

**Central California Alliance for Health**

**Alliance 340B Compliance Program**

**340BX Agreement**

This 340BX Agreement (this “Agreement”) is made and entered into, on this \_\_\_ day of \_\_\_\_\_, 2019, and effective on \_\_\_\_\_, 2019 (the "Effective Date"), by and between Santa Cruz-Monterey-Merced Managed Medical Care Commission, a California public entity, doing business as Central California Alliance for Health (the “Alliance”), and the County of Monterey, a political subdivision of the State of California, on behalf of its Monterey County Clinic Services (“340B Participating Entity”), with reference to the following facts:

WHEREAS, the Alliance is a public entity organized pursuant to Welfare and Institutions Code section 14087.54, Santa Cruz County Code Chapter 7.58, Monterey Municipal Code section 2.45.010, and Merced County Code Chapter 9.43;

WHEREAS, the Alliance and 340B Participating Entity have entered into agreement(s) for the provision of health care services;

WHEREAS, 340B Participating Entity is a 340B Covered Entity (defined below) that has agreed to participate in the Alliance’s 340B Compliance Program by signing this Agreement;

WHEREAS, the 1992 Veteran’s Health Care Act created Section 340B of the Public Health Services Act (“Section 340B”), which classifies certain 340B Covered Entities (defined below) to be eligible to purchase outpatient prescription drugs for their patients at favorable discounts from drug manufacturers who enter into drug purchasing agreements with the United States Department of Health and Human Services (“340B Program”);

WHEREAS, the Alliance and 340B Participating Entity desire to enter into a relationship by which the Alliance, through the services of a 340B Exchange (defined below), assists 340B Participating Entity in implementing 340B Program compliance requirements to avoid drug diversion and duplicate discounts;

WHEREAS, the purpose of this Agreement is to (i) define an agreed upon process for ensuring proper identification of 340B Covered Drugs (defined below) dispensed to Alliance Medi-Cal members to the State of California, so as to ensure compliance with DHCS (defined below) and HRSA (defined below) policy and federal law, (ii) support the mission of 340B Participating Entity to provide services to the most vulnerable members of the community, and (iii) help reinforce appropriate use of taxpayer/Medi-Cal funds in pharmaceutical costs.

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the parties hereto agree as follows:

## ARTICLE I.

### DEFINITIONS AND ACRONYMS

- a. 340B Covered Drugs: means a covered outpatient drug as defined in Section 340B prescribed by an authorized medical provider affiliated with 340B Covered Entity, including Legend Drugs, which, by federal law can be dispensed only pursuant to a prescription and which are required to bear the legend “Caution – Federal law prohibits dispensing without prescription” and which are subject to the limiting definition of “covered outpatient drug” set forth in Section 1927(k) of the Social Security Act, 42 USC 1396r-8(k)(2) & (3).
- b. 340B Covered Entity: means those health care service providers that are (i) eligible to purchase drugs at the 340B drug price as defined in Section 340B and (ii) currently enrolled in the 340B Program.
- c. 340B Exchange: The entity contracted with the Alliance to coordinate with various 340B Participating Entities, their 340B Third Party Administrators, and others in connections with the Alliance’s 340B Compliance Program, and perform data analysis and identification of 340B eligible pharmacy claims for the 340B Covered Entities participating in the Alliance’s 340B Compliance Program.
- d. 340B Third Party Administrator: A 340B Participating Entity’s subcontractor who administers such 340B Participating Entity’s 340B Program.
- e. 340BX Approved Claims: means pharmacy claims for 340B Covered Drugs administered or dispensed to Eligible Patients that meet the requirements identified by HRSA.
- f. 340BX Compliance Fee: means 340B Exchange’s fees set forth in Attachment A in consideration of the services performed by 340B Exchange as provided in this.
- g. 340BX Safety Net Claims File: means the file extract with specified information provided by each 340B Participating Entity or its 340B Third Party Administrator to 340B Exchange on a monthly basis that includes all 340BX Approved Claims. Such file extract must include, at a minimum, the following fields: Date of Service, Claim Date, NDC#, RX#, 340B ingredient cost (i.e., cost of goods sold) and Claim ID (Authorization Number).
- h. 340BX Settlement Invoice: means invoices prepared by 340B Exchange for the collection of the 340BX Compliance Fee and the Alliance Services Fee from 340B Participating Entity.
- i. 340BX Trust Account: 340B Exchange’s bank account in the name of NEC Networks, LLC (for 340B Exchange) at the Bank of San Antonio, or such other account as designated by the Alliance upon written notice to 340B Participating Entity. This account will be utilized by 340B Exchange as a holding account to deposit 340B related funds paid by 340B Participating Entity, and also to transfer funds to the Alliance’s bank account.
- j. Alliance Services Fee: means the fees charged by the Alliance to 340B Participating Entity as set forth in

Attachment A.

- k. Contract Pharmacy: A retail pharmacy dispensing 340B Covered Drugs on behalf of a 340B Covered Entity pursuant to a contract between the 340B Covered Entity and such pharmacy that aligns with the compliance elements of the 340B Program. All eligible Contract Pharmacies are registered with HRSA and listed on the OPA 340B Database:
- <https://340bopais.hrsa.gov/searchlanding>
- l. DHCS: is the State of California’s Department of Health Care Services, the agency responsible for administering the Medi-Cal program in California.
- m. Eligible Patients: means 340B Covered Entity outpatients who are Alliance Medi-Cal members and who 340B Participating Entity determines are eligible to purchase and/or receive 340B Covered Drugs, subject to the limiting definition of “Patient” set forth in 61 Fed. Reg. 55156 (1996), as the same may be modified or amended from time to time.
- n. Health Care Services Agreement: The written agreement between the Alliance and 340B Participating Entity whereby 340B Participating Entity agrees to provide health care services to the Alliance’s members, as amended from time to time.
- o. HRSA: United States Health Resources and Services Administration, the agency responsible for administering the 340B Program.
- p. In-House Pharmacy: A pharmacy that is owned by, and a legal part of, the 340B Covered Entity.
- q. OPA 340B Database: A database overseen by the United States Health Resources and Services Administration Office of Pharmacy Affairs which includes detailed information related to all 340B Covered Entities, Contract Pharmacies, and Manufacturers registered to participate in the 340B Program.
- r. PBM: A subcontractor of the Alliance that contracts with individual dispensing pharmacies to create a network of pharmacies to provide the infrastructure for the pharmacy benefit of the Alliance and meets the definition of a “pharmacy benefits manager” in California Business & Professions Code § 4430(j).
- s. 340B PAD: Any 340B Covered Drug provided or administered by the 340B Covered 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.
- t. Provider Manual: means that document or series of documents created, maintained, updated and distributed from time to time by the Alliance that describes the Alliance’s policies and procedures relating to and provides administrative and program requirements for, the Alliance’s 340B Compliance Program. The Provider Manual is incorporated into this Agreement and made a part hereof.

## **ARTICLE II.**

### **ALLIANCE'S 340B COMPLIANCE PROGRAM**

- a. 340B Participating Entity agrees to participate in, and comply with the terms of, the Alliance's 340B Compliance Program.

## **ARTICLE III.**

### **340B COMPLIANCE FOR 340B CLAIM REPORTING**

- a. The Alliance has established a retrospective reclassification process to assist 340B Participating Entity in complying with the 340B Program. Such process 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.
- b. The Alliance's 340B Compliance Program does not currently include review of 340B PAD claims. Accordingly, 340B PAD claims will not be subjected to the retrospective reclassification process pursuant to this Agreement, and 340B Participating Entity must continue to properly flag 340B PAD claims in accordance with the Provider Manual.
- c. 340B Participating Entity shall be responsible for ensuring that all Contract Pharmacies, In-House Pharmacies, and 340B Participating Entity's 340B Third Party Administrators follow the reporting process set forth in Attachment C.
- d. 340B Participating Entity shall be responsible for monthly submission of the 340BX Safety Net Claims Files to 340B Exchange as set forth in Attachment B.
- e. If one or more of 340B Participating Entity's 340B Third Party Administrators is unwilling to work directly with 340B Exchange, 340B Participating Entity can submit the required data directly to 340B Exchange in the file format provided during the on-boarding process with 340B Exchange. All data files sent directly from 340B Participating Entity to 340B Exchange will be reclassified in the same manner as data files submitted by 340B Participating Entity's 340B Third Party Administrators for the fee outlined in Attachment A.
- f. In the event 340B Participating Entity or one of its 340B Third Party Administrators submits 340B claims for a Contract Pharmacy or In-House Pharmacy to the Alliance rather than submitting such claims to 340B Exchange for reclassification processing, such claims may not be compliant with 340B Program flagging requirements. Accordingly, 340B Participating Entity acknowledges that it will be the sole accountable party regarding any 340B claims that are not reviewed by 340B Exchange should an audit occur.
- g. 340B Participating Entity assumes all responsibility to provide timely, accurate, complete, and necessary data to enable the Alliance through 340B Exchange to perform its services hereunder, and to maintain records to verify the accuracy and completeness of such data. 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.

- h. 340B participating Entity shall adhere to all of the terms of the Provider Manual and the Alliance Pharmacy Department policies and procedures, including without limitation terms of coverage or payment, utilization review, and the Alliance's policies or procedures regarding formulary exceptions.

#### **ARTICLE IV.**

##### **RECLASSIFICATION FEES**

- a. 340B Participating Entity will pay reclassification fees for any 340B Approved Claim reclassified by the 340B Exchange. Payment of these reclassification fees is on a per paid 340B claim basis. The reclassification fees consist of a 340BX Compliance Fee and an Alliance Services Fee, as set forth in Attachment A.
- b. 340B Exchange will issue 340BX Settlement Invoices to 340B Participating Entity for the 340BX Compliance Fee and the Alliance Services Fee based on the prior 90-120 day period 340BX Safety Net Claims Files, commencing immediately after the 1<sup>st</sup> of the month following the Effective Date.
- c. No later than the 3<sup>rd</sup> day of each month, 340B Exchange will provide a monthly 340BX Settlement Invoice to 340B Participating Entity for the 340BX Compliance Fee and the Alliance Services Fee set forth in Attachment A. 340B Participating Entity shall make payment of the invoiced amount through Bank Electronic Fund Transfer (EFT) to the 340BX Trust Account on a monthly basis within twenty (20) calendar days of receipt of the 340BX Settlement Invoice. Attachment B, incorporated herein, sets forth the invoicing schedule associated with reclassification through 340B Exchange. Failure to pay the invoice within twenty (20) calendar days of receipt is grounds for termination of this Agreement by the Alliance as defined in Article VI (Terms and Termination of Agreement).
- d. If 340B Participating Entity determines that a reversal of a 340B claim is necessary, 340B Participating Entity must make such reversal of the 340B claim no later than ninety (90) days after the date of service for consideration of an adjustment to an impacted 340BX Settlement Invoice. Any reversal for a 340B claim made more than ninety (90) days after the date of service will be excluded from any adjustments to the 340BX Settlement Invoice provided by 340B Exchange.

#### **ARTICLE V.**

##### **REPORTING OF CHANGES TO 340B PARTICIPATING ENTITY'S 340B PROGRAM**

- a. It is the responsibility of 340B Participating Entity to report any changes to its internal 340B Program that may affect the terms and/or conditions of this Agreement. These changes require a minimum of 60 days' notice prior to the effective date. 340B Participating Entity shall immediately notify the Alliance and 340B Exchange of all changes to an authorizing official or primary contact for the Alliance 340B Compliance Program.
- b. 340B Participating Entity's failure to report any of the foregoing changes to the Alliance may be considered a material breach and grounds for termination of this Agreement based on Article VI (Terms and Termination

of Agreement).

## ARTICLE VI.

### TERMS AND TERMINATION OF AGREEMENT

- a. Term. The initial term of this Agreement shall begin on the Effective Date and shall continue for an initial term of two (2) years. Thereafter, the Agreement shall renew automatically for additional, successive terms of one (1) year until terminated by either party. This Agreement may be terminated by either party as provided herein.
- b. With Cause Termination of Agreement. Either the Alliance or 340B Participating Entity may terminate this Agreement for cause as set forth below, subject to the notice requirement and cure period set forth below.
  - i. Cause for Termination of Agreement by 340B Participating Entity. The following shall constitute cause for termination of this Agreement by 340B Participating Entity:
    - a. Breach of Material Term and Failure to Cure. The Alliance's material breach of any material term, covenant, or condition and subsequent failure to cure such breach as provided in Section iii, below.
  - ii. Cause for Termination of Agreement by Alliance. The following shall constitute cause for termination of this Agreement by the Alliance:
    - a. Breach of Material Term and Failure to Cure. 340B Participating Entity's material breach of any material term, covenant, or condition and subsequent failure to cure such breach as provided in Section iii, below.
    - b. Insolvency. 340B Participating Entity becomes insolvent, as reasonably determined by the Alliance.
    - c. Non-Payment. Failure by 340B Participating Entity to make any payments due 340B Exchange hereunder within twenty (20) calendar days of receipt of the 340BX Settlement Invoice.
  - iii. Notice of Termination, Cure Period and Effective Date of Termination. The party asserting cause for termination of this Agreement (the "terminating party") shall provide written notice of termination to the other party specifying the breach or deficiency with sufficient information to allow the receiving party to identify the actions necessary to cure such breach. The party receiving the written notice of termination shall have thirty (30) calendar days from the receipt of such notice to cure the breach or deficiency to the satisfaction of the terminating party (the "Cure Period"). If such party fails to cure the breach or deficiency to the reasonable satisfaction of the terminating party within the Cure Period or if the breach or deficiency is not curable, the terminating party shall have the right to provide written notice of failure to cure the breach or

deficiency to the other party following expiration of the Cure Period. The Agreement shall terminate thirty (30) calendar days following receipt of the written notice of failure to cure or at such later date as may be specified in such notice.

c. Automatic Termination:

- i. This Agreement will be immediately terminated without recourse if the State or Federal Government deems the 340B Program, the Alliance's participation therein, or any aspect of this Agreement or the 340B Exchange Contract to be not legally permissible.
- ii. This Agreement will be immediately terminated without recourse if 340B Participating Entity no longer holds an active Health Care Services Agreement with the Alliance.

d. Termination Without Cause. Either party may terminate this Agreement without cause at any time by giving the other party at least one hundred twenty (120) days prior written notice.

e. Termination without New Agreement in Place. If this Agreement is terminated without a new agreement in effect to replace it, the parties acknowledge that the Alliance will terminate reporting 340B Participating Entity's Contract Pharmacy and In-House Pharmacy 340B drug use to the State as of the termination effective date of the Agreement.

f. Wrap-up Period. Any 340B Approved Claims reclassifications initiated prior to the termination date of this Agreement will still be completed, invoiced appropriately, and 340B Participating Entity will remain responsible for submitting payment for any 340BX Compliance Fees and Alliance Services Fees tied to those reclassified claims.

## **ARTICLE VII.**

### **OTHER PROVISIONS**

a. Disputes Between 340B Participating Entity and the Alliance. Any claim, dispute, or other matter arising out of, relating to, or in any way connected with this Agreement, shall be addressed through the Alliance's provider dispute resolution procedure as set forth in the Provider Manual. If the procedure set forth in this Section has been exhausted and such matter is not resolved to the satisfaction of the parties, either party may pursue any available legal remedy. The Alliance retains all immunities applicable to public entities to which it is entitled by law.

b. Entire Agreement. This Agreement, with its Attachments, and Amendments hereto, and the Provider Manual contain all the terms and conditions agreed upon by the parties regarding the subject matter of this Agreement. Any prior agreements, promises, negotiations or representations of or between the parties, either oral or written, relating to the subject matter of this Agreement, which are not expressly set forth in this Agreement are null and void and of no further force or effect.

c. Existing Contract. This Agreement does not supersede nor replace the existing Health Care Services

Agreement(s) between the Alliance and the 340B Participating Entity. In the event of a conflict between this Agreement and the Health Care Services Agreement(s) between the parties, the Health Care Services Agreement(s) shall govern.

- 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 provided herein, no amendments or modifications to this Agreement shall be valid unless (i) such amendments or modifications are made in writing and signed by both parties and (ii) all required regulatory approvals are obtained.
  - i. Legally Required Modifications. The Alliance may amend this Agreement at any time in order to comply with applicable law or any requirements of a private sector Accreditation Organization, as reasonably interpreted by the Alliance. The Alliance shall notify 340B Participating Entity of such amendment. Such amendment shall be effective upon written notice to 340B Participating Entity, and shall not require written consent.
    - 1. DHCS Contract Modifications. The Alliance shall notify 340B Participating Entity of new requirements added to the Alliance's contract with DHCS that are relevant to the 340B Participating Entity's performance under this Agreement in advance of the effective date of the requirement. Such notice shall constitute an amendment to this Agreement and such amendment shall not require consent. 340B Participating Entity must comply with the new requirement within 30 days of the effective date, unless otherwise instructed by DHCS.
  - ii. Non-Material Amendments to Agreement. The Alliance may notify 340B Participating Entity of amendments to non-material terms of this Agreement. Such amendments shall be effective upon written notice to 340B Participating Entity, and shall not require written consent.
- f. Waiver of Breach. The waiver by either party to this Agreement of a breach or violation of any provision of this Agreement shall not operate as or be construed to be a waiver of any subsequent breach or violation thereof.
- g. Force Majeure. The obligations of either party to perform under this Agreement will be excused during each period of delay caused by acts of God and other extraordinary events ("Force Majeure Event"), such as war, riot, insurrection, civil commotion, sabotage, strike or other labor disturbances, fire, flood, earthquake, accidents, explosions that damage plants or facilities, shortages of power or materials, acts or orders of governmental authorities, or any other cause reasonably unavoidable, unforeseeable, and beyond the control of the affected party. In the event that either party ceases to perform its obligations under this Agreement due to the occurrence of a Force Majeure Event and its expected duration is thirty (30) days or less, the non-performing party shall take all reasonable steps to recommence performance of its obligations under this Agreement as soon as possible. In the event that any Force Majeure Event delays a party's performance for more than thirty (30) days following notice by such party pursuant to this Agreement, the other party may

terminate this Agreement immediately upon written notice to such party.

- 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. Invalidity of Sections of Agreement. The unenforceability or invalidity of any paragraph or subparagraph of any section or subsection of this Agreement shall not affect the enforceability and validity of the balance of this Agreement.
- 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.
- l. 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, 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. Without limiting the applicability of the foregoing sentence, 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, (i) the Alliance's obligation to reimburse the 340B Participating Entity for 340B Covered Drugs dispensed to Alliance members under this or any other agreement, (ii) the indemnification obligation set forth in Section VII.q below, or (iii) the gross negligence or willful misconduct of the party seeking the protection of this Section.
- m. HIPAA Compliance. 340B Participating Entity represents and warrants that it is presently and shall remain at all relevant times compliant with the requirements of the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"). 340B Participating Entity represents and warrants with respect to all Protected Health Information ("PHI"), as defined under 45 C.F.R. § 164.501, that it is a Covered Entity under 45 C.F.R. Section 164.501 (and not a business associate of the Alliance), and that it shall use all appropriate safeguards to prevent the use or disclosure of PHI other than as allowed by applicable law.
- 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.

- i. "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.
- o. Independent Contractor Relationship. The relationship between the Alliance and 340B Participating Entity is an independent contractor relationship. Neither 340B Participating Entity nor its employees or agents are employees or agents of the Alliance. Neither the Alliance nor its employees or agents are partners, employees or agents of 340B Participating Entity.
- p. Notices. All notices required or permitted by this Agreement shall be in writing and may be delivered in person or may be sent by registered or certified mail or U.S. Postal Service Express Mail, or by Federal Express or other overnight courier that guarantees next day delivery, or by facsimile transmission. The address or facsimile number specified on the signature page shall be the addresses for delivery or mailing of notice. The parties may change the names, addresses, and facsimile numbers noted above through written notice in compliance with this Section. In all cases, confirmation of receipt of the communication is required for timeliness to be valid.
- q. Indemnification. 340B Participating Entity shall indemnify and hold harmless the Alliance and its directors, officers, employees, affiliates and agents against any claim, loss, damage, cost, expense or liability (including reasonable costs of defense) arising out of or related to a breach of legal duty or breach of this Agreement by 340B Participating Entity, its employees or agents of any services to be performed or arranged by 340B Participating Entity under this Agreement; provided, however, that 340B Participating Entity shall not be responsible for indemnifying the Alliance to the extent such claim for indemnity is caused by a breach of legal duty or breach of this Agreement by the Alliance.
- r. Assignment. Neither this Agreement nor any portion of this Agreement shall be assigned, transferred or pledged in any way by 340B Participating Entity and shall not be subject to execution, attachment or similar process without the prior written consent of the Alliance. A change of ownership through the sale of 340B Participating Entity's stock or assets shall be deemed an assignment requiring consent pursuant to this Section.
- s. Incorporation of Attachments. The schedules, exhibits, addenda, and attachments to this Agreement and the

Provider Manual are integral parts of this Agreement and are incorporated in full herein by this reference.

**ARTICLE VIII.**

**GOVERNING LAW & REGULATORY COMPLIANCE**

- a. Governing Law. This Agreement and the rights and obligations of the parties hereunder shall be construed, interpreted, and enforced in accordance with, and governed by, the laws of the State of California, except where preempted by federal law, and the laws of the United States of America. Each party agrees that it shall bring any action in respect of any claim arising under or relating to this Agreement exclusively in the courts of the State of California and the federal courts of the United States of America located in Santa Cruz County, Monterey County or Merced County, State of California.
  
- b. Antifraud Plan. 340B Participating Entity agrees to comply with the Alliance’s antifraud plan, as detailed in the Provider Manual. 340B Participating Entity will immediately notify the Alliance of (i) investigations of 340B Participating Entity or 340B Participating Entity’s employees in which there are allegations relating to fraud, waste or abuse, and (ii) suspected cases where there is reason to believe that an incident of fraud, waste or abuse has occurred.
  
- c. Compliance with Law. 340B Participating Entity and any subcontractor to 340B Participating Entity shall comply with the Program Requirements set forth in the Provider Manual, in the Attachments hereto, and the regulatory compliance and flow-down provisions in the Health Care Services Agreement, which are incorporated herein by this reference. Any provisions required to be included in the Agreement by applicable law, including the Knox-Keene Health Care Service Plan Act of 1975 (Cal. Health & Safety Code Section 1340 et seq.) and the regulations promulgated thereunder, shall be binding upon and enforceable against the parties to the Agreement and shall be deemed incorporated herein whether or not expressly set forth in the Agreement, including the exhibits hereto.

IN WITNESS WHEREOF, each signatory of this Agreement represents and warrants individually on behalf of himself or herself, and the party on whose behalf he or she executes this Agreement, that he or she is duly authorized to execute this Agreement.

CENTRAL CALIFORNIA ALLIANCE FOR  
HEALTH

THE COUNTY OF MONTEREY  
TaxID: 946000524

By: \_\_\_\_\_

By: \_\_\_\_\_

Print Name: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Alliance Address and Facsimile Number for Notices:

340B Participating Entity Address and Facsimile Number for Notices:

Central California Alliance for Health

ATTN: Provider Services

1600 Green Hills Road

Scotts Valley, CA 95066

Facsimile Number: 831-430-5857

Street: \_\_\_\_\_

City, State ZIP: \_\_\_\_\_

Facsimile Number: (\_\_\_\_) \_\_\_\_\_

**Attachment A:**

**Fee Schedule for Alliance 340B Compliance Program**

<b>340B Claim Type</b>	<b>Fee Breakdown</b>
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 340B Exchange	\$6.00 per paid 340B prescription claim (\$3.50 340BX Compliance Fee + \$2.50 Alliance Services Fee)
Drugs dispensed through CONTRACT PHARMACY but claim must be reclassified as 340B retrospectively via 340B Exchange	\$6.00 per paid 340B prescription claim (\$3.50 340BX Compliance Fee + \$2.50 Alliance Services Fee)

**Attachment B**

**340B Exchange Data and Information Exchange Timeline**

<b><u>TASK</u></b>	<b><u>FROM</u></b>	<b><u>TO</u></b>	<b><u>BY DATE</u></b>
Send 340BX Settlement Invoice	340B Exchange	340B Participating Entity	By 3 <sup>rd</sup> day of month
Receive NCPDP V2.2 File	PBM	340B Exchange	7 <sup>th</sup> of month
Upload 340BX Safety Net Claims Files	340B Participating Entity	340B Exchange	10 <sup>th</sup> of month
Upload 340BX Consolidated Safety Net Claims File	340B Exchange	Alliance	23 <sup>rd</sup> of month
Upload 340BX Reclassification File (NCPDP V2.2 File)	340B Exchange	Alliance	23 <sup>rd</sup> of month
Upload invoice text file	340B Exchange	Alliance	23 <sup>rd</sup> of month
Upload 340B invoice reconciliation report	340B Exchange	Alliance	23 <sup>rd</sup> of month
Payment of 340BX Settlement Invoice	340B Participating Entity	340BX Trust Account	23 <sup>rd</sup> of month
Transfer all monthly Alliance Services Fees	340BX Trust Account	Alliance account	28 <sup>th</sup> of month
Send detailed report of monthly funds invoiced to and collected from 340B Participating Entities (reconciles 340BX Compliance and Alliance Services fees)	340B Exchange	Alliance	28 <sup>th</sup> of month

## Attachment C

### Reporting requirements for 340B Drug Claim Compliance

#### 1. Contract Pharmacy 340B Claims:

- a. 340BX Safety Net Claims File: A file extract which includes 340B Approved Claims will be submitted by the 340B Participating Entity or its 340B Third Party Administrator(s) to 340B Exchange for retrospective reclassification.
  - i. Required fields: The file format will be shared during the 340B Participating Entity's on-boarding process with 340B Exchange.
  - ii. Timing requirements: One file extract should be submitted each month. File should be submitted between the 1<sup>st</sup> and 10<sup>th</sup> of each month ("monthly deadline").
  - iii. File Format: The File Format will be shared during the 340B Participating Entity's on-boarding process with 340B Exchange. Any file format changes will be communicated to the 340B Participating Entity within ninety (90) calendar days before the changes become effective.
  - iv. File Recipients: This file should be sent electronically and securely to 340B Exchange.

#### 2. In-House Pharmacy 340B Claims:

If an In-House Pharmacy processes 340B prescription 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 to indicate the claim was a 340B claim.