340B UPDATE: HRSA INDICATES IT LACKS AUTHORITY TO ENFORCE 340B PROGRAM GUIDANCE

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U.S. Health Care Alert

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The Health Resources and Services Administration (HRSA) recently indicated that it lacks authority to enforce 340B Drug Pricing Program (340B Program) guidance in response to Eli Lilly and Co.'s notice to 340B covered entities that contract pharmacies will no longer be eligible to receive formulations of its erectile dysfunction drug Cialis at 340B prices. Eli Lilly's notice challenges HRSA's longstanding interpretation of the 340B statute in its contract pharmacy guidance that has allowed contract pharmacies to access drugs at 340B prices, effectively inviting HRSA to defend its contract pharmacy guidance and statutory authority in litigation. Notably, HRSA appears to have taken no action against Eli Lilly. Rather, HRSA indicated in a public statement that its guidance documents are unenforceable, which is consistent with the Administration's broader push to prohibit enforcement actions tied to agency guidance. Given this and HRSA's response to Eli Lilly, it appears unlikely that HRSA would take action against either manufacturers or covered entities in regard to 340B Program compliance matters unless either side was acting in direct violation of a statutory program requirement or in regard to one of the areas HRSA has been found to have regulatory authority. This client alert provides an overview of these developments and their potential impact on 340B stakeholders.

BACKGROUND

Section 340B of the Public Health Service Act requires drug manufacturers to sell covered outpatient drugs to covered entities at or below a defined 340B ceiling price.[1] In 1996, HRSA issued guidance permitting covered entities to contract with a pharmacy to provide services to the covered entity's patients.[2] Highlighting that the statute is silent as to permissible drug distribution systems, HRSA noted that “it is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities.”[3]

As part of the guidance, contract pharmacies were allowed to access covered outpatient drugs through a “bill to/ship to” model, whereby the manufacturer would bill the drug to the covered entity but ship the drug to the contract pharmacy.[4] However, covered entities were generally limited to using an in-house pharmacy or contracting with a single contract pharmacy.

In 2010, HRSA issued further guidance regarding 340B contract pharmacy services.[5] The guidance permitted covered entities to contract with multiple contract pharmacies, allowing them to expand access to discounted drugs to patients through a range of pharmacies.[6] In both the 1996 and 2010 guidance, HRSA emphasized that it was neither imposing additional burdens upon manufacturers nor creating new rights for covered entities.[7] In

response to a comment to the 1996 guidance, HRSA agreed that, even in the absence of federal guidelines, covered entities have the right to hire pharmacies to act as their agents in providing pharmaceutical care.[8]

ELI LILLY'S NOTICE TO 340B COVERED ENTITIES

Eli Lilly's Notice

Eli Lilly recently issued a notice to 340B covered entities through HRSA's limited distribution drug notice process indicating that, effective July 1, it is limiting distribution of Cialis "directly to covered entities and their child sites only," noting that "contract pharmacies will not be eligible to receive these formulations of Cialis at the 340B ceiling price."[9] Orders placed with a wholesaler as of June 30 will be honored.[10] The notice provides an "exception process" for covered entities that do not have their own in-house pharmacy.[11] Eli Lilly's decision to challenge HRSA's interpretation in guidance appeared to be inviting HRSA to take action against Eli Lilly to force HRSA to defend its contract pharmacy guidance and statutory authority in litigation.

HRSA's Response to Eli Lilly's Notice

HRSA appears to have taken no action against Eli Lilly following the notice. Instead, in response to questions regarding Eli Lilly's decision, HRSA communicated to 340B Report that, although its 2010 contract pharmacy guidance remains in effect, it is not legally enforceable.[12] In this regard, HRSA noted that, unless there is a clear violation of the 340B statute, its authority to enforce certain 340B policies in guidance is limited.[13] HRSA also indicated that, without "comprehensive regulatory authority," it is unable to develop enforceable 340B policy.[14]

HRSA strongly encouraged manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements.[15] In doing so, HRSA acknowledged that manufacturers that do not honor contract pharmacy orders would significantly limit access to 340B discounted drugs for many underserved and vulnerable populations who may reside in isolated areas and rely on a contract pharmacy as a critical point of access for obtaining their prescriptions.[16]

Eli Lilly's notice came just as HRSA uploaded its federal register notices, including its 2010 guidance, to the Department of Health and Human Services' new Guidance Repository with a disclaimer that "the contents of this document do not have the force and effect of law and are not meant to bind the public in any way."[17] The Guidance Repository was created pursuant to Executive Order 13891 titled, "Promoting the Rule of Law Through Improved Agency Guidance Documents," which requires agencies to treat guidance as nonbinding in law and in practice.[18]

CONCLUSION

In a letter, a coalition of provider groups, including 340B Health, the National Rural Health Association, National Association of Community Health Centers, and the National Health Care for the Homeless Council, among other groups, is asking HRSA to intervene, arguing that Eli Lilly's action violates the 340B statute's requirement that manufacturers must offer 340B prices to eligible covered entities.[19] They note that no provision in the statute allows manufacturers to limit 340B pricing in this regard or require that a drug be shipped to a manufacturer-approved location.

In recent years, however, HRSA has increasingly taken the position that it lacks statutory authority to issue and enforce 340B policy. In 2019, for example, HRSA declined to further defend negative audit findings against

Genesis Health Care, a South Carolina-based Federally Qualified Health Center, which was widely perceived to be as a result of HRSA's lack of statutory authority to enforce a more restrictive patient definition through the audit process.[20] In addition, HRSA no longer proposes to make 340B program eligibility changes as part of its annual budget justifications.[21] Given this and HRSA's response to Eli Lilly, it is unlikely that HRSA would take action against either manufacturers or covered entities in regard to 340B Program compliance matters unless either side was acting in direct and clear violation of a statutory program element or in regard to one of the narrow areas that HRSA has been found to have regulatory authority.[22]

In this regard, one potential response to Eli Lilly's action will be a push to provide greater authority to HRSA legislatively to address contract pharmacy requirements. We would expect various stakeholder groups to be in support, including covered entities, pharmacies, and pharmacy benefit managers (given that they own specialty pharmacies that have significant contract pharmacy arrangements). With such authority, however, it is possible that HRSA might also revisit regulatory restrictions on the 340B Program it considered in the Omnibus Rule/Guidance, which were pulled back due to concerns about HRSA's statutory authority.

K&L Gates' health care and FDA practice and public policy and law practice regularly advise stakeholders on 340B Program implementation and compliance matters and facilitate stakeholder engagement with Congress and the Administration and can assist in this regard.

FOOTNOTES

[1] *See* 42 U.S.C. §256b(a).

[2] *See* 61 Fed. Reg. 43,549 (Aug. 23, 1996).

[3] *Id.*

[4] *Id.*

[5] *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010).

[6] *Id.* at 10,273.

[7] *See* 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010).

[8] *See* 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).

[9] *See* HEALTH RES. & SERVS. ADMIN., 340B DRUG PRICING PROGRAM, MANUFACTURER NOTICES TO COVERED ENTITIES, LIMITED DISTRIBUTION PLAN NOTICE FOR CIALIS® (TADALAFIL) ERECTILE DYSFUNCTION NDCS (2020).

[10] *Id.*

[11] *Id.*

[12] 340B Report is a news service that provides news and analysis about the 340B Drug Pricing Program. *See* Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B REPORT (July 9, 2020).

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *See* Dept. of Health & Human Servs., *340B Federal Register Notices*, HHS Guidance Repository.

[18] *See* 84 Fed. Reg. 55,235 (Oct. 15, 2019).

[19] *See* Tom Mirga, *Hospitals and Other Providers Ask HHS to Halt Lilly and Merck's Clampdowns on 340B; Companies Defend Their Positions*, 340B REPORT (July 17, 2020).

[20] *See* Genesis Health Care, Inc. v. Azar, No. 4:19cv-01531-RBH (D.S.C. 2019). On June 6, 2019, HRSA voluntarily voided its audit findings and closed the audit, and the district court dismissed the case.

[21] *See* Health Res. & Servs. Admin., FY 2021 Justification of Estimates for Appropriations Committees (last reviewed June 2020).

[22] The three areas of the 340B statute where courts have found HHS to have rulemaking authority are: (i) promulgating rules governing the establishment of an administrative dispute resolution process, (ii) issuance of drug ceiling price methodologies, and (iii) the imposition of civil monetary sanctions. See Pharmaceutical Research and Manufacturers of America v. HHS, 43 F. Supp. 3d 28 (D.D.C. 2014).

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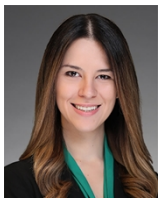

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