Good Samaritan Health & Wellness Center

Policies and Procedures

Subject: **340B Standard Operating Procedure**	Policy #: 6.28
Prepared by: Susan Hamel	Revision #:
	Effective: 08/19/16

6.28 340B Standard Operating Policy and Procedure

PURPOSE

This document contains descriptions of the policies and procedures used at GSHWC to maintain compliance with the 340B Drug Pricing Program.

DEFINTIONS

Definitions of terms may be found in 340B Glossary of Terms

REFERENCES

GSWHC Pharmacy Policies (P &P's), 340B Glossary of Terms, OPA website, HRSA 340B website.

POLICY REVIEW, UPDATES, AND APPROVAL

These policies will be reviewed, updated, by the GSHWC staff involved with the 340B Program annually with documentation and approved by the GSHWC Board of Directors.

BACKGROUND

Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign an agreement with the Secretary of Health and Human Services. This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs. The resulting program is the 340B Drug Pricing Program, which is administered by the federal Health Resources and Services Administration (HRSA) within the Department of Health and Human Services.

Upon registration in the HRSA 340B Database as a participant in the 340B program, entities agree to abide by specific statutory requirements and prohibitions.

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Subject: **340B Eligibility Requirements**	Policy #: 6.28.1
Prepared by: Susan Hamel	Revision #:
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6.28.1 340B Eligibility Requirements

- GSHWC will meet all 340B program eligibility requirements including:

    1. GSHWC's listing in the Office of Pharmacy Affairs (OPA) Database, HRSA 340B Database is complete, accurate, and correct. GSHWC 340B ID--CHC2834700

    2. GSHWC receives a grant or designation consistent with the conferring 340B Eligibility.

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Subject: **340B Compliance**	Policy #: 6.28.2
Prepared by: Susan Hamel	Revision #:
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6.28.2 340B Compliance

340B COMPLIANCE

- GSHWC will comply 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 the entity (diversion). [REFERENCE: Public Law 102-585, Section 602, 340B Guidelines, 340B Policy Releases] (See Pharmacy Policy 6.3)

340B COMPLIANCE PROCEDURE

- GSHWC maintains auditable records demonstrating compliance with the 340B requirements described in the preceding bulleted item.

- GSHWC identifies eligible prescriptions to be those in which: a.) the prescribing provider is employed or under contractual or other arrangements with GSHWC b.) the individual receives a health care service (within the scope of grant/designation for which 340B status was conferred) from this professional such that the responsibility for care remains with GSHWC; and c.) GSHWC maintains records of the individual's health care. (EClinicalWorks and Computer RX)

GSHWC bills Medicaid per Medicaid reimbursement requirements, and as GSHWC has reflected its information on the HRSA 340B Database/Medicaid Exclusion File. GSHWC will be using the Carve-In model and will use only 340B inventory.

  - GSHWC informs HRSA immediately, via completion of change request, of any changes to its information on the HRSA 340B website/Medicaid Exclusion File.

        - Medicaid reimburses for 340B drugs per state policy and does not collect rebates on claims from GSHWC. [Reference: State policy(ies) for 340B reimbursement/billing/duplicate discount prevention (state Medicaid manual, etc.); Appendix: GSHWC's Medicaid information from HRSA Medicaid Exclusion File for all sites, state Medicaid contact(s) information, last documentation from state contact].

- GSHWC has systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements.

- GSHWC conducts routine compliance audits under the direction of the Director of Pharmacy. Audit results are reported to the CEO and the CMO.

- GSHWC acknowledges its responsibility to inform HRSA as soon as reasonably possible if there is any change in 340B eligibility or material breach by the GSHWC of any of the foregoing policies.

- GSHWC acknowledges that if there is a material breach of the 340B requirements, GSHWC 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.

- GSHWC acknowledges the right of a patient to use the pharmacy of their choice.

- GSHWC elects to receive information about the 340B program from trusted sources, including, but not limited to, the following:
    - The Health Resources and Services Administration (HRSA)
    - The 340B Prime Vendor Program, managed by Apexus
    - Any HRSA contractors

RESPONSIBLE STAFF, COMPETENCY

The following GSHWC staff are engaged with 340B program compliance. Pharmacy staff member(s) participating in the 340B program complete initial basic training via webinar on the 340B and Prime Vendor programs (https://www.brainshark.com/apexus/TopFive340BBasics) Pharmacist has training through 340B University. Training is conducted on the 340B program initially upon hire and competency is also verified annually by the Pharmacy Director through verbal assessment and as part of the staff development plan (Reference GSHWC Personnel Training Policy 6.11).

A. Chief Executive Officer
    - Responsible as the principal officer in charge for the compliance and administration of the program
    - Responsible for attesting to the compliance of the program in the form of recertification

B. Chief Financial Officer

- Must account for savings and use of funds to provide care for the indigent under the indigent care agreement
- Responsible for communication of all changes to Medicaid reimbursement for pharmacy services/products that affect 340B status
- Responsible for modeling all managed care contracts (with/without 340B)
- Engages pharmacy in conversations that affect reimbursement
- Responsible for annual or semiannual physical inventory of pharmacy items
- Responsible for establishment of "inventory average" process approved by the external audit firm [reference policy or type of process used—e.g., FIFO], as the inventory will decrease in value due to the same NDCs being purchased at dramatically different discounted 340B prices

C. Chief Pharmacy Officer/Director of Pharmacy
    - Accountable agent for 340B compliance
    - Agent of the CEO or CFO responsible for administering the 340B program to fully implement and optimize appropriate savings and ensure that current policy statements and procedures are in place to maintain program compliance
    - Must maintain knowledge of the policy changes that affect the 340B program, which include, but are not limited to, HRSA rules and Medicaid changes
    - Accountable agent for 340B compliance
    - Day-to-day manager of the program
    - Responsible for maintenance and testing of tracking software
    - Responsible for documentation of policy and procedures
    - Maintains system databases to reflect changes in the drug formulary or product specifications
    - Manages purchasing, receiving, and inventory control processes
    - Continuously monitors product min/max levels to effectively balance product availability and cost-efficient inventory control
    - Ensures appropriate safeguards and system integrity
    - Performs annual inventory and monthly [or other interval] cycle counts
    - Ensures compliance with 340B program requirements of qualified patients, drugs, providers, vendors, payers, and locations
    - Reviews and refines 340B cost savings report detailing purchasing and replacement practices, as well as dispensing patterns
    - Monitors ordering processes, integrating most current pricing from wholesaler; analyzes invoices, shipping, and inventory processes
    - Maintains an internal audit plan of the compliance with the 340B program
    - Responsible for annual or semiannual physical inventory of pharmacy items
    - Responsible for establishment of "inventory average" process approved by the external audit firm [FIFO], as the inventory will decrease in value due to the same NDCs being purchased at dramatically different discounted 340B prices
    - Supports the pharmacy tracking software selection to manage the 340B program
    - Defines process and access to data for compliant identification of eligible patients
    - Archives the data to make them available to auditors when audited
    - Is aware of products covered by 340B and Prime Vendor Program pricing

- Works with the medical staff to use effective therapeutic classes that optimize savings with good clinical outcomes
- Responsible for establishing distribution accounts and maintaining those accounts, such as the 340B account
- Responsible for ordering all drugs from the specific accounts as specified by the process employed

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Subject: **340B Enrollment, Recertification, Change Requests**	Policy #: 6.28.3
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6.28.3 340B ENROLLMENT, RECERTIFICATION, CHANGE REQUESTS POLICY

Policy: GSHWC will recertify their information as listed in the HRSA Database annually by the requested deadline. It is GSHWC's ongoing responsibility to immediately inform HRSA of any changes to its information or eligibility. As soon as GSHWC is aware that it has lost eligibility, it must notify HRSA immediately and stop purchasing (or may be required to repay manufacturers).

1. Recertification Procedure
HRSA requires entities to recertify their information as listed in the HRSA 340B Database annually. The Chief Executive Officer annually recertifies GSHWC's information by following the directions in the recertification email sent from HRSA to the Chief Executive Officer by the requested deadline. 340b.recertification@hrsa.gov.

2. Procedure for Changes to GSHWC's Information in the HRSA 340B Database

1. An online change request will be submitted to HRSA by the Chief Executive Officer for changes to GSHWC's information outside the annual recertification timeframe.

2. The change form will be submitted to HRSA as soon as the entity is aware of the need to make a change to its database entry.

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Subject: **340B Compliance Review**	Policy #: 6.28.4
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6.28.4 340B PROCUREMENT, INVENTORY MANAGEMENT, DISPENSING POLICY

POLICY: To ensure compliance with Federal Regulations regarding 340B Medication Program. The 340B inventory is procured and managed in the following settings:

- In-house pharmacy
- Clinic administration
- GSHWC has established a pricing policy (addressing establishment of usual and customary charges, applying income based discounts, third-party billing/reconciliation, and/or Medicaid [physician-administered drugs, fee-for-service drugs, managed care, Medicaid as secondary payer]). GSHWC pharmacy patients that have qualified for sliding scale levels A-E will pay cost + dispensing fee. The pharmacy will maintain competitive fees with local pharmacies. (See GSHWC Financial Policy 3.23).

Standard Processes

1. GSHWC either uses only 340B inventory. Pharmacists and technicians dispense 340B drugs only to patients meeting eligibility criteria. GSHWC staff places 340B orders from Smith Wholesale through monthly inventory reviews and shelf inspections of par levels by Computer RX.

2. GSHWC staff checks in 340B inventory by examining the wholesaler invoice against the shipment received, and reports inaccuracies to the wholesaler.

3. GSHWC staff maintains records of 340B-related transactions for a period of 7 years in a readily retrievable and auditable format located in Materials Management.

4. 340B inventory is stored in the pharmacy and maintained with a security system. Only pharmacy employees have access to the pharmacy through locked door with coded entry.

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Subject: **340B Compliance Review**	Policy #: 6.28.5
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6.28.5 340B Compliance Review Policy

The GSHWC's 340B compliance review summarizes all activities necessary to ensure comprehensive review of 340B compliance at GSHWC. GSHWC staff is responsible and accountable for overseeing this review process, as well as taking corrective actions based on the findings.

340B Monitoring and Reporting Procedure

MONITORING AND REPORTING

The entity uses the process outlined in the 340B Compliance Self-Assessment: Self-Audit Process to Ensure 340B Compliance.

Additional monitoring or reporting will be added as needed.

		Area of Focus		
Activity	Frequency (suggested)	Entity Eligibility	No Diversion	No Duplicate Discount
Review of all HRSA 340B Database information for GSHWC. GSHWC staff responsible: Pharmacist	Annually	X	X	X
Review of 340B self-audit reports, GSHWC staff responsible: Pharmacist	Quarterly		X	

	340B Glossary of Terms
TERM	**DEFINITIONS**
340B Covered Entity	340B covered entities are facilities/programs listed in the 340B Statute as eligible to purchase drugs through the 340B Program and appear on the Office of Pharmacy Affairs Database.
340B Covered Drug	A covered outpatient drug for purposes of the 340B Program, defined in 1927(k) of the Social Security Act (SSA), is summarized as: An FDA-approved prescription drug, an over-the-counter (OTC) drug that is written on a prescription, a biological product that can be dispensed only by a prescription (other than a vaccine), or FDA-approved insulin.
340B Drug Pricing Program or 340B Program	Section 340B of the Public Health Service Act (1992) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign an agreement 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.
340B Eligible Patient	In summary, an individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if: 1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and 2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and 3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement. An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self- administration or administration in the home setting. An individual registered in a State operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program.
Medicaid Exclusion File	OPA established the Medicaid Exclusion File to help support program integrity regarding the statutory prohibition of duplicate discounts. The Medicaid Exclusion File is maintained on the OPA website and contains the National Provider Identification (NPI) Number or Medicaid Provider Number of those entities which dispense 340B discounted drugs to a Medicaid patient and bill Medicaid. Entities are expected to provide timely and accurate information to OPA for incorporation into the Medicaid Exclusion File. The covered entity should be billing according to their designation on the Exclusion File. The covered entity should immediately inform OPA of any changes. The Medicaid Exclusion File is used as follows: □ Entities using 340B purchased drugs for Medicaid patients must inform OPA of their NPI/Medicaid Provider Number(s). □ Medicaid Agencies use the Medicaid Exclusion File to identify the NPI or Medicaid Provider Number of the entities purchasing at 340B prices. □ The state Medicaid Agency excludes from its rebate requests to manufacturers all claims associated with entities whose NPI/Medicaid Provider Number are listed in the Medicaid Exclusion File. □ Manufacturers use the Medicaid Exclusion File to verify denial of rebate payment on claims associated with entities purchasing at 340B prices.

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. 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. It 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.