



**Office of Pharmacy Affairs Revises 340B Contract Pharmacy Guidelines
HRSA sponsoring live webinar on new guidance Monday, March 29, at 1pm EDT**

On March 5, 2010, HRSA's Office of Pharmacy Affairs ("OPA") published long-awaited guidelines that expand the scope of contract pharmacies that can dispense 340B drugs on behalf of a health center and other 340B covered entities. *See 75. Fed Reg. 10272 (March 5, 2010).*

The revised guidelines are effective April 5, 2010.

The new contract pharmacy guidelines apply to *all* contract pharmacy arrangements, including existing arrangements with a single pharmacy. **HRSA has made it clear that the new guidelines replaces all previous 340B Program guidance on contract pharmacy services and any individual correspondence issued by HRSA on the subject. Therefore, it is extremely important that health centers with a 340B contract pharmacy review the arrangement, and the terms of its contract, in light of the new guidance.** While HRSA stated that the new guidelines do not necessarily require revision of existing contracts, so long as they meet the criteria outlined in the guidance, it also encouraged 340B covered entities to seek competent counsel to advise them on their needs.

Under the new guidelines, a health center can contract with more than one licensed commercial pharmacy to serve any of its delivery sites, including a site that has an in-house pharmacy. Moreover, a health center can have one contract with a pharmacy or a pharmacy chain to cover all of its delivery sites, provided that each of the delivery sites and pharmacy locations is individually identified in the contract and listed on the OPA data base. Previously, multiple contract pharmacy arrangements required OPA approval for an Alternative Methods Demonstration Project (AMDP). HRSA's recognition of a health center's ability to contract with multiple pharmacies and to supplement an in-house pharmacy with one or more contract pharmacies, which NACHC has long advocated, provides health centers with much needed flexibility in designing a pharmaceutical delivery system and maximizing access for their patients.

The new guidelines carry over the key features of the current guidelines, such as the requirements of a written contract, a tracking system to prevent diversion and duplicate discounts, verification of patient eligibility, and maintenance of records to document compliance.

However, the new guidelines contain additional compliance requirements that HRSA did not include in its original notice of the proposed revisions. Among these is the **requirement that a 340B covered entity and its contract pharmacies maintain auditable records of 340B drug transactions, and that the covered entity have an annual independent audit of its compliance with 340B requirements.** Further, the guidance states that covered entities must disclose instances of noncompliance to OPA and the remedial action it plans to take. Finally, HRSA stated that covered entities "should" submit a written certification to OPA that it has a plan in

effect to meet its compliance responsibilities and that its pharmacy contracts satisfy all compliance requirements. HRSA also indicated that it may implement an annual certification process requiring an authorized official of a covered entity to certify that the contract pharmacy was actually performed in a manner that meets all compliance requirements. NACHC will work with HRSA officials for further clarification as to how HRSA plans to implement the new compliance requirements.

Further information on the new guidelines can be found on the OPA website, www.hrsa/opa and on HRSA's Pharmacy Services Support Center website, www.pssc.aphanet.org. **HRSA is sponsoring a live webinar on the new guidelines on Monday, March 29, at 1:00p.m. EDST.** Further information on the webinar will be posted on the OPA website as they become available.

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