

340B ADVISORY COMMITTEE UPDATE

JUNE 2017

340B ADVISORY COMMITTEE

Members: Darcie Antle (Interim Chair)

Viola Lujan

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Amir Khoyi, PharmD

C. Dean Germano

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Robert L. Moore, MD, MPH, MBA, CMO

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Dina M. Cuellar, Director of Regulatory Affairs

Michelle Rollins, Regulatory Compliance Counsel

Stan Leung, PharmD, Director of Pharmacy Services

Dawn R. Cook, Pharmacy Services Program Manager

INTRODUCTION:

The last 340B Advisory Committee Meeting took place on March 1, 2017. The committee previously voted to hold the meetings just twice a year.

The committee agreed that for those quarters when the committee does not meet, an update will be sent out via e-mail to all 340B Advisory Committee Meeting participants.

UPDATE:

340B Contracting Update:

There are currently 312 sites (136 of which are hospitals) in PHC's 14 county service area that are currently listed on the OPA 340B Database as eligible to participate in the 340B Program.

As of June 29, 2016, there are 24 active 340B Compliance Program Agreements, so 24 340B Participating Entities. Those 24 active 340B Compliance Program Agreements cover 108 340B IDs/sites.

There are also one (1) other signed 340B Compliance Program Agreements which will be effective as of July 1, 2017 with 35 IDs/sites.

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With the addition of this 340B Compliance Program Agreements, as of July 1, 2017, there will be 25 active 340B Compliance Program Agreements that cover 143 340B IDs/sites.

There were six (6) 340B Covered Entities invited to join the 340B Compliance Program for the effective date of July 1, 2017. Of those six (6) 340B Covered Entities invited to join the 340B Compliance Program:

- One (1) 340B Covered Entity has signed 340B Compliance Program Agreements (as noted above).
- One (1) 340B Covered Entity is still reviewing the agreement and their 340B Program.
- The other four (4) 340B Covered Entities were contacted about participation in the program due to inquiries about claims they are currently submitted to PHC's Claims Department which require the addition of the modifier of "UD" to reclassify it as a 340B drug claim.

It should be noted that the 340B Covered Entity that has signed the 340B Compliance Program Agreement with the effective date of July 1, 2017 is a hospital. Of the other five (5) 340B Covered Entities invited to join the 340B Compliance Program for the effective date of July 1, 2017, four (4) of those 340B Covered Entities are hospitals.

On-boarding for the 340B Compliance Program occurs on a quarterly basis to match the effective dates for HRSA's registration for the 340B Program. The next round of invitations to participate in the 340B Compliance Program will go out in mid-August 2017. PHC will compile a list of 340B Covered Entities to invite to join the 340B Compliance Program for October 1, 2017 based on input from an introduction letter that will be sent out in July 2017 (see the "340B Compliance Program Introduction Letter" section below).

Financial Summary:

Based on changes made to the type of information collected by 340BX Clearinghouse, the information provided in the financial summary table below will only consists of the 340B Paid Claims Count, 340B Reversal Claim Count, Walgreens 340B Paid Claims Count, 340BX Compliance Fees, PHC 340B Compliance Fees, and Total 340B Compliance Fees paid by the 340B Participating Entities.

The information provided in the table below reflects data since changes were made to the 340B Compliance Program, which were effective as of April 1, 2016.

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Financial summary for 10/1/16 to 12/31/16

Entity	340B Paid Match Claim Count	340B Reversal Claim Count	Walgreens 340B Paid Match Claim Count	340BX Compliance Fee	PHC 340B Compliance Fee	Total 340B Compliance Fees
Alliance Medical Center	88	0	0	\$220.00	\$22.00	\$242.00
CommuniCare Health Centers	504	1	45	\$1,372.50	\$137.25	\$1,509.75
Hill Country Community Clinic	349	2	0	\$872.50	\$87.25	\$959.75
La Clinica De La Raza	0	0	114	\$285.00	\$28.50	\$313.50
Marin Community Clinic Inc.	622	0	0	\$1,555.00	\$155.50	\$1,710.50
Mendocino Coast Clinics, Inc.	680	4	0	\$1,700.00	\$170.00	\$1,870.00
Mendocino Community Health Clinics, Inc.	1,044	2	0	\$2,610.00	\$261.00	\$2,871.00
Mountain Valleys Health Centers, Inc.	543	1	0	\$1,357.50	\$135.75	\$1,493.25
Northeastern Rural Health Clinics, Inc.	631	9	0	\$1,577.50	\$157.75	\$1,735.25
Open Door Community Health Centers	4,616	16	0	\$11,540.00	\$1,154.00	\$12,694.00
Petaluma Health Center	1,949	0	0	\$4,872.50	\$487.25	\$5,359.75
Santa Rosa Community Health Centers	1,456	0	0	\$3,640.00	\$364.00	\$4,004.00
Shasta Community Health Centers	4,594	12	136	\$11,825.00	\$1,182.50	\$13,007.50
Shingletown Medical Center	105	0	0	\$262.50	\$26.25	\$288.75
Sonoma Valley Community Health Center	258	0	0	\$645.00	\$64.50	\$709.50
QUARTER TOTALS:	17,439	47	295	\$44,335.00	\$4,433.50	\$48,768.50

Governor Brown's 2017-2018 Budget Proposal:

On January 10, 2017, the 2017-2018 Governor's Budget proposal was released. The proposal included clarifying language that explicitly applies the requirement of 340B entities providing 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 to both Medi-Cal FFS and Medi-Cal managed care. With May 2017 Revisions to the Governor's Budget, removed this language/proposal.

The May 2017 Revisions to the Governor's Budget introduced an additional proposal regarding the 340B Program. The May Revision proposed statutory changes to end the use of contract pharmacies in the 340B program in Medi-Cal due to concerns raised by federal agencies. It was noted the change would avoid inappropriate duplicate discounts by claiming federal drug rebates on already discounted drugs and prevent unnecessary overpayment in Medi-Cal. On May 18, 2017, the Senate Budget and Fiscal Review Subcommittee unanimously rejected this proposed change which would have ended the use of Contract Pharmacies in the Medi-Cal 340B Program.

340B Compliance Program Introduction Letter:

PHC's 340B Team has drafted an updated introduction letter for its 340B Compliance Program. This decision was based on the major changes made to the 340B Compliance Program in 2016, as well as changes in leadership at several 340B Covered Entities.

The 340B Compliance Program Introduction Letter will be distributed to all of the 340B Covered Entities in the 14 county service area that are not currently participating in PHC's 340B

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Compliance Program. The letter will serve as a reminder that 340B Covered Entities are responsible for ensuring duplicate discounts do not occur, but that PHC has an established 340B Compliance Program that can assist 340B Covered Entities with proper flagging of 340B drug claims. (A copy of the 340B Compliance Program Introduction Letter is enclosed.)

Mega-Guidance:

As reported at the 340B Advisory Committee Meeting held on March 1, 2017, the 340B Program Omnibus Guidance (“Mega-Guidance”) was withdrawn by the Department of Health and Human Services’ Health and Human Services Resources and Services Administration (HRSA) on January 30, 2017.

As of June 29, 2017, there have been no updates regarding the status of the Mega-Guidance or additional guidance being issued by HRSA.

340B Coalition Conferences:

Ms. Cuellar and Ms. Cook will not be attending the 340B Coalition Summer Conference 2017 being held in Washington, D.C., from July 10, 2017 through July 12, 2017.

The 340B Coalition Winter Conference 2018 will be held in San Diego, CA from February 21, 2018 through February 23, 2018.

NEXT 340B ADVISORY COMMITTEE MEETING:

The next 340B Advisory Committee Meeting is scheduled for Wednesday, September 13, 2017, from 10:00 AM to 11:30 AM.

QUESTIONS/COMMENTS:

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

SENT VIA EMAIL ONLY

<Date>

RE: An Introduction to PHC's 340B Compliance Program

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

Partnership HealthPlan of California (PHC) has identified an entity or entities associated with your organization as eligible to participate in the 340B Program with the Health Resources and Services Administration (HRSA). PHC is aware that some 340B Covered Entities have been submitting claims to PHC for 340B eligible drugs, but without an agreement with PHC or appropriate identification of 340B drugs with those claims. Many of these sites did not know that this was occurring.

We are writing this letter to inform you that PHC has a 340B Compliance Program, which was established in 2014. This 340B Compliance Program will benefit 340B Covered Entities and PHC members. This program provides a mechanism for all 340B Covered Entities to include PHC members in their 340B Program in a way that is compliant with state and federal requirements.

As your organization has not entered into a 340B Compliance Program Agreement with PHC, you should not be submitting claims to PHC for 340B drugs, as such claims may not be compliant with 340B Program flagging requirements.

What is 340B?

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

What does 340B require?

At its core, federal law around 340B requires that 340B drugs not be subject to duplicate discounts. That means if a drug is purchased at the 340B price, a state Medicaid agency cannot claim a rebate on that same medication (42 USC 256b(a)(5)(A)(i)). 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. In states where Managed Care

Organizations (MCOs) are used, the MCO is an agent of the State, meaning the MCO is responsible for ensuring compliance with this requirement under Section 340B of the Public Health Services Act.

An MCO, like PHC, must have a carefully structured process in place to ensure the participating 340B Covered Entities have properly identified 340B drugs in compliance with adopted DHCS policies when dispensed to PHC beneficiaries. Our 340B Compliance Program received additional validation when the Department of Health and Human Services (HHS) and CMS published a “final rule” in the Federal Register modernizing the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems on May 6, 2016. Per 42 CFR § 438.3(s), MCOs are required to establish “procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program.” 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.

How will PHC help?

PHC has developed a 340B Compliance Program which helps bring the PHC and its 340B Covered Entity partners who submit claims to PHC for 340B drugs into compliance with the requirements of the 340B Program, including compliant claiming of all 340B drug billing to PHC.

If you have questions about our 340B Compliance Program, please contact the Pharmacy Services Program Manager at the e-mail address below to learn more about our plan, including the steps in our reclassification process which help ensure compliance with the requirements of the 340B Program.

What are the next steps?

In order to help PHC plan for future on-boarding to the 340B Compliance Program, we would appreciate your response to a few questions.

1. **Is your organization currently carving-out all Managed Care Medicaid claims from your 340B Program?**
 - a. **If no, please provide clarification as to your current process/policy.**
 - i. **Please note that any 340B drug claims for PHC members you have submitted may not have been flagged appropriately as 340B, and therefore may be out of compliance. PHC is unable to assist with correction of those previously submitted 340B drug claims.**
2. **Would your organization be interested in participating in PHC’s 340B Compliance Program so that you can carve-in claims for PHC members for 340B eligible drugs in the future?**
3. **Does your organization use a 340B Administrator?**
 - a. **If yes, please provide the name of the organization, as well as information for your contact there including name, phone number, and e-mail address.**

Please send the answers to the questions listed above to the Pharmacy Services Program Manager at: 340BQIP@partnershiphp.org



Here is a list of all 340B Covered Entities that we have identified as eligible to participate in the 340B Program.

HRSA registered 340B Covered Entities affiliated with <340B Covered Entity Name>

340B ID	CE ID	Entity Name	Entity Sub Division Name

We believe our 340B Covered Entity partners have been participating according to the spirit of the 340B Program, but may not have been aware of the requirements of working with 340B in a Medi-Cal Managed Care county. With your help, your 340B Covered Entity(ies), PHC, and DHCS can all ensure that we are all able to comply with the letter of the law.

Thank you,

Dina Cuellar
Director of Regulatory Affairs
Partnership HealthPlan of California

on behalf of

Robert Moore, MD, MPH, MBA, Chief Medical Officer
Stan Leung, PharmD, Director Pharmacy Services