

Institutional Handbook of Operating Procedures
Policy 09.14.13

Section: Clinical Policies.	Responsible Vice President: Executive Vice President and CEO Health System
Subject: Pharmacy	Responsible Entity: Pharmacy Services

I. Title

Use of 340B Drugs and Maintenance of Auditable Records During Emergency Operations/Status.

II. Policy

Circumstances surrounding a public health emergency may warrant additional flexibilities in 340B operations and documentation of compliance with 340B rules, particularly when UTMB hospitals and/or clinics are directly impacted by an emergency. UTMB will continue to ensure it has policies and procedures in place to address the proper dispensing of 340B drugs and will continue to keep auditable records when responding to an emergency.

III. Definition

Public Health Emergency: An emergency need for health care services to respond to a disaster, significant outbreak of an infectious disease, bioterrorist attack or other significant catastrophic event.

IV. Procedures

- A. UTMB will follow and remain updated on HRSA guidelines throughout a public health emergency.
- B. Maintenance of Auditable Records
 - 1. UTMB will maintain auditable records for patients that receive 340B outpatient covered drugs during a public health emergency.
 - 2. UTMB will maintain auditable records of service/clinic openings, closures, or consolidations where 340B outpatient covered drugs are administered and/or prescribed.
 - 3. An abbreviated health record will be maintained when typical documentation is not feasible and may consist of a single form that notes the patient identity, medical evaluation, including any testing, diagnosis, or clinical impressions, and the treatment provided or prescribed.
- C. UTMB will use 340B outpatient covered drugs for patients who receive outpatient health care services delivered using a variety of telehealth technology platforms such as telephones or tele-video to deliver care to new or existing patients during a public health emergency. Health care services may also be provided at consolidated locations or new locations that are not separately registered in the Office of Pharmacy Affairs Information System (OPAIS).
- D. Patients will be considered eligible outpatients if care is provided by a health care professional employed by UTMB, under a contractual relationship or other arrangement with the hospital (e.g. volunteer health professional) such that responsibility for care remains with the hospital; and UTMB either owns the medical record or has joint access to the medical record with the professional providing the care.

- E. If volunteer health professionals are providing health care, emergency documentation will be kept to clearly demonstrate the relationship between the professional and UTMB and that UTMB is responsible for the care provided. The documentation should be kept on file by UTMB and include:
 1. A description of the emergency nature of the situation;
 2. The name and address of the volunteer; and
 3. The volunteer’s relationship to the hospital/child site.

- F. For new offsite outpatient locations that the hospital cannot register or is unable to timely register as a result of the public health emergency, the hospital will follow the procedures regarding patient definition in Section D of this Policy to document that 340B patient definition requirements are met.

- G. **Inventory Management**
 1. If a covered outpatient drug is not available at the 340B price during a public health emergency, UTMB will attempt to purchase the drug at wholesale acquisition cost (WAC) to comply with the 340B statute’s GPO prohibition. If the drug is not available at WAC, the hospital may then use a GPO or GPO private label products.
 2. UTMB will maintain appropriate documentation to demonstrate the inability to purchase a drug at 340B and WAC prices. This includes, but is not limited to, screenshots, emails, invoices showing back orders/out-of-stock attempts to purchase on 340B and WAC accounts, log sheets of purchases, or other documentation of drugs’ unavailability at 340B and WAC prices.

- H. 340B self-audits may be deferred, in consultation with the UTMB Office of Institutional Compliance, to the next regularly scheduled audit in the event a public health emergency precludes UTMB from being able to dedicate the necessary resources to complete audits. Requests will be documented and evaluated on a case-by-case basis.

V. Related UTMB Policies and Procedures

[IHOP – 09.14.03 - Patient Eligibility for the 340B Drug Pricing Program](#)

[IHOP – 09.14.07 - Inventory Management in the 340B Drug Pricing Program](#)

VI. Dates Approved or Amended

<i>Originated: 04/01/2020</i>	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
	02/21/2023

VII. Contact Information

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