
 - a) Method 1 (CSOS)
 - Order is made electronically and split-bill software will split the order based upon accruals.
 - Order will be sent to CSOS approval software for signature and transmission to wholesaler.
 - b) Method 2 (Hardcopy)
 - Accruals are reviewed manually and then a paper DEA 222 form is used to place the order.
 - Order is entered and then the 'Order Split Preview' screen is reviewed to identify available accrued quantities for each account type (i.e., 340B, GPO, WAC).
 - A separate DEA 222 form is completed based upon the available accruals. A note is placed on each DEA 222 form indicating which account to be billed.
 - There is no need to adjust the accumulator manually if ordered from the primary wholesaler when the order is received. The deduction is automatic in the split bill software.
- e. Consignment Inventory
 - i. UTMB utilizes an electronic verified inventory program to manage its consignment inventory.
 - ii. Like the rest of the inventory, UTMB uses a replenishment model with a neutral inventory for mixed-use areas that have a consignment inventory.
 - iii. The physical inventory is considered to be neutral and is replenished only after a container is removed from the electronic cabinet. Replenishment generally occurs within 48 hours, but may occur sooner (e.g., emergency, stock completely depleted).
 - iv. The electronic order is sent to the pharmacy's primary wholesaler and split to accounts with accruals, either GPO or 340B. If insufficient accruals exist, the order is made on the WAC account.
 - v. Orders are then processed as a drop ship order and accruals are decremented accordingly.
- f. Patient-Assistance Program (PAP) for services at the hospital outpatient infusion centers:
 - a) Once an application for PAP is approved by the manufacturer and confirmed, the PAP advocate shall communicate to the pharmacist on duty for the hospital outpatient infusion center.
 - b) The PAP advocate shall add a patient note to the appointment in Epic to identify PAP status.
 - c) PAP-approved drugs that are patient specific are ordered in advance and shall be segregated from other drugs in a secured location and identified as such.
 - d) PAP approved drugs that are for replacement are placed directly into the pharmacy's inventory upon replenishment.
 - e) PAP advocate is notified upon drug receipt so a record can be noted in the PAP system software.

- f) Upon verification and dispensation of a PAP-approved drug, pharmacist shall mark in the electronic record as “patient-supply.”
 - g) PAP approved drug shall not be accumulated or charged.
 - h) Records will be maintained to show each dispensation and restock to ensure compliance.
 - g. Staff reports significant discrepancies in split-billing software quantities to the Senior Pharmacy Manager and 340B Program Director.
- 2. UTMB-owned outpatient pharmacies:
 - a. UTMB dispenses 340B purchased drugs to outpatients including Medicaid patients AND subsequently bills Medicaid for those 340B drugs (carve-in).
 - b. UTMB uses a replenishment model with a neutral inventory for UTMB-owned pharmacies where 340B eligibility is not easily identified prior to dispensing because the areas may serve both eligible and ineligible outpatients.
 - c. The physical inventory is considered to be neutral and is replenished only after the appropriate number of eligible dispensations have accumulated.
 - d. Staff uses accrual data and also performs inventory reviews and shelf inspections to determine purchase order.
 - e. The neutral inventory is managed through the use of EPIC Willow Ambulatory split-billing software.
 - i. The software is used to track and separate the 340B-eligible dispensations. The process used to determine how accumulations are identified as 340B-eligible is outlined in the policy on Patient Eligibility.
 - ii. The software builds 340B accruals based on data feed in EPIC after drugs have been dispensed to patients. Data is obtained from the EPIC including information on encounter location, ordering provider, and plan.
 - iii. Ordering process
 - a) Select the EPIC icon > Pharmacy > Inventory > Select Location Name
 - b) Select Inventory Items > Select (✓) inventory items needed to order > Select “Create Request.”
 - c) EPIC populates a draft inventory request based on the selected items.
 - d) EPIC splits the items into two separate orders (i.e., 340B or WAC) based on the amount of medication accumulated.
 - e) If the user tries to order more than what EPIC has accumulated, a warning will be displayed. The software will not allow the user to order more than what is accumulated.
 - f) EPIC will split the order as appropriate and transmit the order to the wholesaler.
 - g) Once the order is received, the user will receive all items under the appropriate EPIC account. If an item was not received from the wholesaler, the amount received is entered as “0.”

- iv. Accumulation occurs at the 11-digit NDC level and a full package size is accumulated before replenishment. If an exact 11-digit to 11-digit NDC match is not made, accumulations are not earned.
- v. Two accounts are used.
 - a) 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, when products are not available (e.g., drug shortages) such that an 11-digit NDC match is not available, 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.
 - b) 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.



- vi. Accumulations are verified in EPIC prior to placing a drop ship order. The Morris and Dickson ordering portal is used or the order is called in by phone. The order is placed on the appropriate account based on available accruals. When the order is scanned upon receipt, the accumulator is decremented.
- vii. Accumulations are verified in EPIC prior to placing a direct purchase. The company's ordering portal is used or the company is called to place the order on the appropriate account based on available accruals. Upon receipt, the order is scanned and the accumulator is decremented automatically.

- viii. Two options may be used when ordering CII controlled substances. See section IV.G.1.d.xiii for details.
- ix. Staff reports significant discrepancies in split-billing software quantities to the Senior Pharmacy Manager and 340B Program Director.
- f. Meds-to-Beds Discharge Prescriptions
 - i. UTMB fills discharge prescriptions and dispenses 340B purchased drugs to eligible patients prior to discharge as close to the actual day of scheduled discharge to ensure continuity of care.
 - ii. Prescriptions may also be dispensed for patients following outpatient surgeries, outpatient procedures, and outpatient visits (e.g., emergency department visit).
 - iii. Medications are not intended for inpatient use and will not be administered while an inpatient. Medications are intended for self-administration after the patient is discharged and released from UTMB's care.
 - iv. The dispense date may not match the actual discharge date, since it is common to have discharge delays for various clinical and social scenarios.
- g. Patient Assistance Program (PAP) for entity-owned outpatient pharmacies.
 - i. Patient is prescribed a medication and presents it to a UTMB owned pharmacy.
 - ii. Pharmacy staff confirms payor eligibility and patient ability to pay.
 - iii. If financial assistance is needed, pharmacy staff will seek financial assistance on the patient's behalf.
 - iv. If approved, the provider will send an e-prescription to the designated manufacturer affiliated pharmacy.
- 3. Off-campus provider-based (i.e., hospital-based) clinics
 - a. UTMB maintains a 340B only physical inventory at off-campus provider-based (i.e., hospital-based) clinics including Class D clinic pharmacies.
 - b. Staff perform inventory reviews and shelf inspections to determine purchase order and places 340B drug orders.
 - i. Eligible off-campus provider-based (i.e., hospital-based) clinics have a separate 340B wholesaler account to purchase medications. An annual review of wholesaler accounts is performed to verify correct 340B ID numbers are assigned and to ensure appropriate contracts are loaded.
 - ii. Clinic staff are responsible for ensuring that purchases made directly from manufacturers and/or specialty distributors utilize the appropriate customer accounts and do not violate GPO prohibition rules. Accounts are sampled during self-audits to ensure compliance.

- iii. Clinic staff are responsible for ensuring that supplies purchased directly from the designated medical supply vendor do not include outpatient covered drugs. Accounts are sampled during self-audits to ensure compliance.
 - c. Unregistered offsite 340B eligible locations that are reimbursable under Medicare cost reporting rules (i.e., meets the provider-based requirements of the Centers for Medicare & Medicaid Services) but have not yet appeared on a filed Medicare cost report.
 - i. A 340B non-deduct department will be created under the parent's 340B account using the parent 340B ID number for each new clinic that is opened that uses drugs.
 - ii. Once registered, the old department under the parent 340B account will be inactivated and a new separate account will be created.
 - iii. Until registered, WAC accounts will be used for purchases of controlled substances if shipped from the parent to the clinic.
4. Angleton Danbury Campus Indigent Pharmacy Program
- a. UTMB maintains a WAC only physical inventory for the Indigent Pharmacy Program.
 - b. Staff performs inventory reviews and shelf inspections to determine purchase order and places WAC drug orders.
 - i. A separate WAC wholesaler account is used to purchase medications.
 - ii. Staff are responsible for ensuring that purchases made directly from manufacturers and/or specialty distributors utilize the appropriate customer accounts and do not violate the GPO prohibition rules.
 - c. Medications stored in this area may only be used for outpatient take home prescriptions. Transfer of inventory to or from the Inpatient Pharmacy inventory is not permitted under normal circumstances.
5. Contract Pharmacies
- a. UTMB's contract pharmacies are carve-out; therefore, 340B drugs are not dispensed to Medicaid patients.
 - b. UTMB will contract with one or more third party administrator(s) (TPA) to facilitate the design and implementation of the 340B contract pharmacy program. UTMB is responsible for 340B compliance and uses a replenishment model through the TPA's system.
 - c. UTMB electronically submits all patient, prescriber, and location information to the TPA's system to be used to determine eligible 340B prescription claims.
 - d. When a UTMB patient presents a prescription to a contract pharmacy, the prescription is filled, and payment collected per the pharmacy's usual process.
 - e. Prescription transactions from the contract pharmacy are compared to the eligibility file maintained by TPA and if 340B eligible, the amount accumulates at

the 11-digit NDC level. When a NDC reaches a full package size, an order is placed on the 340B contract account and shipped to the contract pharmacy.

- f. UTMB pharmacy pays the wholesaler invoice for all 340B orders placed by the contract pharmacy for eligible transactions.

6. UTMB CMC-owned Pharmacy

- a. The UTMB CMC-owned pharmacy does not serve Medicaid eligible patients; therefore, 340B drugs are not dispensed to Medicaid patients. However, the inmate population are wards of the State that UTMB is legislatively and contractually obligated to serve. UTMB staffs the clinical sites with clinical personnel and maintains control over the inmate's medical care including documentation and entry into the medical record.
- b. UTMB maintains both 340B and non-340B (WAC) separate physical inventories for CMC.
- c. 340B drugs are only dispensed to eligible patients.
- d. Separate 340B and non-340B accounts are maintained for purchasing drugs.
- e. Staff perform inventory reviews and shelf inspections to determine purchase order and place orders from the appropriate wholesaler account accordingly.
- f. Physically separate 340B and non-340B inventories are established by purchase orders through the use of separate accounts, which segregate inventories at the time of purchase.
- g. Staff check in 340B inventory by examining the wholesaler invoice against the order, and report inaccuracies to the wholesaler if needed.
- h. Inventory is placed into its physically separate inventory.

- H. Upon receipt of shipment, UTMB verifies quantity received with quantity ordered and dates and initials all invoices/packing slips. Discrepancies are resolved as needed.

I. Wasted 340B Medication in Mixed-Use Areas

- 1. For multi-dose vials dispensed to patient care areas, the amount administered/used is documented on the MAR and captured by EPIC and sent to the accumulator.
- 2. Single dose vials dispensed to patient care areas.
 - a. For single dose vials that are partially used, and the remainder is greater than one billing unit, the amount administered by staff is documented on the MAR. This amount and calculated waste (scanned package amount minus administered amount) is captured by EPIC and sent to the accumulator.
 - b. For single dose vials that are partially used, and the remainder is less than one billing unit, the amount administered by staff is documented on the MAR. This amount is captured by EPIC and sent to the accumulator. If the administered

amount does not reach a billing unit for certain high cost drugs, then the amount accumulated is rounded to an increment of 1 in the accumulator.

3. Single dose vials used by pharmacy staff to compound items.
 - a. For single dose vials used during pharmacy medication preparation, EPIC Dispense Prep is used. The functionality allows the user to document the amount wasted as long as it is greater than one billing unit. The amount wasted is captured by EPIC and sent to the accumulator when the dose is documented as given on the MAR.

- J. Reverse Distributor – UTMB sends expired or damaged medications to the designated reverse distributor if they cannot be returned to a supplier/wholesaler. Reports are available online.

- K. Return or destruction of inventory is managed per pharmacy policies 6.30, 25.20, and 30.45.

- L. Drug recalls are managed per Pharmacy Policies 20.01 and 55.15.

- M. Transfer of Inventory and Lend/Borrow
 1. UTMB as a 340B hospital covered entity may transfer 340B drugs to any of its 340B eligible outpatient facilities for use by a UTMB 340B eligible patient.
 2. Clinics: Clinics should not share or transfer inventory under normal circumstances to ensure compliance.
 3. CMC: Only in the case of an emergency medical situation and with Director or Associate Vice President of Pharmacy approval will drugs be transferred from a 340B inventory to a non-340B inventory (pharmacy policy 30-25). Replacement will be based on 11-digit NDC.
 4. Hospitals & Mixed-use Areas: Medications may be borrowed or loaned per pharmacy policy 6.25.

- N. 340B Product Unavailable
 1. Clinics, UTMB-owned pharmacies and CMC pharmacy: If a 340B product is not available, will buy at WAC from available source.
 2. Mixed-use Areas: If a 340B product is not available, will buy at WAC. If a GPO accrual is available, will buy at GPO and decrement the accumulator manually and will make a notation of the reason.

V. **Related UTMB Policies and Procedures**

UTMB CMC Pharmacy Departmental [Policy 25.20 Returned Medications and Reclamation Processing](#).

UTMB CMC Pharmacy Departmental [Policy 30.25 Pharmacy Procurement of Drug and Non-Drug Products](#).

UTMB CMC Pharmacy Departmental [Policy 30.30 Inventory Management and Controls](#).

UTMB CMC Pharmacy Departmental Policy [30.45 Safe Handling and Disposal of Pharmaceuticals](#).

UTMB CMC Pharmacy Departmental [Policy 30.55 340B Program Compliance](#).

UTMB CMC Pharmacy Departmental Policy [55.15 Drug Recalls and Defective Products](#).

UTMB Department of Pharmacy. [Policy 6.25 Borrow and Loan](#).

UTMB Department of Pharmacy. [Policy 6.30 Return or Destruction of Inventory Goods – Non-Controlled Substances](#).

UTMB Department of Pharmacy. [Policy 20.01 Drug Recalls](#).

VI. Additional References

[Apexus Tool: 340B Compliance and the Controlled Substance Ordering System \(CSOS\)](#) may be used to articulate compliance solutions in this area.

VII. Dates Approved or Amended

<i>Originated: 04/24/2019</i>	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
10/16/2020	
04/13/2021	
01/11/2022	03/02/2023
	03/07/2023

VIII. Contact Information

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