



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

Members: C. Dean Germano (Chair)
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
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
Edward Hightower, CPhT, Associate Director of
Pharmacy Operations

FROM: Dawn R. Cook
DATE: March 11, 2019

SUBJECT: 340B ADVISORY COMMITTEE MEETING FOR 2018

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: Friday, March 15, 2019 **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 the building. *Ask the receptionist to call Dawn R. Cook</i>	PHC Redding Office 2525 Airpark Drive Redding, CA 96001 <i>*Ask for Atim p'Oyat</i>
---	--

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 15, 2019 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	1:05 pm
III.	Approval of Minutes	Chair	3 - 8	1:10 pm
IV.	Standing Agenda Items			
1.	Partnership HealthPlan of California (PHC) 340B Compliance Program Update	Dawn R. Cook	11 - 14	1:15 pm
V.	Old Business			
1.	Walgreens and submission of 340B claims data	Dawn R. Cook	15	1:30 pm
2.	340B Program in California	Dawn R. Cook	16	1:35 pm
3.	340B Retro Reclassification Process	Dawn R. Cook	17	1:45 pm
VI.	New Business			
1.	Updated 340B Compliance Program Agreement for 2019	Dawn R. Cook	18	1:55 pm
VII.	Additional Items			
1.	340B Compliance Program Agreement – Updated 2019 draft	Dawn R. Cook	22 - 45	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 12, 2018 – 10:00 a.m. to 11:30 a.m.

Commissioners Present / via Teleconference (TC):

C. Dean Germano (Chair); Viola Lujan; Daniel Santi

Staff Present:

Robert Moore, MD, MPH, MBA, CMO; Sonja Bjork, COO; Wendi West; Michelle Rollins; 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

Mr. Germano stated he had just come back from the National Association of Community Health Centers Conference in Orlando. He stated there was a lot of conversation around the 340B, including various congressional committees and the recommendations being presented. He stated they learned PBMs can get rebates from the manufacturers for helping to put drugs on formularies. So under 340B, the manufacturers were saying they were not obligated to pay the rebate amounts to 340B Covered Entities (“Covered Entities”), so what some Covered Entities were doing, at least the In-House Pharmacies was contractually lowering the reimbursement to pharmacies to take back the money lost on the rebates.

AGENDA ITEM II – APPROVAL OF MINUTES

The minutes from the 340B Advisory Committee Meetings on 3/7/18 were approved with one correction. Mr. Germano was listed as Interim Chair and that was changed to Chair. All committee members approved the minutes. 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 9/4/18, there were 340 340B Covered Sites/IDs within PHC's 14 county service area that were eligible to participate in the 340B Program, of which 144 were hospitals. At that point, no additional Covered Entities had been invited to join the 340B Compliance Program.

As of 9/4/18, invoices had been delivered to 19 of the 340B Participating Entities on a monthly basis. Ole Health received its first invoice in September 2018 for claims reclassification that occurred in May of 2018. As of 8/31/18, 18 340B Participating Entities were making monthly wire transfers to the 340BX Trust Account based on the invoices they received for each respective month.

With regard to no additional Covered Entities being invited to join the 340B Compliance Program, Mr. Germano asked if there had been any requests made to join. Ms. Cook noted that as was mentioned at the previous meeting in March 2018, Adventist Health had shown interest, but no new agreements were being executed as PHC waited for final guidance from the State so changes could be made to the 340B Compliance Agreement. In response to a question from Mr. Germano, Ms. Cook noted there were hospitals participating in the 340B Compliance Program. Regarding a question from Mr. Germano about a requirement that Covered Entities actually contribute to the compliance cost as a condition of their participation, Ms. Cook stated it was not a requirement, any payment of fees is tied solely to the use of reclassification services by 340B Clearinghouse.

Ms. West updated Ms. Cook regarding Fairchild Medical Center (FMC). Ms. West spoke to Jonathan Andrus about FMC not using the UD modifier for their PAD claims. Mr. Andrus indicated he would check-in on it and report back to Ms. West. Dr. Moore indicated Fairchild Medical Center was now second only to Shasta Community Health Center in claim volume.

Claims/Financial Summary:

Ms. Cook reviewed the claims and financial information regarding the quarter from 1/1/18 to 3/31/18, noting the information included a separate line for CVS claims, as they were reported separately by Open Door Community Health Centers (ODCHC).

Mr. Santi stated he was under the impression that CVS was working directly with Wellpartner only, and asked Ms. Cook if that was true. Ms. Cook stated she had not heard that, but she would be following up with all 340B Participating Entities to verify whether or not other 340B Administrators were submitting CVS 340B claims.

For the 1/1/18 to 3/31/18 quarter, there were 10,283 340B Paid Matched Claims, 3,972 Walgreens 340B Paid Match Claims, 492 CVS 340B Paid Match Claims for ODCHC, and 4,842 Wellpartner 340B Paid Match Claims for the quarter, for a total of 19,589 Matched Claims for the quarter. The Total 340B Compliance Fees were \$53,869.75. Of that total, \$48,972.50 were 340BX Compliance Fees and \$4,897.25 were PHC 340B Compliance Fees.

Mr. Germano asked if the 340B Compliance Fees for PHC sufficient to covered PHC's costs. Ms. Cook noted that when PHC renegotiated the fees back in 2016, the \$4.50 fee was too high so PHC negotiated the fees down to the current \$2.75 per paid 340B matched claim, of which PHC gets \$0.25. Based on calculations in 2016, if every Covered Entity in the 14 counties signed on and was participating in the 340B Compliance Program, PHC might break even. At this point, as a service to our partners and providers serving our members, PHC considers it to be the cost of doing business. Ms. Bjork stated Ms. McFarland, PHC's CFO, wanted to review the fees after some time to determine if changes needed to be made. PHC had reporting requirements they have to meet for the State for timeliness of claims and when old claims were resubmitted for 340B reclassification, it made us look untimely, as the State looked at the original date of submission.

In response to an inquiry made by Mr. Germano, Ms. Cook stated PHC does not see too many instances of requests being made to reclassify very old claims. ODCHC had that occur when they changed 340B Administrators from CaptureRx to Wellpartner. There was a lag delay of six months, so in July 2018 there were claims reprocessed from back to January 2018. Ms. Cook stated the Quality Measures for State Encounter Data (QMED), as discussed in previous 340B Advisory Committee Meetings, was how the State rated PHC's timeliness with categories like 0-90, 91-180, 181-365, and 365+. To date, PHC had not received any monetary penalties, however, they anticipated that becoming an issue. Ms. Cook noted PHC received more requests for assistance with Physician-Administered Drug (PAD) claims, which needed the addition of the UD modifier to flag them as 340B. Ms. Bjork stated PHC will monitor the requests and react appropriately.

In response to Mr. Germano's initial question about whether the 340B Compliance Fees were covering PHC's costs, Dr. Moore stated more analysis would be needed in the future. The 340B Retro Reclassification Process would be discussed later during the meeting, which included tiered costs and bring in additional 340B Compliance Fees. Ms. Lujan stated that on behalf of the Federally-Qualified Health Centers (FQHCs), she wanted to express much appreciation for keeping the costs lower in terms of the fees, but she also revisited the idea of allowing additional Covered Entities to join the 340B Compliance Program. Dr. Moore stated PHC was pretty close to being able to invite additional Covered Entities to join, but the 340B Compliance Program Agreement needed to be updated first. Allowing more Covered Entities to join would benefit hospitals and other FQHCs.

There was also a breakdown of the total claim counts for each category for each month of the quarter from 1/1/18 to 3/31/18. Ms. Cook noted it was a good example of how some months may show higher numbers of reclassified claims compared to others. Ms. Cook pointed out that in March there was a significant drop in the number of Walgreens claims tied to ongoing issues the 340B Participating Entities had with the data made available by Walgreens. In response to a question from Dr. Moore, Ms. Cook stated the trend of lower Walgreens claim counts continued a bit longer, but would be addressed next.

AGENDA ITEM IV – OLD BUSINESS

Walgreens and submission of 340B claims data:

As noted in the 340B Advisory Committee Update Letter for June 2018, Walgreens continued to be a challenge for the 340B Participating Entities submitting Walgreens 340B claims data to 340BX Clearinghouse for reclassification.

At the time of 340B Advisory Committee Update Letter for June 2018, Walgreens' proposed MCO report for use by Covered Entities in California to assist in compliant submission of 340B claims was still not completed. The 340B Participating Entities submitting Walgreens 340B claims data for reclassification continued to use multiple reports for identifying the needed claims data.

Based on information from Gail Kuwahara, Open Door Community Health Centers (ODCHC), and Amir Khoyi, PharmD, 340B Advisory Committee Member, Walgreens is close to completion of Phase 1 of updates to their reporting portal. Those updates will include the previously discussed MCO report, though the specific report name is not clear at this point. The MCO report may have been ready in July 2019, but it failed during initial testing, so additional changes had to be made.

In response to a question from Mr. Germano, Ms. Cook noted the new report was a specific California solution, not a national solution. In January 2018, there was a phone conversation Dr. Leung and Ms. Cook sat in on between Walgreens, ODCHC, and California Primary Care Association (CPCA) discussing the need for the report. Walgreens already have a solution for other states, so this one was going to specifically tie into what entities would need for California. The draft was shared with PHC, then compared to the file specs from 340BX Clearinghouse. Based on the comparison, the report would provide the data needed for claims reclassification. Ms. Cook anticipated a delay from Walgreens in releasing the report until they knew what the determination was by the State with regard to the budget. In response to an inquiry from Ms. Lujan, Ms. Cook noted if no new report was created, it would just mean the Covered Entities had to continue to use multiple reports to create the submission file. The amount of work required varied from Covered Entity to Covered Entity. Dr. Moore stated even if a new report was used, Covered Entities would want to verify the information for a while.

340B Program in California:

As reported at the time of the 340B Advisory Committee Meeting on 3/7/18, the proposed 2018-2019 Governor's Budget for the State of California was released on 1/10/18. The proposed budget included language that would "restrict 340B Drug Reimbursement within the Medi-Cal."

The May 2018 Revisions to the Governor's Budget showed no change to the proposal regarding the 340B Program. However, the proposal to eliminate the 340B drug discount program for Medi-Cal was rejected by the Legislature and was not included in the budget.

As noted in the 340B Advisory Committee Meeting for June 2018, Local Health Plans of California (LHPC) shared a copy of new proposed 340B Trailer Bill Language (TBL) with the suggested changes they made based on their review. They requested input from PHC prior to submission of their recommendations to the California Department of Health Care Services (DHCS). On 6/20/18, after PHC provided input, Amy Turnipseed, Senior Director of External and Regulatory Affairs, received an update from LHPC indicating the TBL would not go anywhere without buy-in from DHCS. If the TBL did not move forward, LHPC indicated DHCS could move forward with an All-Plan Letter (APL). As noted in the June 2018 update for the 340B Advisory Committee

As of 9/4/18, PHC had received no further communication from DHCS regarding the 340B Program in California. To date, PHC had not seen an additional TBL or a final APL. Dr. Moore noted that as it was the end of the current State Administration, there was likely a delay in further action. Mr. Germano stated he had not heard a lot at the state level. In response to Mr. Germano's inquiry about the proposed TBL, Dr. Moore stated the proposed changes from LHPC were excellent. They took all of PHC's recommendations and incorporated them. In response to Ms. Lujan, Ms. Cook noted everything was status quo for now. Regarding the APL language seen in March 2018, Dr. Moore stated it had major issues. Ms. Cook noted there were issues with what PHC would be responsible for such as auditing. Auditing was impossible for PHC, just as it was for the State. Neither party can audit for 340B. All the State could do was note there might be a duplicate discount violation. Robert Shun, Chief of Medi-Cal Rebate Department at DHCS, stated the party that knew whether or not a claim should be 340B was the

Covered Entity and their 340B Administrators. Ms. Rollins noted that one of the concerns with the draft APL was that it wanted to hold the Health Plan accountable for the accuracy of the data, which was not possible, as PHC had no way of verifying or auditing for 340B. Mr. Germano stated currently it was the responsibility of the Covered Entities to insure the information was complete and accurate.

AGENDA ITEM V – NEW BUSINESS

340B Retro Reclassification Process:

Per the current 340B Compliance Program Agreement, requests for the addition of a missing UD modifier were to be submitted to PHC's Pharmacy Services Program Manager. However, during discussions regarding a request from Sutter Health to add the UD modifier to a large number of claims, almost 13,000 claim service lines, PHC's 340B Team learned there was an existing process in place outlined in PHC's Medi-Cal Provider Manual wherein if an entity needed to correct a claim by adding a modifier, they would go through PHC's Claims Department.

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.

PHC established a work group to develop an updated process for the retroactive reclassification of 340B claims that require the addition of the UD modifier. Sonja Bjork, COO, and Robert L. Moore, CMO, will serve as the Steering Committee for this project. The work group, as well as the steering committee, will each meet once a month. Dawn R. Cook, Pharmacy Services Program Manager, is facilitating all meetings and maintaining the work group's action item spreadsheet.

The work group was addressing the discrepancy between the 340B Compliance Program and PHC's Medi-Cal Provider Manual with regard to the addition of the UD modifier when developing the process, while also updating the 340B exhibit language for the Provider Contracts to insure all documents relaying information regarding the addition of the UD modifier for reclassification of 340B claims outline the same process.

It was determined 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 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.

Current action items for the 340B Retro Reclassification Process Work Group include the following:

- The proposed updated 340B Exhibit language for Provider Contracts was reviewed by outside legal counsel. The comments and recommendations from outside counsel would be reviewed.
- The IT team was updating the Project Charter for the new process and updating the submission template.
- The work group was brainstorming ideas as to how PHC will bill providers for this service

The next 340B Retro Reclassification Process Work Group meeting was scheduled for 9/13/18.

Ms. Cook discussed the brainstorming that was taking place regarding invoices to Covered Entities for this service. Ms. Cook noted this would be a new revenue stream for PHC tied to 340B. With the proposed process, PHC's Claims Department would not had to undertake a huge manual project, as at that time the process was to have providers submit separate Electronic Claims Inquiry Form (eCIF) for each claim line and each eCIF was opened individually. One person in claims could handle 80 to 100 eCIFs a day. As such, requests involving a large number of claims would be a problem. Ms. Cook noted the inquiries she received from drug manufacturers via the State have been small, and we have been handled on a case-by-case basis. Ms. Cook contacted the providers identified, the providers investigated those claims, and they responded to Ms. Cook. If they determine they needed to add the UD modifier to any claim lines, Ms. Cook contacted PHC's Claims Department who then followed up with the provider.

Ms. Bjork noted the 340B Advisory Committee was the first to see the proposed pricing for the 340B Retro Reclassification service. Ms. Bjork stated the new 340B Retro Reclassification Process involved a lot of departments at PHC working together so they were prepared, but PHC did not have all the information. There had been concerns that the inquiries from the drug manufacturers through DHCS were going to spiral out of control. Ms. Cook had been carefully overseeing the current process. Ms. Bjork noted Ms. Cook made it easy for the entities. Ms. Cook tracked everything in a spreadsheet, which reflected that PHC was doing its due diligence with regard to the drug manufacturer inquiries.

In response to Ms. Lujan's inquiry, Ms. Cook noted that with regard to the small volume inquiries discussed, she might receive 35 service lines split between 11 providers. Dr. Moore stated that based on the experience with Sutter, he thought there were lot of claims missing UD modifiers that had not been identified, and PHC's concern was that periodically providers will submit requests to reclassify a large number of claims. PHC wanted to get ahead of any such requests. In response a comment by Ms.

Lujan regarding time frames, as well as an increase in emphasis on 340B regulations, Dr. Moore stated PHC anticipated providers identifying large volumes of claims going back years that missed the UD modifier. PHC would be able to handle large requests with this process. Regarding limits, Dr. Moore noted, theoretically, claims sent to PHC's Claims Department had a one year limit, but the State indicated that even with that restriction, PHC would still have to correct 340B claims. Dr. Moore stated PHC hoped to have Covered Entities signed up as soon as possible so they didn't try to get out of paying the 340B Compliance Fees. The new process, including fees, will be documented for all provider types. Ms. Bjork indicated PHC was adding updated 340B language to hospital contracts and the next phase would be the Primary Care Provider contracts. Dr. Moore noted PHC would update the Provider Manual to reflect the new process and to make it crystal clear that this was the process, whether you sign the 340B Compliance Program Agreement or not, including paying the fees for reclassification.

Ms. Cook stated the fee schedule was drafted not knowing the final guidance from the State regarding the 340B Program. PHC continues to hope the State will require an agreement between the Health Plan and the Covered Entity in order to participate in 340B. However, two fee schedules were created to differentiate those participating in the 340B Compliance Program from those not participating. The payment tiers for each schedule were broken down by the QMED tiers for timeliness, as previously discussed. For 340B Participating Entities, the 340B Compliance Fee per paid claim that matched was much less than the 340B Compliance Fees for the non-participants. It was hoped that the fees would encourage the Covered Entities to put the UD modifier on their PAD claims. Per Ms. Bjork, Patti McFarland, CFO, approved the fee schedules, asking that the process be monitored. After the process was in place for six months, Ms. McFarland will want an update on whether or not the IT solution worked, as well as if really old claims were being submitted.

Besides waiting on guidance regarding 340B, Ms. Bjork noted the State had indicated they were going to put much more scrutiny on QMED deal, with the last couple years serving as a testing phase. To date, the reports have simply reported whether the Health Plan passed or failed. It was anticipated that soon, the State would use the data collected from QMED for rate development.

The committee discussed the causes that might lead to claims missing the UD modifier. Examples included changes to billing service providers and lack of education to new or existing staff. Ms. Bjork noted the new process was just for the PAD claims with the UD modifiers, which was a smaller volume of drug claims compared to Contract Pharmacy claims, so it was only a small portion of the big picture.

In discussing the 340B Compliance Fees, Dr. Moore noted there was no fee if the claim included the UD modifier when initially submitted. Ms. Cook noted 340B Compliance Fee was per claim service line, not the whole claim. The fee schedule was specifically for the reclassification of the Physician-Administered Drug claim service lines that require the UD modifier. However, as the process could be requested by non-participating Covered Entities, it raised questions regarding doing the same with the Contract Pharmacy claims. Ms. Cook explained that at that time, if a Covered Entity was not participating in PHC's 340B Compliance Program, they don't get the assistance of 340BX Clearinghouse. The agreement between PHC and 340BX Clearinghouse, who provided the reclassification service, stated an entity had to have an agreement with PHC in order for them to provide the service. Ms. Cook stated if PHC were to consider offering reclassification of Contract Pharmacy claims to non-participants or using a tiered fee schedule Contract Pharmacy claims based on the age of the claim, it would require renegotiation with 340BX Clearinghouse. Dr. Moore stated it might be best to leave the agreement with 340BX Clearinghouse alone since the Contract Pharmacy claim requests were not happening often and handled on a case-by-case basis.

Ms. Cook stated the issue was what to do if a Covered Entity that was not a participant, but had contract pharmacy claims are suddenly approached due to incorrect coding. Right now, PHC is unable to assist non-participants. If this was something PHC decided it needed to do, it would be tied to PHC being held responsible for accurate data by the State. If that were the case, if PHC was notified that something was not identified as 340B, and they provided no correction assistance, then the Health Plan would be non-compliant. In response to an inquiry from Dr. Moore, Ms. Cook stated all claims, including Contract Pharmacy claims, were part of QMED. With regard to the Contract Pharmacy claims and reclassification of 340B Claims, Dr. Moore felt it would be best if PHC had the 340B Compliance Agreement signed in order to provide the reclassification service. Ms. Bjork stated so far that was PHC's position, but that approach may have to be adjusted depending on the final APL language. Ms. Cook stated that because there had been more of a need for the addition of the UD modifier, the focus was on that aspect of 340B. Plus, that was an area not really captured throughout the years with the 340B Compliance Program, so it would be a focus. However, the non-participant Contract Pharmacy claims might be an issue down the road. Dr. Moore stated that would be a big ask of the State. Ms. Cook stated that for PHC, because the PAD claims were processed in-house, it was easier to manage and oversee with regard to these requests. There could be an increase in the number of providers wanting to join the program. The question would then be whether or not to open the 340B Compliance Program up to Covered Entities physically located outside PHC's 14 county service area, such as specialists, that may use 340B, and have drugs dispensed to PHC members. Dr. Moore stated PHC should only contract within the 14 counties. Ms. Cook reiterated that as Dr. Leung has said previously, PHC was focusing on Covered Entities serving PHC members in its 14 county service area, as their 340B savings were going back to PHC members. Mr. Germano stated that was a strong position to hold and it stood up to scrutiny.

In response to a question from Ms. Lujan, Dr. Moore clarified that for the process of adding the UD modifier, all fees would go directly to PHC. This proposed fees schedule was for retro reclassification with the UD modifier. Those were provider claims, so they come directly to PHC's Claims Department. Ms. Cook indicated that the new 340B Retro Reclassification Process, as well as stronger language regarding the 340B Participating Entities obligation to inform PHC of any changes to its 340B Program, were part of a long list of changes to be made to the 340B Compliance Program Agreement.

Dr. Moore estimated a new, reviewed agreement could be ready in 2019. Ms. Cook reminded the committee they had previously reviewed an updated draft agreement, but that draft had to be put on hold. Many of those previous changes would be seen again in the new draft. PHC wanted to also include language on Tribal Health, specifically looking at arbitration language and tribal sovereignty. Although outside legal counsel had reviewed some initial 340B Exhibit language for the hospital contracts executed through the Provider Relations department, the whole updated 340B Compliance Program Agreement would have to be reviewed by outside legal counsel. Dr. Moore stated optimistically there would be a new agreement ready by for review in early 2019 and ready for use in April 2019, but it may not be until July 2019. Ms. Cook stated the next scheduled 340B Advisory Committee Meeting was scheduled for March 2019, and as much work as could be done by then would be completed. If there was a new agreement, we would terminate all current 340B Compliance Agreements and issue new agreements to avoid confusion. Once the updated agreement was ready, new entities could be invited to join the 340B Compliance Program. Dr. Moore hoped an agreement that was well vetted by outside legal agreement could be ready to present to the committee in March 2019, then use it for April 2019. Dr. Moore stated the draft would be sent out to the committee members in advance for feedback.

Ms. Bjork asked that if an APL was received, it be sent to the committee straight away, as it may require an emergency meeting.

AGENDA ITEM VI – ADDITIONAL ITEMS

Additional comments:

Ms. Cook noted an update letter would be sent out for December 2018. The 340B Advisory Committee Meetings for 2019 were scheduled for 3/15/19 from 1:00 PM to 2:25 PM and 9/25/19 from 10:00 AM to 11:25 AM.

Documents:

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

AGENDA ITEM VII – ADJOURNMENT

Meeting Adjourned: 11:20 a.m.
Respectfully submitted: Dawn R. Cook

The foregoing minutes were APPROVED AS PRESENTED on:

C. Dean Germano, Committee Chairman

Date

The foregoing minutes were APPROVED WITH MODIFICATION on:

C. Dean Germano, Committee Chairman

Date



PARTNERSHIP HEALTHPLAN OF CALIFORNIA

PHC 340B Advisory Committee Meeting

3-15-19

Agenda

- 
- 340B Compliance Program Update

- 
- Walgreens and submission of 340B claims data

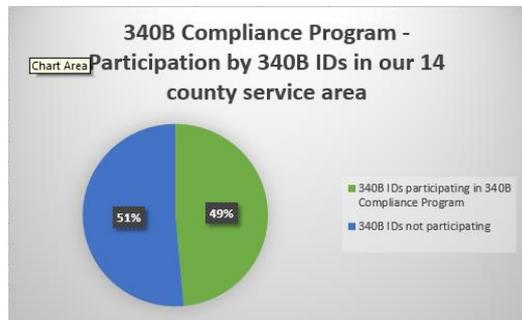
- 
- 340B Program in California

- 
- 340B Retro Reclassification Process

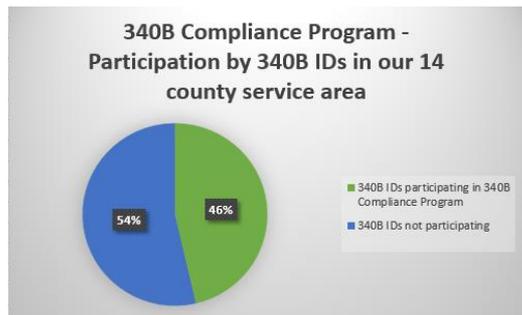
- 
- 340B Compliance Program Agreement

340B Compliance Program Update

- As of 3/7/19, there were 342 active 340B Sites/IDs within PHC's 14 county service area, 143 of which were hospitals. There were 27 executed 340B Compliance Program Agreements covering 166 active 340B Sites/IDs, 42 of which are hospitals.



- As of 4/1/19, there will be 333 active 340B Sites/IDs within PHC's 14 county service area, 143 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)

- No additional 340B Covered Entities have been invited to join the 340B Compliance Program.
- As of 3/7/19, invoices were delivered to 20 of PHC's 340B Participating Entities on a monthly basis. McCloud Healthcare Clinic Inc. received its first invoice in February for claims reclassification that occurred in October 2018.
- As of 2/28/19, 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 7/1/18 to 9/30/18

7/1/18 to 9/30/18													
Entity	340B Paid Match Claim Count	340B Reversal Claim Count	Walgreens 340B Paid Match Claim Count	Walgreens 340B Reversal Match Claim Count	CVS 340B Paid Match Claim Count	CVS 340B Reversal Claim Count	Wellpartner 340B Paid Match Claim Count	Wellpartner 340B Reversal Match Claim Count	SunRx 340B Paid Match Claim Count	SunRx 340B Paid Reversal Claim Count	340BX Compliance Fee	PHC 340B Compliance Fee	Total 340B Compliance Fees
Alliance Medical Center	92	0	0	0	0	0	0	0	0	0	\$ 230.00	\$ 23.00	\$ 253.00
CommuniCare Health Centers	769	0	229	1	0	0	0	0	0	0	\$ 2,495.00	\$ 249.50	\$ 2,744.50
Fairchild Medical Center	1,483	2	0	0	0	0	0	0	0	0	\$ 3,707.50	\$ 370.75	\$ 4,078.25
Hill Country Community Clinic	539	2	0	0	0	0	0	0	0	0	\$ 1,347.50	\$ 134.75	\$ 1,482.25
La Clinica De La Raza	0	0	1,631	2	0	0	0	0	0	0	\$ 4,077.50	\$ 407.75	\$ 4,485.25
Long Valley Health Center	30	0	0	0	0	0	0	0	0	0	\$ 75.00	\$ 7.50	\$ 82.50
Marin Community Clinic Inc.	0	0	0	0	0	0	0	0	0	0	\$ -	\$ -	\$ -
Mendocino Coast Clinics, Inc.	490	3	0	0	0	0	0	0	0	0	\$ 1,225.00	\$ 122.50	\$ 1,347.50
Mendocino Coast District Hospital	168	2	0	0	0	0	0	0	0	0	\$ 420.00	\$ 42.00	\$ 462.00
Mendocino Community Health Clinics, Inc.	1,131	4	390	0	0	0	0	0	0	0	\$ 3,802.50	\$ 380.25	\$ 4,182.75
Mountain Valleys Health Centers, Inc.	238	0	0	0	0	0	0	0	0	0	\$ 595.00	\$ 59.50	\$ 654.50
Northeastern Rural Health Clinics, Inc.	645	0	0	0	0	0	0	0	0	0	\$ 1,612.50	\$ 161.25	\$ 1,773.75
Ole Health	0	0	0	0	0	0	0	0	5,307	8	\$ 13,267.50	\$ 1,326.75	\$ 14,594.25
Open Door Community Health Centers	1,168	3	1,842	10	727	25	5,506	55	0	0	\$ 23,107.50	\$ 2,310.75	\$ 25,418.25
Petaluma Health Center	0	0	0	0	0	0	0	0	0	0	\$ -	\$ -	\$ -
Redwoods Rural Health Center	187	4	0	0	0	0	0	0	0	0	\$ 467.50	\$ 46.75	\$ 514.25
Santa Rosa Community Health Centers	0	0	0	0	0	0	0	0	0	0	\$ -	\$ -	\$ -
Shasta Community Health Centers	3,181	6	1,566	5	0	0	0	0	0	0	\$ 11,867.50	\$ 1,186.75	\$ 13,054.25
Shingletown Medical Center	93	0	0	0	0	0	0	0	0	0	\$ 232.50	\$ 23.25	\$ 255.75
Solano, County of	160	2	0	0	0	0	0	0	0	0	\$ 400.00	\$ 40.00	\$ 440.00
Sonoma Valley Community Health Center	160	2	0	0	0	0	0	0	0	0	\$ 400.00	\$ 40.00	\$ 440.00
Winters Healthcare Foundation	103	1	0	0	0	0	0	0	0	0	\$ 257.50	\$ 25.75	\$ 283.25
QUARTER TOTALS:	10,637	31	5,658	18	727	25	5,506	55	5,307	8	\$ 69,587.50	\$ 6,958.75	\$ 76,546.25

Claims/Financial Summary (cont'd)

Claims/Financial summary for 7/1/18 to 9/30/18

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	CVS 340B Reversal Claim Count	Wellpartner 340B Paid Match Claim Count	Wellpartner 340B Reversal Match Claim Count	SunRx 340B Paid Match Claim Count	SunRx 340B Paid Reversal Claim Count	340BX Compliance Fee	PHC 340B Compliance Fee	Total 340B Compliance Fees
July-18	4,565	11	2,523	9	622	4	2,202	29	1,903	4	\$29,537.50	\$2,953.75	\$32,491.25
August-18	1,720	4	805	1	105	15	786	5	1,636	1	\$12,630.00	\$1,263.00	\$13,893.00
September-18	4,352	16	2,330	8	0	6	2,518	21	1,768	3	\$27,420.00	\$2,742.00	\$30,162.00
TOTAL:	10,637	31	5,658	18	727	25	5,506	55	5,307	8	\$69,587.50	\$ 6,958.75	\$ 76,546.25

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.

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 want 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.
- 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."

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.

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.
- 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 to 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.

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]

Formatted: Normal, Right: 0.28", Space After: 3 pt, Line spacing: single

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

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

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

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

I. Definitions and Acronyms

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

Deleted: ("OPA") 340B Database

Formatted: Highlight

- 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

Deleted: <#>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.*

Deleted: OPA

Deleted: Database

Deleted: <https://opanel.hrsa.gov/340B/Views/CoveredEntity/SearchDirectory>*

Deleted: OPA 340B Database

Deleted: or

Deleted: the Bank of San Antonio

Clearinghouse as a holding account to deposit 340B related funds paid by 340B Participating Entities, and also to transfer funds to PHC's bank account.

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

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

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

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

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

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

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

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

III. Purposes of this Agreement

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

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

IV. 340B Compliance for 340B Claim Reporting

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

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

Formatted

Deleted: Covered Outpatient Drugs

Should a 340B Participating Entity or one of its 340B Administrators choose to submit 340B claims for a Contract Pharmacy or In-House Pharmacy to PHC without having it go through the reclassification process via Clearinghouse, such claims may not be compliant with 340B Program identification (flagging) requirements. The 340B Participating Entity acknowledges that it will be the sole accountable party regarding any Contract Pharmacy or In-House Pharmacy 340B claims that are not reviewed by Clearinghouse should an audit occur. In the event the 340B Participating Entity requires assistance with appropriate identification (flagging) and claims adjudication compliance for 340B claims originating from a Contract Pharmacy or In-House Pharmacy, the 340B Participating Entity will submit a formal written request and file containing the needed claims information to identify each claim. By submitting the formal request to reclassify claims to identify 340B drugs, the 340B Participating Entity acknowledges it will adhere to the established PHC process with Clearinghouse for the fee outlined in Attachment A, PHC will evaluate each request to determine if the request can be fulfilled. PHC will inform the 340B Participating Entity of the decision within 10 business days of receipt of the formal request from the 340B Participating Entity.

b. PAD claims, Physician-Dispensed Drugs, and 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 claims (including PAD claims, Physician-Dispensed 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 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 claims missing the UD modifier, PHC has established a process for assisting 340B Participating Entities to correct 340B claims missing the UD modifier.

iii. With submission of the initial request to assist with identification (flagging) of 340B claims 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.

Commented [DRC1]: Are all PAD claim references, should we not "claim service line" versus just claim? Per previous conversations, provider claims often have multiple service lines associated with a single claim submitted to PHC.

Formatted

Deleted: flagging

Deleted: filed

Deleted: by

Deleted: they may submit a formal written request to PHC along with a file containing the needed claims information to identify each claim

<http://www.partnershiphp.org/Providers/Pharmacy/Pages/340B-Compliance-Program.aspx>.

c. Submission of accurate data

- i. The 340B Participating Entity takes full responsibility for providing accurate, complete, and necessary data to enable PHC and Clearinghouse to perform their services hereunder, and to maintain records to verify the accuracy and completeness of such data.
- ii. The 340B Participating Entity also takes full responsibility for providing accurate, complete, and necessary data when submitting 340B claims data for PAD claims, Physician-Dispensed Drugs, and 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. 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.

Deleted: <#>For additional information please refer to the 340B Compliance Program Policy (add link). By submitting the formal request to assist with identification (flagging) of 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.¶

Formatted: Not Highlight

Formatted: Font color: Auto

Deleted: all

Deleted: to

Deleted: e

Deleted: co

Deleted: its

Commented [DRC2]: For all PAD claim references, should we not "claim service line" versus just claim? Per previous conversations, provider claims often have multiple service lines associated with a single claim submitted to PHC. We do not want them to expect to submit multiple drug lines, but only pay one fee if they are under the same claim.

V. **Reclassification Fees**

a. Contract Pharmacy/In-House Pharmacy claims reclassified by 340BX Clearinghouse

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

Formatted: Numbered + Level: 2 + Numbering Style: i, ii, iii, ... + Start at: 1 + Alignment: Right + Aligned at: 0.75" + Indent at: 1"

Deleted: the

Deleted: prescription

Deleted: the Department of Health Care Services

Deleted: B

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 claims, Physician-Dispensed Drugs, and drug costs submitted as part of a fee-for-service, bundled, or capitated rate reclassified by PHC

Formatted

- i. If the 340B Participating Entity submits PAD claims, Physician-Dispensed Drugs, and 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 claims missing the UD modifier, the 340B Participating Entity will pay reclassification fees for any 340B claim reclassified by PHC, as defined in Attachment A. Payment of these reclassification fees is on a per paid 340B drug claim basis.

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

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

VII. Terms and Termination of Agreement

- a. Term: The initial term of this Agreement shall begin on the Effective Date and shall expire two (2) years after. Thereafter, this Agreement shall renew automatically for additional, successive terms of one (1) year until terminated by either party. This Agreement may be terminated with or without cause based on the provisions herein.
- b. Termination for cause: If a party defaults in any of its obligations under this Agreement, the non-breaching party, at its option, shall have the right to terminate this Agreement by providing thirty (30) calendar days written notice of the material breach of this Agreement to the defaulting party. The defaulting party shall have ten (10) business days to cure such default upon receipt of the

Deleted: ¶

Deleted: and/or

Deleted: of

Deleted: 's Pharmacy Services Program Manager

Field Code Changed

Deleted: the listed

Deleted: as

Deleted: ¶

<#>Protection from excessive 340B Drug Costs¶

¶

<#>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. ¶

<#>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.¶

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.

Deleted: Services Program Manager

IX. Further Agreements

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

Health & Human Services Center for Medicare & Medicaid Services and HRSA with respect to its oversight of the Medicaid and 340B programs, respectively.

X. Other Provisions

a. **Dispute Resolution:** In the event that any dispute between the 340B Participating Entity and PHC arises out of this Agreement, it shall not result in a delay of services as required under this Agreement. However, subject to California Government Code sections 900 *et seq.*, any such dispute shall be resolved as required by the subsections below::

- i. **Meet and Confer:** The parties agree to meet and confer on any issue that is the subject of dispute under this Agreement ("Meet and Confer"), as a condition precedent to arbitration under subsection (ii) below. The party seeking to initiate the Meet and Confer procedure (the "Initiating Party") shall give written notice to the other party describing in general terms the nature of the dispute, the Initiating Party's position, and identifying one or more individuals with authority to resolve the dispute on such party's behalf. The party receiving the notice (the "Responding Party") shall have ten (10) business days with which to respond to the notice. The response shall include the Responding Party's position and shall identify one or more individuals with authority to resolve the dispute on such party's behalf. The individuals so designated shall be known as the "Authorized Individuals." The Authorized Individuals shall meet at a mutually acceptable time and location within thirty (30) calendar days of the Initiating Party's notice and thereafter as often as necessary to exchange relevant information and to attempt to resolve the dispute. If the matter has not been resolved within sixty (60) calendar days of the Initiating Party's notice or if the Responding Party will not meet within thirty (30) calendar day, either party may submit the dispute to binding arbitration in accordance with the following procedures and shall give the other party written notice that the matter is being submitted to binding arbitration. All deadlines specified in this Meet and Confer procedure may be extended by mutual agreement of the parties. In addition, nothing in this subsection shall impede or limit the ability of the parties to submit the dispute to mediation for resolution.
- ii. **Arbitration:** Upon written demand by either party, and after exhaustion of the Meet and Confer procedure set for in subsection (i) above, any dispute arising out of this Agreement, including any issue regarding interpretation, validity, or termination, shall be referred to and submitted to mandatory binding arbitration pursuant to the California Arbitration Act (Code of Civil Procedure Sections 1280 *et seq.*) The arbitration shall be administered by JAMS in

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

- b. Entire Agreement: This Agreement, with its Attachments, constitutes the entire agreement between the parties governing the subject matter of this Agreement. This Agreement replaces any prior written or oral communications or agreements between the parties relating to the subject matter of this Agreement.
- c. Existing Contract: This Agreement does not supersede nor replace the existing Primary Care Provider, Specialty Provider, or Hospital Provider Contract between PHC and the 340B Participating Entity. ~~If this Agreement conflicts with the Provider Contract between the Parties, the Provider Contract shall prevail.~~
- d. Subcontractors: The 340B Participating Entity may use subcontractors to perform its services under this Agreement. The 340B Participating Entity is responsible for their services to the same extent that the 340B Participating Entity would have been had the 340B Participating Entity performed the services without the use of a subcontractor.
- e. Amendment: Except as may otherwise be specified in this Agreement and an applicable Attachment, this Agreement (including its Attachments) may be amended only by both parties agreeing to the amendment in writing, executed by a duly authorized person of each party.
- f. Waiver/Estoppel: Nothing in this Agreement is considered to be waived by any party, unless the party claiming the waiver receives the waiver in writing. No breach of the

Deleted: , with the exception of Section VII of this Agreement, which modifies the Primary Care QIP

Deleted: Aside from Section VII, i

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: _____

By: _____

Title: _____

Date: _____

Address: _____

Signature _____

By: Elizabeth Gibboney

Title: CEO

Date: _____

Address: 4665 Business Center Drive
Fairfield, CA 94534

Attachment A: Fee Schedule for 340B Compliance Program

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

Formatted: Font: Bold

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)

Deleted: prescription

Deleted: prescription

Deleted: 340B PAD claims flagged appropriately by the 340B Participating Entity with the UD Modifier

Deleted: No fee

Deleted: 340B PAD claims not flagged appropriately by the 340B Participating Entity requiring intervention by PHC to add the UD Modifier

Deleted: \$2.75 per paid 340B prescription claim (\$2.75 PHC 340B Compliance Fee)

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

340B PAD claims not flagged appropriately by the 340B Participating Entity requiring intervention by PHC to add the UD modifier.

Formatted: Indent: Left: 0"

Formatted: Font: Bold

Deleted: ¶

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

Deleted: *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

Deleted: ¶

1. Contract Pharmacy 340B Drug Claims:

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

Deleted: One f

Deleted: should

Deleted: should

Deleted: ninety (90)

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.

Deleted: prescription

3. PAD 340B drug claims/Physician-Dispensed Drug 340B drug Claims/340B drug 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 drug claims tied to PADs and Physician-Dispensed Drugs, are flagged appropriately with the UD modifier.

Deleted: a CMS-1500 or UB-04 form or related format

Deleted:

Formatted: Font: Bold

Formatted: Font: Bold

Formatted: Font: Bold

Deleted:

Deleted: 340B claims

Deleted: p

Formatted: Underline

- 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.

Deleted: a

Deleted: CMS-1500 or UB-04 form

Attachment C: 340BX Clearinghouse Reclassification & Invoicing Schedule

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

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

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

Deleted: July 2016

Deleted: June 2016

Deleted: March 2016

Deleted: March 2016

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

Deleted: March 2016

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

Deleted: S
Deleted:

***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.**

Formatted: Font: Not Bold

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

 <div style="background-color: #005696; color: white; padding: 5px;"> Partnership HealthPlan of California 340B Compliance Program Change Notification </div>					
Date of Notification <input type="text" value=""/>					
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"/>				
<p>DESCRIPTION OF CHANGE</p> <table border="1"> <tr> <td style="width: 35%;">Type of Change</td> <td> Choose an item. Please Select One <input type="text"/> </td> </tr> <tr> <td> 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. </td> <td><input type="text"/></td> </tr> </table>		Type of Change	Choose an item. Please Select One <input type="text"/>	Change Details Examples: Name of site or pharmacy, 340B ID #, Address, Contact Information, etc. If applicable, the information provided should match column headers from the respective attachment from the agreement.	<input type="text"/>
Type of Change	Choose an item. Please Select One <input type="text"/>				
Change Details Examples: Name of site or pharmacy, 340B ID #, Address, Contact Information, etc. If applicable, the information provided should match column headers from the respective attachment from the agreement.	<input type="text"/>				
Effective Date of Change: <input type="text" value=""/>					
Please email form to the following email: 340BQIP@partnershiphp.org					
<div style="background-color: red; color: white; padding: 10px 20px; display: inline-block; border-radius: 5px;"> Submit Form </div>					
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 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.”