COVINGTON

COVINGTON & BURLING LLP

E-ALERT | Food & Drug

July 26, 2013

HRSA ISSUES FINAL 340B ORPHAN DRUG EXCLUSION RULE IMPOSING NEW OBLIGATIONS ON COVERED ENTITIES AND CREATING NEW RISKS FOR MANUFACTURERS

The long-awaited Final Rule for the 340B orphan drug exclusion was published earlier this week that, according to the Health Resources and Services Administration (HRSA), seeks to "provide clarity in the marketplace, maintain 340B savings for newly eligible covered entities, and protect the financial incentives for manufacturing orphan drugs."[1] The finalized rule from HRSA implements a provision of the Affordable Care Act (ACA) that allowed four new categories of covered entities to participate in the program while simultaneously narrowing the definition of "covered outpatient drugs" for these entities to exclude orphan drugs. Under the Final Rule, ACA covered entities will be entitled to the 340B ceiling price on an orphan drug only if the entity uses the drug for a non-orphan indication, and use for the orphan indication shall be considered to be outside the 340B program. The effective date of the Final Rule is October 1, 2013, and it will apply only prospectively. Although the Final Rule mirrors many aspects of HRSA's 2011 proposed rule, on which we have previously reported, the Final Rule also contains some key changes and other significant requirements for covered entities and contract pharmacies.

CLARIFICATION OR INCONSISTENCY WITH STATUTORY TEXT?

The Final Rule adopts the 2011 proposal to apply the orphan drug exclusion only when an orphan drug is used for the FDA-designated orphan indication, rather than for all uses of a drug with an orphan designation. Although the Final Rule meets HRSA's goal of providing clarity on orphan drug exclusions for covered entities under the 340B Program, it appears to be inconsistent with the plain language of the statute.

When the ACA expanded the 340B program to include free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals, the condition on this expansion was that for these entities, "the term 'covered outpatient drug' shall not include *a drug* designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition."[2] By its plain language, the statute excludes all sales of the "drug," irrespective of the disease or condition for which the drug is ultimately used. In other contexts, when Congress has intended for an orphan drug benefit to be limited to a specific indication, Congress has clearly stated so.[3]

However, HRSA rejected manufacturers' comments on this issue and stated that "[t]he fact that drugs can have multiple indications, only some of which qualify for orphan designation, has led

---

[1] 78 Fed. Reg. at 44016. The publication of the Final Rule follows a series of developments in what we have observed has been an eventful year for the 340B Drug Discount Program, a program that allows "covered entities" to purchase "covered outpatient drugs" at a discounted price.

[2] 42 U.S.C. § 256b(e) (emphasis added).

[3] *See, e.g.*, Pub. L. 111-148, § 9008(e)(3); 26 U.S.C. § 45C(b)(2)(B); 21 U.S.C. § 360cc (providing that the seven-year period of market exclusivity for orphan drugs applies only to approvals of that drug for the designated rare disease or condition).

[HRSA] to conclude, consistent with the statutory language, that the exemption from the term 'covered outpatient drug' under section 340B(e) of the PHSA applies to orphan drugs only when they are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drug was designated."[4] Although HRSA's interpretation may be subject to some debate, absent challenge, it will govern purchasing of orphan drugs by affected covered entities effective October 1, 2013.

NEW RECORDKEEPING BURDENS FOR 340B ENTITIES AND CONTRACT PHARMACIES

As noted above, pursuant to the Final Rule, only some sales of orphan drugs will be excluded from the 340B program — sales of orphan drugs for orphan indications are to be excluded from the program (and thus not subject to the required discount), and sales of orphan drugs for non-orphan indications may be included and purchased at the statutory discounted price. The Final Rule makes clear that it is the responsibility of covered entities to ensure that orphan drugs purchased through the 340B program are not to be transferred, prescribed, sold, or otherwise used for the orphan indication. Entities must keep auditable records to demonstrate compliance with this requirement and provide such records upon HRSA's request or in response to a government-approved manufacturer audit. The Final Rule adds the new requirement that entities who cannot or do not wish to comply with this record-keeping requirement must notify HRSA and purchase all orphan drugs outside the 340B program, regardless of the indication for which the drug is to be used. Thus, covered entities must affirmatively decide to accept these recordkeeping requirements, and the Final Rule indicates that compliance will be monitored and reaffirmed during annual recertification of covered entities.

Free-standing cancer hospitals must also continue to comply with the prohibition against using a Group Purchasing Organization (GPO) for drugs under the 340B program. However, if this type of entity is purchasing an orphan drug for the orphan indication, which must necessarily be done outside the 340B program, the entity may use the GPO. But, if this entity is unable to track drug use by indication, the entity must purchase all drugs outside the 340B program and may not use the GPO for any purchases of the product. In contrast, an enrolled critical access hospital is permitted to use GPOs for 340B drugs, and may therefore use a GPO to purchase orphan drugs whether or not the drug is used for the orphan indication.

The varying requirements that apply to different entities suggest that manufacturers may want to consider monitoring orphan drug usage by different entities and notify HRSA or initiate the manufacturer audit process in the event of an indication that the requirements of the Final Rule are not being adhered to.

One commenter asked HRSA to clarify how the new record-keeping requirements would apply to contract pharmacies. HRSA made clear that "contract pharmacies are under the same compliance requirements with this rule as a covered entity," and as such, contract pharmacies are required to maintain auditable records and demonstrate compliance in either a HRSA audit or a manufacturer audit.[5] Affected covered entities that utilize a contract pharmacy that is unwilling or unable to maintain such auditable records must purchase all orphan drugs outside the 340B program. Thus, contract pharmacies must consider whether they are willing and able to comply with these new requirements, which may not be required by their current contract pharmacy agreement, but have now been imposed by the Final Rule.

---

[4] 78 Fed. Reg. at 44020.
[5] 78 Fed. Reg. at 44024-44025.

LINGERING UNCERTAINTY ABOUT IMPACT ON OTHER PRICE CALCULATIONS

While the background to the new rule states that "the law does not prohibit manufacturers from charging a price for a drug that is lower than the maximum price that may be charged under section 340B(a)(1),"[6] HRSA does not clarify how sub-ceiling prices will impact a manufacturer's best price calculation under the Medicaid Drug Rebate Program (MDRP). Instead, HRSA declined to address the issue and merely noted that "[i]n the absence of specific guidance, manufacturers may make reasonable assumptions in their calculations."[7] This issue is particularly unclear because of CMS's 2012 proposal to revise the MDRP regulation, which would limit the exclusion from the best price calculation for sales to 340B entities to ''[p]rices charged under the 340B drug pricing program."[8] The existing rule applies to "any prices" charged to a covered entity.[9] Taken together, the regulatory language is ambiguous and could be interpreted to mean that discounts mistakenly offered on orphan drugs that now fall outside the 340B program could have a negative impact on best price calculations. Similarly, inadvertent sales of what are now non-covered drugs (orphan drugs sold for orphan indications) to certain covered entities at discounted prices could also have an impact on the calculation of the non-Federal Average Manufacturer's Price submitted quarterly and annually to the Department of Veterans Affairs. Manufacturers may want to seek clarification from CMS and VA prior to the October 1 effective date of the Final Rule.

* * * *

Covington & Burling LLP has extensive experience with the 340B program, the Veteran's Health Care Act, and other pharmaceutical pricing laws. We will continue to monitor developments in these areas.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our firm:

Jennifer Plitsch	+1.202.662.5611	jplitsch@cov.com
Christopher Pruitt	+1.202.662.5401	cpruitt@cov.com
Stephanie Barclay	+1.202.662.5502	sbarclay@cov.com

---

[6] 78 Fed. Reg. at 44022.
[7] *Id.*
[8] 77 Fed. Reg. 5318, 5363 (Feb. 2, 2012).
[9] 42 C.F.R. § 447.505(d)(1).