3.5.40 340B Program

(a) Policy

California Correctional Health Care Services (CCHCS) shall 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 an eligible patient of the entity. In accordance with the program's intent, the savings generated from participation in the 340B Program shall be used to expand health care services for the incarcerated population including linkage to care upon release. CCHCS shall maintain written policies and procedures that outline the 340B Program operations and systems, mechanisms, and internal controls demonstrating compliance with the 340B Program, and the Systemwide Pharmacy and Therapeutics (P&T) Committee shall review these reports at least quarterly as part of its 340B oversight and compliance program.

(b) Purpose

To outline and to operate a compliant 340B program.

(c) Responsibility

(1) The Deputy Director, Medical Services shall:
- (A) Act as the Authorizing Official for each institution.
- (B) Oversee the compliance and administration of the program within each institution.
- (C) Attest to the compliance of the program through annual recertification.
- (D) Administer the 340B Program to fully implement and optimize appropriate savings.
- (E) Ensure that current policy statements and procedures are in place to maintain program compliance.
- (F) Maintain knowledge of the policy changes that affect the 340B Program including, but not limited to, Health Resources and Services Administration (HRSA) rules and Medicaid changes.
- (G) Monitor any changes in each institution's eligibility/information.

(2) The Statewide Chief of Pharmacy Services shall:
- (A) Act as the Primary Contact to receive communications from HRSA regarding the covered entity's status.
- (B) Assist the Authorizing Official with attesting to the compliance of the 340B Program through recertification.
- (C) Account for total savings from the use of the 340B Program and communicate savings to extend health care services for the incarcerated population to the Sexually Transmitted Diseases (STD) Control Branch corrections liaison.
- (D) Review and refine a 340B cost-savings report that details purchasing, replacement practices, and dispensing patterns.
- (E) Oversee daily operations of the 340B Program by:
  1. Maintaining and testing of tracking software.
  2. Drafting policies and procedures.
  3. Maintaining system databases to reflect changes in the drug formulary or product specifications.
  4. Managing purchasing, receiving, and inventory control processes.
  5. Continually monitoring product minimum/maximum levels to effectively balance product availability and cost-efficient inventory control.
  6. Ensuring appropriate safeguards and system integrity.
  7. Ensuring compliance with 340B Program requirements for eligible patients, drugs, providers, vendors, payers, and locations.
  8. Monitoring ordering processes, integrating most current pricing from wholesaler, analyze invoices, shipping, and inventory processes.

(3) The 340B Central Team shall include, at a minimum, pharmacists and pharmacy technicians, to perform the day-to-day processes to operate the 340B Program including, but not limited to:
- (A) Validating patient eligibilty for the 340B Program.
- (B) Reordering a replenishment supply of medications through the pharmacy's 340B account based on its dispense and administration records for eligible patients.
- (C) Monitoring 340B eligible patients for medication adherence with 340B medications.

(4) The Systemwide P&T Committee shall:
- (A) Serve as the 340B Program oversight committee.

(B) Annually review 340B rules, regulations, and guidelines to ensure consistent participation in accordance with 340B requirements.
(C) Conduct necessary reviews for 340B Program compliance quarterly and:
1. Ensure that the organization meets compliance requirements related to program eligibility, patient definitions, 340B drug diversion, and duplicate discounts via ongoing multidisciplinary teamwork.
2. Integrate departments such as information technology, legal, pharmacy, compliance, and patient financial services to develop standard processes for contract/data review to ensure program compliance.
(D) Oversee the review process of compliance activities, as well as take corrective actions based on findings.
(E) Decide which National Drug Codes (NDCs) shall be part of CCHCS' 340B replenishment program.
(F) Be notified of a material breach.
(G) Review and approve recommendations, including process changes, self-monitoring outcomes, and resolutions.
(H) Review and approve new programs and initiatives funded through savings from the 340B Program.

(d) Procedure

(1) **Eligibility for the 340B Program**
(A) Each covered entity is a sub-recipient of in-kind support from the California Department of Public Health Sexually Transmitted Diseases Control Branch.
(B) CCHCS shall maintain auditable records, policies, and procedures related to the definition of covered outpatient drug that is consistent with the 340B statute and Social Security Act.
(C) Each covered entity shall annually recertify their eligibility to remain in the 340B Drug Pricing Program and update information as needed on the 340B Office of Pharmacy Affairs Information System (OPAIS).
(D) For an individual to receive a 340B medication, the covered entity must meet the following requirements for the definition of an eligible patient by the HRSA:
1. The covered entity must maintain records of the individual's health care.
2. The individual must be under the care of a physician or other health care professional who is employed by, under contract with, or in a referral relationship to the covered entity such that responsibility for the individual's care remains with the covered entity.
3. The individual must receive health care services that are consistent with the services for which in-kind or grant funding has been provided to the covered entity.

(2) **Registration in 340B Program**
The Authorizing Official shall:
(A) Enroll each covered entity in 340B OPAIS to participate in the 340B Program.
(B) Monitor registration dates and deadlines.
(C) Update in 340B OPAIS with Authorizing Official and Primary Contact information.
(D) Annually recertify each covered entity's information on 340B OPAIS.

(3) **Changes to CCHCS Information in 340B OPAIS**
(A) The Authorizing Official shall notify HRSA promptly of any changes to CCHCS' information in 340B OPAIS.
(B) The Authorizing Official shall notify HRSA promptly of changes to any covered entity's grant status.
1. Pharmacies shall stop the purchase of 340B medications as soon as a covered entity loses 340B Program eligibility.
2. The Authorizing Official shall complete the online change request as soon as a change in eligibility is identified.

(4) **Services from the Covered Entity**
(A) The California Department of Public Health Sexually Transmitted Diseases Control Branch shall provide in-kind support to each covered entity through:
1. Condoms for patients.
2. Specialized education for providers regarding public health subjects.
(B) Each covered entity shall provide health care services to the eligible patients. These services may include, but are not limited to:
1. Opt-out screenings for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), gonorrhea, chlamydia, and syphilis as recommended.
2. Serum pregnancy test for all females under 60 years old.
3. Comprehensive sexual health screening and follow-up counseling and services, where indicated.

4. Substance use disorder counseling and treatment, where indicated.
5. Treatment of any diagnosed sexually transmitted diseases.
6. Human papillomavirus vaccine according to national guidelines.
7. Access to contraceptives pursuant to the HCDOM Section 3.1.15, Access to Contraceptive and Family Planning Services.
8. Condoms upon release.
9. Monitoring medication adherence of patient's 340B medications by a pharmacist. When nonadherence is recognized, the pharmacist shall notify the Primary Care Team for additional counseling to address any barriers.

(5) **Prevention of Duplicate Discounts**

Institutions shall not seek reimbursement from Medi-Cal for the cost of medications obtained under the 340B Program. Medi-Cal shall not pay for the drug cost of medication prescribed to an incarcerated individual when the medication is obtained under the 340B Program.

(6) **340B Co-payment and Reimbursement Procedures**

(A) Initial prescriptions, changes, or renewals of 340B medications shall be exempt from co-payment charges to patients.

(B) 340B medications shall not be eligible for medication return reimbursement.

(7) **340B Inventory Procedures**

(A) The 340B Central Team shall maintain a virtual mixed-use replenishment system for inventory across CCHCS, in which an institution will dispense from non-340B inventory, then the 340B Central Team will purchase from a 340B primary vendor a replenishment supply only upon verification of patients' 340B eligibility.

(B) Pharmacy inventory shall be replenished at the 11-digit NDC level as standard practice. In exceptional circumstances, when 11-digit replenishment is not possible, the inventory may be replenished at the 9-digit NDC level with auditable records demonstrating that the appropriate amounts are replenished from the same manufacturer, regardless of the package size.

(C) The 340B Central Team shall identify and oversee separate 340B accounts for each institution used for purchasing drugs.

(D) The 340B Central Team shall perform routine replenishment based on reports generated from administrations and dispenses for 340B eligible patients at each institution.

(E) Inventory replenishment with 340B medications shall not occur for patients in an inpatient setting. Medications needed in a licensed unit (e.g., correctional treatment center, mental health crisis bed) shall come from non-340B inventory.

(F) 340B replenishment products shall be directly shipped from the vendor to the pharmacy at the institution in which the enrolled patient utilized the medication.

(G) The pharmacy at the institution shall verify quantity received with quantity ordered. The pharmacy shall identify, resolve, and document resolution for any inaccuracies.

(H) The covered entity shall maintain records of 340B-related transactions for three years in a readily retrievable and auditable format.

(8) **Diversion Prevention Procedures for 340B-Priced Medications**

(A) Each covered entity shall maintain a separate wholesaler ordering account for 340B-priced medications.

(B) The Systemwide P&T Committee will define which medications are covered in the 340B Program.

(C) Patients eligible for the 340B Program shall possess at least one of the following criteria documented:

1. The patient has a diagnosis of HIV.
2. The patient has a diagnosis or history of HBV or HCV.
3. The patient has a diagnosis or history that includes an STD.
4. The patient has self-reported or had been discovered to partake in high-risk activities (e.g., recent or active substance use disorder, men who have sex with men [MSM], or recent history of multiple sexual partners).

(D) The treating provider must be employed or contracted by the covered entity.

(E) Records demonstrating eligibility for 340B-priced medication shall be stored in the health record of the patients receiving a qualifying medication and available to query in the event of an audit.

(F) The pharmacy at the institution shall maintain records of 340B-priced product orders, inventory, and return of unused supply.

(G) The 340B Central Team pharmacist shall validate eligibility before replenishing any 340B medication by verifying the receipt of STD screening, prevention, counseling, or treatment in the health record in alignment with federal STD guidelines.

(H) Data regarding the inventory and dispensing of 340B medications shall be maintained in the pharmacy medication database.

(I) Pharmacists shall receive 340B replenishment medications at the institution pursuant to Section (d)(7), 340B inventory procedures and shall:

1. Reconcile purchasing records with dispensing records to ensure that covered outpatient drugs purchased through the 340B Program are used only to replenish medications dispensed to 340B eligible patients.
2. Document resolution of inaccuracies.
3. Resolve inventory discrepancies to the greatest extent possible.

(J) CCHCS medical staff shall report significant discrepancies (excessive quantities based on utilization or product shortages) to the 340B Central Team pharmacist within 24 hours of identification of the discrepancy.

(K) Quarterly reports of 340B-related transactions, including inventory records, shall be reviewed by the Systemwide P&T Committee as part of its 340B oversight and compliance program.

(9) **Wasted 340B Medication**

The 340B Central Team shall review:

(A) Previous dispenses or administrations to ensure replenishment is not made for wasted or lost medications by health care staff before ordering a replenishment supply.

(B) Documentation and previous dispenses before ordering a replenishment supply of medications that had been lost by a patient and required an early refill.

(10) **340B Noncompliance/Material Breach**

(A) CCHCS has defined an established threshold of what constitutes a material breach of the 340B Program as non-compliance greater than five percent of 340B purchases.

(B) CCHCS shall ensure that identification of any threshold variation occurs among all its facilities.

(C) The Systemwide P&T Committee shall assess the materiality of the dispensing and replenishment records of 340B-priced medications on a quarterly basis.

(D) The pharmacy at each institution and the 340B Central Team shall maintain records of inventory and ensure 340B-priced medications are only replenished for eligible patients.

(E) In the event that a material breach occurs, upon discovery, the Authorizing Official report shall:

1. Notify HRSA and follow their instructions regarding the Self-Disclosure Process.
2. Contact Apexus Answers for any additional guidance.
3. Notify the manufacturer(s) involved.
4. Coordinate repayment to the manufacturer by:
   a. Requesting preferred method or repayment with receipt requested mail.
   b. Sending a second notice if there is not a response in 90 days.
   c. Repaying the negotiated repayment amount to the manufacturer.
   d. Retaining a copy of all communications and a signed/dated overview of all relevant conversations related to the material breach.

(F) The Authorizing Official shall maintain records of material breach violations, including manufacturer resolution correspondence.

(G) In the event that a finding does not meet the requirements of a material breach, but could lead to a material breach if not corrected, a corrective action plan (CAP) shall be created and filed with the Systemwide P&T Committee. If the CAP requires a policy change, that must also be reported to the Statewide Chief of Pharmacy Services. The CAP should be implemented as soon as possible to prevent future potential material breaches.

(11) **340B Program Compliance Monitoring/Reporting**

(A) The Systemwide P&T Committee shall review the results of an internal audit, conducted annually by an audit team approved by the Committee, to ensure the integrity of the 340B Program.

(B) The covered entity's 340B Authorizing Official shall review 340B OPAIS to ensure the accuracy of the information for each covered entity.

(C) The 340B Central Team shall reconcile purchasing and dispensing records to ensure that covered outpatient drugs purchased through the 340B Program are replenished only for patients eligible to receive 340B medications and that variances are not the result of diversion.
(D) The Authorizing Official shall ensure that a minimum of 10 and maximum of 30 randomly selected records of 340B-priced drug utilization are audited quarterly.
(E) Each covered entity shall maintain records of 340B-related transactions for a period of three years in a readily retrievable and auditable format located in the pharmacy or stored electronically.

References

- Public Health Service Act, Title III, Part D, Section 340B
- Health Resources & Services Administration, 340B Drug Pricing Program, https://www.hrsa.gov/opa/index.html
- Apexus, 340B University OnDemand, https://education.apexus.com/
- Health Care Department Operations Manual, Chapter 3, Article 1, Section 3.1.15, Access to Contraceptive and Family Planning Services

Revision History

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