

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

C. Dean Germano (Chair) Members:

> Viola Lujan Kathryn Powell Amir Khoyi, PharmD Daniel Santi

PHC Staff: Elizabeth Gibboney, CEO

Sonja Bjork COO

Wendi West, Northern Executive Director Michelle Rollins, Director of Legal Affairs

Stan Leung, PharmD, Director of Pharmacy Services Edward Hightower, CPhT, Associate Director of Dawn R. Cook, Pharmacy Services Program Manager

Patti McFarland, CFO

Robert L. Moore, MD, MPH, MBA, CMO Amy Turnipseed, Senior Director of External and

Regulatory Affairs

**Pharmacy Operations** 

FROM: Dawn R. Cook DATE: April 15, 2019

340B ADVISORY COMMITTEE MEETING FOR 2018 **SUBJECT:** 

The 340B Advisory Committee will meet as follows, an additional meeting for 2019, but will return to meeting biannually thereafter. Please review the Meeting Agenda and attached packet, as discussion time is limited.

DATE: Thursday, April 18, 2019 2:00 p.m. -2:55 p.m. TIME:

**LOCATIONS**: Video Conferencing and/or Conference Call

Partnership HealthPlan of CA	PHC Redding Office	Petaluma Health Center, Inc.
Solano Conference Room	2525 Airpark Drive	1455-D N. McDowell Blvd.
4665 Business Center Drive	Redding, CA 96001	Petaluma, CA 94954
Fairfield, CA 94534	*Ask for Atim p'Oyat	*Ask for Hazel, 707-559-7519
*Please park in front of the building.		
*Ask the receptionist to call Dawn R. Cook or		
Debbie Beane		

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

<u>Date:</u> April 18, 2019 Time: 2:00 p.m. – 2:55 p.m. <u>Location: PHC</u>

Welcon	Welcome / Introductions							
	Торіс	Lead	Page #	Time				
I.	Public Comments	Speaker	N/A	2:00 pm				
II.	Opening Comments	Chair	N/A	2:05 pm				
III.	Approval of Minutes	Chair	3 - 8	2:10 pm				
IV.	Standing Agenda Items							
1.	Partnership HealthPlan of California (PHC) 340B Compliance Program Update	Dawn R. Cook	11 - 15	2:15 pm				
V.	Old Business							
1.	Updated 340B Compliance Program Agreement for 2019	Dawn R. Cook	16	2:28 pm				
VI.	New Business							
1.	No new business	N/A	N/A	N/A				
VII.	Additional Items							
1.	340B Compliance Program Agreement – Updated 2019 draft	Dawn R. Cook	20 - 43	N/A				
2.	Termination letter for 340B Compliance Program Agreements 2019	Dawn R. Cook	44	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
March 15, 2019 – 1:00 p.m. to 2:30 p.m.

### **Commissioners Present / via Teleconference (TC):**

C. Dean Germano (Chair); Daniel Santi; Amir Khoyi, PharmD

#### **Staff Present:**

Robert Moore, MD, MPH, MBA, CMO; Stan Leung, PharmD; Tony Hightower, CPhT, and Dawn R. Cook

#### PUBLIC COMMENTS

None presented.

#### WELCOME/INTRODUCTION

Brief introductions were made.

#### AGENDA ITEM I – OPENING COMMENTS

No opening comments were made.

### AGENDA ITEM II - APPROVAL OF MINUTES

The minutes from the 340B Advisory Committee Meetings on 9/12/18 were approved with one correction. On page 1 of the minutes under Agenda Item I, Opening Comments, the words "Covered Entities" was to be changed to "PBM" in the second to last line of the paragraph. There were no committee members who opposed or abstained.

#### AGENDA ITEM III - STANDING AGENDA ITEMS

### PHC 340B Compliance Program Update

### 340B Compliance Program Update:

Ms. Cook noted that as of 3/7/19, there were 342 340B Covered Sites/IDs within PHC's 14 county service area that were eligible to participate in the 340B Program, of which 143 were hospitals. PHC had 27 executed 340B Compliance Program Agreements, which cover 166 active 340B IDs, of which 42 IDs were hospitals.

As of 4/1/19, there would be 333 340B Covered Sites/IDs within PHC's 14 county service area that were eligible to participate in the 340B Program, of which 143 were hospitals. There would still be 27 executed 340B Compliance Program Agreements, which cover 159 active 340B IDs, of which 42 IDs were hospitals. Ms. Cook noted that the change in the number of 340B IDs is a reflection in the additions and terminations of 340B IDs by the 340B Covered Entities.

At that point, no additional Covered Entities had been invited to join the 340B Compliance Program.

As of 3/7/19, invoices had been delivered to 20 of the 340B Participating Entities on a monthly basis. McCloud Healthcare Clinic Inc. received its first invoice in February 2019 for claims reclassification that occurred in October of 2018. As of 2/28/19, there were 20 340B Participating Entities making 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 7/1/18 to 9/30/18, noting the information now included SunRx claims for Ole Health.

For the 7/1/18 to 9/30/18 quarter, there were 10,637 340B Paid Matched Claims, 5,658 Walgreens 340B Paid Match Claims, 727 CVS 340B Paid Match Claims for ODCHC, 5,307 SunRx Paid Match Claims for Ole Health, and 4,842 Wellpartner 340B Paid Match Claims for the quarter, for a total of 27,835 Matched Claims for the quarter. The Total 340B Compliance Fees were \$76,546.25. Of that total, \$69,587.50 were 340BX Compliance Fees and \$6,958.75 were PHC 340B Compliance Fees.

Mr. Germano noted California Primary Care Association (CPCA) had been talking to the Governor's office about the proposal to move the Managed Care Pharmacy benefit to Fee-For-Service (FFS). Regarding the impact to Community Health Centers (CHCs), the possible lost 340B Savings was noted by the State was \$100 million across the state, which the 340B Advisory Committee agreed sounded like a very low figure. Dr. Moore stated there might be an indirect way to come up with a better estimate. Dr. Moore noted that PHC would make up about 1/20th of the Managed Care 340B claims. If you take the number of claims and you multiple it by the average 340B savings a site would make per claim, and then take that number and multiple it by 20, it would be a ballpark estimate. Based on \$100 million, Dr. Moore stated PHC's 340B claims would represent \$5 million per year. Ms. Cook, Mr. Germano, and Mr. Santi all indicated that estimate was too low. Dr. Moore stated maybe the State was being conservative. Ms. Cook noted just three (3) of the 340B Participating Entities would cover \$5 million. Using Shasta Community Health Centers (SCHC) as an example, Dr. Moore and Mr. Santi calculated a 340B Savings of about \$266 per claim. If you multiple \$266 by approximately 125,000 claims per quarter, that would be approximately \$30 million just for current PHC participants. Using that number, you would have almost \$600 million for the State. Mr. Germano noted that even if you cut that in half, at \$300 million, that was still a lot more than \$100 million, which was important as they were negotiating with that number and perhaps under-valuing the impact. Dr. Moore stated there were a lot of variables, and perhaps, the best estimate would be \$500 million. Dr. Moore stated Mr. Germano could relay this information in future discussions with CPCA.

#### AGENDA ITEM IV - OLD BUSINESS

#### Walgreens and submission of 340B claims data:

In the 340B Advisory Committee Update Letter for December 2018, it was reported there were no new updates to report. It appeared PHC's 340B Participating Entities were still waiting for an all-inclusive report to be issued that they could use for reporting Walgreens 340B claims to 340BX Clearinghouse for reclassification.

As of March 2019, Walgreens has finalized the all-inclusive California MCO report for 340B Covered Entities to use when reporting 340B claims data. The 340B Covered Entities should have access to it via their Walgreens portals. However, if they do not have access, they can request to have that report added to their portal.

Per our 340B Participating Entities who have accessed the new report, it does contain the information needed for submission of claims to 340BX Clearinghouse for reclassification, but some manipulation of the data to match the file format used by 340BX Clearinghouse is still required.

Mr. Santi provided feedback on the new reports. He indicated all of the information needed to submit the Walgreens 340B claims to 340BX Clearinghouse was in the new report. However, the 340B Participating Entities would still need to put the data in the file format required by 340BX Clearinghouse, which was a manual process. He indicated preparing the data with the new report took about half the time to prepare as it did previously. Ms. Cook indicated she could ask 340BX Clearinghouse if they would be making any changes to their file format.

#### 340B Program in California:

As reported in the 340B Advisory Committee Update Letter for December 2018, in November 2018, PHC received an updated version of the draft All Plan Letter (APL) regarding the Medicaid Drug Rebate Program in California previously sent in March 2018. PHC felt it was a step in the right direction and, depending upon the final version, it could potentially provide a basis for

making participation in PHC's 340B Compliance Program mandatory for 340B Covered Entities who what to dispense 340B drugs to PHC members.

In December 2018, PHC received another document titled "340B Contract Pharmacy Three-way Agreement Minimum Requirements," which contained language not provided in the updated draft APL. The biggest concern was the requirement for claims to be properly identified as 340B utilizing the department specific identifiers at the time of adjudication. Post adjudication identification of 340B claims would not be permitted. As a large component of PHC's 340B Compliance Program is the post adjudication reclassification performed by 340BX Clearinghouse, such a requirement would have a huge impact on the current 340B Covered Entities participating in PHC's 340B Compliance Program. Mr. Santi commented that it seemed this would eliminate the program, except for perhaps pharmacies that flag at the point-of-sale (POS). Ms. Cook noted yes, but it would also depended on whether the State would still require corrections on older claims through the effective date of any change made.

On 1/10/19, the proposed 2019-2020 Governor's Budget for the State of California was released with the following language: "The Budget proposes to transition all pharmacy services for Medi-Cal managed care to a fee-for-service benefit. A fee-for-service pharmacy program will increase drug rebate savings and help the state secure better prices by allowing California to negotiate with pharmaceutical manufacturers on behalf of a much larger population of Medi-Cal beneficiaries. Such a standardized drug benefit will reduce confusion among beneficiaries without sacrificing quality or outcomes. This proposal is estimated to result in hundreds of millions of dollars in annual savings starting in fiscal year 2021-22." Ms. Cook noted this proposal could also mean the end of the 340B Compliance Program depending on the final guidelines for the switch. She indicated that when she attended the 340B Coalition Winter Conference 2019 at the end of January 2019, one presentation did make it seem that this change would occur and was set for July 2021. Mr. Germano stated he thought that date could have come from a meeting with CPCA, which was shared. He stated more conversations needed to happen. The committee discussed the impact of the proposal on the Health Plan overall.

Ms. Cook noted that at that point, she had not seen any additional information from the State such as an APL or other document. Dr. Moore stated there would like be no decisions made until after the final budget was presented. Mr. Germano indicated he had heard the Governor wanted to extract as much savings out of the Medicaid Program for drugs and use some of that money to pay for the expansion of Medicaid for undocumented individuals. Dr. Moore said it was a really valuable argument so show a successful 340B Program and the benefits for patients of the 340B Covered Entities. Mr. Germano stated that was why the discrepancy in calculating the impact from losing 340B Savings was so important. Mr. Germano stated he would have to reach out to CPCA, and if they had questions, they can contact Ms. Cook.

### 340B Retro Reclassification Process:

As reported in the 340B Advisory Committee Update Letter for December 2018, in light of an increase in the inquiries from drug manufacturers (sent via DHCS) regarding possible duplicate discounts, it was determined that a single 340B Retro Reclassification Process for the addition of the UD modifier needed to be created.

It was determined that the updated process would no longer involve submission of requests to PHC's Claims Department. PHC's IT Team will handle the processing of requests by allowing 340B Covered Entities to submit their requests via a spreadsheet template that can be uploaded electronically. PHC's Pharmacy Services Program Manager will remain the main point of contact for all parties regarding the 340B Retro Reclassification Process.

Recent action items associated with the 340B Retro Reclassification Process Work Group include the following:

- Ms. Cook has been working with various departments to determine what type of acknowledgement is needed from the 340B Covered Entities to acknowledge their consent to pay the fees previously approved by PHC's CFO and presented at a prior 340b Advisory Committee Meeting.
- Cost estimates are being collected from the respective stakeholder departments.
- The IT Team is close to being beginning the work outlined in their project charter

The next 340B Retro Reclassification Process Work Group meeting will be on 3/27/19.

In response to a question from Mr. Santi, Ms. Cook noted that between February 2018 and February 2019, there were about seven (7) requests for reclassification. However, per previous meetings, in 2017, PHC had seen a request from Sutter Health for the reclassification of almost 13,000 claim service lines. One (1) of the seven (7) requests was from Dignity Health for 263 claim lines. A current 340B Participating Entity had submitted a request for close to 3,000 claim lines, and another 340B Covered Entity might be reaching out for claims that go back to April 2018. Ms. Cook noted the issue was not the number of requests, but the number of claim service lines that needed to be reclassified. At that point, PHC's Claims Department handles the requests via a manual process for each claim service line to add the UD modifier. The Sutter Health reclassification project required a lot of overtime, raising questions of the impact of a manual process on PHC's budget. Ms. Cook noted 340B Covered Entities have the ability to add the UD modifier, though various issues can arise. Based on recent inquiries from the

State and correspondence with 340B Covered Entities, Ms. Cook noted it seemed internal audits were increasing. Ms. Cook noted that even with 20 to 30 requests a year, the impact depended on the actual number of claim service lines involved.

Mr. Germano and Mr. Santi discussed the purpose of the UD modifier. Mr. Germano stated during a call the other day with CPCA and National Association for Home Care & Hospice (NAHC), they discussed the third parties auditing for duplicate discount payments. Mr. Santi stated most participants were likely getting requests from Kalderos asking them to identify if claims were 340B claims or not, as SCHC received three (3) requests over the last eight (8) to nine (9) months, going back to 2014. Ms. Cook noted it sounds like they are getting them directly, and some of them are coming via the State as well.

#### AGENDA ITEM V - NEW BUSINESS

### 340B Compliance Program Agreement:

In March 2018, the 340B Advisory Committee reviewed and approved proposed changes to the 340B Compliance Program Agreement.

As reported in the 340B Advisory Committee Update Letter for December 2018, the PHC 340B Team resumed work on another revision of the 340B Compliance Program Agreement. It was decided that PHC would proceed with revisions to the 340B Compliance Program Agreement even though DHCS has yet to provide final guidance as to changes that may or may not be required regarding the 340B Program in the State of California. Ms. Cook reminded the committee that the last time major changes were made to the 340B Compliance Program Agreement was April 2016.

Changes to the agreement include the submission of requests for the addition of the UD modifier (340B Retro Reclassification Process), removal of all references to the Generic Prescription Rate and Primary Care Quality Improvement Program, and updates to the Attachments.

In conjunction with the revisions to the 340B Compliance Program Agreement, PHC's 340B Team is updating the 340B Compliance Program Policy, which will be reviewed and approved by all required committees.

Once the revised 340B Compliance Program Agreement is approved, all current 340B Compliance Program Agreements will be terminated, and a new 340B Compliance Program Agreement using the updated version will be put into place with no disruption of service. This same process was used with the major revision of the 340B Compliance Program Agreement completed in 2016. There will be a termination letter that indicates that the old agreement terminates on the last day of one month, with the new agreement going into effect the first day of the next month, so there were no gaps in participation or services.

In response to a question from Mr. Santi. Dr. Moore stated PHC was asking for the committee's input on the changes. Mr. Santi said that as far as substantive changes, he didn't see anything concerning. Dr. Moore stated the 340B Retro Reclassification Process with the UD modifier was the biggest change.

Ms. Cook noted that many of the changes presented were already approved by the committee in March 2018. There was discussion regarding the possible impact of an APL. Ms. Cook stated there was language in the 340B Compliance Agreement stating that if PHC received guidance from the State dismissing the program or making it not viable, then the agreement could be terminated. Ms. Cook stated PHC was moving forward with business as usual. At that point, PHC could not make participation mandatory, though the draft APL seen in November 2018 seemed to lay the groundwork for that. Dr. Moore stated so it remained a voluntary program.

Ms. Cook noted the biggest change was the reclassification process for Physician-Administered Drug (PAD) claim service lines with the addition of the UD modifier. PHC hoped to finalize the updated agreement and bring on new 340B Covered Entities to the 340B Compliance Program, as there had been no additions since January 2018. There were two (2) 340B Covered Entities interested in joining. Ms. Cook noted a few pieces to the 340B Retro Reclassification Process had to be finalized. Dr. Moore stated the updated agreement would be sent to the State. If there was no response in 30 days, PHC would move forward. If they respond and do not approve it, the old agreement will remain in place.

Dr. Moore indicated that during a call in December 2018 with a number of public hospital and other groups, a lot of probing questions were posed regarding PHC's program, because they were looking at it as potentially a prototype. One concern raised was the number of current participants. Dr. Moore told that group that if participation was made mandatory, then problem would be solved, and goals could be achieved. Dr. Moore stated PHC will strongly encourage everyone to consider participating in the 340B Compliance Program, as it will help protect the 340B Program in California. If PHC can get all the 340B Covered Entities in its service area to join the 340B Compliance Program, that's a very powerful statement.

Dr. Moore stated the other issue brought up was auditing. The call participants in that meeting did not seem to understand that Health Plans do not have the information required for a true audit. Dr. Moore stated he encouraged the State to come up with a way to audit and pay for it. As Ms. Cook indicated that PHC has no true auditing capabilities, as PHC nor the State has access to 340B drug pricing, Dr. Moore asked the committee for input on an auditing function or something that would add more strength in that area within the agreement.

The committee discussed possible options for auditing. Based on input from Mr. Santi, Dr. Moore suggested PHC periodically looking at the PAD claims. He said it would a strategic move, and PHC would not commit to any sanctions or penalties nor would it provide process details. In response to comments from Dr. Moore, Ms. Cook stated recently PHC had identified an issue with Fairchild Medical Center, a 340B Participating Entity, who was not using the UD modifier. Although they were a current participant and had been reminded several times to use the UD modifier, there were thousands of claims missing the UD modifier.

Following additional discussion regarding limitations with regard to available data and differences in 340B purchasing for 340B Covered Entities, Dr. Leung suggested requesting a sample size of PAD claims that received the 340B cost savings, and that would be audited against internal records for the presence of the UD modifier. Dr. Moore liked that recommendation, stating PHC did not have to provide details on frequency or number of audits. However, the addition would make it clear to the State that PHC would have an auditing function.

Mr. Santi discussed the external audit SCHC had just undergone, which were highly encouraged by HRSA. An outside organization was hired to review SCHC's 340B program. One of the recommendations was to obtain some sort of monthly communication from PHC verifying the claims that were reclassified and sent on to the State with the appropriate modifier. It would be kept in SCHC's records to share with HRSA auditors should an audit happen. Mr. Santi stated the request would be tied to Contract Pharmacy claims. Ms. Cook asked if they stated they needed separate documentation from PHC versus the matched claims files currently sent by 340BX Clearinghouse with the data for the claims matched. Mr. Santi stated he could should the auditor the matched claims reports from 340BX Clearinghouse to determine if it would suffice. Ms. Cook stated PHC receives the same reports from 340BX Clearinghouse. Dr. Moore stated if something else was required, consideration could be given to an annual little letter from PHC stating the 340B Participating Entities receive monthly claims reports from our partner, 340BX Clearinghouse, which represent the reclassification that occurred each month.

The committee discussed the benefits of external audits for 340B Covered Entities. Mr. Germano and Mr. Santi commented on the cost tied to such external audits, which though helpful, can be expensive. Dr. Leung mentioned that with other programs, PHC requires that organizations provide proof of policies and procedures (P&P) for various processes. Mr. Santi and Ms. Cook stated it was actually a requirement from HRSA to have P&P in place, with that often being the first thing HRSA looks for during an audit. PHC would not request this as it would be duplicate work for 340B Participating Entities.

With regard to a final draft of the updated 340B Compliance Program Agreement, Ms. Cook stated that once the final pieces of the 340B Retro Reclassification Process were ready, the agreement would be reviewed by the PHC Compliance Team. Based on what was changed, Ms. Cook did not think it needed outside legal review. Dr. Moore stated the agreement would be sent to State for approval. Additional discussion was held regarding when the final draft of the updated agreement would be reviewed and approved for use, Ms. Cook indicated that based on the conversation that day, it seemed it would not happen any earlier than July 2019. Ms. Cook stated the agreement was an attachment tied to the 340B Compliance Program Policy. The changes to the policy involve some of the definitions, but it was mainly the retro reclassification with the UD modifier, including a new attachment to the policy tied to the instructions. The agreement could not be used until the updated policy was approved by the necessary PHC committees. Dr. Moore questioned the timing of sending the updated agreement to the State in relation to the committee reviews. Ms. Cook noted the policy had to be approved by PHC's Internal Quality Improvement (IQI) Committee, Pharmacy & Therapeutics (P&T) Committee, and Physician Advisory Committee (PAC). The 340B Advisory Committee only provides input and approval to move forward with suggested changes, not policy approval. When the updated agreement was sent to the State, it would include the updated policy.

Ms. Cook outlined concerns regarding the delay in approving the agreement for use. Dr. Moore suggested the 340B Advisory Committee not wait until September 2019 or even June 2019 to meet again. Dr. Moore stated a meeting could be held in April 2019 if the committee wanted to be aggressive, so that the updated 340B Compliance Program Policy (which includes the agreement) would be seen by the PHC's Board April 2019. Dr. Moore and Dr. Leung stated they could help ensure the updated 340B Compliance Program Policy made it on the agenda for IQI and P&T. Ms. Cook noted the 340B Compliance Program Policy was typically given final approval by PAC. Dr. Moore stated maybe we can plan a meeting to review the draft in mid-April. Ms. Cook then stated that PAC is the final approval for this policy. Dr. Moore stated the Board takes precedence over PAC, and he reiterated that a short 340B Advisory Committee Meeting could be scheduled for mid-April to share the final updated agreement with the 340B Advisory Committee before it is put into use. Ms. Cook stated she would schedule a meeting in mid-April, but Brown Act rules would apply.

Dr. Khoyi asked if the old agreement could be used if the intent was to have all old agreements switch to the new one, as there were some 340B Covered Entities in trouble who could use the service. Ms. Cook stated Dr. Khoyi was referring to Lake County Tribal Health Consortium (LCTHC) who had already seen the old agreement and had expressed interested in joining much like Adventist Health. The issue was Robert Shun from DHCS had inquired as to why LCTHC could not have their claims corrected. Dr. Khoyi said the State had stopped helping 340B Covered Entities with claims correction. Ms. Cook noted the issue for LCTHC was not so much the PAD claims, as it was the pharmacy claims because 340BX Clearinghouse would not process anything for a 340B Covered Entity that was not participating in PHC's 340B Compliance Program. In order to use the services provided by 340BX Clearinghouse, a 340B Covered Entity had to sign PHC's 340B Compliance Program Agreement. Dr. Khoyi stated LCTHC were about to sign the agreement when PHC put a hold on the on-boarding of new 340B Covered Entities. Mr. Germano stated that speaks to getting the agreement ready faster. Ms. Cook stated LCTHC was having to carve-out until such a time that they are able to use the services of 340BX Clearinghouse. Dr. Moore stated there were other steps required to work with 340BX Clearinghouse. Ms. Cook stated a 340B Covered Entity needed to be able to send test files to 340BX Clearinghouse with the on-boarding. The 340B Covered Entity had to sign a non-disclosure agreement (NDA) to get the file specs for the required file format. In response to Dr. Moore's question regarding the speed of that process, Ms. Cook stated as long as the 340B Covered Entity had a 340B Administrator or IT team working to make it happen, it was fairly quick. Ms. Cook stated LCTHC and anyone else who might see the file specs would have to sign a separate NDA to get the file specs, so they could start working on creating the file on their end. Dr. Moore stated they could start getting the back work done before they sign the agreement. Ms. Cook will work with 340BX Clearinghouse to verify if LCTHC can start the process including whether they need a letter of intent.

• **ACTION ITEM:** The committee entertained a motion to have an additional 340B Advisory Committee Meeting in April 2019 to review the updated 340B Compliance Program Agreement. All committee members were in favor of the motion. There were no committee members who opposed or abstained. The motion was passed.

### AGENDA ITEM VI – ADDITIONAL ITEMS

#### Additional comments:

Ms. Cook noted an update letter would be sent out for June 2019. There was a 340B Advisory Committee Meetings scheduled for 9/25/19 from 10:00 AM to 11:25 AM. Ms. Cook would work on scheduling an additional 340B Advisory Committee Meeting in mid-April 2019 in order to review the updated 340B Compliance Program Agreement.

### **Documents:**

No additional documents were made available to the committee for review prior to commencement of the meeting:

### AGENDA ITEM V1I - ADJOURNMENT

Meeting Adjourned:	2:20 p.m.		
Respectfully submitted:	Dawn R. Cook		
The foregoing minutes we	ere APPROVED AS PRESENTE	ED on:	
		<del></del>	
C. Dean German	o, Committee Chairman	Date	
The foregoing minutes we	ere APPROVED WITH MODIF	CATION on:	
C. Dean German	o, Committee Chairman	Date	



# PARTNERSHIP HEALTHPLAN OF CALIFORNIA

### **PHC 340B Advisory Committee Meeting**

### Agenda

• 340B Compliance Program Update

• 340B Program in California

• 340B Compliance Program Agreement

### 340B Compliance Program Update

- ➤ As of 4/1/19, there were 334 active 340B Sites/IDs within PHC's 14 county service area, 144 of which were hospitals.
- ➤ There were 27 executed 340B Compliance Program Agreements covering 159 active 340B Sites/IDs, 42 of which are hospitals.





### 340B Compliance Program Update (cont'd)

- ➤ PHC is in discussions with three (3) organizations regarding on-boarding to the 340B Compliance program. With the addition of these three (3) organizations, we would add:
  - > Six (6) additional 340B Compliance Program Agreements
    - Adventist Health Ukiah Valley
    - Lake County Tribal Health Consortium Inc.
    - Modoc Medical Center
    - > St. Helena Hospital, DBA Adventist Health St. Helena
    - St. Helena Hospital Clearlake
    - Willits Hospital Inc.
  - > Those agreements cover 37 Active 340B Sites/IDs, 32 of which are hospitals.
  - If all six (6) agreements are executed, there would be 33 executed 340B Compliance Program Agreements covering 196 active 340B Sites/IDs, 74 of which would be hospitals.



### 340B Compliance Program Update (cont'd)

- As of 4/15/19, invoices were delivered to 21 of PHC's 340B Participating Entities on a monthly basis. Marin Community Clinic received its first invoice since January 2017, as it contracted with Rite-Aid pharmacies, requiring claims be reclassified by 340BX Clearinghouse. The invoice delivered on 4/3/19 was for claims reclassification that occurred in December 2018.
- As of 3/31/19, there were 20 340B Participating Entities making monthly wire transfers to the 340BX Trust Account based on the invoice received for that respective month.

### **Claims/Financial Summary**

### Claims/Financial summary for 10/1/18 to 12/31/18

	10/1/18 to 12/31/18												
Entity	340B Paid Match Claim Count	340B Reversal Claim Count	Walgreens 340B Paid Match Claim Count	Walgreens 340B Reversal Match Claim Count	Paid Match	CVS 340B Reversal Claim Count	Wellpartner 340B Paid Match Claim Count	340B Poromal	340B Paid Match	SunRx 340B Paid Reversal Claim Count	340BX Compliance Fee	PHC 340B Compliance Fee	Total 340B Compliance Fees
Alliance Medical Center	111	0	0	0	0	0	0	0	0	0	\$ 277.50	\$ 27.75	\$ 305.25
CommuniCare Health Centers	697	1	229	0	0	0	0	0	0	0	\$ 2,315.00	\$ 231.50	\$ 2,546.50
Fairchild Medical Center	1,102	3	0	0	0	0	0	0	0	0	\$ 2,755.00	\$ 275.50	\$ 3,030.50
Hill Country Community Clinic	457	0	0	0	0	0	0	0	0	0	\$ 1,142.50	\$ 114.25	\$ 1,256.75
La Clinica De La Raza	0	0	1,606	12	0	0	0	0	0	0	\$ 4,015.00	\$ 401.50	\$ 4,416.50
Long Valley Health Center	35	1	0	0	0	0	0	0	0	0	\$ 87.50	\$ 8.75	\$ 96.25
Marin Community Clinic Inc.	82	0	0	0	0	0	0	0	0	0	\$ 205.00	\$ 20.50	\$ 225.50
McCloud Healthcare Clinic	340	0	0	0	0	0	0	0	0	0	\$ 850.00	\$ 85.00	\$ 935.00
Mendocino Coast Clinics, Inc.	493	2	0	0	0	0	0	0	0	0	\$ 1,232.50	\$ 123.25	\$ 1,355.75
Mendocino Coast District Hospital	159	1	0	0	0	0	0	0	0	0	\$ 397.50	\$ 39.75	\$ 437.25
Mendocino Community Health Clinics, Inc.	1,152	3	396	5	0	0	0	0	0	0	\$ 3,870.00	\$ 387.00	\$ 4,257.00
Mountain Valleys Health Centers, Inc.	247	1	0	0	0	0	0	0	0	0	\$ 617.50	\$ 61.75	\$ 679.25
Northeastern Rural Health Clinics, Inc.	597	2	0	0	0	0	0	0	0	0	\$ 1,492.50	\$ 149.25	\$ 1,641.75
Ole Health	0	0	0	0	0	0	0	0	3,830	10	\$ 9,575.00	\$ 957.50	\$ 10,532.50
Open Door Community Health Centers	577	1	3,032	12	0	0	5,593	36	0	0	\$ 23,005.00	\$ 2,300.50	\$ 25,305.50
Petaluma Health Center	0	0	0	0	0	0	0	0	0	0	\$ -	\$ -	\$ -
Redwoods Rural Health Center	143	0	0	0	0	0	0	0	0	0	\$ 357.50	\$ 35.75	\$ 393.25
Santa Rosa Community Health Centers	0	0	0	0	0	0	0	0	0	0	\$ -	\$ -	\$ -
Shasta Community Health Centers	2,564	5	2,265	7	0	0	0	0	0	0	\$ 12,072.50	\$ 1,207.25	\$ 13,279.75
Shingletown Medical Center	85	0	0	0	0	0	0	0	0	0	\$ 212.50	\$ 21.25	\$ 233.75
Solano, County of	94	1	0	0	0	0	0	0	0	0	\$ 235.00	\$ 23.50	\$ 258.50
Sonoma Valley Community Health Center	160	1	0	0	0	0	0	0	0	0	\$ 400.00	\$ 40.00	\$ 440.00
Winters Healthcare Foundation	107	2	0	0	0	0	0	0	0	0	\$ 267.50	\$ 26.75	\$ 294.25
QUARTER TOTALS:	9,202	24	7,528	36	0	0	5,593	36	3,830	10	\$ 65,382.50	\$ 6,538.25	\$ 71,920.75

TOTAL 340B CLAIMS RECLASSIFIED BY 340BX CLEARINGHOUSE THIS QUARTER:

26,153

### Claims/Financial Summary (cont'd)

### Claims/Financial summary for 10/1/18 to 12/31/18

Month	CRX 340B Paid Match Claim Count	CRX 340B Reversal Claim Count	Walgreens 340B Paid Match Claim Count	Walgreens 340B Reversal Match Claim Count	CVS 340B Paid Match Claim Count	Reversal Claim	Wellpartner 340B Paid Match Claim Count	Wellpartner 340B Reversal Match Claim Count	Match	SunRx 340B Paid Reversal Claim Count		PHC 340B Compliance Fee	Total 340B Compliance Fees
October-18	3,286	6	3,001	3	0	0	1,890	6	1,656	3	\$24,582.50	\$2,458.25	\$27,040.75
November-18	3,163	9	2,330	12	0	0	1,995	9	1,984	6	\$23,680.00	\$2,368.00	\$26,048.00
December-18	2,753	9	2,197	21	0	0	1,708	21	190	0	\$17,120.00	\$1,712.00	\$18,832.00
TOTAL:	9,202	24	7,528	36	0	0	5,593	36	3,830	9	\$65,382.50	\$ 6,538.25	\$ 71,920.75
			TOTAL 340B	CLAIMS RECI	ASSIFIED B	Y 340BX C	LEARINGHO	OUSE THIS Q	UARTER:		26,153		

### 340B Compliance Program Agreement

- On 3/15/19, the 340B Advisory Committee met with the focus being changes to the 340B Compliance Program as reflected in an updated draft of the 340B Compliance Program Agreement.
- As noted on 3/15/19, changes to the agreement included the submission of requests for the addition of the UD modifier (340B Retro Reclassification Process), removal of all references to the Generic Prescription Rate and Primary Care Quality Improvement Program, and updates to the Attachments.
- ➤ The 340B Advisory Committee requested a special meeting be held after the updated draft was finalized and approved in conjunction with approval of the updated 340B Compliance Program Policy by all required committees.
- PHC's 340B Team updated the 340B Compliance Program Policy, which was reviewed and approved by the Internal Quality Improvement (IQI) Committee on 4/9/19, the Physician Advisory Committee (PAC) on 4/10/19, and the Pharmacy and Therapeutics (P&T) Committee on 4/11/19. The updated 340B Compliance Program Policy including the draft of the 340B Compliance Program Agreement will be reviewed by the Board on 4/24/19, as part of the PAC minutes.
- As the updated draft 340B Compliance Program Agreement was approved, all current 340B Compliance Program Agreements will be terminated, and a new 340B Compliance Program Agreement using the updated draft will be put into place for each respective 340B Participating Entity with no disruption of service. A draft termination letter has been drafted and is ready for use with the updated draft 340B Compliance Program Agreement.

### **Updates and Meetings**

# 340B Advisory Committee Schedule 2019

- Update Letter:
  - June 2019
- Meetings:
  - September 25, 2019 from 10:00 AM to 11:25 AM

# Questions?

## Thank You



### 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 1<sup>st</sup> day of [<month><year>] (the "Effective Date").

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

### I. Definitions and Acronyms

- a. 340B drug: Any covered outpatient drug purchased on a discounted basis under the 340B program, as defined by 42 U.S.C. § 256b and its implementing regulations, that is purchased via a qualified 340B Program distributor.
- b. 340B Administrator: A subcontractor hired by a 340B Participating Entity to administer the 340B Program, usually for a fee.
- c. 340B Covered Entity: A healthcare provider registered with HRSA and approved to participate in the 340B Program.
- d. 340B Participating Entity: A 340B Covered Entity that agrees to participate in PHC's 340B Compliance Program by signing this Agreement.
- e. HRSA: United States Health Resources and Services Administration.
- f. DHCS: California Department of Health Care Services.
- g. Pharmacy Benefits Manager ("PBM"): A subcontractor of PHC that contracts with individual dispensing pharmacies to create a network of pharmacies to provide the infrastructure for the pharmacy benefit of PHC and meets the definition of a "pharmacy benefits manager" in Business & Professions Code § 4430(j).
- h. 340B Office of Pharmacy Affairs Information System ("340B OPAIS"): A database overseen by OPA which includes detailed information related to all 340B Covered Entities, Contract Pharmacies, and Manufacturers all registered to participate in the 340B Program.

- i. 340BX Clearinghouse ("Clearinghouse"): The entity contracted with PHC to coordinate with various 340B players and perform data analysis and identification of 340B eligible pharmacy claims for the 340B Participating Entities.
- j. PHC 340B Advisory Committee: A subcommittee of the PHC Board of Commissioners charged with overseeing PHC's 340B Compliance Program.
- k. Contract Pharmacy: A retail pharmacy dispensing 340B-purchased drugs on behalf of a 340B Covered Entity, based on a contract between the 340B Covered Entity and the pharmacy. A Contract Pharmacy operates with a mixed inventory of drugs (340B and non-340B Covered Outpatient Drugs). All eligible Contract Pharmacies are registered with HRSA and listed on the 340B OPAIS: https://340bopais.hrsa.gov/home
- 1. In-House Pharmacy: A pharmacy in which the 340B Covered Entity owns the 340B drugs, pharmacy, and license. The 340B Covered Entity purchases the 340B drugs, which are dispensed to eligible patients, as defined by HRSA. The 340B Covered Entity is fiscally responsible for the pharmacy and pays the pharmacy staff. The pharmacy is (i) located on the premises of the 340B Covered Entity, (ii) provides services solely to the 340B Covered Entity's patients, (iii) through the 340B Covered Entity's providers, and (iv) dispenses only drugs and supplies purchased under the 340B Program to PHC beneficiaries. For the purposes of this Agreement, if all conditions, (i) through (iv), are not met, then the pharmacy would be considered a Contract Pharmacy, even though it might be physically located on the premises of the 340B Covered Entity. In-House Pharmacies are not registered with HRSA nor are they listed on the 340B OPAIS.
- m. Provider/In-House Dispensing: The 340B Covered Entity owns drugs; employs or contracts with providers licensed in the state to dispense drugs on its behalf; holds a clinic dispensary license issued by the California Board of Pharmacy; and is fiscally responsible for the operation of the dispensary. These entities submit claims for 340B Covered Outpatient Drugs using the CMS-1500 format, UB-04 format, or electronic 837 file format, which are not first processed by a PBM providing services under a direct contract with the 340B Participating Entity and on its behalf.
- n. Physician-Administered Drug ("PAD"): Any covered outpatient drug provided or administered by the 340B Participating Entity to one of its patients, and billed by a provider other than a pharmacy. Such providers include, but are not limited to, physician offices, clinics, and hospitals. A covered outpatient drug is broadly defined as a drug that may be dispensed only upon prescription, and is approved for safety and effectiveness as a prescription drug under the Federal Food, Drug and Cosmetic Act. PADs include both injectable and non-injectable drugs. These drugs may sometimes be referred to as Physician-Dispensed Drugs.
- o. 340BX Trust Account: A bank account in the name of NEC Networks, LLC (for Clearinghouse) at BBVA Compass Bank. This account will be utilized by

- Clearinghouse as a holding account to deposit 340B related funds paid by 340B Participating Entities, and also to transfer funds to PHC's bank account.
- p. UD Modifier: Approved modifier code for use in billing Medi-Cal. This modifier code is used by Section 340B providers to denote services provided or drugs purchased under the 340B Program.

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

The Veterans Health Care Act of 1992 established the 340B Program in section 340B of the Public Health Service Act. The 340B Program requires drug manufacturers participating in Medicaid to provide discounted covered outpatient drugs to certain eligible health care entities, known as <u>Covered Entities</u>. Congress intended for the savings from discounted drugs purchased under the 340B Program "to enable [participating] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

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

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

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

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

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

### III. Purposes of this Agreement

- a. To define an agreed upon process for ensuring proper identification of 340B drugs dispensed to PHC beneficiaries to the State of California, so as to ensure compliance with DHCS and HRSA policy and federal law.
- b. To support the mission of 340B Participating Entities to provide services to the most vulnerable members of the community.

c. To help reinforce judicious use of taxpayer/Medi-Cal funds in pharmaceutical costs.

### IV. 340B Compliance for 340B Claim Reporting

### a. Contract Pharmacy/In-House Pharmacy claims processed by the PBM

- i. PHC has contracted with and implemented a retrospective reclassification process through Clearinghouse that is intended to prevent 340B claims to which the State is not entitled to a rebate, from being improperly adjudicated for rebates paid under 42 U.S.C. § 1396r-8. This process was tested and found to be functional. PHC has notified the 340B Participating Entity and DHCS that, to the best of its knowledge, all 340B Covered Outpatient Drugs prescribed by that entity and retrospectively reclassified by Clearinghouse are identified to DHCS in a way that the State requires in order to ensure that no duplicate discounts are ultimately received and retained for the use of 340B Covered Outpatient Drugs.
- ii. Payments for 340B drugs billed as claims to PHC will be paid at the network or contracted rate negotiated between the 340B Contract/In-House Pharmacy and the PBM, subject to the requirements of Welfare & Institutions Code § 14087.325(d). PHC does not have access to information regarding rates established between the 340B Contract/In-House Pharmacies and the PBM.
- iii. The 340B Participating Entity shall be responsible for ensuring any Contract Pharmacies, In-House Pharmacies, and the 340B Participating Entity's 340B Administrators follow the compliance process required by PHC, as defined in Attachment B. The 340B Administrators, if any, are listed in Attachment G.
- iv. If one or more of a 340B Participating Entity's 340B Administrators is unwilling to work directly with Clearinghouse, the 340B Participating Entity can submit the required data directly to Clearinghouse in the file format that can be provided during the on-boarding process with Clearinghouse. If so requested, a current example of the file format shall be provided to a 340B Covered Entity prior to execution of this Agreement for its review after a non-disclosure agreement (NDA) from Clearinghouse is completed by a 340B Covered Entity. If a 340B Covered Entity's 340B Administrator needs access to the file specs, the 340B Administrator will have to sign a separate NDA. All data files sent directly from the 340B Participating Entity to Clearinghouse will be reclassified in the same manner as data files submitted by the 340B Participating Entity's 340B Administrators for the fee outlined in Attachment A.
- v. PHC has established a mechanism to assist its 340B Participating Entities in appropriately identifying (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 The 340B Participating Entity identification (flagging) requirements. acknowledges that it will be the sole accountable party regarding any Contract Pharmacy or In-House Pharmacy 340B claims that are not reviewed by Clearinghouse should an audit occur. In the event the 340B Participating Entity requires assistance with appropriate identification (flagging) and claims adjudication compliance for 340B claims originating from a Contract Pharmacy or In-House Pharmacy, the 340B Participating Entity will submit a formal written request and file containing the needed claims information to identify each claim. By submitting the formal request to reclassify claims to identify 340B drugs, the 340B Participating Entity acknowledges it will adhere to the established PHC process with Clearinghouse for the fee outlined in Attachment A. PHC will evaluate each request to determine if the request can be fulfilled. PHC will inform the 340B Participating Entity of the decision within 10 business days of receipt of the formal request from the 340B Participating Entity.

- b. PAD claim service lines, Physician-Dispensed Drug claim service lines, and claim service lines for drug costs submitted as part of a fee-for-service, bundled, or capitated rate processed by PHC's Claims Department
  - i. The 340B Participating Entity is the sole responsible party for the proper identification (flagging) of all 340B drug claim service lines (including PAD claim service lines, Physician-Dispensed Drugs claim service lines, and claim service lines for drug costs submitted as part of a fee-for-service, bundled, or capitated rate) submitted for 340B drugs requiring the use of the UD Modifier (refer to Attachment B). Clearinghouse is not involved with this type of 340B drug identification (flagging), as it is completed by the 340B Participating Entity.
  - ii. In the event the 340B Participating Entity requires assistance with identification (flagging) of 340B drugs on claim service lines missing the UD modifier, PHC has established a process for assisting 340B Participating Entities to correct claim service lines for 340B drugs missing the UD modifier.
  - iii. With submission of the initial request to assist with identification (flagging) of 340B drugs on claim service lines with the addition of the UD Modifier, the 340B Participating Entity acknowledges it will adhere to PHC's process for correcting each claim and adding the UD modifier for the fee outlined in Attachment A for the initial request, as well as for all subsequent requests.

iv. For additional information, please refer to the 340B Compliance Program Policy and associated attachments located on PHC's external website, <a href="http://www.partnershiphp.org/Providers/Pharmacy/Pages/340B-Compliance-Program.aspx">http://www.partnershiphp.org/Providers/Pharmacy/Pages/340B-Compliance-Program.aspx</a>.

### c. Submission of accurate data

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

### V. Reclassification Fees

- a. Contract Pharmacy/In-House Pharmacy claims reclassified by 340BX Clearinghouse
  - i. The 340B Participating Entity will pay reclassification fees for any 340B claim reclassified by Clearinghouse. Payment of these reclassification fees is on a per paid 340B drug claim basis. The reclassification fees include a 340BX Compliance Fee and a PHC 340B Compliance Fee, as defined in Attachment A. The 340BX Compliance Fee is for the reclassification services provided by Clearinghouse. The PHC 340B Compliance Fee will be put towards the costs associated with the operation and continuous maintenance of the PHC 340B Compliance Program, and as to which PHC has not previously been compensated under its agreement with DHCS.
  - ii. No later than the 3<sup>rd</sup> 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 3<sup>rd</sup> day of any month

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

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

- amounts due, at an amount equal to one and one-half percent (1.5%) per month, to accrue on a daily basis on any unpaid balances.
- v. Regarding reversal of 340B Claims, any reversal for a 340B Claim occurring ninety (90) days after the date of service will be excluded from any adjustments to the invoice provided by Clearinghouse.
- b. PAD claim service lines, Physician-Dispensed Drug claim service lines, and claim service lines for drug costs submitted as part of a fee-for-service, bundled, or capitated rate reclassified by PHC
  - i. If the 340B Participating Entity submits PAD claim service lines, Physician-Dispensed Drug claim service lines, and claim service lines for drug costs submitted as part of a fee-for-service, bundled, or capitated rate with the UD modifier on the necessary service lines to identify it is a 340B drug claim, there is no 340B Compliance Fee charged.
  - ii. In the event the 340B Participating Entity requires PHC's assistance with identification (flagging) of 340B drugs on claim service lines missing the UD modifier, the 340B Participating Entity will pay reclassification fees for any claim service line reclassified as 340B with the addition of the UD modifier by PHC, as defined in Attachment A. Payment of these reclassification fees is on a per paid 340B drug claim service line basis.

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

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

### VII. Terms and Termination of Agreement

- a. Term: The initial term of this Agreement shall begin on the Effective Date and shall expire two (2) years after. Thereafter, this Agreement shall renew automatically for additional, successive terms of one (1) year until terminated by either party. This Agreement may be terminated with or without cause based on the provisions herein.
- b. Termination for cause: If a party defaults in any of its obligations under this Agreement, the non-breaching party, at its option, shall have the right to terminate this Agreement by providing thirty (30) calendar days written notice of the material breach of this Agreement to the defaulting party. The defaulting party shall have ten (10) business days to cure such default upon receipt of the notice, and if timely cured, no termination shall occur. This Agreement will be immediately terminated without recourse if the State or Federal Government deems the program not legally permissible and all options for appeal are exhausted.
- c. Early termination: This Agreement may be terminated by either the 340B Participating Entity or PHC upon one hundred twenty (120) days' written notice without cause or sooner by mutual consent.
- d. If this Agreement is terminated without a new agreement in effect to replace it, the parties acknowledge that PHC will not be able to report the 340B Participating Entity's 340B drug use to the State. The 340B Participating Entity agrees that upon termination of this Agreement, it will no longer provide 340B drugs to PHC members.
- e. Wrap-up Period. Any business reclassifications initiated prior to the termination date of this Agreement will still be completed, invoiced appropriately, and the 340B Participating Entity will remain responsible for submitting payment for any 340B Compliance Fees tied to those reclassified claims.

### VIII. Mechanism of Notice

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

### IX. Further Agreements

All parties to this Agreement agree to take no action that violates 42 U.S.C. 1320a-7b (Section 1128B of the Social Security Act), also known as the "Anti-Kickback Statute." The 340B Participating Entity represents and warrants that it and all of its employees, agents, and subcontractors performing services related to this Agreement are not currently excluded from participation under federal health care programs pursuant to 42 U.S.C. 1320a-7, are not currently the subject of any pending exclusion proceeding under that section, and have not been adjudicated or determined to have committed any action that would subject it to mandatory or permissive exclusion under that section for which such an exclusion has not been implemented. The parties to this Agreement agree that they are, and shall remain subject to so long as they remain a 340B Covered Entity, the statutes, rules, regulations, and other binding guidance adopted by the United States Department of Health & Human Services Center for Medicare & Medicaid Services and HRSA with respect to its oversight of the Medicaid and 340B programs, respectively.

### X. Other Provisions

- a. Dispute Resolution: In the event that any dispute between the 340B Participating Entity and PHC arises out of this Agreement, it shall not result in a delay of services as required under this Agreement. However, subject to California Government Code sections 900 *et seq.*, any such dispute shall be resolved as required by the subsections below::
  - i. Meet and Confer: The parties agree to meet and confer on any issue that is the subject of dispute under this Agreement ("Meet and Confer"), as a condition precedent to arbitration under subsection (ii) below. The party seeking to initiate the Meet and Confer procedure (the "Initiating Party") shall give written notice to the other party describing in general terms the nature of the dispute, the Initiating Party's position, and identifying one or more individuals with authority to resolve the dispute on such party's behalf. The party receiving the notice (the "Responding Party") shall have ten (10) business days with which to respond to the notice. The response shall include the Responding Party's position and shall identify one or more individuals with authority to resolve the dispute on such party's behalf. The individuals so designated shall be known as the "Authorized Individuals." The Authorized Individuals shall meet at a mutually acceptable time and location within thirty (30) calendar days of the Initiating Party's notice and thereafter as often as necessary to exchange relevant information and to attempt to resolve the dispute. If the matter has not been resolved within sixty (60) calendar days of

- the Initiating Party's notice or if the Responding Party will not meet within thirty (30) calendar day, either party may submit the dispute to binding arbitration in accordance with the following procedures and shall give the other party written notice that the matter is being submitted to binding arbitration. All deadlines specified in this Meet and Confer procedure may be extended by mutual agreement of the parties. In addition, nothing in this subsection shall impede or limit the ability of the parties to submit the dispute to mediation for resolution.
- Arbitration: Upon written demand by either party, and after exhaustion of the ii. Meet and Confer procedure set for in subsection (i) above, any dispute arising out of this Agreement, including any issue regarding interpretation, validity, or termination, shall be referred to and submitted to mandatory binding arbitration pursuant to the California Arbitration Act (Code of Civil Procedure Sections 1280 et. seq.) The arbitration shall be administered by JAMS in accordance with the JAMS Comprehensive Arbitration Rules & Procedures by a single arbitrator in Solano County, California. If possible, the arbitrator shall be an attorney with at least 15 years of experience, including at least five years of experience in health care. The arbitrator's fees and expenses and the arbitration administrative fees shall be divided evenly between the parties. Each party shall bear its own costs and expenses, including attorneys' fees. The award or judgment of the arbitrator shall be accompanied by a written statement of the basis for the award or judgment and may be enforced by any court of competent jurisdiction. The arbitrator shall have no authority to provide a remedy or award damages that would not be available to a prevailing party in a court of law, and the arbitrator shall have no authority to award punitive damages. The award or judgment of the arbitrator shall be final and binding and shall not be subject to de novo judicial review. It is the express intention and understanding of the parties that each shall be entitled to enforce its respective rights under any provision of this Agreement through specific performance, in addition to recovering damages caused by a material breach of any provision thereof, and to obtain any and all other equitable remedies as may be awarded by the arbitrator. Notwithstanding the above, each party shall have the right to seek provisional remedies from a court of competent jurisdiction in accordance with California law. The provisions of this subsection (ii) shall survive termination of this Agreement.
- b. Entire Agreement: This Agreement, with its Attachments, constitutes the entire agreement between the parties governing the subject matter of this Agreement. This Agreement replaces any prior written or oral communications or agreements between the parties relating to the subject matter of this Agreement.

- c. Existing Contract: This Agreement does not supersede nor replace the existing Primary Care Provider, Specialty Provider, or Hospital Provider Contract between PHC and the 340B Participating Entity. If this Agreement conflicts with the Provider Contract between the Parties, the Provider Contract shall prevail.
- d. Subcontractors: The 340B Participating Entity may use subcontractors to perform its services under this Agreement. The 340B Participating Entity is responsible for their services to the same extent that the 340B Participating Entity would have been had the 340B Participating Entity performed the services without the use of a subcontractor.
- e. Amendment: Except as may otherwise be specified in this Agreement and an applicable Attachment, this Agreement (including its Attachments) may be amended only by both parties agreeing to the amendment in writing, executed by a duly authorized person of each party.
- f. Waiver/Estoppel: Nothing in this Agreement is considered to be waived by any party, unless the party claiming the waiver receives the waiver in writing. No breach of the Agreement is considered to be waived unless the non-breaching party waives it in writing. A waiver of one provision does not constitute a waiver of any other provision. A failure of either party to enforce, at any time, any of the provisions of this Agreement or to exercise any option which is herein provided in this Agreement will in no way be construed to be a waiver of such provision of this Agreement.
- g. Force Majeure: Each party will take commercially reasonable steps to prevent and recover from disruptive events that are beyond its control and represents that it has backup systems in place in case of emergencies or natural disasters. If either party shall be, wholly or in part, unable to perform any or part of its duties or functions under this Agreement because an act of war, riot, terrorist action, weather-related disaster, earthquake, governmental action, unavailability or breakdown of equipment, or other industrial disturbance which is beyond the reasonable control of the party obligated to perform and which by the exercise of reasonable diligence such party is unable to prevent (each a "Force Majeure Event"), then, and only upon giving the other party notice by telephone, facsimile, or in writing within a reasonable time and in reasonably full detail of the Force Majeure Event, such party's duties or functions shall be suspended during such inability; provided, however, that in the event that a Force Majeure Event delays such party's performance for more than thirty (30) calendar days following the date on which notice was given to the other party of the Force Majeure Event, the other party may terminate this Agreement. Neither party shall be liable to the other for any damages caused or occasioned by a Force Majeure Event. Government actions resulting from matters that are subject to the control of the party shall not be deemed Force Majeure Events.

- h. Counterparts: This Agreement may be executed by electronic signatures or in one or more counterparts, each of which shall be deemed an original, but all of which, together, shall constitute one agreement.
- i. Severability: If any provision of this Agreement is held to be invalid or unenforceable by a court of competent jurisdiction, then the remaining portions of the Agreement shall be construed as if not containing such provision, and all other rights and obligations of the parties shall be construed and enforced accordingly.
- j. Survival of Terms: Any provisions of this Agreement or any Attachments, which by their nature extend beyond the expiration or termination of this Agreement, and those provisions that are expressly stated to survive termination, shall survive the termination of this Agreement and shall remain in effect until all such obligations are satisfied.
- k. Warranties: Except as expressly stated herein, there are no warranties, express or implied, by any party in connection with this Agreement. All warranties not specifically stated herein, including warranties of merchantability or fitness for a particular purpose, are excluded and shall not apply to the products or services to be provided under this Agreement.
- 1. Limitation of Liability: In no event shall any party be liable to any other party, whether in contract, warranty, tort (including negligence, product liability or strict liability) or otherwise, for any indirect, incidental, consequential, special, exemplary, punitive, or similar damages (including without limitation damages for lost revenue, profit, business, use or data, or for any failure to realize savings or other benefits), even if advised of the possibility of any of the foregoing. The entire liability of any party to any other party under or in relation to this Agreement for any loss or damage, and regardless of the form of action shall be limited to proven, actual, out-of-pocket expenses that are reasonably incurred. In no event shall the aggregate liability of any party relating to or arising from this Agreement for any and all causes of action exceed \$100,000. This limitation on liability shall in no event be interpreted to apply to, or otherwise act to reduce, PHC's obligation to reimburse the 340B Participating Entity for 340B Covered Outpatient Drugs dispensed to PHC beneficiaries under this or any other agreement.
- m. Medical Records: All parties to this Agreement shall comply with all applicable state and federal laws and regulations regarding confidentiality of patient records, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Privacy Standards (45 C.F.R. Parts 160 and 164), the Standards for Electronic Transactions (45 C.F.R. Parts 160 and 162), and the Security Standards (45 C.F.R. Part 162) (collectively, the "Standards") promulgated or to be promulgated by the Secretary of Health and Human Services on and after the applicable effective dates specified in the Standards. Notwithstanding the foregoing,

- the parties shall be permitted to enter into such Business Associate Agreements as are permitted or required by HIPAA.
- n. Confidential Information: All Confidential Information (as defined below) shall be the property of the disclosing party. Each party agrees the receiving party shall (i) use at least the same degree of care to prevent unauthorized use and disclosure of disclosing party's Confidential Information as the receiving party uses with respect to its own Confidential Information (but in no case less than a reasonable degree of care); (ii) use the disclosing party's Confidential Information only in performance of the receiving party's obligations under this Agreement or for internal purposes to improve the quality of service performed under this Agreement; and (iii) except as otherwise expressly provided herein, not disclose or grant access to the disclosing party's Confidential Information to any third party, without the prior written consent of the disclosing party.

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

Agreed to and accepted by:

340B PARTICIPATING ENTITY:	PHC:	
Signature:	Signature	
By:	By:	Elizabeth Gibboney
Title:	Title:	CEO
Date:	Date:	
Address:	Address:	4665 Business Center Drive
		Fairfield, CA 94534

### Attachment A: Fee Schedule for 340B Compliance Program

### 340B claims for drugs dispensed through In-House or Contract Pharmacies

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

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

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

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

### Attachment B: Reporting requirements for 340B Drug Claim Compliance

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

- a. <u>Retrospective Claims</u>: 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 1<sup>st</sup> and 10<sup>th</sup> of each month ("monthly deadline").
  - iii. File Format: The File Format will be shared during the 340B Participating Entity's on-boarding process with Clearinghouse. Any file format changes will be communicated to the 340B Participating Entity within thirty (30) calendar days before the changes become effective.
  - iv. File Recipients: This file should be sent electronically and securely to Clearinghouse.

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

- a. If an In-House Pharmacy processes 340B drug claims at the POS, all claims for drugs purchased through the 340B program and submitted through a PBM must have "20" entered into the Submission Clarification Code (DK-420) to indicate the claim was a 340B claim.
- b. If an In-House Pharmacy submits claims directly to PHC, all claims must have a UD modifier listed after the HCPCS code for each and every 340B-purchased drug billed via paper or electronically using the CMS-1500 format, UB-04 format, 837 file format, or other related format.
- 3. PAD 340B drug claim service lines/Physician-Dispensed Drug 340B drug claim service lines/340B drug claim service lines for drug costs submitted as part of a feefor-service, bundled, or capitated rate:
  - a. The 340B Participating Entity is responsible for insuring all 340B drug claim service lines tied to PADs, Physician-Dispensed Drugs, or drug costs submitted as part of a fee-for-service, bundled, or capitated rate are flagged appropriately with the UD modifier.
  - b. All claim service lines for drugs purchased through the 340B Program and submitted as part of claims sent directly to PHC must have a UD modifier listed after the HCPCS code for each and every 340B-purchased drug billed via paper or electronically using the CMS-1500 format, UB-04 format, 837 file format, or other related format.

Attachment C: 340BX Clearinghouse Reclassification & Invoicing Schedule

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

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

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

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

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

<sup>\*</sup>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 Partnership HealthPlan of California 340B Compliance Program Change Notification MCALIFORNIA					
Date of Notification					
340B Participating Entity Name					
Contact Name					
Contact Title					
Contact Phone Number					
Contact e-mail address					
Type of Change		Choose an item.  Please Select One			
Change Details  Examples: Name of site or pharmacy, 340B  Contact Information, etc. If applicable, the is should match column headers from the respective meaning the agreement.	nformation provided				
Effective Date of Change:					
Please email form to the following email: 340BQIP@partnershiphp.org					
Eureka   (707) 8	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#	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.

Attachment H: Contract Pharmacies registered on 340B OPAIS

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

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

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

### **Attachment I: In-House Pharmacies**

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

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

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



<Month/Day/Year>>

<340B PARTICIPATING ENTITY NAME><340B PARTICIPATING ENTITY ADDRESS>

RE: Termination of 340B Compliance Program Agreement <a href="Month/Day/Year">Month/Day/Year</a> between <a href="mailto:s40B"><340B PARTCIPATING ENTITY</a> and Partnership HealthPlan of California

Pursuant to Section VII. Terms of the Agreement, of the 340B Compliance Agreement executed <a href="Month/Day/Year">Month/Day/Year</a> and subsequently amended, parties mutually agree to an early termination of the Agreement and all subsequent related Amendments, herein collectively referred to as (the "Agreement"). The termination is effective March 31, 2019.

Please note, per the Agreement, the 340B Compliance Fee of \$2.75 per paid 340B drug claim will be billed for all requests for the addition of the UD modifier to claims submitted prior March 31, 2019. As of April 1, 2019, all 340B Compliance Fees will follow the fee schedule outlined in the updated version of the 340B Compliance Program Agreement, which will have an effective date of April 1, 2019.

The Agreement executed <Month/Day/Year> is hereby terminated and voided in its entirety as of the date set forth in this Notice and is superseded and replaced with a new 340B Compliance Agreement executed as of April 1, 2019.

Agreed to and accepted by:

340B PARTICIPATING ENTITY:	HEALTH PLAN:	
By:	By:	
Printed Name:	Printed Name:	
Title:	Title:	
Date:	Date:	