AMBULATORY CARE NETWORK

HIGH DESERT HEALTH SYSTEM

COUNTY OF LOS ANGELES - DEPARTMENT OF HEALTH SERVICES

Department of Pharmacy POLICY AND PROCEDURE

POLICY NUMBER: 1327
VERSION: 3

SUBJECT: High Desert - 340 B Policy

PURPOSE:

A. To define a systematic approach to protect the integrity of and adherence to the rules and regulations of the Health Resources and Services Administration (HRSA) 340B Drug Pricing Program (340B Program).

B. To provide guidelines and procedures for managing 340B drug purchasing and compliance at High Desert Multi-Service Ambulatory Care Clinic under Los Angeles county, Department of Health Services. Note- High Desert Regional Health Center Pharmacy supplies medication to 340b covered entities under High Desert Multi-Service Ambulatory Care Clinic.

POLICY:

A. High Desert Regional Health Center Pharmacy participates in the 340B Program and complies with guidelines and regulations to ensure that 340B drug products are purchased only for eligible facilities and patients.

B. Staff follow the processes identified within this policy which address the four key compliance elements for administration of the 340B Program:

1. Covered entity / patient eligibility compliance.
2. Anti-diversion inventory controls / compliance.
3. Medicaid pricing compliance.
4. State Medicaid cost rebate verification (compliance with "double-dipping" prohibition).

DEFINITIONS:

1. **340B Drug Pricing Program (340B Program)** – A drug pricing program that resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to "covered entities" including disproportionate share hospitals.
2. **Covered Entities** - Facilities and programs eligible to purchase discounted drugs through the 340B Program.
3. **Diversion** - Covered entities are required to prevent the resale or transfer of drugs purchased at 340B prices to non- eligible patients/facilities. Failure to ensure appropriate use is considered diversion.
4. **Health Resources Services Administration (HRSA)** - An agency of the U.S. Department of Health and Human Services that is the primary Federal agency for improving access to health care services for people who are uninsured, isolated or medically vulnerable. The primary mission of HRSA is to improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs.
5. **Medicaid Exclusion File** - Covered entities are required to designate in the application process whether 340B drugs will be utilized for Medicaid patients. HRSA maintains this

information in the Medicaid Exclusion File which is available to state Medicaid programs. The purpose of this file is to exclude 340B drugs from Medicaid rebate requests. This prevents drug manufacturers from providing duplicate discounts – upfront as the 340B drug price and the later as the Medicaid rebate.

6. **Office of Pharmacy Affairs (OPA)** - A component of the Health Resources and Services Administration Healthcare Systems Bureau which provides administration of the 340B Program, through which certain federally funded grantees and other safety net health care providers may purchase prescription medication at significantly reduced prices.
7. **Public Health Service (PHS)** – A division of the United States Department of Health and Human Services with the purpose of delivering public health promotion and disease prevention programs and advancing public health science. Agencies within the PHS include the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Health Resources and Services Administration (HRSA).
8. **Prime Vendor** - The 340B Prime Vendor Program (PVP) is managed by Cardinal through a contract awarded by Health Resources and Services Administration (HRSA), the federal government branch responsible for administering the 340B Drug Pricing Program.

COMPETENCIES REQUIRED:

A. High Desert Regional Health Center determines the knowledge and educational requirement for each 340B program role.

B. Pharmacy staff will complete basic training on the 340B Program initially upon hire and/or as needed via https://www.brainshark.com/apexus/TopFive340BBasics

C. Education updates and training as needed
- Department Meetings
- Facility Memo or Newsletter
- Distribution and review of policy and procedures.

D. Training and education records are maintained and available for review.

PROCEDURE

I. COVERED ENTITY ELIGIBILITY:

- High Desert Regional Health Center is eligible to participate in the 340B Program by meeting one of the following eligibility criteria:
  - Family Planning Clinic (Type X)
  - Ryan White Care Act grantee

- High Desert Regional Health Center Pharmacy serves as a contract pharmacy and in house pharmacy to 340B covered entities under Los Angeles County, Department of Health Services High Desert Regional Health Center.

A. Procurement Compliance:

1. Establishing a Prime Vendor 340B Purchasing Account:
   i. Once an entity sub-division is established and the 340B eligibility of its patients is determined, a pharmacy purchasing account is established through the Prime Vendor.
   ii. If 340B-eligible patients are to be treated, the account is designated as a 'PHS' account and appropriate PHS contract pricing from the Prime Vendor is loaded.
   iii. Eligibility of the account is verified by the Prime Vendor through OPA (see

references for a listing of High Desert Multi Service Ambulatory Care Clinic accounts).

B. Purchasing Drugs on 340B Accounts:

1. Prime Vendor purchases:

   i. Separate Prime Vendor accounts are maintained for the purchase of 340B medications.
   ii. Each account is populated with the 340B contract load and is designated as a 340B account in the account name.
   iii. The contract load is performed each quarter with new purchase prices provided by HRSA/OPA through the Prime Vendor.
   iv. 340B purchases from the Prime Vender are purchased on a 340B specific account.
   v. These purchases are made on an 11 digit NDC to NDC basis.

2. Direct Purchases:
   i. Drugs not available from the prime vendor may be purchased from the manufacturer using a direct account if approved by DHS central procurement

C. **Returns:**

In the event a non-340B medication is purchased under a 340B account or a 340B medication is purchased under a non-340B account the medication shall be returned, credited, and replenished under the correct account.

II. PATIENT/PRESCRIBER ELIGIBILITY COMPLIANCE:

Eligible medication orders or prescriptions are filled with 340B-purchased inventory for qualified patients.

A. An individual is considered a patient of a covered entity if:

1. The covered entity has established a relationship with the individual, which includes maintaining records of the individual's health care.
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 individual's care remains with the covered entity. For example, patient's eligible under the Ryan White Care Act shall be dispensed medications utilizing 340B purchased inventory for patients who were seen by HIV Clinic and given prescriptions from the provider at the HIV Clinic.

B. An individual is not considered a "patient" if the sole healthcare service rendered is the dispensing of a drug.

III. ANTI-DIVERSION INVENTORY CONTROLS / COMPLIANCE:

No 340B may be resold or transferred to any party other than a patient as previously defined.

A. Pharmacy Inventory Management:

1. The 340B inventory is stored in a secure area with restricted access, per California State Board of Pharmacy regulations.
2. Replenishment inventory for all 340B inventory areas is purchased using the appropriate 340B accounts with the wholesaler by procurement staff with specialized training
3. Pharmacists and technicians may only utilize 340B drug inventory for dispensing to patients/clinics that are identified as 340B-eligible through the HRSA 340B program.
4. Pharmacy staff will place requests for ordering through daily inventory reviews and shelf inspection of PAR levels, using the appropriate wholesaler account for replenishment.

5. Staff are to verify all received 340B wholesaler shipments by examining the wholesaler invoice against the order. Packing slips are compared to the physical shipment and any discrepancies are reported to the appropriate pharamcy supervisor, who in turn works with DHS Pharmacy Procurement to ensure that appropriate payment is made to the drug wholesaler.
6. Physical inventories are utilized to simplify the ordering, dispensing and inventory process which facilitates compliance with 340B program regulations.
7. High Desert Regional Health Center Pharmacy maintains records of all 340B related transactions for a period of 3 years.

B. Reconciliation:

1. Pharmacy procurement staff will be responsible on a quarterly basis and/or as needed basis when applicable to reconcile inventory and dispensing of 340B drugs from the pharmacy and/or clinics to ensure compliance with the appropriate dispensing of 340B medication.

C. GPO Exclusion Compliance: Separate Inventory:

1. Separate inventories are maintained in the High Desert Regional Health Pharmacy for 340B drug purchases and non-340B drug purchases.
2. Inventories are clearly segregated and marked as 340B.
3. Pharmacists and technicians may only utilize 340B drug inventory for dispensing to patients/clinics that are identified as 340B-eligible through the HRSA 340B program.

D. Transfer of drugs between 340B and non-340B inventory:

1. ***Transfer from a 340B to a non-340B inventory*.** Transfers between the two inventories are implemented only in rare circumstances, typically in response to a critical patient need, and according to the following procedure:

    a) HDRHC Staff records the transaction on a borrow/loan transaction log.
    b) HDRHC Staff reconciles the process by transferring back to the separated 340B inventory area through a purchase on the borrowing areas non-340B account of the same National Drug Code (NDC) and quantity that was borrowed.
    c) Reconciliation is completed within 30 days of the original loan date, provided that the product is available and not subject to a drug shortage.
    d) All 340B retrospective drug replenishment shall be done on an 11-digit NDC specific basis.

2. ***Transfer from a non-340B to a 340B inventory*.** Transfers between the two inventories are implemented only in rare circumstances, typically in response to a critical patient need, and according to the following procedure:

    a) HDRHC Staff records the transaction on a borrow/loan transaction log.
    b) HDRHC Staff reconciles the process by transferring back to the separated non-340B inventory area through a purchase on the borrowing areas 340B account of the same National Drug Code (NDC) and quantity that was borrowed.
    c) Reconciliation is completed within 30 days of the original loan date,

provided that the product is available and not subject to a drug shortage.

d) All 340B retrospective drug replenishment shall be done on an 11-digit NDC specific basis.

IV. COMPLIANCE WITH DUPLICATE DISCOUNT PROHIBITION

A. HDRHC dispenses or administers 340B drugs to its Medicaid patients and bills Medicaid for those 340B drugs.

1. HDRHC has answered "yes" to the question "Will the covered entity dispense 340B purchased drugs to Medicaid Patients?" on the HRSA 340B database, documenting the use of 340B purchased drugs for Medicaid patients.
2. Answering YES to this question, places the 340B purchases on the Medicaid exclusion list.
3. The Medicaid exclusion list is provided to the State via HRSA-OPA and maintained as part of the Medicaid Exclusion file on the HRSA web site.

B. HDRHC bills Medicaid per state Medicaid reimbursement requirements.

1. Cost based reimbursement clinics (CBRC) billing (clinic administered drugs is not itemized, but the drug costs included are the actual acquisition costs for drug purchases. For 340B eligible areas, the CBRC billing to the state Medicaid program includes actual 340B cost.
2. All itemized claims to managed Medi-Cal health plan contain a 340B marker to designate 340B eligible claims to the medical health plan PBM. In addition, all California carve out drugs which result in a claim to the State Medi-Cal program directly contain a 340B marker in the claims detail submitted.
    a) Monthly review of fee-for-service (FFS) claims to the State Medi-Cal website program to ensure all claims contain a designated 340B marker.
    b) Action will be taken for all inappropriate claims to ensure duplicate discount prohibition is not violated.
3. Medicaid Billing Number (MBN) and /or National Provider Identifier (NPI) used to bill Medicaid FFS for 340B drugs purchase and provided to eligible patients for HDRHC Pharmacy is 1902029614.
4. HDRHC informs HRSA immediately of any changes in its Medicaid Exclusion File (MEF) information by updating the HRSA 340B Database before the 15th of the month prior to the quarter when the change takes effect.
5. HDRHC regularly reviews its 340B Database MEF record.

V. 340B PROGRAM COMPLIANCE OVERSIGHT, MONITORING AND REPORTING

A. Compliance Accountability

1. HDRHC has full accountability for compliance with all requirements to ensure eligibility and to prevent diversion and duplicate discounts. Auditable records will be maintained to demonstrate compliance.

B. Self-Audit

1. HDRHC will have a monitoring program to ensure compliance with the 340B program. HDRHC will:

a) Review the HRSA 340B Database to ensure the accuracy of the information for the parent site, off-site locations and contract pharmacies.

b) Ensure covered outpatient drugs purchased through the 340B program are dispensed or administered only to patients eligible to receive 340B drugs.

c) Reconcile dispensing records to patient's health care records to ensure that all medications dispensed were provided to patients eligible to receive 340B drugs.

C. Material Breach

1. HDRHC defined a "material breach" of compliance as violations that exceed 10% of total 340B purchases or impact to one manufacturer.
2. Violations that meet or exceed this threshold and that remain non-correctable within the entity defined period timeframe of review will be immediately or as soon reasonably possible to HRSA at (340Bselfdisclosure@hrsa.gov) and applicable manufactures using the following self-disclosure template, https://www.hrsa.gov/opa/self-disclosures/self-disclosure.html
3. HDRHC 340B Oversite Committee oversees this process, review potential violations and determines if a breach has occurred. The committee identifies to whom to self-disclose the breach dependent on the materiality determination and the corrective action plan resolution.

D. Oversight

1. The oversight of the 340B Program is the responsibility of the 340B Leadership Group comprised of the following individuals:

a) Chief Executive Officer, CEO
- Responsible as the authorizing official in charge for the compliance and administration of the program
- Responsible for attesting to the compliance of the program through recertification

b) Department of Finance – CFO
- Responsible for communication of all changes to the Medicare cost reporting regarding clinics or revenue centers.
- Responsible for communication of all changes to the Medicaid reimbursement for pharmacy services/products that affect 340B status.

c) Director of Pharmacy
- Accountable agent for 340B compliance
- Agent of the CEO or CFO responsible to administer 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, including, but not limited to, HRSA rules and Medicaid changes
- Must coordinate constant knowledge of any change in clinic eligibility/information
- Often responsible as the primary contact for the 340B Program

d) Pharmacy Procurement/Inventory Manager
- Responsible for establishing two distribution accounts and

maintaining those accounts: non-340B account and 340B account

- Responsible for ordering all drugs from the specific accounts as specified by the process employed
- Responsible for segregation, removal, and/or return of 340B drugs, including reverse distributor transactions
- Responsible for reconciliation of lend and borrow transactions

2. The 340B Leadership Group has the following responsibilities:
    a) Setting the general direction and policy for 340B drug purchasing and compliance.
    b) Establishing an audit plan for audits conducted by the Department of Pharmacy Services in collaboration with the Department of Finance as well as by an external consulting group. The external audit plan is conducted annually as defined by OPA guidelines.
    c) Reviewing reports, trends, and audit results.
    d) Maintaining information on current best practices by sending key High Desert Regional Health Center personnel to related conferences and/or training programs.
    e) Providing compliance and oversight direction.
    f) Providing appropriate resources.
    g) Determining needed modifications or expansion.
    h) Correcting and/or reporting deficiencies within expected timeframes.
    i) Communication to leadership of potential changes/trends to the 340B program that will impact the institution.

A. 340B Program related records and transactions are maintained for a period of seven (3) years in a readily retrievable and auditable format.

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