Name of Policy:	**340B Program**
Policy Number:	3364-133-119
Department:	Pharmacy
Approving Officer:	Chief Pharmacy Officer
Responsible Agent:	Acute Care Director of Pharmacy
Scope:	UTMC

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Effective Date: 04/01/2021

Initial Effective Date: 4/1/2016

_____ New policy proposal
_____ Major revision of existing policy
__x__ Minor/technical revision of existing policy
_____ Reaffirmation of existing policy

(A) Definitions

Definitions of terms may be found in Appendix A, Glossary of Terms, and on the Apexus Website under the link of 340B Glossary of Terms

(B) Policy Statements

1. 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 manufacturers may charge certain covered entities for covered outpatient drugs. The resulting program is called the 340B Program. The federal Health Resources and Services Administration (HRSA) /Department of Health and Human Services (DHHS) administers the program.

The University of Toledo Medical Center (UTMC) is registered on the HRSA site as a participant in the 340B Program. Therefore, UTMC may access 340B drugs and agrees to abide by specific statutory requirements and prohibitions.

This document contains descriptions of the policies and procedures used at UTMC to maintain compliance with the 340B Program. This policy will be reviewed, updated, and approved by UTMC Steering Committee annually.

2. 340B Policy Statements

As a participant in the 340B Drug Pricing Program, UTMC's drug inventory management, including product selections, purchasing, storage, replenishment, returns, distribution, billing and record keeping meets the following objectives:

a. UTMC uses any savings generated from 340B in accordance with 340B Program intent. The intent of section 340B program was to help stretch scarce resources as far as possible, reaching more patients that are eligible and providing more comprehensive services. The mission of UTMC is to improve the human condition by providing patient-centered, university-quality care. Participating in the 340B program enables UTMC to provide more comprehensive care and enhanced services to more patients, including subsidizing and supporting access to prescription medications. Examples listed in Appendix B.
b. UTMC meets all 340B Program eligibility requirements.
c. UTMC is a state government-owned hospital. Appendix C is a copy of the HRSA certification document.
d. UTMC's HRSA 340B Database covered entity listing is complete, accurate, and correct. UTMC informs HRSA immediately of any changes to its information on the HRSA website including Medicaid exclusion file. UTMC uses 340B only within the four walls of UTMC or within outpatient clinics that are reimbursable on the most recently filed cost report and registered on the HRSA 340B Database. New child sites are registered during the quarterly enrollment periods. For the most recent cost-reporting period that ended before the calendar quarter involved, UTMC had a disproportionate share adjustment percentage greater than 11.75%. Particular cost report focus areas include worksheet A (reimbursable lines typically 50-118), C (reimbursable clinics with charges), E (DSH %), S (date and time of most recent report), S2 (type of control) and clinics list (what is in line 90 clinics).
e. UTMC will follow the current HRSA guidelines on replenishing 340B drugs dispensed to a patient before the outpatient facility in which a patient was treated appears in HRSA's covered database.
f. UTMC may capture 340B for qualifying events in sites that do not yet appear on our Medicare Cost Report. The following conditions for these claims must be met:

a. New department or clinic must be provider based, whether within the four walls of the hospital or at a separate address
    i. Rules are found in 42 CFR §413.65
b. New department or clinic will appear as reimbursable on our next Medicare Cost Report
c. UTMC will demonstrate compliance with the 340B patient definition
d. UTMC will maintain auditable 340B records for these new sites

g. UTMC does not obtain covered outpatient drugs through a GPO or other group purchasing arrangement, except in accordance with GPO Policy Release. Outpatient drugs that are not 340B eligible are purchased at WAC or through a non-GPO contract with the manufacturer.
h. UTMC maintains auditable records demonstrating compliance with the 340B requirement described in the preceding bullet.
i. UTMC maintains records of the individual's health care. A 340B eligible encounter may be a billable or non-billable visit for direct or supportive care given in person or via telehealth by an eligible provider.
j. Medications prescribed before a qualifying outpatient event occurs that are to be used before or during the qualifying outpatient event (eyedrops for a procedure, colonoscopy preps, calming agents, etc) may be deemed 340B eligible provided the patient meets the other tenets of eligibility for the patient definition.
k. UTMC will purchase 340B medications only for outpatients that meet the definition of an eligible patient. The hospital uses information in its ADT system to determine whether a hospital patient is an outpatient. Appendix E has a screen shot of patient status indicator. Dispensations to hospital patients with an outpatient status are 340B eligible up until the time of inpatient admission. The ADT time stamp indicating a change in status controls the status for 340B purposes.
l. Per HRSA's exemption to the GPO exclusion, UTMC may use GPO drugs for outpatients in offsite facilities only when they (1) are located at a different physical address than the parent hospital, (2) are not registered on the HRSA 340B database as participating in the 340B program (3) purchase drugs through a separate pharmacy wholesaler account and (4) maintains records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on the HRSA 340B database. The clinics that may utilize GPO drugs are as follows:
    a. UTP clinics
    b. Student Medical Center
    c. Main Campus Medical Center (MCMC)
    d. Promedica affiliate locations (Neurology, Falzone, Toledo Hospital, etc.)
m. 340B eligible prescriptions are generated from eligible service locations only.
n. UTMC interprets Section 1927 (k) of the Social Security Act and evaluated for inclusion for 340B outpatient definition non-reimbursable drugs, drugs bought on pharmacy but billed using a non-pharmacy CDM code and drugs where direct reimbursement is not identifiable. Drugs determined as not covered outpatient drugs for purposes of 340B are listed in Appendix F.
o. For purposes of the 340B program, UTMC has defined patients to include all outpatient UTMC patients within the hospital and at the HRSA registered clinics. Providers are on the hospital's eligible prescriber list as employed by UTMC, or under contractual or other arrangement with UTMC and the individual received a health care service from this professional such that the responsibility for care remains with UTMC.
    - For the hospital and infusion center, UTMC has defined provider as employed, contracted or credentialed providers for drugs administered by professional staff. Rationale includes:
        - Revenue & expense is on reimbursable section of the cost report of UTMC. UTMC bills the payer for the health care services associated with administering the drugs as well as the drugs itself
        - Patient is registered as an outpatient at UTMC
        - Health care service as well as drug administration is provided within UTMC
        - UTMC is responsible for care provided at the registered UTMC sites
        - UTMC owns and maintains records of the individual's care
        - Credentialed provider writing order and directing drug administration. For purposes of the 340B Program, all licensed independent practitioners who provide and document patient care services shall be considered a health care professional. This may include but is not limited to: physicians,

pharmacists, nurses, nurse practitioners, physician assistants, counselors, social workers, respiratory therapists, etc.
    - 340B drugs are administered on site by an employed or contracted health care professional
    - An employed provider is on site to respond to emergencies

  Non-credentialed providers are not included in 340B
- For medications administered at child sites and for prescriptions, only patients seen by employed and contracted providers will be included in the 340B program.
- The current credentialed provider list is updated as providers are added or removed. UTMC IT will provide a credentialed provider list monthly to our split-billing vendor. Appendix G is a sample of provider list that is sent to our split billing software vendor.
- In accordance with HRSA regulations, employees of UTMC, UT, or UTP will not receive 340B medications unless the employee meets all the eligibility criteria set in the above sections.

p. UTMC 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 and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of UTMC.
q. UTMC's Medicaid status is reported on the HRSA online database and is reviewed and updated quarterly unless there is a reportable change in information. UTMC informs HRSA immediately of any changes to its information on the HRSA 340B Database /Medicaid Exclusion File.
r. UTMC will strip any charges for administered drugs to out-of-state Medicaid plans from our hospital billing.
s. UTMC has systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements. UTMC hires independent, external auditors to examine our entire program every 1-2 years.
t. UTMC uses contract pharmacy services and the contract pharmacy arrangement is performed in accordance with HRSA requirements and guidelines. These requirements and guidelines include, but are not limited to, that the hospital obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism).
u. UTMC acknowledges its responsibility to contact HRSA as soon as reasonably possible if there is any change in 340B eligibility or material breach by the hospital of any of the foregoing policies. UTMC acknowledges that if there is a breach of the 340B requirements, UTMC may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.
v. UTMC maintains records of 340B related transactions in a readily retrievable and auditable format electronically. Invoices are stored in an electronic format in an invoice management system. Auditable records will be maintained for a period of time that complies with federal, state and local requirements as per UTMC records retention policy.
w. Pharmacy inventory is stored in the hospital pharmacy, Dana Cancer Center pharmacy, Health Science Campus Outpatient Pharmacy, UT Access Pharmacy and contract pharmacies. Only pharmacy employees have access to the through ID badge or key limited entry system, protected by a security system. Patient care area/clinic inventory is stored in secured, limited access automated dispensing cabinets or key locked limited access cabinets.
x. UTMC elects to receive information about the 340B Program from trusted sources, including, but not limited to:
    - HRSA
    - The 340B Prime Vendor Program, managed by Apexus
    - Any HRSA contractors

(C) Responsible Staff

The following UTMC staff are engaged with 340B program compliance

1. <u>Chief Pharmacy Officer – HRSA Authorizing Official</u>
    a. Responsible as the principal officer in charge for the compliance and administration of the program
    b. Responsible for attesting to the compliance of the program in form of recertification
    c. Must account for savings and use of funds to provide care for the indigent under the indigent care agreement

d. Responsible for communication of all changes to the Medicare Cost report regarding clinics or revenue centers of the cost report
e. Responsible for communication of all changes to Medicaid reimbursement for pharmacy services/products that impact 340B status
f. Responsible for modeling all managed care contracts (with/without 340B)
g. Engages pharmacy in those conversations that impact reimbursement
h. Responsible for annual physical inventory of pharmacy items
i. Responsible for establishment of "inventory average" process approved by the external audit firm

2. HRSA Primary Contact(s)
    a. Accountable agent for 340B compliance
    b. Responsible to administer the 340B program to fully implement and optimize appropriate savings and ensure current policy statements and procedures are in place to maintain program compliance
    c. Must maintain knowledge of the policy changes that impact the 340B program which includes, but not limited to, HRSA rules and Medicaid changes
    d. Must coordinate constant knowledge of any change in clinic eligibility/information
    e. Responsible for documentation of policy and procedures
    f. Monitor ordering processes, integrating most current pricing from wholesaler, analyze invoices, shipping, and inventory processes
    g. Work with the medical staff to use effective therapeutic classes that optimize savings with good clinical outcomes

3. 340B Specialists
    a. Accountable agents for 340B compliance
    b. Day to day managers of the program
    c. Responsible for maintenance and testing of tracking software
    d. Maintain system databases to reflect changes in the drug formulary or product specifications
    e. Assure appropriate safeguards and system integrity
    f. Assure compliance with 340B program requirements of qualified patients, drugs, providers, vendors, payers, and locations
    g. Review and refine 340B cost savings report detailing purchasing, and replacement practices, as well as dispensing patterns
    h. Be aware of products covered by 340B and Prime Vendor Program pricing

4. Corporate Compliance Officer
    a. Designs and maintains an internal audit plan of the compliance of the 340B program
    b. Designs the annual plan to cover all changes in the program from the past year

5. Clinical Informatics Pharmacist
    a. Support the Pharmacy software selection of tracking software to manage the 340B program
    b. Define process and access to data for compliant identification of outpatient utilization for eligible patients
    c. Archive the data to be available to auditors when audited.

6. Pharmacy Procurement/Buyer
    a. Continuously monitor product min/max levels to effectively balance product availability and cost efficient inventory control
    b. Responsible for establishing and maintaining direct accounts for GPO ("own use") class of trade as well as direct 340B and WAC accounts
    c. Responsible for ordering all drugs from the specific accounts as specified by the process employed
    d. Responsible for establishing three distribution accounts and maintaining those accounts; i.e., non-GPO/non-340B WAC account, 340B account, and GPO account
    e. Manage purchasing, receiving and inventory control processes

The 340B program is included in the pharmacy annual staff competency plan. For the 340B pharmacy specialists, comprehensive training is conducted on the 340B Program initially upon hire, verified annually and maintained through one or more of the following options:

- 340B updates and guidance documents as published by HRSA and Apexus
- Participation in webinars and conferences related to the 340B program
- Attendance at 340B University or 340B University on-line webinars
- Attendance at 340B Health conferences and review of guidance documents

(D) Enrollment, Recertification, Change Requests

1. Enrollment Procedure: New Clinic Sites

a. UTMC evaluates a new service area or facility to determine if the location is eligible for participation in the 340B Program. The criteria used is as follows:
   a. Service area must be fully integrated into DSH
   b. Appear as a reimbursable clinic on the most recently filed cost report
   c. Have outpatient drug use
   d. Have patients that meet the 340B patient definition

b. If a new clinic meets these criteria, UTMC Authorizing Official completes the online registration process during the registration window. This includes submitting any updated cost report information, as required by HRSA.

1) Enrollment Procedure: New Contract Pharmacy

a. UTMC ensures a signed contract pharmacy services agreement is in place between UTMC and contract pharmacy prior to registration on the HRSA 340B Database. This ensures the UTMC legal counsel has reviewed the contract and verified that all Federal, State, and local requirements have been met.
b. UTMC Authorizing Official completes the online registration process during the registration window.
c. UTMC ensures that the contract pharmacy registration request is certified online within fifteen days from the date the online registration was completed.
d. UTMC begins the contract pharmacy arrangement only on or after the effective date shown on the HRSA 340B Database.

2) Recertification Procedure

a. HRSA requires entities to recertify their information as listed in the HRSA 340B Database annually.
b. UTMC's Authorizing Official annually recertifies UTMC information by following the directions in the recertification email sent from the HRSA to the Authorizing Official by the requested deadline. Specific recertification questions should be sent to 340b.recertification@hrsa.gov.

3) Changes to Information in HRSA 340B Database Procedure

a. It is UTMC's ongoing responsibility to immediately inform HRSA of any changes to its information or eligibility. As soon as UTMC is aware that it loses eligibility, it will notify HRSA immediately and stop purchasing (or may be required to repay manufacturers).
b. An online change request will be submitted to HRSA for changes to UTMC information outside of the annual recertification timeframe. The change form will be submitted to HRSA as soon as UTMC is aware of the need to make a change to its HRSA 340B Database information. UTMC can expect changes to be reflected within about 2 weeks of submission of the changes/requests.

4) Changes to Apexus 340B Prime Vendor Program (PVP) profile

a. Apexus changes are completed at www.340bpvp.com. This includes updating 340B PVP Participation Information such as DEA number, distributor and/or contacts. To update HRSA Information, UTMC completes the 340B Change Form as detailed above. After the HRSA 340B Database has been updated, the PVP database will be updated during the nightly synchronization.

(E) Procurement, Inventory Management, Dispensing

1. UTMC 340B Inventory Model

Location	340B Inventory Process
Main hospital pharmacy	Mixed use
Health science campus outpatient pharmacy	WAC and 340B
UTMC clinics (within 4 walls) and child sites	WAC
Dana Cancer Center	340B in pharmacy, WAC in clinic
UT Access Pharmacy	WAC and 340B
Contract pharmacies	Contract pharmacy replacement model

2. 340B Separate Physical Inventory Processes - Dana Cancer Center & UTMC Clinics

a. UTMC uses physically separate 340B inventory at Dana Cancer Center & UTMC Clinics. Pharmacists and technicians dispense 340B drugs to eligible patients.
b. UTMC staff place 340B orders from their designated wholesaler or direct from manufacturers through daily inventory reviews and shelf inspections of periodic automatic replenishment (PAR) levels.
c. UTMC staff checks in 340B inventory by examining the wholesaler invoice against the order, and reports inaccuracies to the wholesaler.
d. UTMC staff maintains records of 340B related transactions in a readily retrievable and auditable format.
e. Dana Cancer Center products may be ordered and prepared in advance of the patient arriving for the visit.

3. Mixed-use Settings Accumulation

a. UTMC purchases mixed-use inventory according to eligible accumulations.

GPO	WAC/Non-340B, Non-GPO	340B
GPO/Inpatient class of trade: Inpatient status determined by hospital by the ADT date/time	Products that do not have an 11 digit NDC match on the 340B contract but are otherwise eligible for 340B purchase Non-340B eligible outpatients, i.e.: • Administration or dispensing occurred at a clinic within 4 walls of parent, but not 340B eligible • HSC outpatient pharmacy open to public • Lost charges or wasted product • First purchase Offsite/unregistered outpatient clinics	Patients met 340B patient definition and received services on an outpatient basis in a 340B registered/participating hospital clinic

b. UTMC administers/dispenses drugs to patients.
c. UTMC's split billing software converts from patient charges to purchase size units, accumulates by charge code and/or NDC into the GPO, 340B or WAC accumulations as applicable, and maintains an eligible balance for each NDC. When the 11-digit match is not possible, 340b specialists should be notified; they must maintain documentation of the action taken when the 11-digit NDC match is not available. Our split billing software uses patient/clinic/prescriber information to determine the appropriate account for ordering and prepares the replenishment order.
d. Replenishment drug orders are placed from the wholesaler daily according to eligible accumulations created from the split billing software.
e. For medications not available from our wholesaler, UTMC staff checks the available accumulation balances in the split billing software before placing the order and orders the medication on the appropriate account (i.e.,

GPO, WAC or 340B). Once the medication and invoice are received, staff manually enters the quantities into the accumulator.

f. UTMC staff checks in 340B inventory by examining the wholesaler invoice against the order, and reports inaccuracies to the wholesaler.
g. UTMC staff reports significant discrepancies (excessive quantities based upon utilization or product shortages) to UTMC manager within 3 working days.
h. UTMC staff maintains records of 340B related transactions in a readily retrievable and auditable format.

4. Contract Pharmacy Processes

a. UTMC has contracted with other pharmacies for the implementation of 340B contract pharmacy program. UTMC is responsible for 340B compliance.
b. UTMC uses a replenishment model for contract pharmacy services.
c. 340B eligible prescriptions are generated from eligible locations and may be presented to the contract pharmacies via e-prescribing, hard copy, fax or phone. The pharmacy staff dispenses prescriptions to patients.
d. Our split billing software receives claims data and accumulates drug on an 11-digit NDC match until unit of use is met, uses patient/clinic/prescriber information to determine the appropriate contract for ordering, and prepares the order.
e. The contract pharmacy staff places 340B orders on behalf of UTMC, based upon 340B eligible use as determined by the split billing software, from our wholesaler. Orders will flow into the split billing software.
f. UTMC pays invoice to the wholesaler for all 340B drugs.
g. The contract pharmacy staff receives 340B replenishment order by examining the wholesaler invoice against the order, and reports inaccuracies to wholesaler and UTMC manager.
h. For medications not available from the wholesaler, the contract pharmacy staff checks the available accumulation balances in the split billing software before placing the order and orders the medication on the appropriate account (i.e., GPO, WAC or 340B). Once the medication and invoice are received, staff manually enter the quantities into the accumulator.
i. The contract pharmacy notifies UTMC if they do not receive 11-digit NDC replenishment order within 3 days of original order fulfillment request. UTMC will reimburse the contract pharmacy at a pre-negotiated rate for such drugs.
j. Any non-replenishment 340B inventory is stored at the contract pharmacy, and is clearly marked as belonging to the UTMC.
k. The inventory is protected by a security system. Only current pharmacy employees have access to the pharmacy.
l. Any claim billed at a contract pharmacy to Medicaid FFS or any Managed Medicaid Organization be it primary, secondary or tertiary will be excluded from 340B eligibility per HRSA statute.

5. Physical Inventory

a. A physical inventory is conducted biannually. Inventory valuation for the inpatient and health science campus outpatient pharmacy is at a blended rate on weighted purchase percentages (e.g., 340B, GPO and WAC as applicable) through the wholesaler. For DCC, valuation will be at 340B cost as this is a 340B only area.

6. Returns

a. A returned drug will be credited on the account based on the price paid for the drug (i.e., 340B, GPO, WAC) as documented in the most recent purchase invoice(s). The amount of credit assigned to a particular account will not exceed the amount of drug bought under that account as documented in the purchase.

7. Reverse Distributor Credits

a. The credit for any drugs that have expired or removed from the inventory will be credited to the primary account for each location (i.e., hospital pharmacy at 340B, health science outpatient pharmacy at 340B, Dana at 340B).

8. GPO-only

a. Appendix F lists the items that may be purchased under the GPO account only.

9. Transfer of Inventory and Lend/Borrow

a. Covered outpatient drugs should generally not be sold or transferred to anyone other than a patient.
b. Transfers should only occur when an emergent patient care need arises.
c. 340B drugs may be transferred from one eligible area of UTMC to another eligible area of UTMC within the same 340B ID number as the parent (Ryan White program is a separate 340B ID). Specific product, NDC and quantity should be documented with purchasing invoices when transferring between 340B only areas (i.e., DCC and clinics) and hospital mixed use areas.
d. Transfers between non-340B and 340B inventory areas of UTMC and other entities outside UTMC are only in rare or emergent patient care circumstances, and according to the following procedure
    - UTMC staff records the transfer transaction in a log.
    - UTMC staff reconciles the process by transfer back to the inventory area through a purchase on the borrowing area's account of the same NDC and quantity that was borrowed, whenever feasible. Reconciliation is completed within a month of the original loan date and documented in the transfer log.

10. 340B Product Unavailable

a. If the designated wholesaler or other pharmaceutical company refuses to sell enough of a 340B priced drug to serve all of UTMC's 340Beligible patients, UTMC does not purchase the remainder using a GPO or other group purchasing agreement except in the case of emergent patient care needs (these exceptions are documented). Apexus has a template for reporting to HRSA when a 340B price is unavailable for a covered outpatient drug.

(F) Billing, Charging, and NDC Maintenance

1. NDC Maintenance

a. The pharmacy CDM codes and CDM descriptions or the primary NDC is utilized for charging. The patient billing extract provides this NDC to the split billing software for use in drug accumulation and replenishment.
b. When a new/different NDC is purchased that will be the new primary NDC, the buyer notifies the IT pharmacist to update the CDM. Interim products/NDCs ordered due to drug shortages will be evaluated monthly to determine if this interim product will be the new agent purchased.
c. In UTMC clinics, the person administering the medication will note the medication and the actual NDC utilized in the outpatient clinic EMR. Charging personnel utilize the noted NDC in billing.
d. For prescriptions, the NDC of product dispensed is utilized.

2. Charging/Billing

a. The electronic medical record and billing system charge for medications at the time a medication is dispensed from pharmacy, time removed from automated dispensing machines or at 11:59pm when manual charges (e.g., emergency code carts, manual procedural charges) are dropped. UTMC enters manual charges upon notification and back dates the charge to the service date.
b. UTMC clinic medication charges are entered to be charged with the clinic visit.
c. Prescriptions are charged upon dispensing.

3. Pricing

a. UTMC will bill using usual and customary GPO cost for billing hospital medications in the hospital pharmacy EMR and outpatient clinic EMR unless prohibited by law.

4. Extract

a. Medications transactions posted for prior day (e.g., charges, credits) are electronically extracted from the hospital pharmacy EMR daily. The split billing software screens for provide eligibility based on the provider files submitted and maintained by UTMC.
b. Pharmacy staff makes manual adjustments to the extract:
    i. Entry of purchases upon receipt for items not in the wholesaler EDI (e.g., direct purchases, secondary wholesaler)

ii. Removal of patient assistance medication replacement program medications upon receipt

(G) Contract Pharmacy Elements

HRSA has provided essential Contract Pharmacy Compliance Elements as guidance for the contractual provisions expected in all contract pharmacy arrangements. Appendix I includes excerpts from the HRSA document.

(H) Monitoring and Reporting

UTMC monitors continuing eligibility to participate in the 340B program and conducts regular program audits to ensure comprehensive review of the 340B program.

UTMC has an internal audit plan reviewed annually by the internal compliance officer and the 340B Steering Committee. Appendix J outlines the audit plan. Additional guidance is outlined in the Apexus 340B Compliance Self-Assessment: Self-Audit Process to Ensure 340B Compliance. UTMC is responsible and accountable for overseeing this review process, as well as taking corrective actions based upon findings. Documentation of corrective actions and resolutions are maintained.

UTMC is responsible for contacting HRSA as soon as reasonably possible if there is any material breach by the hospital. UTMC defines a material breach of compliance that would require self-disclosure as a violation(s) that equal or exceed 5% of 340B annual purchases. Violations identified through internal self-audits, independent external audits, or otherwise that meet or exceed this threshold will be immediately reported to HRSA and applicable manufacturers.

Potential material breaches (e.g., patient type or location eligibility, numerous patients or medications involved, medication units incorrect) should be reported immediately to the Chief Pharmacy Officer for further investigation. They should be reported to the Authorizing Official, 340B Steering Committee, and Director of Compliance, if findings are verified.

The UTMC 340B Steering Committee oversees this process, reviews situations, and makes decisions about meeting the material breach definition and self-disclosure on behalf of the registered hospital.
Refer to the Apexus self-reporting noncompliance tool and HRSA self-disclosure instructions for reporting 340B noncompliance.

Other reports to be maintained:

- Copy of the most recent HRSA compliance audit and any findings/corrective action
- Copy of the most recent external compliance audits and any findings/corrective action

(I) References

1. HRSA 340B Drug Pricing Program http://www.hrsa.gov/opa/index.html
2. HRSA OPA 340B Database http://opanet.hrsa.gov/opa/Default.aspx
3. 340B Prime Vendor Program (Apexus) https://www.340bpvp.com/controller.html
4. 340B Prime Vendor Program FAQs https://www.340bpvp.com/resource-center/faqs/
5. 340B University Tool and Resources https://www.apexus.com/solutions/education/340b-tools
6. HRSA audit results: http://www.hrsa.gov/opa/programintegrity/auditresults/results.html
7. Section 1927 (k) of the Social Security Act: http://www.ssa.gov/OP_Home/ssact/title19/1927.htm
8. HRSA Manufacturer Audit Guidelines and Dispute Resolution Process ftp://ftp.hrsa.gov/bphc/pdf/opa/FR12121996.htm
9. 340B Public Health Service Act http://www.hrsa.gov/opa/programrequirements/phsactsection340b.pdf
10. Select Federal Register Notices
    http://www.hrsa.gov/opa/programrequirements/federalregisternotices/index.html;
    http://www.hrsa.gov/opa/programrequirements/policyreleases/medicaidexclusionclarification020713.pdf
    http://www.hrsa.gov/opa/programrequirements/policyreleases/clarificationmedicaidexclusion.pdf

11. Statutory Prohibition on Group Purchasing Organization Participation
    http://www.hrsa.gov/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf
12. 340B Health Outline of Hospital Responsibilities and 340b Compliance Checklist
    http://www.340bhealth.org/
13. Section 1927 of the Social Security Laws, Definition of "Covered Outpatient Drug"
    https://www.ssa.gov/OP_Home/ssact/title19/1927.htm

Approved by:		**Review/Revision Date:**
		Revision: 10/2016 Revision: 9/2017 Revision: 6/2018 Revision: 9/2019 Revision: 3/6/2020 Revision: 02/02/2021 Revision 4/1/2021
/s/ Lindsey Eitniear Pharm D, BCPS Acute Care Director of Pharmacy	04/07/2021 Date	
/s/ Russell Smith Pharm D, BCPS Chief Pharmacy Officer	04/07/2021 Date	
Review/Revision Completed By: *Pharmacy*		**Next Review Date: 04/01/2024**
Policies Superseded by This Policy:		