Chapter 11
Contract Pharmacies

A. General Information

1. What is a contract pharmacy?

Health centers and other covered entities may choose to provide access to affordable medication to their 340B eligible patients by entering into a contract with an “outside” pharmacy – typically a pharmacy that is not owned or operated by the 340B covered entity. This outside pharmacy is called a contract pharmacy. Health centers may utilize multiple contract pharmacies to increase patient access to 340B drugs. It is important to note that a health center remains fully responsible for the compliance of all contract pharmacy sites that dispense drugs on its behalf.

2. Pros & cons of using a contract pharmacy

In conjunction with the issues discussed in Section 8.A.7, Health Centers should consider the following nonexhaustive list of pros and cons when deciding whether to use a contract pharmacy model (as opposed to an inhouse model.) Pros:

- Using contract pharmacies makes it easier for health centers to participate in 340B if they do not want or are unable to offer in-house pharmacy services, or if they want to supplement such services.

- Contract pharmacies may increase patient access to 340B drugs by partnering with pharmacies that may be more convenient for the patient.

- Relying exclusively on contract pharmacies eliminates the health center’s cost of operating an in-house pharmacy.

Cons:

- Compliance responsibilities are more complicated, as the FQHC is responsible for the activities of a separate organization(s).

- Relative to an in-house pharmacy model, using a contract pharmacy may result in higher costs and lower 340B savings for the health center, depending on how the contract with the pharmacy is structured.

- Also depending on how the contract is structured, patients may be charged higher fees when they get their drugs from a contract pharmacy compared to an in-house pharmacy.

- Using contract pharmacies appears to increase the likelihood that an FQHC will be audited (and the more contract pharmacy sites, the higher the chances of being audited).

3. Is there a limit on the number of contract pharmacy sites?

At this time, neither the 340B statute nor OPA limit the number of contract pharmacies that a FQHC (or other covered entity) may have. However, this was not always the case. Prior to 1996, a covered entity had to have an in-house pharmacy in order to participate in 340B. Starting in 1996, OPA began allowing covered entities without an in-house pharmacy to contract with a commercial pharmacy. Beginning in 2010, covered entities with in-house
pharmacies were allowed to also provide 340B drugs to their eligible patients through contractual arrangements. Furthermore, covered entities were no longer restricted to one contract pharmacy and began contracting with multiple independent and chain pharmacies. Since that time, there has been a dramatic increase in the number of contract pharmacies participating in 340B, leading to increased oversight and heightened emphasis on program integrity.

4. How many contracts are needed?

According to the OPA website, FQHCs (emphasis added):

“must have a written contract in place with each specific pharmacy organization being used under a contract pharmacy arrangement, including a full listing of all pharmacy locations in that organization that may be utilized.”

5. FQHCs are fully responsible contract pharmacies’ compliance

It is critical to keep in mind that use of a contract pharmacy arrangement does not lessen a FQHC’s duty to ensure compliance with the statute and OPA The health center is fully responsible for their contract pharmacies’ compliance with all 340B requirements. The health center is fully responsible for the contract pharmacies’ compliance of contract pharmacy sites that dispense drugs on its behalf. Rather, health centers retain full responsibility for their contract pharmacies’ compliance with all 340B requirements. compliance of contract pharmacy sites that dispense drugs on its behalf. For this reason, health centers using contract pharmacies must ensure a robust compliance framework is in place and that they have the capacity to monitor compliance within that framework. These compliance activities are discussed on the OPA website, and in Section 11.D. In addition, the first step in ensuring a compliant contract pharmacy model is to establish a well-written contract, as discussed in Section 11.C.

B. Operating a Contract Pharmacy Arrangement

1. How contract pharmacy arrangements operate

The health center pays a fee to the contract pharmacy for services the pharmacy performs. This may be a specified fee per transaction and may also include fees related to third-party administrators (TPAs.) The fee is negotiated between the health center and the pharmacy and is not governed by the 340B statute. See Section 11.C.4 for further discussion of fees.

It is important to carefully examine the terms of the proposed contract, including the fee structure. For example, health centers should avoid signing contracts which effectively transfer a significant part of the 340B benefit from the health center (whom Congress intended to receive the benefit) to the contract pharmacy.

A “ship to/bill to” arrangement may be used, in which the health center is responsible for purchasing 340B drugs from suppliers or manufacturers with instructions to ship the drugs directly to the contract pharmacy. The supplier or manufacturer will bill the health center for the cost of the drugs shipped.

In a physically separate inventory model (see Section 10.A.4), the health center will purchase 340B drugs and request the distributor to ship the drugs directly to the contract pharmacy. The contract pharmacy will then store...
the health center’s 340B-purchased drugs in a physically separate location from its own inventory. The contract pharmacy will take drugs from this inventory to dispense to the health center’s 340B eligible patients.

Most contract pharmacy arrangements operate under a “replenishment” or virtual inventory model. (See Section 10B.) In this model, the health center purchases 340B drugs and requests the distributor to ship the drugs directly to the contract pharmacy. The contract pharmacy then places the drugs into its own inventory to replace the drugs dispensed to 340B eligible patients.

The contract pharmacy must maintain a tracking system to identify which drugs taken from the inventory are dispensed to 340B eligible patients. Many health centers hire companies that use specialized software to identify which drugs dispensed to patients were eligible for 340B pricing. In some cases, a contract pharmacy may require the health center to use the pharmacy’s own software. Regardless of the arrangement, the health center bears the full responsibility for ensuring that 340B drugs are dispensed only to eligible patients.

2. Example of contract pharmacy arrangement with a TPA

- An FQHC signs a written contract with a contract pharmacy (often known as a Pharmacy Services Agreement) for the dispensing of 340B drugs.

- Both the FQHC and the contract pharmacy may contract with a Third Party Administrator (TPA) to facilitate data capture and reporting. There may also be an arrangement with a third-party to track inventory usage using specialized tracking software to prevent diversion and duplicate discounts. In our example we will use the term Virtual Inventory Manager (VIM) to denote the inventory tracking company. Note that the FQHC’s contract with the TPA or VIM does not take the place of a separate contract with the contract pharmacy.

- A patient purchases drugs from the contract pharmacy.

- Using an electronic routing device called a “switch”; the contract pharmacy sends a payment request (claim) for the drug sold to the TPA. The “switch” provides a secure portal for the transmission of patient information.
• The TPA verifies the appropriate insurer and based upon the policy terms, determines payment to the contract pharmacy for the drug. The TPA forwards the payment for the drug, via the switch, to the contract pharmacy. (As discussed below, the TPA may withhold its fees from the payment to the pharmacy.)

• On a periodic basis, the FQHC sends patient and provider information to the VIM.

• The contract pharmacy also uses the switch to transmit to the VIM records of all drugs it has dispensed.

• Using tracking software, the VIM matches data from the contract pharmacy files to the FQHC files. If a script meets eligibility criteria, the drug dispensed is eligible for 340B purposes.

• The VIM sends a report of the matches to the FQHC, TPA and the pharmacy. The report ("accumulation report") is used by the FQHC to re-order or "replenish" the 340B eligible drugs dispensed by the contract pharmacy.

• The FQHC purchases the "replenishment" drugs using its own 340B purchasing account. In some instances, the contract pharmacy may order the drugs itself on behalf of the FQHC by using the FQHC’s 340B account. (See Section 11.B.3 for a discussion of which organization should place the actual order.) The invoice is sent to the FQHC for payment. ("Bill-to-FQHC/Ship-to-contract pharmacy, or "Bill-to/Ship-to")
• The drugs are shipped by the drug distributor directly to the contract pharmacy. The contract pharmacy places the shipment in its inventory. ("Ship-to")

• The contract pharmacy, TPA, VIM and FQHC all receive a portion of monies collected from the sale of the drugs. The contract pharmacy receives its dispensing fees; the TPA and VIM receive their negotiated administrative fees; and the FQHC keeps the remaining collections.

• The FQHC will use the amount received to pay the 340B invoices. Any amount remaining (340B savings) can be used by the FQHC to provide other services to its patients.

3. Can vendors order or purchase 340B drugs for a FQHC? UPDATED

In this response, please note the important distinction between ordering and purchasing 340B drugs. While there has been some uncertainty about whether a TPA or contract pharmacy may order drugs on a FQHC’s behalf, it is clear that they may never purchase 340B drugs on their own accounts, even if they do so on a FQHC’s behalf.

Ordering: This is an example of an issue, discussed in Section 1C, where requirements are unclear. In the past, OPA informed some health center organizations that only an FQHC can order 340B drugs on behalf of its patients, and that TPAs and contract pharmacies may not do so, even if the drugs are ordered on the FQHC’s account and billed directly to the FQHC. However, at least one major pharmacy chain routinely orders 340B drugs on behalf of the covered entities with whom it contracts — and includes a provision requiring this arrangement in its standard contract — and this arrangement has yet to result in audit findings. In addition, documents distributed by 340B University suggest that vendors may submit replenishment orders directly to the distributor. Therefore, health centers are well-advised to consider risks and benefits of both approaches before choosing which to follow.
**Purchasing:** Regardless of which organization places the orders, it must be clear that it is the FQHC (or other covered entity) that purchases the 340B drugs. It is illegal for an organization who is not a covered entity to purchase drugs under the 340B program. For example, while a contract pharmacy might be permitted to order 340B drugs on behalf of the FQHC on the FQHC’s account, they are strictly prohibited from ordering 340B drugs on their own account.

### 4. Can vendors deduct fees directly from 340B revenues? **UPDATED**

This is another example of an issue, discussed in **Section 1C**, where requirements are unclear. In the past, OPA informed some health center organizations that contract pharmacies must forward the full amount that they collected for 340B drugs directly to the FQHC; the FQHC must then – in a separate transaction – pay the contract pharmacy and TPA their fees. However, many current contract pharmacies arrangements do not comply with this practice; rather, the pharmacy and TPA fees are deducted upfront before any proceeds are sent to the FQHC.

To date, no audit findings have resulted from these upfront deductions. Nonetheless, it is recommended that FQHCs have contract pharmacies forward the full amount of collections to them, and to pay fees in a second, subsequent transaction.

### 5. Can contract pharmacies “carve in” Medicaid patients?

Please see **Section 9.E.** for a full discussion of this issue. In short, **contract pharmacies are prohibited from using 340B drugs to fill Medicaid fee for service prescriptions unless:**

- the FQHC, the contract pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts

- this three-way arrangement is in writing and has been submitted to HRSA/OPA.

OPA proposed a similar requirement for Medicaid managed care patients in the draft mega-guidance issued in August 2015, but this proposal was never finalized.

### C. Elements of a Contract with a Contract Pharmacy

**1. OPA’s essential elements of a contract with a contract pharmacy**

The FQHC and contract pharmacy must have in place a written contract which lists all health center sites and contract pharmacy locations that are part of the agreement.

OPA has provided a list of essential elements to address in contract pharmacy arrangements. These include:

(a) “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 billing address for all 340B drug purchases.” (See **Section 8.A.8** for a discussion of “bill to/ship to” arrangements.)

(b) “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 management services and other clinical pharmacy services)."

(c) "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 contract pharmacy, 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 the covered entity’s contract or the covered entity’s In-house pharmacy, the manufacturer is not required to offer this drug at the 340B price.” (See Section 8.B for a discussion of this issue.)

**Important Considerations in 340B Contract Pharmacy Arrangements**

1. The covered entity is responsible for 340B compliance.
2. The covered entity and pharmacy must maintain auditable records.
3. Understand the terms of your contract and flow of the money. A covered entity can lose money on a contract pharmacy arrangement.
4. The use of contract pharmacies may trigger HRSA audits.
5. Medicaid fee-for-service prescriptions should not be included in arrangement unless the State has approved and notified HRSA.
6. Savings from the 340B Program inure to the covered entity; not to the contract pharmacy.

(d) “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.”

(e) "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.]"

(f) “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)."

(g) “The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of 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.”

(h) “The covered entity and the contract pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines. 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 340B prices to an individual who is not a patient of the covered entity…. 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.”

(i) “Neither party will use drugs purchased under 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.” (See Chapter 9 for a discussion of Medicaid issues.)
(j) “The covered entity and the 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.”

(k) “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.

“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.”

(l) “Upon written request to the covered entity, a copy of the contract pharmacy service agreement will be provided to the Office of Pharmacy Affairs.

2. No OPA model for contract with contract pharmacy

OPA has not offered a model contract for FQHCs (or other covered entities) or use with contract pharmacies. However, in its March 10, 2010 Federal Register Notice, OPA included a non-exhaustive list of sample provisions for FQHCs and other covered entities to include in contracts with contract pharmacies. This list is contained in Appendix Four. Please note that, as OPA states in the Notice, these terms are:

“for illustrative purposes and are not intended to be comprehensive, exhaustive or required. They offer sample provisions for consideration, but are not intended to be used as the complete terms of the contract.”

When adopting any sample contract, FQHCs should ensure that their final contracts reflect all circumstances and requirements that are specific to their state, organization, and 340B program.

3. Sample contracts with contract pharmacies & TPAs UPDATED

The Texas Association of Community Health Centers (TACHC) has two sample contracts that are used by participants in its 340Better program: These are contracts:

- between a health center and its TPA (which TACHC calls a Pharmacy Benefit Administrator or PBA) which administers a replenishment model.
- Among a health center, TPA, and contract pharmacy

These contracts are much longer and more detailed than the standard contracts that contract pharmacies and TPAs offer to health centers and other covered entities, and they are specifically written to address the unique circumstances faced by health centers. These contracts have also been reviewed by both Apexus and legal counsel.

Appendix Five contains more information on both of these contracts, including:

- a summary of the issues they address,
- a description of the inter-related nature of both contracts, and
• how to access the full contracts from either TACHC’s 340Better program or their PBA, 340Basics.

Remember that when adopting any sample contract, FQHCs should ensure that their final contracts reflect all circumstances and requirements that are specific to their state, organization, and 340B program.

At this time, NACHC is not aware of other sample contracts with contract pharmacies and TPAs which are both specific to FQHCs’ needs and requirements, and which the parties are willing to share. If there are other examples, please contact regulatoryaffairs@nachc.org and we will include this information in future editions of this Manual as appropriate.

4. Best practices re: fees paid to vendors

OPA does not have any specific requirements around the level or structure of fees to be paid by FQHCs to contract pharmacies or TPAs. Rather, these fees are negotiated between the FQHC and the vendor.

However, health centers are well-advised to ensure that the fee structures in their contracts are consistent with the Congressional intent behind the 340B program, which stated that the program’s benefits are to accrue to the covered entities. (See Section 3.A.2.) While contract pharmacies and TPAs should be appropriately reimbursed for their costs, fees structure which result in their retaining a significant share of the 340B savings are not consistent with this intent.

Peer Perspective

“This is extremely important for FQHCs. The majority of the contracts written today call for a percentage of the cost of drug to be paid to the 340B Vendor. The 340B Vendor has no money invested in the cost of the drug—the FQHC is paying for the drugs. On expensive medications this amounts to a sizable “fee” going to the vendor. FQHCs do not have to sign these contracts.”
For these reasons, “best practice” for FQHCs generally entails seeking to negotiate contracts in which:

- contract pharmacies receive a flat dispensing fee for each drug. (Note that flat fees may vary based on the drug, as some drugs involve higher dispensing costs than others.)

- TPAs are reimbursed on a per-transaction basis.

Thus, as a general rule, **FQHCs are strongly advised to avoid contracts in which the contract pharmacy or TPA keeps a percentage of the 340B revenues.** These structures can result in some of the benefits of the 340B program accruing directly to the contract pharmacy or TPA, particularly in the case of higher-cost drugs. However, see the following “Peer Perspective” text box for some additional complexities to consider.

**Peer Perspective**

“I agree 100% that FQHC’s should generally seek to avoid contracts which include sharing of a percentage of the 340B revenue. However, more and more pharmacies are moving toward a lower flat fee plus a percentage of the retail amount collected to protect potential lost margin on the higher priced specialty drugs, etc. The flat fees would require multiple tiers of pricing to manage to keep the pharmacy whole on the more expensive and higher margin drugs. Pharmacies are more likely to carve out these drugs from their 340B contracts if their fixed fees are not enough to cover what they would normally realize. Though not ideal, the flat fee plus a percentage of the amount collected could be reasonable if it is substantiated to represent the average the pharmacy would normally collect on non-340B claims and it is not directly tied to 340B benefit. Pharmacies should be willing to share their actual acquisition cost to justify the proposed percentage methodology for auditing purposes.”

5. TPAs may not contract with a contract pharmacy on FQHC’s behalf

No, FQHCs may not rely on their TPAs to contract with contract pharmacies on their behalf. Rather, in order for an FQHC to use a contract pharmacy, there must be a contract executed directly between the FQHC and the contract pharmacy. Note, however, that the T may assist the FQHC with the contracting process.

D. Ensuring Compliance of Contract Pharmacies

As stated in Section 11.A.5, FQHCs are fully responsible for their contract pharmacies’ compliance with all 340B requirements. OPA provides guidance to FQHCs (and other covered entities) on how to ensure this compliance on its website, in a section entitled “**Five Requirements for 340B Compliance in Contract Pharmacy**”. This section discusses both these OPA requirements, as well as Section 330 requirements that apply under the contract pharmacy model.
1. OPA’s requirements for contract pharmacy oversight

A well-written contract is only one element of ensuring compliance in contract pharmacy arrangements. On its web page on contract pharmacy oversight, OPA lists the following oversight activities and provides links to resources to each. The FQHC must:

1. Conduct independent annual audits and/or adequate oversight mechanism of its contract pharmacies; (see Sections 11.D.1 and 11.D.2)

2. Develop written 340B Program policies and procedures related to contract pharmacy oversight; (see Section 12.A.9)

3. Maintain auditable records at both the FQHC and contract pharmacy; (see Section 13.A.3)

4. Ensure that the written contract pharmacy agreement lists each contract pharmacy location individually;

5. Do not use contract pharmacy for 340B purposes until:
   - the contract has been finalized and signed; and
   - the contract has been registered on the OPA database (which may not be done until the contract has been signed by all parties – see Section 5.B.3); and
   - the effective date of the registration has been reached (see Section 5.C.1);

6. Ensure that 340B drugs are only provided to 340B eligible patients; (see Chapter 7 for a discussion of patient eligibility.)

7. Carve-out Medicaid at contract pharmacies or develop an alternative arrangement to work in collaboration with the state Medicaid agency to ensure duplicate discounts do not occur and report this to OPA; (see Chapter 9 for a discussion of Medicaid issues) and

8. Maintain accurate information in OPAIS, including FQHC contact information, contract pharmacy information, and Medicaid fee-for-service billing information. (See Chapter 6.)

Again, please see the OPA website for links to resources to assist in meeting each of these requirements.

2. Audit expectations re: contract pharmacies

As discussed in the Section 11.D, although it not explicitly required by statute, OPA currently expects all covered entities – including FQHCs - to conduct annual independent audits of each contract pharmacy location. As discussed in Section 13.B.3, the independent auditor should not have a financial interest in the contract pharmacy arrangement.

Apexus addresses these expectations in the following FAQ:
In addition, in the draft Program Guidance released in August 2015, OPA proposed:

- to make annual independent audits mandatory
- to require FQHCs (and other covered entities) to compare its 340B prescribing records with the contract pharmacy’s 340B dispensing records at least quarterly.

While this guidance was never finalized, FQHCs would be well advised to implement these, or similar, oversight measures.

3. **Contract pharmacies must registered and recertified on OPAIS**

Each contract pharmacy site must be separately registered in the OPAIS, and must be recertified annually. These issues are discussed at length in Chapter 5 and Chapter 6. In particular, please see Section 5.B.4, which outlines specific considerations related to registering contract pharmacy sites.

4. **Checklist for self-auditing contract pharmacies**

A sample checklist is contained in Appendix Eight, Self-Audit Tools.

E. **For More Information**

**Official OPA Guidance on Contract Pharmacies**

- OPA’s initial guidelines on contract pharmacy arrangements were published in March 2010 and are available at [http://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf](http://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf)
- OPA’s official webpage on “Contract Pharmacy Oversight” is at [http://www.hrsa.gov/opa/updates/contractpharmacy02052014.html](http://www.hrsa.gov/opa/updates/contractpharmacy02052014.html)
• OPA also has a general website on contract pharmacy services at http://www.hrsa.gov/opa/implementation/contract/

Other Resources on Contract Pharmacies

• As previously discussed, the official source of OPA-aligned policy information is Apexus. Contact information is available at Section 3.D.1.

• An excellent resource for health centers considering their pharmacy options is The Bridge to 340B Comprehensive Pharmacy Services Solutions in Underserved Populations by Katheryne Richardson available at http://www.hrsa.gov/opa/files/bridgeto340b.pdf. This document provides a comprehensive discussion of different pharmacy strategies, worksheets to conduct needs assessments, and case studies reflecting the various options.