America’s Voice for Community Health Care

The National Association of Community Health Centers (NACHC) represents Community and Migrant Health Centers, as well as Health Care for the Homeless and Public Housing Primary Care Programs and other community-based health centers.

Founded in 1971, NACHC is a nonprofit advocacy organization providing education, training and technical assistance to health centers in support of their mission to provide quality health care to medically underserved populations.
The NACHC Mission

To promote the provision of high quality, comprehensive and affordable health care that is coordinated, culturally and linguistically competent, and community directed for all medically underserved populations.
For further information about NACHC and America’s Health Centers

Visit us at www.nachc.com
NACHC 340B Webinar Series
Part 2: Contract Pharmacies

Cynthia (Cindy) R. DuPree
Partner, Draffin & Tucker, LLP
January 27, 2016
What is a contract pharmacy?
What is a contract pharmacy?

• Dispenses drugs to FQHC patients on behalf of FQHC
• Contract between FQHC and pharmacy
• Typically pharmacy not owned by FQHC
What are the benefits to using a contract pharmacy?
What are benefits?

• Ability to participate in 340B when there is no in-house pharmacy
• Increase patient access to lower cost medications
• Cost-effective delivery system
Patient choice

• Cannot require patients to use the contract pharmacy
• Must inform patient of freedom-of-choice
How does a contract pharmacy arrangement work?
How does it work?

FQHC chooses a pharmacy partner

– Proximity to patients
– Cost of services
– Ability to be compliant
A Covered Entity signs a written contract with a Contract Pharmacy (often known as a Pharmacy Services Agreement) for the dispensing of 340B drugs.
Both the Covered Entity and Contract Pharmacy contract with a Third-Party Administrator (TPA) to facilitate data capture and reporting. TPAs often use specialized tracking software to prevent diversion and duplicate discounts.
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 a Pharmacy Benefits Manager (PBM). The “switch” provides a secure portal for the transmission of patient information.
The PBM verifies the appropriate insurer and based upon the policy terms, determines payment to the Contract Pharmacy for the drug. The PBM forwards the payment for the drug, via the switch, to the Contract Pharmacy.
On a periodic basis, via the switch, the Covered Entity sends patient information to the TPA.
The Contract Pharmacy also uses the switch to transmit to the TPA records of all drugs it has dispensed.
Using tracking software, the TPA matches data from the Contract Pharmacy files to the Covered Entity files. If the data matches, the drug dispensed is eligible for 340B purposes.
The TPA sends a report of the matches to the Covered Entity. The report ("accumulation report") is used by the Covered Entity to re-order or "replenish" the 340B eligible drugs dispensed by the Contract Pharmacy.
The Covered Entity purchases the “replenishment” drugs using its own 340B purchasing account. In some instances, the Contract Pharmacy may order the drugs itself using the Covered Entity’s 340B account.
Bill-to

The invoice is sent to the Covered Entity for payment. ("Bill-to-Covered-Entity/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")
Periodically, the Contract Pharmacy will send to the TPA the amounts it has collected for the 340B drugs sold. The Contract Pharmacy will typically withhold its fees (negotiated in the contract with the Covered Entity) and send the remaining amount to the TPA.
The TPA will then forward the collections to the Covered Entity after it has withheld its negotiated TPA fee.
The Covered Entity will use the amount received to pay the 340B invoices. Any amount remaining (340B savings) can be used by the Covered Entity to provide other services to its patients.
QUESTIONS?
Physically separate inventory in contract pharmacy
340B Program

Pre-purchased inventory model (physical inventory)

Contract Pharmacy

Covered entity patients

Other patients
How do you register a contract pharmacy?
Registration

Electronically on HRSA website
• Registration is completed during same open enrollment windows as the covered entity.
• EACH contract pharmacy location must be separately registered.
Registration

• Before registration
  – Written, fully executed contract
  – Pharmacy name, location, and contact info
  – Ship to address (street address)
Parent / child relationships

If a contract pharmacy serves patients from ALL child sites, register under parent.

If a contract pharmacy is registered under a child site only, it can serve only 340B patients from that child site.
FAQ ID: 1555
Last Modified: 10/22/2014

Q: If our contract pharmacy has been purchased by another pharmacy, do we need to update our records with OPA?

A: If a contract pharmacy has **changed** ownership, HRSA considers this to be a new contract pharmacy arrangement. The covered entity must have a written contract in place with the new contract pharmacy and register the contract pharmacy arrangement on the 340B database prior to use. Covered entities must complete the online portion of the contract pharmacy registration process during an open registration period. For information on how to register a contract pharmacy, see [http://www.hrsa.gov/opa/implementation/contract/index.html](http://www.hrsa.gov/opa/implementation/contract/index.html).

The covered entity must also terminate the contract pharmacy relationship established under the previous owners. To effectuate the termination, complete an online termination request: [http://opanet.hrsa.gov/OPA_Mod/CPRegCeSearch.aspx](http://opanet.hrsa.gov/OPA_Mod/CPRegCeSearch.aspx). Failure to report a **change** in ownership may result in a lapse in 340B access through the specific contract pharmacy.

**Walgreens-Rite Aid Aid merger under more federal scrutiny**
QUESTIONS?
What does a contract look like?
Essential elements to address

Federal Register / Vol. 75, No. 43 / Friday, March 5, 2010 / Notices

(3) Essential Covered Entity Compliance Elements

The following are essential elements to address in contract pharmacy arrangements: (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. See Section 1 of Appendix. 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 all 340B drug purchases.

(b) The agreement will specify the responsibility of the parties to the comprehensive pharmacy service.
a) Covered entity (CE) will, pursuant to HHS grant and Federal, State and local laws:

1. Purchase the drugs
2. Maintain title to drugs
3. Assume responsibility for pricing
4. Use a “ship to, bill to” procedure
b) Agreement will specify responsibility of parties to provide:
Essential elements

c) Patient must be informed of freedom to choose pharmacy provider.
d) Contract pharmacy may provide other services to CE patients; however, 340B pricing is restricted to CE patients.
e) Both parties will adhere to Federal, State, and local laws and requirements. Both parties are aware of potential for civil and criminal penalties.
f) Contract pharmacy will provide CE with reports related to Program operations:

1. Billing statements
2. Collection status
3. Receiving records
4. Dispensing records
g) Parties will establish and maintain a tracking system to prevent diversion.
h) Parties will develop a system to verify patient eligibility. 340B drugs will not be sold or transferred to a non-eligible patient.

3.1. **Eligibility Verification.** Health Center will provide all Eligible Patients with a prescription which will contain, but not necessarily be limited to, the barcode provided by Walgreens, the patient payment responsibility amount for those Eligible Patients whose prescriptions are not reimbursable by a Private Insurer, the applicable Health Center Location name, address and identification number, the eligible prescriber’s name, and the Eligible Patient’s full name (“Authorization”). Such Authorization will establish eligibility and serve as evidence of Health Center’s authorization for Eligible Patients to receive 340B Drugs.
340B drugs will not be dispensed as Medicaid prescriptions unless there is an agreement with the State.
Essential elements

j) Documentation, information, and mechanisms are available for periodic independent audits performed by the covered entity.
k) Both parties understand each is subject to audits by outside agencies and that pertinent records are maintained and are accessible.
I) Upon written request, a copy of the contract pharmacy service agreement will be provided to the Office of Pharmacy Affairs.
QUESTIONS?
Are there specific oversight requirements?
Independent audits

Authorizing Signature

The undersigned represents and confirms that he/she is fully authorized to legally bind the covered entity and certifies that the contents of any statement made or reflected in this document are truthful and accurate. The undersigned further acknowledges the 340B covered entity’s responsibility to abide by the following:

As an Authorized Official, I certify on behalf of the covered entity that:

(1) all information listed on the 340B Program database for the covered entity will be complete, accurate, and correct;
(2) the covered entity will meet all 340B Program eligibility requirements;
(3) the covered entity will comply with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity;
(4) the covered entity will maintain auditable records demonstrating compliance with the requirements described in paragraph (3) above;
(5) the covered entity has systems/mechanisms in place to ensure ongoing compliance with the requirements described in (3) above;
(6) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines including, but not limited to, that the covered entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism);
(7) the covered entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material change in 340B eligibility and/or material breach by the covered entity of any of the foregoing; and
(8) the covered entity acknowledges that if there is a breach of the above that the covered entity may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and, depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.

In addition, I have read all applicable registration instructions and I am aware that my registration will not be reviewed if the required supporting documents are not submitted today.

☑ By checking this box, I confirm that I have read the above statements and fully understand my obligations.

Signed By Official
FAQ ID: 1422
Last Modified: 10/22/2014

Q: What are the audit and compliance requirements under the contract pharmacy guidelines?

A: The covered entity must have sufficient information to ensure ongoing compliance and the timely recognition of any 340B Program compliance problem at all contract pharmacy locations. The covered entity remains responsible for the 340B drugs it purchases and dispenses through a contract pharmacy. All covered entities are required to maintain auditable records and provide oversight of their contract pharmacy arrangements. HRSA expects that covered entities will utilize independent audits as part of fulfilling their ongoing obligation of ensuring 340B Program compliance. 340B Program violations found during internal or independent audits must be disclosed to HRSA along with the covered entity’s plan to address the violation. This information should be mailed to: Health Resources and Services Administration, Office of Pharmacy Affairs, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857.

Additionally, HRSA audits of covered entities include a covered entity’s contract pharmacies. A contract pharmacy will be removed from the 340B Program if the covered entity is not providing oversight of its contract pharmacy arrangement.
HRSA oversight requirements

- Conduct independent annual audits and/or adequate oversight mechanism;
- Develop written 340B Program policies and procedures related to contract pharmacy oversight;
HRSA oversight requirements

• Maintain auditable records and both the covered entity and contract pharmacy;
• Ensure written contract pharmacy agreement lists each contract pharmacy individually and is in place before registering contract pharmacy in 340B Program;
HRSA oversight requirements

• Do not use contract pharmacy for 340B purposes until it has been registered, certified, and pharmacy is listed on the covered entity’s 340B record;

• Ensure that 340B drugs are only provided to 340B eligible patients;
HRSA oversight requirements

• 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 HRSA;
Maintain accurate information in the HRSA 340B database, including covered entity contact information, and Medicaid billing information.

http://www.hrsa.gov/opa/updates/contractpharmacy02052014.html
340 ID: CHC12872-00

OPA Findings:

1. Incorrect 340B database record – incorrect entries for entity’s name; offsite outpatient facilities were not listed on the 340B database; registered contract pharmacy without written contract in place.

2. Entity did not provide contract pharmacy oversight.

3. Diversion – 340B drug dispensed at a contract pharmacy for a prescription written at an ineligible site by an ineligible provider, not supported by responsibility of care.

Sanctions: Termination of contract pharmacy from 340B Program; Repayment to manufacturers.

Corrective Action: Pending.
Where can you find more information?
• Federal Register/Vol. 75, No. 43/Friday, March 5, 2010/Notices
• The Bridge to 340B Comprehensive Pharmacy Services Solutions in Underserved Populations by Katheryne Richardson

Want to learn more?
NACHC Information

• NACHC website guidance
• Upcoming webinars

2/03 – Recent Developments
2/10 – Compliance/Self-audits
For more information or questions:
Cindy DuPree
Draffin & Tucker, LLP
Atlanta, Georgia
cdupree@draffin-tucker.com

NACHC and America’s Health Centers
www.nachc.com