Healthcare Systems Bureau

DATE: February 5, 2014

TO: 340B Covered Entities

FROM: CDR Krista Pedley, Director, Office of Pharmacy Affairs

SUBJECT: Contract Pharmacy Oversight

HRSA is committed to strengthening 340B Program integrity efforts and ensuring that our management and oversight supports the continued success of the 340B Program. In particular, we have renewed our focus on program integrity in the area of contract pharmacy arrangements. Contract pharmacy arrangements are not common in the 340B Program. The overwhelming majority (82 percent) of covered entities do not contract with pharmacies. Of the approximately 20 percent of covered entities that have an arrangement with a contract pharmacy, 75 percent have fewer than 5 contract pharmacy arrangements. However, these arrangements present unique compliance challenges.

According to the 340B Peer Network, contract pharmacies can enable covered entities to expand the type and volume of care they provide to vulnerable patient populations. First, for those covered entities that offer reduced price medications to their low-income uninsured patients, contract pharmacies make medications more accessible by offering additional locations and extended hours. Second, while HRSA lacks the statutory authority to govern how covered entities use savings, these covered entities have described using the savings generated by contract pharmacies to support numerous activities that enhance access for underserved populations. Common examples include clinical pharmacy programs (i.e., medication adherence, medication management) and sliding fee discounts for other services. In addition, contract pharmacy use helps these covered entities reduce costs incurred by the substantial space, staffing, and capital costs required to run an in-house pharmacy.

For covered entities with contract pharmacy arrangements, vigilant oversight is critical. Covered entities are responsible for ensuring compliance of their contract pharmacy arrangement with all 340B Program requirements to prevent diversion and duplicate discounts (75 Fed. Reg. 10272 (Mar. 5, 2010)). All covered entities are required to maintain auditable records and are expected to conduct annual audits of contract pharmacies that are performed by an independent auditor. HRSA conducts audits to ensure covered entities are appropriately providing oversight of their contract pharmacy arrangements. To the extent that any compliance activity or audit performed by a covered entity indicates a violation of 340B Program requirements, such finding must be disclosed to HRSA along with the covered entity's plan to address the violation. As demonstrated in the 340B Program audits finalized to date, covered entities' oversight of contract pharmacies did not always meet expectations outlined in 340B Program guidance specific to diversion and duplicate discounts found at a contract pharmacy. In addition, if HRSA finds a covered entity providing no oversight of its contract pharmacy arrangement, this is a violation of program requirements and HRSA will no longer permit the participation of that contract pharmacy arrangement.

In addition to contract pharmacy oversight, per HRSA's March 2010 contract pharmacy guidelines, contract pharmacies must carve-out Medicaid (i.e., not use 340B drugs for Medicaid patients), unless the covered entity otherwise has an arrangement with the state Medicaid agency to prevent duplicate discounts. The covered entity must report such arrangements to HRSA. Covered entities found carving-in Medicaid at their contract pharmacies will be cited in an audit. HRSA also audits the ability of a covered entity and its contract pharmacy to prevent duplicate discounts, and the sanction associated with that violation is manufacturer repayment if a duplicate discount occurred.

For your reference, HRSA has compiled the chart below outlining contract pharmacy oversight requirements and links to resources offered by our contracted 340B Prime Vendor Program.

I appreciate your shared commitment to compliance with 340B Program requirements.

5 Requirements for 340B Compliance in Contract Pharmacy

Contract Pharmacy Oversight Requirements	Resources
1. Conduct independent annual audits and/or adequate oversight mechanism.	• Examples of self-audit protocols (by entity type) https://www.340bpvp.com/resource-center/other-resources/compliance-self-assessment/ • Considerations when working with contract pharmacy vendors https://docs.340bpvp.com/documents/public/resourcecenter/340B_Compliance_SelfAssessment_Vendors.pdf
2. An expectation to develop written 340B Program policies and procedures involving contract pharmacy oversight; maintain auditable records at both 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; and contract pharmacy may not be utilized for purposes of the 340B Program until it has been registered, certified, and pharmacy is listed on the covered entity's 340B database record.	• Sample policies and procedures (by entity type) https://www.340bpvp.com/resource-center/other-resources/standard-operating-procedures/ • Examples of auditable records are discussed at every 340B University session. https://www.340bpvp.com/340b-university/ • Maintain a written contract that adheres to the contract pharmacy compliance elements discussed in the published contract pharmacy guidelines http://www.hrsa.gov/opa/programrequirements/federalregisternotices/contractpharmacyservices030510.pdf
3. Ensure that 340B drugs are only provided to 340B-eligible patients.	• Definition of an eligible patient http://www.hrsa.gov/opa/eligibilityandregistration/index.html • Considerations for handling referral prescriptions https://docs.340bpvp.com/documents/public/resourcecenter/All_Entity_Policy_Practice_Referral

	_Relationships.pdf • Best Practices for health care professional relationships https://docs.340bpvp.com/documents/public/resourcecenter/Hospitals_Policy_Practice_HealthCare_Professional_Agreements.pdf
4. 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.	• Contract pharmacy guidelines, which state that 340B drugs should not be dispensed to Medicaid patients via a contract pharmacy, absent an arrangement to prevent duplicate discounts http://www.hrsa.gov/opa/programrequirements/federalregisternotices/contractpharmacyservices030510.pdf • The Apexus Answers Call Center provides state Medicaid contact information https://www.340bpvp.com/about-us/contact-us/ • FAQ #1929 provides bullets points to guide your Medicaid Agency discussion https://www.340bpvp.com/resourceCenter/faqSearch.html?category=content&Ntt=1929
5. Maintain accurate information in the HRSA 340B database, including covered entity contact information, contract pharmacy information, and Medicaid billing information.	• Update existing 340B database information by submitting a change request http://opanet.hrsa.gov/opa/CRPublicSearch.aspx • Register new contract pharmacies during a quarterly registration period http://opanet.hrsa.gov/opa/CRPublicSearch.aspx • Recertify annually http://www.hrsa.gov/opa/programrequirements/recertification/index.html