Contract Pharmacy Restrictions, Legal Challenges, and Congressional Action: What to Expect from the 340B Drug Pricing Program

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As safety net providers participating in the 340B Drug Pricing Program (340B Program) continue to grapple with the health and economic impact of the COVID-19 pandemic, they are facing an increasing number of restrictions on the use of contract pharmacy arrangements as well as data sharing requests from drug manufacturers. Safety net providers have asked the Health Resources and Services Administration (HRSA) to intervene, attracting the attention of a number of policymakers in Congress who have started to weigh options for improving the 340B Program and potentially addressing these actions. Given HRSA's inaction to date, safety net providers have challenged these actions in federal court, requesting orders for the Department of Health and Human Services (HHS) and HRSA to enforce their right to contract pharmacy arrangements. It is possible that Congress and President Joe Biden's administration may be hesitant to take action due to the litigation; however, if Congress intervenes, potential legislative action could include overarching authority for HRSA as well as program transparency requirements for providers. This article provides an overview of these developments and what to expect from the 340B Program in the years ahead.

Background

The 340B Drug Pricing Program

In 1992, Congress created the 340B Program to help safety net providers stretch scarce federal resources by requiring drug manufacturers to sell covered outpatient drugs to participating providers at or below a defined 340B ceiling price.[1] Section 340B(a)(4) of the Public Health Service Act specifies which providers are eligible to participate in the 340B Program.[2] Eligible providers,

referred to as "covered entities," include qualifying hospitals; federally qualified health centers (FQHCs), FQHC "look-alikes," and other health centers; Ryan White HIV/AIDS Program grantees; and several specialized clinics, among others.[3] To maintain eligibility, covered entities must recertify eligibility and meet program integrity requirements.

HRSA's Authority to Issue and Enforce 340B Policy

HRSA is the agency in charge of administering and overseeing the 340B Program, which it does through regulatory and sub-regulatory guidance. In 2014, the U.S. District Court for the District of Columbia found that Section 340B of the Public Health Service Act authorizes HRSA to promulgate regulations in key areas—including the establishment of an administrative dispute resolution (ADR) process, the standards and methodology for calculating ceiling prices, and the imposition of monetary civil sanctions—but otherwise does not confer broad authority for the agency to issue regulations to administer the program.[4]

In recent years, HRSA has increasingly taken the position that it lacks statutory authority to issue and enforce 340B regulatory and sub-regulatory guidance. For example, HRSA has no longer proposed to make 340B Program eligibility changes as part of its annual budget justifications, which the agency has proposed in previous years.[5] Additionally, in 2019, HRSA declined to defend negative audit findings against Genesis Health Care, a South Carolina–based FQHC, which was widely perceived to be as a result of the agency's perceived lack of authority to enforce more restrictive program eligibility through the audit process.[6]

Manufacturer Contract Pharmacy Actions

Against this backdrop, several drug manufacturers have taken actions to restrict contract pharmacy access to 340B pricing. In this regard, HRSA has permitted covered entities to contract with a pharmacy to provide 340B services since 1996.[7] While HRSA initially limited covered entities to contracting with a single contract pharmacy, HRSA subsequently issued contract pharmacy guidance in 2010 permitting them to rely on multiple contract pharmacies.[8] In 2018, the Government Accountability Office estimated that, since that time, the number of contract pharmacies increased from about 1,300 to approximately 20,000 in 2017.[9]

Contract Pharmacy Carve-Out

Despite HRSA's 2010 contract pharmacy guidance in support of contract pharmacy arrangements, on July 1, 2020, Eli Lilly and Company (Eli Lilly) ceased distribution of its drug Cialis to 340B contract pharmacies and limited distribution to covered entities and their 340B Program enrolled child sites only, a policy that was extended to its other products effective September 1, 2020. On August 17, 2020, AstraZeneca similarly informed covered entities that it would stop replenishing drugs to contract pharmacies beginning on October 1, 2020. Eli Lilly and AstraZeneca offered a carve-out for covered entities that lack an in-house pharmacy.

In addition, on October 30, 2020, Novartis informed covered entities that it would stop providing 340B pricing to hospitals on drugs shipped to contract pharmacies that are more than 40 miles away from the hospitals' parent sites, beginning on November 16, 2020. On November 18, 2020, United Therapeutics informed covered entities that it will only process orders for contract pharmacies if they are for a "valid 340B purpose" and only for those contract pharmacies that the covered entity utilized for a 340B purchase between January 1 and September 30 of 2020, essentially freezing covered entities from enrolling new contract pharmacies. Additionally, United Therapeutics indicated that it will only fill orders if the covered entity provides claims data for all

340B contract pharmacy orders for orders placed after May 13, 2021.

Most recently, on December 1, 2020, Novo Nordisk announced that it will no longer facilitate distribution of 340B products to a contract pharmacy of any hospital covered entity types beginning on January 1, 2021. Like Eli Lilly and AstraZeneca, Novo Nordisk offered a carve-out for entities without an in-house pharmacy.

Data Sharing Requirements

At the same time, Merck, Sanofi, and Novartis began requesting that covered entities share contract pharmacy claims data through Second Sight Solutions' 340B ESP platform, with Sanofi and Novartis explicitly indicating that, like Eli Lilly and AstraZeneca, they would also cease replenishment to contract pharmacy locations for covered entities that do not share claims data. While Sanofi has moved forward with its new policy, it appears as of this writing that Novartis has yet to implement the new policy. Merck indicated that the use of 340B ESP is voluntary while cautioning that, absent "significant cooperation" from covered entities, it may seek claims information in a manner that is more burdensome for covered entities.

Kalderos Rebate Model

Finally, Kalderos announced that it is adding a new software solution called "340B Pay" to the Kalderos Drug Discount Management Program. Instead of providing upfront discounts for 340B purchases, 340B Pay will implement a rebate program for 340B purchases. We understand that the covered entities would purchase drugs at a non-340B price and receive the discount through a rebate after the purchase.

Initial Responses to Manufacturer Actions

Administrative Response

In response, a number of provider groups and policymakers have sent letters to HHS and HRSA asking them to intervene and enforce the agency's 2010 guidance in support of contract pharmacy arrangements. A 340B coalition, including 340B Health, the American Hospital Association (AHA), and other provider groups, specifically asked HHS to prevent drug manufacturers from restricting access to 340B pricing and prohibit them from taking action against covered entities that do not submit claims data to 340B ESP.[10]

HRSA initially indicated that, although its 2010 guidance in support of contract pharmacy arrangements remains in effect, it is not legally enforceable.[11] HRSA noted that, unless there is a clear violation of the 340B statute, its authority to enforce 340B guidance is limited, adding that, without comprehensive statutory authority, it is "unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program."[12] However, HRSA subsequently indicated that it is "considering" whether manufacturers' policies violate the 340B statute and whether sanctions may apply.

On September 22, 2020, HHS took the extraordinary step of making public its response to a request for a pre-enforcement advisory opinion by Eli Lilly as to whether its actions would subject it to sanctions. HHS told Eli Lilly that it should not interpret HRSA's response as tantamount to agency agreement with their position, highlighting that the timing of the new policies is insensitive to the recent state of the economy.[13] In addition, HHS suggested that a *qui tam* False Claims Act suit against Eli Lilly is a potential consequence in the event that it knowingly violates a material condition of the program that results in overcharges.[14]

Congressional Response

Congressional leaders in both the House and Senate have also asked HHS and HRSA to intervene. In the House, a bipartisan group of more than 243 members of

Congress sent a letter to HHS and HRSA stressing that these actions violate the 340B statute.[15] This letter followed a letter by House Energy and Commerce (E&C) Committee leaders stressing that "Congress has provided [HHS] with tools, including manufacturer auditing rights and civil monetary penalties, to enforce [the 340B statute]."[16] In the Senate, a group of 28 senators urged HHS to take "immediate and appropriate enforcement action," while a group of senators wrote to Pharmaceutical Research and Manufacturers of America, 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."[17]

With respect to Kalderos' rebate model, a bipartisan group of 217 policymakers sent a letter urging HHS to take action to stop manufacturers and vendors, specifically Kalderos, from changing the 340B Program from a discount model to a rebate model, stating that such actions are "inconsistent with HRSA's long-standing guidance that the 340B program is an upfront discount program."[18] They expressed their concerns that the changes "would give drug manufacturers tremendous leverage over covered entities."[19]

Meanwhile, Republican leaders from the House E&C Committee and the Senate Health, Education, Labor, and Pensions (HELP) Committee issued a request for information regarding the 340B Program.[20] While the Senate HELP Committee Chairman Lamar Alexander (R-TN) and House E&C Committee Ranking Member Greg Walden (R-OR) broadly invited ideas on "how to improve" the 340B Program, they indicated that they had been following manufacturers' contract pharmacy actions closely and expressed their view that "contract pharmacies are an important part of the continued discussion around 340B modernization."[21] They otherwise noted that there is confusion about program requirements and lack of data to maintain integrity.

In this regard, it is worth noting that Republicans in the House E&C Committee and Senate HELP Committee have advocated for changes to the 340B Program in recent years. In 2018, for example, the House E&C Committee issued a report where the committee found that HRSA lacks sufficient authority to oversee the 340B Program. Among other things, the committee recommended as part of the report 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. The Senate HELP Committee held 340B hearings following the release of the report, where Chairman Alexander advocated for increased accountability and transparency in the program.[22]

To this end, Senator Mike Braun (R-IN) introduced the Fair Care Act of 2020.[23] While most of the provisions in the bill are aimed at addressing the cost and quality of health care, it contains transparency requirements impacting 340B covered entities.[24] As part of the proposal, 340B Disproportionate Share Hospitals (DSHs), children's hospitals, and free-standing cancer hospitals would be required to report data on patient insurance status, charity care costs, and acquisition costs and reimbursements for 340B drugs.[25] In addition, they would have to report all "third-party vendors or other similar entities" that they contract with for 340B services.[26] DSH hospitals would need to submit data on their "low-income outpatient utilization rate."[27] Senator Braun's bill failed to advance last Congress; however, because Senator Braun is a member of the Senate HELP Committee, the bill may serve as the basis for future 340B legislative proposals.

Stakeholder Challenges to Manufacturer Actions

Community Health Centers Lawsuit

Given the limited administrative and congressional response to manufacturers' contract pharmacy actions, the National Association of Community Health Centers, which represents FQHCs, filed a complaint in the U.S. District Court for the District of Columbia in October 2020, asking the court to compel HHS to issue 340B ADR regulations as required under the Affordable Care Act (ACA).[28] The 340B ADR process would replace HRSA's current informal dispute resolution process for resolving overcharge complaints.

When there is an overcharge dispute between covered entities and manufacturers, HRSA generally recommends that covered entities work directly with manufacturers in good faith to resolve the dispute. Covered entities may report an overcharge using a form that Apexus, HRSA's 340B Prime Vendor, has made available for reporting overcharges, though it is unclear what action, if any, the agency takes following such reporting. Covered entities may otherwise file an overcharge complaint with HRSA, which the agency reviews through an informal dispute resolution process.[29] According to the Government Accountability Office, however, the agency's informal dispute resolution process has only been used a handful of times.[30]

In 2010, Congress required the Secretary of HHS to promulgate formal 340B ADR regulations as part of the ACA.[31] In 2016, HRSA issued proposed ADR regulations, which the agency withdrew without explanation in 2017.[32] The FQHCs argue that other than the ADR regulations, covered entities have no other—much less an adequate—remedy to challenge the drug manufacturers' actions, stressing that HHS' inaction is harming FQHCs and their patients, who are among the most vulnerable and underserved.[33]

More specifically, the FQHCs are requesting (i) a declaration that HHS violated the 340B statute by failing to implement the 340B ADR process; (ii) a declaration that HHS violated the Administrative Procedure Act; (iii) an order requiring HHS to promulgate 340B ADR regulations no later than 60 days from the order; (iv) maintenance of jurisdiction over the matter pending defendants' compliance with the order; (v) an award of legal fees and other expenses; as well as (vi) "such other relief as the court deems just and proper."[34]

Notably, on December 14, 2020, HHS issued the long-awaited 340B Drug Pricing Program Alternative Dispute Resolution final rule, providing a pathway for covered entities to challenge manufacturers' contract pharmacy actions.[35] Under the final rule, two or more covered entities may jointly file claims of overcharging by manufacturers and associations or organizations may file claims on behalf of multiple covered entities.

In response to the final rule, the AHA issued a statement acknowledging that the final rule is an important step toward protecting 340B hospitals and other covered entities while noting that the ADR process alone "is not sufficient to address drug companies' repeated illegal attempts to attack 340B hospitals, and the patients and communities they serve."[36] Similarly, 340B Health said that the process is not an appropriate or timely solution, adding that these actions are a clear violation of the 340B statute and that HHS has the authority—and the responsibility—to block them immediately and order recourse for affected hospitals.[37]

Ryan White Clinics Lawsuit

Also in October 2020, Ryan White Clinics for 340B Access and two of its members filed a complaint in the U.S. District Court for the District of Columbia asking the

court to more broadly compel the Secretary of HHS to enable them to use contract pharmacy arrangements, arguing that they are being harmed by the Secretary's failure to enforce their rights to 340B pricing because such pricing allows them to provide services that they will need to scale back or otherwise eliminate unless the Secretary intervenes.[38]

Like the FQHCs, the Ryan White Clinics are asking for an order requiring HHS to promulgate the 340B ADR regulations, which were subsequently issued on December 14, 2020.[39] The Ryan White Clinics are also asking for a declaration that they are "entitled to purchase and dispense covered outpatient drugs through contract pharmacies at 340B discounts" as well as orders directing HHS to, among other things, (i) enforce their rights to purchase drugs through contract pharmacies at 340B pricing; (ii) force the manufacturers to refund them for overpayments on drugs they have refused to sell at 340B prices when ordered via contract pharmacies; (iii) impose civil monetary penalties upon drug manufacturers unless and until they honor contract pharmacy arrangements; and (iv) revoke the pharmaceutical pricing agreement of any manufacturer that does not offer drugs at 340B discounts when ordered via a contract pharmacy.[40]

On November 23, 2020, the Ryan White Clinics filed a memorandum requesting an injunction directing HHS to protect covered entities' rights to contract pharmacy arrangements as well as a declaration affirming those rights.[41] The Ryan White Clinics argue that judicial intervention is still needed because, even if the 340B ADR regulations are finalized, the regulations will not take effect until it is too late, adding that the process could stretch into months—if not years—while patients lose access to needed drugs.[42]

Associations and Hospitals Lawsuit

Most recently, in December 2020, five national hospital organizations, including AHA and 340B Health, a pharmacy trade organization, and three hospitals filed a lawsuit in the U.S. District Court for the Northern District of California challenging the manufacturers' actions regarding contract pharmacy arrangements.

The associations and hospitals are requesting a declaratory judgment that HRSA's indication, as noted above, that it lacks authority to enforce its guidance in support of contract pharmacy arrangements is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law in violation of the Administrative Procedure Act.[43] Among other things, they are also requesting an order for HHS and HRSA to require manufacturers to provide covered outpatient drugs at or below 340B ceiling prices to covered entities when they dispense those drugs through contract pharmacies; an order directing HHS and HRSA to require manufacturers to refund the hospitals and association members the difference between what each covered entity paid for the drugs and the 340B ceiling price; as well as an order directing them to refer the matter to the HHS Office of Inspector General for assessment of civil monetary penalties.[44]

In the event that the court finds that HRSA's indication that it lacks authority to require manufacturers to sell 340B drugs at or below 340B ceiling prices to covered entities that dispense those drugs through contract pharmacies is not final agency action that can be challenged, the associations and hospitals are requesting a declaratory judgment that the failure of HHS and HRSA to decide whether the manufacturers' actions comply with the 340B statute is agency action unlawfully withheld or delayed.[45] They also request an order directing them to issue a decision on whether the manufacturers' decision not to sell 340B drugs at or below the 340B ceiling price when dispensed through contract pharmacies complies with the 340B statute and inform the court as to their

decisions and the actions they will take to address manufacturers' conduct.[46]

Looking Ahead: What to Expect From the 340B Program

On December 30, 2020, HHS issued an advisory opinion concluding that manufacturers are required to sell drugs at 340B pricing for replenishment to contract pharmacies. HHS argued that the 340B statute requires manufacturers to sell covered outpatient drugs to covered entities at or below the ceiling price regardless of whether the covered entity opts to use contract pharmacies.[47] HHS further argued that this "core requirement of the 340B statute" is reflected on each manufacturer's pharmaceutical pricing agreement.[48] The advisory opinion, however, did not indicate what action, if any, HHS or HRSA may take in the future with regard to manufacturers that are currently refusing to honor contract pharmacy arrangements.

In this regard, it is worth noting that Xavier Becerra, Attorney General of California and President Joe Biden's current pick for Secretary of HHS, is leading an effort by 29 state attorneys general to get HRSA to stop manufacturers from limiting 340B pricing on drugs dispensed via contract pharmacies. In December, the state attorneys general sent a letter to HHS and HRSA urging them to use their "authority and any available measures, including imposition of civil penalties where appropriate, to hold those drug manufacturers in violation of the law directly accountable," adding in the letter that "the vulnerable and underserved patients of 340B covered entities of our states and nationwide deserve no less."[49]

In January 2021, AstraZeneca, Eli Lilly, and Sanofi filed complaints challenging HHS' advisory opinion in federal district courts in Delaware, Indiana, and New Jersey. All three manufacturers argue that HHS' reading of the 340B statute is contrary to the statute's plain text, history, and purpose. They are broadly asking for the courts to issue orders setting aside the advisory opinion, arguing that the advisory opinion violates the Administrative Procedure Act because it was issued without following proper procedure, is in excess of statutory authority, and is otherwise not in accordance with law. In addition, the manufacturers are asking for the courts to issue orders declaring that they are not required to offer 340B discounts to contract pharmacies.

Absent administrative, judicial, or congressional action, it is likely that more drug manufacturers will restrict contract pharmacy access to 340B pricing and request claims data from covered entities. As noted above, judicial action is already pending, and covered entities should follow the trajectory of that litigation closely. The litigation could conceivably force administrative action by HRSA, but it could also place into question HRSA's authority as to all contract pharmacy arrangements if the court makes a finding as to HRSA's authority to issue and enforce its 2010 contract pharmacy guidance in support of contract pharmacies.

Moreover, while the litigation has triggered action by HRSA on the 340B ADR regulations, it is possible that the ADR pathway may stretch into months if not years. In this regard, it is worth noting that several covered entities have started to submit ADR petitions. However, any such ADR finding would likely be subject to litigation by manufacturers as to HRSA's authority to implement its 2010 contract pharmacy guidance.

Accordingly, most likely, it will be necessary for Congress to intervene if contract pharmacy arrangements are to be sustained. Drug manufacturers' contract pharmacy actions have attracted the attention of a number of policymakers in both the House and Senate, which have written to HHS and the pharmaceutical industry on this matter. It is possible, however, that Congress and President Joe Biden's administration may be hesitant to take action due to the pending litigation in federal court. Even if Congress works on a legislative fix

to these actions, it would likely include overarching program authority for HRSA to better regulate all 340B Program stakeholders as well as program transparency requirements for participating providers. As such, any legislative fix should be closely watched by covered entities and will likely come with new compliance requirements for covered entities as well as manufacturers in the years ahead.

Endnotes

1. H.R. Rep. No. 102-384(II), at 12 (1992).
2. 42 U.S.C. § 256b(a)(4).
3. *Id*.
4. PhRMA v. U.S. Dep't of Health & Hum. Servs., No. 13-1501, 2014 WL 2171089 (D.D.C. 2014).
5. *See, e.g.*, Health Res. & Servs. Admin., FY 2021 Justification of Estimates for Appropriations Committees (last reviewed June 2020).
6. *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.
7. *See* 61 Fed. Reg. 43,549 (1996).
8. *See* 75 Fed. Reg. 10,272 (2010).
9. *See* Government Accountability Office, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement (June 2018).
10. *See* Letter from 340B Health et al. to Alex M. Azar, Sec'y, U.S. Dep't of Health & Hum. Res. (last visited Dec. 2020).
11. *See* Tom Mirga, HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B REPORT (July 9, 2020).
12. *Id*.
13. *See, e.g.*, Health Res. & Servs. Admin., HHS Response to Lilly (last visited Dec. 2020).
14. *Id*.
15. *See* Letter from Rep. David B. McKinley et al. to Alex M. Azar, Sec'y, U.S. Dep't of Health & Hum. Res. (last visited Dec. 2020).
16. *See* Press Release, House Energy & Commerce Comm., E&C Leaders to Azar: Protect the 340B Drug Pricing Program (last visited Dec. 2020).
17. *See* Letter from Sen. Richard Blumenthal et al. to Stephen J. Ubl, President, PhRMA (last reviewed Dec. 2020).
18. See Letter from Rep. Cindy Axne et al. to Alex M. Azar, Sec'y, U.S. Dep't of Health & Hum. Res. (last visited Dec. 2020).
19. *Id.*
20. *See* Press Release, House Energy & Commerce Comm., Walden and Alexander Ask for Input on Modernizing 340B Drug Pricing Program (Oct. 9, 2020)
21. *Id*.
22. *Id*.
23. *See* Fair Care Act of 2020 (S. 4796) - 116th Congress (2019-2020).
24. *Id*.
25. *Id*.
26. *Id*.
27. *Id*.
28. *See* Complaint, Nat'l Ass'n of Community Health Ctrs. v. Azar, No. 20-cv-3032 (D.D.C. Oct. 21, 2020).
29. 61 Fed. Reg. 65,406 (1996).
30. *See* Government Accountability Office, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (2011).
31. 42 U.S.C. § 256b(d)(3).
32. 81 Fed. Reg. 53,381 (2016).
33. *See* Complaint, Nat'l Ass'n of Community Health Ctrs. v. Azar, No. 20-cv-3032 (D.D.C. Oct. 21, 2020).
34. *Id*.
35. 85 Fed. Reg. 80,632 (2020).
36. *See* Am. Hosp. Ass'n, AHA Statement on Final 340B Alternative Dispute Resolution Rule (Dec. 10 2020).
37. *See* 340B Health, Statement on HRSA's Final 340B Alternative Dispute Resolution Rule (Dec. 10, 2020)
38. *See* Complaint, Ryan White Clinics for 340B Access v. Azar, No. 20-cv2906 (D.D.C. Oct. 9, 2020).
39. *Id*.
40. *Id*.
41. *See* Memorandum of Points and Authorities in Support of Motion for a Temporary Restraining Order and Preliminary Injunction, Ryan White Clinics for 340B Access v. Azar, No. 20-cv2906 (D.D.C. Nov. 23, 2020).
42. *Id*.
43. *See* Complaint, American Hospital Ass'n v. HHS, No. 3:20-cv-08806 (N.D. Ca. Dec. 11, 2020).
44. *Id*.
45. *Id*.
46. *Id*.
47. *See* U.S. Dep't of Health & Hum. Servs., Office of the General Counsel, Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program (Dec. 2020).
48. *Id*.
49. *See* State of California Department of Justice, Attorney General Becerra Leads Bipartisan Coalition on 340B Drug Pricing Program Requirements (Dec. 2020).

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