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## HRSA's Office of Pharmacy Affairs Releases Long-Awaited 340B Contract Pharmacy Guidelines

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**On March 5, 2010, the federal Office of Pharmacy Affairs ("OPA") released new final guidelines for the utilization of contract pharmacies for the dispensing of drugs under the prescription drug discount program established under Section 340B of the Public Health Service Act (the "340B program"). The new guidelines authorize entities that are eligible to participate in the 340B program ("340B covered entities") to utilize multiple contract pharmacies instead of limiting them to a single point for pharmacy services. Proposed guidelines for multiple contract pharmacy arrangements were originally published more than three years ago, in January 2007.**

The new guidelines replace previous 340B program guidance regarding contract pharmacy arrangements, which required 340B covered entities that wished to use multiple contract pharmacies to apply to OPA for approval of an Alternative Methods Demonstration Project ("AMDP").

Under the new guidelines, covered entities that wish to use contract pharmacy services to dispense 340B drugs must have a written contract in place with the contract pharmacy or pharmacies. The contract must list all pharmacy locations that may be utilized under the agreement. A covered entity that has more than one 340B-eligible site may have individual contract pharmacy agreements for each site, or may include multiple 340B-eligible sites within a single contract pharmacy agreement. Contract pharmacy arrangements may be used in lieu of in-house pharmacy services, or they may be used to supplement in-house pharmacy services.

The guidelines provide that a contract pharmacy arrangement may involve only one 340B covered entity, although that entity may have multiple 340B-eligible sites. Any arrangement that involves a network of covered entities will continue to require OPA approval through the AMDP process. 340B covered entities remain responsible for ensuring that contract pharmacy arrangements comply with all requirements of the 340B program, including the prohibition against diversion of 340B

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drugs to individuals who do not qualify as patients of the covered entity for 340B purposes.

The new guidelines outline the essential elements of a contract pharmacy arrangement, which include the following:

The arrangement must utilize a "ship to, bill to" procedure, under which the covered entity purchases the drug, maintains title to the drug, and assumes responsibility for establishing its price. Where a covered entity has more than one 340B-eligible site, it may choose between having each site billed individually or designating a single covered-entity billing address for all 340B drug purchases.

The agreement will specify the responsibility of the parties to provide comprehensive pharmacy services.

The covered entity must inform patients of their freedom to choose a pharmacy provider. If a patient does not elect to use a contract pharmacy, the patient may fill the prescription at a pharmacy provider of the patient's choice.

The contract pharmacy may provide other services to the covered entity or its patients.

Both the contract pharmacy and the covered entity must adhere to all applicable laws.

The contract pharmacy must provide the covered entity with reports relating to the contract pharmacy services, including billing statements, status reports of collections and receiving and dispensing records.

The contract pharmacy, with the assistance of the covered entity, must maintain a tracking system suitable to prevent diversion of 340B drugs to individuals who are not patients of the covered entity. The covered entity and the pharmacy must develop a system to verify patient eligibility.

340B drugs may not be dispensed to Medicaid patients unless the covered entity, the pharmacy, and the state Medicaid program have established an arrangement to prevent duplicate discounts.

The contract pharmacy must maintain all pertinent records separately from the pharmacy's own operations, and must make those records available to the covered entity, OPA, and pharmacy manufacturers in the case of an audit.

The guidelines also provide that annual audits performed by an independent outside auditor with experience auditing pharmacies are expected. In addition, a covered entity that enters into contract

pharmacy arrangements will be required to submit to OPA a certification that it has a contract in place with the pharmacy that satisfies the requirements set forth in the final rule, and that it has a plan to meet its ongoing responsibilities to ensure compliance. In addition, covered entities must continue to register their contract pharmacy arrangements with OPA.

Click [here](#), for a copy of the final rule.

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