



340B Compliance Program Agreement
Between
Partnership HealthPlan of California
And
[340B Covered Entity Name]

This 340B Compliance Program Agreement (this “Agreement”) is entered into between [340B Covered Entity Name] (“340B Participating Entity”) whose offices are located in [Enter City], California and Partnership HealthPlan of California (“PHC”), whose offices are located in Fairfield, CA.

The effective date of this Agreement is the **1st day of [<month><year>]** (the “Effective Date”).

PHC is a county organized health system (“COHS”) contracted with the State of California Department of Health Services (“DHCS”) to develop and maintain a health care delivery system for assigned Medi-Cal Beneficiaries in certain designated counties in California.

I. Definitions and Acronyms

- a. 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.
- b. 340B Administrator: A subcontractor hired by a 340B Participating Entity to administer the 340B Program, usually for a fee.
- c. 340B Covered Entity: A healthcare provider registered with HRSA and approved to participate in the 340B Program.
- d. 340B Participating Entity: A 340B Covered Entity that agrees to participate in PHC’s 340B Compliance Program by signing this Agreement.
- e. HRSA: United States Health Resources and Services Administration.
- f. DHCS: California Department of Health Care Services.
- g. Pharmacy Benefits Manager (“PBM”): A subcontractor of PHC that contracts with individual dispensing pharmacies to create a network of pharmacies to provide the infrastructure for the pharmacy benefit of PHC and meets the definition of a “pharmacy benefits manager” in Business & Professions Code § 4430(j).
- h. 340B Office of Pharmacy Affairs Information System (“340B OPAIS”): A database overseen by 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 (“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.
- 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 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. Such providers include, but are not limited to, physician offices, clinics, and hospitals. A covered outpatient drug is broadly defined as a drug that may be dispensed only upon prescription, and is approved for safety and effectiveness as a prescription drug under the Federal Food, Drug and Cosmetic Act. PADs include both injectable and non-injectable drugs. These drugs may sometimes be referred to as Physician-Dispensed Drugs.
- 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.

II. Preamble (Source: OIG: “State Medicaid Policies and Oversight Activities Related to 340B Purchased Drugs,” June 2011; 81 FR 27498, May 2016):

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 Covered Entities. Congress intended for the savings from discounted drugs purchased under the 340B Program “to enable [participating] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

Covered Entities include disproportionate share hospitals, Title X family planning clinics, federally qualified health centers, Ryan White Program grantees, comprehensive hemophilia diagnostic treatment centers, and IHS contracted Health Centers, among others. To participate in the 340B Program, Covered Entities must register with the Health Resources and Services Administration (HRSA), the agency responsible for administering the 340B Program. After the entity has registered, HRSA enters the entity’s information into HRSA’s covered entity database, and the information is updated annually.

Once approved, Covered Entities may purchase and dispense drugs under the 340B Program (hereinafter referred to as 340B-purchased drugs) through In-House Pharmacies, or they may enter into contracts with retail pharmacies to dispense 340B-purchased drugs on their behalf. A retail pharmacy dispensing 340B-purchased drugs on behalf of a Covered Entity is referred to as a Contract Pharmacy. Covered Entities may purchase drugs at or below 340B ceiling prices, which are the maximum prices drug manufacturers can charge for each 340B-purchased drug. The 340B ceiling price is calculated using a statutorily defined formula based on the average manufacturer price (AMP) of drugs. In general, AMP is the average price paid to drug manufacturers for drugs distributed to retail community pharmacies. Drug manufacturers must calculate and report AMP to the Centers for Medicare & Medicaid Services (CMS). The 340B ceiling price of a drug is generally much lower than its retail price.

Covered Entities choose whether to dispense 340B-purchased drugs to Medicaid patients, which affects how they interact with State Medicaid agencies. If Covered Entities choose

not to dispense 340B-purchased drugs to Medicaid patients, by default those dispensed drugs will have been purchased outside of the 340B Program. Because of that, Covered Entities can bill State Medicaid agencies at the standard reimbursement rates that those agencies have established for all retail pharmacies. Covered Entities might make this choice because their State Medicaid agencies' standard reimbursement rates for covered outpatient drugs are higher than the purchase prices. However, if Covered Entities elect to dispense 340B-purchased drugs to Medicaid patients, specific 340B policies and guidance apply.

State Medicaid agencies may set specific policies for Covered Entities that dispense 340B-purchased drugs to Medicaid patients (340B policies). Under Section 2012 of the Affordable Care Act ("ACA"), the State is not entitled to collect rebates on drugs provided to Medicaid beneficiaries if that drug was purchased through the 340B Program.

On May 6, 2016, the Department of Health and Human Services (HHS) and CMS published a "final rule" in the Federal Register modernizing the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. Per 42 CFR § 438.3(s)(3), Managed Care Organizations (MCOs) are required to establish "procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program." MCO agreements are required to ensure the Covered Entities follow any guidance issued by the State Medicaid Agency regarding drugs purchased through the 340B program and properly identifying drugs as such so that the State Medicaid Agency does not collect rebates to which it is not entitled. An MCO like PHC must have a carefully structured process in place to ensure the participating 340B Covered Entities have properly identified 340B drugs in compliance with properly adopted DHCS policies when dispensed to PHC beneficiaries. That process will ensure reliable communication of drug status (vis-à-vis 340B status) that is communicated through any contract pharmacy, any 340B Administrators, any contracted PBM contracted by the Managed Care Plan, and PHC to the State. The State then has the responsibility to ensure duplicate discounts are not claimed for the same prescription.

III. Purposes of this Agreement

- a. To define an agreed upon process for ensuring proper identification of 340B drugs dispensed to PHC beneficiaries to the State of California, so as to ensure compliance with DHCS and HRSA policy and federal law.
- b. To support the mission of 340B Participating Entities to provide services to the most vulnerable members of the community.
- c. To help reinforce judicious use of taxpayer/Medi-Cal funds in pharmaceutical costs.

IV. 340B Compliance for 340B Claim Reporting

- a. Contract Pharmacy/In-House Pharmacy claims processed by the PBM
 - i. PHC has contracted with and implemented a retrospective reclassification process through Clearinghouse that is intended to prevent 340B claims to which the State is not entitled to a rebate, from being improperly adjudicated for rebates paid under 42 U.S.C. § 1396r-8. This process was tested and found to be functional. PHC has notified the 340B Participating Entity and DHCS that, to the best of its knowledge, all 340B Covered Outpatient Drugs prescribed by that entity and retrospectively reclassified by Clearinghouse are identified to DHCS in a way that the State requires in order to ensure that no duplicate discounts are ultimately received and retained for the use of 340B Covered Outpatient Drugs.
 - ii. Payments for 340B drugs billed as claims to PHC will be paid at the network or contracted rate negotiated between the 340B Contract/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.
 - iii. The 340B Participating Entity shall be responsible for ensuring any Contract Pharmacies, In-House Pharmacies, and the 340B Participating Entity's 340B Administrators follow the compliance process required by PHC, as defined in Attachment B. The 340B Administrators, if any, are listed in Attachment G.
 - iv. If one or more of a 340B Participating Entity's 340B Administrators is unwilling to work directly with Clearinghouse, the 340B Participating Entity can submit the required data directly to Clearinghouse in the file format provided during the on-boarding process with Clearinghouse. If so requested, a current example of the file format shall be provided to a 340B Covered Entity prior to execution of this Agreement for its review after a non-disclosure agreement (NDA) from Clearinghouse is completed by a 340B Covered Entity. If a 340B Covered Entity's 340B Administrator needs access to the file specs, the 340B Administrator will have to sign a separate NDA. All data files sent directly from the 340B Participating Entity to Clearinghouse will be reclassified in the same manner as data files submitted by the 340B Participating Entity's 340B Administrators for the fee outlined in Attachment A.
 - v. PHC has established a mechanism to assist its 340B Participating Entities in appropriately identification (flagging) 340B drug claims via Clearinghouse. Should a 340B Participating Entity or one of its 340B Administrators choose to submit 340B claims for a Contract Pharmacy or In-House Pharmacy to PHC without having it go through the reclassification process via

Clearinghouse, such claims may not be compliant with 340B Program identification (flagging) requirements. The 340B Participating Entity acknowledges that it will be the sole accountable party regarding any Contract Pharmacy or In-House Pharmacy 340B claims that are not reviewed by Clearinghouse should an audit occur. In the event the 340B Participating Entity requires assistance with appropriate identification (flagging) and claims adjudication compliance for 340B claims originating from a Contract Pharmacy or In-House Pharmacy, the 340B Participating Entity will submit a formal written request and file containing the needed claims information to identify each claim. By submitting the formal request to reclassify claims to identify 340B drugs, the 340B Participating Entity acknowledges it will adhere to the established PHC process with Clearinghouse for the fee outlined in Attachment A. PHC will evaluate each request to determine if the request can be fulfilled. PHC will inform the 340B Participating Entity of the decision within 10 business days of receipt of the formal request from the 340B Participating Entity.

- b. 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 processed by PHC's Claims Department
 - i. The 340B Participating Entity is the sole responsible party for the proper identification (flagging) of all 340B drug claims (including PAD claim service lines, Physician-Dispensed Drugs 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 340B drug identification (flagging), as it is completed by the 340B Participating Entity.
 - ii. In the event the 340B Participating 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 for 340B drugs missing the UD modifier.
 - iii. With submission of the initial request to assist with identification (flagging) of 340B drugs on claim service lines with the addition of the UD Modifier, the 340B Participating Entity acknowledges it will adhere to PHC's process for correcting each claim and adding the UD modifier for the fee outlined in Attachment A for the initial request, as well as for all subsequent requests.
 - iv. For additional information, please refer to the 340B Compliance Program Policy and associated attachments located on PHC's external website, <http://www.partnershiphp.org/Providers/Pharmacy/Pages/340B-Compliance-Program.aspx>.
- c. Submission of accurate data

- i. The 340B Participating Entity takes full responsibility for providing accurate, complete, and necessary data to enable PHC and Clearinghouse to perform their services hereunder, and to maintain records to verify the accuracy and completeness of such data.
- ii. The 340B Participating Entity also takes full responsibility for providing accurate, complete, and necessary data when submitting 340B drug claims data for 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 identified (flagged) by inclusion of the UD Modifier to PHC for transmittal to the State.
- iii. Periodically, PHC may request a sample size of the 340B Participating Entity's 340B PAD claim service lines for completion of a limited scope audit regarding proper identification of 340B drug claims using the UD modifier.
- iv. Such data will be made available by 340B Participating Entity to HRSA or other federal, state, or local authorities in the case of an audit, and the 340B Participating Entity shall maintain such records for a period of time that complies with all applicable laws.

V. Reclassification Fees

- a. Contract Pharmacy/In-House Pharmacy claims reclassified by 340BX Clearinghouse
 - i. The 340B Participating Entity will pay reclassification fees for any 340B claim reclassified by Clearinghouse. Payment of these reclassification fees is on a per paid 340B drug claim basis. The reclassification fees include a 340BX Compliance Fee and a PHC 340B Compliance Fee, as defined in Attachment A. The 340BX Compliance Fee is for the reclassification services provided by Clearinghouse. The PHC 340B Compliance Fee will be put towards the costs associated with the operation and continuous maintenance of the PHC 340B Compliance Program, and as to which PHC has not previously been compensated under its agreement with DHCS.
 - ii. No later than the 3rd day of each month, Clearinghouse shall invoice the 340B Participating Entity monthly for the 340BX Compliance Fee and PHC 340B Compliance Fee described on Attachment A. Should the 3rd day of any month fall on a weekend or a holiday, Clearinghouse shall invoice the 340B Participating Entity on the next business day. The 340B Participating Entity shall make payment of the invoiced amount through bank Electronic Fund Transfer (EFT) funds transfers from the 340B Participating Entity's account(s) to the 340BX Trust Account on a monthly basis, which funds transfers shall be sent by the 340B Participating Entity within twenty (20) calendar days of invoice from

Clearinghouse. Invoices sent to the 340B Participating Entity will include the 340B Claim Counts, 340BX Compliance Fee Amount, and PHC 340B Compliance Fee Amount. Clearinghouse will provide an accompanying file to the 340B Participating Entity containing claims information sufficient to determine, on a per-claim basis, the accuracy and propriety of the amounts claimed on the invoice. Please refer to Attachment C for the invoicing schedule associated with reclassification through Clearinghouse. Failure to pay the fees in Attachment A within twenty (20) calendar days of receipt of the invoice as provided by Clearinghouse is grounds for immediate termination of this Agreement by PHC as defined in Section VIII. Terms of Agreement. Any such impending termination must be preceded by a seven (7) calendar day final notice providing the entity the opportunity to pay for any arrears. If payment of this fee is repeatedly made after the seven (7) day final notice, this may result in termination from the 340B Compliance Program and termination of this Agreement.

- iii. The reclassification fees outlined in Attachment A may be changed with ninety (90) calendar days' written notice of such intent without affecting the remainder of this Agreement. Any changes to the fees would be based on the costs associated with the 340B Compliance Program, including the reclassification services provided by Clearinghouse and the administrative fees for PHC. The 340B Participating Entity will be notified of any changes to the reclassification fees listed in Attachment A. The notice will be accompanied by supporting documentation explaining the basis of the change. The 340B Participating Entity has ninety (90) calendar days from the date of notification to respond, in writing, to the proposed change. The 340B Participating Entity should respond by acknowledging agreement to the proposed change by signing the Amendment or providing a written outline of why the 340B Participating Entity does not agree to the change.
- iv. There will be a 90 to 120 day delay in the invoicing process to ensure 340B Participating Entities have sufficient time for cash in-flow from their respective 340B Administrators. (The invoicing schedule is provided in Attachment C.) In the event a 340B Participating Entity is not timely in remitting payment of the invoiced amount within twenty (20) calendar days of receipt of the invoice, then the 340B Participating Entity shall be subject to interest charged on all amounts due, at an amount equal to one and one-half percent (1.5%) per month, to accrue on a daily basis on any unpaid balances.
- v. Regarding reversal of 340B Claims, any reversal for a 340B Claim occurring ninety (90) days after the date of service will be excluded from any adjustments to the invoice provided by Clearinghouse.

- b. 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 reclassified by PHC
 - i. If the 340B Participating Entity submits 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 with the UD modifier on the necessary service lines to identify it is a 340B drug claim, there is no 340B Compliance Fee charged.
 - ii. In the event the 340B Participating Entity requires PHC's assistance with identification (flagging) of 340B drugs on claim service lines missing the UD modifier, the 340B Participating Entity will pay reclassification fees for any claim service line reclassified as 340B with the addition of the UD modifier by PHC, as defined in Attachment A. Payment of these reclassification fees is on a per paid 340B drug claim service line basis.

VI. Reporting of Changes to 340B Participating Entity's 340B Program

- a. 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, conditions, and/or processes outlined in this Agreement.
- b. Attachment D defines some of the types of changes a 340B Participating Entity must communicate to PHC along with the time period they have to complete said notification.
- c. All changes shall be submitted to PHC using the Change Notification Form shown in Attachment E. A fillable version of the form will be made available to the 340B Participating Entity at the time the 340B Compliance Program Agreement is executed. Forms will be submitted to PHC's Pharmacy Department by e-mail at 340BQIP@partnershiphp.org.
- d. 340B Participating Entity's failure to report to PHC any of the types of changes listed in Attachment D in the respective timeframe indicated in Attachment D is considered a material breach and grounds for termination of this Agreement based on Section VIII. Terms and Termination of Agreement.

VII. Terms and Termination of Agreement

- a. Term: The initial term of this Agreement shall begin on the Effective Date and shall expire two (2) years after. Thereafter, this Agreement shall renew automatically for additional, successive terms of one (1) year until terminated by either party. This Agreement may be terminated with or without cause based on the provisions herein.

- b. Termination for cause: If a party defaults in any of its obligations under this Agreement, the non-breaching party, at its option, shall have the right to terminate this Agreement by providing thirty (30) calendar days written notice of the material breach of this Agreement to the defaulting party. The defaulting party shall have ten (10) business days to cure such default upon receipt of the notice, and if timely cured, no termination shall occur. This Agreement will be immediately terminated without recourse if the State or Federal Government deems the program not legally permissible and all options for appeal are exhausted.
- c. Early termination: This Agreement may be terminated by either the 340B Participating Entity or PHC upon one hundred twenty (120) days' written notice without cause or sooner by mutual consent.
- d. If this Agreement is terminated without a new agreement in effect to replace it, the parties acknowledge that PHC will not be able to report the 340B Participating Entity's 340B drug use to the State. The 340B Participating Entity agrees that upon termination of this Agreement, it will no longer provide 340B drugs to PHC members.
- e. Wrap-up Period. Any business reclassifications initiated prior to the termination date of this Agreement will still be completed, invoiced appropriately, and the 340B Participating Entity will remain responsible for submitting payment for any 340B Compliance Fees tied to those reclassified claims.

VIII. Mechanism of Notice

For the purposes of this Agreement, notice may be written and sent by US mail or hand delivered to Partnership HealthPlan of California, Attn: Pharmacy Department - 340B Compliance Program, 4665 Business Center Drive, Fairfield, CA 94534 or it may be sent via electronic communication (e-mail: 340BQIP@partnershiphp.org). In all cases, confirmation of receipt of the communication is required for timeliness to be valid.

IX. Further Agreements

All parties to this Agreement agree to take no action that violates 42 U.S.C. 1320a-7b (Section 1128B of the Social Security Act), also known as the "Anti-Kickback Statute." The 340B Participating Entity represents and warrants that it and all of its employees, agents, and subcontractors performing services related to this Agreement are not currently excluded from participation under federal health care programs pursuant to 42 U.S.C. 1320a-7, are not currently the subject of any pending exclusion proceeding under that section, and have not been adjudicated or determined to have

committed any action that would subject it to mandatory or permissive exclusion under that section for which such an exclusion has not been implemented. The parties to this Agreement agree that they are, and shall remain subject to so long as they remain a 340B Covered Entity, the statutes, rules, regulations, and other binding guidance adopted by the United States Department of Health & Human Services Center for Medicare & Medicaid Services and HRSA with respect to its oversight of the Medicaid and 340B programs, respectively.

X. Other Provisions

- a. **Dispute Resolution:** In the event that any dispute between the 340B Participating Entity and PHC arises out of this Agreement, it shall not result in a delay of services as required under this Agreement. However, subject to California Government Code sections 900 *et seq.*, any such dispute shall be resolved as required by the subsections below:
 - i. **Meet and Confer:** The parties agree to meet and confer on any issue that is the subject of dispute under this Agreement ("Meet and Confer"), as a condition precedent to arbitration under subsection (ii) below. The party seeking to initiate the Meet and Confer procedure (the "Initiating Party") shall give written notice to the other party describing in general terms the nature of the dispute, the Initiating Party's position, and identifying one or more individuals with authority to resolve the dispute on such party's behalf. The party receiving the notice (the "Responding Party") shall have ten (10) business days with which to respond to the notice. The response shall include the Responding Party's position and shall identify one or more individuals with authority to resolve the dispute on such party's behalf. The individuals so designated shall be known as the "Authorized Individuals." The Authorized Individuals shall meet at a mutually acceptable time and location within thirty (30) calendar days of the Initiating Party's notice and thereafter as often as necessary to exchange relevant information and to attempt to resolve the dispute. If the matter has not been resolved within sixty (60) calendar days of the Initiating Party's notice or if the Responding Party will not meet within thirty (30) calendar day, either party may submit the dispute to binding arbitration in accordance with the following procedures and shall give the other party written notice that the matter is being submitted to binding arbitration. All deadlines specified in this Meet and Confer procedure may be extended by mutual agreement of the parties. In addition, nothing in this subsection shall impede or limit the ability of the parties to submit the dispute to mediation for resolution.
 - ii. **Arbitration:** Upon written demand by either party, and after exhaustion of the Meet and Confer procedure set for in subsection (i) above, any dispute arising

out of this Agreement, including any issue regarding interpretation, validity, or termination, shall be referred to and submitted to mandatory binding arbitration pursuant to the California Arbitration Act (Code of Civil Procedure Sections 1280 et. seq.) The arbitration shall be administered by JAMS in accordance with the JAMS Comprehensive Arbitration Rules & Procedures by a single arbitrator in Solano County, California. If possible, the arbitrator shall be an attorney with at least 15 years of experience, including at least five years of experience in health care. The arbitrator's fees and expenses and the arbitration administrative fees shall be divided evenly between the parties. Each party shall bear its own costs and expenses, including attorneys' fees. The award or judgment of the arbitrator shall be accompanied by a written statement of the basis for the award or judgment and may be enforced by any court of competent jurisdiction. The arbitrator shall have no authority to provide a remedy or award damages that would not be available to a prevailing party in a court of law, and the arbitrator shall have no authority to award punitive damages. The award or judgment of the arbitrator shall be final and binding and shall not be subject to de novo judicial review. It is the express intention and understanding of the parties that each shall be entitled to enforce its respective rights under any provision of this Agreement through specific performance, in addition to recovering damages caused by a material breach of any provision thereof, and to obtain any and all other equitable remedies as may be awarded by the arbitrator. Notwithstanding the above, each party shall have the right to seek provisional remedies from a court of competent jurisdiction in accordance with California law. The provisions of this subsection (ii) shall survive termination of this Agreement.

- b. Entire Agreement: This Agreement, with its Attachments, constitutes the entire agreement between the parties governing the subject matter of this Agreement. This Agreement replaces any prior written or oral communications or agreements between the parties relating to the subject matter of this Agreement.
- c. Existing Contract: This Agreement does not supersede nor replace the existing Primary Care Provider, Specialty Provider, or Hospital Provider Contract between PHC and the 340B Participating Entity. If this Agreement conflicts with the Provider Contract between the Parties, the Provider Contract shall prevail.
- d. Subcontractors: The 340B Participating Entity may use subcontractors to perform its services under this Agreement. The 340B Participating Entity is responsible for their services to the same extent that the 340B Participating Entity would have been had the 340B Participating Entity performed the services without the use of a subcontractor.
- e. Amendment: Except as may otherwise be specified in this Agreement and an applicable Attachment, this Agreement (including its Attachments) may be amended

- only by both parties agreeing to the amendment in writing, executed by a duly authorized person of each party.
- f. Waiver/Estoppel: Nothing in this Agreement is considered to be waived by any party, unless the party claiming the waiver receives the waiver in writing. No breach of the Agreement is considered to be waived unless the non-breaching party waives it in writing. A waiver of one provision does not constitute a waiver of any other provision. A failure of either party to enforce, at any time, any of the provisions of this Agreement or to exercise any option which is herein provided in this Agreement will in no way be construed to be a waiver of such provision of this Agreement.
 - g. Force Majeure: Each party will take commercially reasonable steps to prevent and recover from disruptive events that are beyond its control and represents that it has backup systems in place in case of emergencies or natural disasters. If either party shall be, wholly or in part, unable to perform any or part of its duties or functions under this Agreement because an act of war, riot, terrorist action, weather-related disaster, earthquake, governmental action, unavailability or breakdown of equipment, or other industrial disturbance which is beyond the reasonable control of the party obligated to perform and which by the exercise of reasonable diligence such party is unable to prevent (each a "Force Majeure Event"), then, and only upon giving the other party notice by telephone, facsimile, or in writing within a reasonable time and in reasonably full detail of the Force Majeure Event, such party's duties or functions shall be suspended during such inability; provided, however, that in the event that a Force Majeure Event delays such party's performance for more than thirty (30) calendar days following the date on which notice was given to the other party of the Force Majeure Event, the other party may terminate this Agreement. Neither party shall be liable to the other for any damages caused or occasioned by a Force Majeure Event. Government actions resulting from matters that are subject to the control of the party shall not be deemed Force Majeure Events.
 - h. Counterparts: This Agreement may be executed by electronic signatures or in one or more counterparts, each of which shall be deemed an original, but all of which, together, shall constitute one agreement.
 - i. Severability: If any provision of this Agreement is held to be invalid or unenforceable by a court of competent jurisdiction, then the remaining portions of the Agreement shall be construed as if not containing such provision, and all other rights and obligations of the parties shall be construed and enforced accordingly.
 - j. Survival of Terms: Any provisions of this Agreement or any Attachments, which by their nature extend beyond the expiration or termination of this Agreement, and those provisions that are expressly stated to survive termination, shall survive the termination of this Agreement and shall remain in effect until all such obligations are satisfied.
 - k. Warranties: Except as expressly stated herein, there are no warranties, express or implied, by any party in connection with this Agreement. All warranties not

specifically stated herein, including warranties of merchantability or fitness for a particular purpose, are excluded and shall not apply to the products or services to be provided under this Agreement.

1. **Limitation of Liability:** In no event shall any party be liable to any other party, whether in contract, warranty, tort (including negligence, product liability or strict liability) or otherwise, for any indirect, incidental, consequential, special, exemplary, punitive, or similar damages (including without limitation damages for lost revenue, profit, business, use or data, or for any failure to realize savings or other benefits), even if advised of the possibility of any of the foregoing. The entire liability of any party to any other party under or in relation to this Agreement for any loss or damage, and regardless of the form of action shall be limited to proven, actual, out-of-pocket expenses that are reasonably incurred. In no event shall the aggregate liability of any party relating to or arising from this Agreement for any and all causes of action exceed \$100,000. This limitation on liability shall in no event be interpreted to apply to, or otherwise act to reduce, PHC's obligation to reimburse the 340B Participating Entity for 340B Covered Outpatient Drugs dispensed to PHC beneficiaries under this or any other agreement.
- m. **Medical Records:** All parties to this Agreement shall comply with all applicable state and federal laws and regulations regarding confidentiality of patient records, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Privacy Standards (45 C.F.R. Parts 160 and 164), the Standards for Electronic Transactions (45 C.F.R. Parts 160 and 162), and the Security Standards (45 C.F.R. Part 162) (collectively, the "Standards") promulgated or to be promulgated by the Secretary of Health and Human Services on and after the applicable effective dates specified in the Standards. Notwithstanding the foregoing, the parties shall be permitted to enter into such Business Associate Agreements as are permitted or required by HIPAA.
- n. **Confidential Information:** All Confidential Information (as defined below) shall be the property of the disclosing party. Each party agrees the receiving party shall (i) use at least the same degree of care to prevent unauthorized use and disclosure of disclosing party's Confidential Information as the receiving party uses with respect to its own Confidential Information (but in no case less than a reasonable degree of care); (ii) use the disclosing party's Confidential Information only in performance of the receiving party's obligations under this Agreement or for internal purposes to improve the quality of service performed under this Agreement; and (iii) except as otherwise expressly provided herein, not disclose or grant access to the disclosing party's Confidential Information to any third party, without the prior written consent of the disclosing party.

"Confidential Information" means non-public information that the disclosing party designates as being confidential to the receiving party or which, under

the circumstances surrounding disclosure ought to be treated as confidential by the receiving party, including without limitation, information received from others that the disclosing party, is obligated to treat as confidential. Confidential Information does not include information that (i) is or subsequently becomes generally available to the public other than by a breach of a confidentiality obligation; (ii) is already in the possession of receiving party prior to disclosing party's disclosure to receiving party; (iii) is independently developed by receiving party without use or reference to the disclosing party's Confidential Information; or (iv) becomes available to receiving party from a source other than the disclosing party other than by a breach of a confidentiality obligation.

Agreed to and accepted by:

340B PARTICIPATING ENTITY:

PHC:

Signature: _____
By: _____
Title: _____
Date: _____
Address: _____

Signature _____
By: Elizabeth Gibboney
Title: CEO
Date: _____
Address: 4665 Business Center Drive
Fairfield, CA 94534

Attachment A: Fee Schedule for 340B Compliance Program**340B claims for drugs dispensed through In-House or Contract Pharmacies**

340B Claim Type	340B Compliance Fee Breakdown
Drugs dispensed through IN-HOUSE PHARMACY or CONTRACT PHARMACY with claim appropriately flagged as 340B at Point-of-Sale (POS)	No fee
Drugs dispensed through IN-HOUSE PHARMACY but claim must be reclassified as 340B retrospectively via Clearinghouse*	\$2.75 per paid 340B drug claim (\$2.50 340BX Clearinghouse Fee + \$0.25 PHC 340B Compliance Fee)
Drugs dispensed through CONTRACT PHARMACY with retrospective 340B reclassification via Clearinghouse*	\$2.75 per paid 340B drug claim (\$2.50 340BX Clearinghouse Fee + \$0.25 PHC 340B Compliance Fee)

*See Section V.a.1 regarding basis for reclassification fees. These fees are subject to adjustment with proper notice and justification.

340B drug claim service lines not flagged appropriately by the 340B Participating Entity requiring intervention by PHC to add the UD modifier.

Age of claim service line	340B Compliance Fee
0 – 90 days	\$2.75
91 -180 days	\$5.50
181 – 365 days	\$7.75
365 days +	\$10.00

Attachment B: Reporting requirements for 340B Drug Claim Compliance

1. **Contract Pharmacy 340B Drug Claims:**

- a. **Retrospective Claims:** A file extract which includes 340B approved claims will be submitted by the 340B Participating Entity or its 340B Administrator(s) to Clearinghouse for retrospective reclassification.
 - i. **Required fields:** The file format will be shared during the 340B Participating Entity's on-boarding process with Clearinghouse.
 - ii. **Timing requirements:** File extracts must be submitted each month for the previous month's 340B drug claims. File must be submitted between the 1st and 10th of each month ("monthly deadline").
 - iii. **File Format:** The File Format will be shared during the 340B Participating Entity's on-boarding process with Clearinghouse. Any file format changes will be communicated to the 340B Participating Entity within thirty (30) calendar days before the changes become effective.
 - iv. **File Recipients:** This file should be sent electronically and securely to Clearinghouse.

2. **In-House Pharmacy 340B Drug Claims:**

- a. If an In-House Pharmacy processes 340B drug claims at the POS, all claims for drugs purchased through the 340B program and submitted through a PBM must have "20" entered into the Submission Clarification Code (DK-420) to indicate the claim was a 340B claim.
- b. If an In-House Pharmacy submits claims directly to PHC, 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 the CMS-1500 format, UB-04 format, 837 file format, or other 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:** The 340B Participating Entity is responsible for insuring all 340B drug claims tied to PADs, Physician-Dispensed Drugs, or drug costs submitted as part of a fee-for-service, bundled, or capitated rate are flagged appropriately with the UD modifier.

- a. All claim service lines 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 the CMS-1500 format, UB-04 format, 837 file format, or other related format.

Attachment C: 340BX Clearinghouse Reclassification & Invoicing Schedule

Calendar Quarter	Calendar Month	340B Claim Reclassification	340BX Clearinghouse Invoice to 340B Participating Entity	340B Participating Entity Payment (Wire Transfer) to 340BX Trust Account	Monthly Payment of PHC 340B Compliance Fees from 340BX Trust Account to PHC
		By 20th	By 3rd	By 23rd	By 28th
Q1	JAN	DEC	SEP	SEP	SEP
Q1	FEB	JAN	OCT	OCT	OCT
Q1	MAR	FEB	NOV	NOV	NOV
Q2	APR	MAR	DEC	DEC	DEC
Q2	MAY	APR	JAN	JAN	JAN
Q2	JUN	MAY	FEB	FEB	FEB
Q3	JUL	JUN	MAR	MAR	MAR
Q3	AUG	JUL	APR	APR	APR
Q3	SEP	AUG	MAY	MAY	MAY
Q4	OCT	SEP	JUN	JUN	JUN
Q4	NOV	OCT	JUL	JUL	JUL
Q4	DEC	NOV	AUG	AUG	AUG

Example: In the month of January 2019, the following actions will take place:

- By the 20th day of the month, the 340B claims from December 2018 (the month prior) will be reclassified.
- By the 3rd day of the month (unless the 3rd day of the month falls on a weekend or holiday), Clearinghouse will send an invoice to the 340B Participating Entity for all fees associated with the reclassification of the September 2018 340 claims (four months prior).
- By the 23rd day of the month (unless the 3rd day of the month falls on a weekend or holiday), the 340B Participating Entity will submit payment for the fees associated with the September 2018 claims (four months prior) as per the invoice submitted by Clearinghouse.
- By the 28th day of the month (unless the 3rd day of the month falls on a weekend or holiday), Clearinghouse will transfer the PHC 340B Compliance Fees associated with the


September 2018 claims (four months prior), as per the invoice submitted by Clearinghouse, from the 340BX Trust Account to PHC's bank account.

Attachment D: Types of Changes to 340B Participating Entity's 340B Program that must be reported to PHC (using form under Attachment E)

Type of Change	Timeframe for reporting change to PHC*
340B Participating Entity contracts with a new 340B Administrator	Immediately
340B Participating Entity terminates a contract with a 340B Administrator	Immediately
New 340B Participating Entity child site/associated site/grantee becomes eligible to participate in 340B Program	60 days or more prior to effective date
340B Participating Entity site is terminated from the 340B Program	60 days or more prior to effective date
New Contract Pharmacy is added to 340B Participating Entity's Pharmacy Network	60 days or more prior to effective date
Contract Pharmacy is removed from the 340B Participating Entity's Pharmacy Network	60 days or more prior to effective date
340B Participating Entity opens an In-House Pharmacy	60 days or more prior to effective date
340B Participating Entity closes an In-House Pharmacy	60 days or more prior to effective date
Any change to Authorizing Official or Primary Contact as outlined on OPA 340B Database	Immediately

***If it is not possible for a 340B Participating Entity to provide notification of a change within the timeframe noted in the table, the 340B Participating Entity should notify PHC of the change as soon as possible via a change notification form and should include the details regarding the delay.**

Attachment E: Change Notification Form for reporting changes to PHC**

	Partnership HealthPlan of California 340B Compliance Program Change Notification
Date of Notification	<input type="text" value=""/>
340B Participating Entity Name	<input type="text" value=""/>
Contact Name	<input type="text" value=""/>
Contact Title	<input type="text" value=""/>
Contact Phone Number	<input type="text" value=""/>
Contact e-mail address	<input type="text" value=""/>
DESCRIPTION OF CHANGE	
Type of Change	Choose an item. Please Select One <input type="text"/>
Change Details Examples: Name of site or pharmacy, 340B ID #, Address, Contact Information, etc. If applicable, the information provided should match column headers from the respective attachment from the agreement.	<input type="text"/>
Effective Date of Change:	<input type="text" value=""/>
<p>Please email form to the following email: 340BQIP@partnershiphp.org</p> <p>Submit Form</p>	
<p>Eureka Fairfield Redding Santa Rosa (707) 863-4414 340BQIP@partnershiphp.org</p>	

**This form will be sent to the 340B Participating Entity following execution of the 340B Compliance Program Agreement.

Attachment F: Entities covered under this Agreement

340B ID#	CE ID#	Entity Name	Entity Sub Division Name	Site NPI	Consents to having claims information sent to 340BX Clearinghouse (Yes or No)

If the 340B Covered Entity chooses to participate in PHC’s 340B Compliance Program, the 340B Covered Entity is to fill-in any missing information in the table above before submitting the signed agreement.

Attachment G: 340B Administrators associated with 340B Participating Entity

340B Administrator (Organization Name)	Contact information (Contact person, title, phone number, e-mail address)	Consents to send claims information to 340BX Clearinghouse (Yes or No)

If the 340B Covered Entity chooses to participate in PHC’s 340B Compliance Program, the 340B Covered Entity is to fill-in any missing information in the table above before submitting the signed agreement.

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Attachment H: Contract Pharmacies registered on 340B OPAIS

Pharmacy Name	Pharmacy Contact information (Contact person, title, phone number, e-mail address)	Effective date	NPI

If the 340B Covered Entity chooses to participate in PHC’s 340B Compliance Program, the 340B Covered Entity is to fill-in any missing information in the table above before submitting the signed agreement.

If the 340B Covered Entity choosing to participate in PHC’s 340B Compliance Program has no Contract Pharmacies, the 340B Covered Entity should complete the table above by noting “Not Applicable.”

Attachment I: In-House Pharmacies

Pharmacy Name	Pharmacy Contact information (Contact person, title, phone number, e-mail address)	Effective date	NPI	Consents to send claims information to 340BX Clearinghouse if deemed necessary (Yes or No)

If the 340B Covered Entity chooses to participate in PHC’s 340B Compliance Program, the 340B Covered Entity is to fill-in any missing information in the table above before submitting the signed agreement.

If the 340B Covered Entity choosing to participate in PHC’s 340B Compliance Program has no In-House Pharmacies, the 340B Covered Entity should complete the table above by noting “Not Applicable.”