

340B CONTRACT PHARMACY GUIDE FOR 318 GRANTEES AND SUBGRANTEES



**National Coalition
of STD Directors**

Note: This information is provided by NCSDD for general information purposes and does not constitute legal advice. The 340B Contract Pharmacy Guide is designed for 318 grantees and subgrantees, including but not limited to those receiving a grant or contract funded under the PCHD NOFO (19-1901) and the Ending the HIV Epidemic (EHE) NOFO (20-2010).

Table of Contents

Introduction	3
The 340B Drug Pricing Program.....	5
Eligible Entities.....	6
Patient Eligibility and the Prevention of Drug Diversion.....	7
Intersection with Medicaid and Prevention of Duplicate Discounts.....	8
Pharmaceutical Dispensing Models.....	10
In-House Dispensing.....	10
Grantee Combined Purchasing and Distribution.....	11
Contract Pharmacy.....	13
Contract Pharmacy Overview.....	14
What is a Contract Pharmacy?.....	14
Pros and Cons of Using a Contract Pharmacy.....	15
The Players.....	16
How Does a Contract Pharmacy Arrangement Work?.....	17
Regulation of Contract Pharmacies.....	19
Elements of Contract Pharmacy Services Agreements.....	20
Registration and Recertification.....	23
Prevention of Drug Diversion.....	24
Medicaid.....	24
Audit Requirements.....	25
Policies and Procedures.....	26
Inventory Management.....	27
Next Steps for Considering Contract Pharmacy Arrangements.....	28



Introduction

The 340B Drug Pricing Program (340B Program) is a federal program that requires **pharmaceutical manufacturers** to provide outpatient drugs at a discount to certain safety net providers, referred to as “covered entities.” The purpose of the 340B Program, as stated in congressional history, is to help eligible providers “stretch scarce Federal resources as far as possible reaching more eligible patients and providing more comprehensive services.”¹ Entities eligible for 340B discounted pricing are set forth in statute and generally include certain federally funded grantees and safety net hospitals among others.

PHARMACEUTICAL MANUFACTURER

A manufacturer that engages in the production, processing, packing, labeling, and distribution of prescription drugs and sells outpatient drugs to 340B covered entities.

While the 340B Program contemplates many different types of dispensing arrangements for covered entities, retail pharmacies became eligible to serve as contract pharmacies in 1996 to help covered entities expand the reach of their 340B pharmacy dispensing services. The Health Resources and Services Administration’s Office of Pharmacy Affairs (herein, referred to as HRSA), further expanded the ability of covered entities to utilize retail pharmacies by allowing multiple contract pharmacy arrangements in 2010. The proliferation of contract pharmacy arrangements since release of the guidance has allowed covered entities to offer their eligible patients a greater number of locations to receive their medications and offer expanded health care services to more patients in need, but it has also brought on additional scrutiny by government regulators and the pharmaceutical industry and calls for increased oversight.



Introduction

This Guide is designed to assist **318 grantees and subgrantees** navigate the complex contract pharmacy landscape. It will help covered entities assess the benefits and drawbacks of working with a contract pharmacy or multiple pharmacies to expand their pharmacy fulfillment services. The information is intended to provide general guidance for 318 grantees and subgrantees that wish to enter into contract pharmacy arrangements to enhance 340B dispensing and is not intended nor should it be construed as legal advice. Covered entities should consult with legal counsel before entering into contract pharmacy arrangements. The Guide is not intended to be comprehensive and will be maintained and updated as needed to reflect changes in regulations or policies.

318 GRANTEES AND SUBGRANTEES

An entity or program that receives a grant, in the form of direct funding or an in-kind contribution, that is authorized and funded under Section 318 of the Public Health Service Act to prevent and treat sexually transmitted diseases. Section 318 funds the PCHD (NOFO 19-1901) and EHE (NOFO 20-2010) programs.





The 340B Drug Pricing Program

As a part of Medicaid reform, Congress enacted the Medicaid Drug Rebate Program (MDRP) in 1990 to ensure Medicaid receives the lowest price on a drug that a pharmaceutical manufacturer offers any other purchaser.² It requires manufacturers to pay rebates to states for drugs based on the drug's average manufacturer price (AMP) and best price, or the lowest price for a drug made available in the private sector, as a condition of having their products covered by Medicaid (at the time of enactment, the rebate requirement only applied to Medicaid fee-for-service programs, as managed care was a fairly new concept in the insurance marketplace). An unintended consequence of the MDRP was that pharmaceutical manufacturers now had a disincentive to continue offering deep discounts on drugs to other public sector and non-profit safety net providers (as many had before enactment of the MDRP) since it could lower their AMP and best price, thereby resulting in having to pay higher rebates to Medicaid. As a result, drug prices began to rise substantially for safety net providers.

In response, Congress created the **340B Drug Pricing Program**, as an amendment to the Veterans Health Care Act of 1992,³ requiring manufacturers that participate in Medicaid to offer discounted drugs to certain safety net providers set forth in statute. The 340B discount, referred to as the 340B ceiling price, is the maximum amount a drug manufacturer can charge a 340B provider enrolled in the Program, and is a statutory formula based on the same components as the Medicaid drug rebate formula (AMP from the preceding quarter for the smallest unit of drug minus the Unit Rebate Amount). A manufacturer may offer pricing that is lower than the 340B ceiling price and many do.

340B DRUG PRICING PROGRAM

A federal program that requires pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program to provide outpatient drugs to 340B covered entities at or below the 340B ceiling price. The purpose of the 340B Program is to enable covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.



The 340B Drug Pricing Program

The purpose of the 340B Program (as stated in congressional history and endorsed by HRSA) is to reduce the cost of drugs for these providers and generate additional resources that can be used to help them expand more comprehensive care to more eligible patients.⁴ Estimates in savings on drug costs are significant and generally range from 20-50 percent. These savings allow safety net providers to devote resources that otherwise would have been spent on paying for prescription drugs to offer more services to low-income, uninsured, and medically vulnerable patients in their community. In addition, an important component of the 340B Program is that a patient's insurance or financial status is not relevant in terms of eligibility. The intent behind that is to allow 340B providers to bill a patient's insurance and utilize the revenue generated from the reimbursement (assuming a provider can bill and be reimbursed at more than what it cost to purchase the 340B drug) to further the mission and expand the provider's reach to more eligible patients.⁵

Eligible Entities

The 340B Program is targeted at supporting public and nonprofit health care organizations that have certain federal designations or receive funding from specific federal programs. The entities eligible for 340B pricing, referred to as “**covered entities**”, are set forth in the 340B statute and include federally funded grantees, such as Section 318 grantees and subgrantees, Title X family planning projects, federally qualified health centers and look-alikes, and certain hospital types (disproportionate share, children's, critical access hospitals etc.). The full list of eligible entities may be found [here](#).

COVERED ENTITY

A facility or program that is listed in the 340B statute as eligible to purchase drugs through the 340B Program.

To participate in the 340B Program, covered entities must register during a quarterly registration period with the 340B [Office of Pharmacy Affairs Information System \(OPAIS\)](#) by completing and submitting enrollment information. Once HRSA verifies eligibility, covered entities can begin purchasing 340B discounted products at the start of the next quarter. Covered entities are required to comply (and annually certify compliance) with all 340B requirements, including those intended to ensure that only eligible patients receive 340B drugs and that Medicaid rebates for 340B drugs are prevented.



The 340B Drug Pricing Program

340B OPAIS

The database operated by the Office of Pharmacy Affairs that includes information on eligible covered entities, contract pharmacy arrangements, and participating drug manufacturers. It also includes 340B pricing information.

Patient Eligibility and the Prevention of Drug Diversion

The 340B statute prohibits the resale or transfer of 340B outpatient drugs to individuals who are not considered “patients” of a covered entity, referred to as **drug diversion**.⁶ In other words, only a “patient” as defined by HRSA guidance can receive 340B drugs. An individual is considered a patient of the covered entity if:

1. The covered entity has an established relationship with the individual, such that the covered entity maintains records of the individual’s health care;
2. The individual receives health care services from a professional who is either employed by or works under contract with the covered entity; and,
3. The individual receives a service or range of services consistent with the grant funding that made the covered entity eligible for 340B drugs.

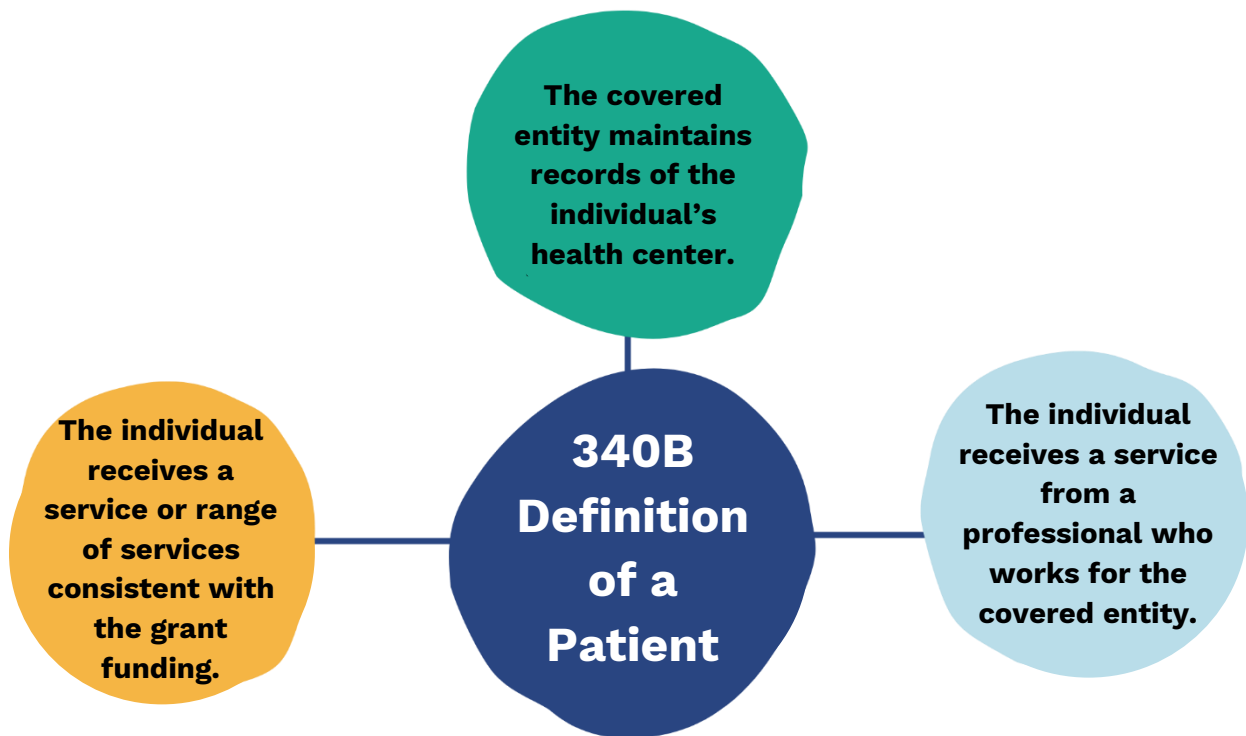
Diversion can occur if a 340B drug is dispensed to an individual who does not meet the 340B definition of a patient above, or is sold, transferred, or dispensed to patients of ineligible entities or to an ineligible facility or program within the same entity that is 340B eligible.

DRUG DIVERSION

The sale or transfer of a 340B purchased drug to an individual who does not meet the 340B definition of a patient. This can also occur if drugs are sold or transferred to an entity that is not eligible for 340B pricing.



The 340B Drug Pricing Program



Intersection with Medicaid and Prevention of Duplicate Discounts

The 340B statute protects pharmaceutical manufacturers from giving a 340B discount upfront to a covered entity and paying a rebate to Medicaid on the same drug,⁷ which is called a **duplicate (or double) discount**. If a manufacturer wants its products covered by Medicaid, it must agree to participate in both the Medicaid Drug Rebate Program and the 340B Program; however, it is only required to provide a single discount on a drug dispensed to a Medicaid patient. When registering in OPAIS, a covered entity must indicate whether it intends to use 340B drugs with Medicaid fee-for-service (FFS) patients (called “carving-in”) and enter all Medicaid and National Provider Identifier (NPI) numbers with which it intends to bill Medicaid for 340B drugs in HRSA’s [Medicaid Exclusion File](#) (MEF). States and manufacturers refer to the MEF to identify claims with 340B drugs that should be excluded from rebate requests to manufacturers. The MEF is only supposed to represent a covered entity’s use of 340B with Medicaid FFS patients, however, some states incorrectly refer to it to exclude drugs dispensed to Medicaid managed care beneficiaries from its rebate requests.



The 340B Drug Pricing Program

DUPLICATE DISCOUNT

A prohibited duplicate discount occurs when a covered entity purchases a drug at a 340B price and a Medicaid agency collects a rebate on the same unit of drug.

At the 340B Program's inception, the protection against double discounts only applied to FFS Medicaid, as managed care was just emerging and states were not entitled to rebates on drugs dispensed to patients covered under its managed care plans. That changed with passage of the Affordable Care Act (ACA) in 2010, which required states to collect rebates for drugs dispensed to Medicaid managed care patients with the exception of drugs purchased under the 340B Program. Although there is no national or standardized system like the MEF to identify claims with 340B drugs for exclusion from a state's Medicaid managed care rebate requests, the Centers for Medicare and Medicaid Services (CMS) issued an [Informational Bulletin](#) with best practices a state can use to avoid billing manufacturers for Medicaid rebates for drugs purchased under the 340B Program. Some states have successfully navigated this (e.g., requiring the use of modifier codes), while others have not (e.g., having no policy in place, incorrectly relying on the MEF to identify MCO claims with 340B drugs, or not allowing covered entities to use 340B drugs with Medicaid MCO patients). Covered entities should work with their state and its MCOs and pharmacy benefit managers (PBMs) to ensure the state is on notice when a 340B drug is dispensed to a patient enrolled in a state's Medicaid MCO plan.

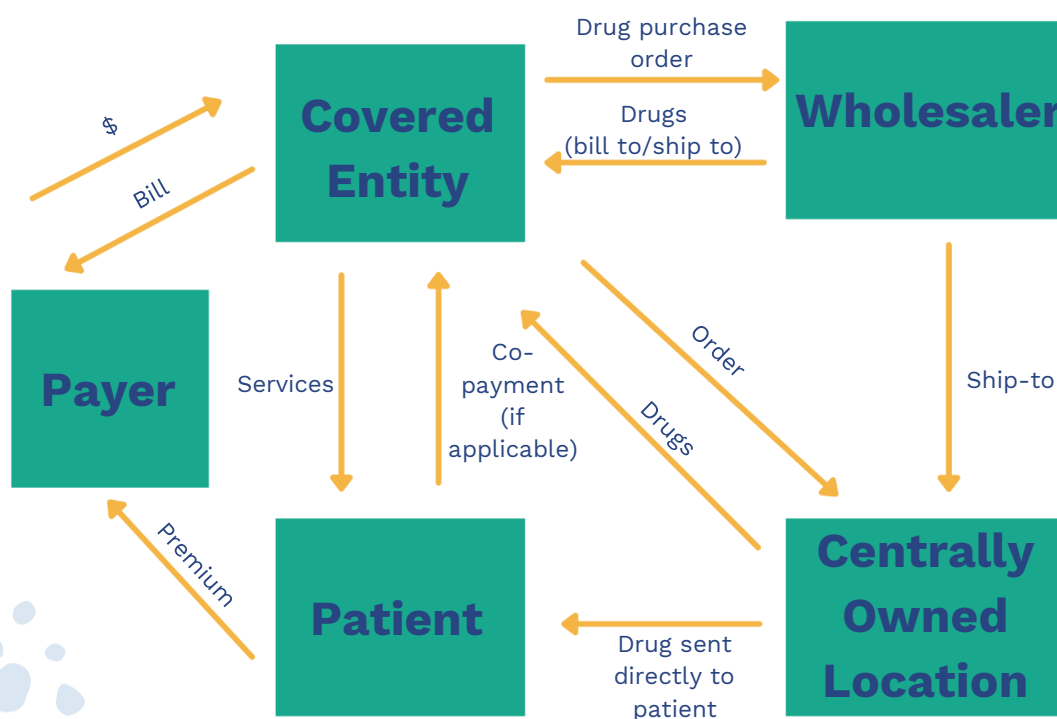




Pharmaceutical Dispensing Models

There are several types of pharmaceutical dispensing models, each with its own advantages and disadvantages, depending on the covered entity's operational structure and state pharmacy regulations. Covered entities can dispense drugs through more than one type of dispensing model. For example, a covered entity can offer both in-house dispensing (if authorized by state law) and pharmacy services through its contracted pharmacy arrangements. Regardless of how a covered entity chooses to offer pharmacy dispensing services, it remains responsible for preventing drug diversion and duplicate discounts, and ensuring compliance with all other 340B requirements. In other words, the responsibility for 340B compliance remains with the covered entity even if it delegates dispensing to another entity that is owned by or in a contractual relationship with the covered entity. The most common pharmacy dispensing models include:

1. **In-house dispensing or dispensing through a centrally owned location:** In this scenario, the covered entity purchases and stocks the medication at the health care delivery site or has it shipped to a central location that is owned and operated by the covered entity. The health care provider will generate the prescription and either dispense or administer it directly to the patient during the visit or have it dispensed by the central location to the patient, usually by mail. The covered entity purchasing the 340B medications would need to be registered in OPAIS. When registering in OPAIS, each covered entity is assigned a unique identifier, called a 340B ID, that includes a reference to the type of entity it is followed by a series of numbers. For example, the 340B ID for a 318 grantee or subgrantee would look like "STDXXXX". If a central location is used to store and/or dispense medications, it should be listed in OPAIS as the covered entity's shipping address (rather than as a unique covered entity).





Pharmaceutical Dispensing Models

2. **Grantee Combined Purchasing and Distribution:** Each entity (or grant program within an entity) with a unique 340B ID is considered a separate covered entity for purposes of the 340B Program. Manufacturers, wholesalers, distributors and others rely on the 340B IDs to confirm the eligibility and the appropriate shipment of 340B drugs. The sharing of 340B inventory across or between 340B IDs is not allowed unless approved by HRSA. There are situations in which a grantee (which does not have an associated site or a parent/child relationship in OPAIS) may wish to purchase medications and distribute it to its subgrantees. This is common with 318 PCHD (NOFO 19-1901) grantees, where a state health department purchases medications and then distributes the medications to its subgrantees (e.g., local health clinics and contracted providers). Although the state, through its receipt of a 318 grant, is a covered entity once registered with OPAIS, each subrecipient receiving medications from the state is also eligible for 340B and may register to get its own 340B ID. This will allow the subrecipient to purchase drugs other than those that the state has provided to expand its formulary and offer more medication options for its patients. HRSA will allow a combined purchasing and distribution model on a case-by-case basis. The 340B Prime Vendor has developed a [Grantee Combined Purchasing and Distribution Request](#), which can assist covered entities with submitting a proposal to HRSA for review and approval.

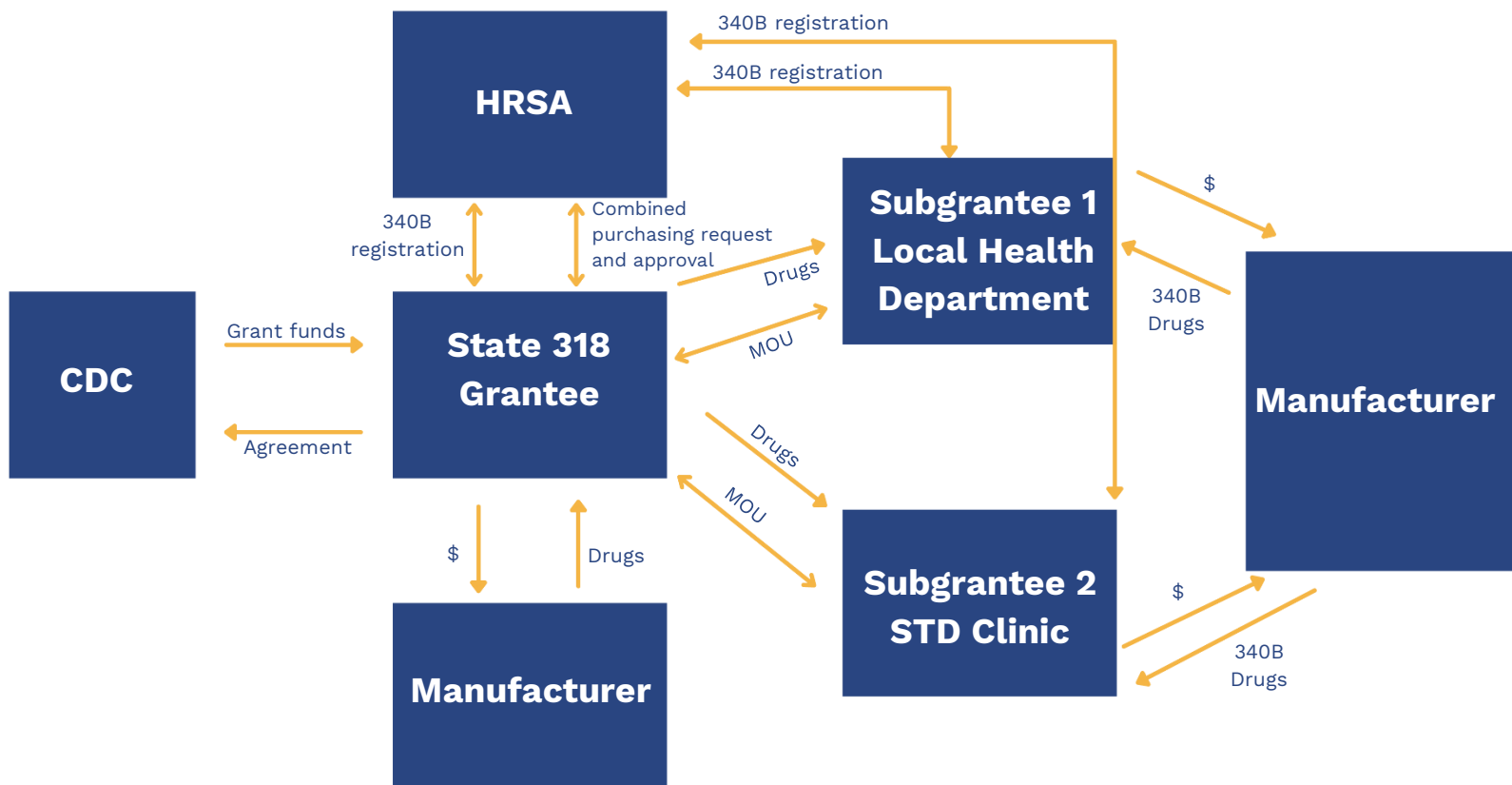
TIP: If you receive a 318 in-kind contribution in the form of medications from your state but are not yet registered in OPAIS with your own 340B ID, you should consider doing so, as it will allow you to purchase other drugs at a 340B discounted price.



Pharmaceutical Dispensing Models

TIP: A combined purchasing and distribution request has a better chance of being approved if:

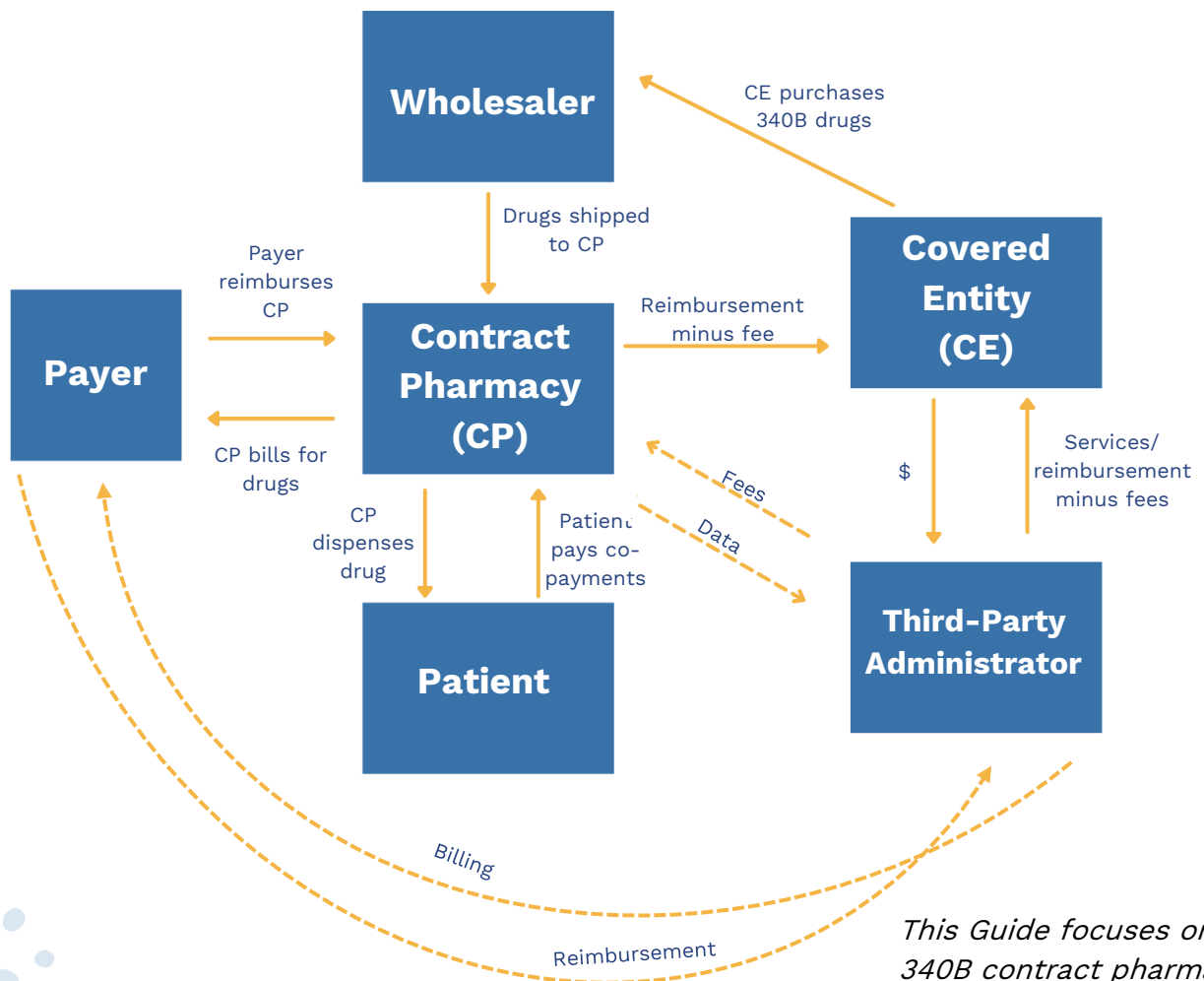
- The entities share the same 340B entity type and grant number (for example, a state STD program that purchases on a single account and distributes to the local health departments or STD clinic throughout the state);
- The proposal addresses how 340B Program compliance elements will be met, including the maintenance of auditable records; and
- The entity (340B ID) which is responsible for the combined purchasing accepts responsibility for all 340B Program compliance for drugs purchased through the model and ensures that any receiving entities are also in compliance.





Pharmaceutical Dispensing Models

3. **Contract Pharmacy (Third-Party Vendor):** Another model involves a covered entity contracting with a third-party pharmacy vendor to dispense prescriptions written by the clinician. A covered entity may contract with a pharmacy vendor in the same state or in a different state (which may require additional licensing and state regulatory requirements). Under this arrangement, the covered entity would purchase prescription drugs through the manufacturer, group purchasing organization (GPO), or the distributor, which will send the drugs directly to the contracted pharmacy. The clinician employed by (or under contract with) the covered entity prescribes a drug and the pharmacy fills and dispenses or mails the drug to the patient. In some cases, the pharmacy will handle billing insurance or collecting copayments, if applicable, from the patient; in other cases, the covered entity retains this responsibility. There are often more parties involved with this type of arrangement, such as a third-party administrator (TPA), which may be engaged to help a covered entity build their pharmacy networks and manage their contract pharmacy programs. A pharmacy under contract to *dispense* 340B drugs on behalf of a covered entity must be registered in OPAIS regardless of whether it also bills and collects payments as a part of its contracted services



This Guide focuses on the 340B contract pharmacy arrangement.



Contract Pharmacy Overview

What is a Contract Pharmacy?

A 340B **contract pharmacy** is a contractual arrangement between a 340B covered entity and a pharmacy (or multiple pharmacies) to dispense pharmaceutical supplies to the covered entity's 340B eligible patients. Contract pharmacy arrangements may facilitate 340B participation for covered entities that are subject to restrictive state pharmacy dispensing laws, do not have in-house pharmacy capacity, or for those that want to supplement their in-house pharmacy services.

CONTRACT PHARMACY

A 340B covered entity may contract with a pharmacy or pharmacies to provide pharmacy dispensing services to the covered entity's patients.

In 1996, HRSA issued guidance allowing covered entities to enter into a single contract pharmacy arrangement in response to complaints by many covered entities that wanted to participate in the 340B Program but could not because they did not have an in-house pharmacy (e.g., due to the lack of resources, state law restrictions, or for other reasons). HRSA took the position that a covered entity had a right to contract with a retail pharmacy to act as its agent to dispense 340B drugs.⁸ HRSA expanded covered entities' ability to create networks of contracted pharmacies for their 340B programs by issuing guidance in 2010 authorizing the use of multiple contract pharmacies.⁹ Covered entities may establish agreements with different pharmacies or through a single contract with a chain pharmacy that has multiple locations or both.

Covered Entity and Contract Pharmacy Dispensing Options

In-clinic dispensing only

Use of single contract pharmacy without in-clinic dispensing

Use of single contract pharmacy supplementing in-clinic dispensing

Use of multiple contract pharmacies (without in-clinic dispensing)

Use of multiple contract pharmacy supplementing in-clinic dispensing



Contract Pharmacy Overview

Pros and Cons of Using a Contract Pharmacy

Covered entities should consider the following pros and cons when deciding whether to use a contract pharmacy dispensing model. This list is not exhaustive.

Pros	Cons
Allows for 340B participation if a covered entity does not have an in-house pharmacy	Increases 340B compliance requirements and complexity
Supplements in-house pharmacy services	May result in higher costs (e.g., fees) to dispense drugs to patients relative to an in-house dispensing model
Increases patient access to 340B drugs at pharmacy locations that may be more convenient	May decrease 340B savings for a covered entity (some of the savings is used to cover dispensing and other administrative fees)
Expand the reach of the covered entity's pharmacy dispensing services	Patients may experience higher costs for drugs picked up a pharmacy
Can increase the volume of drugs dispensed and revenue, which can be used to expand services to more patients	Adds complexity to a covered entity's 340B program, increasing the chance for targeted HRSA audits

It is essential that a covered entity assess the contract pharmacy arrangement from both a financial and operational perspective to ensure that the use of such an arrangement supports the covered entity in meeting its mission and expanding patient access to pharmaceuticals and health care services.





Contract Pharmacy Overview

The Players

While contract pharmacy arrangements vary considerably, there are generally four types of players (or functions) involved in a typical arrangement:

1. **Covered entities** hold the relationship with the eligible patient and generate the prescription through a health care service. The covered entity remains responsible for ensuring that every participant involved in the contract pharmacy arrangement complies with all 340B requirements.
2. **Contract pharmacies** dispense prescriptions to eligible patients on behalf of covered entities. In some cases, the contract pharmacy will bill a patient's insurance and collect co-payments, if applicable, whereas in other cases the covered entity retains this function.
3. **Manufacturers/wholesalers (also called distributors)** process, ship, and bill for 340B inventory orders placed by a covered entity or a contract pharmacy on the covered entity's behalf.
4. **Third-Party Administrators (TPAs)** are contracted vendors that help covered entities with the administration of their 340B contract pharmacy arrangements. TPAs are often used to track inventory usage using specialized tracking software to prevent diversion and duplicate discounts.

THE ROLE OF 340B THIRD PARTY ADMINISTRATORS

A TPA (sometimes referred to as a 340B Pharmacy Benefit Manager) typically performs the following functions for covered entities:

- Identify and select pharmacies to participate in the arrangement
- Determine which drug claims are 340B eligible
- Track inventory used by contract pharmacies and replenish with 340B inventory
- Manage the billing and collection of payments and splitting the fees and revenue between the parties
- Retain auditable records to ensure 340B compliance



Contract Pharmacy Overview

How Does a Contract Pharmacy Arrangement Work?

The covered entity and contract pharmacy (or pharmacies) execute a contract setting forth the services the pharmacy will perform, the negotiated fees (this may also include fees related to the functions of a TPA), and all 340B compliance requirements. The contract pharmacy must be licensed by the appropriate state Board of Pharmacy to dispense medications and qualified to fulfill the pharmacy services requested of it on behalf of the covered entity. HRSA does not have a template contract, but specifies elements that must be addressed in the contract (see below).

The covered entity typically will pay a dispensing fee to the contract pharmacy for each prescription dispensed, as well as any other agreed upon fees to execute the agreement. Covered entities should carefully review the fee structure to make sure that it is not transferring too much of the 340B benefit in fees to the contract pharmacy, which has been the subject of increased scrutiny by members of Congress and manufacturers.






In most cases, the covered entity will purchase the drugs and have them shipped to the contract pharmacy (called a ship-to/bill-to arrangement); however, sometimes the pharmacy will purchase the 340B inventory directly from the manufacturer or **wholesaler** and have it billed to the covered entity's account. Although contract pharmacy arrangements vary, the following example illustrates how a covered entity, contract pharmacy and TPA may work together to dispense 340B drugs. Not all covered entities use a TPA; some have their own staff or software to manage the inventory and fees.

WHOLESALER

A drug wholesaler (also called a distributor) is an organization that provides drugs to entities, acting as the distributor between the drug manufacturer and the entity.



Contract Pharmacy Overview

-  **Step 1:** A 340B eligible patient fills a prescription at a contract pharmacy and pays any applicable copayments with fees.
-  **Step 2:** If the patient has health insurance, the contract pharmacy will submit the claim to the health insurance company. The insurer will reimburse the pharmacy. (Note: In some cases, the covered entity retains the billing function and pays a dispensing fee to the pharmacy or the TPA will bill the insurance company and remit applicable fees and payments to the pharmacy and covered entity.)
-  **Step 3:** The contract pharmacy submits prescription transactions (e.g., patient and prescription information) to the TPA (or to the covered entity if it is reconciling patient eligibility and prescriptions).
-  **Step 4:** The TPA (or covered entity) reviews the pharmacy prescription transactions to determine which are eligible for 340B.
-  **Step 5:** For 340B eligible prescriptions, the contract pharmacy deducts the negotiated fee with the covered entity from the reimbursed amount (including payments collected from the health insurer and patient) and submits the remainder to the TPA (or to the covered entity).
-  **Step 6:** The TPA deducts the fee previously negotiated with the covered entity and submits the balance of the payment to the covered entity.¹⁰
-  **Step 7:** When a full package size quantity is used (based on a drug's 11-digit National Drug Code or NDC), the TPA or covered entity will send a report to re-order or replenish the 340B eligible drugs dispensed by the contract pharmacy (more information on inventory management processes below).



Regulation of Contract Pharmacy Arrangements

Elements of Contract Pharmacy Services Agreements

When entering into a contract pharmacy arrangement, the covered entity is required to execute a contract with the pharmacy or pharmacies to provide pharmacy dispensing services. Typically, the pharmacy will provide an agreement as a starting point. However, it is essential that a covered entity work with legal counsel to ensure its interests, including acceptable fees, are taken into account. The contract should address the following (nonexhaustive list of) issues:

1. The procedures that each party will follow with respect to handling funds, including third party reimbursement and co-payments and the amount and distribution of fees and revenue;
2. Inventory management, including the process for purchasing and billing, **replenishment** and true-ups (discussed in Inventory Management), and formulary management (the parties will agree which drugs will be dispensed by the pharmacy on the covered entity's behalf; it may only be a select group of drugs);
3. Workflow processes, including each party's roles and responsibilities and the timeframe to accomplish them;
4. A list of all participating pharmacy locations; in identifying pharmacies, the covered entity should consider pharmacy location, pharmacy participation in third party payer networks, and the ability of the pharmacy to implement the covered entity's sliding fee scale or other grant or care management requirements;
5. Designation of wholesalers/distributors that will be shipping 340B drugs to the pharmacy(ies); and,
6. Terms to ensure compliance with 340B federal requirements, including prohibitions against duplicate discounts and drug diversion and the maintenance of readily available auditable records.

REPLENISHMENT

Replenishment occurs when a non-340B drug is dispensed to a 340B-eligible patient by the contract pharmacy, and the covered entity later replaces the non-340B dispensed drug with a 340B drug.



Regulation of Contract Pharmacy Arrangements

If the covered entity is also using a TPA, the contract should clarify the roles and responsibilities of all parties involved. The covered entity and contract pharmacy each will need to enter into a separate agreement with the TPA or, alternatively, a three-party contract can be executed to reduce the number of contracts and possibility of contradictory terms.

FEES

Services performed by the pharmacy are usually reimbursed at an agreed-upon flat dispensing fee paid per prescription by the Covered Entity to the pharmacy. Other dispensing fee arrangements include tiered pricing, where a different dispensing fee may apply for certain drugs, or a percentage-based fee. Percentage-based compensation arrangements must be arranged in a way to ensure there is no violation of federal and state anti-kickback statutes.

While HRSA does not have a template contract pharmacy agreement, it has provided a non-exhaustive list of 340B related elements that should be addressed in contract pharmacy agreements and sample language.¹¹ The covered entity should review the contract and ensure this language is included or the issue is otherwise appropriately addressed.

Element	HRSA Suggested Language
Ownership of 340B Drug Ship-to/Bill-to Procedure	“The covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price, pursuant to the terms of an HHS grant (if applicable) and any applicable Federal, State and local laws. A “ship to, bill to” procedure is used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased, but ships the drug directly to the contract pharmacy....In cases where a covered entity has more than one site, it may choose between having each site billed individually or designating a single covered entity billing address for all 340B drug purchases.”
Comprehensive Pharmacy Fulfillment Services	“The agreement will specify the responsibility of the parties to provide comprehensive pharmacy services (e.g.,dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy



Regulation of Contract Pharmacy Arrangements

	management services and other clinical pharmacy services). Each covered entity has the option of individually contracting for pharmacy services with a pharmacy(ies) of its choice. Covered entities are not limited to providing comprehensive pharmacy services to any particular location and may choose to provide them at multiple locations and/or “in-house.””
Patient Choice of Pharmacy Protection	“The covered entity will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice. When a patient obtains a drug from a pharmacy other than a covered entity's contract pharmacy or the covered entity's in-house pharmacy, the manufacturer is not required to offer this drug at the 340B price.”
Other Services and Eligible Patients	“The contract pharmacy may provide other services to the covered entity or its patients at the option of the covered entity (e.g., home care, delivery, reimbursement services). Regardless of the services provided by the contract pharmacy, access to 340B pricing will always be restricted to patients of the covered entity.”
Compliance with Federal and State Law	“The contract pharmacy and the covered entity will adhere to all Federal, State, and local laws and requirements. Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if either violates Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]”
Contract Pharmacy Reporting	“The contract pharmacy will provide the covered entity with reports consistent with customary business practices (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records).”
Tracking System to Prevent Drug Diversion	“The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities.”
Patient Eligibility Verification	“The covered entity and the contract pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines.



Regulation of Contract Pharmacy Arrangements

	<p>The system should be subject to modification in the event of change in such guidelines. Both parties agree that they will not resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity. See 42 U.S.C. 256b(a)(5)(B). The covered entity understands that it may be removed from the list of covered entities because of its participation in drug diversion and no longer be eligible for 340B pricing.”</p>
Prevention of Duplicate Discounts (Medicaid)	<p>“Neither party will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to the OPA, HRSA, by the covered entity.”</p>
Independent/Self-Audits Performed by the Covered Entity	<p>“The covered entity and contract pharmacy will identify the necessary information for the covered entity to meet its ongoing responsibility of ensuring that the elements listed herein are being complied with and establish mechanisms to ensure availability of that information for periodic independent audits performed by the covered entity.”</p>
HRSA and Manufacturer Audits	<p>“Both parties understand that they are subject to audits by outside parties (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts. See 42 U.S.C. 256b(a)(5)(c). The contract pharmacy will assure that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be accessible separately from the pharmacy's own operations and will be made available to the covered entity, HRSA, and the manufacturer in the case of an audit. Such auditable records will be maintained for a period of time that complies with all applicable Federal, State and local requirements.”</p>
Availability of Contract to OPA	<p>“Upon written request to the covered entity, a copy of the contract pharmacy service agreement will be provided to the Office of Pharmacy Affairs.”</p>



Regulation of Contract Pharmacy Arrangements

A covered entity should work with its legal counsel to ensure the contract pharmacy agreement is in compliance with applicable federal law, including, but not limited to, the federal anti-kickback and fraud and abuse statutes, the FDA's track and trace law, and HIPAA privacy and security requirements. The contract also should address any applicable state and local law requirements.

Registration and Recertification

A covered entity is required to register each contract pharmacy arrangement in OPAIS during the set registration periods (the first two weeks of every quarter). Once approved by HRSA and uploaded into OPAIS, the contract pharmacy can begin dispensing drugs to a covered entity's 340B eligible patients at the beginning of the subsequent quarter. Drug manufacturers and wholesalers look in OPAIS to verify a covered entity's 340B eligibility and its authorized contract pharmacy arrangements.



A covered entity is required to certify to OPA that it has signed and has in effect an agreement with all participating contract pharmacies that addresses 340B requirements, including, but not limited to, the prohibition against diversion and duplicate discounts, the maintenance of auditable records, and the performance of annual audits. Covered entities are also expected to recertify, usually on an annual basis, ongoing contract pharmacy compliance with 340B rules.



Regulation of Contract Pharmacy Arrangements

Prevention of Drug Diversion

The covered entity and contract pharmacy must agree to not resell or transfer a 340B drug to an individual who is not a “patient” of the covered entity. HRSA requires contract pharmacy arrangements to have a tracking system which verifies patient eligibility; however, the contract pharmacy is not required to confirm that the individual is a patient of the covered entity before filling a prescription. There must also be a periodic comparison of the covered entity’s prescribing records with the contract pharmacy’s dispensing records. This is a function that a TPA often performs on behalf of a covered entity.

It is important to keep in mind that the covered entity retains full responsibility for the compliance of its contracted pharmacies in preventing diversion. If incidents of drug diversion are discovered, the covered entity would be required to notify the manufacturer and may be asked to reimburse the difference between the 340B and non-340B price. For material breaches, the covered entity would be required to notify HRSA in writing and develop a corrective action to prevent further diversion. In some cases, HRSA may terminate the contract pharmacy arrangement.

Medicaid

As discussed above, the 340B statute protects manufacturers from paying duplicate discounts (a 340B discount to a covered entity and a rebate to the state on the same drug) on drugs dispensed to Medicaid patients. This protection extends to manufacturers regardless of whether a drug is dispensed in-house by the covered entity or through a contracted pharmacy. In many cases, a contract pharmacy does not know at the point of dispensing or billing whether a patient should be given a 340B priced drug (resulting in states seeking rebates on 340B drugs). To prevent this, HRSA prohibits contract pharmacies from dispensing 340B drugs to Medicaid fee-for-service (FFS) patients unless there is an arrangement between the covered entity, contract pharmacy, and state Medicaid agency that prevents duplicate discounts. These arrangements must be reported to and approved by HRSA.¹² In lieu of such arrangements, most states have 340B policies requiring contract pharmacies to “carve-out” claims for their Medicaid FFS enrollees (in other words, a covered entity and contract pharmacy are prohibited from dispensing and billing Medicaid FFS programs for 340B drugs).



Regulation of Contract Pharmacy Arrangements

MEDICAID CARVE-IN OR CARVE-OUT

When a covered entity elects to use 340B drugs with its Medicaid patients and indicates such in OPAIS, this is called “carving-in.” When a covered entity does not use 340B drugs with its Medicaid patients, this is called “carving-out.” It is generally an all or nothing election in Medicaid FFS programs. Covered entities should consult their state pharmacy laws and managed care contracts for guidance in dispensing 340B drugs to Medicaid managed care patients.

Prior to passage of the ACA, it was common practice for contract pharmacies to dispense 340B drugs to eligible patients with Medicaid managed care insurance because there was no issue with duplicate discounts. This has become more complicated since ACA extended the rebate program to Medicaid managed care drugs and exempted 340B drugs from rebates. A covered entity should consult with legal counsel and work with its state to seek direction on how a covered entity’s contract pharmacy(ies) should handle Medicaid managed care claims for 340B drugs in order for the state to meet its obligation to remove those claims from manufacturer rebate requests.

Audit Requirements

HRSA expects covered entities to perform annual audits of contract pharmacy arrangements to ensure compliance with all 340B Program requirements.¹³ The contract pharmacy must agree to make records available for use by an independent auditor or self-audits performed by the covered entity. If a covered entity is also using a TPA to help manage its contract pharmacy arrangement, it is recommended that the TPA not be the entity performing an independent audit. HRSA’s contracted technical assistance vendor, Apexus, has created a sample self-audit tool for a covered entity to perform its own audit of a contract pharmacy, as well as a checklist for what to look for when hiring an outside independent auditor.¹⁴

A covered entity that discovers that drug diversion or duplicate discounts have occurred (or are occurring) at a contract pharmacy must take immediate steps to correct the problem and ensure compliance. The covered entity should consult with its legal counsel to determine the circumstances under which it must self-report



Regulation of Contract Pharmacy Arrangements

instances of non-compliance to HRSA. HRSA may terminate the contract pharmacy arrangement if it finds that the covered entity is not exercising proper oversight.

HRSA and manufacturers have the right to audit the records of covered entities and their contract pharmacies to assess compliance with the restrictions against diversion and duplicate discounts. Auditable records should be maintained in accordance with applicable Federal, state and local law.

Policies and Procedures

Covered entities should develop and maintain written policies and procedures related to contract pharmacy oversight. These policies must address the procedures put into place to prevent incidences of drug diversion and duplicate discounts at contract pharmacies.





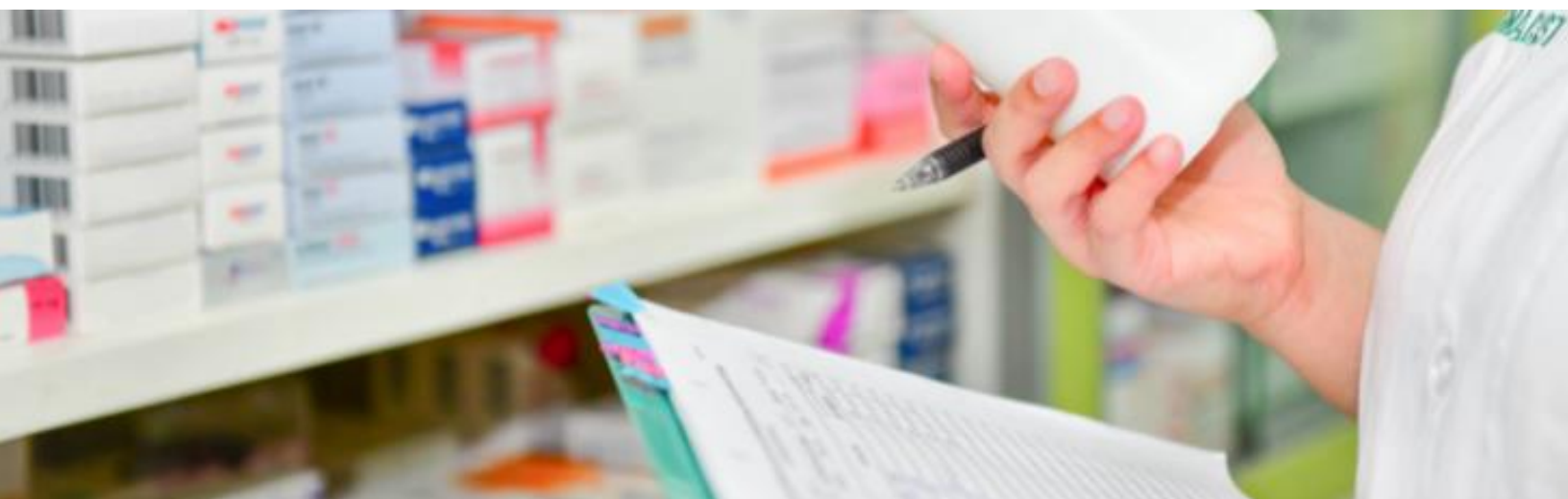
Inventory Management

Contract pharmacies typically use either a physical separation or replenishment model to manage 340B inventory. In a physically separate inventory model, the covered entity will purchase 340B drugs and have them shipped by the distributor directly to the contract pharmacy. The contract pharmacy will store the 340B drugs in a separate location from its own inventory and dispense drugs from the covered entity's 340B inventory to eligible patients.

Most contract pharmacies use an inventory replenishment (also called “virtual”) model, where the covered entity purchases 340B drugs and has the distributor ship them to the contract pharmacy. The contract pharmacy places the drugs into its own inventory to replace the non-340B drugs that were dispensed to 340B patients. The contract pharmacy must maintain a tracking system to identify which drugs were taken from its inventory and dispensed to 340B eligible patients. The agreement between the covered entity and contract pharmacy should specify the timing and process for replenishment.

TRUE-UPS

The contract pharmacy will likely want to include a process in the contract for the reconciliation (also called “true-up”) of drug inventory on a periodic basis and when the agreement is terminated. The “true-up” process addresses situations where the pharmacy's inventory cannot be timely replenished with 340B inventory because of drug shortages, the discontinuation of drugs, or for other reasons. It identifies a process -- usually the covered entity agreeing to pay -- to make the pharmacy whole in the event replenishment cannot occur.





Next Steps for Considering a Contract Pharmacy Arrangement

The use of a contract pharmacy can enhance a covered entity's 340B dispensing options and generate revenue to help the covered entity fulfill its mission and that of the 340B Program -- providing more comprehensive health care services to more eligible patients. However, given the complexity of these arrangements, as discussed in this Guide, it is essential that a covered entity analyze the arrangement from a financial, operational, and legal perspective to ensure it is the right decision and to set up the arrangement in a way that provides the intended benefit and complies with all federal, state, and local law. Following, are suggested steps for covered entities considering a contract pharmacy arrangement:

1. **Conduct a business review:** How will using a contract pharmacy or pharmacies support your business, mission, and the patients you serve?
2. **Identify the pros and cons of contract pharmacy arrangements:** Do the pros of using contract pharmacy services outweigh any negative considerations?
3. **Assess the benefits and drawbacks of using a third-party vendor (TPA) to facilitate and manage contract pharmacy arrangements:** Does the use of a TPA make a contract pharmacy more workable operationally? Is it still worth it financially after all applicable fees are paid to the TPA and the contract pharmacy(ies)?
4. **Engage experienced counsel:** It is important to work with counsel that understands the 340B Program to assist the covered entity in its contract negotiations, minimize legal risks, and ensure compliance with 340B rules and applicable federal and state law.

About NCSD

National Coalition of STD Directors is a national organization representing health department STD directors, their support staff, and community-based organizations across 50 states, seven large cities, and eight US territories. NCSD advances effective STD prevention programs and services in every community across the country.

Contact

For more information or questions, please contact Stephanie Arnold Pang at sarnold@ncsddc.org.

¹ H.R. Rep. 102-384(II), at 12.

² Social Security Act, 42 U.S.C. § 1396r-8.

³ Public Health Service Act, 42 U.S.C. § 256b.

⁴ H.R. Rep. 102-384(II), at 12.

⁵ “If the covered entities were not able to access resources freed up by the drug discounts when they ... bill private insurance, their programs would receive no assistance from the enactment of Section 340B and there would be no incentive for them” to enroll or remain in the Program. HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program, Established by Section 340B of the Public Health Service Act (2005), *available at* www.hrsa.gov/hemophiliatreatment/340Bmanual.htm.

⁶ 58 Fed. Reg. 68922 et. seq. (Dec. 29, 1993).

⁷ 42 U.S.C. §256(a)(5)(A), Social Security Act, 42 U.S.C. § 1396r-8(a)(5)(C).

⁸ 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996).

⁹ 75 Fed. Reg. 10272, et. seq. (Mar. 5, 2010).

¹⁰ GAO, Drug Discount Program, Federal Oversight of 340B Contract Pharmacies Needs Improvement, GAO 18-840 (June 2018).

¹¹ 75 Fed. Reg. 10277 (Mar. 5, 2010).

¹² Apexus has a “[Contract Pharmacy Medicaid Carve-In Checklist](#)” that can be used by a covered entity, contract pharmacy, and state to request HRSA’s approval of an arrangement allowing Medicaid billing for 340B drugs dispensed through a contract pharmacy.

¹³ 75 Fed. Reg. 10274 (Mar. 5, 2010).

¹⁴ <https://www.340bpvp.com/resource-center/340b-tools>, click on Grantees and select “Self-Audit: Contract Pharmacy” or “Independent Audit Request for Proposal Checklist”.