340B UPDATE: RYAN WHITE CLINICS SUE IN RESPONSE TO CONTRACT PHARMACY ACTIONS AS CONGRESS REQUESTS INFORMATION ON WAYS TO IMPROVE THE 340B PROGRAM

Date: 16 October 2020

Health Care and FDA Alert

By: Andrew D. Ruskin, Victoria K. Hamscho

Covered entities participating in the 340B Drug Pricing Program (340B Program) continue to grapple with drug manufacturers' actions to limit contract pharmacy access to 340B pricing. Ryan White clinics recently sued the Department of Health and Human Services (HHS) and Health Resources and Services Administration (HRSA) in federal district court, asking the court to direct the Secretary of HHS to:

- declare that they are entitled to dispense drugs through contract pharmacies at 340B pricing;
- promulgate 340B administrative dispute resolution regulations;
- enforce their rights to dispense drugs through contract pharmacies at 340B pricing;
- use his power to force manufacturers to refund them for overpayments on drugs they have refused to sell at 340B prices when ordered via contract pharmacy arrangements;
- use his power to impose civil monetary penalties upon drug manufacturers unless and until they honor contract pharmacy arrangements; and
- revoke the pharmaceutical pricing agreement (PPA) of any manufacturer that does not offer drugs at 340B pricing when ordered via a contract pharmacy.

Republican leaders from the Senate Health, Education, Labor, and Pensions (HELP) Committee and House Energy and Commerce (E&C) Committee are also requesting stakeholder feedback by October 30 on ways to improve the 340B Program. This client alert provides an overview of these developments.

Key takeaways include:

- The Ryan White clinics' lawsuit could put into play a decision by a court as to the enforceability of HRSA's 340B guidance which, if decided in the negative, could result in HRSA withdrawing its guidance supporting contract pharmacy arrangements and render these arrangements problematic.
- The congressional request for information could lay the groundwork for legislative action to empower HRSA to address the contract pharmacy actions, but it could come with new overarching program oversight authority for HRSA along with program transparency requirements.

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

BACKGROUND

As reported in our client alerts (here and here), several drug manufacturers have taken actions in recent weeks to limit contract pharmacy access to 340B pricing. Eli Lilly and Co. (Eli Lilly) and AstraZeneca recently stopped replenishing drugs to 340B contract pharmacies and limiting distribution to covered entities and their child sites only. Merck, Sanofi, and Novartis requested that covered entities share contract pharmacy claims data through Second Sight Solutions' 340B ESP platform, with Sanofi and Novartis explicitly indicating that they would cease replenishment to contract pharmacy locations—akin to Eli Lilly and AstraZeneca—for entities that do not participate. While we understand Sanofi has moved forward with its policy, it appears as of this writing that Novartis has yet to implement the new policy.

In response, several provider groups and policymakers have written to HHS and HRSA asking them to intervene. HRSA indicated initially that, although its 2010 guidance supporting contract pharmacy arrangements remains in effect, it is not legally enforceable.[1] HRSA noted that, unless there is a clear violation of the 340B statute, its authority to enforce guidance is limited.[2] More recently, HRSA indicated that it is "considering" whether the manufacturers' actions violate the 340B statute and whether sanctions may apply.[3] HHS also made public a response to one of these manufacturers, where it noted that HRSA has "significant concerns" with its actions and has yet to make a final determination as to enforcement action, cautioning that HRSA's response to date should not be viewed as an endorsement.[4]

RYAN WHITE CLINICS' LAWSUIT

In response to these actions, Ryan White Clinics for 340B Access (RWC-340B) and two of its members filed a complaint in the U.S. District Court for the District of Columbia late last week asking the court to compel the Secretary of HHS to enable them to use contract pharmacy arrangements.[5] The complaint notes that Eli Lilly, Sanofi, AstraZeneca, and Novartis have denied 340B pricing to them by refusing to sell their drugs through the 340B wholesaler accounts associated with contract pharmacies.[6] They note that the Secretary's failure to enforce their rights to 340B pricing is harming them, as 340B pricing allows them to provide services that will be scaled back or eliminated unless the Secretary intervenes.[7]

Specifically, they are asking for a declaration that they are "entitled to purchase and dispense covered outpatient drugs through contract pharmacies at 340B discounts."[8] They note that the 340B statute directs the Secretary of HHS to execute PPAs with manufacturers that "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price," arguing that the statute contains no exemption permitting manufacturers to restrict 340B sales based upon delivery location.[9] They further argue that manufacturers that charge covered entities more than the ceiling price for drugs ordered via contract pharmacies have thus overcharged the covered entities in violation of the 340B statute and civil monetary penalties regulation.[10]

In addition, RWC-340B and its members are asking for an order requiring the Secretary of HHS to promulgate 340B administrative dispute resolution (ADR) regulations, which Congress required the Secretary to issue no later than September 2010.[11] They argue that by failing to implement ADR as Congress mandated and failing to take action on its own initiative to enforce the statutory requirement for manufacturers to honor 340B pricing, the Secretary has deprived them of their property interests under the Due Process Clause of the Fifth Amendment

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

and their procedural due process rights.[12] In this regard, RWC-340B and its members further argue that HHS' refusal to enforce their rights to purchase drugs at 340B pricing through contract pharmacy arrangements is arbitrary, capricious, an abuse of discretion and not in accordance with the law in violation of the Administrative Procedure Act.[13]

In addition to the declaration that they are entitled to purchase drugs through contract pharmacies at 340B pricing and an order requiring the Secretary to issue ADR regulations, RWC-340B and its members are asking for orders directing the Secretary of HHS to (i) enforce their rights to purchase and dispense drugs through contract pharmacies at 340B pricing; (ii) use his power to force the manufacturers to refund them for overpayments on drugs they have refused to sell at 340B prices when ordered via contract pharmacy arrangements; (iii) use his power to impose civil monetary penalties upon drug manufacturers unless and until they honor contract pharmacy arrangements; and (iv) revoke the PPA of any manufacturer that does not offer drugs at 340B discounts when ordered via a contract pharmacy.[14]

CONGRESSIONAL REQUEST FOR INFORMATION

The same day RWC-340B filed its complaint in federal court, Senate HELP Committee Chairman Lamar Alexander (R-TN) and House E&C Committee Ranking Member Greg Walden (R-OR) issued a statement inviting 340B stakeholders to submit ideas on “how to improve” the 340B Program.[15] They directed stakeholders to submit comments and recommendations on how to improve the program by October 30th to the following email addresses: 340B@help.senate.gov and 340B@mail.house.gov.

Chairman Alexander and Ranking Member Walden stated that, while they continue to hear reports of the program benefiting patients, “clear changes are long overdue.”[16] They noted that there is confusion about the program's requirements and lack of data necessary to maintain the integrity of the program. In regard to the manufacturers' recent actions, they added that, while “contract pharmacies serve an important role in improving access to prescription drugs,” it is “clear that such pharmacies are not referenced in law.”[17] They noted that they have been “following this activity closely” and “believe contract pharmacies are an important part of the continued discussion around 340B modernization.”[18]

Republicans in the Senate HELP Committee and the House E&C Committee have advocated for changes to the 340B Program in recent years. Back in 2018, for example, the Senate HELP Committee held a hearing titled “Perspectives on the 340B Drug Pricing Program,” where Chairman Alexander advocated for increased accountability and transparency in the 340B Program.[19] The hearing followed a report by the House E&C Committee, where the committee found that HRSA lacks sufficient authority to oversee the 340B Program.[20] Among other things, the committee recommended providing authority to HRSA to oversee the program and increasing transparency, including by ensuring that covered entities have access to ceiling prices and requiring covered entities to disclose information about 340B savings.[21]

CONCLUSION

340B stakeholders should be mindful of the potential impact of these recent developments. While the congressional request for information could lay the groundwork for legislative action to empower HRSA to address contract pharmacy actions, it could come with new overarching authority for HRSA and enhanced

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

transparency. Moreover, although the Ryan White clinics' action will likely face several hurdles, including key questions of standing, it could put into play a decision by a court as to the enforceability of HRSA's contract pharmacy guidance which, if decided in the negative, could result in HRSA withdrawing its guidance supporting contract pharmacy arrangements and rendering all contract pharmacy arrangements problematic.

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, including with the submission of comments.

FOOTNOTES

[1] *See* Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B REPORT (July 9, 2020), here.

[2] *Id.*

[3] *See* Bronwyn Mixter, HRSA is Investigating *Whether Manufacturer Policies to Restrict 340B Pricing at Contract Pharmacies Violates Statute*, 340B REPORT (Sept. 2, 2020), here.

[4] *See* Letter from Robert B. Charrow, Gen. Counsel, Dep't of Health & Hum. Res. to Anat Hakim, Senior Vice President & Gen. Counsel, Eli Lilly (Sept. 21, 2020), here.

[5] *See* Complaint, Ryan White Clinics for 340B Access v. Azar, D.D.C. (No. 20-cv-2906) [Hereinafter referred to as "Complaint"].

[6] Complaint at 3.

[7] *Id.* at 4.

[8] *Id.* at 31.

[9] *Id.*

[10] *Id.* at 32.

[11] *Id.*

[12] Complaint at 33.

[13] *Id.* at 34.

[14] *Id.* at 35-6.

[15] *See* Press Release, House Energy & Commerce Comm., Walden and Alexander Ask for Input on Modernizing 340B Drug Pricing Program (Oct. 9, 2020), here.

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *See Perspectives on the 340B Drug Pricing Program: Hearing before the Senate Health, Educ., Lab., &*

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

Pensions Comm., 115th Cong. (2018), here.

[20] *See* HOUSE ENERGY & COMMERCE COMM., REVIEW OF THE 340B PROGRAM (2018), here.

[21] *Id*.

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.