Institutional Handbook of Operating Procedures Policy 09.14.00	
Section: Clinical Policies	Responsible Vice President: Executive Vice President and CEO Health System
Subject: Pharmacy	Responsible Entity: Pharmacy Services

I. Title

340B Drug Pricing Program Plan

II. Purpose

UTMB has written policies and procedures to oversee the 340B Program operations, provide oversight of contract pharmacies, and maintain a compliant 340B Program.

III. Background

Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of Health and Human Services. This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs.

UTMB is an eligible covered entity and participates in the 340B program and is able to receive the discounted pricing under the Program. The 340B Program was designed to allow eligible covered entities, such as UTMB, to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

The 340B Program is administered by the federal Health Resources and Services Administration (HRSA) in the Department of Health and Human Services (DHHS).

Upon registration of the parent on the HRSA 340B OPAIS (Office of Pharmacy Affairs Information System) as a participant in the 340B Program, the entity:

A. Agrees to abide by specific statutory requirements and prohibitions.
B. May access 340B drugs.

IV. 340B Policy Statements

The University of Texas Medical Branch (UTMB), including the campuses, clinics, UTMB-owned pharmacies, contract pharmacies, and Correctional Managed Care (CMC), complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, prohibition against the use of a GPO for outpatient covered drugs, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity.

UTMB uses any savings generated from 340B in accordance with 340B Program intent.

UTMB has systems, mechanisms, and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements.

UTMB maintains auditable records demonstrating compliance with the 340B Program. These reports are reviewed by UTMB quarterly for the Health System and bi-annually for CMC as part of its 340B self-audit and compliance program.

V. Policy Review, Updates, and Approval

These written policies and procedures will be updated and approved whenever there is a clarification, or change, in the rules, regulations, or guidelines to the 340B Program requirements. Otherwise, the policies will be reviewed and approved as outlined per *IHOP - 01.01.03 - Institutional Policy Development, Approval and Maintenance*.

VI. Definitions

Authorizing Official - An Authorizing Official is someone who represents and confirms that he/she is fully authorized to legally bind a 340B covered entity into a relationship with the federal government and has knowledge of the practices and eligible programs at that site. This is the person responsible for and to whom the federal government would contact concerning compliance issues, integrity evaluations, and audits. Covered entities are required to provide HRSA with their Authorizing Official's name and contact information upon enrollment, and to update this information when any changes are made. The Authorizing Official is also responsible for completing OPA's online registration process for 340B covered entities and outpatient facilities as well as the annual recertification process. The Authorizing Official must also approve contract pharmacy registrations.

340B covered entity (CE) - 340B covered entities are facilities/programs that are listed in the 340B statute as eligible to purchase drugs through the 340B Program and appear on 340B OPAIS.

340B Drug Pricing Program (340B Program) – The 340B Program is a federal program that requires drug manufacturers participating in the Medicaid Drug Rebate Program to provide covered outpatient drugs to enrolled covered entities at or below the statutorily defined ceiling price. This limits the price that manufacturers may charge covered entities for covered outpatient drugs. This requirement is described in Section 340B of the Public Health Service Act and is codified at 42 USC §256b.

340B eligible patient – An individual is a 340B eligible patient if (1) UTMB has established a relationship with the individual, such that UTMB maintains records of the individual's health care and (2) the patient receives health care services from a health care professional who is either employed by UTMB or provides health care under contractual or other arrangements such that responsibility for the care provided remains with UTMB. An individual will not be considered a 340B eligible patient of UTMB if the only health care service received by the individual from UTMB is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

340B eligible locations – Any onsite or offsite clinics, departments, or services 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). 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 revenue and expenses. UTMB will consider using 340B drugs in an unregistered offsite location or a new location within the four walls of the parent hospital that has not yet appeared on the Medicare cost

report because it was not operational when the most recent cost report was filed. In such cases, 340B drugs may be used for individuals that meet HRSA's definition of patient.

Contract pharmacy - 340B covered entities may contract with a pharmacy or pharmacies to provide services to the covered entity's patients, including the service of dispensing the entity-owned 340B drugs. To engage in a contract pharmacy arrangement, the entity and pharmacy (or pharmacies) must have a written contract that aligns with the compliance elements listed in guidance and must list the contract pharmacy on 340B OPAIS during a quarterly registration period.

Disproportionate share hospital (DSH) - Disproportionate share hospitals serve a significantly disproportionate number of low-income patients; as such, they receive adjustment payments to provide additional help. The primary method of qualification is based on the sum of the percentage of Medicare inpatient days and the percentage of total patient days attributable to patients eligible for Medicaid but not eligible for Medicare Part A. Among other requirements, DSHs must have a DSH adjustment percentage >11.75% to be 340B eligible.

Duplicate discount - Prohibited by the 340B statute, a duplicate discount occurs when a covered entity obtains a 340B discount on a medication and a Medicaid agency obtains a discount in the form of a rebate from the manufacturer for the same medication.

GPO Prohibition - The GPO Prohibition, per 340B statute, prohibits 340B participating disproportionate share hospitals (DSH), children's hospitals (PED), and free-standing cancer hospitals (CAN) from obtaining covered outpatient drugs through group purchasing organizations (GPOs). Upon enrollment, an entity official signs a form attesting that the hospital will comply with the GPO Prohibition. This applies to the hospital as of the date of listing in 340B OPAIS. Upon recertification of information from 340B OPAIS, the hospital official attests to compliance with the GPO Prohibition.

Group Purchasing Organization (GPO) - A Group Purchasing Organization is an organization created to leverage the purchasing power of entities to obtain discounts from vendors based on the collective buying power of the GPO members. GPOs are common in the drug industry; the GPO may set mandatory purchasing participation levels from its members or be completely voluntary. Disproportionate share hospitals are prohibited from purchasing covered outpatient drugs from a GPO or GPO-like arrangement. However, drugs used for inpatients may be purchased from a GPO.

Health Resources and Services Administration (HRSA) - An agency of the U.S. Department of Health and Human Services, HRSA is the primary federal agency for improving access to health care services for people who are uninsured, isolated, or medically vulnerable. Comprising five bureaus and ten offices, HRSA provides leadership and financial support to health care providers in every state and U.S. territory. The Office of Pharmacy Affairs (OPA), the office responsible for administering the 340B Program, falls under the Healthcare Systems Bureau within HRSA.

HRSA 340B OPAIS - The 340B Office of Pharmacy Affairs Information System (OPAIS) provides access to covered entity and manufacturer records, user accounts, change requests, recertification, and registrations. This system increases the integrity and effectiveness of 340B stakeholder information and focuses on three key priorities: security, user accessibility, and accuracy.

Medicaid carve-in - 340B entities may elect to use drugs purchased at 340B prices to bill for Medicaid patients. This activity is termed a "Medicaid carve-in." Entities must inform HRSA whether they are carving in by answering "yes" on the Medicaid billing question in 340B OPAIS. Entities must also provide each Medicaid state it plans to bill, and the billing number(s) it will list on the bill to the state. Billing number(s) may include the billing provider's national provider identifier (NPI) only, state assigned Medicaid number only, or both NPI and state assigned Medicaid number. This information listed for each covered entity site (340B ID) in OPAIS is used to generate a quarterly Medicaid Exclusion File, which is the official data source used by stakeholders to determine which covered entity sites bill Medicaid for 340B drugs.

Medicaid carve-out - 340B entities may elect to use non-340B drugs to bill for Medicaid patients. This activity is termed a "Medicaid carve-out." Entities may choose to do this so they can receive fair Medicaid reimbursement.

Medicaid Exclusion File - HRSA established the Medicaid Exclusion File (MEF) to help support program integrity regarding the statutory prohibition of duplicate discounts and it serves as the official data source to determine whether 340B drugs are billed to Medicaid fee-for-service (FFS). The Medicaid Exclusion File is maintained on the HRSA 340B OPAIS and contains the National Provider Identification (NPI) number or Medicaid provider number of entities that use 340B discounted drugs to bill Medicaid for their patients. Entities are expected to provide updated information to HRSA for incorporation into the Medicaid Exclusion File. The MEF does NOT apply to Medicaid managed care organization patients.

Mixed-use setting - A hospital area that serves a mixed patient type of both inpatients and outpatients. These include facilities such as surgery centers, cardiac catheter labs, infusion centers, and emergency departments or pharmacies serving these locations.

National Drug Code (NDC) - Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for human drugs. The FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory, which is currently updated semimonthly. The NDC is an 11-digit number; the first segment (5 digits) of the NDC indicates the manufacturer, the second segment (4 digits) indicates the drug product, and the third segment (2 digits) indicates the package size.

National Provider Identifier (NPI) - The National Provider Identifier (NPI) is a unique identification number for covered health care providers. Covered health care providers and all health plans and health care clearinghouses must use the NPIs in the administrative and financial transactions adopted under HIPAA. The NPI is a 10-position, intelligence-free numeric identifier (10-digit number).

Office of Pharmacy Affairs (OPA) - The Office of Pharmacy Affairs (OPA) is the HRSA office responsible for administering the 340B Program.

Own use – Purchases that reasonably may be regarded as being used by the hospital in the sense that such use is a part of, and promotes, the hospital's intended institutional operation in the care of persons who are its patients.

Recertification – HRSA is required by statute to conduct annual recertification of participating 340B covered entities' information listed in 340B OPAIS. As part of this process, an Authorizing Official from each 340B entity certifies basic information about the entity and its 340B compliance.

Replenishment (340B outpatient drug) – 340B outpatient drug replenishment occurs when a non-340B drug is initially dispensed to a 340B eligible patient, and an entity later replaces the non-340B dispensed drug with 340B purchased inventory. The replaced inventory, although it was purchased at 340B prices, is no longer considered 340B inventory because it is replacing a non-340B drug dispensed to a 340B eligible patient.

Replenishment models operate on a neutral inventory premise. The inventory that is purchased "replenishes" a dispensing/administration activity that already occurred in the past. When this reorder arrives in the pharmacy, it becomes neutral and that package can be dispensed to any patient. In essence, the arrival of the replenishment order turns the drug that was originally dispensed with neutral inventory to an actual 340B transaction. This leaves that neutral inventory to reside on the shelf for the next dispensation.

Split-billing software – Split-billing software is used to manage a replenishment inventory model. This software helps the entity track data (e.g., eligible dispensations) and uses logic chosen by the entity to virtually separate 340B from non-340B transactions after they occur. The software then determines from which account each transaction should be reordered. The term "split-billing" is used to describe the software which "splits" a purchase order into two or three different accounts (e.g., 340B, GPO, non-GPO/WAC). It helps the entity place orders in appropriate accounts while maintaining auditable records of the accumulations and purchases.

Wholesale Acquisition Cost (WAC) - The price paid by a wholesaler (or direct purchaser) in the United States for drugs purchased from the drug's manufacturer or supplier. Publicly available WAC lists do not represent actual transaction prices and do not include prompt pay or other discounts, rebates, or reductions in price.

VII. Relevant Federal and State Statutes

Public Law 102-585, Section 602
340B Guidelines
340B Policy Releases

VIII. Related UTMB Policies and Procedures

IHOP - 01.01.03 - Institutional Policy Development, Approval and Maintenance

IX. Dates Approved or Amended

Originated: 04/09/2019	
Reviewed with Changes	*Reviewed without Changes*
10/15/2020	02/28/2022
	03/02/2023

X. Contact Information

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