

March 9, 2010

HRSA Issues Notice Allowing 340B Programs to Contract with Multiple Pharmacies

On March 5, 2010, the Health Resources and Services Administration (“HRSA”) issued a [final notice](#), effective April 5, 2010, that allows covered entities participating in the 340B Drug Pricing Program to contract with multiple contract pharmacies to provide discounted drugs. This long-awaited development (the proposed notice was issued in January 2007) makes it easier for a wide range of providers, including disproportionate share hospitals, federally qualified health centers, and other publicly funded clinics, to make discounted medications available to their patients.

Prior to this notice, covered entities could contract with multiple pharmacies only by participating in an alternative methods demonstration program (“AMDP”). Covered entities were otherwise limited to using a single in-house pharmacy or contracting with a single contract pharmacy, based on concerns that the discounted drugs would be diverted to individuals using the pharmacies who do not qualify as patients of the 340B covered entities. As a result of this restriction, however, many providers noted transportation or other difficulties that limited patients’ ability to access the single pharmacy. By contracting with multiple pharmacies (or multiple chain pharmacy locations), covered entities will be able to expand access to medically indigent populations through more conveniently located pharmacies in their communities.

Basic Program Elements

Participation in the contract pharmacy program is optional. Covered entities planning to use contract pharmacy services pursuant to this notice should consider the following:

- **Written Contract**—There must be a written contract between the covered entity and the contract pharmacy.
 - **Single Covered Entities with Multiple 340B-Eligible Sites**—A single covered entity that has more than one 340B-eligible site at which it provides health care may have individual contracts for each such site or include multiple sites within a single pharmacy services contract.
 - **Contract Updates**—A covered entity that already has a contract with a single pharmacy may need to revise its existing contracts to ensure that it is in compliance with new rules.
- **Identification of Pharmacies**—If a covered entity plans to use any alternative to the single location or single pharmacy model, it must submit its name and 340B identification number and the names of all participating pharmacies to HRSA.
- **Chain Pharmacies**—Covered entities may enter into a single agreement with a chain pharmacy, but each participating pharmacy location in the chain must be listed on the contract and must comply with its terms.
- **Network Arrangements**—Arrangements in which a network of more than one covered entity form a unified distribution system still must be approved under the AMDP process.

Program Integrity

HRSA remains committed to the integrity of the 340B program, including preventing the diversion of covered drugs to non-qualified patients, and preventing drugs from being subject to duplicate discounts under both the 340B program and Medicaid rebate program. While the final notice includes some recommended contract language, the exact method of ensuring compliance is left up to the covered entity. At a minimum, however, the final notice now requires, rather than suggests as in the proposed version, the following provisions to be addressed in an agreement:

- Ship to, Bill to Procedure—The covered entity must purchase the drug; the manufacturer will bill the covered entity but ship to the contract pharmacy.
- Comprehensive Pharmacy Services—The agreement between the covered entity and the contract pharmacy must set forth who is responsible for services, including dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile and counseling, and medication therapy management services. The covered entity must specify which arrangements, if any, it is using and the names of participating pharmacies.
- Tracking System—The contract pharmacy, along with the covered entity, must create and maintain a tracking system to prevent diversion of drugs to non-qualified individuals.
- Patient Eligibility Verification—The covered entity and the contract pharmacy must develop a system to verify patient eligibility in order to ensure that only those eligible to receive discounted drugs do so.
- Arrangements to Prevent Duplicate Discounts—If a party wants to dispense Medicaid prescriptions under 340B, the contract pharmacy, covered entity, and state Medicaid agency must have an established system to prevent duplication of discounts.
- Audits—Both the contract pharmacy and covered entity must be aware that they are subject to audits related to the drug resale or transfer prohibition and prohibition against duplicate discounts.

Additional obligations required by the Office of Pharmacy Affairs (“OPA”), which administers the 340B program, include the following:

- Certification of Contract Pharmacy Compliance—Covered entities must submit to the OPA a certification that states that the contract pharmacies will comply with the program integrity requirements.
- Immediate Response in the Event of Diversion or Duplicate Discounts—If a covered entity determines that drug diversion or duplicate discounts have occurred, it must take remedial action and notify the OPA of steps taken to remedy the situation.
- Recertification Process for Covered Entities—Beyond contract pharmacy requirements, the OPA used this notice to implement a new recertification requirement, most likely to be performed annually, in which covered entities certify their compliance with 340B requirements.

If you would like to learn more about the issues raised by this update, please contact your usual Ropes & Gray attorney.

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