



# Life Sciences Health Industry Alert

If you have questions or would like additional information on the material covered in this Alert, please contact one of the authors:

**Joseph W. Metro**

Partner, Washington, D.C.  
+1 202 414 9284  
jmetro@reedsmith.com

**Elizabeth O'Brien**

Associate, Washington, D.C.  
+1 202 414 9289  
eobrien@reedsmith.com

...or the Chair of the Life Sciences Health Industry Group,

**Michael K. Brown**

Partner, Los Angeles  
+1 213 457 8018  
mkbrown@reedsmith.com

## Office of Pharmacy Affairs Publishes Final Notice Allowing Covered Entities to Use Multiple Contract Pharmacies

Under the Public Health Service Act's Section 340B drug pricing program ("340B Program"), manufacturers who sell covered outpatient drugs to specific federal grantees, federally-qualified health center look-alikes, and qualified disproportionate share hospitals ("covered entities") must agree to charge less than the statutorily-prescribed maximum price for those drugs. This results in significant savings on drugs for the covered entities. Previously, the Health Resources and Services Administration ("HRSA") Office of Pharmacy Affairs ("OPA") had specified procedures under which discounts could be made available to covered entities engaging a single contract pharmacy, and had conducted an Alternative Methods Demonstration Project ("AMDP") program in which HRSA approved a limited number of covered entities using multiple contract pharmacies.

On March 5, 2010, the Office of Pharmacy Affairs published a Final Notice allowing covered entities to use multiple contract pharmacies. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010), available at <http://edocket.access.gpo.gov/2010/pdf/2010-4755.pdf>. This Final Notice replaces "Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services (61 Fed. Reg. 43,549) and all other previous 340B Program guidance regarding non-network contract pharmacy services. For previous guidance, see <http://www.hrsa.gov/opa/federalregister.htm>. These final guidelines give covered entities and contract pharmacies a great deal of freedom in structuring their contract pharmacy services agreements, so long as they implement and maintain mechanisms to ensure compliance with 340B Program rules, especially against diversion of drugs.

### A. Contract Pharmacy Services Mechanism

#### 1. Pharmacy services contracts: basic compliance issues

Under the Final Notice, covered entities may contract with multiple pharmacies in order to supplement "in-house" pharmacy services or to increase patient access to 340B drugs. The Final Notice requires that each covered entity has a written contract in place between itself and a contract pharmacy, in compliance with the certification requirements described below. HRSA gives covered entities wide latitude in designing these contracts, but reminds covered entities that they are responsible for ensuring against illegal diversion and meeting the other 340B Program requirements.

#### 2. Potential alternatives to single location/single pharmacy model

Covered entities may contract with multiple pharmacies if (a) there is a written agreement that addresses the compliance issues mentioned above; (b) the written agreement fully addresses essential covered entity compliance elements and the covered entity's ongoing responsibility to ensure compliance, and includes a list of all pharmacy locations covered by the agreement; (c) all 340B Program requirements are met and no drug diversion is created; (d) the arrangements include one or a combination of multiple contract pharmacy sites and/or using contract pharmacy(ies) to supplement in-house pharmacies; and (e) the arrangement involves one single 340B covered entity unless authorized in writing by HRSA.

#### 3. Essential covered entity compliance elements

HRSA provides a long list of essential covered entity compliance elements. But, as noted in the comments, these are merely elements and not model contract provisions. The elements include the following provisions:

(a) Pursuant to applicable federal, state and local laws, the covered entity must purchase and maintain title to the drug and establish its price using the "ship to, bill to" procedure. Under this procedure, the covered entity buys the drug from the manufacturer, the manufacturer ships the drug to the contract pharmacy, and the manufacturer bills the covered entity. For a covered entity with

more than one site, the covered entity can choose to have each site billed individually for 340B drug purchases or to have one single billing address.

(b) Covered entities may provide comprehensive pharmacy services to one or multiple locations and/or in-house. The agreement between the covered entity and the pharmacy(ies) must specify the responsibility of the parties to provide the pharmacy services, including, for example, dispensing, recordkeeping, etc.

(c) A patient may choose any pharmacy provider to fill his/her prescription. If the patient chooses to fill her prescription at a pharmacy that is not the covered entity's contract pharmacy, then the manufacturer of the drug does not have to provide that drug at the 340B price.

(d) The covered entity may elect that the contract pharmacy provide other services to the covered entity or its patients (e.g. home care or delivery); however, only patients of the covered entity will have access to the 340B pricing.

(e) The covered entity and contract pharmacy(ies) must adhere to all federal, state, and local laws.

(f) The contract pharmacy must provide the covered entity with reports consistent with customary billing statements.

(g) The contract pharmacy, with the assistance of the covered entity, must establish and maintain a tracking system to prevent diversion to individuals who are not patients of the covered entity.

(h) The covered entity and contract pharmacy must develop a system to verify patient eligibility, as specified by HSRA guidelines, in order to avoid drug diversion to individuals who are not patients of the covered entity.

(i) The covered entity, contract pharmacy, and state Medicaid agency must establish an arrangement before either the covered entity or the contract pharmacy provides 340B-purchased drugs to dispense a Medicaid prescription.

(j) In order to comply with these elements, the covered entity and contract pharmacy must establish key information to collect to ensure compliance and procedures so the covered entity can perform periodic independent audits.

(k) Both the contract pharmacy and covered entity are subject to outside audits by the Department of Health and Human Services and participating manufacturers. The contract pharmacy must maintain reimbursement accounts and dispensing records and keep those records accessible to the covered entity, HRSA and manufacturer in the case of an audit.

(l) The covered entity must provide the pharmacy service agreement(s) to HRSA upon written request.

#### **4. Covered entity's ongoing compliance responsibilities**

The covered entity must engage an independent, outside auditor to perform annual audits to ensure against diversion and to prevent distributing Medicaid rebates on discounted drugs. However, HRSA gives covered entities discretion in the exact methods used, as long as the audits follow standard business practices.

#### **5. Certification**

To ensure that a covered entity "has acted in a manner which limits the potential for drug diversion," covered entities must submit certain certifications to HRSA that confirm compliance with the contract requirements and ongoing compliance responsibilities. Additionally, the Final Rule requires periodic recertification (most likely annually) of the covered entity's contact information, ongoing 340B eligibility, adherence to the rules governing covered pharmacy arrangements, and the methodology used to ensure compliance.

#### **6. Anti-Kickback Statute**

Finally, covered entities and contract pharmacies must consider the Medicare and Medicaid anti-kickback statute (42 U.S.C. §1320a-7b(b)) in negotiating and executing the governing contract pharmacy service agreement.

#### **B. Suggested Contract Provisions**

HRSA attached four sample contract provisions as an appendix to the Final Rule. HRSA noted that these sample provisions are not intended to provide a comprehensive model contract but instead

are for illustrative purposes. The sample provisions include provisions for (1) the covered entity's ownership of and direct billing for covered drugs; (2) the covered entity's verification of the contract pharmacy's tracking system to ensure against diversion of covered drugs; (3) the covered entity's opportunity to examine the tracking system; and (4) restrictions on the pharmacy's dispensing of covered drugs.

## C. Comments and Responses

HRSA received 32 comments in response to the proposed guidelines for contract pharmacy services. Many of the comments questioned HRSA's administration of certain processes and procedures. Through its responses, HRSA reiterated that each covered entity bears responsibility for implementation and compliance with the terms of the 340B Program.

**Audits.** Drug manufacturers sought the ability to audit covered entities to ensure against drug diversion. Other commenters questioned who would conduct audits of covered entities, suggested borrowing the audit requirements from the AMDP process, and questioned OPA's role in the process. HRSA's responses to these comments stress the importance of independent audits of covered entities in ensuring integrity and also confirm that covered entities would be responsible for creating and implementing their own audit procedures, including possible implementation of audits of contract pharmacies. Moreover, HRSA does not require covered entities to submit audits unless there is a situation that warrants HRSA's request of those records.

**Diversion.** On the issue of diversion, commenters challenged inadequate safeguards against diversion and questioned record segregation and policies and procedures against diversion. In responding to these comments, HRSA reaffirmed the necessity of safeguards to protect against diversion, encouraged the use of record segregation as one of the many to comply with 340B requirements, and reiterated the need for covered entities to have in place written policies and procedures to prevent diversion as required by the 340B Program.

**Network Models.** HRSA discussed comments regarding the use of network arrangements, which are arrangements involving a network of more than one covered entity. HRSA declined to include network arrangements under this guidance until network arrangements have been tested by the AMDP process.

**Model Agreement Provisions/Covered Entity Compliance Elements.** HRSA's overall response to comments regarding the Covered Entity Compliance Elements was to emphasize that the covered entity bears responsibility for complying with the 340B Program. HRSA also declined to require covered entities to provide copies of contracts to anyone—including manufacturers—upon request.

**Miscellaneous Comments.** One commenter questioned whether anti-kickback provisions would prohibit pharmacies from offering Medication Therapy Management and mail-order pharmacy services. Without opining on the question specifically, HRSA reminded covered entities that they are not exempt from anti-kickback provisions.

HRSA addressed a question about whether a manufacturer who extends the 340B drug price to a patient who declines to use the contract pharmacy would set a new best price for the drug. The Administration states that answering that question was beyond the purview of the Final Rule, but encourages questions about best price to contact the Centers for Medicare and Medicaid Services.

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For additional information on the notice or other questions regarding the 340B Program or other government pricing programs, please contact Elizabeth O'Brien or Joseph W. Metro in the Washington office.

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