



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

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

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

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

cc: Sonja Bjork, COO, PHC

FROM: Dawn R. Cook
DATE: November 27, 2017

SUBJECT: ADDITIONAL 340B ADVISORY COMMITTEE MEETING FOR 2017

The 340B Advisory Committee will meet as follows, the third meeting of 2017, but will return to meeting biannually. Please review the Meeting Agenda and attached packet, as discussion time is limited.

DATE: Monday, December 4, 2017 **TIME: 11:00 a.m. – 12:00 p.m.**

LOCATIONS: Video Conferencing

Partnership HealthPlan of CA Solano Conference Room 4665 Business Center Drive Fairfield, CA 94534 <i>*Please Park in Front of Bldg. *Ask the receptionist to call Dawn R. Cook</i>	PHC Redding Office 2525 Airpark Drive Redding, CA 96001 <i>*Ask for Susie</i>	PHC Santa Rosa Office 495 Tesconi Circle Santa Rosa, CA 95401 <i>*Ask for Sheila</i>
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Please contact Dawn R. Cook at (707) 419-7979 or e-mail 340BOIP@partnershiphp.org if you are unable to attend.

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

Date: December 4, 2017 Time: 11:00 a.m. – 12:00 p.m. Location: PHC

PUBLIC COMMENTS		Speaker	2 minutes	
		Speaker	2 minutes	
<i>Welcome / Introductions</i>				
	<i>Topic</i>	<i>Lead</i>	<i>Page #</i>	<i>Time</i>
I.	Opening Comments	Chair		11:04 am
II.	Approval of Minutes	Chair	3 - 7	11:08 am
III.	Standing Agenda Items			
1.	Partnership HealthPlan of California (PHC) 340B Compliance Program Update	Dawn R. Cook	10 - 11	11:10 am
IV.	Old Business			
1.	Planning for changes to the 340B Compliance Program and Agreement	Dawn R. Cook	12	11:20 am
2.	Changes to 340BX Clearinghouse matching criteria	Dawn R. Cook	13	11:32 am
V.	New Business			
1.	340B Advisory Committee – Member Updates	Dawn R. Cook	14	11:37 am
2.	DHCS notification and manufacturers seeking refunds for rebates	Dawn R. Cook	15	11:42 am
VI.	Additional Items			
1.	Letter to 340B Participating Entities identified by DHCS	Dawn R. Cook	19	N/A
2.	Reminder letter regarding the UD modifier	Dawn R. Cook	20 - 22	N/A
VII.	Adjournment			



PARTNERSHIP HEALTHPLAN OF CALIFORNIA (PHC)

Minutes of the Meeting

PHC 340B Advisory Committee held at PHC Fairfield Office

4665 Business Center Drive, Fairfield, California 94534

Napa/Solano Room

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

Commissioners Present / via Teleconference (TC):

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

Staff Present:

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

PUBLIC COMMENTS

None presented.

WELCOME/INTRODUCTION

Brief introductions were made.

AGENDA ITEM I – OPENING COMMENTS

None presented.

AGENDA ITEM II – APPROVAL OF MINUTES

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

AGENDA ITEM III – STANDING AGENDA ITEMS

PHC 340B Compliance Program Update

340B Compliance Program Update:

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

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

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

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

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

Claims/Financial Summary:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

AGENDA ITEM IV – OLD BUSINESS

There was no old business to address during this meeting.

AGENDA ITEM V – NEW BUSINESS

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

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

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

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

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

340BX Clearinghouse Update:

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

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

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

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

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

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

AGENDA ITEM VI – ADDITIONAL ITEMS

Additional comments:

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

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

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

Documents:

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

- None

AGENDA ITEM VII – ADJOURNMENT

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

The foregoing minutes were APPROVED AS PRESENTED on:

Viola Lujan, Acting Committee Chairman

Date

The foregoing minutes were APPROVED WITH MODIFICATION on:

Viola Lujan, Acting Committee Chairman

Date



PARTNERSHIP HEALTHPLAN OF CALIFORNIA

PHC 340B Advisory Committee Meeting

12-4-17

Agenda

- 
- 340B Compliance Program Update

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- Planning for changes to the 340B Compliance Program

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- Changes to 340BX Clearinghouse matching criteria

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- 340B Advisory Committee – Member Updates

- 
- DHCS notification and manufacturers seeking refunds for rebates

340B Compliance Program Update

- As of 12/1/17, there were 325 340B Covered Sites within PHC's 14 county service area, 146 of which are hospitals.
- There are 148 sites/340B IDs (27 entities/agreements) currently active in the 340B Compliance Program.
- There will be an additional two (2) sites/340B IDs (one entity/agreement) active in the 340B Compliance Program effective 1/1/18.
- 340B Clearinghouse has received Walgreens claims files from five(5) 340B Participating Entities, four (4) of which have already received invoices for those claims.
- Invoices and wire transfers continue to be respectively delivered and received for 15 340B Participating Entities on a monthly basis.
- There were 15 340B Participating Entities that made monthly wire transfers to the 340BX Trust Account based on the invoice received for that respective month.

Claims/Financial Summary

Claims/Financial summary for 4/1/17 to 6/30/17

4/1/17 to 6/30/17									
Entity	340B Paid Match Claim Count	340B Reversal Claim Count	Walgreens 340B Paid Match Claim Count	Walgreens 340B Reversal Match Claim Count	Wellpartner 340B Paid Match Claim Count	Wellpartner 340B Reversal Match Claim Count	340BX Compliance Fee	PHC 340B Compliance Fee	Total 340B Compliance Fees
Alliance Medical Center	114	0	0	0	0	0	\$ 285.00	\$ 28.50	\$ 313.50
CommuniCare Health Centers	636	5	340	0	0	0	\$ 2,440.00	\$ 244.00	\$ 2,684.00
Fairchild Medical Center	2,319	2	0	0	0	0	\$ 5,797.50	\$ 579.75	\$ 6,377.25
Hill Country Community Clinic	378	1	0	0	0	0	\$ 945.00	\$ 94.50	\$ 1,039.50
La Clinica De La Raza	0	0	1,204	0	0	0	\$ 3,010.00	\$ 301.00	\$ 3,311.00
Marin Community Clinic Inc.	0	0	0	0	0	0	\$ -	\$ -	\$ -
Mendocino Coast Clinics, Inc.	523	3	0	0	0	0	\$ 1,307.50	\$ 130.75	\$ 1,438.25
Mendocino Community Health Clinics, Inc.	1,327	2	383	0	0	0	\$ 4,275.00	\$ 427.50	\$ 4,702.50
Mountain Valleys Health Centers, Inc.	427	0	0	0	0	0	\$ 1,067.50	\$ 106.75	\$ 1,174.25
Northeastern Rural Health Clinics, Inc.	620	0	0	0	0	0	\$ 1,550.00	\$ 155.00	\$ 1,705.00
Open Door Community Health Centers	57	2	0	0	0	0	\$ 142.50	\$ 14.25	\$ 156.75
Redwoods Rural Health Center	0	0	0	0	0	0	\$ -	\$ -	\$ -
Petaluma Health Center	46	0	0	0	0	0	\$ 115.00	\$ 11.50	\$ 126.50
Santa Rosa Community Health Centers	0	1	0	0	0	0	\$ -	\$ -	\$ -
Shasta Community Health Centers	4,353	23	1,533	0	0	0	\$ 14,715.00	\$ 1,471.50	\$ 16,186.50
Shingletown Medical Center	91	0	0	0	0	0	\$ 227.50	\$ 22.75	\$ 250.25
Solano, County of	9	1	0	0	0	0	\$ 22.50	\$ 2.25	\$ 24.75
Sonoma Valley Community Health Center	189	0	0	0	0	0	\$ 472.50	\$ 47.25	\$ 519.75
QUARTER TOTALS:	11,089	40	3,460	0	0	0	\$ 36,372.50	\$ 3,637.25	\$ 40,009.75

Month	Total 340B Paid Match Claim Count	Total 340B Reversal Claim Count	Walgreens 340B Paid Match Claim Count	Walgreens 340B Reversal Match Claim Count	Wellpartner 340B Paid Match Claim Count	Wellpartner 340B Reversal Match Claim Count	340BX Compliance Fee	PHC 340B Compliance Fee	Total 340B Compliance Fees
April-17	2,839	10	738	0	0	0	\$8,942.50	\$894.25	\$9,836.75
May-17	3,391	14	1,531	0	0	0	\$12,305.00	\$1,230.50	\$13,535.50
June-17	4,859	16	1,191	0	0	0	\$15,125.00	\$1,512.50	\$16,637.50
TOTAL:	11,089	40	3,460	0	0	0	\$ 36,372.50	\$ 3,637.25	\$ 40,009.75

Planning for changes to the 340B Compliance Program Agreement

- In April 2016, PHC completed a major overhaul of the 340B Compliance Program including revision of the 340B Compliance Program Agreement. This was followed by the execution of a major amendment in October 2016 when the final version of the current 340B Compliance Program Agreement was adopted.
- Since the last 340B Advisory Committee Meeting on 9/13/17, communication with the California Department of Health Care Services (DHCS) and Sutter Health, as well as amongst various PHC Departments has brought process information to light that will need to be updated in the 340B Compliance Program Agreement. Specifically, the use of the UD modifier and requests for the addition of that modifier will need to be addressed.
- Based on the possible changes that need to be made to the 340B Compliance Program Agreement, PHC will have to undergo renegotiation of the terms of the agreement with 340BX Clearinghouse, which would likely produce an amendment.
- When the 340B Compliance Program Agreement is updated, the 340B Compliance Program Policy will also have to be updated and sent for review by all appropriate committees.

Changes to 340BX Clearinghouse matching criteria

- During the 340B Advisory Committee Meeting on 9/13/17, updates regarding 340BX Clearinghouse were provided. One of the updates was that the matching criteria used for reclassifying 340B claims was changed. At that point, there was only one month of claims data to review, July 2017, but the change in criteria seemed to have made a difference. The main reason for claims not matching was “Prescription Reference Number,” but it was determined that was tied to the dates of claims which PHC submitted to the State in August 2017.
- At the time of the 340B Advisory Committee Meeting on 9/13/17, a request was made for an update in the next few months.
- As of November 2017, three (3) months of unmatched claims data has been reviewed. Based on analysis of the data, the “Prescription Reference Number” reason code is still the main reason for claims not matching. Once again, a connection was seen with the dates of the claims submitted to the State by PHC each month.

340B Advisory Committee – Member Updates

- Chair of the 340B Advisory Committee
 - C. Dean Germano, CEO of Shasta Community Health Center, is assuming the role of Chair of the 340B Advisory Committee. He will be Interim Chair on 12/4/17, with his effective date as Chair being the date of the next Board Meeting on 12/6/17.

- Resignations
 - Julie Johnston resigned from the 340B Advisory Committee as she left her position at Shasta Community Health Center. This information will be presented to the Board for approval on 12/6/17.

- New members
 - Daniel Santi, Director of Finance at Shasta Community Health Center, has been nominated as a new member of the 340B Advisory Committee. This nomination will be presented to the Board for approval on 12/6/17.

DHCS notification and Manufacturers seeking refunds for rebates

- On 10/24/17, PHC received an e-mail from DHCS identifying four (4) 340B Covered Entities that may not be including 340B identifiers on their County Organized Health System (COHS) Physician-Administered Drug (PAD) claims. The four (4) 340B Covered Entities identified all participate in PHC's 340B Compliance Program.
- In response to PHC's request for additional information, on 10/26/17, DHCS informed PHC that there are several large disputes they are working on now concerning possible duplicate discounts. Drug manufacturers can dispute claims as far back as 1992. The drug manufacturers are working with new contractors to review older periods and are becoming much more aggressive in disputing rebates.
- In light of the information above, the 340B Team drafted two letters.
 - The first letter was specifically for the four (4) 340B Covered Entities identified by DHCS, which may not be including 340B identifiers on their COHS PAD claims. Those letters were sent to the respective 340B Covered Entities via e-mail on 11/13/17.
 - The second letter is draft as a friendly reminder regarding the use of the UD modifier, as well as reminder that PHC has a 340B Compliance Program. This letter will be sent to all 340B Covered Entities in PHC's 14 county service area, with the exception of Sutter Health, Sonoma Valley Hospital, and the four (4) 340B Covered Entities that were sent the first letter.

Updates and Meetings

340B Advisory Committee Schedule for 2018

- Meeting: March 7, 2018, 1:00 PM to 2:30 PM
- Update Letter: June 2018
- Meeting: September 12, 2018, 10:00 AM to 11:30 AM

Questions?

Thank You



November 13, 2017

Dear <340B Participating Entity Authorizing Official>:

Partnership HealthPlan of California (PHC) has a 340B Compliance Program, which was established in 2014. <340B Participating Entity> is a current participant in PHC's 340B Compliance Program.

PHC was recently contacted by the Medi-Cal Rebate Branch of the California Department of Health Care Services (DHCS) regarding 340B Covered Entities that may not be including 340B identifiers on their County Organized Health System (COHS) Physician-Administered Drug (PAD) claims. PADs are medications administered or dispensed by your health center clinicians directly to patients and billed through your usual claims system (not medications dispensed by a pharmacy and billed through our Pharmacy Benefit Manager).

<340B Participating Entity> was named as one of the 340B Covered Entities which may not be including the UD modifier when submitting your PAD claims to PHC. Unless a PAD claim is denied (claims are never denied based on the use of the UD modifier), PHC submits that information to the State.

DHCS informed us that auditors hired by pharmaceutical companies are going back as far as 1992 to look for duplicate discounts. PHC was not provided any further details, such as specific time frames or claims, nor specific directives on how to handle any identified errors. Due to this lack of information, PHC has not determined what specific course of action should be taken at this time, should duplicate discounts be identified.

Until additional information is provided to PHC or your organization, it is recommended that you take this opportunity to review your PAD claims and claims submission process to ensure the appropriate 340B identifier is included for all 340B PAD claims. If you identify claims missing the UD modifier on claims submitted to Fee-For-Service (FFS) Medi-Cal (including all claims from before PHC assumed responsibility for Medi-Cal Managed Care), DHCS may direct you to work with the manufacturer to make compensatory payments. If you identify claims missing the UD modifier for PHC member claims, DHCS has indicated that they prefer you work with us. If you identify claims that need to be modified, please contact the Pharmacy Services Program Manager at 340BQIP@partnershiphp.org before submitting any modified claims.

Best regards,

Robert L. Moore, MD, MPH, MBA
Chief Medical Officer
Partnership HealthPlan of California

SENT VIA EMAIL ONLY

<Date>

RE: Use of the UD modifier / 340B Compliance Program

Dear <340B Covered Entity's Authorizing Official's name> (<340B Covered Entity Name>):

Partnership HealthPlan of California ("PHC") has identified an entity or entities associated with your organization as eligible to participate in the 340B Drug Pricing Program ("340B Program") with the Health Resources and Services Administration ("HRSA"). Please forward this letter to the person overseeing compliance for your 340B Program.

340B is the Section of the Public Health Services Act that allows certain eligible health care entities ("Covered Entities") to get discounted drugs. The 340B Program was intended to "enable [participating] entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Examples of these Covered Entities include Federally Qualified Health Centers, Rural Health Centers affiliated with Critical Access Hospitals, Family Planning Clinics, Tribal Health Centers, and several classes of hospitals.

PHC is aware that some 340B Covered Entities have been submitting claims to PHC for 340B eligible drugs, but without an executed 340B Compliance Program Agreement with PHC or appropriate identification of 340B drugs with those claims.

PHC has a 340B Compliance Program, which was established in 2014. This 340B Compliance Program benefits Covered Entities and PHC members. This program provides a mechanism for all Covered Entities to include PHC members in their 340B Program in a way that is compliant with state and federal requirements, including compliant claiming of all 340B drug billing to PHC.

If your organization has not entered into a 340B Compliance Program Agreement with PHC, PHC recommends that you do not submit claims to PHC for 340B drugs, as such claims may not be compliant with 340B Program flagging requirements.

Use of the UD modifier

This letter serves as a friendly reminder that in order to comply with federal law, 340B claims for Physician-Administered Drugs (“PADs”), Physician-Dispensed Drugs, and drug costs submitted as part of a bundled or capitated rate must be filled out correctly to prevent duplicate discounts. A duplicate discount occurs when the drug manufacturer gives a provider the discounted 340B drug price, but also pays a rebate to a state Medicaid agency. Federal law around 340B requires that 340B drugs not be subject to duplicate discounts. That means if a drug is purchased at the 340B price, a state Medicaid agency cannot claim a rebate on that same medication (42 USC 256b(a)(5)(A)(i)). Under Section 2012 of the Affordable Care Act (ACA), a state Medicaid agency is not entitled to collect rebates on drugs provided to Medicaid beneficiaries if that drug was purchased through the 340B Program.

The California Department of Health Care Services (“DHCS”) has informed PHC that one or more pharmaceutical companies have hired private auditors to look through claims and pharmacy sales data to identify potential duplicate discounts, going back as far as 1992. These companies are then reaching out to the states to investigate further.

In order to prevent the duplicate discount, providers must include the appropriate code on the claim. All 340B claims for PADs, Physician-Dispensed Drugs, and drug costs submitted as part of a bundled or capitated rate require a “UD” in the modifier field when submitted for reimbursement. All of those claims must have a UD modifier listed after the HCPCS code for each and every 340B-purchased drug billed via paper or electronically using a CMS-1500 or UB-04 form or related format.

The role of a Managed Care Organization/Health Plan with regard to the 340B Drug Pricing Program?

In states where Managed Care Organizations (MCOs) are used, the MCO is an agent of the State, meaning the MCO is responsible for ensuring compliance with this requirement under Section 340B of the Public Health Services Act tied to the 340B Program. 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 adopted DHCS policies when dispensed to PHC beneficiaries.

Our 340B Compliance Program received additional validation when 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 on May 6, 2016. Per 42 CFR § 438.3(s), 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.”

We ask Covered Entities to sign a 340B Compliance Program Agreement to ensure 340B Participating Entities and PHC are agreeing to partner in the data submission process for 340B drugs prescribed by the 340B Participating Entities. This process ensures 340B drugs are identified to DHCS in a way that the State requires in order to avoid duplicate discounts



4665 Business Center Drive
Fairfield, California 94534

If you have questions about our 340B Compliance Program, please contact the Pharmacy Services Program Manager at 340BQIP@partnershiphp.org to learn more, including the steps in our reclassification process which help ensure compliance with the requirements of the 340B Program, as well as how to join our 340B Compliance Program.

Thank you,

Dina M. Cuellar, BA, CPhT
Director of Regulatory Affairs
Partnership HealthPlan of California

DRAFT