340B UPDATE: CONGRESS AND THE ADMINISTRATION RESPOND TO DRUG MANUFACTURERS' 340B CONTRACT PHARMACY ACTIONS

Date: 25 September 2020

Health Care and FDA Alert

By: Andrew D. Ruskin, Victoria K. Hamscho

In recent weeks, several drug manufacturers have taken actions that impact covered entities participating in the 340B Drug Pricing Program (340B Program) and their contract pharmacies. Eli Lilly and Co. (Eli Lilly) and AstraZeneca informed covered entities that they will stop replenishing drugs to 340B contract pharmacies and limit distribution to covered entities and their child sites only. In addition, Merck, Sanofi, and Novartis requested that covered entities share contract pharmacy claims data through Second Sight Solutions' 340B ESP platform. Sanofi explicitly indicated that failure to participate would result in a similar refusal to replenish contract pharmacy claims.

In response, several provider groups and policymakers have written to the Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) asking them to intervene. HHS recently responded to some of these actions. This client alert provides an overview of these developments and impact on 340B Program 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] Since 1996, HRSA has permitted covered entities to contract with a pharmacy to provide services to 340B eligible patients.[2] In guidance, HRSA allowed contract pharmacies to access drugs at 340B prices through what is known as a “bill to/ship to” model.[3] Under the “bill to/ship to” model, the drug manufacturer would bill the drug to the covered entity but ship the drug to the contract pharmacy.

Although covered entities were initially limited to using an in-house pharmacy or contracting with a single contract pharmacy, HRSA issued contract pharmacy guidance in 2010 permitting covered entities to contract with multiple contract pharmacies.[4] In both the 1996 and 2010 guidance, HRSA argued that it was neither imposing additional burdens upon drug manufacturers nor creating new rights for 340B covered entities by allowing them to contract with contract pharmacies.[5]

DRUG MANUFACTURER 340B ACTIONS

Carve Out of Contract Pharmacies

©2005-2026 K&L Gates LLP. All Rights Reserved.

In July, Eli Lilly announced that it would cease distribution of its erectile dysfunction drug Cialis to 340B contract pharmacies and limit distribution to covered entities and their child sites only, effective July 1. Eli Lilly subsequently issued a notice informing covered entities that it would be limiting distribution of "all 340B ceiling priced products" to covered entities and their child sites effective September 1. Eli Lilly said it would allow replenishment of a single contract pharmacy partner for entities that lacked an in-house outpatient pharmacy as well as replenishment of insulin products provided, in key part, that: 340B eligible patients are able to acquire the insulin at the 340B price (i.e., at the current penny price); neither the covered entity nor the contract pharmacy marks-up or charges a dispensing fee for the insulin; and no insurer or payor is billed.

Following in the footsteps of Eli Lilly, AstraZeneca sent letters to covered entities and wholesalers in August informing them that, beginning on October 1, it would also stop replenishing drugs to 340B contract pharmacies and limit distribution to covered entities and their child sites only. In a subsequent notice sent to covered entities, AstraZeneca identified a list of excluded products from contract pharmacy replenishment, which notably did not include all of AstraZeneca's retail portfolio. Like Eli Lilly, AstraZeneca also offered a carve-out for replenishment of a single contract pharmacy partner for covered entities that lacked an in-house outpatient pharmacy.

Data Sharing Requirements

Merck, Sanofi, and Novartis have sent notices to covered entities requiring that they share contract pharmacy claims data for their products through Second Sight Solutions' 340B ESP platform. The drug manufacturers note that the data request is part of a program integrity initiative. In this regard, however, the drug manufacturers indicate that they are requesting pharmacy claims data to prevent not only Medicaid duplicate discounts, which are addressed by statute, but also Part D and commercial "duplicate discounts" in instances in which the manufacturer by contract has agreed with the pharmacy benefit manager not to pay rebates on the 340B Program claims.

Merck requested that covered entities participate by August 14 while Sanofi and Novartis requested that they participate by October 1. Merck and Novartis both indicated that they may take further action against covered entities that do not participate by August 14 and October 1, but their notices did not indicate if, and if so, when, they would seek such remedies. Sanofi, however, explicitly indicated that it will cease replenishment to contract pharmacy locations—akin to Eli Lilly's and AstraZeneca's actions—for entities that do not participate by October 1.

These data sharing requirements raise practical challenges, including review of the arrangement under health care privacy regimes, the acceptance of the 340B ESP Terms of Use, and the authority of covered entities under existing agreements with contract pharmacy partners and/or their third-party administrators (TPAs) to share the data. Some contract pharmacy partners and/or TPAs have informed covered entities that they will not authorize the release of certain data.

HRSA'S INITIAL RESPONSE TO THESE ACTIONS

In early responses to these developments, HRSA indicated that, although its 2010 guidance remains in effect, it is not legally enforceable.[6] HRSA noted that, unless there is a clear violation of the 340B statute, its authority to enforce guidance is limited, adding that it is unable to develop enforceable policy without authority.[7] Most recently,

©2005-2026 K&L Gates LLP. All Rights Reserved.

HRSA indicated that it is “considering” whether manufacturers' policies violate the 340B statute and whether sanctions may apply.[8]

In this regard, over the past few years, HRSA has increasingly taken the position that it lacks statutory authority to issue and enforce 340B Program subregulatory and regulatory guidance. As discussed in more detail in our client alert here, 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 perceived to be as a result of HRSA's lack of statutory authority to enforce a more restrictive patient definition through the audit process.[9] In addition, HRSA has not proposed to make 340B Program eligibility changes as part of its annual budget justifications as it had done in previous years.[10]

STAKEHOLDER AND CONGRESSIONAL RESPONSE

Notwithstanding HRSA's initial position, a number of provider groups and policymakers have sent letters to HHS and HRSA asking them to intervene in this matter. A 340B coalition, including 340B Health, the American Hospital Association, and several provider groups, asked HHS to prohibit manufacturers from taking action against covered entities that do not submit their data to 340B ESP and to prevent them from limiting 340B pricing.[11]

Following up, congressional leaders in both the House and Senate have also asked HHS and HRSA to step in. In the House, a bipartisan group of more than 243 members of Congress, including a number of Republicans, sent a letter to HHS and HRSA on September 12 stressing that these manufacturer actions violate the 340B statute.[12] This letter followed a letter by House Energy and Commerce Committee leaders expressing their concerns over these actions and noting that “Congress has provided [HHS] with tools, including manufacturer auditing rights and civil monetary penalties, to enforce [the 340B statute].”[13]

In the Senate, a group of 28 senators, including Senate Majority Whip John Thune (R-SD)—the Senate's second-highest ranking Republican—wrote to HHS on September 18 urging the department to take “immediate and appropriate enforcement action.”[14] A group of 22 Democratic senators wrote to an industry trade association requesting a response “regarding steps being taken by the industry to end denials of 340B pricing for drugs dispensed through contract pharmacies and demands for contract pharmacy claims data no later than September 29, 2020.”[15]

HHS RESPONDS TO CONTRACT PHARMACY CARVE-OUTS

In response, on September 22, HHS took the extraordinary step of making public its most recent response to Eli Lilly's request for a pre-enforcement advisory opinion as to whether its actions would subject it to sanctions. In its response letter, HHS noted that HRSA has “significant initial concerns” with Eli Lilly's recent actions. HHS said that HRSA is continuing to review Eli Lilly's policy and has yet to make a final determination as to any potential enforcement action.[16] However, HHS stressed that Eli Lilly should not view this as “somehow endorsing Lilly's policy,” adding that “Lilly's decision to interpret HRSA's responses as tantamount to definitive agency agreement with Lilly's position is incorrect.”[17] HHS also expressed its view that Eli Lilly's timing for the pricing changes is “insensitive to the recent state of the economy,” highlighting specifically the price of Lilly's stock and increased income during the course of the COVID-19 pandemic.[18]

©2005-2026 K&L Gates LLP. All Rights Reserved.

CONCLUSION

As noted above, Merck originally set a deadline of August 14 for covered entities to begin sharing their contract pharmacy data, and Sanofi and Novartis are requiring that covered entities participate in their pharmacy claims data sharing program by October 1. Likewise, AstraZeneca was poised to take action to terminate contract pharmacy replenishment of certain of its drugs effective October 1. How manufacturers will respond to the congressional and administrative response is yet to be seen. K&L Gates' health care and FDA practice and public policy and law practice regularly advise 340B stakeholders on 340B Program compliance and strategy matters and facilitate engagement with Congress and the administration on 340B Program matters.

FOOTNOTES

[1] *See* 42 U.S.C. § 256b(a).
[2] *See* 61 Fed. Reg. 43,549 (Aug. 23, 1996).
[3] *Id*.
[4] *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010).
[5] *See* 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010).
[6] *See* Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B REPORT (July 9, 2020), here.
[7] *Id*.
[8] *See* Tom Mirga, *HRSA is Investigating Whether Manufacturer Policies to Restrict 340B Pricing at Contract Pharmacies Violates Statute*, 340B REPORT (July 9, 2020), here.
[9] *See* Genesis Health Care, Inc. v. Azar, No. 4:19-cv-01531-RBH (D.S.C. 2019). On 6 June 2019, HRSA voluntarily voided its audit findings and closed the audit, and the district court dismissed the case.
[10] *See* HEALTH RES. & SERVS. ADMIN., FY 2021 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES, here (last visited Sept. 2020).
[11] *See* Letter from 340B Health et al. to Alex M. Azar, Sec'y, U.S. Dep't of Health & Hum. Res., here (last visited Sept. 2020).
[12] *See* Letter from Rep. David B. McKinley et al. to Alex M. Azar, Sec'y, U.S. Dep't of Health & Hum. Res., here, (last visited Sept. 2020).
[13] *See* Press Release, House Energy & Commerce Comm., E&C Leaders to Azar: Protect the 340B Drug Pricing Program, here, (last visited Sept. 2020).
[14] *See* Press Release, Senator John Boozman, Boozman Urges HHS to Protect 340B Prescription Drug Pricing Program, here, (last visited Sept. 2020).
[15] *See* Letter from Rep. Richard Blumenthal et al. to Stephen J. Ubl, President, PhRMA, here, (last reviewed September 2020).
[16] *See* HEALTH RES. & SERVS. ADMIN., HHS LETTER TO LILLY, here, (last reviewed Sept. 2020).
17 *Id*.
18 *Id*.

©2005-2026 K&L Gates LLP. All Rights Reserved.

KEY CONTACTS



ANDREW D. RUSKIN
PARTNER

WASHINGTON, DC
+1.202.778.9415
ANDREW.RUSKIN@KLGATES.COM



VICTORIA K. HAMSCHO
ASSOCIATE

WASHINGTON, DC
+1.202.778.9137
VICTORIA.HAMSCHO@KLGATES.COM

This publication/newsletter is for informational purposes and does not contain or convey legal advice. The information herein should not be used or relied upon in regard to any particular facts or circumstances without first consulting a lawyer. Any views expressed herein are those of the author(s) and not necessarily those of the law firm's clients.

©2005-2026 K&L Gates LLP. All Rights Reserved.