PARTNERSHIP HEALTHPLAN OF CALIFORNIA

POLICY / PROCEDURE

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I. RELATED POLICIES:
N/A

II. IMPACTED DEPTS:
A. Pharmacy
B. Provider Relations
C. Administration (Finance)

III. DEFINITIONS:
A. 340B Program: The Veterans Health Care Act of 1992 established the 340B Program in section 340B of the Public Health Service Act. The 340B Program requires drug manufacturers participating in Medicaid to provide discounted covered outpatient drugs to certain eligible health care entities, known as 340B Covered Entities (see definition below).
B. 340B Drug: Any covered outpatient drug purchased on a discounted basis under the 340B program, as defined by 42 U.S.C. § 256b and its implementing regulations, that is purchased via a qualified 340B Program distributor.
C. HRSA: United States Health Resources and Services Administration.
D. 340B Covered Entity: A healthcare provider registered with HRSA and approved to participate in the 340B Program.
E. 340B Participating Entity: A 340B Covered Entity that agrees to participate in PHC's 340B Compliance Program and signs a 340B Compliance Program Agreement.
F. 340B Administrator: A subcontractor hired by a 340B Participating Entity to administer the 340B program, usually for a fee.
G. DHCS: California Department of Health Care Services.
H. 340B Office of Pharmacy Affairs Information System ("340B OPAIS"): A database overseen by Office of Pharmacy Affairs (OPA) which includes detailed information related to all 340B Covered Entities, Contract Pharmacies, and Manufacturers all registered to participate in the 340B Program.
I. 340BX Clearinghouse: The entity contracted with PHC to coordinate with various 340B players and perform data analysis and identification of 340B eligible pharmacy claims for the 340B Participating Entities.

J. PHC 340B Advisory Committee: A subcommittee of the PHC Board of Commissioners charged with overseeing PHC's 340B Compliance Program, including review and approval of the 340B QIP program and related proposals.

K. Contract Pharmacy: A retail pharmacy dispensing 340B-purchased drugs on behalf of a 340B Covered Entity, based on a contract between the 340B Covered Entity and the pharmacy. A Contract Pharmacy operates with a mixed inventory of drugs (340B and non-340B Covered Outpatient Drugs). All eligible Contract Pharmacies are registered with HRSA and listed on the 340B OPAIS: https://340bopais.hrsa.gov/home

L. In-House Pharmacy: A pharmacy in which the 340B Covered Entity owns the 340B drugs, pharmacy, and license. The 340B Covered Entity purchases the 340B drugs, which are dispensed to eligible patients, as defined by HRSA. The 340B Covered Entity is fiscally responsible for the pharmacy and pays the pharmacy staff. The pharmacy is (i) located on the premises of the 340B Covered Entity, (ii) provides services solely to the 340B Covered Entity's patients, (iii) through the 340B Covered Entity's providers, and (iv) dispenses only drugs and supplies purchased under the 340B Program to PHC beneficiaries. For the purposes of this Agreement, if all conditions, (i) through (iv), are not met, then the pharmacy would be considered a Contract Pharmacy, even though it might be physically located on the premises of the 340B Covered Entity. In-House Pharmacies are not registered with HRSA nor are they listed on the 340B OPAIS.

M. Provider/In-House Dispensing: The 340B Covered Entity owns drugs; employs or contracts with providers licensed in the state to dispense drugs on its behalf; holds a clinic dispensary license issued by the California Board of Pharmacy; and is fiscally responsible for the operation of the dispensary. These entities submit claims for 340B Covered Outpatient Drugs using the CMS-1500 format, UB-04 format, or electronic 837 file format, which are not first processed by a Pharmacy Benefits Manager (PBM) providing services under a direct contract with the 340B Participating Entity and on its behalf.

N. Physician-Administered Drug ("PAD"): Any covered outpatient drug provided or administered by the 340B Participating Entity to one of its patients, and billed by a provider other than a pharmacy. A physician-administered drug is an outpatient drug other than a vaccine that is typically administered by a health care provider in a physician's office or other outpatient clinical setting. For example, drugs that are infused or injected are typically physician-administered drugs. The provider bills the state Medicaid program for the drug using the appropriate national drug code (NDC) and Healthcare Common Procedure Coding System code. States may maintain a list of (1) which drugs are considered physician-administered drugs and must be provided in a clinical setting, and (2) which drugs are considered outpatient drugs and must be dispensed by a pharmacy.

O. 340BX Trust Account: A bank account in the name of NEC Networks, LLC (for Clearinghouse) at BBVA Compass Bank. This account will be utilized by Clearinghouse as a holding account to deposit 340B related funds paid by 340B Participating Entities, and also to transfer funds to PHC's bank account.

P. UD Modifier: Approved modifier code for use in billing Medi-Cal. This modifier code is used by Section 340B providers to denote services provided or drugs purchased under the 340B Program

Q. Medi-Cal Rx: The program title established by the State of California Department of Health Care Services (DHCS) for the new system of how Medi-Cal pharmacy benefits will be administered through the fee-for-service (FFS) delivery system, beginning on January 1, 2022, subject to change as determined and communicated by the California Department of Health Care Services (DHCS).

Policy/Procedure Number: MCRP4060		Lead Department: Health Services
Policy/Procedure Title: 340B Compliance Program		☒ **External Policy** ☐ **Internal Policy**
Original Date: 10/02/2014	**Next Review Date: 02/09/2023** **Last Review Date: 02/09/2022**	
Applies to:	☒ **Medi-Cal**	☐ **Employees**

IV. ATTACHMENTS:

A. 340B Compliance Program Agreement
B. Reclassification of 340B drug claim service lines requiring the UD modifier
C. PHC 340B Compliance Program White Paper
D. Partnership HealthPlan 340B Policy for Primary Care Entities

V. PURPOSE:

A. The purpose of this policy is to outline the requirements for participation in PHC's 340B Compliance Program, which is established to ensure 340B Covered Entities and PHC are complying with Federal and State 340B regulations. The data submission process outlined for the 340B Compliance Program is set-up so that 340B drugs prescribed by the 340B Covered Entities are identified to DHCS in a way that the State requires in order to ensure that no duplicate discounts are received and retained for the use of 340B drugs. This policy will be applied consistently across each class of 340B Covered Entity and set forth standards of accountability that are reasonable and meaningful.

   This policy shall apply in scope and pursuant to APL 20-020, Governor's Executive Order N-01-19 regarding Transitioning Medi-Cal Pharmacy Benefit from Managed Care to Medi-Cal Rx (the pharmacy benefit carve-out to Medi-Cal Fee-for-Service). Any & all policy items pertaining to pharmacy prescription claims &/or pharmacy drug Treatment Authorization Requests (TARs) shall not apply upon implementations of Medi-Cal Rx.

VI. POLICY / PROCEDURE:

A. Analysis of 340B Covered Entities as outlined by HRSA:
   1. A master list of entities identified as eligible to participate in the 340B Program (340B Compliance Program – 340B Covered Entity Master Tracking List) has been compiled by PHC using information from the 340B OPAIS on HRSA's website, https://340bopais.hrsa.gov/home. Those entities are referred to as 340B Covered Entities.
      a. On a quarterly basis, a report is run from the 340B OPAIS to see if there are new 340B Covered Entities added to the 340B Program or if previously participating 340B Covered Entities have terminated their enrollment.
   2. PHC compares the information from the quarterly report to the 340B Compliance Program – 340B Covered Entity Master Tracking List. The 340B Compliance Program – 340B Covered Entity Master Tracking List is updated based on the information in the report.
   3. Each quarter, PHC determines if additional 340B Covered Entities will be invited to join the 340B Compliance Program. Invitee determination is based on consideration by PHC of factors such as expressed interest from 340B Covered Entities, as well as input from PHC's Chief Medical Officer (CMO) and Director of Pharmacy Services.

B. 340B Compliance Program Agreement:
   1. There is a single 340B Compliance Program Agreement that covers all possible pharmacy arrangements and 340B drug distribution methods (Attachment A).
   2. Once an agreement is entered into between PHC and a 340B Covered Entity, the entity is referred to as a 340B Participating Entity.
   3. All 340B Participating Entities are tracked on a separate document, 340B Compliance Program – Current 340B Participating Entities-Tracking Document.

a. When the quarterly report is run from the 340B OPAIS, PHC reviews the information and compares it to any Change Notification forms received from 340B Participating Entities to determine if any changes were not communicated to PHC.

C. Billing Rates:
1. Until the Medi-Cal Rx program takes effect, as determined and communicated by DHCS, payments for 340B Covered Outpatient Drugs billed as claims to PHC will be paid at the network or contracted rate negotiated between the 340B Participating Entity's Contract or In-House Pharmacy and the PBM, subject to the requirements of Welfare & Institutions Code § 14087.325(d). PHC does not have access to information regarding rates established by the 340B Contract/In-House Pharmacies and the PBM. This is applicable to all 340B drug claims for all of the following pharmacy inventory types:
   a. Dispense only 340B drugs
   b. Dispense both 340B drugs and non-340B drugs
   c. Listed on Medicaid Exclusion File and dispense only 340B drugs
   d. Listed on Medicaid Exclusion File and dispense both 340B drugs and non-340B drugs
2. Payments for 340B Covered Outpatient Drugs billed as medical benefit claims to PHC will be paid at the contracted rate established between the 340B Participating Entity and PHC

D. Invoicing and Compliance Fees for 340B Participating Entities:
1. 340B drug claims reclassified through 340BX Clearinghouse: There will be a 90 to 120 day lag in the invoicing process for these claims. The invoices will come from 340BX Clearinghouse and reflect the 340BX Compliance Fees, as well as the PHC 340B Compliance Fees.
2. 340B drug claim service lines administered through PHC's medical benefit and reclassified through PHC: The invoices for this service will come from PHC and reflect the PHC 340B Compliance Fees.

E. Reporting of Changes to 340B Participating Entity's 340B Program
1. It is the responsibility of the 340B Participating Entity to communicate any changes to its internal 340B Program that may affect any of the terms and/or conditions of the 340B Compliance Program Agreement.
2. A form is provided to the 340B Participating Entity to use when reporting changes to PHC.
3. Changes that should be reported to PHC include, but are not limited to, the following:
   a. 340B Participating Entity contracts with a new 340B Administrator
   b. 340B Participating Entity terminates a contract with a 340B Administrator
   c. New child site/associated site/grantee for the 340B Participating Entity becomes eligible to participate in the 340B Program
   d. 340B Participating Entity site is terminated from the 340B Program
   e. New Contract Pharmacy is added to the 340B Participating Entity's Pharmacy Network
   f. Contract Pharmacy is removed from the 340B Participating Entity's Pharmacy Network
   g. 340B Participating Entity opens an In-House Pharmacy
   h. 340B Participating Entity closes an In-House Pharmacy
   i. Any change to the contact information for the 340B Participating Entity on the OPA 340B OPAIS including Authorizing Official or Primary Contact
4. It is the responsibility of the 340B Covered Entity to report any and all of the changes noted above to HRSA directly. This information is outlined in the Program Requirements on the HRSA website, https://www.hrsa.gov/opa/program-requirements/index.html

F. Data Reporting Requirements:
   1. Contract Pharmacy 340B Claims:
      a. For the exact language, please refer to the Agreement. The file format will be shared during the 340B Covered Entity's on-boarding process with 340BX Clearinghouse. Any file format changes will be communicated to the 340B Participating Entity within thirty (30) calendar days before the changes become effective.
      b. Per HRSA, the 340B Covered Entity must have sufficient information to ensure ongoing compliance and the timely recognition of any 340B Program compliance problem at all Contract Pharmacy locations. The 340B Covered Entity remains responsible for the 340B drugs it purchases and dispenses through a Contract Pharmacy. All 340B Covered Entities are required to maintain auditable records and provide oversight of their Contract Pharmacy arrangements.
   2. In-House Pharmacy Claims:
      a. If an In-House Pharmacy submits 340B drug claims directly to PHC through PHC's medical benefit billing process, all claims must have a UD modifier listed after the HCPCS code for each and every 340B-purchased drug billed via paper or electronically using a CMS-1500 format, UB-04 format, 837 format, or related format.
   3. PAD 340B drug claim service lines/Physician-Dispensed Drug 340B drug claim service lines/340B drug claim service lines for drug costs submitted as part of a fee-for-service, bundled, or capitated rate:
      a. The 340B Covered Entity is responsible for insuring all 340B drug claim service lines tied to PADs, Physician Dispensed Drugs, or drug costs submitted as part of a fee-for-service, bundled, or capitated rate are identified (flagged) appropriately.
      b. All claims for drugs purchased through the 340B program and submitted as claims directly to PHC must have a UD modifier listed after the HCPCS code for each and every 340B-purchased drug billed via paper or electronically using a CMS-1500 format, UB-04 format, 837 file format, or other related format.
      c. Periodically, PHC may request a sample size of the 340B Participating Entity's PAD claims for completion of a limited scope audit regarding proper identification of 340B claims using the UD modifier.

G. Requests for reclassification of PAD claim service lines, Physician-Dispensed Drug claim service lines, and claim service lines for drug costs submitted as part of a fee-for-service, bundled, or capitated rate
   1. The 340B Covered Entity is the sole responsible party for the proper identification (flagging) of all 340B drug claims (including PAD claim service lines, Physician-Dispensed Drug claim service lines, and claim service lines for drug costs submitted as part of a fee-for-service, bundled, or capitated rate) submitted for 340B drugs requiring the use of the UD Modifier (refer to Attachment B). Clearinghouse is not involved with this type of identification (flagging), as it is completed by the 340B Covered Entity.
   2. In the event the 340B Covered Entity requires assistance with identification (flagging) of 340B drugs on claim service lines missing the UD modifier, PHC has established a process for assisting 340B Participating Entities to correct claim service lines missing the UD modifier to identify 340B drugs. For additional information please refer to Attachment B, Reclassification of 340B drug claim service lines requiring the UD modifier, of this policy.

H. Drug Manufacturer Inquiries and Duplicate Discounts:
   1. PHC learns of Drug Manufacturer inquiries through DHCS or directly from the 340B Covered Entities.
      a. If the inquiry comes from DHCS, PHC follows up with the 340B Covered Entity, providing them with the appropriate information to determine if a paid claim or claim service line was in fact tied to a 340B drug.

1) PHC can assist with PAD claim service line reclassification for all 340B Covered Entities.
2) However, 340B Covered Entities must participate in the 340B Compliance Program in order to get assistance from 340BX Clearinghouse with reclassification of Contract Pharmacy claims retroactively.
3) If necessary, the 340B Covered Entity may need to work directly with the Drug Manufacturer to reach a solution.
4) It is ultimately the responsibility of the 340B Covered Entity to resolve any outstanding issues with the Drug Manufacturers.

b. If a 340B Covered Entity reaches out to PHC to correct a claim, PHC will work with the 340B Covered Entity to determine next steps.
1) PHC can assist with PAD claim service line reclassification for all 340B Covered Entities. However, 340B Covered Entities must participate in the 340B Compliance Program in order to get assistance from 340BX Clearinghouse with reclassification of Contract Pharmacy claims retroactively.
2) If necessary, the 340B Covered Entity may need to work directly with the Drug Manufacturer to reach a solution.
3) It is ultimately the responsibility of the 340B Covered Entity to resolve any outstanding issues with the Drug Manufacturers

I. If a 340B Covered Entity determines a duplicate discount has occurred, it is the responsibility of the 340B Covered Entity to self-disclose that information to HRSA.
1. HRSA provides instructions regarding entity self-disclosures on its website, https://www.hrsa.gov/opa/self-disclosures/self-disclosure.html.

VII. REFERENCES:

A. HRSA 340B Drug Pricing Program - https://www.hrsa.gov/opa/index.html
B. HRSA Office of Pharmacy Affairs – 340B OPAIS - https://340bopais.hrsa.gov/home
C. HRSA 340B Program Requirements - https://www.hrsa.gov/opa/program-requirements/index.html
D. HRSA Entity Self Disclosures - https://www.hrsa.gov/opa/self-disclosures/self-disclosure.html

VIII. DISTRIBUTION:

A. PHC Department Directors
B. PHC Provider Manual

IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE: PHC Pharmacy Services Department with 340B Advisory Committee oversight.

X. REVISION DATES:

04/02/15; 10/06/16; 05/09/18; 03/04/19; 02/12/20; 11/11/20; 02/10/21; 02/09/22

*Through 2017, Approval Date reflective of the Pharmacy and Therapeutics Committee meeting date. Effective January 2018, Approval Date reflects that of the Physician Advisory Committee's meeting date.

PREVIOUSLY APPLIED TO: N/A

XI. POLICY DISCLAIMER:

A. In accordance with the California Health and Safety Code, Section 1363.5, this policy was developed with involvement from actively practicing health care providers and meets these provisions:
1. Consistent with sound clinical principles and processes;
2. Evaluated and updated at least annually;

3. If used as the basis of a decision to modify, delay or deny services in a specific case, the criteria will be disclosed to the provider and/or enrollee upon request.

B. The materials provided are guidelines used by PHC to authorize, modify or deny services for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under PHC.

C. PHC's authorization requirements comply with the requirements for parity in mental health and substance use disorder benefits in 42 CFR 438.910.