



**PARTNERSHIP HEALTHPLAN OF CALIFORNIA
340B ADVISORY COMMITTEE ~ MEETING NOTICE**

Members: C. Dean Germano (Chair)
Darcie Antle
Viola Lujan
Kathryn Powell
Amir Khoyi, PharmD
Daniel Santi

PHC Staff: Elizabeth Gibboney, CEO
Robert L. Moore, MD, MPH, MBA, CMO
Patti McFarland, CFO
Wendi West, Northern Executive Director

Dina M. Cuellar, CHC, Director of Regulatory Affairs
Michelle Rollins, Director of Legal Affairs
Stan Leung, PharmD, Pharmacy Services Director
Dawn R. Cook, Pharmacy Services Program Manager

cc: Sonja Bjork, COO, PHC

FROM: Dawn R. Cook
DATE: March 2, 2018

SUBJECT: ADDITIONAL 340B ADVISORY COMMITTEE MEETING FOR 2017

The 340B Advisory Committee will meet as follows and will continue to meet biannually. Please review the Meeting Agenda and attached packet, as discussion time is limited.

DATE: Wednesday, March 7, 2018 **TIME: 1:00 p.m. – 2:30 p.m.**

LOCATIONS: Video Conferencing and/or Conference Call

Partnership HealthPlan of CA Solano Conference Room 4665 Business Center Drive Fairfield, CA 94534 <i>*Please Park in Front of Bldg. *Ask the receptionist to call Dawn R. Cook</i>	PHC Redding Office 3688 Avtech Parkway Redding, CA 96002 <i>*Ask for Susie</i>	PHC Santa Rosa Office 495 Tesconi Circle Santa Rosa, CA 95401 <i>*Ask for Sheila</i>
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Please contact Dawn R. Cook at (707) 419-7979 or e-mail 340BQIP@partnershiphp.org if you are unable to attend.

**REGULAR MEETING OF
PARTNERSHIP HEALTHPLAN OF CALIFORNIA'S
340B ADVISORY COMMITTEE - MEETING AGENDA**

Date: March 7, 2018 Time: 1:00 p.m. – 2:30 p.m. Location: PHC

<i>Welcome / Introductions</i>				
	<i>Topic</i>	<i>Lead</i>	<i>Page #</i>	<i>Time</i>
I.	Public Comments	Speaker	N/A	1:00 pm
II.	Opening Comments	Chair	N/A	1:04 pm
III.	Approval of Minutes	Chair	3 - 12	1:08 pm
IV.	Standing Agenda Items			
1.	Partnership HealthPlan of California (PHC) 340B Compliance Program Update	Dawn R. Cook	15 - 16	1:10 pm
V.	Old Business			
1.	Changes to the 340B Compliance Program Agreement	Dawn R. Cook	17	1:20 pm
2.	DHCS notification regarding 340B flags and manufacturers seeking refunds for rebates	Dawn R. Cook	18	1:33 pm
VI.	New Business			
1.	Walgreens and submission of 340B claims data	Dawn R. Cook	19	1:45 pm
2.	Governor's Budget Proposal for 2018-2019 and the 340B Program in California	Dawn R. Cook	20	1:55 pm
3.	PHC Webinar: Managing the 340B Enigma - PHC's Journey Through the 340B Program	Dawn R. Cook	21	2:10 pm
VII.	Additional Items			
1.	340B Compliance Program Agreement - Draft for changes before July 2018	Dawn R. Cook	25 - 48	N/A
2.	Draft of Third Major Amendment for all Current Agreements	Dawn R. Cook	49 - 60	N/A
VIII.	Adjournment			



PARTNERSHIP HEALTHPLAN OF CALIFORNIA (PHC)

Minutes of the Meeting

PHC 340B Advisory Committee held at PHC Fairfield Office

4665 Business Center Drive, Fairfield, California 94534

Napa/Solano Room

September 13, 2017 – 10:00 a.m. to 11:30 a.m.

Commissioners Present / via Teleconference (TC):

Viola Lujan (Acting Chair); Julie Johnston; Amir Khoyi, PharmD; Kathryn Powell

Staff Present:

Robert Moore, MD, MPH, CMO; Patti McFarland, CMO; Stan Leung, PharmD; and Dawn R. Cook

PUBLIC COMMENTS

None presented.

WELCOME/INTRODUCTION

Brief introductions were made.

AGENDA ITEM I – OPENING COMMENTS

None presented.

AGENDA ITEM II – APPROVAL OF MINUTES

The minutes from the 340B Advisory Committee Meeting on March 1, 2017 were approved. There were no abstentions.

AGENDA ITEM III – STANDING AGENDA ITEMS

PHC 340B Compliance Program Update

340B Compliance Program Update:

Ms. Cook noted that as of 9/12/17, there were 313 340B Covered Entities (sites) within PHC's 14 county service area that were eligible to participate in the 340B Program, of which 137 were hospitals. Ms. Cook noted that as of 9/12/17, PHC had 145 sites (27 entities) currently active in the 340B Compliance Program.

340BX Clearinghouse had received Walgreens 340B claims files from four (4) 340B Participating Entities, two (2) of which had already received invoices for those claims. A fifth 340B Participating Entity was working towards submission of Walgreens 340B claims. There was a sixth 340B Participating Entity that indicated they would also be submitting Walgreens 340B claims. PHC had seen an increase in the number of 340B Participating Entities able to use the data they received from Walgreens to submit claims to 340BX Clearinghouse to be flagged as 340B and help prevent duplicate discounts. Ms. Johnston had been promoting compliance with regard to reporting Walgreens 340B claims on every statewide call.

Ms. Johnston asked if PHC would be able to share file format used for resubmitting claims to the State with the 340B flags. Ms. Cook noted it was the same format used for all claims submissions to the State, but the “20” noting it was a 340B claim would be in the appropriate column. Ms. Cook would forward Ms. Johnston a PDF listing the NCPDP 2.2 fields used for anyone submitting to the State. Ms. Johnston also noted there had been a low matching rate with the Walgreens 340B claims, so 340BX Clearinghouse was reviewing that process. Ms. Cook noted the change in the matching criteria and some of what was discovered in the last month would be discussed later.

The 340B Compliance Program Agreement was under review by one (1) Federally Qualified Health Center with one (1) site. The Agreement was also under review for five (5) hospitals that would have 11 sites as of 10/1/17.

Invoices and wire transfers continued to be respectively delivered and received for 15 340B Participating Entities on a monthly basis. There were 15 340B Participating Entities that made monthly wire transfers to the 340BX Trust Account based on the invoices they received for each respective month.

Claims/Financial Summary:

Ms. Cook reviewed the claims and financial information regarding the quarter from 1/1/17 to 3/31/17. For the 1/1/17 to 3/31/17 quarter, the Total 340B Compliance Fees were \$41,362.75. Of that total, \$37,602.50 were 340BX Compliance Fees and \$3,760.25 were PHC 340B Compliance Fees. There were 13,583 340B Paid Matched Claims for the quarter. Ms. Cook noted this was the first quarter the Walgreens claims were represented in the data.

Ms. Cook commented that the claims counts tended to fluctuate quite a bit across the board, but the reason was unknown. Ms. Johnston noted it could relate to the prescription filling patterns of patients. Ms. Johnston then stated Mr. Germano, CEO of Shasta Community Health Center (SCHC), observed that Open Door Community Health Center (ODCHC) used to have a higher claims counts than SCHC, but now they were quite low. Dr. Moore noted ODCHC had talked to PHC. Ms. Cook indicated there were some issues with regard to the change in their 340B Administrator, which had been addressed and corrected. There would be a significant increase in the number of claims seen at first due to older claims being reclassified, but in a few months, everything would balance out again.

In response to an inquiry from Ms. Lujan regarding the number of Walgreens 340B claims reported, Ms. Cook noted PHC did expect to see an increase in the number of Walgreens 340B claims, as more 340B Participating Entities were beginning to submit that claims information to 340BX Clearinghouse. Ms. Cook was reminding 340B Participating Entities that stated Walgreens was carving out for them to actually audit the claims to verify that fact, as there could be issues with them still carving-in without the entities' knowledge.

With regard to Dr. Moore asking about the dates tied to the claims being reported, Ms. Cook noted the process had changed mid-year. When an entity received an invoice now, it was for any claim that was processed/reclassified that month, whether it was an older claim or a current claim. Previously, older claims were retroactively documented for the month following the date of service, which caused issues with invoices.

Ms. Johnston asked if PHC had received any feedback from the State regarding the claims reclassified through 340BX Clearinghouse. Ms. Cook stated no, and PHC still had not received any communication back from the State regarding the submission of the updated 340B Compliance Program Agreement. The only communication Ms. Cook had with DHCS was with the Medi-Cal Rebate Department regarding their process for going after Manufacturer rebates including the timelines for that process. Dr. Moore asked Ms. Cook to share the process. PHC submitted claims data to the State, the data was uploaded to DHCS' automated system, and that system was programmed to look for these flags, whether it be a UD modifier for Physician-Administered Drugs (PADs) or the “20” for claims submitted on an NCPDP file. Claims with the appropriate flags were removed and set aside as 340B. If the claim was missing an appropriate flag, that claim was sent over to Medi-Cal Rebate Department, where it was automatically set-up for manufacturer rebate. The Medi-Cal Rebate Department team doesn't see the claim until after that invoice is produced to send to the manufacturer.

Ms. Cook noted not every 340B Covered Entity received those e-mails. The Medi-Cal Rebate Department looks at the Medicaid Exclusion File, even though it was not used for Medi-Cal Managed Care. If a 340B Covered Entity had submitted other claims that may have had a 340B flag, and then some claims were missing the flags, then Medi-Cal Rebate Department would send an e-mail to the entity indicating they may have committed a duplicate discount violation. The 340B Covered Entity was told it had two courses of action it could take. It could work with your Health Plan or County Organized Health System (COHS) to correct the claim or it could work with drug manufacturer to arrange for repayment. DHCS also indicated there was no cut-off date for submission of corrected claims. They could go back as far as they like.

Dr. Moore noted there was a caveat when submitting late claims, as DHCS monitored the timeliness of claims. DHCS could potentially leverage fines against PHC for having a lot of claims that were submitting late. Ms. Cook noted PHC was required to meet certain thresholds for Quality Measures for Encounter Data (QMED). For QMED, PHC had timeliness thresholds for

submission of our claims to the State, which were 90 days, 180 days, 365 days, and greater than 365 days. PHC, as a Health Plan, had to meet certain percentages for each of those thresholds. The State would accept corrected claims for any past date, but PHC, as a Health Plan, was still responsible for meeting timeliness thresholds. PHC would have to find a balance for these two conflicting requests. Ms. Cook discussed an example of this conflict with regard to ODCHC's older claims that needed to be submitted to the State. Any 340B Covered Entity with old claims to reclassify submitted a request for assistance. Ms. Cook had to contact PHC's Director of Electronic Data Interchange (EDI) to have him determine how reclassification of the older claims would affect the QMED percentages. It was approved, so 340BX Clearinghouse completed the reclassification. PHC had been able to accommodate all the requests of this nature received thus far, but the hope was to receive fewer and fewer requests. Dr. Moore stated that all of the late requests are going through the 340BX Clearinghouse, but we have to give them permission to reclassify late claims for those Contract Pharmacy claims.

Dr. Moore stated PHC was developing its next generation agreement to address those issues that were not foreseen. It will have to go through legal review, then brought to the committee. Dr. Moore stated another tidbit was that the State wanted all claims data 45 days after the end of each calendar quarter. Ms. Cook noted the Health Plan had 45 days from the end of the previous quarter to submit data to the State, as the State has to submit its request for rebates from the manufacturers by 60 days following the end of the quarter. Due to that schedule, the entities heard about the possible duplicate discounts after the fact.

With the 45 day requirement in mind, Dr. Moore stated PHC was considering a change to the fee schedule. The usual fee would apply if claims data is received within 45 days, but if it goes beyond that State deadline, PHC would increase the rate to help cover additional expenses. At the one year mark, PHC would likely instruct the 340B Covered Entities to contact the drug manufacturers regarding repayments. Ms. Cook noted she had started the redline of a new agreement, but putting completing it would take time as they take QMED timeframes into consideration compared to what is currently in the agreement. In response to a comment from Ms. Lujan regarding the fees seeming punitive, Dr. Moore noted they were not intended to be punitive, but to cover the costs of the additional work needed for reclassifying older claims. As for upfront, preventative measures and solutions, Ms. Cook noted that will be education for 340B Participating Entities because they would likely see an amendment based on the new agreement versus terminating the current agreements and reissuing new agreements as they did in 2016.

Returning to the topic of fluctuations in the number of 340B claims submitted and matched, Dr. Moore stated PHC would try to find a way to notice big variations that might flag that something was awry. Ms. Cook noted they were looking to have reports generated by 340BX Clearinghouse to monitor the Contract Pharmacy claims. With regard to the PAD claims and use of the UD modifier, Ms. Cook was working with PHC's Health Analytics team to create a report to monitor those claims. The Health Analytics team would create a report on a monthly basis, and Ms. Cook would review it for variations and provide updates to 340B Participating Entities on a monthly basis. This should help because the State used calendar quarters for seeking rebates, not rolling quarters. Ms. Johnston stated the reason they can't do a rolling quarter is due to the price changes for 340B drugs from the manufacturers. PHC would likely run a pilot with a few entities to see if sending these reports helps, and then launch it if it was successful.

Ms. Johnston asked if the substantially lower 340B Compliance Fees were enough to currently cover the costs that PHC was incurring for running the 340B Compliance Program. Dr. Moore noted a lot of new entities had joined, but an annual review would be needed for a proper assessment. PHC had picked the \$0.25 per paid 340B drug claim assuming program growth would be needed to be break even. Ms. Cook noted that PHC knew going into it that it was more important to provide this service to our community partners, so it was the cost of doing business. Based on the analysis PHC completed prior to the actual switch in fees, it would have required that almost every eligible 340B Covered Entity in the 14 county service area would have to join to break even. When the 340B Participating Entities add sites, it increases the number of claims, so that was a small example of growth. At this point, the fees were not technically covering the costs. Dr. Moore noted that if we do adopt the progressive fee schedule to cover the higher costs of late changes it could help.

Ms. Johnston asked if PHC had seen an increase in the number of 340B Covered Entities joining since the drastic drop in the fees. Ms. Cook noted the number of entities participating doubled since the new agreement was introduced. She stated that of those that had on-boarded in the last year, several only do PAD claims and flagging claims themselves with the UD modifier, so they came in knowing they weren't paying the fee. She felt word about the program had spread over the last year.

Dr. Moore noted 340BX Clearinghouse had bumps in the road as they tried to ensure a program they could market to other organizations. Ms. Cook noted that when communicating with entities, she was sure to separate CaptureRx from 340BX Clearinghouse, by only using the name 340BX Clearinghouse (or 340B Exchange). She noted these were two different programs. PHC had been able to work with 340BX Clearinghouse quite well, now having designated people to work with on a regular basis.

Ms. Lujan thought it would be helpful to provide an update regarding the 340B Compliance Program, such as at a consortia meeting. Ms. Cook had been working on a reintroduction letter to send to all of the 340B Covered Entities in PHC's 14 county service area regarding the updated program, but it was on hold as additional questions and possible changes arose. Dr. Moore

stated the update would be delayed due to work on the updated agreement, and perhaps waiting for approval from the State. When PHC sent the current 340B Compliance Program Agreement to the State, the attached message noted PHC would assume the program was still approved if there was no response, but PHC would prefer a response. Ms. Johnston noted she was pretty sure SCHC and ODCHC would be willing to provide testimonials about the amount of money participating in the program meant for their health centers, as the savings made a huge impact for those health centers. Based on all factors, Dr. Moore stated PHC would push to have the updated agreement ready in early 2018 for a start in April 2018. Ms. Cook noted it would also have to go before the committee. If an additional meeting was needed prior to March 2018, it would be scheduled.

AGENDA ITEM IV – OLD BUSINESS

There was no old business to address during this meeting.

AGENDA ITEM V – NEW BUSINESS

Planning for changes to the 340B Compliance Program and Agreement:

Ms. Cook noted PHC completed a major overhaul of the 340B Compliance Program in 2016 including revision of the 340B Compliance Program Agreement.

Over the last year, PHC's 340B Team had compiled a list of additional changes to the 340B Compliance Program Agreement. Some of the additional changes included the elimination of any reference to the Primary Care Provider (PCP) Quality Improvement Program (QIP), which for the 340B Compliance Program was tied to the Generic Prescription Rate. That was no longer going to be part of the PCP QIP as of 1/1/18, so that would no longer be a factor. Other changes included adding additional information regarding PADs including reclassification information and submission of requests for assistance. There would be clarification regarding timelines for reclassification by 340BX Clearinghouse and/or PHC, including due dates, number of attempts made to match claims, and consideration of reclassification assistance requests as it related to QMED. There would also be restructuring the fee schedule based on timeliness of data submission by 340B Participating Entities.

Based on the nature of some of the possible changes, PHC would have to undergo renegotiation of the agreement with 340BX Clearinghouse, which would likely produce an amendment. Such a negotiation would take many months, so looking for an April 2018 start for a new agreement seems fitting. If/when the 340B Compliance Program Agreement was updated, the 340B Compliance Program Agreement would also have to be updated and reviewed through all necessary committees.

Dr. Moore stated if there is no 340B Advisory Committee meeting until March 2018, a few committee members may be asked to review the draft early via e-mail for input and comment, and then final approval would be sought from the whole committee. Per Dr. Moore, after considering all attorneys that had provided input on the 340B Compliance Program Agreement, the 340B Team chose the one they felt would be best to provide advice on the new agreement. Ms. Cook was in communication with an attorney who was reviewing her obligations. Dr. Moore noted that since she also worked with Federally Qualified Health Centers (FQHCs), she had to get waivers signed for conflict of interest.

340BX Clearinghouse Update:

Ms. Cook noted there were two new members of the 340BX Clearinghouse team: Robert Carlson, Product Manager, and Matt Sullivan, 340B Exchange Manager. There was a gentleman named Raul Vadillo who provides IT support at 340BX Clearinghouse. Mr. Carlson and Mr. Sullivan were both new to 340BX Clearinghouse. Ms. Cook met Mr. Sullivan when he came to Fairfield for a meet and greet. Having these two gentlemen join 340BX Clearinghouse was a move forward as there was a time period wherein Ms. Cook had no direct contact at 340BX Clearinghouse, so she worked with Mr. Vadillo in IT, but he could not really speak to the operations side of the business.

Based on review of unmatched claims data and consideration of input from the 340B Participating Entities, there were changes made to the matching criteria used for the reclassification of the claims as 340B by 340BX Clearinghouse. One example of an issue was with Date of Service versus Date of Adjudication, so that was no longer the primary matching item. Ms. Cook confirmed Ms. Johnston's explanation that if a prescription was filled other than the date it was written, it would not match.

The new matching criteria were used for the first time during August 2017. There were still 3,842 unmatched 340B claims from the July 2017 claims data submitted. Of those unmatched claims, 3,785 claims (98.5 percent) did not match due to the Reason Code of "Prescription Reference Number." Additional analysis determined the reason for this was the timeline for submission of claims data to the State by PHC. Ms. Cook and Mr. Carlson reviewed the unmatched claims for all 340B Participating Entities that submitted claims. They saw that any claim from 7/14/17 and after did not match. Ms. Cook contacted the Director of EDI and asked for clarification regarding which claims were actually submitted to the State and when. In August 2017, the claims data sent was actually for the last two (2) weeks of June 2017 and the first two (2) weeks of July 2017, which accounted for the unmatched claims seen for the July 2017 file from 7/14/17 and later. In September 2017,

additional review would be done to see if the claims that did not match in August matched in September. If claims are matching by the second round, then not having an initial match for "Prescription Reference Number" would not be deemed an error, but due to time period for the claims that were submitted to the State. Based on that, two (2) rounds would be needed. At that time, three (3) attempts at matching were made, but that might have to be limited to two (2) based on additional analysis and consideration of QMED.

With regard to PHC's submission to the State and the time period for submitted claims, Dr. Moore indicated PHC could try to have 340BX Clearinghouse sync to our submission schedule, which Ms. Cook noted would have to be negotiated. Ms. Cook stated she was not sure that there was a specific date used by EDI to cut off the claims for submission, and as such it would not always occur on the same date. Ms. Cook stated they wanted to see how the new matching criteria affected matching over the next few months. Ms. Cook noted the remaining 57 unmatched claims had been addressed. Ms. Lujan asked to have the committee updated.

Ms. Cook explained that when an invoice was sent to a 340B Participating entity, an Excel spreadsheet listing all matched claims tied to that invoice was included. The hope was to send an unmatched claim report after each attempt at matching to the 340B Participating Entities, but after new matching criteria was in place for a few months. When those reports were sent out in the future, they would include an explanation regarding the submission timeframes, including mention that the Prescription Reference Number was tied to the submission date to the State, which would likely match the next month. Currently, 340BX Clearinghouse only sent reports upon request. In response to Ms. Lujan's question about the manner PHC was currently submitting claims data versus a full month cycle, Mr. Leung said it was likely tied to a four week turnaround based on two files received from MedImpact. Ms. Johnston noted the feedback PHC would provide with the unmatched reports was exactly what the State was looking for to close the loop back to the entities.

AGENDA ITEM VI – ADDITIONAL ITEMS

Additional comments:

Ms. Cook noted the next update e-mail will be issued in December 2017. The date for the next 340B Advisory Committee Meeting was to be determined, but it would be in March 2018.

Ms. Cook noted that Ms. Antle had still been the Interim Chair, but had not been named the Chair. It was determined that Ms. Cook would ask Ms. Antle if she was interested in the position. Whomever was chosen as the Chair, that information would have to be presented to the Board.

As Mr. Germano was unable to attend the meeting, Ms. Johnston would have him sign the meetings from the 340B Advisory Committee Meeting on 3/1/17 at a later time.

Documents:

The following documents were made available to the committee for review prior to commencement of the meeting:

- None

AGENDA ITEM VII – ADJOURNMENT

Meeting Adjourned: 11:00 a.m.
Respectfully submitted: Dawn R. Cook

The foregoing minutes were APPROVED AS PRESENTED on:

Viola Lujan, Acting Committee Chairman

Date

The foregoing minutes were APPROVED WITH MODIFICATION on:

Viola Lujan, Acting Committee Chairman

Date



PARTNERSHIP HEALTHPLAN OF CALIFORNIA (PHC)

Minutes of the Meeting

PHC 340B Advisory Committee held at PHC Fairfield Office

4665 Business Center Drive, Fairfield, California 94534

Napa/Solano Room

December 4, 2017 – 11:00 a.m. to 12:00 p.m.

Commissioners Present / via Teleconference (TC):

C. Dean Germano (Acting Chair); Viola Lujan;

Staff Present:

Elizabeth Gibboney, CEO, Robert Moore, MD, MPH, CMO, Michelle Rollins, Stan Leung, PharmD, and Dawn R. Cook

PUBLIC COMMENTS

None presented.

WELCOME/INTRODUCTION

Brief introductions were made. Daniel Santi, Director of Finance at Shasta Community Health Center, was present as a guest.

AGENDA ITEM I – OPENING COMMENTS

None presented.

AGENDA ITEM II – APPROVAL OF MINUTES

The minutes from the 340B Advisory Committee Meeting on 9/13/17 were not approved due to lack of quorum. These minutes will be reviewed for approval at the next 340B Advisory Committee Meeting.

AGENDA ITEM III – STANDING AGENDA ITEMS

PHC 340B Compliance Program Update

340B Compliance Program Update:

Ms. Cook noted that as of 12/1/17, there were 325 340B Covered Sites within PHC's 14 county service area that were eligible to participate in the 340B Program, of which 146 were hospitals. Ms. Cook noted that as of 12/1/17, PHC had 148 sites/340B IDs (27 entities/agreements) currently active in the 340B Compliance Program. Ms. Cook noted there would be an additional two (2) sites/340B IDs (one entity/agreement) active in the 340B Compliance Program effective 1/1/18.

340BX Clearinghouse had had received Walgreens claims files from five (5) 340B Participating Entities, four (4) of which had already received invoices for those claims.

Invoices continued to be delivered to 11 of the 340B Participating Entities on a monthly basis. Those 11 340B Participating Entities were making monthly wire transfers to the 340BX Trust Account based on the invoices they received for each respective month.

In response to a question from Mr. Germano, Ms. Cook indicated there were a few hospitals that are currently participating in PHC's 340B Compliance Program. The hospitals participating were Fairchild Medical Center, Marin General Hospital, Mendocino Coast District Hospital, NorthBay Healthcare Group, and Sonoma Valley Hospital. Ms. Cook also confirmed that Fairchild Medical Center, Mendocino Coast District Hospital, and NorthBay Healthcare Group had separate health clinics and Contract Pharmacies. In response to a question from Ms. Lujan, Ms. Cook indicated PHC's 340B Compliance Program covered a little less than half of the total number of 340B eligible IDs in its 14 county service area. Mr. Germano commented that hospitals may be slowing down their programs due to the issue with 340B and Medicare Part B, and they might consider dropping their 340B programs completely at some point if they were capable of doing so.

Claims/Financial Summary:

Ms. Cook reviewed the claims and financial information regarding the quarter from 4/1/17 to 6/30/17, noting the information now included claims submitted for Walgreens and claims submitted by WellPartner. Open Door Community Health Centers (ODCHC) terminated their agreement with CaptureRx, 340B Administrators, and WellPartner was the new 340B Administrator. WellPartner's claim counts would be listed separately on the invoices sent by 340BX Clearinghouse each month. WellPartner had successfully submitted claims to 340BX Clearinghouse. Per the information provided at the last 340B Advisory Committee meeting in September 2017, there was a delay in getting the claims from WellPartner reclassified, as they were doing a negotiation, and there were some issues with the transfer between WellPartner and 340BX Clearinghouse. They had been working it out, but PHC was not in the loop in the beginning. PHC became aware of the situation later and agreed to allow the reclassification of claims back to January 2017. That reclassification started in July 2017. Ms. Cook had seen the more recent transactions, which reflected successful file submission.

For the 4/1/17 to 6/30/17 quarter, the Total 340B Compliance Fees were \$40,009.75. Of that total, \$36,372.50 were 340BX Compliance Fees and \$3,637.25 were PHC 340B Compliance Fees. There were 11,089 340B Paid Matched Claims and 3,460 Walgreens 340B Paid Match Claims for the quarter, for a total of 14,549 Matched Claims for the quarter.

AGENDA ITEM IV – OLD BUSINESS

Planning for changes to the 340B Compliance Program and Agreement:

In April 2016, PHC completed a major overhaul of the 340B Compliance Program including revision of the 340B Compliance Program Agreement. This was followed by the execution of a major amendment in October 2016 when the final version of the current 340B Compliance Program Agreement was adopted. As a reminder, Ms. Cook noted some of the changes included the elimination of the 340B Quality Improvement Program (QIP) and decrease in the 340B Compliance Fees from \$4.50 per paid 340B drug claim to \$2.75 per paid 340B drug claim.

Since the last 340B Advisory Committee Meeting on 9/13/17, communication with the California Department of Health Care Services (DHCS) and Sutter Health, as well as amongst various PHC Departments had brought process information to light that would need to be updated in the 340B Compliance Program Agreement. Specifically, the use of the UD modifier and requests for the addition of that modifier would need to be addressed. Ms. Cook noted that in the current version of the 340B Compliance Program Agreement, if any of the 340B Participating Entities wanted to add the UD modifier to previously paid claims, they would contact the Pharmacy Services Program Manager, provide a list of claims, and PHC would have a process in place to assist them. However, recently PHC received requests from Sutter Health to have previously paid claims updated with the addition of the UD modifier. During those discussions, it was uncovered that based on the language in the PHC Medi-Cal Provider Manual, PHC's 340B Team could not make that request of our providers with regard to the addition of the UD modifier, as there was already a process in place to correct a modifier on a paid claim. In light of that, PHC will have to update that part of the 340B Compliance Agreement. Some language in the Provider Manual may actually be updated due to a lack of information regarding time frames for submission.

In response to a question from Mr. Germano, Ms. Cook noted that similar to the use of the "20" code for the pharmacy claims, the UD modifier must be listed on provider claim submissions processed by PHC's Claims Department to the State to indicate when drugs were purchased through the 340B Program. Some claims that should have the UD modifier may not have that flag for any number of reasons such as lack of education, system error, etc. The onus was on the 340B Covered Entity to include the modifier. PHC would not deny or reject a claim based on the UD modifier. If the modifier was on the claim, it flowed through to the State. Ms. Cook noted the two options DHCS noted in e-mails sent to the 340B Covered Entities when notifying them of possible duplicate discount violations were to get the claim corrected or work with the drug manufacturer to arrange for repayment of the savings they received. Of course, the 340B Covered Entity would try to get the claim corrected so that the savings weren't lost. As this process did not involve 340BX Clearinghouse, in good faith, PHC's 340B Team outlined in the

340B Compliance Agreement that requests for the addition of the UD modifier would go through them for tracking and educational purposes. The 340B Team was not aware of the information that was already in the Provider Manual regarding those sorts of changes, as in the addition of a modifier. Based on discussions with Provider Relations and Claims regarding a request from Sutter Health, all departments were getting on the same page and working towards updating documents for consensus on process.

Based on the possible changes that need to be made to the 340B Compliance Program Agreement, PHC would have to undergo renegotiation of the terms of the agreement with 340BX Clearinghouse, which would likely produce an amendment. The 340B Compliance Program with 340B Covered Entities nor the agreement between PHC and 340BX Clearinghouse outlined the specifics regarding how many reclassification attempts would be made. The current process was to have 340BX Clearinghouse attempt matching the claims three times. However, due to thresholds PHC must comply with for Quality Measures for Encounter Data (QMED) from the State, allowing those three attempts puts PHC past the first threshold. Ms. Cook noted the 340B Team felt two months or two attempts would be the compromise they would try to negotiate in an amendment with 340BX Clearinghouse, then address this in the 340B Compliance Program Agreement and an amendment for executed agreements.

When the 340B Compliance Program Agreement is eventually updated, the 340B Compliance Program Policy would be updated and sent for review by all appropriate committees. Once approved by all appropriate committees, it would be put on PHC's external website. The policy shared externally included the template for the agreement and the White Paper explaining the background of the 340B Program. In response to a question from Mr. Germano, Ms. Cook noted the agreement with 340BX Clearinghouse was a two year agreement with a one year Evergreen clause.

Changes to 340BX Clearinghouse matching criteria:

During the 340B Advisory Committee Meeting on 9/13/17, updates regarding 340BX Clearinghouse were provided. One of the updates was that the matching criteria used for reclassifying 340B claims was changed. At that point, there was only one month of claims data to review, July 2017, but the change in criteria seemed to have made a difference. The main reason for claims not matching was "Prescription Reference Number," but it was determined that was tied to the dates of claims which PHC submitted to the State in August 2017.

At the time of the 340B Advisory Committee Meeting on 9/13/17, a request was made for an update in the next few months.

As of November 2017, three (3) months of unmatched claims data has been reviewed. Based on analysis of the data, the "Prescription Reference Number" reason code is still the main reason for claims not matching. Once again, a connection was seen with the dates of the claims submitted to the State by PHC each month.

Based on this, there was some discussion about sending an unmatched claims report to the 340B Participating Entities on a monthly basis. Ms. Cook spoke with 340BX Clearinghouse, and they were still looking into making the report available. PHC hoped to provide the report to all 340B Participating Entities in the future. At that time, an unmatched claims report was only being provided to one 340B Participating Entity regularly, with it being otherwise available on an as-requested basis. Making that report available would allow issues on the 340B Covered Entity's side or the 340B Administrator side to be addressed in a timelier manner. The committee agreed this would be a good tool. Ms. Cook noted distributing the reports would help all parties involved. Ms. Cook reminded the committee of the biggest issue causing claims not to match which was discussed during the last 340B Advisory Committee. The biggest issue was tied to the reason code Prescription Reference Number. The Prescription Reference Number was not assigned until after a claim was submitted to the State by PHC. Ms. Cook noted the submission date to the State was somewhat fluid, being a moving four week period, not a set full month. Although this would continue to be an issue, PHC would still like to provide the information to the 340B Participating Entities, so they were always in the loop and have an idea of the time frames from month-to-month. PHC would provide an explanation in the beginning, explaining the "Prescription Reference Number" issue, as those were basically like pended claims if they were just a month older. If there were claims that were older with that reason code or other reason codes, then the 340B Covered Entity would investigate. Based on her review of unmatched claim reports that cover a one month period, 60 to 90 days, and more than 90 days, Ms. Cook stated the matching process by 340BX Clearinghouse has improved.

AGENDA ITEM V – NEW BUSINESS

340B Advisory Committee – Members Updates:

With regard to the Chair of the 340B Advisory Committee, previously Darcie Antle had been the interim chair. Ms. Cook noted she had been unable to reach Ms. Antle for several months. Ms. Gibboney noted Ms. Antle had been off the Board of Commissioners for PHC for quite a long time. Ms. Cook had tried to reach her via her office number, cell phone number, and e-mails, but there had been no response. Dr. Moore stated that if there was no communication from Ms. Antle by the time of the next committee meeting, he would take that information to the Board. Per Dr. Moore's request, C. Dean Germano, CEO of

Shasta Community Health Center, was asked to take on the role of Chair of the 340B Advisory Committee, and Mr. Germano accepted. He would be Interim Chair on 12/4/17, with his effective date as Chair being the date of the next Board Meeting on 12/6/17.

With regard to resignations, Julie Johnston resigned from the 340B Advisory Committee as she left her position at Shasta Community Health Center. This information would be presented to the Board for approval on 12/6/17. Ms. Cook stated Ms. Johnston was now employed by CaptureRx, the sister company of 340BX Clearinghouse. Mr. Germano noted that as Ms. Johnston was an advocate for the Health Centers, as well as PHC, she would hopefully be able to provide CaptureRx with important insight. Ms. Cook noted that Ms. Johnston was working for CaptureRx, the 340B Administration side, and not 340BX Clearinghouse, however, she would still be a good contact to have.

With regard to new members, Daniel Santi, Director of Finance at Shasta Community Health Center, had been nominated as a new member of the 340B Advisory Committee. This nomination would be presented to the Board for approval on 12/6/17. Dr. Moore and Ms. Gibboney had reviewed Mr. Santi's CV in advance and recommended we move forward with presenting the request for his inclusion to the Board.

DHCS notification and manufacturers seeking refunds for rebates:

On 10/24/17, PHC received an e-mail from DHCS identifying four (4) 340B Covered Entities that may not be including 340B identifiers on their County Organized Health System (COHS) Physician-Administered Drug (PAD) claims. The four (4) 340B Covered Entities identified were all participating in PHC's 340B Compliance Program. Ms. Cook noted that DHCS was referring to the use of the UD modifier.

In response to PHC's request for additional information, on 10/26/17, DHCS informed PHC that there were several large disputes they were working on at that time concerning possible duplicate discounts. Drug manufacturers could dispute claims as far back as 1992. The drug manufacturers were working with new contractors to review older periods and were becoming much more aggressive in disputing rebates.

In light of the information above, the 340B Team drafted two letters. The first letter was specifically for the four (4) 340B Covered Entities identified by DHCS, which may not be including 340B identifiers on their COHS PAD claims. Those letters were sent to the respective 340B Covered Entities via e-mail on 11/13/17. Ms. Cook noted she had yet to receive any response from those four (4) 340B Covered Entities. Mr. Germano stated he felt we would see more proposals regarding the 340B Program in the coming budget year for California.

The second letter was drafted as a friendly reminder regarding the use of the UD modifier, as well as a reminder that PHC had a 340B Compliance Program. This letter would be sent to all 340B Covered Entities in PHC's 14 county service area, with the exception of Sutter Health, Sonoma Valley Hospital, and the four (4) 340B Covered Entities that were sent the first letter. With regard to the exceptions, Ms. Cook noted that PHC had just been in discussions with Sutter Health regarding the use of the UD modifier. Sonoma Valley Hospital had signed on to the program very recently, at which time this specific topic was discussed. Sonoma Valley Hospital joined PHC's program in July 2017, having only become eligible for 340B in January 2017. Ms. Cook noted they had required some education regarding the use of the UD modifier. Then, there were the four (4) 340B Covered Entities that received a specific letter per DHCS, so they would not get the second letter. Ms. Cook noted PHC would include the 340B Participating Entities, so that the same information was being shared with everyone. Ms. Cook noted the second letter was reviewed by the 340B Team, as well as the Compliance Team, so it was ready to be sent out, but we wanted the 340B Advisory Committee to be made aware of it before it was distributed.

In response to a question from Ms. Lujan, Ms. Cook indicated the use of the UD modifier was noted in the current agreement, but again, it was up to the 340B Covered Entity to supply the UD modifier on all 340B claims sent to PHC's Claims Department. In the future, the part of the 340B Compliance Program Agreement regarding requesting corrections of claims that need the UD modifier added would be updated to make it clear that those requests must go through the Claims Department to process, as was already outlined in PHC's Medi-Cal Provider Manual. Ms. Cook noted at that point the only thing there was in writing regarding PHC's responsibility was tied to the CMS Final Rule stating the Health Plan had to have a mechanism in place to help exclude 340B information from the rebate process and prevent the duplicate discount. With regard to PHC's responsibility to change the claims, Ms. Cook noted additional clarification was needed, as the State has not laid out a clear process or guidelines. PHC did not have anything in writing stating PHC must update claims when requested. PHC needed some sort of document from the State to use as a reference, so that it can be included in the 340B Compliance Program Agreement, as well as any other communication. PHC tried to accommodate requests for assistance from entities, but as PHC had added responsibilities to the State as a Health Plan, like QMED mentioned earlier, adjustments were being made.

With regard to the UD modifier issue, Ms. Cook noted that the fact that DHCS gives the 340B Covered Entities two options for action when alerting them to possible duplicate discounts, that seemed to confirm ultimate responsibility for accurate claims data fell to the 340B Covered Entities and not the Health Plan. Dr. Moore if there was a duplicate discount the responsibility

fell to the 340B Covered Entity, as PHC and the State had no way of knowing which drugs were 340B, as they do not have access to 340B Drug Pricing information. PHC made all attempts to assist with claims correction, but there was no clear mandate that it was required. Ms. Cook stated the only way PHC could provide assistance as based on the information provided by the 340B Covered Entities, and again, it was written into the 340B Compliance Agreement that providing timely and accurate information was a requirement, which was also listed in the Final Rule. PHC in turn submitted timely information to the State to help prevent duplicate discount. There was an ongoing issue with conflicting priorities for PHC based on requirements from the State regarding encounter data. The State has set thresholds for better encounter data and was moving towards setting penalties if those thresholds were not met.

Dr. Moore noted communication from the State only stated the entities may have duplicate discount issues with no real confirmation. Dr. Moore stated PHC would not know if there was a duplicate discount, but the manufacturers can connect all the dots. The manufacturers could audit to determine if duplicate discounts were provided on any given drug. This could be a very big issue, especially if they went back to 1992. Ms. Cook noted they would likely focus on the most recent decade, but even that would be big. Dr. Moore stated this early meeting was held as this was a big issue, which could just be the tip of the iceberg. Mr. Germano stated it was his understanding the PHC is the only MCO that actually has an agreement approved by the State of California to do this. Dr. Moore said that was what the State was telling people, and they are currently not looking to approve any other programs.

Ms. Gibboney stated that Pharma may also be using some of the data they get from these expeditions, as part of their advocacy with the Federal Government about duplicate discounts and using the program in ways that they hadn't anticipated. Ms. Cook voiced concern that all of the recent activity from the Governor's budget proposal to the increased drug manufacturer audits pointed towards possible attempts in the future to completely eliminate the 340B Program for Medicaid in the State of California. Mr. Germano stated that from Covered Entity point of view, the money generated from 340B went directly into their programs and services, and it helped to underwrite a lot of things for which they had no other funding. Compliance was the key to stopping from losing it all.

Dr. Moore stated he and Ms. Gibboney called the early meeting to get this message out and talk about our strategy which was basically education. Mr. Germano noted legislators may need to help force the State to address concerns. The State needed to outline the process by which the Health Plans and the 340B Covered Entities could comply. Organizations like NAHC were aware of the issues, but he had not heard of any other action. Mr. Santi noted hospitals seemed to be the big targets, and perhaps that would be the stopping point. In response to a question from Dr. Moore, Ms. Gibboney noted the issue could be brought up again with LHPC. If the 340B Program was not a priority for in the budget in January 2018, then she thought that would be a good sign. Dr. Moore stated it would not hurt to mention concerns to legislators when seeing them for other issues.

AGENDA ITEM VI – ADDITIONAL ITEMS

Additional comments:

Ms. Cook noted the 340B Advisory Committee Schedule for 2018 included a meeting scheduled for 3/7/18 from 1:00 PM to 2:30 PM, an update letter to be sent in June 2018, and a meeting on 9/12/18 from 10:00 AM to 11:30 AM.

Documents:

The following documents were made available to the committee for review prior to commencement of the meeting:

- Letter to 340B Participating Entities identified by DHCS
- Reminder letter regarding the UD modifier

AGENDA ITEM VII – ADJOURNMENT

Meeting Adjourned: 12:00 p.m.
Respectfully submitted: Dawn R. Cook

The foregoing minutes were APPROVED AS PRESENTED on:

C. Dean Germano, Acting Committee Chairman

Date

The foregoing minutes were APPROVED WITH MODIFICATION on:

C. Dean Germano, Acting Committee Chairman

Date



PARTNERSHIP HEALTHPLAN OF CALIFORNIA


PHC 340B Advisory Committee Meeting

3-7-18


Agenda


- 
- 340B Compliance Program Update

- 
- Changes to the 340B Compliance Program Agreement

- 
- DHCS notification regarding 340B flags and manufacturers seeking refunds for rebates

- 
- Walgreens and submission of 340B claims data

- 
- Governor's Budget Proposal for 2018-2019 and the 340B Program in California

- 
- PHC Webinar: Managing the 340B Enigma - PHC's Journey Through the 340B Program

340B Compliance Program Update

- As of 3/1/18, there were 333 340B Covered Sites within PHC's 14 county service area, 144 of which are hospitals.
- There are 153 sites/340B IDs (28 entities/agreements) currently active in the 340B Compliance Program.
- At this point, no additional 340B Covered Entities are being invited to join the 340B Compliance Program.
- Invoices are being delivered to 18 340B Participating Entities on a monthly basis.
- As of 3/1/18, there were 18 340B Participating Entities that made monthly wire transfers to the 340BX Trust Account based on the invoice received for that respective month.

Claims/Financial Summary

Claims/Financial summary for 7/1/17 to 9/30/17

7/1/17 to 9/30/17									
Entity	340B Paid Match Claim Count	340B Reversal Claim Count	Walgreens 340B Paid Match Claim Count	Walgreens 340B Reversal Match Claim Count	Wellpartner 340B Paid Match Claim Count	Wellpartner 340B Reversal Match Claim Count	340BX Compliance Fee	PHC 340B Compliance Fee	Total 340B Compliance Fees
Alliance Medical Center	92	2	0	0	0	0	\$ 230.00	\$ 23.00	\$ 253.00
CommuniCare Health Centers	775	1	301	1	0	0	\$ 2,690.00	\$ 269.00	\$ 2,959.00
Fairchild Medical Center	1,681	13	0	0	0	0	\$ 4,202.50	\$ 420.25	\$ 4,622.75
Hill Country Community Clinic	387	1	0	0	0	0	\$ 967.50	\$ 96.75	\$ 1,064.25
La Clinica De La Raza	0	0	1,363	5	0	0	\$ 3,407.50	\$ 340.75	\$ 3,748.25
Long Valley Health Center	43	0	0	0	0	0	\$ 107.50	\$ 10.75	\$ 118.25
Marin Community Clinic Inc.	0	0	0	0	0	0	\$ -	\$ -	\$ -
Mendocino Coast Clinics, Inc.	509	2	0	0	0	0	\$ 1,272.50	\$ 127.25	\$ 1,399.75
Mendocino Coast District Hospital	82	0	0	0	0	0	\$ 205.00	\$ 20.50	\$ 225.50
Mendocino Community Health Clinics, Inc.	1,468	2	410	0	0	0	\$ 4,695.00	\$ 469.50	\$ 5,164.50
Mountain Valleys Health Centers, Inc.	413	6	0	0	0	0	\$ 1,032.50	\$ 103.25	\$ 1,135.75
Northeastern Rural Health Clinics, Inc.	666	2	0	0	0	0	\$ 1,665.00	\$ 166.50	\$ 1,831.50
Open Door Community Health Centers	0	10	0	0	24,697	33	\$ 61,742.50	\$ 6,174.25	\$ 67,916.75
Redwoods Rural Health Center	0	0	0	0	0	0	\$ -	\$ -	\$ -
Petaluma Health Center	27	2	0	0	0	0	\$ 67.50	\$ 6.75	\$ 74.25
Santa Rosa Community Health Centers	0	0	0	0	0	0	\$ -	\$ -	\$ -
Shasta Community Health Centers	2,770	55	2,242	8	0	0	\$ 12,530.00	\$ 1,253.00	\$ 13,783.00
Shingletown Medical Center	86	3	0	0	0	0	\$ 215.00	\$ 21.50	\$ 236.50
Solano, County of	1,533	13	0	0	0	0	\$ 3,832.50	\$ 383.25	\$ 4,215.75
Sonoma Valley Community Health Center	200	0	0	0	0	0	\$ 500.00	\$ 50.00	\$ 550.00
QUARTER TOTALS:	10,732	112	4,316	14	24,697	33	\$ 99,362.50	\$ 9,936.25	\$ 109,298.75

Month	Total 340B Paid Match Claim Count	Total 340B Reversal Claim Count	Walgreens 340B Paid Match Claim Count	Walgreens 340B Reversal Match Claim Count	Wellpartner 340B Paid Match Claim Count	Wellpartner 340B Reversal Match Claim Count	340BX Compliance Fee	PHC 340B Compliance Fee	Total 340B Compliance Fees
July-17	3,518	2	1,260	0	9,295	0	\$35,182.50	\$3,518.25	\$38,700.75
August-17	4,192	92	1,705	8	12,529	21	\$46,065.00	\$4,606.50	\$50,671.50
September-17	3,022	18	1,351	6	2,873	12	\$18,115.00	\$1,811.50	\$19,926.50
TOTAL:	10,732	112	4,316	14	24,697	33	\$ 99,362.50	\$ 9,936.25	\$109,298.75

Changes to the 340B Compliance Program Agreement

- As discussed at the last 340B Advisory Committee Meeting on 12/4/17, the 340B Team realized there was information that needed to be updated in the 340B Compliance Program Agreement.
- In light of a piece regarding the 340B Program in the Governor's Budget Proposal for 2018-2019 (to be discussed later), it was decided that at this point the 340B Team would focus on changes to the 340B Compliance Program Agreement that would not require outside legal review or renegotiation of the terms of the agreement with 340BX Clearinghouse.
- Changes to the agreement include the use of the UD modifier, submission of requests for the addition of the UD modifier, removal of all references to the Generic Prescription Rate and Primary Care Quality Improvement Program, and updates to the Attachments. These changes were made to the agreement with an amendment listing all the changes drafted for all current 340B Participating Entities that will be distributed after approval by the 340B Advisory Committee.
- When the 340B Compliance Program Agreement is updated and approved by the 340B Advisory Committee, the 340B Compliance Program Policy will also be updated to reflect the changes made to agreement. The policy will then be sent through all appropriate committees for review and approval.

DHCS notification regarding 340B flags and manufacturers seeking refunds for rebates

- As discussed at the 340B Advisory Committee Meeting on 12/4/17, PHC had received various communications from DHCS regarding 340B Covered Entities and the use of 340B identifiers on their Physician-Administered Drug (PAD) claims, as informing PHC that drug manufacturers were working with new contractors to review older periods and were becoming much more aggressive in disputing rebates tied to possible duplicate discounts.
- In light of the information above, the 340B Team drafted a reminder letter regarding the use of the UD modifier and PHC's 340B Compliance Program. That letter will be sent to all 340B Covered Entities in PHC's 14 county service area on 12/28/17, with the exception of Sutter Health, Sonoma Valley Hospital, and the four (4) 340B Covered Entities that were sent a personalized letter in November 2017.
- On 1/11/18, PHC received an e-mail from Robert Shun, Chief, Medi-Cal Drug Rebate Branch. He was contacted by Eli Lilly's consultant, Kalderos, regarding 39 claims from 11 providers that did not include a 340B identifier. PHC was asked to work with the providers to correct any claims that were "incomplete." At this point, PHC is still determining the next steps.
- When Mr. Leung and Ms. Cook attended the 340B Coalition Winter Conference 2018 from 2/21/18 to 2/23/18, there was much discussion regarding the increase in number of manufacturer inquiries, including specific breakout sessions to discuss those inquiries.

Walgreens and submission of 340B claims data

- In December 2017, PHC was made aware that Walgreens was no longer providing the identifiers in the reports available to the 340B Covered Entities contracted with them that allowed 340B Covered Entities to create the files our 340B Participating Entities submitted to 340BX Clearinghouse for 340B claim reclassification.
- Due to that change, 340B Participating Entities had to find other ways to create the required files. Shasta Community Health Center (SCHC) combined information from two reports to create their submission file. 340BX Clearinghouse is currently working on finalizing instructions on how to create a submission file via the process used by SCHC.
- When the issues with the reports arose, Open Door Community Health Centers (ODCHC) reached out to the California Primary Care Association (CPCA) for assistance. On 1/10/18, ODCHC and CPCA had a conference call with Walgreens to discuss how to make the 340B Program work more smoothly in California, specifically regarding the reporting. Per that discussion, Walgreens sent a report template they proposed for use by 340B Covered Entities. Based on PHC's comparison of that template to the file specs from 340BX Clearinghouse, the proposed report would work. Walgreens indicated it would take four (4) to six (6) months to complete coding. As of 2/4/18, CPCA was waiting on final approvals to give Walgreens the green light.

Governor's Budget Proposal for 2018-2019 and the 340B Program in California

- On 1/10/18, the proposed 2018-2019 Governor's Budget for the State of California was released with the following language: "Restrict 340B Drug Reimbursement within the Medi-Cal Program—The Budget proposes to restrict the use of federal 340B Drug Pricing Program reimbursements within the Medi-Cal program, effective July 1, 2019. The proposal allows the state to comply with existing federal requirements, helps protect program integrity, prevents unnecessary overpayments, collects additional drug rebates, and mitigates the amount of time and resources expended to resolve drug rebate disputes related to 340B claims."
- The Governor's proposed budget seeks to eliminate 340B program participation for Medi-Cal fee-for-service and Medi-Cal managed care effective 7/1/19. Should this elimination occur, it will be extremely detrimental to the health centers and hospitals in our 14 county service area that rely on those funds to provide much needed assistance to the underserved population.
- At the 340B Coalition Winter Conference 2018 held 2/21/18 through 2/23/18, PHC's 340B Compliance Program was discussed during the Medicaid Billing and Reimbursement breakout session. Amber Ott from the California Hospital Association acknowledged that PHC's 340B Compliance Program is the only program approved by the State of California. Ms. Ott noted that the State of California has used PHC's program as an example. Although the State of California wants other Health Plans to look to PHC's program as a guide, they are not looking to approve any other programs at this time, which is likely tied to the elimination proposal.

PHC Webinar: Managing the 340B Enigma - PHC's Journey Through the 340B Program

- In January 2018, Liz Gibboney, CEO from PHC, attended the Local Health Plans of California (LHPC) Annual Retreat. There was a lot of interest expressed in PHC's 340B Compliance Program, especially in light of the proposal regarding the 340B Program included in the proposed Governor's Budget for 2018-2019 for the State of California. Ms. Gibboney volunteered to have PHC host a webinar for interested LHPC plans.
- PHC will host a webinar covering the following topics: 340B Basics, 340B Program Requirements, PHC's 340B Compliance Program, and the Future of 340B/PHC's Recommendations.
- Presenters will include Dr. Moore, Mr. Leung, and Ms. Cook. Kathie Powell, MA, MSHA, CEO from Petaluma and Rohnert Park Health Centers will also be joining as a guest speaker. Ms. Powell will discuss how important the 340B Program is to the financial health of health centers, for what types of activities they use the extra funding, and the impact on health centers if the funding (340B savings) received from participation in the program were no longer available.
- The webinar is scheduled for Thursday, 3/22/18, from 12:00 PM to 1:30 PM.

Updates and Meetings

340B Advisory Committee Schedule for 2018

- Update Letter: June 2018
- Meeting: September 12, 2018, 10:00 AM to 11:30 AM



Questions?



Thank You



340B Compliance Program Agreement

Between

Partnership HealthPlan of California

And

[340B Covered Entity Name]

~~**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 (“OPA”) 340B Database 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. Quality Improvement Program (“QIP”): A quality incentive program used by PHC to incentivize quality. PHC has a Primary Care QIP applying to contract primary care providers.~~
- ~~j.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.
- ~~k.j.~~ PHC 340B Advisory Committee: A subcommittee of the PHC Board of Commissioners charged with overseeing PHC’s 340B Compliance Program.
- ~~l.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 ~~OPA—340B Database~~OPAIS: <https://340bopais.hrsa.gov/home>
<https://opanet.hrsa.gov/340B/Views/CoveredEntity/SearchDirectory>
- ~~n.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 ~~OPA 340B Database~~340B OPAIS.
- ~~o.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, ~~or~~ 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.
- ~~p.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 ~~the Bank of San Antonio~~ 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. 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.
- b. Payments for 340B ~~Covered Outpatient Drugs~~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.
- c. 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.
- d. 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 onboarding 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.

e. PHC has established a mechanism to assist its 340B Participating Entities in appropriately 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 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 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.

~~f.—f.~~ The 340B Participating Entity is the sole responsible party for the proper flagging of all 340B claims (including PAD claims, Physician-Dispeded Drugs, and drug costs submitted as part of a fee-for-service, bundled, or capitated rate) ~~filed submitted~~ for 340B drugs ~~by requiring~~ the use of the UD Modifier (refer to Attachment B). Clearinghouse is not involved with this type of flagging, as it is completed by the 340B Participating Entity, so there is no fee associated with the addition of the UD modifier. In the event the 340B Participating Entity requires assistance with flagging 340B claims missing the UD modifier, the 340B Participating Entity they may submit a formal written request to PHC along with a file containing the needed claims information to identify each claim. By submitting the formal request to assist with flagging 340B claims with the UD Modifier, the 340B Participating Entity acknowledges it will adhere to PHC's process for correcting each claim and add the UD modifier for the fee outlined in Attachment A should follow the process outlined in the PHC Medi-Cal Provider Manual here: Section 3: Claims, PHC Medi-Cal Provider Appeal Process (CIF and Appeal Timelines), First Level Appeal – PHC Medi-Cal Claims Inquiry Form Process – 1. Electronic Claims Inquiry Form System (e-CIF).

http://www.partnershiphp.org/Providers/Policies/Documents/Claims/Medi-Cal_Section%203.Subsection%20VIII.A.pdf

~~g.~~ g. The 340B Participating Entity takes all-full responsibility ~~to for~~ providing ge accurate, ~~eo~~complete, and necessary data to enable PHC and Clearinghouse to perform ~~its~~ their services hereunder, and to maintain records to verify the accuracy

and completeness of such data. The 340B Participating Entity also takes full responsibility for providing accurate, complete, and necessary data when submitting 340B claims data flagged with the UD Modifier to PHC for transmittal to the State. 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. The 340B Participating Entity will pay reclassification fees for any 340B claim reclassified by ~~the~~ Clearinghouse. Payment of these reclassification fees is on a per paid 340B ~~prescription 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 ~~the Department of Health Care Services~~ DHCS.
- b. 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 ~~B~~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.
- c. 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.
 - d. 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.
 - e. 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.

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, ~~and/or~~ conditions, ~~and/or processes~~ of 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 Services Program Manager by e-mail at 340BQIP@partnershiphp.org.

- d. 340B Participating Entity's failure to report to PHC ~~the listed~~any of the types of changes listed in Attachment D in the respective timeframe ~~as~~ 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.~~ **Protection from excessive 340B Drug Costs**

- ~~a. The generic prescription rate hereunder (the "Generic Prescription Rate") will be calculated and reported to the 340B Participating Entity as part of the Primary QIP Program reporting.~~
- ~~b. If the annual Generic Prescription Rate falls below 85.0% as defined in the PHC Primary Care QIP (see PHC website for details), the dollars allocated for such Primary Care QIP will be reduced by 20% for that payment year, which is paid on October 31st of each year.~~

~~VIII.~~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.

IX.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 Services Program Manager, 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.

X.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.

XI.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, with the exception of Section VII of this Agreement, which modifies the Primary Care QIP. Aside from Section VII, 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.
 - 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, 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: _____

Signature _____

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

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

DRAFT

Attachment A: Fee Schedule for 340B Compliance Program

340B Claim Type	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 prescription 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 prescription drug claim (\$2.50 340BX Clearinghouse Fee + \$0.25 PHC 340B Compliance Fee)
340B PAD claims flagged appropriately by the 340B Participating Entity with the UD Modifier	No fee
340B PAD claims not flagged appropriately by the 340B Participating Entity requiring intervention by PHC to add the UD Modifier	\$2.75 per paid 340B prescription claim (\$2.75 PHC 340B Compliance Fee)

*Denotes: See Section V. subpart “a” regarding basis for reclassification fees. These fees are subject to adjustment with proper notice and justification.

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:** ~~One file extracts should~~ **must** be submitted each month **for the previous month's 340B drug claims**. File ~~should~~ **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 ~~ninety (90)~~ **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 ~~prescription 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 a CMS-1500 format, UB-04 format, 837 file format, or other related format ~~CMS-1500 or UB-04 form or related format~~.

3. **PAD 340B claims/-Physician-Dispensed Drug 340B Claims/340B claims for drug costs submitted as part of a fee-for-service, bundled, or capitated rate:** The 340B Participating Entity is responsible for insuring that all 340B claims tied to PADs and Physician-Dispensed Drugs ~~340B claims~~ are flagged appropriately.

- a. 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, CMS-1500 or UB-04 form 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 ~~July 2016~~January 2018, the following actions will take place:

- By the 20th day of the month, the 340B claims from ~~June 2016~~December 2017 (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 ~~March 2016~~September 2017 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 ~~March 2016~~September 2017 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


~~March 2016~~September 2017 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*
<u>340B Participating Entity contracts with a new 340B Administrator</u>	<u>Immediately</u>
<u>340B Participating Entity terminates a contract with an 340B Administrator</u>	<u>Immediately</u>
New child <u>site/associated site/grantee</u> becomes eligible to participate in 340B Program	60 days or more prior to effective date
Site is terminated from the 340B Program	60 days or more prior to effective date
New Contract Pharmacy added to 340B Participating Entity's Pharmacy Network	60 days or more prior to effective date
Contract Pharmacy is removed from 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"/>
340B Participating Entity Name	<input type="text"/>
Contact Name	<input type="text"/>
Contact Title	<input type="text"/>
Contact Phone Number	<input type="text"/>
Contact e-mail address	<input type="text"/>
DESCRIPTION OF CHANGE	
Type of Change	<input type="text" value="Choose an item."/> <input type="text" value="Please Select One"/>
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"/>
Please email form to the following email: 340BQIP@partnershiphp.org	
Submit Form	
Eureka Fairfield Redding Santa Rosa (707) 863-4414 340BQIP@partnershiphp.org	

**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.

DRAFT

Attachment H: Contract Pharmacies registered on ~~OPA-340B Database~~ 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.”

<NUMBER> Amendment to the 340B Compliance Program Agreement

Between

Partnership HealthPlan of California

And

<340B Participating Entity Name>

This <NUMBER> Amendment is made to the 340B Compliance Program Agreement (the “Agreement”) executed on the 1st day of <MONTH> 2016 and is entered into effective as of the **1st day of January 2018**, by and between Partnership HealthPlan of California (“PHC” or “Health Plan”), whose offices are located in Fairfield, CA, and <340B Participating Entity Name> (“340B Participating Entity”) whose offices are located in <CITY>, California.

RECITALS

WHEREAS, PHC and the 340B Participating Entity previously entered into the Agreement executed the 1st day of <MONTH> 2016; and

WITNESSETH

NOW, THEREFORE, the parties hereto agree to amend the Agreement as follows:

Section I, Definitions and Acronyms, is deleted and replaced in its entirety with the following:

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.

Section IV, 340B Compliance for 340B Claim Reporting, is deleted and replaced in its entirety with the following:

IV. 340B Compliance for 340B Claim Reporting

- a. 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.
- b. 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.

- c. 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.
- d. 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.
- e. PHC has established a mechanism to assist its 340B Participating Entities in appropriately 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 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 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.
- f. The 340B Participating Entity is the sole responsible party for the proper flagging of all 340B claims (including PAD claims, Physician-Dispended Drugs, and 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 flagging, as it is completed by the 340B Participating Entity, so there is no fee associated with the addition of the UD modifier. In the event the 340B Participating Entity requires assistance with flagging 340B claims missing the UD modifier, the 340B Participating Entity should follow the process outlined in the PHC Medi-Cal Provider Manual here: Section 3: Claims, PHC Medi-Cal Provider Appeal Process (CIF and Appeal Timelines), First Level Appeal- PHC Medi-Cal Claims Inquiry Form Process – 1. Electronic Claims Inquiry Form System (e-CIF). http://www.partnershiphp.org/Providers/Policies/Documents/Claims/Medi-Cal_Section%203.Subsection%20VIII.A.pdf

- g. 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. The 340B Participating Entity also takes full responsibility for providing accurate, complete, and necessary data when submitting 340B claims data flagged with the UD Modifier to PHC for transmittal to the State. 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.

Section V, Reclassification Fees, Sub-sections “a” and “B” are changed to reflect the following:

V. Reclassification Fees

- a. 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.
- b. 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

Section VI, Reporting of Changes to 340B Participating Entity's 340B Program, is deleted and replaced in its entirety with the following:

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 Services Program Manager 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.

Section VII, Protection from excessive 340B Drug Costs, is deleted in its entirety.

Section VIII, Terms and Termination of Agreement, is changed to reflect the following title:

Section VII, Terms and Termination of Agreement

Section IX, Mechanism of Notice, is changed to reflect the following title:

Section VIII, Mechanism of Notice

Section X, Further Agreements, is changed to reflect the following title:

Section IX, Further Agreements

Section XI, Other Provisions, is changed to reflect the following title:

Section X, Other Provisions

Attachment A, Fee Schedule for 340B Compliance Program, is deleted and replaced in its entirety with the following:

Attachment A: Fee Schedule for 340B Compliance Program

340B Claim Type	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 prescription drug claim (\$2.50 340BX Clearinghouse Fee + \$0.25 PHC 340B Compliance Fee)

Attachment B, Reporting requirements for 340B Drug Claim Compliance, is deleted and replaced in its entirety with the following:

Attachment B: Reporting requirements for 340B Drug Claim Compliance

a. 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.

b. 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.

c. PAD 340B claims/Physician-Dispensed Drug 340B Claims/ 340B claims for drug costs submitted as part of a bundled or capitated rate: The 340B Participating Entity is responsible for insuring that all 340B claims tied to PADs, Physician-Dispensed Drugs, and drug costs submitted as part of a fee-for-service, bundled, or capitated rate are flagged appropriately.

- a. 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 the CMS-1500 format, UB-04 format, 837 file format, or other related format.

Attachment C, 340BX Clearinghouse Reclassification & Invoicing Schedule, is deleted and replaced in its entirety with the following:

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 2018, the following actions will take place:

- By the 20th day of the month, the 340B claims from December 2017 (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 2017 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 2017 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 2017 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), is deleted and replaced in its entirety with the following:

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 an 340B Administrator	Immediately
New child site becomes eligible to participate in 340B Program	60 days or more prior to effective date
Site is terminated from the 340B Program	60 days or more prior to effective date
New Contract Pharmacy added to 340B Participating Entity’s Pharmacy Network	60 days or more prior to effective date
Contract Pharmacy is removed from 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, Entities covered under this Agreement, is deleted and replaced in its entirety with the following:

Attachment F: Entities covered under this Agreement

340B 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 H, Contract Pharmacies registered on OPA 340B Database, is changed to reflect the following title:

Attachment H: Contract Pharmacies registered on 340B OPAIS

Agreed to and accepted by:

340B PARTICIPATING ENTITY:

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

HEALTH PLAN:

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

DRAFT