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HRSA ISSUES REVISED GUIDELINES FOR 340B CONTRACT PHARMACY SERVICES

On March 5, 2010, the Health Resources and Services Administration (HRSA) issued a Final Notice regarding contract pharmacy services and the 340B Drug Pricing Program.[1] Effective April 5, 2010, these guidelines replace HRSA's previous guidance on this issue. Previously, 340B covered entities could dispense their 340B drugs either through an in-house pharmacy or a contract pharmacy, with one contract pharmacy allowed for each covered entity site that lacked an in-house pharmacy. Under the new guidance, covered entities may use multiple contract pharmacy service sites, either alone or in combination with in-house pharmacy services, and may do so without prior approval by HRSA. Where a contract pharmacy arrangement is used, the 340B covered entity purchases and pays for its 340B drugs, but the manufacturer or wholesaler ships the drugs directly to one or more contract pharmacies for distribution to patients of the covered entity.

I. OVERVIEW OF 340B CONTRACT PHARMACY ARRANGEMENTS

Although the 340B statute requires manufacturers to provide discounts to covered entities on covered outpatient drugs, it contains no requirement that covered entities dispense 340B drugs themselves. HRSA has taken the position that covered entities may therefore use a contract pharmacy to distribute drugs, as long as they comply with the statutory prohibitions against drug diversion and double discounts. The 340B statute prohibits covered entities from diverting drugs to individuals who are not patients of the entity, and it places an obligation on covered entities to insure that, with respect to drugs dispensed to Medicaid beneficiaries, the state does not seek a Medicaid rebate on drugs sold to the covered entity at the 340B discounted price.[2]

In 1996, HRSA published guidelines governing contract pharmacy arrangements.[3] Under these guidelines, covered entities could have only one contract pharmacy dispensing 340B drugs for any site, and they were limited to either an in-house pharmacy or a contract pharmacy at each site, but not both. The Alternative Methods Demonstration Projects (AMDP) program, which HRSA created in 2001, provided a limited exception to this general rule. Under the AMDP

1 75 Fed. Reg. 10,272 (Mar. 5, 2010).
2 42 U.S.C. § 256b(a)(5)(A), (B).
3 61 Fed. Reg. 43,549 (Aug. 23, 1996).

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program, covered entities that apply and are approved by HRSA may: (a) use multiple contract pharmacy service sites; (b) use a contract pharmacy to supplement in-house pharmacy services; and/or (c) develop a network of covered entities.

The new guidelines allow for the first two options above without prior approval through the AMDP program. Covered entities now have three options for contract pharmacy services: (a) contract with a single pharmacy for each covered entity clinical site; (b) use multiple contract pharmacy service locations; and/or (c) use a contract pharmacy or pharmacies to supplement in-house pharmacy services, by purchasing 340B drugs at both an in-house pharmacy and at least one additional contract pharmacy location. Covered entities are not limited in the number of contract pharmacies they may use. HRSA has declined, however, to allow "networks" (groups of various covered entities) to contract for pharmacy services without approval through the AMDP process, citing concerns about maintaining the integrity of the 340B program with such complex arrangements.[4]

II. ESSENTIAL COVERED ENTITY COMPLIANCE ELEMENTS

Other than permitting these new multiple-pharmacy arrangements, the new guidelines make few substantive changes to the 1996 contract pharmacy guidelines. Notably, where covered entities were previously "encouraged" to have a contract pharmacy service agreement in place with the contract pharmacy, such a written agreement is now required. A covered entity that has more than one 340B eligible site may have individual contracts for each such site, or the covered entity may include multiple sites within a single pharmacy services contract if the sites are "integral parts" of the covered entity over which it has legal control.[5] A separate contract is required for each pharmacy; in the case of chain pharmacies, the contract must list all pharmacy locations included under the agreement.[6]

The guidelines do not require any specific provisions in these written agreements between covered entities and their contract pharmacies. Instead, the guidelines include a list of "essential covered entity compliance elements," and some "suggested" contract provisions. According to HRSA, the essential compliance elements are guidance for the type of contractual provisions expected in such agreements, but are not intended to be required contract provisions.[7] All covered entities must certify that all the compliance elements have been "addressed" in each contract pharmacy agreement (as discussed in Section IV), but entities have discretion to negotiate contract provisions suitable to their individual circumstances.[8] Further muddying the waters, the notice includes an appendix of "suggested contract provisions," but these provisions differ from the essential covered entity compliance elements and do not mention the 340B prohibition on duplicate discounts. According to HRSA , the appendix provisions "are not meant to be comprehensive, exhaustive or required" and "are not intended to be used as the complete terms of the contract."[9] The covered entity bears ultimate responsibility for ensuring compliance with the 340B program requirements.

HRSA has also removed the suggested contract provision, present in the 1996 guidelines, that covered entities provide copies of their contract pharmacy contracts to manufacturers upon request. The current guidelines state that if a manufacturer demonstrates a "reasonable need" for a copy of the contract and its request for a copy has been denied, the manufacturer may ask HRSA to obtain a copy.[10]

III. ONGOING RESPONSIBILITY OF COVERED ENTITY TO ENSURE COMPLIANCE

Although the revised guidelines emphasize that covered entities have a responsibility to prevent diversion and duplicate discounts, they do not require that covered entities or contract pharmacies use any specific

4 75 Fed. Reg. at 10,275, 10,277.
5 *Id.* at 10,275.
6 *Id.* at 10,275, 10,277.
7 *Id.* at 10,277.
8 *Id.* at 10,276.
9 *Id.*
10 *Id.*

mechanisms to prevent violations. Instead, the essential covered entity compliance elements include a general requirement that the covered entity and contract pharmacy "identify the necessary information for the covered entity to meet its ongoing [compliance responsibilities] and establish mechanisms to ensure availability of that information for periodic independent audits performed by the covered entity."[11] The guidelines intentionally do not specify the precise method, personnel, or items for satisfying this requirement.[12]

Therefore, while AMDP programs are audited annually by an independent, outside auditor for drug diversion and duplicative discounts, HRSA did not retain an outside audit requirement in the contract pharmacy guidelines. Instead, "[a]nnual audits performed by an independent outside auditor with experience auditing pharmacies are expected, although the exact method of ensuring compliance is left up to the covered entity."[13] HRSA also rejected the AMDP requirement that it be provided all audit results; however, if any compliance activity or audit indicates that there has been a violation of the 340B program requirements, these findings must be disclosed to HRSA along with the covered entity's plan to address the violation.[14]

HRSA also declined to require several suggested mechanisms to safeguard against diversion. For example, one comment suggested that HRSA limit the number of contract pharmacies that covered entities could use or prohibit the use of out-of-state pharmacies, because monitoring such pharmacies could be extremely difficult. HRSA stated that it understood the commenter's concerns, but reiterated that it did not intend to prescribe the methods covered entities should use to ensure compliance.[15] HRSA also refused to prohibit contract pharmacies from dispensing 340B drugs without confirming beforehand that the individual is a "patient" of the covered entity at the time the prescription is filled. In response to a comment suggesting such a requirement, HRSA said that while only patients of the covered entity are eligible to receive 340B drugs, "at this time, HRSA has chosen not the require time-of-service verification as suggested in the comment."[16] As a practical matter, it is unclear how a contract pharmacy could satisfy its obligation to ensure against diversion without time-of-services verification.

IV. CERTIFICATION

The revised guidelines impose a mandatory certification requirement on covered entities. Entities must certify to HRSA that they have signed and have in effect an agreement with their contract pharmacy or pharmacies that fully addresses the essential covered entity compliance elements, and that they have a plan to meet their ongoing responsibilities to ensure compliance. In addition, any covered entity using multiple contract pharmacy locations or supplementing its in-house pharmacy services with contract pharmacy services must specify which arrangement it is using and the names of the participating pharmacies. Covered entities must also notify HRSA of any material changes in their contract pharmacy arrangements that require changes in the covered entity database.[17]

The names of covered entities that submit a certification, or an approved alternative mechanism, will be listed on the HRSA 340B website. The guidelines also state that HRSA may conduct a periodic recertification process (likely annually) where covered entities would affirmatively certify their ongoing program compliance. HRSA currently expects that this process would include the following certifications:

> (1) That all information listed on the database for that covered entity is complete, accurate, and correct; (2) that the covered entity met the 340B eligibility requirements throughout the prior year and continues to do so; (3) that any contract pharmacy arrangement was actually performed in accordance with specified requirements including, but not limited to, that the

11 *Id.* at 10,278.
12 *Id.* at 10,274.
13 *Id.* at 10,278.
14 *Id.* at 10,274, 10,278.
15 *Id.* at 10,276.
16 *Id.* at 10,277.
17 *Id.* at 10,278-79.

covered entity obtained sufficient information from the contractor to ensure compliance with applicable policy and legal requirements; and (4) the methodology utilized to ensure compliance (e.g., through independent audit or other mechanism).[18]

HRSA does not specify when it expects to start this annual recertification process. Once operational, however, the proposed recertification process has the potential to add transparency and accountability to the contract pharmacy process.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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18 *Id.* at 10,279.