



**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
Robert L. Moore, MD, MPH, MBA, CMO
Amy Turnipseed, Senior Director of External and
Regulatory Affairs
Edward Hightower, CPhT, Associate Director of
Pharmacy Operations

Patti McFarland, CFO
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

cc: Sonja Bjork, COO, PHC

FROM: Dawn R. Cook
DATE: September 6, 2018

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: Wednesday, September 12, 2018 **TIME: 10:00 a.m. – 11:30 a.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>
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Please contact Dawn R. Cook at (707) 419-7979 or e-mail 340BQIP@partnershiphp.org if you are unable to attend.

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

Date: September 12, 2018 Time: 10:00 a.m. – 11:30 a.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	10:00 am
II.	Opening Comments	Chair	N/A	10:05 am
III.	Approval of Minutes	Chair	3 - 8	10:10 am
IV.	Standing Agenda Items			
1.	Partnership HealthPlan of California (PHC) 340B Compliance Program Update	Dawn R. Cook	11 - 13	10:15 am
V.	Old Business			
1.	Walgreens and submission of 340B claims data	Dawn R. Cook	14	10:30 am
2.	340B Program in California	Dawn R. Cook	15	10:40 am
VI.	New Business			
1.	340B Retro Reclassification Process	Dawn R. Cook	16-17	10:55 am
VII.	Additional Items			
1.	N/A	Dawn R. Cook	N/A	N/A
VIII.	Adjournment			



PARTNERSHIP HEALTHPLAN OF CALIFORNIA (PHC)

Minutes of the Meeting

PHC 340B Advisory Committee held at PHC Fairfield Office

4665 Business Center Drive, Fairfield, California 94534

Napa/Solano Room

March 7, 2018 – 1:00 p.m. to 2:00 p.m.

Commissioners Present / via Teleconference (TC):

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

Staff Present:

Robert Moore, MD, MPH, MBA, CMO; Wendi West; Amy Turnipseed; Stan Leung, PharmD; and Dawn R. Cook

PUBLIC COMMENTS

None presented.

WELCOME/INTRODUCTION

Brief introductions were made.

AGENDA ITEM I – OPENING COMMENTS

Mr. Germano stated this was a watershed moment with 340B. He thanked PHC for taking such a leadership role in this area.

AGENDA ITEM II – APPROVAL OF MINUTES

The minutes from the 340B Advisory Committee Meetings on 9/13/17 were approved with no corrections. All committee members approved the minutes. There were no committee members who opposed or abstained.

The minutes from the 340B Advisory Committee Meetings on 12/4/17 were approved with no corrections. 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 3/1/18, there were 333 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. As of 3/1/18, PHC had 153 sites/340B IDs (28 entities/agreements) currently active in the 340B Compliance Program. That number equated to just under half the total number of 340B Covered Sites/IDs within PHC's 14 county service area. At that point, no additional 340B Covered Entities were being invited to join the 340B Compliance Program.

Invoices continued to be delivered to 18 of the 340B Participating Entities on a monthly basis. Those 18 340B Participating Entities were making monthly wire transfers to the 340BX Trust Account based on the invoices they received for each respective month.

Claims/Financial Summary:

Ms. Cook reviewed the claims and financial information regarding the quarter from 7/1/17 to 9/30/17, noting the information now included claims submitted for Walgreens, as well as claims submitted by Wellpartner. Wellpartner was the 340B Administrator for Open Door Community Health Centers (ODCHC).

For the 7/1/17 to 9/30/17 quarter, the Total 340B Compliance Fees were \$109,298.75. Of that total, \$99,362.50 were 340BX Compliance Fees and \$9,936.25 were PHC 340B Compliance Fees. There were 10,732 340B Paid Matched Claims, 4,316 Walgreens 340B Paid Match Claims, and 24,697 Wellpartner 340B Paid Match Claims for the quarter, for a total of 39,745 Matched Claims for the quarter.

Ms. Cook indicated the large Wellpartner claim count was due to transfer issues that occurred when ODCHC transitioned from having CaptureRx as their primary 340B Administrator to Wellpartner. As such, there were older claims were reclassified during the 7/1/17 to 9/30/17 quarter, including claims dated back to January 2017. Ms. Lujan asked if the extensive fees were additional fees. Ms. Cook clarified that the over \$67,000 paid by ODCHC was just paying the standard 340B Compliance Fees for the service of having the much older claims reclassified. Ms. Cook noted the data for Long Valley Health Center and Mendocino Coast District Hospital was new, as they were now receiving invoices for services.

There was also a breakdown of the total claim counts for each category for each month of the quarter from 7/1/17 to 9/30/17. Ms. Cook reminded the committee that the month-to-month claim totals vary throughout the year. The exception for the quarter under review was the inclusion of the older 340B claims from Wellpartner.

AGENDA ITEM IV – OLD BUSINESS

Changes to the 340B Compliance Program and Agreement:

As discussed at the last 340B Advisory Committee Meeting on 12/4/17, the 340B Team realized there was information that needed to be updated in the 340B Compliance Program Agreement. In light of a piece regarding the 340B Program in the Governor's Budget Proposal for 2018-2019 (to be discussed later), it was decided that at this point the 340B Team would focus on changes to the 340B Compliance Program Agreement that would not require outside legal review or renegotiation of the terms of the agreement with 340BX Clearinghouse.

Changes to the agreement include the use of the UD modifier, submission of requests for the addition of the UD modifier, removal of all references to the Generic Prescription Rate and Primary Care Quality Improvement Program, and updates to the Attachments. These changes were made to the agreement with an amendment listing all the changes drafted for all current 340B Participating Entities that will be distributed after approval by the 340B Advisory Committee. All current 340B Compliance Program Agreements would remain in place. As PHC was not on-boarding any new 340B Covered Entities, PHC would only be sending out amendments to the current participants.

Once the 340B Compliance Program Agreement was updated and approved by the 340B Advisory Committee, the 340B Compliance Program Policy would be updated to reflect the changes made to agreement. The policy would then be sent through all appropriate committees for review and approval. The approval process included approval by three groups: 1) Internal Quality Improvement (IQI) in March 2018; 2) Pharmacy & Therapeutics Committee (P&T) in April 2018; and 3) Physician Advisory Committee in May 2018.

Mr. Germano asked Ms. Cook to provide more detail to the committee regarding the changes made prior to a vote being taken to have PHC team move forward with the updated 340B Compliance Program Agreement. Ms. Cook indicated any references to the Primary Care Provider (PCP) Quality Improvement Program (QIP), including Section VII, were removed from the 340B Compliance Agreement, as the Generic Prescription Rate was removed from the PCP QIP as of January 1, 2018. The database used by HRSA was revamped so the link to the database in the agreement was updated so participants would go to the appropriate site.

Language was added indicating new participants to PHC's 340B Compliance Program would onboard with 340BX Clearinghouse. Participants would have to sign a non-disclosure agreement (NDA) in order to receive the file specs to prepare files to send to 340BX Clearinghouse as it was proprietary information. In response to a question from Dr. Khoyi, Ms. Cook clarified that any party planning to receive a copy of the file specs would have to sign a separate NDA for 340BX Clearinghouse, including the 340B Participating Entities' 340B Administrators.

Based on input from Shasta Community Health Centers (SCHC), language was added regarding the submission of requests to have claims sent to 340BX Clearinghouse for delayed reclassification. A 340B Participating Entity would submit a request to PHC, the request would be reviewed with the IT team to determine if it could be fulfilled, and PHC would provide a decision to the 340B Participating Entity within 10 business days of receipt of the request. Evaluation of the requests were tied to timeliness thresholds for Quality Measures for Encounter Data (QMED) that PHC had to meet.

The biggest change was tied to the handling of requests for the addition of the UD modifier to Physician-Administered Drug (PAD) claims. Per the current 340B Compliance Program Agreement, requests for the addition of a missing UD modifier would be submitted to PHC's Pharmacy Services Program Manager. However, during discussions regarding a request from Sutter Health, 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. As such, the agreement was updated to reflect the existing process, which was also noted in the provider contracts through Provider Relations. The Claims and Provider Relations Departments were made aware of the updates. In response to a question from Ms. West, Ms. Cook noted the 340B Team was working with other PHC departments to allow 340B Participating Entities to submit bulk requests in spreadsheet form versus individual claim requests. Submission of requests in batch form via a spreadsheet would reduce the man hours spent by PHC to fulfill requests and would be easier for the providers. Ms. Cook noted Attachment A of the agreement was also updated to remove a fee for the addition of the UD modifier, as there was no fee associated with the Claims Department process.

In response to a question from Ms. Lujan, Ms. Cook noted the updated agreement would be the standard template. Any of the current 340B Participating Entities would only sign an amendment that would likely be retroactive to 1/1/18. The updates to the agreement would not make any changes to their monthly processes for the 340B Compliance Program. With regard to any of the current participants, Ms. Cook noted they had not submitted any requests for the addition of the UD modifier, so PHC could easily make the amendments retroactive. The amendments were tied to the original agreement signed by each 340B Participating Entity, and the agreement had an Evergreen clause. The only difference with this group of amendments would be if there were any changes to the sites or pharmacies for the respective 340B Participating Entity.

Ms. Cook responded to an inquiry from Dr. Khoiyi regarding 340B Covered Entities that may have been in the process of discussing joining the program and the effect of these changes. Ms. Cook noted that at this point, PHC was holding off on bringing on new entities due to proposed language in the Governor's budget. When PHC opens it up again to entities, the updated agreement would be used. Ms. Cook indicated that if an entity was planning to go live and carve-in by July of 2018, and if PHC's 340B Team agreed to bring them onboard, the entity would receive updated agreement.

In response to a question from Mr. Germano, Ms. Cook noted she had sent the agreement out to a few entities, but no responses had been received at that point. With regard to one of the entities, Lake County Tribal Health Consortium (LCTHC), Ms. Cook had not heard from them. Dr. Khoiyi noted LCTHC had the agreement reviewed by their attorney, but the delay was likely tied to their 340B Administrator. The only other party that was interested at this point was Adventist Health, with whom Ms. Cook had ongoing correspondence for years. Ms. Cook had a conference call with them to discuss a proposal Adventist Health sent to PHC regarding a file spec and the submission process for 340BX Clearinghouse. With regard to what could occur with the Governor's budget, Adventist Health still wanted to move forward with joining the program, even if they were only participating for a year. At that time, Adventist Health had the NDA to review so they can get the file specs and verify they could provide the data required. Ms. Cook noted it would be the determination of her supervisors as to whether or not Adventist Health would be on-boarded. Ms. Cook noted there had been no specific date given to the entities for joining.

- **ACTION ITEM:** The committee entertained a motion to approve the changes to the 340B Compliance Program Agreement presented, as well as the proposed Amendment. All committee members were in favor of the motion. There were no committee members who opposed or abstained. The motion was passed.

DHCS notification and manufacturers seeking refunds for rebates:

As discussed at the 340B Advisory Committee Meeting on 12/4/17, PHC had received various communications from DHCS regarding 340B Covered Entities and the use of 340B identifiers on their Physician-Administered Drug (PAD) claims, informing PHC that drug manufacturers were working with new contractors to review older periods and were becoming much more aggressive in disputing rebates tied to possible duplicate discounts. In light of that information, the 340B Team drafted a reminder letter regarding the use of the UD modifier and PHC's 340B Compliance Program. That letter was sent to all 340B Covered Entities in PHC's 14 county service area on 12/28/17, with the exception of Sutter Health, Sonoma Valley Hospital, and the four (4) 340B Covered Entities that were sent a personalized letter in November 2017.

On 1/11/18, PHC received an e-mail from Robert Shun, Chief, Medi-Cal Drug Rebate Branch. He was contacted by Eli Lilly's consultant, Kalderos, regarding 39 claims from 11 providers that did not include a 340B identifier. PHC was asked to work with the providers to correct any claims that were "incomplete." At that point, PHC was still determining the next steps. Ms. Cook noted there had just been a meeting at PHC with Sonja Bjork, COO of PHC, to discuss these inquiries. Per that meeting,

Ms. Cook would be moving forward with contacting the providers sited and informing them that DHCS has notified PHC of possible duplicate discounts and requesting that they review the data and determine if there has been an issue.

With regard to the Eli Lilly claims and a question from Mr. Germano regarding the scale of this issue, Dr. Leung felt this was just a sampling to test the waters to see what steps PHC would take with regard to the notice we received from the State. This was likely just the tip of the iceberg, not just for Eli Lilly, but for all drug manufacturers. Dr. Leung stated there were likely more consultants like Kalderos based on the information received at the 340B Coalition Winter Conference in February 2018. Due to their need for accurate accounting of their drug sales price in addition to claw back, it seemed a lot of manufacturers were hiring consultants to review the rebates paid to the State, as well as the drug discounts from 340B purchases. Consultants would look at the universal claims, then send out notices to the 340B Covered Entities in the form of a Good Faith Inquiry (GFI) to see what further actions could be taken.

Ms. Cook noted the earliest date of service for the 39 Eli Lilly claims was January 2017. Of those 39 claims, eight (8) of those were pharmacy claims, and the rest were PAD claims, so consultants looking at both types of claims. Ms. Cook indicated the inquiry did not indicate the specific time frame reviewed and just know the dates of service for the claims identified. Ms. Cook noted manufacturers could technically go back as far as 1992 for their inquiries, which would be difficult for any health center. Mr. Shun from DHCS had stated the focus was more on claims from 2010 to the present, which could still be a lot of work and headache for the 340B Covered Entities. When Mr. Leung and Ms. Cook attended the 340B Coalition Winter Conference 2018 from 2/21/18 to 2/23/18, there was much discussion regarding the increase in the number of manufacturer inquiries. Ms. Cook noted it was not just occurring in California, but across the nation. As such, they had representatives from the manufacturers at the conference to discuss those inquiries and the related processes.

Per Ms. Cook, PHC recently received two new reports from Mr. Shun. These reports were quarterly reports, one for PAD claims and one for Pharmacy Claims. PHC was asked to review these informational-only e-mails. The e-mails noted only the provider would know if the claims should or should not have been 340B. The information was provided to the Health Plan in case PHC wanted to contact any of these covered entities regarding the possibility of a duplicate discount violation. PHC was to decide how to move forward. In the last one and a half years, PHC saw an increase in the feedback, requests, and information from DHCS with regard to 340B claims. In response to a question from Mr. Santi, Ms. Cook noted she previously asked if Mr. Shun contacted every 340B Covered Entity, each quarter, after the State completed the quarterly rebate invoice submissions. Per Mr. Shun, the State might contact a 340B Covered Entity if a red flag was raised, but otherwise, no. Ms. Cook was not sure if the State still contacted 340B Covered Entities about possible duplicate discount violations, giving them two choices: (1) Contact the Health Plan to ask for assistance with correction or (2) contact the manufacturer to arrange for repayment.

Mr. Germano said it was his understanding that a lot of these consultants were going after the State to repay the rebates, which was fodder for the State to be displeased, as they were looking at tens of millions of dollars potentially. Ms. Cook noted one of the pieces of information learned at the last 340B Coalition Winter Conference was there were four states that requested the manufacturers work directly with 340B Covered Entities and not contact the state. California was one of those four states. So although one of the representatives from the manufacturers stated manufacturers would prefer to work with the State, the State of California is putting the responsibility on the 340B Covered Entities. From a 340B Covered Entity standpoint, Mr. Germano would prefer the manufacturers worked with them versus the State, as he thinks it could possibly further undermine their ability to keep the program going based on the effect on the State. In addition, Ms. Lujan stated the responsibility for compliance and use of the 340B Program had always been with the 340B Covered Entities.

AGENDA ITEM V – NEW BUSINESS

Walgreens and submission of 340B claims data:

In December 2017, PHC was made aware that Walgreens was no longer providing the identifiers in the reports available to the 340B Covered Entities contracted with them that allowed 340B Covered Entities to create the files our 340B Participating Entities submitted to 340BX Clearinghouse for 340B claim reclassification.

Due to that change, 340B Participating Entities had to find other ways to create the required files and insure 340BX Clearinghouse was only receiving claims data for PHC members. Shasta Community Health Center (SCHC) combined information from two reports to create their submission file. 340BX Clearinghouse was working on finalizing instructions on how to create a submission file via the process used by SCHC. Ms. Cook had a conference call with Matt Sullivan from 340BX Clearinghouse who stated they sent the finalized instructions to Dolly Davar at La Clinica de la Raza to test the instructions. They were waiting for her feedback, but they had not received anything at that point as the instructions had just been sent to Ms. Davar for review in the last week.

When the issues with the reports arose, Open Door Community Health Centers (ODCHC) reached out to the California Primary Care Association (CPCA) for assistance. On 1/10/18, ODCHC and CPCA had a conference call with Walgreens to

discuss how to make the 340B Program work more smoothly in California, specifically regarding the reporting. Ms. Cook and Dr. Leung were also on that call. Per that discussion, Walgreens sent a report template they proposed for use by 340B Covered Entities. They indicated the “MCO report” template would be for use across California, so anyone reporting to a Health Plan would be able to use it. Based on PHC’s comparison of that template to the file specs from 340BX Clearinghouse, the proposed report would work. Walgreens indicated it would take four (4) to six (6) months to complete coding. As of 2/4/18, CPCA was waiting on final approvals to give Walgreens the green light. Currently, Ms. Cook noted all parties seemed to be waiting on additional feedback from Walgreens verifying they were moving forward so they would have a start date for the four to six months for completion of the report template.

Mr. Germano noted the short term fix was to use the process from SCHC, and the longer term fix was would come from CPCA and Walgreens. Mr. Santi stated Walgreens would likely hold off on moving forward until the budget was released. Ms. Cook agreed since the call with Walgreens on 1/10/18 was the same day the initial Governor’s budget was released.

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

On 1/10/18, the proposed 2018-2019 Governor’s Budget for the State of California was released with the following language: “Restrict 340B Drug Reimbursement within the Medi-Cal Program—The Budget proposes to restrict the use of federal 340B Drug Pricing Program reimbursements within the Medi-Cal program, effective July 1, 2019. The proposal allows the state to comply with existing federal requirements, helps protect program integrity, prevents unnecessary overpayments, collects additional drug rebates, and mitigates the amount of time and resources expended to resolve drug rebate disputes related to 340B claims.”

The proposal sought to eliminate 340B Program participation for Medi-Cal Fee-For-Service (FFS) and Medi-Cal Managed Care effective 7/1/19. Should that elimination occur, it would be extremely detrimental to the health centers and hospitals in PHC’s 14 county service area that rely on those funds to provide much needed assistance to the underserved population.

At the 340B Coalition Winter Conference 2018, PHC’s 340B Compliance Program was discussed during the Medicaid Billing and Reimbursement breakout session. Amber Ott from the California Hospital Association (CHA) acknowledged PHC’s 340B Compliance Program as the only program approved by the State of California. Ms. Ott noted the State of California had used PHC’s program as an example, and although other Health Plans were to look to PHC’s program as a guide, they were not approving any other programs at that time. Ms. Cook noted that in line with that information, other Health Plans had contacted PHC with questions and requests for more information about PHC’s 340B Compliance Program over the last several months. At that point, PHC was waiting to see what the revisions to the Governor’s budget proposal would be at the end of April or early May 2018. Ms. Cook was not sure what organizations, if any, had submitted any feedback or rebuttals to the proposal.

Based on what he knew of PHC’s 340B claim volume, Mr. Germano estimated the impact of the elimination in his region would be in the range of as much as \$30 million. The elimination proposal was a priority issue at CPCA in terms of a legislative priority. CPCA was gearing up for a battle primarily through the legislature, as this was worrisome for the entities dependent on the funds to help support services. In response to a comment from Mr. Germano, Dr. Moore felt advocacy was the key issue given the fact that so many of the providers in PHC’s network rely on these funds for a lot of their income, which was something the State needed to understand.

Mr. Germano’s opinion was PHC’s role in this was to demonstrate to the legislature that there was a mechanism for compliance if the State was willing to embrace it. Compliance was a key issue in the State’s proposal. The part that was going to be a challenge was the revenue lost by the State for not being able to claim the rebates tied to 340B. The figure for the possible loss for the State had not been made public.

In response to a question from Dr. Khoiyi, Ms. Cook noted PHC’s 340B Compliance Program was approved in July of 2014. PHC had sent the updated agreements to the State for review. Since the original program was approved, Dr. Moore stated PHC had sent upgraded agreements, but the State had not responded. When the updated agreements were sent, it was noted that should PHC not receive a response, PHC would consider the updates approved. Ms. Cook noted the core of PHC’s program was 340BX Clearinghouse’s process for reclassifying Pharmacy claims. Other than the fee for the service, the actual process had not really changed as far as claims reclassification and resubmission to the State.

PHC Webinar: Managing the 340B Enigma - PHC’s Journey through the 340B Program:

In January 2018, Liz Gibboney, CEO from PHC, attended the Local Health Plans of California (LHPC) Annual Retreat. There was a lot of interest expressed in PHC’s 340B Compliance Program, especially in light of the proposal regarding the 340B Program included in the proposed Governor’s Budget for 2018-2019 for the State of California. Ms. Gibboney volunteered to have PHC host a webinar for interested LHPC plans.

PHC would host a webinar covering the following topics: 340B Basics, 340B Program Requirements, PHC's 340B Compliance Program, and the Future of 340B/PHC's Recommendations. Presenters would include Dr. Moore, Dr. Leung, and Ms. Cook. Kathie Powell, MA, MSHA, CEO from Petaluma and Rohnert Park Health Centers would be joining as a guest speaker. Ms. Powell would discuss how important the 340B Program is to the financial health of health centers, for what types of activities they use the extra funding, and the impact on health centers if the funding (340B savings) received from participation in the program were no longer available.

The webinar was scheduled for Thursday, 3/22/18, from 12:00 PM to 1:30 PM. Ms. Cook noted PHC created a link for the webinar that LHPC distributed to representatives from local health plans, including C-Suite and Compliance Officers.

AGENDA ITEM VI – ADDITIONAL ITEMS

Additional comments:

Ms. Cook noted an update letter would to be sent in June 2018. The next 340B Advisory Committee Meeting was scheduled for 9/12/18 from 10:00 AM to 11:30 AM.

Documents:

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

- 340B Compliance Program Agreement - Draft for changes before July 2018
- Draft of Third Major Amendment for all Current Agreements

AGENDA ITEM VII – ADJOURNMENT

Meeting Adjourned: 2:00 p.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

9-12-18

Agenda

- 
- 340B Compliance Program Update

- 
- Walgreens and submission of 340B claims data

- 
- 340B Program in California

- 
- 340B Retro Reclassification Process

340B Compliance Program Update

- As of 9/4/18, there were 340 340B Covered Sites within PHC's 14 county service area, 144 of which were hospitals.
- No additional 340B Covered Entities have been invited to join the 340B Compliance Program at this time.
- As of 9/4/18, invoices were delivered to 19 of PHC's 340B Participating Entities on a monthly basis. Ole Health received its first invoice in September 2018 for claims reclassification that occurred in May 2018.
- As of 8/31/18, there were 18 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 1/1/18 to 3/31/18

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	340BX Compliance Fee	PHC 340B Compliance Fee	Total 340B Compliance Fees
Alliance Medical Center	105	0	0	0	0	0	0	0	\$ 262.50	\$ 26.25	\$ 288.75
CommuniCare Health Centers	708	3	438	1	0	0	0	0	\$ 2,865.00	\$ 286.50	\$ 3,151.50
Fairchild Medical Center	1,439	7	0	0	0	0	0	0	\$ 3,597.50	\$ 359.75	\$ 3,957.25
Hill Country Community Clinic	370	1	0	0	0	0	0	0	\$ 925.00	\$ 92.50	\$ 1,017.50
La Clinica De La Raza	0	0	1,662	13	0	0	0	0	\$ 4,155.00	\$ 415.50	\$ 4,570.50
Long Valley Health Center	61	0	0	0	0	0	0	0	\$ 152.50	\$ 15.25	\$ 167.75
Marin Community Clinic Inc.	0	0	0	0	0	0	0	0	\$ -	\$ -	\$ -
Mendocino Coast Clinics, Inc.	519	1	0	0	0	0	0	0	\$ 1,297.50	\$ 129.75	\$ 1,427.25
Mendocino Coast District Hospital	55	1	0	0	0	0	0	0	\$ 137.50	\$ 13.75	\$ 151.25
Mendocino Community Health Clinics, Inc.	1,381	1	158	2	0	0	0	0	\$ 3,847.50	\$ 384.75	\$ 4,232.25
Mountain Valleys Health Centers, Inc.	222	2	0	0	0	0	0	0	\$ 555.00	\$ 55.50	\$ 610.50
Northeastern Rural Health Clinics, Inc.	544	0	0	0	0	0	0	0	\$ 1,360.00	\$ 136.00	\$ 1,496.00
Open Door Community Health Centers	1,064	3	1,714	4	492	9	4,842	20	\$ 20,280.00	\$ 2,028.00	\$ 22,308.00
Petaluma Health Center	0	0	0	0	0	0	0	0	\$ -	\$ -	\$ -
Redwoods Rural Health Center	117	0	0	0	0	0	0	0	\$ 292.50	\$ 29.25	\$ 321.75
Santa Rosa Community Health Centers	0	0	0	0	0	0	0	0	\$ -	\$ -	\$ -
Shasta Community Health Centers	2,945	7	0	0	0	0	0	0	\$ 7,362.50	\$ 736.25	\$ 8,098.75
Shingletown Medical Center	85	0	0	0	0	0	0	0	\$ 212.50	\$ 21.25	\$ 233.75
Solano, County of	385	2	0	0	0	0	0	0	\$ 962.50	\$ 96.25	\$ 1,058.75
Sonoma Valley Community Health Center	166	0	0	0	0	0	0	0	\$ 415.00	\$ 41.50	\$ 456.50
Winters Healthcare Foundation	117	1	0	0	0	0	0	0	\$ 292.50	\$ 29.25	\$ 321.75
QUARTER TOTALS:	10,283	29	3,972	20	492	9	4,842	20	\$48,972.50	\$4,897.25	\$ 53,869.75

Claims/Financial Summary (cont'd)

Claims/Financial summary for 1/1/18 to 3/31/18

Month	CRX 340B Paid Match Claim Count	CRX 340B Reversal Claim Count	Walgreens 340B Paid Match Claim Count	Walgreens 340B Reversal Match Claim Count	CVS 340B Paid Match Claim Count	CVS 340B Reversal 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
January-18	4,691	15	1,098	1	115	1	2,283	10	\$20,467.50	\$2,046.75	\$22,514.25
February-18	3,458	10	2,589	11	235	2	1,730	5	\$20,030.00	\$2,003.00	\$22,033.00
March-18	2,134	4	285	8	142	6	829	5	\$8,475.00	\$847.50	\$9,322.50
TOTAL:	10,283	29	3,972	20	492	9	4,842	20	\$ 48,972.50	\$ 4,897.25	\$ 53,869.75

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 340B 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.

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 of 9/4/18, PHC has received no further communication from DHCS regarding the 340B Program in California. To date, we have seen no additional TBL and no APL.

340B Retro Reclassification Process

- Per the current 340B Compliance Program Agreement, requests for the addition of a missing UD modifier are 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, 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 is 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.

340B Retro Reclassification Process (cont'd)

- 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.
- 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 will now be reviewed.
 - The IT team is updating the Project Charter for the new process and updating the submission template.
 - The work group is brainstorming ideas as to how PHC will bill providers for this service.
- The next 340B Retro Reclassification Process Work Group meeting will be on 9/13/18.

340B Advisory Committee Schedule

2018 - 2019

- **Update Letter:**
 - December 2018
- **Meetings:**
 - March 15, 2019 from 1:00 PM to 2:25 PM
 - September 25, 2019 from 10:00 AM to 11:25 AM

Questions?

Thank You