LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES
HARBOR-UCLA MEDICAL CENTER

SUBJECT: 340B DRUG PRICING PROGRAM **POLICY NO.** 803

CATEGORY: Provision of Care	**EFFECTIVE DATE:** 10/16
POLICY CONTACT: Jennie Ung, PharmD	**UPDATE/REVISION DATE:** 2/22
REVIEWED BY COMMITTEE(S): 340B Program Oversight Compliance Committee	

PURPOSE:
To provide guidelines and procedures for managing 340B program compliance at Harbor-UCLA Medical Center (Harbor-UCLA).

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).

POLICY:
Harbor-UCLA participates in the federal 340B Program and complies with guidelines and regulations to ensure that this program is utilized for eligible patients only.

Harbor-UCLA staff follow the processes identified within this policy that address the four key compliance elements for the administration of the 340B Program:

a. Covered entity / patient eligibility compliance;
b. Anti-diversion inventory controls/compliance;
c. Medicaid pricing compliance; and
d. State Medicaid cost rebate verification (compliance with "double-dipping").

Harbor-UCLA monitors the hospital's disproportionate share adjustment percentage to ensure this percentage exceeds 11.75% when participating in the 340B program.

Harbor-UCLA does not obtain covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement, except in accordance with HRSA GPO Policy Release 2013-1.

Harbor-UCLA uses 340 B-priced drugs only for outpatient discharge prescriptions and outpatient clinics that are listed on a reimbursable line item of the hospital's most recently filed Medicare cost report or registered on the OPA database.

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Program Requirements:

1. Keep 340B information accurate and up to date
2. Recertify annually
3. Prevent diversion to ineligible patients; covered entities (CEs) must not resell or otherwise transfer 340B drugs to ineligible patients.
4. Duplicate Discount Prohibition – CEs must accurately report how they bill Medicaid fee-for-service drugs on the Medicaid Exclusion File (MEF), as mandated.
5. Prepare for program audits – CEs are subject to audit by manufacturers or the federal government. Any CE that fails to comply with 340B program requirements may be liable to manufacturers for refunds of the discounts obtained.

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. **Disproportionate Share Hospitals (DSH):** Facilities that serve a significantly disproportionate number of low-income patients.
4. **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.
5. **Group Purchasing Organization (GPO):** An organization that represents and organizes a group of hospitals to evaluate and select pharmaceutical products. Using the purchasing power of the entire group, the GPO negotiates contracts that are more favorable than a single organization could achieve.
6. **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.
7. **Hospital-Based Clinic:** A clinic that appears on a reimbursable line of the most recently filed Medicare Cost report and is thus eligible for 340 B-priced drugs.
8. **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.
9. **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.
10. **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).

11. **Mixed Use Areas:** A hospital location that serves both outpatients and inpatients as designated by the Harbor-UCLA patient registration system.
12. **WAC**: Wholesale Acquisition Cost. Wholesale acquisition cost (WAC) is the list price paid by a wholesaler, distributor, and other direct accounts for drugs purchased from the wholesaler's supplier.

PROCEDURE:

I. COVERED ENTITY ELIGIBILITY Harbor-UCLA is eligible to participate in the 340B Program by meeting the following criteria for inclusion:

- Harbor-UCLA is part of the public-sector Los Angeles County Department of Health Services system.
- Harbor-UCLA meets Disproportionate Share Hospital (DSH) percentage of greater than 11.75%.

Harbor-UCLA onsite clinics and all HRSA-registered "child sites" appear on a reimbursable line item on the most recently filed Medicare cost report. Any updates or changes to the HRSA database will be approved by the Harbor-UCLA Chief Executive Officer- as the Covered Entity Authorizing Official.

COMPLIANCE:

A. Procurement Compliance: Purchasing Drugs on 340B Accounts

1. Separate drug wholesaler accounts are maintained for the purchase of 340B-priced medications. Each account is populated with the 340B contract load by the drug wholesaler and is designated with a "PHS" designation in the account name. The drug wholesaler loads new 340B drug acquisition costs, as provided by the manufacturer, on a quarterly basis. It is the drug wholesaler's contracted responsibility to apply these manufacturer costs to all 340B accounts affiliated with Harbor-UCLA.
2. Each ship-to location lead (i.e. area /inventory management supervisor or lead) is responsible for ensuring that all purchases placed on its 340B (PHS) wholesaler account are only for replenishment of 340B inventory.

B. Eligible 340B Medications

The definition of 340B covered drug shall be consistent with section 1927 (k) of the Social Security Act:

1. FDA-approved prescription drugs;
2. Over-the-counter (OTC) drugs written on a prescription;
3. Biological products that can be dispensed only by a prescription (other than vaccines); and
4. FDA-approved insulin.

II. PRESCRIBER AND PATIENT ELIGIBILITY

A. Prescriber Eligibility

A health care professional must be either employed by Harbor-UCLA or provide health care under contractual or other arrangement (e.g., referral for consultation) coordinated by Harbor-UCLA. Only outpatient or outpatient discharge prescriptions issued by an eligible prescriber are eligible for 340B purchased medications.

B. Patient Eligibility

1. An individual is considered a patient of Harbor-UCLA if:

a. Harbor-UCLA has an established a relationship with the individual, which includes maintaining records of the individual's health care.
b. The individual receives health care services from a health care professional who is either employed by Harbor-UCLA or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the individual's care remains with Harbor-UCLA.

2. At Harbor-UCLA, a patient is considered eligible for 340B medications in the following cases:
   a. The patient is treated in a hospital-based clinic that appears as reimbursable on the most recently filed Medicare cost report and has an eligible outpatient medication order written by a prescriber employed by, or under contract with Harbor-UCLA, or other arrangements (e.g. referral for consultation) for this patient have been made.
   b. The patient is discharged from Harbor-UCLA and has an eligible prescription for outpatient use that is written by an eligible prescriber.

III. ANTI-DIVERSION INVENTORY CONTROLS/COMPLIANCE

No 340B drugs may be resold or transferred to any party other than an eligible patient as previously defined (unless the party is a bona fide agent of either the hospital or patient).

WAC-purchased drugs will be used to replenish medication stock in any Harbor-UCLA mixed use area when inventory segregation procedures are not considered appropriate to ensure compliance with 340B policies.

A. Outpatient Pharmacy Dispensing

1. All 340B eligible outpatient prescriptions are filled with 340B-purchased medications.
2. Harbor-UCLA outpatient pharmacies can only dispense 340B purchased medications to 340B eligible patients. (Refer to section II for eligibility criteria)
3. Outpatient designated staff (i.e. typist) are responsible for ensuring all eligibility criteria are validated prior to processing.

B. Pharmacy Inventory Management

1. The 340B inventory is stored in a secured pharmacy area with restricted access, per California State pharmacy regulations.
2. Replenishment inventory for all 340B inventory areas is purchased using the appropriate 340B accounts with the wholesaler.
3. GPO medications are neither stored nor dispensed in the outpatient pharmacies, or any other 340B inventory area.
4. Pharmacists and technicians may only utilize 340B drug inventory for unit stock replenishment of hospital areas that are identified as 340B-eligible through Medical Center review.
5. Pharmacy staff will place requests for ordering through daily inventory reviews and shelf inspections of PAR levels, utilizing the appropriate wholesaler account for replenishment.
6. Staff is 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 pharmacy supervisor, who in turn works with DHS Pharmacy Procurement to ensure that appropriate payment is made to the drug wholesaler.
7. Harbor-UCLA maintains records of all 340 B-related transactions.

C. 340B Replenishment -- Automated Dispensing Cabinets (ADCs)

1. The Pharmacy will maintain a log of all the ADCs within the hospital and clinic settings, identifying the appropriate pharmacy purchasing program designated - 340B, GPO, or WAC- for each ADC cabinet.
2. The pharmacy purchasing program designation - 340B, GPO, or WAC - will be determined by the population of patients – inpatient versus outpatient vs. mixed use-- treated within that specific patient care area.
    a. Clinic ADCs will only be designated as 340B if the medications pulled from the cabinet are exclusively used to treat outpatients.
    b. ADCs located in hospital areas will be designated as GPO only if the medications pulled from the cabinet are exclusively used to treat inpatients.
    c. ADCs located in mixed-use areas, e.g., areas that treat both inpatients and outpatients with medications obtained from an ADC, will be designated as WAC.
3. At no time shall the supplies of 340B, GPO, and WAC medications be mixed inside an ADC.
4. At no time shall 340B medications be used for inpatients.
5. At no time shall GPO medications be used for outpatients.

D. Stocking of ADCs

1. Pharmacy will stock 340B ADCs solely with medications removed from the 340B supply within the Pharmacy or Pharmacy stockroom.
2. Pharmacy will stock GPO ADCs only with medications removed from the GPO supply within the Pharmacy or Pharmacy stockroom.
3. Pharmacy will stock WAC ADCs only with medications removed from the WAC supply within the Pharmacy or Pharmacy storeroom.
4. The ADCs will be restocked as needed according to a refill report generated by ADC. The refill report will specify the medications to be refilled into the ADC. The medication will be removed from the appropriate 340B, GPO, or WAC medication stock inside the Pharmacy according to the designation of the ADC.

E. 340B Outpatient Clinic Replenishment - Non-Automated Replenishment

1. On routine basis, the Pharmacy Director or her Designee will work with the hospital and clinic staff to identify areas that are considered eligible for 340B clinic stock replenishment. Any areas that are not considered 340B-compliant will be designated for WAC-purchased drug storage.
2. Pharmacists and technicians shall only dispense 340B floor stock drugs to clinic areas designated as 340B-eligible.
3. The Pharmacy shall maintain records of all 340B-drug replenishment to clinic areas for a period of three years.
4. Inpatients treated in Hospital clinics that stock 340B medications will receive their medications for that treatment, upon written order, from the GPO supply in the Pharmacy.

F. Oncology Pharmacy Area

1. The oncology pharmacy area maintains segregated inventory of 340B-purchased drugs and GPO-purchased drugs. The 340B-purchased drugs are to be utilized only for qualified 340B-eligible patients. The GPO-purchased drugs are to be utilized for qualified inpatients.
2. Pharmacy staff will review the admission status of each patient prior to removing oncology drug from inventory. All outpatient medication that is dispensed to an eligible 340B clinic will be removed from the 340B inventory, and all inpatient medication that is dispensed will be removed from the GPO inventory. During initial oncology medication order check, the pharmacist shall

ensure that the appropriate inventory stock is utilized for oncology drug preparation for the specific dose.

3. Refrigerated oncology drugs
   a. GPO-purchased oncology drugs will be stored in a refrigerator labeled with the appropriate color-coded non-340B label.
4. Non-refrigerated
   a. 340B-purchased oncology drugs will be stored in a separate and distinct bin labeled with the appropriate color-coded 340B label.
   b. GPO-purchased oncology drugs will be stored in bins labeled with the appropriate color-coded non-340B label.
5. All replenishment orders shall be generated by Autopharm software - automated inventory management system (via Talyst).

G. GPO Exclusion Compliance -- Separate Inventory

1. Separate inventories are maintained in the Harbor-UCLA main inpatient pharmacy for 340B drug purchased agents, GPO purchased agents and WAC purchased agents. Inventories will be clearly segregated as 340B, GPO, or WAC inventory.
2. Pharmacists and technicians shall only dispense 340B drugs to clinics identified as "340B eligible". See "340B Clinic Replenishment- Non-Automated Replenishment" section above.
3. Diluents for infusions, large volume parenteral and contrast media that are part of, incident to another service, where payment for the drug is made as part of the payment for the service ("bundled drugs") rather than for the drug alone, then they may be purchased through GPO arrangement.
4. Emergency medication supplies such as crash carts, RSI kits, stockpiles, etc. are designated as GPO only/inpatient area stock.

H. Transfers from GPO to 340B- Emergency Situations

Transfers between GPO and 340B inventory are implemented only in rare circumstances, typically in response to a critical patient need, and according to the following procedure:

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

IV. PREVENTION OF DUPLICATE DISCOUNTS

A. Harbor-UCLA dispenses or administers 340B drugs to its Medicaid patients and bills Medicaid for those 340B drugs (carve-in)
   1. Harbor-UCLA has answered "Yes" to the question "Will the covered entity dispense 340B purchased drugs to Medicaid Patients?" on the HRSA 340B database

B. Harbor-UCLA bills Medicaid per state Medicaid reimbursement requirements:
   1. Cost Based Reimbursement Clinic (CBRC) billing for in-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 drug cost.

2. All itemized claims to managed Medi-Cal health plans contain a 340B marker to designate 340B-eligible claims to the Medi-Cal 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 details submitted.
   a. Monthly review of all claims to managed care PBM and Medicaid to ensure all claims are identified with a 340B indicator.
   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 purchased and provided to eligible patients.
   a. Parent site
      i. 1376565309 (FPACT)
      ii. 1194840306 (OPD pharmacy)
      iii. 1629193081 (N22 pharmacy)
      iv. 1205950524 (FMC pharmacy)
   b. Child Site
      i. FHC40376F (Lomita Clinic)
4. Harbor-UCLA 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.

C. Harbor-UCLA regularly reviews its 340B Database MEF record

D. Oversight and Monitoring of Cardinal Central Fill Pharmacy

1. Cardinal Central Fill Pharmacy Process:
   i. Harbor-UCLA screens for 340B eligibility and verifies patient, prescriber, and outpatient clinic eligibility and submits claims for all prescriptions referred to and subsequently filled by the Cardinal Central Fill pharmacy. At no time does the Central Fill Pharmacy perform eligibility screening and/or fills prescriptions without Harbor-UCLA prior eligibility verification and approval.
   ii. Central Fill Pharmacy uses 11-digit NDC match accumulation and replenishment model for all of Harbor-UCLA's 340B dispensation.
   iii. Harbor-UCLA implements a "bill-to, ship-to" arrangement to replenish all 340B drugs filled by its Central Fill pharmacy; the Central Fill pharmacy receives the shipment, the invoices are billed to Harbor-UCLA.
   iv. Harbor-UCLA receives, reviews, and reconciles the invoices for drugs dispensed by the Central Fill pharmacy and pays for all 340B drugs.

2. Harbor-UCLA routinely conducts internal reviews of its central fill ~~contract~~ pharmacy for compliance with 340b Program requirements.
   i. All central fill prescriptions are written from Harbor-UCLA clinic included as a reimbursed outpatient service cost center on the most recently filed Medicare Cost Report.
   ii. The care that resulted in the 340B prescription is supported in the patient's medical record.
   iii. The prescribing provider is employed, contracted or under another arrangement with Harbor-UCLA at the time of writing the prescription so that Harbor-UCLA maintains responsibility for the care.

iv. An 11-digit NDC match can be documented for accumulation and/or replenishment of a 340B dispensation.
v. Harbor-UCLA ensures that no prescriptions are billed to Medicaid by the central fill pharmacy

3. Harbor-UCLA conducts routine audits of the Central Fill pharmacy for compliance with 340B program requirements.
   i. Quarterly audit of central fill prescriptions for 340B eligibility.
   ii. All central fill invoices are reviewed and reconciled for accuracy (11-digit NDC match and quantity).

V. Training and Education

A. Initial basic training upon hire for all pharmacy staff and oversight committee members
   1. https://vimeo.com/393313129 OR
   2. Any equivalent training video on 340B Drug Pricing Program Basics
B. Education updates and training, as needed
C. Training and education records are maintained and available for review.

VI. 340B PROGRAM COMPLIANCE OVERSIGHT, MONITORING, AND REPORTING

A. Compliance Accountability

Harbor-UCLA 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. Self-audits must include the following elements to ensure program compliance:

1. Prescription is written from clinic that is registered and included as a reimbursed outpatient service cost center on the most recently filed Medicare cost report
2. Patient eligibility
3. Provider eligibility
4. Eleven (11)-digit NDC match (if a virtual inventory is used)

B. Material Breach

Harbor-UCLA defined a "material breach" of compliance as a violation(s) that exceeds 5% of Harbor's total annual 340B purchases. Such violations require self-disclosure. Violations identified through internal self-audits, independent external audits, or otherwise that meet or exceed this threshold, and that remain non-correctable within a reasonable timeframe, will immediately be reported as soon as reasonably possible to HRSA at (340Bselfdisclosure@hrsa.gov) and applicable manufacturers using the following self-disclosure template:

- https://docs.340bpvp.com/documents/public/resourcecenter/ALL_Entities_Self_Reporting_340B_Non_Compliance.docx.

Harbor-UCLA has a 340B Program Oversight Committee that oversees this process, reviews potential violations, performs materiality assessment, and determines if a breach has occurred. The committee identifies to whom to self-disclose the breach dependent on that materiality determination and the corrective action plan resolution.

On behalf of Harbor-UCLA, the 340B Oversight Committee reviews this policy annually, makes decisions about the material breach definition and self-disclosure, and submits changes to the hospital's Executive Leadership for approval.

C. Self-Audit

1. Harbor-UCLA will have a monitoring program to ensure compliance with the 340B program. Harbor-UCLA will:
   a. Review the HRSA 340B Database to ensure the accuracy of the information for the parent site, off-site locations, and contract pharmacies, if any;
   b. Ensure compliance with the GPO Prohibition;
   c. Ensure covered outpatient drugs purchased through the 340B program are dispensed or administered only to patients eligible to receive 340B drugs; and,
   d. Reconcile dispensing records to patients' health care records to ensure that all medications dispensed were provided to patients eligible to receive 340B drugs.
      - 30 outpatient prescriptions per pharmacy per quarter
      - 30 clinic orders where 340B drugs are administered per quarter
   e. The oversight committee will review internal audit results and assess the findings for any material breaches in 340B program requirements and will report any such breaches as described above.
2. Harbor-UCLA will maintain records of 340 B-related transactions as required in a readily retrievable and auditable format for three (3) years.

D. Program Oversight

1. Harbor-UCLA will ensure program integrity and compliance with 340B program requirements through a 340B Program Oversight Committee.
2. The 340B Program Oversight Committee includes the Chief Executive Officer/Chief Operations Officer, Chief Financial Officer (or designee), Pharmacy Director, and the Pharmacy Procurement/Inventory Manager. This Committee
   a. Meets at least every six months, including times when a potential diversion incident is identified.
   b. Reviews rules/regulations/guidelines to ensure consistent policy and procedures and oversight throughout the entity.
   c. Identifies activities necessary to conduct comprehensive reviews of 340B Compliance
      - Ensures the organization meets compliance requirements of program eligibility, patient definition, drug diversion, and duplicate discounts.
      - Integrates departments such as IT, pharmacy, compliance, finance, and administration to develop standard processes for contract/data review to ensure program compliance.
   d. Oversees the review process of compliance activities, as well as taking corrective actions based on findings.
      - Oversight committee assesses if the results are indicative of a material breach
      - Reviews and approves work group recommendations (process changes, self-monitoring outcomes, and resolution.
3. Member responsibilities:
   a. Chief Executive Officer/Chief Operations Officer:
      - Responsible as the authorizing official in charge of the compliance and administration of the program.
      - Responsible for attesting to the compliance of the program through recertification
   b. Chief Financial Officer/designee:
      - Responsible for communication of all changes to the Medicare cost report regarding clinics or revenue centers.

- Responsible for communication of all changes to Medicaid reimbursement for pharmacy services/products that affect 340B status.

c. Chief Information Officer/Designee (ad hoc)
- Provides technical support for the 340B split billing pharmacy tracking software that helps manage the 340B Program. Implements all interfaces and ensures accurate identification of patient admission status for 340B compliance.

d. Pharmacy Director:
- Accountable agent for 340B purchasing and replenishment compliance
- 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
- Maintains knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA rules and Medicaid changes
- Coordinates with the CFO on any change in clinic eligibility/information
- Responsible as the primary contact for the 340B Program

e. Pharmacy Manager (i.e. Outpatient Pharmacy Manager, Inpatient Inventory Management Manager)
- Responsible for establishing distribution accounts and maintaining those accounts: 340B account, GPO account, and WAC
- 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.
- Responsible for pharmacy staff training and education.