The 340B Drug Pricing Program: An Evolving Legal and Policy Landscape

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In recent years, safety net providers participating in the 340B Drug Pricing Program (340B Program) have been subject to an increasing number of restrictions on the use of contract pharmacy arrangements as well as data sharing requirements from drug manufacturers. While the U.S. Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) have intervened, their actions have been challenged in federal courts by both providers requesting that the government take further action to protect their contract pharmacy arrangements as well as by manufacturers challenging the government's enforcement authority. With a couple of federal appellate courts poised to rule anytime soon on the challenges brought by manufacturers, it is possible that the issue could reach the Supreme Court. Given the limited action at the federal level, some states have taken the lead in responding. Arkansas and Louisiana have enacted legislation prohibiting contract pharmacy restrictions, which have been challenged in court. With the start of the 118th Congress, all eyes are now on Congress, where key policymakers have highlighted the need for intervention. Any potential legislative action would likely be part of a larger effort to reform the 340B Program, which could include express enforcement authority for HRSA as well as program transparency requirements. Providers and manufacturers should be alert to these developments as they are likely to have a significant impact on all stakeholders. 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 Enforcement Authority

HRSA is the agency in charge of administering and overseeing the 340B Program, which it does through regulatory and subregulatory 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 to the agency to issue regulations for administering the program.[4]

Likely as a result of this decision, HRSA has increasingly taken the position that it lacks statutory authority to issue and enforce 340B regulatory and subregulatory guidance. For example, HRSA has no longer proposed to make 340B Program eligibility changes as part of its annual budget justifications as it had in the past.[5] More recently, 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] The U.S. District Court for the District of South Carolina dismissed the case, but the U.S. Court of Appeals for the Fourth Circuit reversed the decision in 2022, remanding to the district court for further proceedings.[7] Multiple drug manufacturers have now asked the South Carolina federal district court to dismiss Genesis's challenge to HRSA's interpretation of the 340B Program "eligible patient" definition.[8]

Contract Pharmacy Actions and 340B Transparency

Against this backdrop, a number of drug manufacturers began taking actions to restrict contract pharmacy access to 340B pricing. Since 1996, HRSA has permitted covered entities to contract with a pharmacy to provide 340B services.[9] While HRSA initially limited covered entities to an in-house pharmacy or contracting with a single contract pharmacy, HRSA subsequently issued 340B contract pharmacy guidance in 2010 permitting them to rely on multiple contract pharmacies.[10] In recent years, it has been estimated that the number of contract pharmacies has increased from about 1,300 in 2010 to more than 30,000 in 2022.[11]

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 child sites only, a policy that Eli Lilly later extended to its other products and has since amended. Over the past three years, a number of drug manufacturers have similarly stopped replenishing drugs to contract pharmacies. Others have requested that covered entities share contract pharmacy claims data, oftentimes in exchange for access to 340B pricing.

As of August 2023, 24 manufacturers have imposed some type of restriction or requirement on the use of contract pharmacy arrangements. According to a July 2023 report by 340B Health, an advocacy organization representing covered entities, 2021 340B revenue for hospitals declined by $1.5 billion after Eli Lilly,

AstraZeneca, Novartis, Novo Nordisk, and Sanofi—the first manufacturers to impose restrictions—implemented their new contract pharmacy policies in 2021.[12] 340B Health further estimates that $8.4 billion in 340B revenue is at risk from the manufacturers with contract pharmacy policies as of 2023.[13]

Because the 340B Program was created to help safety net providers stretch scarce federal resources, a key concern has been the use by covered entities of 340B savings. Senate Health, Education, Labor, and Pensions (HELP) Committee Ranking Member Bill Cassidy, for example, has stated that Congress should increase 340B Program transparency and accountability to preserve the intent of the program because of "certain providers that clearly do not treat low-income patients take advantage of the program's loose requirements to access the discounted drugs to maximize profit," which "costs pharmaceutical companies billions."[14]

A couple of states have similarly began taking actions to increase 340B Program transparency. The Governor of Minnesota, for example, recently signed into law a health care financing bill with key 340B Program provisions, including a requirement for covered entities in the state to report the total acquisition cost for drugs purchased at the 340B price, the total payment received for these drugs, and the total payment made to contract pharmacies.[15]

Initial Government Response to Manufacturer Actions

Administrative Response

In response, a number of provider groups and policymakers sent letters to HHS and HRSA asking them to intervene and enforce the agency's 2010 guidance in support of 340B contract pharmacy arrangements. A 340B coalition, including 340B Health, the American Hospital Association (AHA), and several 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.[16]

HRSA initially indicated that, although its 2010 guidance in support of contract pharmacy arrangements remained in effect, it was not legally enforceable.[17] 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 statutory authority.[18] HRSA later indicated that the agency was "considering" whether the manufacturers' policies violate the 340B statute and whether sanctions may apply.[19] At the end of 2020, however, HHS issued an Advisory Opinion declaring that the 340B statute permits contract pharmacy arrangements.[20] A few months later, HHS sent violation letters to several manufacturers, informing them of the department's view that their policies were unlawful and ordering them to rescind their policies.

Congressional Response

Congressional leaders in both the House and Senate also asked HHS and HRSA to intervene on the matter. 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.[21] This letter followed a letter by House Energy and Commerce Committee leaders stressing that "Congress has provided [HHS] with tools, including manufacturer auditing rights and civil monetary penalties, to enforce [the 340B statute]."[22] In the Senate, a group of 28 senators urged HHS to take "appropriate enforcement action," while a separate group of senators wrote to Pharmaceutical Research and Manufacturers of America (PhRMA), 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 data."[23]

Stakeholder Challenges to Manufacturer Actions

Given the limited administrative and congressional response to manufacturers' contract pharmacy actions, a number of provider groups moved to sue HHS in federal district courts. At issue in most of these lawsuits has been the promulgation of 340B ADR regulations as required under the Affordable Care Act (ACA), which would replace HRSA's informal dispute resolution process for resolving overcharge complaints.

The 340B ADR Process

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. According to the Government Accountability Office, however, the agency's informal dispute resolution process has only been used a handful of times. In 2010, Congress required HHS to promulgate formal 340B ADR regulations as part of the ACA. In 2016, HRSA issued proposed 340B ADR regulations, which the agency withdrew without explanation in 2017.[24]

Provider Group Challenges

In 2020, the National Association of Community Health Centers (NACHC), which represents FQHCs, filed a complaint in the U.S. District Court for the District of Columbia asking the court to compel HHS to issue 340B ADR regulations.[25] The FQHCs argued that other than the ADR process, covered entities have no appropriate remedy to challenge the drug manufacturers' actions, stressing that HHS' inaction in this regard was harming FQHCs and their patients, who are among the most vulnerable and underserved.

Ryan White Clinics for 340B Access and two of its members also 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 were being harmed by the Secretary's failure to enforce their rights to 340B pricing because such pricing allows them to provide services that they would need to scale back or otherwise eliminate unless the Secretary intervened.[26] Like the FQHCs, the Ryan White Clinics asked for an order requiring the Secretary of HHS to promulgate the 340B ADR regulations.

Amid the litigation, in December 2020, HHS issued a 340B ADR final rule.[27] In response, the parties asked the court to stay the proceedings while they turned to the ADR process, with the NACHC most recently dismissing its lawsuit voluntarily after losing its claims through the process.[28] In 2021, the AHA brought a lawsuit against HHS arguing more broadly that its failure to enforce 340B access is in violation of the Administrative Procedure Act.[29] However, the court granted the government's motion to dismiss holding that Congress intended for covered entities to engage in the ADR process before engaging the judiciary.[30]

In 2022, HHS issued a proposed rule to further implement the 340B ADR process, noting that the agency had encountered "policy and operational challenges" during the implementation of the previously issued rule.[31] HHS accepted public feedback and comments on the proposal, which it intends to finalize this year.[32]

Manufacturer Challenges to Government Actions

As provider groups filed lawsuits challenging the government's limited response to contract pharmacy restrictions, manufacturers moved to challenge the government's ability to enforce 340B requirements. Eli Lilly, AstraZeneca, Novo Nordisk, Sanofi, Novartis, United Therapeutics, and Boehringer Ingelheim all initiated lawsuits challenging the government's response, including its Advisory Opinion, violation letters, and 340B ADR rule. Last year, district courts issued differing decisions, some siding with the manufacturers and others siding with the government, which has resulted in three appellate courts hearing these cases.

The U.S. Court of Appeals for the Third Circuit consolidated the cases of AstraZeneca, Novo Nordisk, and Sanofi. In January 2023, the appeals court issued its decision, largely siding with the manufacturers. While the appeals court upheld the 2020 340B ADR final rule, it held that the statute does not require delivery to "an unlimited number of contract pharmacies" and that the government may not enforce its interpretation of the statute against the manufacturers.[33] The Third Circuit's decision has fueled more restrictive policies from several manufacturers as stakeholders await two related appellate decisions on this matter.

The U.S. Court of Appeals for the District of Columbia Circuit will be issuing soon its decision on a similar consolidated case brought by Novartis and United Therapeutics challenging HHS' violation letters. The district court sided with the manufacturers, holding that the 340B statute does not prohibit manufacturers from attaching conditions on the sales of covered drugs through contract pharmacies.[34] Notably, the district court added that "any future enforcement action must rest on a new statutory provision, a new legislative rule, or a well-developed legal theory that Section 340B precludes the specific conditions at issue here."[35]

The U.S. Court of Appeals for the Seventh Circuit is also poised to issue its decision soon on the lawsuit brought by Eli Lilly challenging HHS' Advisory Opinion and violation letter. The district court set aside HHS' advisory opinion as being arbitrary and capricious.[36] While the district court also deemed HHS' violation letter arbitrary and capricious given its changing position on whether it has authority to enforce 340B, the court found that HHS did not exceed the scope of its statutory authority.[37] According to the court, while the statute does not unambiguously require drug manufacturers to deliver drugs to an unlimited number of contract pharmacies, it also does not allow Eli Lilly to unilaterally impose contract pharmacy limitations.[38]

What to Expect From the 340B Program

Absent judicial or congressional action, we anticipate more drug manufacturers to restrict contract pharmacy access to 340B pricing and continue to request claims data from covered entities. If the District of Columbia Circuit and the Seventh Circuit rule in a similar manner as the Third Circuit, 340B contract pharmacy arrangements will likely be further limited. If the pending appellate decisions side with the government and produce a circuit split, we expect the issue to be appealed to the Supreme Court.

In the meantime, all eyes are on Congress. Drug manufacturers' contract pharmacy actions have attracted the attention of key policymakers in the House and Senate, who have written to HHS and manufacturers. The actions have also attracted the attention of state legislators, resulting in two states—Arkansas and Louisiana—recently enacting laws prohibiting restrictions on contract pharmacy arrangements.[39] PhRMA sued to declare

Arkansas' law unconstitutional. The federal district court in Arkansas disagreed, and PhRMA's appeal is pending before the U.S. Court of Appeals for the Eighth Circuit.[40] In July 2023, PhRMA also challenged Louisiana's contract pharmacy law.[41]

Given the above, we expect continued efforts to urge Congress resolve the issue legislatively. In the past several months, there has been speculation that Rep. Doris Matsui (D-CA), a longstanding advocate for 340B covered entities, will be introducing legislation soon addressing the contract pharmacy issue.[42] In this regard, it is worth noting that, even if Congress works on a legislative fix, it would likely be a part of a more comprehensive legislative package addressing the 340B Program that could include overarching program authority for HRSA as well as program transparency requirements for participating covered entities.

Back in 2020, when policymakers were first alerted to these developments, Republican leaders from the Senate HELP Committee and House Energy and Commerce Committee issued a Request for Information regarding the 340B Program.[43] While then Senate HELP Committee Chairman Lamar Alexander (R-TN) and then House Energy and Commerce Committee Ranking Member Greg Walden (R-OR) broadly invited ideas on "how to improve" the 340B Program, they indicated that they had been following the ongoing contract pharmacy actions and expressed their view that "contract pharmacies are an important part of the continued discussion around 340B modernization."[44]

In the current 118th Congress, Sen. John Thune (R-SD), the Senate's second-ranking Republican, along with a bipartisan group of six of his colleagues, issued another Request for Information requesting feedback on "policy solutions that would ensure the [340B] program has stability and oversight."[45] The letter specifically asks for feedback on "on ways to improve accountability of covered entities in the program and ensure there is adequate appropriate transparency."[46] In the House, Rep. Larry Bucshon (R-IN) introduced a bill that was recently approved by the Energy and Commerce Committee that would require covered entities to report data on patients served, costs, and revenues, and for HRSA to publish such data.[47] The bill also would let HRSA audit covered entity records to determine how they use their net income from 340B.

As the 2024 election approaches, it will become increasingly difficult for Congress to enact 340B Program legislation. While Congress has indicated interest in addressing drug pricing policies before the end of 2023, there are few legislative days left and a number of competing priorities that could prevent enactment this year. That said, covered entities and manufacturers should be alert to these developments and their potential impact on their operations. No matter how the courts and legislators proceed on this matter, these developments are likely to have a significant impact on all stakeholders in the 340B Program, particularly as they continue to grapple with the economic impact of the pandemic and their path to recovery 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. Department of Health and Human Services, 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 (2021).
6. 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. Genesis Healthcare, Inc. v. Becerra, 39 F.4th 253 (4th Cir. 2022).
8. *See, e.g.*, Brief for Janssen Pharmaceutical Companies as Amici Curiae in Support of Defendants' Motion

for Summary Judgement, Genesis Healthcare, Inc. v. Becerra (No. 4:19-cv-01531-RBH).
9. 61 Fed. Reg. 43,549 (Aug. 23, 1996).
10. 75 Fed. Reg. 10,272 (Mar. 5, 2010).
11. *See* Government Accountability Office, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement (June 2018); *see also* Tom Mirga, The New Rules of 340B Contract Pharmacy, 340B REPORT (May 24, 2022).
12. *See* Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals, 340B Health (July 2023).
13. *Id*.
14. *See* Bill Cassidy, Sen. Bill Cassidy: Smart, practical ways to lower drug prices, Stat (July 2023).
15. *See* Minnesota Session Law Chapter 70 (2023).
16. *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).
17. *See* Tom Mirga, HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B REPORT (July 9, 2020).
18. *Id*.
19. *See* Tom Mirga, HRSA is Investigating Whether Manufacturer Policies to Restrict 340B Pricing at Contract Pharmacies Violates Statute, 340B REPORT (Sept 2, 2020).
20. *See* Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, HHS Off. Gen. Couns. (Dec. 30, 2020).
21. *See* Letter from Rep. David B. McKinley et al. to Alex M. Azar, Sec'y, U.S. Dep't of Health & Hum. Res. (Sept. 14, 2020).
22. *See* Press Release, House Energy & Commerce Comm., E&C Leaders to Azar: Protect the 340B Drug Pricing Program (last visited Sept. 20, 2020).
23. *See* Letter from Sen. Richard Blumenthal et al. to Stephen J. Ubl, President, PhRMA (Sept. 15, 2020).
24. 81 Fed. Reg. 53,381 (Aug. 12, 2016).
25. Complaint, National Association of Community Health Centers v. Azar, No. 1:20CV03032 (D.D.C. Oct. 21, 2020).
26. Complaint, Ryan White Clinics for 340B Access v. Azar, 2020 WL 5992292 (D.D.C. Oct. 9, 2020).
27. 85 Fed. Reg. 80,631 (Dec. 14, 2020).
28. Joint Status Report, Ryan White Clinics for 340B Access v. Azar, 2020 WL 5992292 (D.D.C. Feb. 16, 2021).
29. Order Grant'g Mot. to Dismiss, Am. Hosp. Ass'n v. Dep't of Health & Hum. Servs., No. 4:20-CV-08806-YGR, 2021 WL 616323 (N.D. Cal. Feb. 17, 2021); Notice of Voluntary Dismissal, ECF No. 25 (Nov. 30, 2022).
30. *Id*.
31. 87 Fed. Reg. 73,516 (Nov. 30, 2022).
32. *See* Office of Information and Regulatory Affairs, Spring 2023 Regulatory Agenda, Department of Health and Human Services, 40B Drug Pricing Program; Administrative Dispute Resolution Final Rule, RIN: 0906-AB28.
33. Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs., 58 F.4th 696 (3d Cir. 2023).
34. Novartis Pharms. Corp. v. Espinosa, No. 21-CV-1479 (DLF), 2021 WL 5161783 (D.D.C. Nov. 5, 2021).
35. *Id*. at 21.
36. Eli Lilly & Co. v. United States Dep't of Health & Hum. Servs., No. 121CV00081SEBMJD, 2021 WL 5039566, at *25 (S.D. Ind. Oct. 29, 2021).
37. *Id*. at 22.
38. *Id*. at 24.
39. Arkansas Act 1103 (2021) and Louisiana Act 358 (2023).
40. Appeal, Pharmaceutical Research and Manufacturers of America v. Arkansas Insurance Department, 4:21-CV-864-BRW (8th Cir. Feb. 28, 2023).
41. Complaint, Pharmaceutical Research and Manufacturers of America v. Attorney General of Louisiana, 6:23-cv-00997 (W.D. La. July 23, 2023).
42. *See* Tom Mirga, U.S. Rep. Matsui Expected to File 340B Contract Pharmacy Bill in Connection with 340B Conference, 340B REPORT (June 29, 2023).
43. *See* Press Release, House Energy & Commerce Comm., Walden and Alexander Ask for Input on Modernizing 340B Drug Pricing Program (Oct. 9, 2020).
44. *Id*.
45. *See* Sen. John Thune (R-SD), Letter to 340B Stakeholders Regarding the 340B Drug Pricing Program (June 16, 2023).
46. *Id*.
47. *See* 340B Transparency Act (118th Congress - H.R. 329).

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