PARTNERSHIP HEALTHPLAN OF CALIFORNIA
340B ADVISORY COMMITTEE ~ MEETING NOTICE

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

PHC Staff: Elizabeth Gibboney, CEO
Robert L. Moore, MD, MPH, CMO
Patti McFarland, CFO
Margaret Kisliuk, Northern Executive Director
Michelle Rollins, Associate Director of Regulatory Affairs
Stan Leung, PharmD, Pharmacy Services Director
Dina Cuellar, CPhT, Associate Director, Pharmacy Operations
Dawn R. Cook, Pharmacy Services Program Manager

cc: Sonja Bjork, COO, PHC

FROM: Dawn R. Cook
DATE: February 23, 2017

SUBJECT: 340B ADVISORY COMMITTEE MEETING

The 340B Advisory Committee will meet as follows and will continue to meet once per calendar quarter. Please review the Meeting Agenda and attached packet, as discussion time is limited.

DATE: Wednesday, March 1, 2017 TIME: 9:00 a.m. – 10:30 a.m.

LOCATIONS: Video Conferencing

Partnership HealthPlan of CA Solano Conference Room 4665 Business Center Drive *(Please Park in Front of Bldg.* *Ask the receptionist to call Dawn R. Cook)* Fairfield, CA 94534	PHC Redding Office *(Ask for Susie)* 3688 Avtech Parkway Redding, CA 96002	PHC Santa Rosa Office *(Ask for Sheila)* 495 Tesconi Circle Santa Rosa, CA 95401

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 1, 2017 Time: 9:00 a.m. – 10:30 a.m. Location: PHC

PUBLIC COMMENTS	Speaker	2 minutes	
	Speaker	2 minutes	
Welcome / Introductions			

	Topic	***Lead***	***Page #***	***Time***
I.	Opening Comments	Chair		9:04 am
II.	Approval of Minutes	Chair	3 - 7	9:08 am
III.	Standing Agenda Items			
1.	Partnership HealthPlan of California (PHC) 340B Compliance Program Update	Dawn R. Cook	10 - 11	9:10 am
IV.	Old Business			
1.	Mega-Guidance Update	Dawn R. Cook	12	9:25 am
2.	340B Compliance Program Policy	Dawn R. Cook	13	9:30 am
V.	New Business			
1.	Governor Brown's 2017-2018 Budget Proposal	Dawn R. Cook	14	9:40 am
VI.	Additional Items			
1.	Updated PHC 340B Compliance Program Policy - Attachment	Dawn R. Cook	18 - 57	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 8, 2016 – 3:00 p.m. to 4:30 p.m.

Commissioners Present / via Teleconference (TC):
Darcie Antle (Interim Chair); Viola Lujan; Amir Khoyi, PharmD

Staff Present:
Patti McFarland, CFO, Robert Moore, MD, MPH, CMO, Michelle Rollins, 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 June 8, 2016 were approved.

AGENDA ITEM III – STANDING AGENDA ITEMS

PHC 340B Compliance Program Update

General Update:

Ms. Cook noted that as of 9/7/16, PHC had 82 sites (17 entities) currently active in the 340B Compliance Program.

340BX Clearinghouse had new branding for all invoices, as well as new e-mail addresses to separate it from CaptureRx.

PHC completed the 340B Compliance Program Agreement, which was sent to 18 entities.

Invoices have successfully been sent to 12 340B Participating Entities (henceforth referred to as "Entities") on a monthly basis. The new invoice template was used starting in July 2016 for the April 2016 claims.

To date, 12 340B Participating Entities are making monthly wire transfers to the 340BX Trust Account based on the respective monthly invoice received.

340B Quality Improvement Program (QIP) and Quality Withhold Repayments:

Ms. Cook noted the 340BQIP Quarterly Reports for 1/1/16 through 3/31/16 were received from 12 340B Participating Entities. This was the last quarter of the 340B QIP, as the QIP was eliminated from the 340B Compliance Program.

All of 340B QIP Quarterly Reports for Calendar Quarter 1/1/16 to 3/31/16 were reviewed by Dr. Moore. The 12 340B Participating Entities that submitted reports received a score of 100% based on timely data submission, as well as reporting on their Safe Use of Opioids measures and Supplementary Quality Improvement (QI) Initiative. Based on those scores, the 12 340B Participating Entities received 100% of their 340B QIP Quality Withhold funds. The 340B QIP Quality Withhold Repayment checks were mailed on 8/11/16. The total 340B QIP Quality Withhold amount repaid to those 12 340B Participating Entities for that quarter was $444,019.96. All entities had received their checks.

Financial Summary:

Ms. Cook reviewed the financial information regarding the quarter from 1/1/16 to 3/31/16, as well as the financial information from the beginning of the program, 6/1/14 to 3/31/16. For the 1/1/16 to 3/31/16 quarter, the 340B Quality Withhold totaled $444,019.96 (all of which was repaid to the 340B Participating Entitles), the 340B Compliance Fees totaled $60,642.00, and there were 13,476 340B Paid Matched Claims. As reminder, these 340B Compliance Fees reflect the $4.50 per paid prescription claim fee. Once the new price structure kicks in with the new invoicing, we will see a reduction in the dollar amount for the 340B Compliance Fees. With regard to the year-to-date, 6/1/14 to 3/31/16, the 340B Quality Withhold totaled $2,956,329.39 (all of which was repaid, as all 340B Participating Entities scored 100%), the 340B Compliance Fees totaled $463,432.50, and there have been 102,985 340B Paid Matched Claims.

Ms. Lujan asked why all of the financial information currently reported will no longer be reported in the future. Ms. Cook explained that with the changes made to the program, 340BX Clearinghouse will not be collecting financial data that some 340B Administrators/Third Party Administrators deem to be proprietary. Also, the reporting of that financial information plays no role in the reclassification process, so it falls outside the scope of the newly revamped 340B Compliance Program. Ms. Lujan asked if there will be any financial reporting. Ms. Cook noted there would still be reporting of the 340B Compliance Fees and claims counts.

340B Compliance/Contracting Update:

As of 9/7/16, there were 284 340B Covered Entities (sites) within PHC's 14 county service area that were eligible to participate in the 340B Program. Ole Health and PHC had been in discussions regarding the 340B Compliance Program. They should be signing the agreement in the next few weeks for a retroactive effective date of 7/1/16. Santa Rosa Community Health Centers was granted an extension of the agreement effective 7/1/14 through 12/31/16 to allow time to negotiate terms with one of their 340B Administrators to align with PHC's 340B Compliance Program. PHC invited three (3) additional 340B Covered Entities to join the 340B Compliance Program for the effective date 10/1/16. PHC hoped to include hospitals when inviting 340B Covered Entities in October 2016 to join the 340B Compliance Program for the effective date 1/1/17.

Mr. Germano asked if hospitals would see any profit from participating in the 340B Program. Dr. Moore noted those hospitals with infusions might see some profit. Mr. Germano asked if Dignity Health was coming on board. Ms. Cook stated Dignity Health was not coming on board at this time.

Dr. Moore added that there had been some success with the Walgreens 340B claims test file that Shasta Community Health Center sent to 340BX Clearinghouse. Dr. Moore thanked Mr. Germano and Ms. Johnston for pushing the program and being proponents of the 340B Compliance Program in the community.

Mr. Germano noted there may be other Health Plans reaching out to PHC as they may want to replicate this type of program in other parts of the state.

Dr. Moore stated PHC submitted the updated 340B Compliance Program Agreement to DHCS for any corrections or changes, stating that if there was no response, PHC would assume everything is okay. To date, PHC had not received any response from DHCS, so it was assumed everything was okay. Dr. Khoyi asked who the contact was used by PHC for submission. Dr. Moore noted the agreement was sent to Dr. Paul Pontrelli. Dr. Khoyi informed the committee that Dr. Pontrelli left DHCS approximately two months prior to the date of the meeting. Ms. Cook noted the only other contact she had at DHCS was Robert Shun. Dr. Khoyi noted PHC would have to contact the person in charge of policies, but Ms. Cook noted PHC was not aware of who that person might be. Dr. Moore noted everything should be fine as they approved the original policy, and the new one was actually much more straightforward.

In response to a question from Mr. Germano regarding who had responsibility for the integrity of this program at the state and federal levels, Dr. Moore stated CMS oversees the State and the Office of Pharmacy Affairs oversees the Health Centers.

AGENDA ITEM IV – OLD BUSINESS

Committee Membership:

Ms. Cook reminded the committee that Roger Clarkson stepped down from the 340B Advisory Committee. Mr. Clarkson did submit his official resignation letter on 7/26/16. The remaining members of the 340B Advisory Committee were: Darcie Antle, C. Dean Germano, Julie Johnston, Viola Lujan, Kathryn Powell, and Amir Khoyi, PharmD. Dr. Moore stated the Board was notified of the change, and if any Board members showed interest in the 340B Advisory Committee, to pass that information on to him. Ms. Cook noted that to date, she had not received any information regarding possible new members for the 340B Advisory Committee.

AGENDA ITEM V – NEW BUSINESS

Centers for Medicare & Medicaid (CMS) Final Rule – 5/6/16:

Per Ms. Cook, 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 5/6/16. (Federal Register Volume 81 Number 88, May 6, 2016). Per 43 CRF § 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." Ms. Cook noted that with this, there was finally something in writing that the MCOs must have a system in place to help prevent duplicate discounts. Dr. Moore noted the State had not actually promulgated that to PHC, but PHC had been in compliance a couple years in advance. Ms. Cook noted MCOs actually had until 7/1/17 to submit their plans. The Final Rule provided further support for PHC's 340B Compliance Program which was established to assist 340B Covered Entities in being compliant with submission of properly identified 340B claims data to the State. PHC had been reaching out to entities for a few years, but this was the first piece in writing that could be cited which showed PHC was required to have a mechanism in place. The 340B Compliance Program was the mechanism which helped to identify those 340B claims so they were excluded from the back-end manufacturer rebates the State could claim for Medicaid/Medi-Cal prescription claims. Ms. Cook noted this piece of information would be added to a new introduction letter, which PHC would share with 340B Covered Entities to update them on the current 340B Compliance Program.

Mr. Germano said that what was interesting about the CMS Final Rule was that it was silent on the issue of whether states had to allow MCOs and Community Health Centers (CHCs) to participate. He noted there were some states that continue to not allow MCO and eligible CHC entities from participating in the 340B Program. The Final Rule did not clarify whether states had to allow other entities to participate or not, so that was a bit of a disappointment because to some extent, the State of California could change gears and decide CHCs can no longer participate. Ms. Cook stated information regarding the Final Rule had not be conveyed to PHC by the State directly just yet.

New PHC 340B Compliance Program Agreement – Overview of agreement and communication with 340B Covered Entities:

Per Ms. Cook, PHC updated the 340B Compliance Program Agreement and changed several pieces of the program including a couple important changes that came to light with PHC's discussions with Ole Health which it was felt needed to be reflected in the agreement. We found their input very helpful.

PHC created a single, all-inclusive agreement, which was approved for use. The new 340B Compliance Program Agreement was sent to all the 340B Participating Entities, as well as new 340B Covered Entities. Based on input from a few of the entities, a few additional changes were made to the agreement. Most changes were minor including updating the form types to use with the UD modifier listed on Attachment B.

The updated agreement also noted 340B Participating Entities would be the sole parties responsible for appropriate flagging of all In-House Pharmacy and Physician Administered Drug (PAD) 340B Claims requiring the UD modifier. The PAD claims go directly to PHC's Claims Department and do not go through the Pharmacy Benefits Manager (PBM). PHC would only provide assistance with reclassification when a formal written request was submitted. Once again, the onus was put on the 340B Participating Entities to ensure they flagged their 340B claims accordingly. If for some reason during their internal audits they identify that a UD modifier was missed, they could send a written request to Ms. Cook, who would work with them to collect the information needed for those specific claims. She would work with the Claims Department as it would be a special project for them, and they consistently have a very long list of special projects. With this special project, the $2.75 340B Compliance Fee would kick in and the whole $2.75 for those claims would actually go to PHC versus a split with 340BX Clearinghouse.

In response to a question from Ms. Lujan, Ms. Cook said this was a retroactive type of adjustment and the entities could only go back for 90 days. Ms. Cook noted that in the case of the PAD claims, the Claims Department goes in and adds the UD modifier. Dr. Moore stated the 90 days was more because the State won't go back any further. If PHC tried to go back later, the State would reject it. Ms. Cook noted the State seeks its rebates from the manufacturers for the Medicaid/Medi-Cal claims on a quarterly basis. This was a disincentive for the 340B Participating Entities not to flag appropriately and hopefully it promoted internal auditing more often. Regarding her discussions with 340B Covered Entities, Ms. Cook stated she promoted the idea of regular internal audits, as well as audits of Contract Pharmacies.

Cost Analysis: 340B Compliance Program 1/1/14 to 3/31/16

In the last 340B Advisory Committee meeting, the group discussed putting together a snapshot that showed whether or not PHC had recouped the cost of the 340B Compliance Program thus far based on the compliance fees collected. Ms. Cook noted that the first incarnation of the 340B Compliance Program ended effective 3/31/16 with the creation of a single agreement and major changes to the program, including fee structure. Per the discussion held at the previous 340B Advisory Committee meeting in June 2016, an updated cost analysis was completed to determine if the 340B Compliance Fees generated from 6/1/14 to 3/31/16 covered the operational costs for development and maintenance of the 340B Compliance Program from 1/1/14 to 3/31/16.

Ms. Cook noted that after completing the analysis and working with Accounting, Dr. Moore, and Naresh Vemparala, the operational costs for the program (1/1/14 to 3/31/16) totaled $421,124.00, which excludes the costs associated with time spent by PHC's Senior Leadership team. The 340B Compliance Fees collected between 6/1/14 and 3/31/16 totaled $463,432.50. The net revenue was $42,308.50.

Mr. Germano asked if going forward, as more eligible entities were added, would the operational costs of the program be a fixed cost for the most part or would it be variable. Dr. Moore noted that the timing for PHC going from negative to positive was around 1/31/16, so it was a successful trial, but it could have gone the other way. Our projection based on $0.25 per paid 340B Claim was assuming of substantial growth, so we will be negative again pretty quickly and for quite a while until we get a lot of entities to join. Ms. Cook noted that the operational cost itself won't vary because it is based on a set calculation for man hours. Dr. Moore noted that going forward we actually decreased the number of hours because we are no longer doing the Quality Improvement Program (QIP) piece. Ms. Cook noted that though the number of hours she spends on program was decreased, PHC will go from collecting $4.50 per paid 340B prescription claim to $0.25 per paid 340B prescription claim. When PHC did calculations during negotiations with 340BX Clearinghouse for that agreement, it looked as though PHC would have to get almost every eligible 340B Covered Entity, including hospitals, in the 14 county service area to join the 340B Compliance Program in order to break even.

Ms. McFarland stated PHC does not want to make a profit from the 340B Compliance Program, so if there was significant growth, then adjusting the 340B Compliance Fees could be considered. Mr. Germano stated he felt PHC shouldn't have to eat the cost of the program either, and there should be enough wiggle room with the 340B Compliance Fees so that costs could be covered. In response to Dr. Khoyi asking if the calculations were based on the previous fees, Ms. Cook stated yes. She noted the 340B Compliance Fees actually changed with the new agreements when the 340B Participating Entities signed them retroactive to 4/1/16.

Dr. Moore noted the substantial upfront costs of the program were born by the pilot sites. If a new Health Plan were to start a similar program, they would have to take that into account. Dr. Moore stated the estimate that was calculated by Mr. Vemparala was likely a fixed cost for the Health Plan, and was not based on volume of claims. That cost for the first couple years, of about $450,000, to get the program up and running was probably a useful number to share with other Health Plans. Ms. Cook agreed, stating that estimate was based on set-up costs for IT and other parties, and was not tied to the number of claims.

Ms. Lujan asked if the claim volume would be significant enough that it would warrant some sort of change to the current program. Dr. Moore stated the system was set, so the number of claims processed could be increased, but it would not affect anything. The only exception would be any special project requests that have to be completed for PAD claims.

AGENDA ITEM VI – ADDITIONAL ITEMS

Additional comments:

Ms. Cook noted she had last minute information to add regarding the Mega-Guidance. HRSA submitted the Mega-Guidance to the White House Office of Management and Budget (OMB) for review on 9/1/16. OMB reviews all federal agency rules prior to their publication in the Federal Register. The review should take no more than 90 days, but there was no minimum period. OMB could extend the review on a one-time basis for no more than 30 days and HRSA could extend it indefinitely. When the review was complete, OMB could clear the Mega-Guidance for publication in the Federal Register or send it back to HRSA for

further consideration. It was estimated that the Mega-Guidance would be released sometime in December 2016. In response to a question from Dr. Moore, Ms. Cook noted there had been no responses posted from HRSA regarding the comments submitted by PHC.

Dr. Moore stated the next regularly scheduled meeting would be next quarter. Quarterly meetings had been held due to the 340B QIP. As things were pretty stable, he asked Ms. Cook what she thought about the meetings being held every six months. Ms. Cook stated there would be no reason hold an actual meeting in three months at this point. She stated she could send an update for the 340B Compliance Program by e-mail for those quarters when the committee did not meet. Mr. Germano stated he was okay with holding committee meetings twice a year, and if something came up wherein a meeting needed to be held, it could be done with proper notice. Ms. Lujan stated she agreed with moving to meeting every six months with the understanding that a meeting could be called if anything urgent or concerning arose.
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- **ACTION ITEM:** The committee entertained a motion to move the 340B Advisory Committee meetings to one every six months with e-mail updates during the other two quarters of the year. Ms. Lujan stated it was so moved and Mr. Germano seconded the motion. There were three (3) ayes (Ms. Antle, Ms. Lujan, and Mr. Germano, zero (0) nays, and zero (0) abstains. The motion was passed

Ms. Cook noted the 340B Compliance Program Policy was updated to reflect the changes of the program. The policy would go through review by the Internal Quality Improvement Committee, the Pharmacy & Therapeutics Committee, and the Physicians Advisory Committee.

- **ACTION ITEM:** Bring updated 340B Compliance Program Policy to a future 340B Advisory Committee Meeting following approval.

Ms. Cook noted that PHC would send representatives to the next 340B Coalition Conference in February 2017, at which point, it was hoped there would be additional information regarding the Mega-Guidance.

Dr. Khoyi had a question regarding the 340B Compliance Program Agreement, noting there was still a reference to QIP. Ms. Cook clarified that the reference was to the Primary Care QIP which is still in place.

Documents:

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

- Updated PHC 340B Compliance Program Agreement

AGENDA ITEM V1I – ADJOURNMENT

Meeting Adjourned: 3:55 p.m.
Respectfully submitted: Dawn R. Cook

The foregoing minutes were APPROVED AS PRESENTED on:

_____ _____
Darcie Antle, Interim Committee Chairman Date

The foregoing minutes were APPROVED WITH MODIFICATION on:

_____ _____
Darcie Antle, Interim Committee Chairman Date

PARTNERSHIP HEALTHPLAN OF CALIFORNIA

PHC 340B Advisory Committee Meeting

3-1-17

Agenda

- 340B Compliance Program Update
- Mega-Guidance Update
- 340B Compliance Program Policy
- Governor Brown’s 2017-2018 Budget Proposal

340B Compliance Program Update

- As of 2/28/17, there are 306 340B Covered Sites within PHC's 14 county service area, 132 of which are hospitals.
- There are 101 sites (22 entities) currently active in the 340B Compliance Program
- 340B Clearinghouse has received Walgreens claims files from four (4) 340B Participating Entities, two (2) of which have already received invoices for those claims.
- The 340B Compliance Program Agreement is currently under review by six (6) hospital entities (29 sites).
- Invoices and wire transfers continue to be respectively delivered and received for 11 340B Participating Entities on a monthly basis.
- There were 11 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 7/1/16 to 9/30/16

Entity	340B Paid Match Claim Count	340B Reversal Claim Count	340BX Compliance Fee	PHC 340B Compliance Fee	Total 340B Compliance Fees
Alliance Medical Center	118	0	$295.00	$29.50	$324.50
CommuniCare Health Centers	714	1	$1,785.00	$178.50	$1,963.50
Hill Country Community Clinic	320	0	$800.00	$80.00	$880.00
Mendocino Coast Clinics, Inc.	657	0	$1,642.50	$164.25	$1,806.75
Mendocino Community Health Clinics, Inc.	1203	1	$3,007.50	$300.75	$3,308.25
Mountain Valleys Health Centers, Inc.	487	2	$1,217.50	$121.75	$1,339.25
Northeastern Rural Health Clinics, Inc.	494	0	$1,235.00	$123.50	$1,358.50
Open Door Community Health Centers	4024	7	$10,060.00	$1,006.00	$11,066.00
Shasta Community Health Centers	4097	10	$10,242.50	$1,024.25	$11,266.75
Shingletown Medical Center	103	3	$257.50	$25.75	$283.25
Sonoma Valley Community Health Center	287	0	$717.50	$71.75	$789.25
TOTALS:	12504	24	$31,260.00	$3,126.00	$34,386.00

MONTH	340B Paid Match Claim Count	340B Reversal Claim Count	340BX Compliance Fee	PHC 340B Compliance Fee	Total 340B Compliance Fees
Jul-16	6319	19	$15,797.50	$1,579.75	$17,377.25
Aug-16	4010	0	$10,025.00	$1,002.50	$11,027.50
Sep-16	2175	5	$5,437.50	$543.75	$5,981.25
TOTAL:	12504	24	$31,260.00	$3,126.00	$34,386.00

Mega-Guidance Update

- On Monday, 1/30/17, the Department of Health and Human Services' Health and Human Services Resources and Services Administration (HRSA) withdrew its 340B Program Omnibus Guidance also know as the Mega-Guidance.
- The withdrawal of the Mega Guidance came 10 days after the new federal administration's regulatory freeze.
- HRSA may consider reissuing similar formal guidance in the future, but it could be more difficult given the recent executive order requiring the elimination of two regulations for each new regulation implemented.
- Uncertainty exists regarding the direction of the 340B Program.

340B Compliance Program Policy

- With the changes made to the 340B Compliance Program, the 340B Compliance Program Policy had to be updated.
- Some of the changes reflected in the updated policy include the decreased 340B Compliance Fees, elimination of the 340B Quality Improvement Program (QIP), and reporting requirements for changes.
- The updated 340B Compliance Program Policy includes the updated 340B Compliance Program Agreement, as well at the updated 340B Compliance Program White Paper.
- The 340B Compliance Program Policy was approved at IQI, P&T, and PAC.

Governor Brown's 2017-2018 Budget Proposal

- On 1/10/17, the 2017-2018 Governor's Budget proposal was released. The Department proposes clarifying statutory provisions related to the use of and reimbursement for drugs purchased under the 340B program in Medi-Cal. Existing statute requires 340B entities that provide drugs to Medi-Cal beneficiaries to use only drugs purchased under the 340B program and bill at their actual 340B acquisition cost plus any applicable dispensing fee. The Department is proposing clarifying language that explicitly applies these requirements to both Medi-Cal FFS and Medi-Cal managed care.

- PHC will have to monitor this situation and how it could affect our 340B Compliance Program.

- Per the California Budget website, revisions will take place in May 2017 based upon the latest economic forecasts.

Updates and Meetings

- **Next 340B Advisory Committee Update E-mail: June 2017**
- **Next 340B Advisory Committee Meeting: 9/13/17.**

Questions?

Thank You

PARTNERSHIP HEALTHPLAN OF CALIFORNIA

POLICY / PROCEDURE

<table>
<tr><td colspan="3">Policy/Procedure Number: MCRP4060</td><td colspan="3">Lead Department: Health Services</td></tr>
<tr><td colspan="3">Policy/Procedure Title: 340B Compliance Program</td><td colspan="3">☒ External Policy
☐ Internal Policy</td></tr>
<tr><td colspan="2">Original Date: 10/02/2014</td><td colspan="4">Next Review Date: 11/09/2017
Last Review Date: 11/09/2016</td></tr>
<tr><td>Applies to:</td><td>☒ Medi-Cal</td><td>☐ Healthy Kids</td><td colspan="3">☐ Employees</td></tr>
<tr><td rowspan="2">Reviewing Entities:</td><td>☒ IQI</td><td>☒ P & T</td><td colspan="3">☐ QUAC</td></tr>
<tr><td>☒ OPERATIONS</td><td>☐ EXECUTIVE</td><td>☐ COMPLIANCE</td><td>☐ DEPARTMENT</td></tr>
<tr><td rowspan="2">Approving Entities:</td><td>☐ BOARD</td><td>☐ COMPLIANCE</td><td>☒ FINANCE</td><td>☒ PAC</td></tr>
<tr><td>☐ CEO ☐ COO</td><td>☐ CREDENTIALING</td><td colspan="2">☒ DEPT. DIRECTOR/OFFICER</td></tr>
<tr><td colspan="3">Approval Signature: Robert L. Moore, MD, MPH</td><td colspan="3">Approval Date: 05/13/2015</td></tr>
</table>

I. RELATED POLICIES:

A. PHC 340B Policy for Primary Care Entities

II. IMPACTED DEPTS:

A. Pharmacy
B. Provider Relations
C. Administration (Finance)

III. DEFINITIONS:

A. 340B Program: 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 340B Covered Entities (see definition below).
B. 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.
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 and signs a 340B Compliance Program Agreement.
E. 340B Administrator: A subcontractor hired by a 340B Participating Entity to administer the 340B program, usually for a fee.
F. HRSA: United States Health Resources and Services Administration.
G. DHCS: California Department of Health Care Services.
H. 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.
I. 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.

J. 340BX 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.

K. PHC 340B Advisory Committee: A subcommittee of the PHC Board of Commissioners charged with overseeing PHC's 340B Compliance Program, including review and approval of the 340B QIP program and related proposals.

L. 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 OPA 340B Database: https://opanet.hrsa.gov/340B/Views/CoveredEntity/SearchDirectory.

M. 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 OPA 340B Database.

N. 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 or UB-04 format, which are not first process by a PBM providing services under a direct contract with the 340B Participating Entity and on its behalf.

O. 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.

P. 340BX Trust Account: A bank account in the name of NEC Networks, LLC (for Clearinghouse) at the Bank of San Antonio. This account will be utilized by Clearinghouse as a holding account to deposit 340B related funds paid by 340B Participating Entities, and also to transfer funds to PHC's bank account.

IV. ATTACHMENTS:

A. 340B Compliance Program Agreement

B. PHC 340B Compliance Program White Paper

Policy/Procedure Number: MCRP4060		Lead Department: Health Services	
Policy/Procedure Title: 340B Compliance Program		☒ **External Policy** ☐ **Internal Policy**	
Original Date: 10/02/2014		**Next Review Date: 11/09/2017** **Last Review Date: 11/09/2016**	
Applies to:	☒ **Medi-Cal**	☐ **Healthy Kids**	☐ **Employees**

V. PURPOSE:

The purpose of this policy is to outline the requirements for participation in PHC's 340B Compliance Program, which is established to ensure 340B Participating Entities and PHC are complying with Federal and State 340B regulations. The data submission process outlined for the 340B Compliance Program is set-up so that 340B drugs prescribed by the 340B Participating Entities are identified to DHCS in a way that the State requires in order to ensure that no duplicate discounts are received and retained for the use of 340B drugs. This policy will be applied consistently across each class of 340B Covered Entity and set forth standards of accountability that are reasonable and meaningful.

VI. POLICY / PROCEDURE:

A. Analysis of 340B Covered Entities as outlined by HRSA:
   1. A list of entities identified as eligible to participate in the 340B Program (340B Compliance Program – 340B Covered Entity Master Tracking List) has been compiled by PHC using information from the OPA 340B Database on HRSA's website, http://opanet.hrsa.gov/opa/CESearch.aspx. Those entities are referred to as 340B Covered Entities.
      a. On a quarterly basis, a report is run from the OPA 340B Database to see if there are new 340B Covered Entities added to the 340B Program or if previously participating 340B Covered Entities have terminated their enrollment.
   2. PHC sends an introduction letter to the new 340B Covered Entities describing PHC's 340B Compliance Program and requirements for joining the program.
   3. If a 340B Covered Entity indicates they would like to join the 340B Compliance Program, it is requested that they sign an Agreement with PHC.

B. 340B Compliance Program Agreement:
   1. There is a single 340B Compliance Program Agreement that covers all possible pharmacy arrangements and 340B drug distribution methods (Attachment A).
   2. Once an agreement is entered into between PHC and a 340B Covered Entity, the entity is referred to as a 340B Participating Entity.
   3. All 340B Participating Entities are tracked on a separate document, 340B Compliance Program – Current 340B Participating Entities-Tracking Document.

C. Billing Rates:
   1. Payments for 340B Covered Outpatient Drugs billed as claims to PHC will be paid at the network or contracted rate negotiated between the 340B Participating Entity's Contract or In-House Pharmacy and the PBM. This is applicable to all 340B drug claims for all of the following pharmacy inventory types:
      a. Dispense only 340B drugs
      b. Dispense both 340B drugs and non-340B drugs
      c. Listed on Medicaid Exclusion File and dispense only 340B drugs
      d. Listed on Medicaid Exclusion File and dispense both 340B drugs and non-340B drugs

D. Invoicing and Compliance Fees for 340B Participating Entities:
   1. 340B prescription claims reclassified through 340BX Clearinghouse: There will be a 90 to 120 day

lag in the invoicing process for these claims. The invoices will come from 340BX Clearinghouse and reflect the 340BX Compliance Fees, as well as the PHC 340B Compliance Fees. The 340B Participating Entity is the sole responsible party for the proper flagging of all 340B claims (including PAD claims) filed for 340B drugs by the use of the UD Modifier (refer to Attachment B). In the event the 340B Participating Entity requires assistance with flagging 340B claims missing the UD modifier, they may submit a formal written request to PHC along with a file containing the needed claims information to identify each claim. By submitting the formal request to assist with flagging 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 the 340B Compliance Program Agreement (Attachment A).

E. Reporting of Changes to 340B Participating Entity's 340B Program
   1. 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 and/or conditions of the 340B Compliance Program Agreement.
   2. A form is provided to the 340B Participating Entity to use when reporting changes to PHC.
   3. Changes that should be reported to PHC are as follows:
      a. New site for the 340B Participating Entity becomes eligible to participate in the 340B Program
      b. 340B Participating Entity site is terminated from the 340B Program
      c. New Contract Pharmacy is added to the 340B Participating Entity's Pharmacy Network
      d. Contract Pharmacy is removed from the 340B Participating Entity's Pharmacy Network
      e. 340B Participating Entity opens an In-House Pharmacy
      f. 340B Participating Entity closed an In-House Pharmacy
      g. Any change to the contact information for the 340B Participating Entity on the OPA 340B Database including Authorizing Official or Primary Contact

F. Data Reporting Requirements:
   1. Contract Pharmacy 340B Claims:
      a. For the exact language, please refer to the Agreement. The file format will be shared during the 340B Participating Entity's on-boarding process with 340BX Clearinghouse. Changes in the file format will be communicated in advance.
   2. In-House Pharmacy Claims:
      a. If an In-House Pharmacy processes 340B prescription 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 a CMS-1500 or UB-04 form or related format.
   3. PAD 340B Claims:
      a. The 340B Participating Entity is responsible for insuring that all PAD 340B claims are flagged appropriately.
      b. 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 a CMS-1500 or UB-04 form or related format.

VII. REFERENCES:

A. http://www.hrsa.gov/opa/index.html

Policy/Procedure Number: MCRP4060			Lead Department: Health Services
Policy/Procedure Title: 340B Compliance Program			☒ **External Policy** ☐ **Internal Policy**
Original Date: 10/02/2014		**Next Review Date: 11/09/2017** **Last Review Date: 11/09/2016**	
Applies to:	☒ **Medi-Cal**	☐ **Healthy Kids**	☐ **Employees**

VIII. DISTRIBUTION:

A. PHC Department Directors

B. PHC Provider Manual

IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE: PHC Pharmacy Services Department with 340B Advisory Committee oversight.

X. REVISION DATES:

04/01/2015; 08/22/2016

PREVIOUSLY APPLIED TO:

Click here to enter date.

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. Office of Pharmacy Affairs ("OPA") 340B Database: A database overseen by OPA which includes detailed information related to all 340B Covered Entities, Contract Pharmacies, and Manufacturers all registered to participate in the 340B Program.
i. 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.
j. 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.
k. PHC 340B Advisory Committee: A subcommittee of the PHC Board of Commissioners charged with overseeing PHC's 340B Compliance Program.
l. 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 OPA 340B Database:
https://opanet.hrsa.gov/340B/Views/CoveredEntity/SearchDirectory
m. 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 OPA 340B Database.
n. 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 or UB-04 format, which are not first process by a PBM providing services under a direct contract with the 340B Participating Entity and on its behalf.
o. 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.

p. 340BX Trust Account: A bank account in the name of NEC Networks, LLC (for Clearinghouse) at the Bank of San Antonio. This account will be utilized by Clearinghouse as a holding account to deposit 340B related funds paid by 340B Participating Entities, and also to transfer funds to PHC's bank account.

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 CRF § 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. 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.
b. Payments for 340B Covered Outpatient 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).
c. 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.
d. 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 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. 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.
e. PHC has established a mechanism to assist its 340B Participating Entities via Clearinghouse. Should a 340B Participating Entity or one of its 340B Administrators choose to submit 340B claims for a Contract Pharmacy or In-House Pharmacy to PHC without having it go through the reclassification process via Clearinghouse, such claims may not be compliant with 340B Program flagging requirements. The 340B Participating Entity acknowledges that it will be the sole accountable party regarding any 340B claims that are not reviewed by Clearinghouse should an audit occur. In the event the 340B Participating Entity

requires assistance with appropriate flagging and claims adjudication compliance for 340B claims, 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.

f. The 340B Participating Entity is the sole responsible party for the proper flagging of all 340B claims (including PAD claims) filed for 340B drugs by the use of the UD Modifier (refer to Attachment B). In the event the 340B Participating Entity requires assistance with flagging 340B claims missing the UD modifier, they may submit a formal written request to PHC along with a file containing the needed claims information to identify each claim. By submitting the formal request to assist with flagging 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.

g. The 340B Participating Entity takes all responsibility to provide accurate, complete, and necessary data to enable PHC and Clearinghouse to perform its services hereunder, and to maintain records to verify the accuracy and completeness of such data. Such data will be made available by 340B Participating Entity to HRSA or other federal, state, or local authorities in the case of an audit, and the 340B Participating Entity shall maintain such records for a period of time that complies with all applicable laws.

V. Reclassification Fees

a. The 340B Participating Entity will pay reclassification fees for any 340B claim reclassified by the Clearinghouse. Payment of these reclassification fees is on a per paid 340B prescription 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 the Department of Health Care Services.

b. 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 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.

c. 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.
d. 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.
e. 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.

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 and/or conditions of this Agreement.
b. Attachment D defines 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. Forms will be submitted to PHC's Pharmacy Services Program Manager by e-mail at 340BQIP@partnershiphp.org.
d. 340B Participating Entity's failure to report to PHC the listed type of change in the respective timeframe as 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. Protection from excessive 340B Drug Costs

a. 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.
b. 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.

VIII. Terms and Termination of Agreement

a. Term: The initial term of this Agreement shall begin on the Effective Date and shall expire two (2) years after. Thereafter, this Agreement shall renew automatically for additional, successive terms of one (1) year until terminated by either party. This Agreement may be terminated with or without cause based on the provisions herein.
b. Termination for cause: If a party defaults in any of its obligations under this Agreement, the non-breaching party, at its option, shall have the right to terminate this Agreement by providing thirty (30) calendar days written notice of the material breach of this Agreement to the defaulting party. The defaulting party shall have ten (10) business days to cure such default upon receipt of the notice, and if timely cured, no termination shall occur. This Agreement will be immediately terminated without recourse if the State or Federal Government

deems the program not legally permissible and all options for appeal are exhausted.

c. Early termination: This Agreement may be terminated by either the 340B Participating Entity or PHC upon one hundred twenty (120) days' written notice without cause or sooner by mutual consent.
d. If this Agreement is terminated without a new agreement in effect to replace it, the parties acknowledge that PHC will not be able to report the 340B Participating Entity's 340B drug use to the State. The 340B Participating Entity agrees that upon termination of this Agreement, it will no longer provide 340B drugs to PHC members.
e. Wrap-up Period. Any business reclassifications initiated prior to the termination date of this Agreement will still be completed, invoiced appropriately, and the 340B Participating Entity will remain responsible for submitting payment for any 340B Compliance Fees tied to those reclassified claims.

IX. 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 Services Program Manager, 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.

X. 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.

XI. 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, with the exception of Section VII of this Agreement, which modifies the Primary Care QIP. Aside from Section VII, if this Agreement conflicts with the Provider Contract between the Parties, the Provider Contract shall prevail.
d. Subcontractors: The 340B Participating Entity may use subcontractors to perform its services under this Agreement. The 340B Participating Entity is responsible for their services to the same extent that the 340B Participating Entity would have been had the 340B Participating Entity performed the services without the use of a subcontractor.
e. Amendment: Except as may otherwise be specified in this Agreement and an applicable Attachment, this Agreement (including its Attachments) may be amended only by both parties agreeing to the amendment in writing, executed by a duly authorized person of each party.

f. Waiver/Estoppel: Nothing in this Agreement is considered to be waived by any party, unless the party claiming the waiver receives the waiver in writing. No breach of the Agreement is considered to be waived unless the non-breaching party waives it in writing. A waiver of one provision does not constitute a waiver of any other provision. A failure of either party to enforce, at any time, any of the provisions of this Agreement or to exercise any option which is herein provided in this Agreement will in no way be construed to be a waiver of such provision of this Agreement.

g. Force Majeure: Each party will take commercially reasonable steps to prevent and recover from disruptive events that are beyond its control and represents that it has backup systems in place in case of emergencies or natural disasters. If either party shall be, wholly or in part, unable to perform any or part of its duties or functions under this Agreement because an act of war, riot, terrorist action, weather-related disaster, earthquake, governmental action, unavailability or breakdown of equipment, or other industrial disturbance which is beyond the reasonable control of the party obligated to perform and which by the exercise of reasonable diligence such party is unable to prevent (each a "Force Majeure Event"), then, and only upon giving the other party notice by telephone, facsimile, or in writing within a reasonable time and in reasonably full detail of the Force Majeure Event, such party's duties or functions shall be suspended during such inability; provided, however, that in the event that a Force Majeure Event delays such party's performance for more than thirty (30) calendar days following the date on which notice was given to the other party of the Force Majeure Event, the other party may terminate this Agreement. Neither party shall be liable to the other for any damages caused or occasioned by a Force Majeure Event. Government actions resulting from matters that are subject to the control of the party shall not be deemed Force Majeure Events.

h. Counterparts: This Agreement may be executed by electronic signatures or in one or more counterparts, each of which shall be deemed an original, but all of which, together, shall constitute one agreement.

i. Severability: If any provision of this Agreement is held to be invalid or unenforceable by a court of competent jurisdiction, then the remaining portions of the Agreement shall be construed as if not containing such provision, and all other rights and obligations of the parties shall be construed and enforced accordingly.

j. Survival of Terms: Any provisions of this Agreement or any Attachments, which by their nature extend beyond the expiration or termination of this Agreement, and those provisions that are expressly stated to survive termination, shall survive the termination of this Agreement and shall remain in effect until all such obligations are satisfied.

k. Warranties: Except as expressly stated herein, there are no warranties, express or implied, by any party in connection with this Agreement. All warranties not specifically stated herein, including warranties of merchantability or fitness for a

particular purpose, are excluded and shall not apply to the products or services to be provided under this Agreement.

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:		**Signature**	
By:		By:	Elizabeth Gibboney
Title:		Title:	CEO
Date:		Date:	
Address:		Address:	4665 Business Center Drive Fairfield, CA 94534

Attachment A: Fee Schedule for 340B Compliance Program

340B Claim Type	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 prescription 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 prescription claim ($2.50 340BX Clearinghouse Fee + $0.25 PHC 340B Compliance Fee)
340B PAD claims flagged appropriately by the 340B Participating Entity with the UD Modifier	No fee
340B PAD claims not flagged appropriately by the 340B Participating Entity requiring intervention by PHC to add the UD Modifier	$2.75 per paid 340B prescription claim ($2.75 PHC 340B Compliance Fee)

*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

1. **Contract Pharmacy 340B 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: One file extract should be submitted each month. File should 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 ninety (90) calendar days before the changes become effective.
        iv. File Recipients: This file should be sent electronically and securely to Clearinghouse.
2. **In-House Pharmacy 340B Claims:**
    a. If an In-House Pharmacy processes 340B prescription 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 a CMS-1500 or UB-04 form or related format.
3. **PAD 340B Claims:** The 340B Participating Entity is responsible for insuring that all PAD 340B claims are flagged appropriately.
    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 a CMS-1500 or UB-04 form or related format.

Attachment C: 340BX Clearinghouse Reclassification & Invoicing Schedule

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

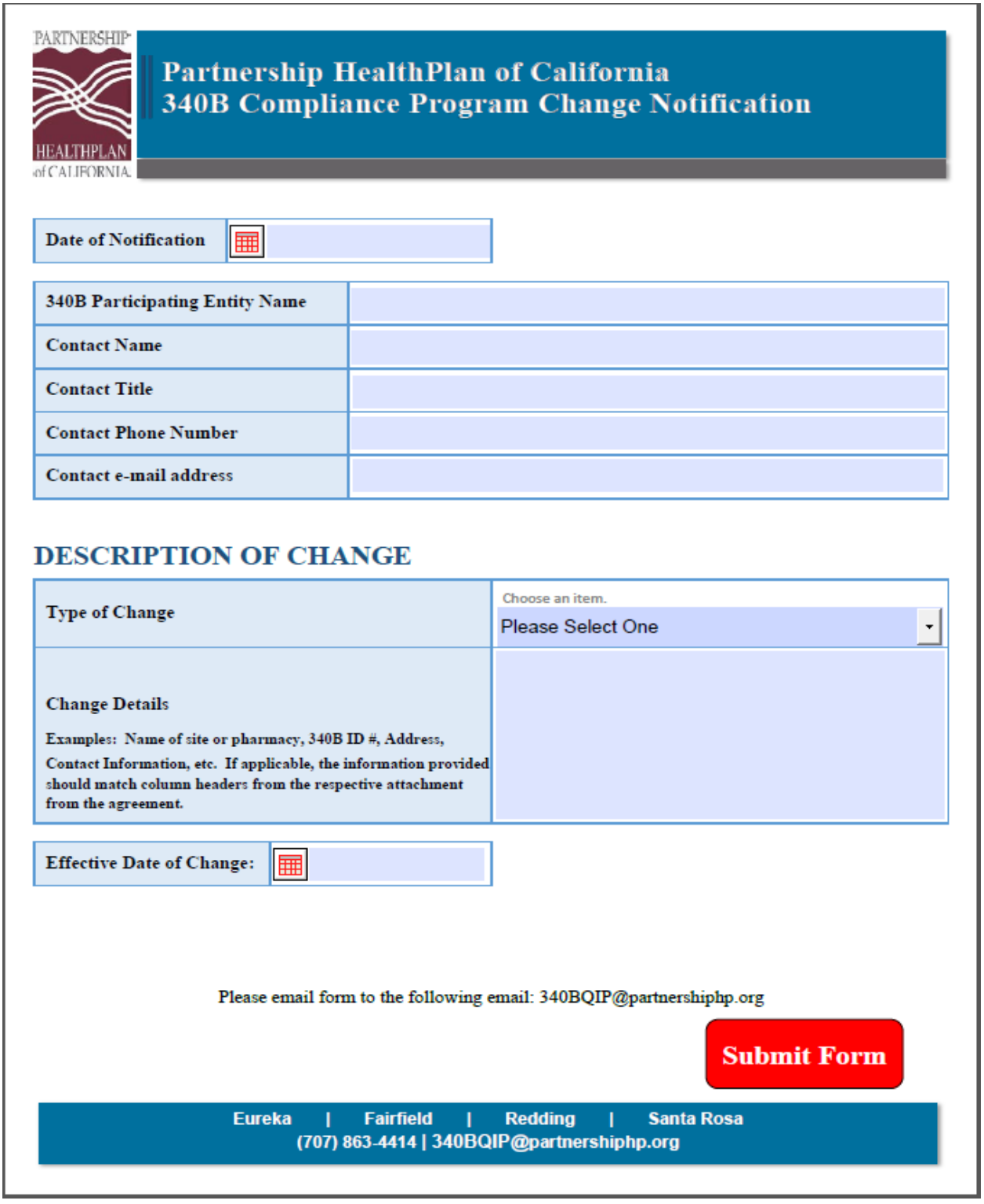
Example: In the month of July 2016, the following actions will take place:

- By the 20th day of the month, the 340B claims from June 2016 (the month prior) will be reclassified.
- By the 3rd day of the month, Clearinghouse will send an invoice to the 340B Participating Entity for all fees associated with the reclassification of the March 2016 340 claims (four months prior).
- By the 23rd day of the month, the 340B Participating Entity will submit payment for the fees associated with the March 2016 claims (four months prior) as per the invoice submitted by Clearinghouse.
- By the 28th day of the month, Clearinghouse will transfer the PHC 340B Compliance Fees associated with the March 2016 claims (four months prior), as per the invoice submitted by Clearinghouse, from the 340BX Trust Account to PHC's bank account.

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

Type of Change	Timeframe for reporting change to PHC
New child site becomes eligible to participate in 340B Program	60 days or more prior to effective date
Site is terminated from the 340B Program	60 days or more prior to effective date
New Contract Pharmacy added to 340B Participating Entity's Pharmacy Network	60 days or more prior to effective date
Contract Pharmacy is removed from 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

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



Partnership HealthPlan of California
340B Compliance Program Change Notification

Date of Notification	

340B Participating Entity Name	
Contact Name	
Contact Title	
Contact Phone Number	
Contact e-mail address	

DESCRIPTION OF CHANGE

Type of Change	Choose an item. Please Select One
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.	

Effective Date of Change:	

Please email form to the following email: 340BQIP@partnershiphp.org

Submit Form

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.

Attachment H: Contract Pharmacies registered on OPA 340B Database

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

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

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

Attachment I: In-House Pharmacies

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

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

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

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340B Compliance Program White Paper

Background Information

Purpose of the 340B Program: The Veterans Health Care Act of 1992 established the 340B Program in section 340B of the Public Health Service Act (PHS 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."

Who can participate? Covered Entities include Disproportionate Share Hospitals (DSHs), Family Planning Clinics (FPs), Federally Qualified Health Centers (FQHCs), Ryan-White treatment centers for HIV, comprehensive hemophilia treatment centers, and IHS-affiliated/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 Covered Entity's information into HRSA's 340B Database, and the information is updated annually.

How does the Program work? 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.

340B Program and Medicaid: 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, they instead dispense drugs that were 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 agency's 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. (Source: OIG: "State Medicaid Policies and Oversight Activities Related to 340B Purchased Drugs" June 2011)

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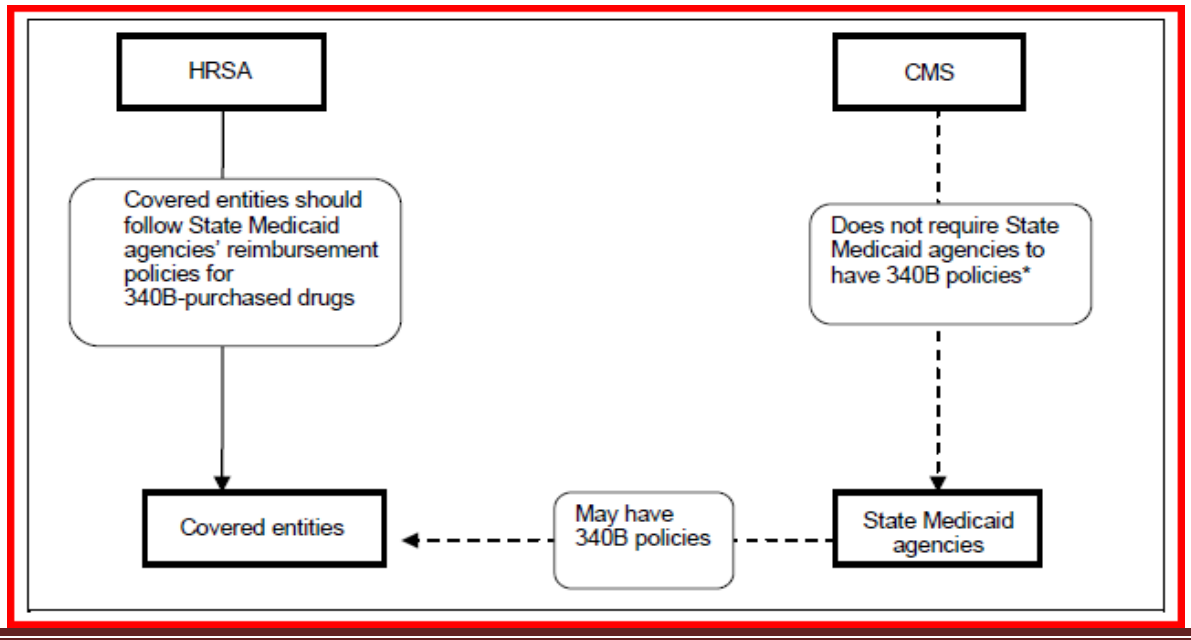
State Policy: State Medicaid agencies may set specific policies for Covered Entities that dispense 340B-purchased drugs to Medicaid patients (340B policies), though CMS does not require them to do so. If a State Medicaid agency's 340B policy requires Covered Entities to bill and be reimbursed for 340B-purchased drugs at their actual acquisition costs (AAC), then the State Medicaid agency receives the full benefit of the 340B discount. If a State Medicaid agency's 340B policy allows Covered Entities to bill and be reimbursed for 340B-purchased drugs above AAC, then the State Medicaid agency shares a portion of the savings from the 340B discount with Covered Entities.

HRSA has twice issued guidance for Covered Entities that bill State Medicaid agencies for 340B-purchased drugs. In 1993, HRSA issued guidance stating:

> When a covered entity submits a bill to the State Medicaid agency for a drug purchased by or on behalf of a Medicaid beneficiary, the amount billed shall not exceed the entity's actual acquisition cost (AAC) for the drug, as charged by the manufacturer. … This will assure that the discount to the covered entity will be passed on to the State Medicaid agency. (Federal Register Volume 58, Number 87, Page 27293, May 7, 1993 and Federal Register Number 248 Page 68923, December 29, 1993)

In 2000, HRSA altered its guidance, stating that it was reconsidering the AAC provision in its 1993 guidance, and directed Covered Entities to "refer to their respective Medicaid State agency drug reimbursement guidelines for applicable billing limits." (Federal Register Volume 65, Number 51, Page 13984, March 15, 2000). This makes explicit the joint oversight of the 340B program as shown in the following graphic:



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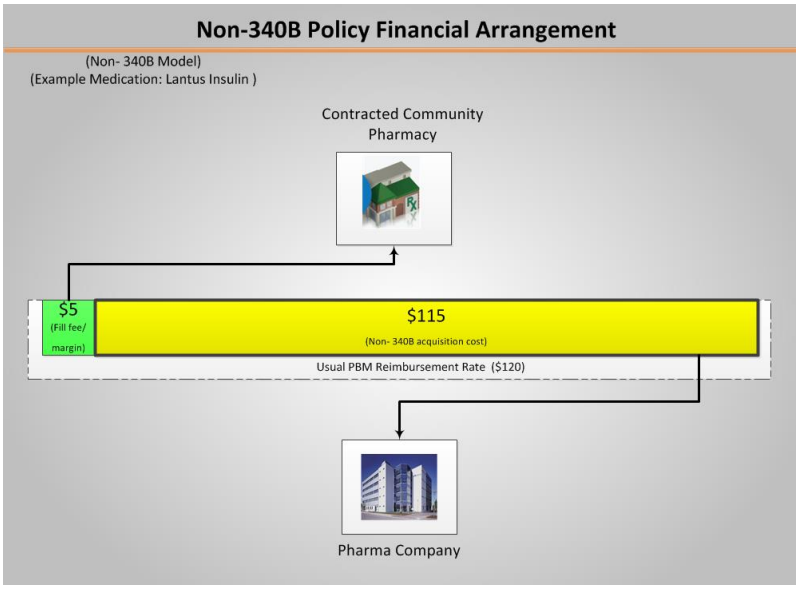
To make the difference between usual prescribing and 340B prescribing more understandable, please refer to the following graphics, which look at an example of a long acting, brand name insulin: Lantus Insulin, which sells for about $120 retail for a 10 ml vial.

This first graphic shows how the money flows for a non-340B Prescription:



The next graphic shows what California State 340B Policy for Medi-Cal requires for 340B for Fee-For-Service (FFS) and County Organized Health System (COHS) plans that do not have another contracted arrangement. The savings would be accrued by the Health Plan. This can only be billed on a CMS-1500 or UB-04 format, not through the Pharmacy Benefits Manager (PBM).

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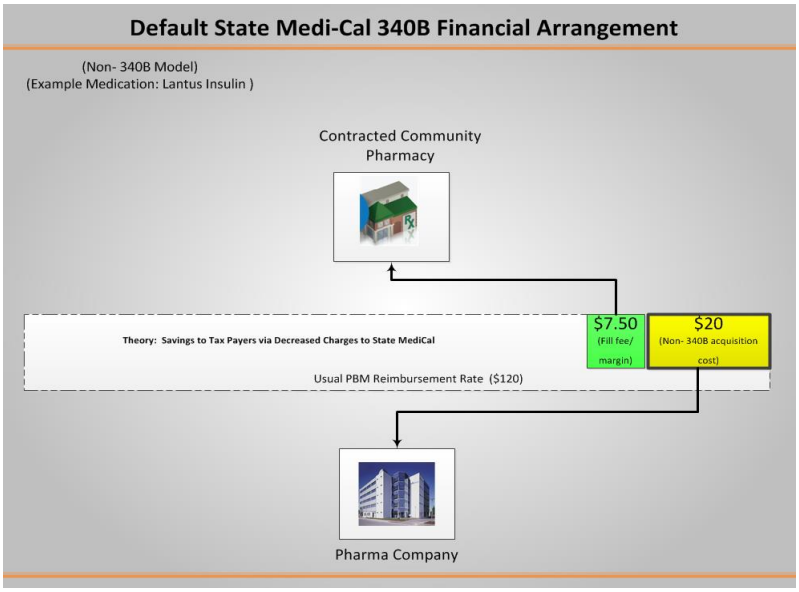
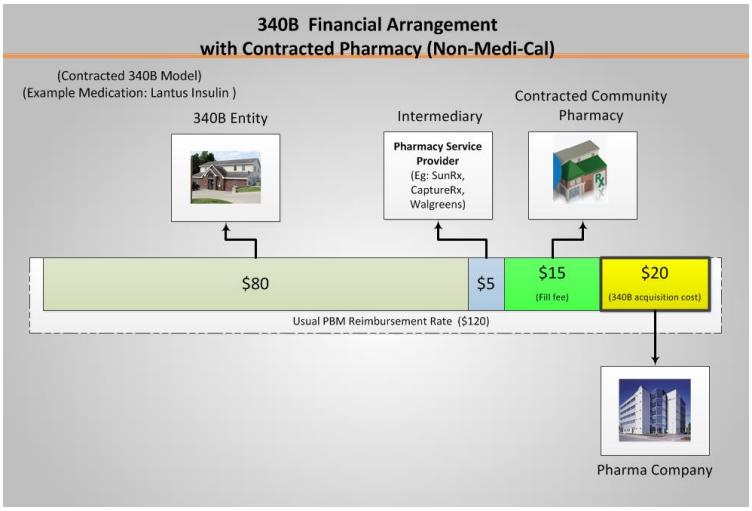


For comparison, this graphic shows the money flow for a 340B Contract Pharmacy arrangement for Non-Medi-Cal:



Finally, this graphic shows the money flow for an In-House 340B Pharmacy (for non-Medi-Cal). Several I.H.S. Health Centers have In-House licensed full-service pharmacies; this would apply to them. This would also apply to outpatient facilities affiliated with a critical access hospital (CAH) with its own full service outpatient pharmacy:

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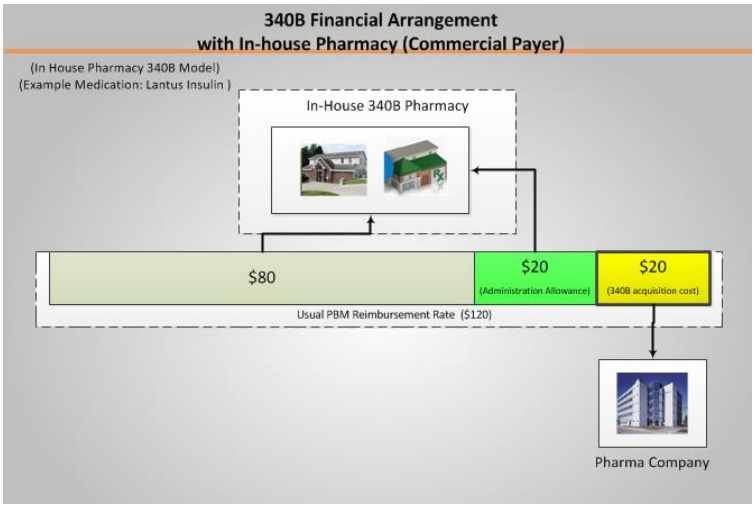

Provisions in the Affordable Care Act (ACA): The ACA requires "the development of more detailed guidance describing methodologies and options available to Covered Entities for billing covered drugs to State Medicaid agencies in a manner that avoids duplicate discounts." The proposed regulations for this provision have been published and largely focused on using increased audits to ensure duplicate discounts are not occurring. (Federal Register Volume 77 Number 22, February 2, 2012 pp. 5318-5367 "Medicaid Program: Covered Outpatient Drugs") The final rule was due in January 2014.

California State Medi-Cal 340B Policy: California DHCS provided a list of questions and answers regarding the 340B policy on its website, http://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_10802.asp.

The answers are somewhat ambiguous and the information on the website has not been updated since a US district court injunction (see below for details) of a 2009 law **requiring** 340B In-House Pharmacies to use 340B drugs for all Medi-Cal patients (Medi-Cal Pharmacy Bulletin 710, August, 2009).

Specifically, FAQ #5 states:

> Q: **Does this change apply to both Medi-Cal FFS and Medi-Cal Managed Care**?
>
> A: The requirement to dispense 340B program drugs applies to the Medi-Cal FFS program and rebate-eligible County Organized Health System (COHS) plans. Reimbursement is based on the applicable contract rates with the individual plans.

This answer is ambiguous about what constitutes the "contract rates with the individual plans." The contract could refer to the contract between the State and the Health Plan or the Covered

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Entity and the Health Plan, or even possibly the pharmacy and the Health Plan through the PBM intermediary. For this reason, different legal counsels have interpreted this differently.

FAQ #8 excludes rebate-eligible COHS (like PHC), but indicates that a higher than 340B reimbursement can be *negotiated* with Managed Care Plans:

> Q: **Can a Covered Entity bill a Medi-Cal Managed Care Plan at a rate higher than the acquisition cost plus a fee?**
>
> A: A Covered Entity using a 340B program contract pharmacy may arrange with the contract pharmacy to dispense 340B program drugs to Medi-Cal managed care recipients and bill for such 340B program drugs at the contract rate negotiated with the plan (excluding drugs dispensed to members of rebate-eligible COHS plans).

In this case the basis of the "contract rate negotiated with the plan" might be interpreted as either 1) The rate set forth in a contract between the Managed Care Plan and the Covered Entity after negotiation or 2) The negotiated rate paid by the Pharmacy Benefit Manager (on behalf of the Managed Care Plan) to the pharmacy for non-340B acquired drugs. Again, this ambiguity has led different legal counsels to interpret this differently.

In May 2013, PHC asked for clarification from the Pharmacy Branch of DHCS on the ability of COHS to negotiate a higher than 340B rate with Covered Entities:

> PHC: Just as CMS and HRSA give flexibility to State Medicaid agencies to negotiate with Covered Entities to pay greater than the Actual Acquisition Costs, can County Organized Health Systems negotiate with Covered Entities to pay greater than the Acquisition Cost + Dispensing Fee, notwithstanding California's 340B Policy that appears to not allow this option for fee-for-service Medi-Cal? We have been told that a previous DHCS Pharmacy Director verbally told the COHS/LI Pharmacy Directors that this was permitted, and this verbal permission has been acted upon and operationalized by plans around the State, but we have not seen any written confirmation of this flexibility. For legal clarification, the Health Plans would appreciate this confirmation.
>
> DHCS: Question #5 of the FAQ document addresses the question. The Policy is a 340B drug must be dispensed to a COHS managed beneficiary, but the reimbursement rate is based on the contract rate of the individual plan.

PHC's interpretation of the way DHCS chose to answer this specific question is that COHS do have flexibility to contract with eligible providers for a rate higher than the 340B acquisition cost. Others who agree with this interpretation include SunRx and CaptureRx (two large 340B Administrators) and all the partners working together on the 340B plan at Cen Cal Health

(another COHS). CaptureRx is the largest 340B administrator nationwide, and specifically excludes all COHS from any 340B savings opportunity in their program.

To summarize, state policy, not affected by the injunction below, requires Covered Entities to charge 340B acquisition cost plus set fill fee **if** 340B drugs are prescribed for patients with fee–for-service Medi-Cal. The intent of this policy was to save taxpayer money, but it had the effect of removing the incentive for Covered Entities to use 340B drugs for Medi-Cal, resulting in little savings to the State as prescriptions were filled from commercial sources instead of using the 340B program. The State allows, but does not require, COHS to negotiate a different rate for 340B drugs. In counties with a COHS, in the absence of a contract with the COHS that specifies something different, 340B pharmacies that fill a prescription for 340B drugs must follow California State 340B Policy on identification of the claim and payment of the claim at the Acquisition Cost plus allowed fill fee rate.

2013 Court Case: The 2013 injunction issued by the US District Court (AIDS Healthcare Foundation v. Toby Douglas, Case: CR-09-8199-R) applies to a specific 2009 statute (the part of the 2009 Budget requiring in-house 340B pharmacies to only dispense 340B drugs at a specified reimbursement rate), and does not apply to 340B Covered Entities using contracted pharmacies. In the injunction, the court said that DHCS implemented the regulation before getting the required State Plan Amendment (SPA) approved by CMS first. Since there is material financial harm that would result to the plaintiffs from the implementation of the 340B provision of the 2009 Budget Act, the State should have waited for CMS to approve the SPA before proceeding. The injunction does not mention or otherwise prohibit COHS from negotiating with 340B Covered Entities with in-house pharmacies in the same way they negotiate with those with contracted pharmacy arrangements. The State has said that it plans to appeal the injunction, but if CMS accepts a SPA on this topic, the injunction will likely be invalidated.

In September 2013, PHC specifically inquired about how the status of this decision:

> PHC: What is the State's response and plan to the injunction in issued by the US District Court (AIDS Healthcare foundation v. Toby Douglas, Case: CR-09-8199-R)?
>
> State: 340B Covered Entities may "carve-out" claims for dates of service on or after 5/3/13. If billing for 340B drug, the Covered Entity should bill at acquisition cost and is reimbursed based on agreement with COHS plan.

(Please note that the above information was based on the information PHC had prior to development and implementation of its 340B Compliance Program. In May of 2015, DHCS confirmed that no new policy clarifications around 340B and this topic would be coming until the lawsuit is resolved.)

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340B Compliance

Overall Reporting Responsibility: 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 (Federal Register Volume 81 Number 88, May 6, 2016, pp. 27546-27555 "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care and Revisions Related to Third Party Liability"). Per 43 CRF § 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.

Enforcement of Reporting Responsibility: Health Plans are empowered to direct their PBMs to cease contracting with a Covered Entity if this is required to ensure the state requirement for 340B prescribed drug reporting is fulfilled. PHC confirmed this in a communication with DHCS:

> PHC: Can a Medi-Cal Managed Care Plan prevent a Covered Entity from billing any pharmacy claims for 340B medications (by disenrollment from the PBM network) if the Health Plan's PBM cannot recognize that a 340B drug has been procured? For example the Health Plan pays the retail cost of the drug and then the 340B Covered Entity retrospectively runs the drug through them and keeps the difference between retail and the 340B charge. In that instance, the PBM uses the initial transaction, because they are unaware of the retrospective transaction.

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DHCS: Medi-Cal Managed Care Plan has the authority to establish its provider network provided it does so within the requirements of the agreement. As such, a Managed Care Plan could potentially dis-enroll a 340B Covered Entity by choice.

Penalty for Non-compliance: As best we can interpret, here are the penalties for non-compliance with the 340B notification requirement.

- Covered Entity must pay the pharmaceutical company the difference between the 340B acquisition cost and usual wholesale cost of the drug, for each patient where the use of a 340B drug was not allowed or not reported to the State. In addition, the 340B Covered Entity may have its 340B Covered Entity status revoked by HRSA.
- Medicaid Health Plan not reporting data to the State: There is no penalty specified for the Medicaid Health Plan. In the specific case where a Medicaid Health Plan had a shared savings contract with the 340B Covered Entity, a 340B Covered Entity penalized for 340B drug use not reported to the State could ask that the shared savings be returned from the Health Plan to the 340B Covered Entity, to cover the above penalty.
- State Medicaid Organizations: Penalty would be revised filing for rebate, such that the rebate normally going to the State would be recouped.

PHC will attempt to work with 340B pharmacies associated with a 340B Covered Entity that has an agreement with PHC to achieve compliance. If this is not possible, and the pharmacy is knowingly using 340B drugs without submitting the information required for PHC to assure compliance, PHC may take appropriate corrective measures including, but not limited to, directing our PBM to cease contracting with the pharmacy in question. .

State Notification options: Notification of the use of 340B prescribed drugs may be done through flagging the point of-sale (POS) file submitted to the PBM which can then be forwarded to the State by the Health Plan or by retrospective reconciliation (cancelling prior prescription notification of non-340B drug and replacing with notification of prescription with 340B prescribed drug) with the State. In either case, the reporting methodology must be documented, validated, and audited on a regular basis to ensure compliance.

Current National Scope of 340B Drug Programs: Capture Rx estimates that 3% of all prescriptions are filled via 340B, for a total savings (nation-wide) of $7 Billion.

The following diagram illustrates how the 340B flag moves from the 340B Covered Entity to the State, how the general flow of money occurs in the different scenarios, and how it relates to the State Medicaid rebate:

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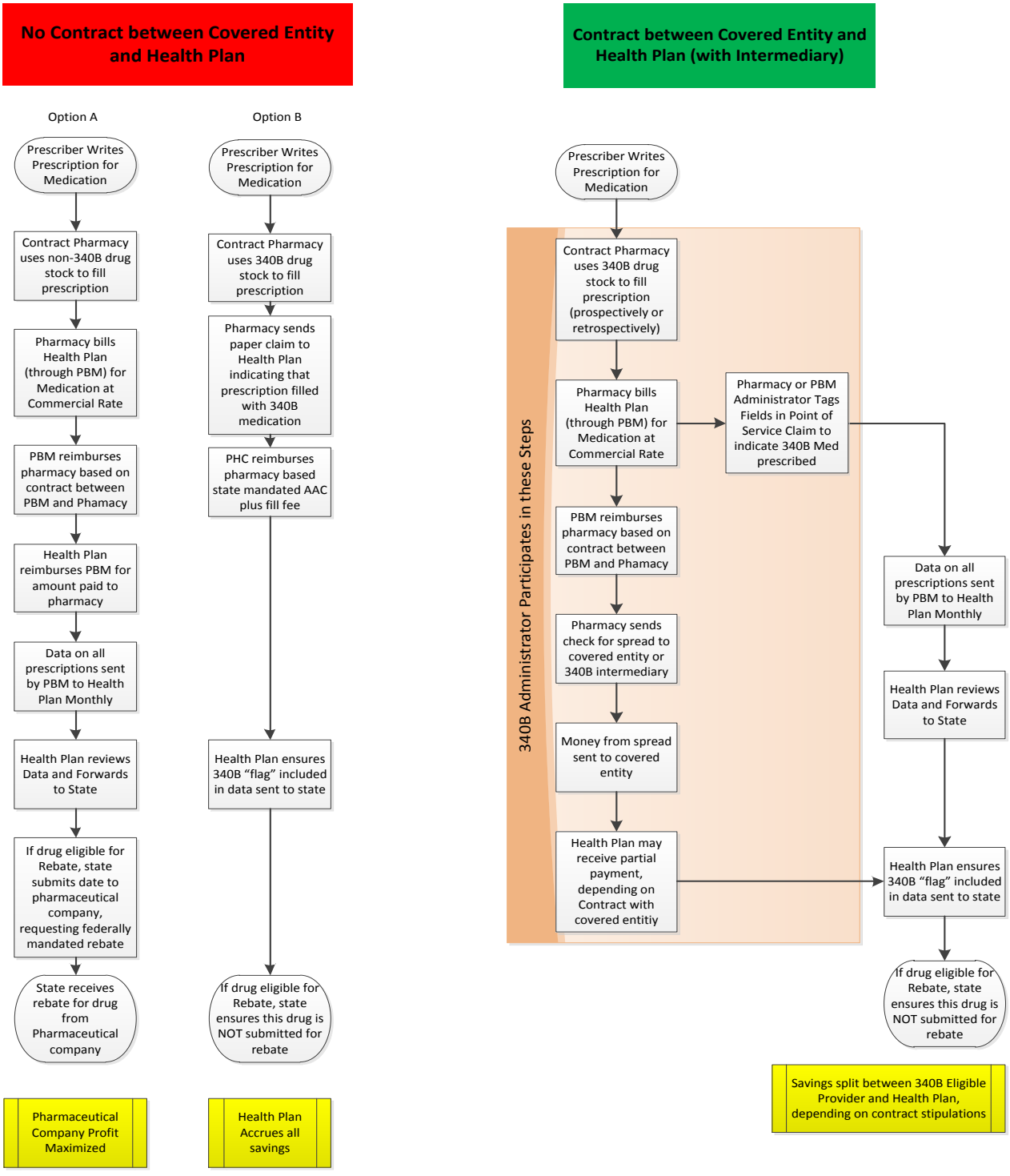

PHC used these principles to develop a compliance plan for the 340B program. From the experience of our sister COHS, CenCal Health Plan, and confirmed by our experience in current

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340B pilots, ensuring that all reporting occurs correctly is labor intensive. Any 340B Covered Entity signing an agreement with PHC on an alternative payment methodology must agree to follow this policy. Covered Entities following this policy will be issued a statement of 340B reporting compliance which they can submit for their own 340B audits.

PHC's experience with 340B programs

PHC started several years ago to set up pilot 340B programs.

We learned several lessons based on this experience:

1. 340B intermediary companies such as SunRx (affiliated with Our Pharmacy Benefit Manager) and CaptureRx faced challenges setting up program involving Medi-Cal. These challenges included explaining how the system works in a way community pharmacies will agree to sign on; agreeing to rates for pharmacies; getting sufficient volume for smaller clinics to generate significant revenue; success or failure depends on the strength of the project management provided by the intermediary companies; and ensuring that the State ends up being notified of use of 340B drugs.
2. Compliance around reporting the use of 340B drugs to the State has proven much more challenging than anticipated. The complexity of the flow of information from 340B Covered Entity to the State is part of the issue. The lack of state and federal monitoring of Medi-Cal claims that used 340B drugs is another factor; all the Health Centers above passed 340B audits that did not investigate if the State was aware of the 340B claims. It was only through the diligence of PHC's internal investigations that we became aware of the problem. We believe this situation is quite widespread in the rest of California and throughout the country. PHC may have been the first organization to become aware of the scope of the problem. Considerable time was taken to analyze the problem and develop a reporting solution.
3. Attempts to negotiate shared savings between health centers and the Health Plan led to a number of inconsistencies in policy, variable documentation of agreements and impaired relationships with our current and future primary care 340B Covered Entities. PHC determined that any savings from the 340B Program should stay with the 340B Covered Entities.

Other Health Plan Experience with 340B

Cen Cal Health: The 340B program creates a strong financial incentive to use brand name drugs instead of less expensive generic alternatives. Cen Cal Health (a County Organized Health System in Santa Barbara and San Luis Obispo) has a large 340B program with the largest health centers in its network, based on splitting the difference between the 340B price and the usual PBM acquisition cost: 50% goes to the health centers, and 50% recouped as savings to the

Health Plan. As a Health Plan, Cen Cal Health has a generic prescription rate 3-5% lower than PHC's, in spite of what they consider to be a robust prior authorization process. The resulting difference in total drug costs attributable to this difference between our Health Plans generic prescription rate is three times greater than the dollars that Cen Cal Health receives from splitting the savings on 340B drugs. The Primary Care 340B policy must include a system to strongly dis-incentivize increase use of Brand-Name drugs. CenCal Health tracks 340B compliance internally, with about a half FTE analyst at the Health Plan.

Alameda Health Plan: Reportedly has a similar arrangement to Cen Cal Health, but agrees to allow the Health Centers to recoup a larger percentage of the price difference.

Texas, New York, Washington D.C.: CaptureRx has developed a Clearinghouse function to help track 340B drug compliance for Health Plans. Insuring compliance with regulations requires employing some resources at the Health Plan level and may include some contracted services. Tracking the generic prescription versus brand name rate to look for over-use of brand name will take additional resources. Together, this would form a 340B compliance unit. There is no experienced organization in California that has done this clearinghouse function previously.

Other related 340B information.
On the specialist side of health care, the financial implications of the 340B program on eligible providers can lead to misaligned incentives, which can have negative impacts, including over-treating certain patients and corporate consolidation (Wall Street Journal: July 31, 2013: "How ObamaCare Hurts Cancer Patients").

Revisions to PHC's 340B Compliance Program and Policy

In 2016, after the program had been up and running for two years, PHC decided to evaluate the 340B Compliance Program. Taking into consideration feedback from Covered Entities participating in the program and other Covered Entities in its service area, as well as the information from the "Final Rule" from CMS in May 2016, changes were made to the overall program. With those changes, PHC updated its 340B Compliance Program Policy.