Partnership HealthPlan of California (PHC)

340B Compliance Program White Paper

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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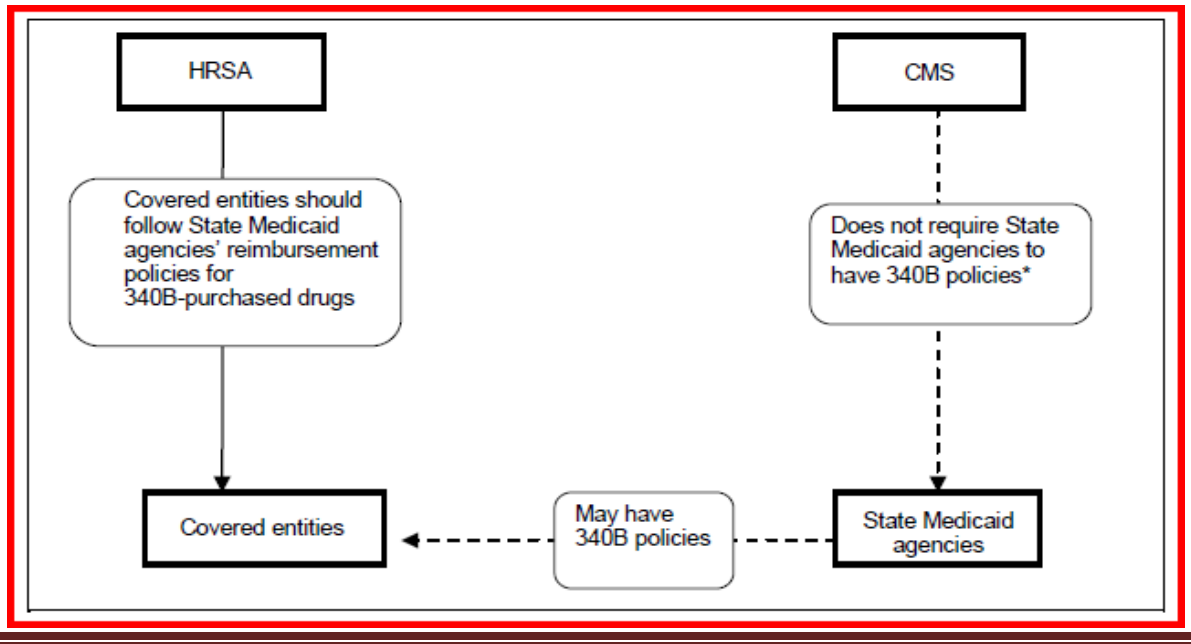
State Policy: State Medicaid agencies may set specific policies for Covered Entities that dispense 340B-purchased drugs to Medicaid patients (340B policies), though CMS does not require them to do so. If a State Medicaid agency's 340B policy requires Covered Entities to bill and be reimbursed for 340B-purchased 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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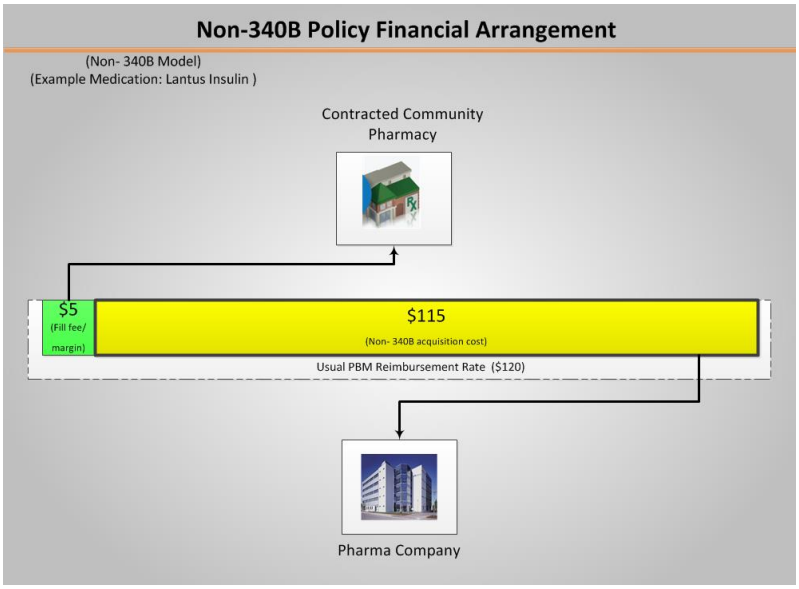
To make the difference between usual prescribing and 340B prescribing more understandable, please refer to the following graphics, which look at an example of a long acting, brand name insulin: Lantus Insulin, which sells for about $120 retail for a 10 ml vial.

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 format, UB-04 format, or electronic 837 format, not through the Pharmacy Benefits Manager (PBM).

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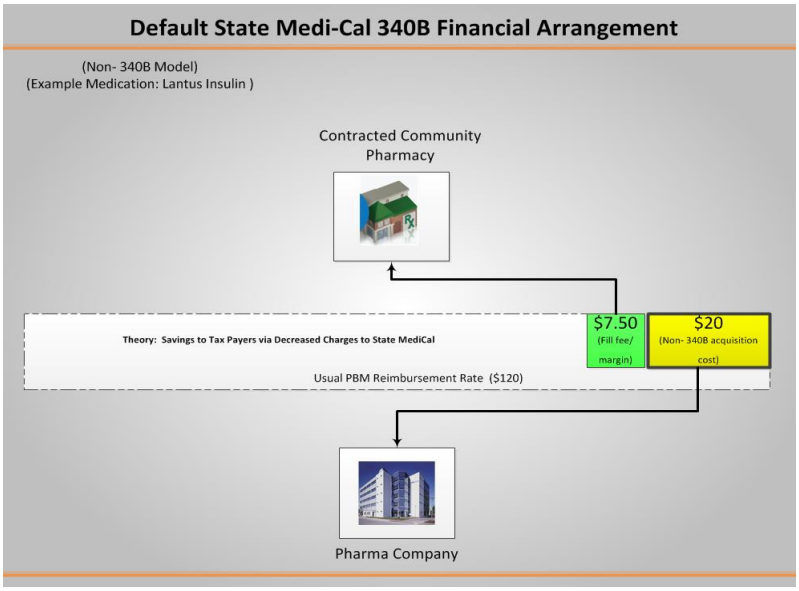
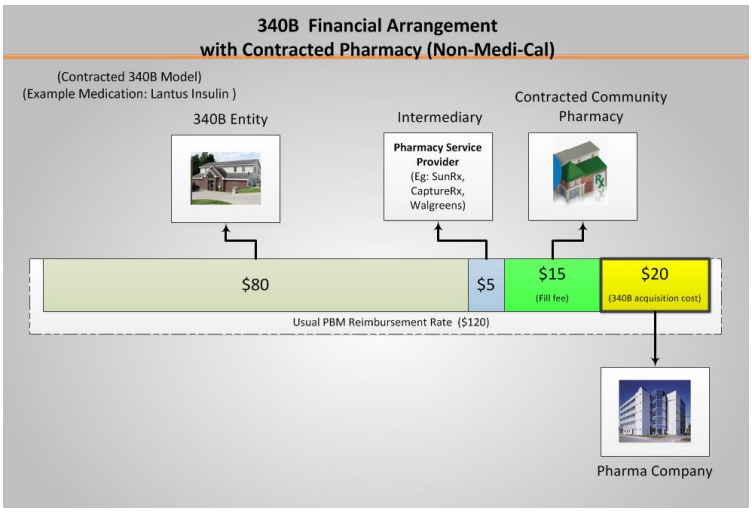


For comparison, this graphic shows the money flow for a 340B Contract Pharmacy arrangement for Non-Medi-Cal:



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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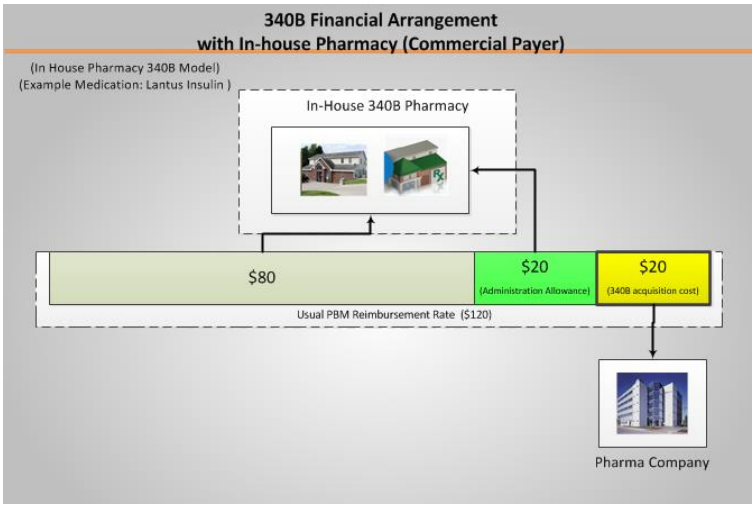

Provisions in the Affordable Care Act (ACA): The ACA requires "the development of more detailed guidance describing methodologies and options available to Covered Entities for billing covered drugs to State Medicaid agencies in a manner that avoids duplicate discounts." The proposed regulations for this 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: In the August 2009, Medi-Cal Update for Pharmacy (Medi-Cal Pharmacy Bulletin 710, August, 2009), California DHCS provided a list of questions and answers regarding the 340B Program. The answers were somewhat ambiguous (see below for details).

(As PHC was gathering information in 2013, it was noted the information had not been updated since a US district court injunction of a 2009 law **requiring** 340B In-House Pharmacies to use 340B drugs for all Medi-Cal patients.)

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

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.

It should be noted 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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On November 8, 2016, the United States Court of Appeals, Ninth Circuit, handed down a decision in the case of AIDS Healthcare Foundation v. Toby Douglas. The permanent injunction was vacated.

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.

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.

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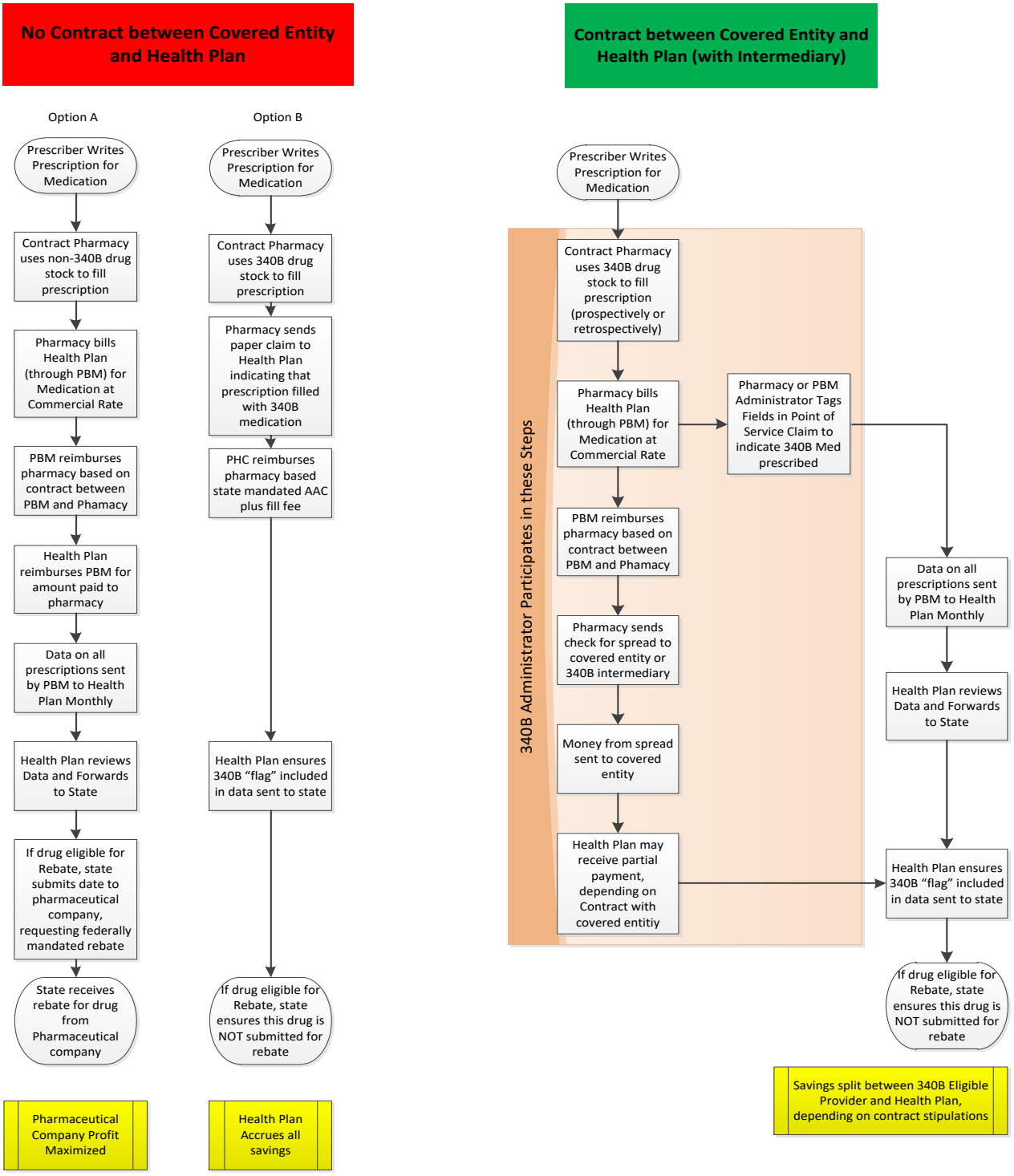
The following diagram illustrates how the 340B flag moves from the 340B Covered Entity to the State, how the general flow of money occurs in the different scenarios, and how it relates to the State Medicaid rebate:



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 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.

In April 2019, additional changes were made to the 340B Compliance Program Agreement regarding requests for reclassification by PHC of 340B drugs on claim service lines requiring the addition of the UD modifier, as well as elimination of any mention of the Primary Care Provider (PCP) Quality Improvement Program (QIP). With those changes, PHC updated its 340B Compliance Program Policy.

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In October 2019, PHC made additional changes to the 340B Compliance Program Policy based on input from DHCS following its review of the updated 340B Compliance Program Agreement. Changes to the policy included clarification regarding all 340B Covered Entities being accountable for preventing duplicate discounts, 340B Covered Entities' responsibility to report changes to their 340B Programs to HRSA, oversight of Contract Pharmacies by the 340B Covered Entities, and handling drug manufacturer inquiries by PHC and 340B Covered Entities.