

340B ADVISORY COMMITTEE UPDATE

DECEMBER 2018

340B ADVISORY COMMITTEE

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

PHC Staff: Elizabeth Gibboney, CEO
Sonja Bjork, COO
Robert L. Moore, MD, MPH, MBA, CMO
Patti McFarland, CFO
Wendi West, Northern Executive Director
Amy Turnipseed, Senior Director of External and Regulatory Affairs
Michelle Rollins, Director of Legal Affairs
Stan Leung, PharmD, Director of Pharmacy Services
Tony Hightower, Associate Director of Pharmacy Operations
Dawn R. Cook, Pharmacy Services Program Manager

INTRODUCTION:

The last 340B Advisory Committee Meeting took place on September 12, 2018.

UPDATE:

340B Contracting Update:

As of December 31, 2018, there are 341 340B IDs/sites (144 of which are tied to hospitals) in PHC's 14 county service area, which are eligible to participate in the 340B Program.

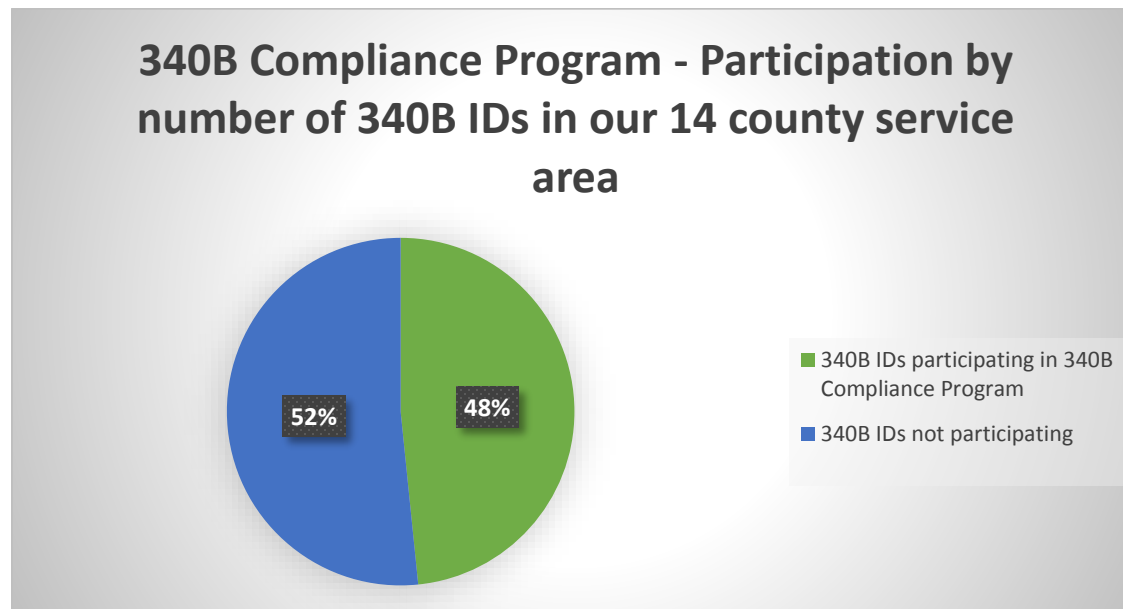
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As of January 1, 2019, there will be 341 340B IDs/sites (143 of which will be tied to hospitals) in PHC's 14 county service area, which will be eligible to participate in the 340B Program.

As of December 31, 2018, there are 27 active 340B Compliance Program Agreements, so 27 340B Participating Entities. Those 27 active 340B Compliance Program Agreements cover 164 340B IDs/sites (42 of which are tied to hospitals).

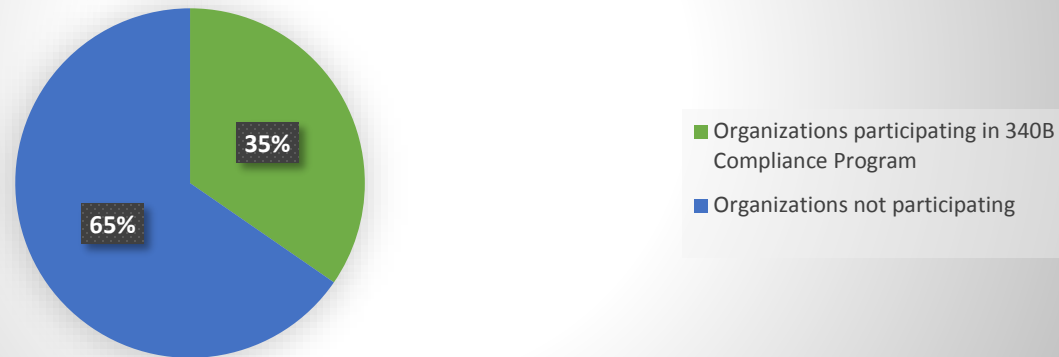
As of January 1, 2019, there will be 27 active 340B Compliance Program Agreements that cover 165 340B IDs/sites (42 of which will be tied to hospitals).

As you can see below, although only 35% of the 340B eligible organizations have an agreement with PHC to participate in the 340B Compliance Program, that 35% covers almost half (48%) of the 340B IDs in our 14 county service area.



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340B Compliance Program - Participation by number of 340B eligible organizations (number of agreements we would have) in our 14 county service area



On-boarding for the 340B Compliance Program continues to be on hold in anticipation of final direction from the Department of Health Care Services (DHCS) with regard to the 340B Program in the form of an All Plan Letter (APL).

Financial Summary:

The information provided in the table below reflects data provided by 340BX Clearinghouse regarding the reclassification process and invoicing tied to the 340B Compliance Program.

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Financial summary for 4/1/18 to 6/30/18

4/1/18 to 6/30/18													
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	88	0	0	0	0	0	0	0	0	0	\$ 220.00	\$ 22.00	\$ 242.00
CommuniCare Health Centers	711	2	383	1	0	0	0	0	0	0	\$ 2,735.00	\$ 273.50	\$ 3,008.50
Fairchild Medical Center	1,552	4	0	0	0	0	0	0	0	0	\$ 3,880.00	\$ 388.00	\$ 4,268.00
Hill Country Community Clinic	541	2	0	0	0	0	0	0	0	0	\$ 1,352.50	\$ 135.25	\$ 1,487.75
La Clinica De La Raza	0	0	1,478	1	0	0	0	0	0	0	\$ 3,695.00	\$ 369.50	\$ 4,064.50
Long Valley Health Center	53	0	0	0	0	0	0	0	0	0	\$ 132.50	\$ 13.25	\$ 145.75
Marin Community Clinic Inc.	0	0	0	0	0	0	0	0	0	0	\$ -	\$ -	\$ -
Mendocino Coast Clinics, Inc.	567	1	0	0	0	0	0	0	0	0	\$ 1,417.50	\$ 141.75	\$ 1,559.25
Mendocino Coast District Hospital	191	1	0	0	0	0	0	0	0	0	\$ 477.50	\$ 47.75	\$ 525.25
Mendocino Community Health Clinics, Inc.	1,336	9	132	0	0	0	0	0	0	0	\$ 3,670.00	\$ 367.00	\$ 4,037.00
Mountain Valleys Health Centers, Inc.	301	0	0	0	0	0	0	0	0	0	\$ 752.50	\$ 75.25	\$ 827.75
Northeastern Rural Health Clinics, Inc.	639	1	0	0	0	0	0	0	0	0	\$ 1,597.50	\$ 159.75	\$ 1,757.25
Ole Health	0	0	0	0	0	0	0	0	5,812	5	\$ 14,530.00	\$ 1,453.00	\$ 15,983.00
Open Door Community Health Centers	1,057	1	1,728	1	424	7	5,360	32	0	0	\$ 21,422.50	\$ 2,142.25	\$ 23,564.75
Petaluma Health Center	0	0	0	0	0	0	0	0	0	0	\$ -	\$ -	\$ -
Redwoods Rural Health Center	193	1	0	0	0	0	0	0	0	0	\$ 482.50	\$ 48.25	\$ 530.75
Santa Rosa Community Health Centers	0	0	0	0	0	0	0	0	0	0	\$ -	\$ -	\$ -
Shasta Community Health Centers	3,227	8	2,697	7	0	0	0	0	0	0	\$ 14,810.00	\$ 1,481.00	\$ 16,291.00
Shingletown Medical Center	102	1	0	0	0	0	0	0	0	0	\$ 255.00	\$ 25.50	\$ 280.50
Solano, County of	110	5	0	0	0	0	0	0	0	0	\$ 275.00	\$ 27.50	\$ 302.50
Sonoma Valley Community Health Center	209	3	0	0	0	0	0	0	0	0	\$ 522.50	\$ 52.25	\$ 574.75
Winters Healthcare Foundation	114	0	0	0	0	0	0	0	0	0	\$ 285.00	\$ 28.50	\$ 313.50
QUARTER TOTALS:	10,991	39	6,418	10	424	7	5,360	32	5,812	5	\$ 72,512.50	\$ 7,251.25	\$ 79,763.75

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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
April-18	4,983	21	2,576	1	215	7	2,349	24	0	0	\$25,307.50	\$2,530.75	\$27,838.25
May-18	3,253	11	2,427	1	17	0	1,509	3	4,121	0	\$28,317.50	\$2,831.75	\$31,149.25
June-18	2,755	7	1,415	8	192	0	1,502	5	1,691	5	\$18,887.50	\$1,888.75	\$20,776.25
TOTAL:	10,991	39	6,418	10	424	7	5,360	32	5,812	5	\$ 72,512.50	\$ 7,251.25	\$ 79,763.75

Walgreens and submission of 340B claims data:

There are no new updates to report. It appears PHC's 340B Participating Entities are still waiting for an all-inclusive report to be issued that they can use for reporting Walgreens 340B claims to 340BX Clearinghouse for reclassification.

340B Program in California and pending APL:

On January 10, 2018, 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."

In March 2018, PHC received a draft All Plan Letter (APL) regarding the Medicaid Drug Rebate Program in California. The APL was sent to all Health Plans for review. The APL outlined new guidelines for the submission of claims to the DHCS, including 340B claims. PHC provided feedback to DHCS.

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. The Administration had proposed trailer bill language to prohibit 340B Covered Entities from purchasing discounted drugs through the 340B program for Medi-Cal managed care and Fee-For-Service (FFS) patients, in order to eliminate duplicate discounts of drugs purchased through the 340B program.

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In November 2018, PHC received an updated version of the draft APL previously sent in March 2018. Upon initial review and discussion regarding the updated draft APL, PHC felt it was a step in the right direction and, depending upon the final version, 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.

However, in December 2018, PHC received another document titled "340B Contract Pharmacy Three-way Agreement Minimum Requirements," which contained additional information not provided in the updated draft APL. With regard to information not conveyed in the updated draft APL, the biggest concern was language regarding 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 have a huge impact on the current 340B Covered Entities participating in PHC's 340B Compliance Program.

As of December 31, 2018, no other updates have been provided to PHC nor has any final documentation, such as the final APL, been issued by the State.

340B Retro Reclassification Process:

As reported during the 340B Advisory Committee Meeting on September 12, 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.

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.

It was determined that the updated process would no longer involve submission of requests to PHC's Claims Department. PHC's Electronic Data Interchange (EDI) 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:

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- Ms. Cook met the Finance and EDI teams to determine what information should be collected to in order to set providers up to use the service, have providers acknowledge the costs for the service, and allow Finance to create and distribute invoices for services rendered.
- The IT team is updating the Project Charter and Business Requirements Document (BRD) to reflect new information PHC will request from providers, as well as additional actions to be taken by the EDI team as part of the process.
- Due to the pending APL and possible changes to the 340B Program in the State of California, this project is not being labeled as High Priority for all departments involved. However, work will continue with the hopes that clarification will be received sooner than later.

The next 340B Retro Reclassification Process Work Group meeting will be on Tuesday, January 29, 2019 at 3:00 PM.

Changes to the 340B Compliance Program Agreement:

The PHC 340B Team will soon resume work on a major revision of the 340B Compliance Program Agreement. The revision will be based on final language issued by the DHCS regarding the 340B Program, likely in the form of the final APL, as well as the final approved process for 340B retro reclassification of claims (if it is still needed).

340B Coalition Conferences:

Ms. Cook will be attending the 340B Coalition Winter Conference 2019 in San Diego, CA from January 30, 2019 through February 1, 2019.

NEXT 340B ADVISORY COMMITTEE MEETING:

The next 340B Advisory Committee Meeting is scheduled for Friday, March 15, 2019, from 1:00 PM to 2:30 PM.

QUESTIONS/COMMENTS:

If you have any questions or comments, please forward them to the Pharmacy Services Program Manager at 340BQIP@partnershiphp.org.