LEE ROSEBUSH / LINDSAY HOLMES

340B Compliance Issues: Contracting with Contract Pharmacies

Lee Rosebush provides his clients with legal counsel that is grounded in first-hand experience. Whether his clients are confronted with legal issues related to the naming of a drug, clinical trials, marketing, promotions, or advertising, Lee possesses a strong understanding of the pharmaceutical industry which, combined with his attention to detail and experience working with biologics, medical device, and health care companies, gives clients a single source for regulatory and litigation counsel. He can be reached at lrosebush@bakerlaw.com.

Lindsay Holmes focuses her practice on regulatory and transactional health care matters primarily in the health care and life sciences industry. She has experience advising clients on data privacy and security matters, as well as counseling on fraud and abuse and FDA regulatory matters. She can be reached at lholmes@bakerlaw.com,

Covered Entities Must Put in Place Auditing and Monitoring Policies to Ensure their Covered Entities Are Acting Properly

The 340B Drug Pricing Program allows 340B covered entities to engage outside pharmacies (contract pharmacies) to dispense 340B covered drugs to eligible patients. By doing so, the thought is to allow covered entities who (1) may not have an in-house pharmacy; (2) may not have sufficient pharmacy resources; or (3) would like to supplement pharmacy services to provide 340B drugs to patients through a third-party pharmacy. Currently, covered entities are permitted to use multiple contract pharmacies.[1]

Although beneficial from the patient access perspective, there are a number of compliance issues associated with the use of contract pharmacies by a covered entity in the 340B setting. For example, by using contract pharmacies, one could argue that there is an increased possibility of (1) duplicate discounts; (2) 340B drugs being diverted to non-eligible patients; and (3) the potential lack of oversight by a covered entity (as the pharmacy is not in-house). To address these issues, the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) has issued a number of guidance documents relating to contract pharmacies.

ELEMENTS OF AGREEMENTS

In 2010, HRSA issued a final notice outlining required contract provisions for contract pharmacies in the 340B program. The final notice was aimed at reducing the likelihood of 340B drugs being diverted to non-eligible patients and decreasing duplicate discounts (discounts for both Medicaid rebates and 340B pricing).[2] In the final notice, HRSA provided examples of the essential

elements for arrangements involving contract pharmacies. Specifically, the elements include:

1. the covered entity utilizing a "bill to, ship to" model where the covered entity purchases the 340B drugs, but the drugs are shipped directly to the contract pharmacy from the manufacturer or distributor;
2. a requirement that the covered entity inform patients of their freedom to choose a pharmacy provider;
3. written specification of pharmacy services to be provided;
4. a requirement that parties will comply with federal, state, and local laws;
5. the contract pharmacy implementing a tracking system to prevent 340B drug diversion;
6. the parties developing a system to verify patient eligibility;
7. prohibition on duplicate discounts (Medicaid and 340B); and
8. Health and Human Services (HHS) and the covered entity retain the right to audit the contract pharmacy.[3]

Covered Entity Liability

Although covered entities may utilize contract pharmacies, it should be noted that the ultimate responsibility for the disposition of 340B drugs remains with the covered entity. While a contract may include indemnification clauses, the contract will not cover responsibility for both regulatory and PR-related issues. Consequently, the covered entity is responsible for ensuring that the dispensing model that the contract pharmacy utilizes meets the ongoing requirements of the 340B Drug Pricing Program, including that 340B drugs are not diverted to non-eligible patients and that there are no duplicate discounts.[4]

For this reason, covered entities should conduct audits of their contract pharmacies to ensure ongoing compliance. In addition, covered entities should require that contract pharmacies keep adequate records to ensure the proper tracking of 340B drugs.[5]

New Mega Guidance

Recently, HRSA released the 340B Drug Pricing Program Omnibus Guidance, which reinforces the responsibilities of covered entities.[6] This Omnibus Guidance addresses the risks associated with contract pharmacies and means for covered entities to address these issues, including duplicate discounts. In the Omnibus Guidance, HRSA reiterated its position that a covered entity "retain complete responsibility" for contract pharmacy compliance with program requirements. While the 2010 final notice recommended that covered entities audit contract pharmacies annually, the Omnibus Guidance proposes standards for those audits and quarterly reviews of contract pharmacies. In fact, HRSA noted that it expects covered entities "to conduct quarterly review and annual independent audits of each contract pharmacy location."[7]

The Omnibus Guidance also encourages covered entities to evaluate current arrangements with contract pharmacies to ensure that the arrangements meet the parameters of the 340B Drug Pricing Program and benefit the covered entity in the way intended. In the Guidance, HRSA goes on to state that HHS has audited covered entity contracts with contract pharmacies and observed that covered entities do not "have sufficient mechanisms in place to ensure their contract pharmacies' compliance with all 340B Program requirements."[8]

Covered entities are not only expected to have independent auditors to review each contract pharmacy annually but also to compare 340B prescribing records with those of the contract pharmacy's dispensing records to determine that no duplicate discounts or diversions have occurred. Interestingly, on the duplicate discount front, the Omnibus Guidance also states that "when a contract pharmacy is listed on the public 340B database it will be presumed that the contract pharmacy will not dispense 340B drugs to Medicaid FFS or MCO patients."[9] Therefore, if a covered entity would like a contract pharmacy to dispense 340B drugs to these

patients, the covered entity must supply HHS with the agreement with the contract pharmacy and the state Medicaid/managed care organization (MCO) describing how the parties will prevent duplicate discounts. Then, only once the agreement is approved by HHS may a covered entity utilize a contract pharmacy in this way.

Finally, it is the responsibility of the covered entity to correct any instances of identified diversion or duplicate discounts by the covered entity and report the corrective action to HHS. HHS retains the authority to discontinue a contract pharmacy agreement if it determines that the pharmacy is not in compliance with the 340B Drug Pricing Program. This does not absolve the covered entity of liability for any diversion or duplicate discounts that occurred at that location. In fact, liability can include repayment of 340B drug costs to manufacturers.

So, What Does This All Mean?

While there was initial concern about whether the 340B Drug Pricing Program might even continue, the Omnibus Guidance demonstrates that the program will survive. With that said, covered entities must put in place auditing and monitoring policies to ensure their covered entities are acting properly. In addition, with the emphasis in the Omnibus Guidance on the fraud and abuse laws, covered entities will need to ensure their arrangements in the 340B area satisfy the federal and state anti-kickback statutes and related laws.

Endnotes:

1. Notice Regarding 340B Drug Pricing Program — Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).
2. *Id.*
3. *Id.* at 10277-10278.
4. *Id.*
5. *Id.*
6. 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300 (Aug. 28, 2015).
7. *Id. Id.* at 52321.
8. *Id. Id.* at 52311.
9. *Id. Id.* at 52309.