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HRSA Finally Publishes *Final* Contract Pharmacy Guidelines For 340B Program

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On March 5, 2010, the Health Resources and Services Administration ("HRSA") published the ***final*** Contract Pharmacy Guidelines, nearly three years after the close of the comment period to its proposed guidelines.[1] The final guidelines now formally recognize the ability of a 340B covered entity to enter into a broader range of arrangements with contract pharmacies.

To what extent can covered entities enter agreements with contract pharmacies?

Prior to the issuance of these final guidelines, a covered entity was allowed to use only a single point of service for pharmacy such that it could not supplement an in-house pharmacy with a contract arrangement. Also, prior to the issuance of these final guidelines, a covered entity could only enter into an agreement with one contract pharmacy. A limited variety of other arrangements could be approved as Alternative Methods Demonstration Projects. These final guidelines now expand the types of permissible contract pharmacy arrangements.

First, covered entities may enter into agreements with multiple contract pharmacies, either through multiple contracts with individual pharmacies or through a single contract with a chain pharmacy that identifies the specific pharmacy locations that will participate. Second, covered entities now are allowed to enter into arrangements with the contract pharmacies to supplement pharmacy services that the covered entity, itself, provides to patients of the covered entity. HRSA, however, did refuse to incorporate network arrangements (*i.e.*, arrangements involving a network of more than one covered entity) into the expanded types of allowable contractual arrangements because

[1] Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010). http://edocket.access.gpo.gov/2010/pdf/2010-4755.pdf.

of ongoing concerns about the ability of such arrangements to maintain program integrity.

What are the essential covered entity compliance elements for contract pharmacy arrangements?

HRSA declined to incorporate a list of model contract terms into the final guidelines. Instead, HRSA provided a list of essential elements that must be addressed in contract pharmacy arrangements. These essential elements include:

- a covered entity must be the party purchasing the drug;
- the agreement must specify that the parties will provide comprehensive pharmacy services;
- the covered entity must inform patients that they are free to choose a pharmacy provider;
- the contract pharmacy may provide other services to the covered entity or its patients;
- both parties will adhere to federal, state and local laws;
- the contract pharmacy must provide the covered entity with reports that are consistent with standard business practice;
- both parties will work together to establish and maintain a tracking system sufficient to prevent diversion and verify patient eligibility;
- the drugs purchased under 340B will not be used to fill Medicaid prescriptions;
- both parties will identify information that is necessary for the covered entity to evaluate whether the program is in compliance and the contract pharmacy will make such information available for use in independent audits performed by covered entity;
- both parties will be subject to outside audits; and
- a copy of the contract must be provided to the Office of Pharmacy Affairs ("OPA") upon written request.

What significant proposals from the public comments did HRSA reject?

HRSA rejected any significant proposals from the public for having additional requirements on covered entities and their contract pharmacies, including mandatory audits and mandatory contract submission. In response to comments proposing that covered entities conduct mandatory audits, HRSA noted that "[a]s long as covered entities comply with their obligations under the guidelines, HRSA prefers to leave the method of compliance to the judgment of the covered entities."[2] HRSA rejected the proposal that covered entities must submit contracts to HRSA, by stating that "HRSA does not have the need, or the resources to collect and review each contract," although

[2] 75 Fed. Reg. 10,274.

HRSA did emphasize that "the covered entity bears responsibility for compliance . . . and will be held accountable" if the covered entity fails to comply.[3]

Conclusion

HRSA's lack of authority and resources to undertake additional oversight functions and its insistence that the covered entity is responsible for ensuring compliance of its own behavior with contract pharmacy arrangements is consistent with its position historically.

Significantly, the Patient Protection and Affordable Care Act, provides HRSA with additional authority to penalize covered entity noncompliance. Included in this new authority is the ability to require covered entities that "knowingly and intentionally" divert drugs to non-patients to pay interest on amounts they are required to refund to manufacturers.[4] Additionally, this section grants HRSA the authority to "remove the covered entity from the drug discount program" if the covered entity's drug diversion "was systematic and egregious as well as knowing and intentional."[5] Consequently, there may be sufficient additional pressure to encourage covered entity compliance even in the absence of the additional oversight sought by the public during this protracted public comment period.

Finally, it should be noted that HRSA has not yet finalized another set of proposed guidelines issued in early 2007 intended to clarify the definition of "patient of the entity," which, significantly, determines the individuals to whom covered entities may dispense drugs purchased under the 340B Program.

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This Client Alert was authored by Constance A. Wilkinson, Benjamin S. Martin and Daniel Gottlieb. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the EpsteinBeckerGreen attorney who regularly handles your legal matters.

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EDITOR

[3] 75 Fed. Reg. 10,276.
[4] H.R. 3590 § 7102. (Section (a)(5)(B) prohibits covered entities from "sell[ing] or otherwise transfer[ring] a drug to an individual who is not a patient of the covered entity").
[5] H.R. 3590 § 7102.

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