The 340B Drug Pricing Program 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 (PHSA). Section 340B imposes a cap on the cost of Covered Outpatient Drugs used by particular federal grantees, federally-qualified health center look-a-likes and qualified Disproportionate Share Hospitals (DSH). Entities that participate in this program are eligible for significant savings on pharmaceuticals. 340B pharmaceuticals are available to patients with prescriptions written by hospital providers and by specialists to whom the patients were referred to by those providers. The PHSA requires pharmaceutical manufacturers, whose drugs are covered by the Medicaid Program, to agree to provide discounts on covered drugs that are purchased by specified government sponsored facilities called “Covered Entities.” These Covered Entities typically serve the nation’s most vulnerable patient populations. The amount of the discount applied to the drug cost is calculated based on the Medicaid rebate formula and is deducted from the manufacturer's selling price. The best price discount is available to any retailer, provider, nonprofit entity, or the government under the Medicaid 1990 rebate program; however, Covered Entities are free to negotiate even deeper discounts than the best price amount.

I. 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) as applicable to Disproportionate Share Hospitals (DSH).

B. To provide guidelines and procedures for managing 340B drug purchasing and compliance at Community Medical Centers (ABC).

II. DEFINITIONS

A. 340B Authorizing Official - The 340B Authorizing Official is the individual who assumes ultimate responsibility for the oversight, management, and compliance of ABC 340B programs. The Chief Financial Officers (CFO) from both ABC and DEF will serve as the 340B Authorizing Official for their respective facilities.

B. 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 (PHSA). Section 340B imposes a cap on the cost (i.e. “ceiling price”) of covered outpatient drugs to “Covered Entities” including Disproportionate Share Hospitals (DSH). The program is administered by the Office of Pharmacy Affairs (OPA) under Health Resources and Services Administration (HRSA).

C. Covered Entities - Facilities and programs eligible to purchase discounted drugs through the 340B Drug Pricing Program, as described in Section 340B of the Public Health Service Act.

D. Covered Outpatient Drug: A Covered Outpatient Drug is defined in section 1927(k) of the Social Security Act.
Security Act and/or the Medicaid rebate statute.

E. **Patients of the Covered Entity or Eligible Patient:** 340B discounted drugs may only be furnished to Patients of the Covered Entity (on an outpatient basis), as defined by the following criteria:

1. The health center has established a relationship with the individual, such that the center maintains 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 health center or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the health center.
3. An individual is not considered a “patient” if the sole health care service rendered is the dispensing of a drug.

F. **Duplicate Discount or Double Dipping:** Double price reduction secondary to a 340B drug discount (front end discount) and a Medicaid rebate (back end discount) on the same drug.

G. **Disproportionate Share Hospitals (DSH)** - Facilities that serve a significantly disproportionate number of low-income patients.

H. **EPIC** - The patient management/patient accounting system and electronic medical record system used by ABC.

I. **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.

J. **GPO Exclusion File** - A list of drugs that do not meet the definition of Covered Outpatient Drug as defined in this policy.

K. **Health Resources and Services Administration (HRSA)** - An agency of the United States 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.

L. **Hospital Based Clinic** - A clinic that appears on a reimbursable line of the ABC most recently filed Medicare Cost Report and is thus eligible for 340B priced drugs.

M. **Inpatient Status** - ABC determine that patients have an Inpatient Status according specific EPIC Patient Types at the time of medication dispensation. Inpatient Status qualifies a drug for GPO pricing.

N. **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 (for Covered Entities that utilize 340B discounted medications for this patient population). This prevents drug manufacturers from providing Duplicate Discounts.

O. **Mixed Use Area** - A location that serves both outpatients and inpatients as designated by the ABC patient registration system and/or admission-discharge-transfer (ADT) system. These areas include but are not limited to: Emergency Department, Surgery, Cardiac Catheterization, Cardiology, Endoscopy and Radiology.

P. **Office of Pharmacy Affairs (OPA)** - A component of the Health Resources and Services Administration Healthcare Systems Bureau which provides administration of the 340B Program.

Q. **Outpatient Status** - ABC determine that patients have an Outpatient Status according to specific EPIC Patient Types at the time of medication dispensation. If the medication is a Covered Outpatient Drug, Outpatient Status qualifies a drug for 340B pricing.

R. **Patient Type** - A patient status indicator found within the EPIC system. ABC use the Patient Type field to define inpatients and outpatients of the hospital.

S. **Prime Vendor** - The 340B Prime Vendor Program (PVP) is managed by Apexus through a contract awarded by Health Resources and Services Administration (HRSA). Apexus is responsible for securing sub-ceiling discounts on outpatient drug purchases and discounts on other pharmacy related products and services for participating entities.

T. **Recertification** - HRSA’s Office of Pharmacy Affairs (OPA) is required by statute to conduct annual Recertification of participating 340B Covered Entities’ information listed in the 340B Database. As part of this process, an Authorizing Official from each 340B entity certifies basic information about the entity and its 340B compliance with OPA. Covered Entities with inaccurate information in the 340B Database run a high risk of being removed from the program.
U. **Splitting Software** - Software employed, on an ongoing basis, to manage the splitting of 340B-eligible medication usage from 340B-ineligible medication usage in order to replenish eligible medication inventories on the 340B contract.

**III. POLICY**

A. XXXXXXXXXXXXX (**ABC**) and XXXXXXXXXXXXXXX (**DEF**) are **ABC** facilities that participate in the 340B Drug Pricing Program and comply with all regulations required by providing comprehensive services to uninsured patients and third party patients through an in house pharmacy and contract pharmacy network.

B. Establish processes to ensure compliance with the four key elements for administration of the 340B Program:
   1. Covered Entity / patient eligibility compliance;
   2. Anti-Diversion inventory controls;
   3. Medicaid pricing compliance;
   4. State Medicaid cost rebate verification (compliance with “Double-Dipping” prohibition).

C. The 340B policy will be formally reviewed annually by the 340B Leadership Group before the annual recertification process. As part of the yearly Recertification process, the 340B Leadership Group (as defined in Section V of this policy) will conduct a review of the 340B policy. If updates are needed in the policy, the 340B Leadership Group will make the appropriate revisions and bring the policy to the 340B Leadership Group for approval prior to completing the Recertification process.

**IV. EQUIPMENT**

N/A

**V. PROCEDURE**

A. **ABC** use savings generated for 340B according to Program intent and meets all 340B program eligibility requirements.

B. **ABC**'s OPA Database Covered Entity listing is complete, accurate, and correct. However, if any **ABC** child sites or contract pharmacies become ineligible for 340B pricing, **ABC** will notify OPA to request decertification from the 340B program without delay.

C. **ABC** is eligible to participate in the 340B Program by meeting the criteria for inclusion:
   1. Private non-profit corporation which maintains contract(s) with State of California/local government for provision of patient services;
   2. Disproportionate share adjustment percentage greater than 11.75 for the most recent cost reporting period ending before the calendar quarter involved;
   3. Certification that Covered Outpatient Drugs are not purchased through a GPO or other group purchasing arrangement.

D. **ABC** use 340B only in outpatient locations and/or clinics that are registered on the OPA database (or within the four walls of the main hospital), fully integrated into **ABC**, and reimbursable on the most recently filed Medicare Cost Report.

   1. Changes to 340B registration will be made online ([http://opanet.hrsa.gov/opa/](http://opanet.hrsa.gov/opa/)) in accordance to the OPA quarterly update schedule, as applicable.
   2. In some situations, a waiver for addition to the 340B Program prior to the next filing of the Medicare Cost Report is requested. The **ABC** 340B authorizing official submits a letter to Health Resources Service Administration (HRSA) for approval. When such approval is granted, the **ABC** Department of Finance notifies the Department of Pharmaceutical Services in writing of the eligibility.
   3. Annually, at the time of 340B Program Recertification, facility/area eligibility is validated by **ABC** 340B Program Manager and the facility CFO's and Pharmacy.
   4. Demographical updates (i.e. address corrections, change of Authorizing Official, etc.) may be requested at any time from the Office of Pharmacy Affairs using the change request form provided on the OPA website. Instructions for completing the online change request may be
found at http://opanet.hrsa.gov/opa/

5. The ABC 340B Corporate Program Manager facilitates the update process. The 340B Authorizing Officials, with assistance from the facility Pharmacy Directors will have ultimate responsibility for the accuracy of information on the OPA database.

E. ABC certify that Covered Outpatient Drugs are not purchased through a GPO or other group purchasing arrangement.

1. Any drug that is given to or administered to an ambulatory patient, which is billed by pharmacy separately with the intention of getting paid, will be considered a Covered Outpatient Drug. In addition, drugs administered to indigent patients meeting HRSA patient definition guidelines will be considered Covered Outpatient Drugs.

2. Covered Outpatient Drugs will typically be purchased at 340B prices; however, Covered Outpatient Drugs may also be purchased at independently negotiated, non-GPO vendor contracts or at sub-ceiling contracts offered by the 340B Prime Vendor Program.

3. Covered Outpatient Drugs without 340B prices or independently-negotiated vendor contracts will be purchased under a separate Wholesale Acquisition Cost (WAC) account.

4. Exceptions to a listed Covered Outpatient Drug (as defined in the Medicaid rebate statute) can be made if the drug:
   a. “part of” or “incident to” another service, is part of a bundled charge of the service, and given in the same setting as the service
   b. Is purchased for a facility outside the four walls of the hospital that is not currently eligible for the 340B Program. These off-site outpatient facilities of the hospital meet all of the following criteria:
      i. Are located at a different physical address than the parent;
      ii. Are not registered on the OPA 340B database as participating in the 340B Program;
      iii. Purchase drugs through a separate pharmacy wholesaler account than the 340B participating parent; and
      iv. The hospital 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 OPA 340B database
   c. Does not meet the definition of a legend drug according to the State or Federal regulations.

5. Outpatient purchases may be made on a GPO account for drugs that do not meet the definition of a Covered Outpatient Drug.
   a. A list of these medications will be maintained by ABC in the GPO Exclusion File
   b. Drugs listed on the GPO Exclusion File will be purchased by ABC under a separate wholesaler account

6. ABC may utilize GPO purchased drugs remaining in inventory at the time of transition until those GPO purchased drugs are expended. ABC will keep auditable records to demonstrate that accumulation occurs to inpatient GPO or outpatient 340B based upon eligible patients. A non-GPO outpatient account is available for replenishment for Covered Outpatient Drugs in the event a 340B product is not available. Refer to HRSA OPA FAQ section on GPO prohibition.

F. Patient/Prescriber Eligibility Compliance:

1. 340B discounted drugs may only be furnished to Patients of the Covered Entity (see Definitions).
2. A patient is considered qualified for 340B medications in the following cases:
   a. The patient is treated at ABC or in a Hospital-Based Clinic that appears as reimbursable on the most recently filed Medicare cost report, and has an eligible medication order for physician-administered drugs or an eligible prescription for pharmacy dispensed drugs, written by a prescriber employed by, under contract with or has a referral relationship with ABC.
b. The patient is treated in a hospital-based mixed use area and is classified as an outpatient by the patient registration or ADT system at the time of dispensing of the 340B eligible medication.

c. **ABC** maintain records of patients’ healthcare through the EPIC system

d. **ABC** validate that the patient has an Outpatient Status at the time the medication is dispensed to a qualified patient.

e. Medications dispensed to an inpatient are not eligible for 340B discounted drugs.

f. Patient status will be determined by patient class indicators in EPIC. A list of Inpatient and Outpatient Status indicators will be provided to and stored within the MacroHelix software. The patient status indicators can be found by selecting “qualification filters” under “administrator settings” in MacroHelix.

3. Data Files and/or interfaces will be created by the **ABC** Information Technology Department to assist with the determination of patient eligibility. The Information Technology department has the responsibility to create data files according to the appropriate specifications. The validation of these files will be the responsibility of the 340B Program Manager with support from the **ABC** pharmacy team members.

G. Procurement Compliance:

1. Purchase Account Set Up:

   a. Each 340B purchasing site will establish a minimum of 2 purchasing accounts – one for purchasing pharmaceuticals at Wholesale Acquisition Cost (WAC) and one for purchasing 340B discounted pharmaceuticals.

   b. 340B purchasing accounts may be established through the Prime Vendor (Apexus), through the facility wholesaler and/or directly with manufacturers, as appropriate. In each case, the 340B purchasing account must be maintained separately from any other pricing account.

   c. Eligibility to establish a 340B account will be verified against the Covered Entities’ current 340B OPA registration. Refer to Guidelines to **ABC** Procurement.

2. Virtual Inventory Management:

   a. **ABC** will utilize a virtual inventory model thus relieving staff of the need to make determinations regarding the stock to be utilized at the time of dispensing.

   b. Virtual inventory management requires Splitting Software to distinguish 340B eligible outpatient medication usage from 340B ineligible outpatient medication usage and inpatient medication usage (in the mixed use setting).

   c. Initial inventory acquisition will be purchased via a WAC pricing account.

   d. 340B eligible medication usage will be accumulated and replenished through a 340B pricing account, matched on an 11 digit National Drug Code (NDC) basis. If changes in purchasing are dictated by availability, changes are noted in the accumulator. Nine (9) digit NDC matches may be required, if 11 digit matches are not possible. In the event of a nine-digit replenishment, **ABC** will keep auditable records demonstrating that the appropriate amounts are replenished from the same manufacturer, regardless of the package size. Nine-digit NDC replenishment will not be part of standard operations and will only be utilized in exceptional circumstances.

   e. Inpatient medication usage (in the mixed use setting) will be accumulated and replenished through a GPO pricing account.

   f. All other medication usage will be replenished through a WAC pricing account.

3. Reverse Distribution and Sharing of Product:

   a. Reverse distribution, the return of medications to the manufacturer for credit, occurs from the WAC inventory (the 340B inventory is virtual). No adjustments to the 340B or GPO accounts are necessary.

   b. In the event of medication shortages and recalls, any product sharing will occur from the WAC inventory. No adjustments to the 340B or GPO account are necessary.

4. 340B drugs are not 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).

5. Crediting/Rebilling and Returns:
   
a. In the event a medication is ordered under the wrong account, the order will be immediately canceled. If cancellation is not possible, the medication will be physically returned to the pharmacy wholesaler.

   
b. Credits of purchased medications and subsequent rebills are processed in the event a 340B contracts are not loaded appropriately by the pharmacy wholesaler. ABC Pharmacy Directors or their designee will have the ultimate responsibility for the oversight of wholesaler contract compliance.

H. Compliance with Duplicate Discount Prohibition:

1. State Medicaid agencies are required to exclude claims for 340B purchased drugs from Medicaid rebate requests to prevent subjecting drug manufacturers to Duplicate Discounts.

2. Since California is a mandatory “Medicaid carve-in” state for in-house 340B programs, ABC will document the use of 340B purchased drugs for Medicaid patients. This is done by answering “Yes” to the following question during registration: “Will you bill Medicaid for drugs purchased at 340B price?” So doing places ABC on the Medicaid Exclusion List.

3. The Medicaid Exclusion List is provided to the State via HRSA-OPA and is maintained as part of the Medicaid Exclusion File on the HRSA website. This alerts the State Medicaid Agency to not seek rebates from manufacturers.

4. With regards to ABC external contract pharmacy arrangements, as per OPA recommendations, neither ABC nor contracted pharmacies will use drugs purchased under section 340B to dispense Medicaid prescriptions. Medicaid prescriptions will be carved-out from the 340B Program.

I. ABC use contract pharmacy services (if applicable), and the contract pharmacy arrangement is performed in accordance with OPA requirements and guidelines including, but not limited to, that the hospital obtains sufficient information from the contractor(s) to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance.

J. ABC have systems/mechanism and internal controls in place to reasonably ensure ongoing compliance with 340B requirements.

K. Program Oversight

1. Oversight of the ABC 340B Program is the responsibility of the ABC Corporate Finance and the facilities Pharmacy Leadership with assistance from (collectively referred to as the 340B Leadership Group)
   
a. ABC Corporate 340B Program Manager

   
b. Chief Financial Officer(s) (or designee)

   
c. Chief Operations Officer(s) (or designee)

   
d. Pharmacy Director(s) / Manager(s)

   
e. Pharmacy Supervisor(s)

   
f. Information Systems Pharmacy Specialist

2. The 340B Leadership Group has the following responsibilities:

   
a. Setting the general direction and policy for the ABC 340B Drug Purchasing Program (including possible program modification and/or expansion);

   
b. Ensure accurate OPA registration;

   
c. Ensure Recertification is reviewed and filed annually;

   
d. Establishing, implementing and maintaining a plan for internal monitoring and reporting (See Appendix - Monitoring Plan);

   
e. Monitoring reports, trends, and results;

   
f. Monitoring regulatory clarifications and policy decisions related to the 340B Program to ensure ongoing compliance as the 340B Program evolves;

   
g. Budgeting for necessary resources;

   
h. Correcting and/or reporting deficiencies;

   
i. Communicating to hospital leadership potential changes/trends to the 340B program.
3. Compliance issues are immediately reported to the Community Medical Center Senior Vice President, Chief Audit, Ethics and Compliance Officer and 340B Leadership Group for development of an appropriate correction plan.

L. Billing Medicaid:

1. ABC shall adhere to state and Federal rules and regulations with the regards to Medicaid billing practices, and the pricing of Medicaid claims to ensure compliance with the Duplicate Discount Prohibition. Refer to Corporate Charging Policy.

2. The 340B Authorizing Official will have ultimate responsibility for Medicaid 340B billing compliance. The Authorizing Official may designate a pharmacy resource or corporate resource to assist in the day-to-day management of Medicaid billing.

VI. DOCUMENTATION

N/A

VII. PATIENT TEACHING

N/A

Referenced Documents

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