340B UPDATE: DELAWARE COURT DENIES 340B PROGRAM STATUTE REQUIRING CONTRACT PHARMACY ARRANGEMENTS

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U.S. Health Care and FDA Alert

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Recent court decisions and the subsequent rescission of a key advisory opinion have left the status of contract pharmacy programs in continued flux. On 30 December 2020, the Department of Health and Human Services (HHS) released Advisory Opinion 20-06 (the Advisory Opinion) stating that drug manufacturers are required to deliver drugs to contract pharmacies and charge no more than the 340B ceiling price. On 16 June 2021, the U.S. District Court for the District of Delaware issued a Memorandum Opinion (Decision) in *AstraZeneca Pharmaceuticals LP v. Becerra*, a case that challenged the validity of the Advisory Opinion, narrowly holding that Congress has not clearly and unambiguously spoken regarding the unlimited use of contract pharmacies by covered entities under the 340B Program.[1] Two days after the Decision was released, HHS filed a Notice in cases that challenged HHS's issuance of the Advisory Opinion, stating that it was withdrawn.[2] Subsequently, the parties filed a Joint Status Report in the AstraZeneca case on 21 June 2021, in which HHS argued that the case as to the Advisory Opinion is moot and should no longer factor into a court's decision.[3] However, the parties agreed that the case should continue as to the legality of HHS's letter, which raises the possibility of the imposition of civil monetary penalties if drug manufacturers, including AstraZeneca, do not resume selling via the contract pharmacy model. On 30 June, 2021, the court determined that "HHS's withdrawal of the Opinion does not moot this litigation."[4] Additionally, the court set aside and vacated the Advisory Opinion.[5]

KEY TAKEAWAYS INCLUDE:

First Substantive Court Ruling

The Decision is most noteworthy for being the first substantive ruling regarding HHS's authority to implement the contract pharmacy model among the various courts that are currently considering this issue.

Withdraw of Advisory Opinion

The nearly immediate withdraw of the Advisory Opinion means HHS intends to fight this issue on the merits of its original 1996 and 2010 contract pharmacy guidance in lieu of getting bogged down in the arguments found in the Advisory Opinion.

Civil Monetary Penalties

HHS made it clear in the Joint Status Report that it intends to take enforcement action against the manufacturers in question as outlined in the letters sent to manufacturers on 17 May 2021, on which formal action is likely to be forthcoming.

Restarting the ADR Process

Effective 21 June 2021, Secretary Xavier Becerra appointed six members to the 340B administrative dispute resolution (ADR) board (Board).[6] Notably, the ADR regulations issued by HHS have been contested, including the issuance of a preliminary injunction halting their implementation in one case. Please see our summaries of the ADR regulation and these actions (here and here).

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.[7] The Health Resources Services Administration (HRSA) issued guidance in 1996 permitting covered entities eligible for 340B Program pricing to contract with a pharmacy to provide drug dispensing to the covered entity's patients.[8] 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.[9] As reported in our alerts (here and here), several drug manufacturers have taken actions to limit covered entities' use of contract pharmacies in the 340B Program, including complete prohibitions on their use, with limited exceptions. On 30 December 2020, HHS released the Advisory Opinion regarding the use of contract pharmacies, concluding that, because contract pharmacies act as agents of covered entities, drug manufacturers are required to deliver drugs to such pharmacies and charge no more than the 340B ceiling price.[10] Specifically, the Advisory Opinion argued that the core requirement of the 340B statute requires manufacturers to offer covered entities drugs at or below the ceiling price, and this requirement is in no way qualified by how the covered entity chooses to distribute the drugs, including through the use of contract pharmacies. Shortly thereafter, four drug companies and a trade association filed separate declaratory judgment actions against HHS seeking to invalidate the opinion, arguing both that HHS lacks the authority to issue the opinion and that it did not follow proper procedures in its issuance.[11]

HRSA warned of potential, additional actions against certain manufacturers on 17 May 2021 (see our alert on this topic here). Specifically, it sent letters to six drug manufacturers stating that they must permit covered entities to receive 340B pricing at contract pharmacies. Subsequently, AstraZeneca, Eli Lilly, and Sanofi responded to HRSA's letters by filing additional pleadings in their ongoing litigation against HHS to seek relief from HRSA's 1 June deadline, which was subsequently delayed to 10 June. If the drug manufacturers failed to comply, HHS cited its ability to take enforcement action, including the implementation of civil monetary penalties.

SUMMARY OF THE DECISION

In the case at issue, AstraZeneca filed a declaratory action asserting that the Advisory Opinion released by HHS on 30 December 2020[12] was issued in violation of the Administrative Procedures Act. Specifically, AstraZeneca's amended complaint in this matter contained three[13] relevant claims for declaratory relief: “(i) in promulgating and enforcing the Opinion, the government failed to observe notice-and-comment procedures, in violation of 5 U.S.C. § 706(2)(D); (ii) the Opinion exceeds the government's authority under the 340B statute, in violation of § 706(2)(A) [and] (C); [and] (iii) the Opinion is arbitrary and capricious, in violation of § 706(2)(A).”[14] AstraZeneca moved for summary judgment, and HHS filed a cross-motion to dismiss, or, in the alternative, motion for summary judgment. In the Decision, the court ruled solely on HHS's motion to dismiss, denying it except to claims abandoned by the drug manufacturer.

In finding that the Advisory Opinion is “legally flawed,”[15] the court stated that the statutory language is ambiguous regarding the permissible use of an unlimited number of contract pharmacies. In its analysis, it noted that the

statutory text does not use the term “pharmacy,” and, therefore, it is “highly unlikely (if not impossible) that the statute conveys a single, clear, and unambiguous directive with respect to that word.”[16] Importantly, in arriving at this conclusion, the court seemingly sided with neither party's interpretation of the statute and, again, stressed that Congress has been silent on this issue, stating, “Both parties agree that only Congress may add requirements to the 340B statute . . . [y]et both parties' interpretations of the status effectively, and impermissibly, add requirements to it.”[17]

The court also rejected the argument that the opinion was a restatement of HHS's long-held position and instead concluded that this was an analysis of the “must offer” provision of the 340B statute.[18] Specifically, the court found that the focus of the opinion is different from prior guidance issued by HRSA in 1996 and 2010, in which the court argued HRSA only made use of contract pharmacies permissive as to covered entities. In this regard, the court stated, “[T]he Opinion is the first document in which HHS explicitly concluded that drug manufacturers are required by statute to provide 340B drugs to multiple contract pharmacies.”[19]

HHS' RESPONSE TO THE DECISION

Subsequently, HHS filed a Notice of its withdraw of the Advisory Opinion, stating that such withdraw “should not be interpreted as a concession that Defendants agree with the Court's holdings, including its determination that the Advisory Opinion is reviewable. Rather, the Advisory Opinion was withdrawn 'in an effort to avoid confusion and unnecessary litigation, in recognition of the narrow function the Opinion was intended to serve.'”[20] In the subsequent Joint Status Report filed by the parties, HHS requested that the case as to the Advisory Opinion be dismissed as moot.[21] As noted above, subsequent to the Decision, and despite the Advisory Opinion's withdraw by HHS, AstraZeneca nonetheless asked the court to vacate and set aside the Advisory Opinion, arguing that HHS “may not escape the implications of this Court's Memorandum Opinion by withdrawing the Advisory Opinion only after this Court rejected the statutory interpretation adopted in that Opinion, but before the Court issued judgment.”[22]

Although the parties disagreed on the proper process for moving forward with regard to the Advisory Opinion, “[t]he Parties [did] agree that the litigation should continue and that the Court should decide the legality of the HRSA Violation Letter.”[23]

On 30 June 2021, the court issued a Memorandum Opinion that set and aside and vacated the Advisory Opinion. It also denied HHS's argument that case is now moot stating that “although HHS withdrew the [Advisory] Opinion , HHS has made it clear that its position on the 340B statute has not changed. Because HHS . . . intend[s] to act in accordance with the withdrawn [Advisory] Opinion, this litigation is not moot.”[24] The court also granted AstraZeneca's motion for summary judgement on the claim that HHS acted arbitrarily and capriciously, but denied the motion on the claims regarding notice and comment rulemaking and exceeding its statutory authority. Lastly, the parties submitted another Joint Status Report on 6 July 2021, in which they agreed that AstraZeneca will file its Second Amended Complaint by 9 July 2021 and otherwise set deadlines for the case.[25]

ADR DEVELOPMENTS

In related 340B developments, effective 21 June 2021, Secretary Becerra appointed six members to the Board.[26] Previously, on the day of President Biden's inauguration, former Secretary Alex Azar announced that he had appointed six members and two ex officio members to the Board. However, the announcement was

withdrawn by the Biden administration the next day. Nonetheless, Secretary Becerra retained two of the former appointees for voting positions on the Board, as well as both former ex officio appointees. Currently, at least three dispute resolution filings have been submitted and, despite any pending court challenges, HHS appears to be moving forward with the ADR process.

MANUFACTURER RESPONSES TO HRSA LETTER

On 29 June 2021, three manufacturers publicly released their responses to the HRSA letter.[27] Overall, each manufacturer reiterated its position that it believes it is in compliance with the law and that HHS has no reasonable basis for threatening to impose civil monetary penalties if such manufacturers do not resume permitting covered entities to use an unlimited amount of contract pharmacies. The letters also generally reiterate the positions that these manufacturers have taken in related litigation; namely, that the 340B statute does not require manufacturers to sell via the contract pharmacy model and that HRSA has not taken a clear position on this issue over the years. Additionally, certain manufacturers urged HHS to defer to the outcome of this litigation prior to imposing any penalties and that the imposition of penalties would be contrary to the positions that it has taken in these cases.

NEXT STEPS

The Decision is most noteworthy as the first substantive ruling regarding the use of contract pharmacies among the various courts that are currently considering this issue. Importantly, however, the court did not determine whether HRSA had authority to establish the contract pharmacy model. Instead, it simply concluded that the 340B statute alone does not require manufacturers to participate in the contract pharmacy model. As a next step, the court has not yet ruled on how the case will proceed in light of the withdrawal of the Advisory Opinion, and its decision will be forthcoming.

Of more significance, based on the Joint Status Report filing, it would appear that HRSA is poised to take action in the near term against the manufacturers as threatened in its 17 May letters, such as through the imposition of civil monetary penalties. Additionally, by taking action to repopulate the Board, HHS has indicated that it will move forward with resolving disputes via this mechanism, despite any ongoing court challenges to the validity of the regulations promulgating the ADR rules.

K&L Gates' Health Care and FDA practice and public policy and law practice regularly advise stakeholders on 340B Program compliance and strategy matters and facilitate engagement with Congress and the administration on 340B matters.

FOOTNOTES

[1] AstraZeneca Pharm. LP v. Becerra, C.A. No. 21-27--LPS (D. Del. June 16, 2021) (mem.), at 17.

[2] *See* Eli Lilly & Co. v. Becerra, Docket No. 1:21-cv-00081 (S.D. Ind.); AstraZeneca Pharm. LP v. Azar, Docket No. 1:21-cv-00027 (D. Del.); Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health and Hum. Servs., Docket No. 3:21-cv-00634 (D.N.J.).

[3] Joint Status Report (June 21, 2021), *Azar*, Docket No. 1:21-cv-00027.

[4] Memorandum Order, *Azar*, Docket No. 1:21-cv-00027.

[5] *Id*

[6] Appointment of Administrative Dispute Resolution Board Members, 86 Fed. Reg. 33,317 (June 24, 2021).

[7] *See* 42 U.S.C. § 256b(a).

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

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

[10] Dept. of Health & Hum. Res. Adv. Op. No. 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020).

[11] See *Eli Lilly*, Docket No. 1:21-cv-00081; *Azar*, Docket No. 1:21-cv-00027; *Sanofi-Aventis*, Docket No. 3:21-cv-00634 (D.N.J.); Novo Nordisk Inc. v. U.S. Dep't of Health & Hum. Servs., No. 3:21-cv-00806-FLW-LHG (D.N.J.); Pharm. Rsch. & Mfrs. of Am. v. Cochran, No. 8:21-cv-99198-PWG (D. Md.).

[12] Dept. of Health & Hum. Res. Adv. Op. No. 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020).

[13] The fourth claim, that the government failed to post AstraZeneca's notice to covered entities on the HRSA website, was abandoned by the manufacturer. See Azar, Docket No. 1:21-cv-00027 at 23.

[14] *Id*. at 7.

[15] *Id*. at 17.

[16] *Id*. at 18.

[17] *Id*. at 21.

[18] *Id*. at 10.

[19] *Id*. at 12.

[20] Notice, *Azar*, Docket No. 1:21-cv-00027.

[21]Joint Status Report, *Azar*, Docket No. 1:21-cv-00027.

[22] *Id*.

[23] *Id*.

[24] Memorandum Order, *Azar*, Docket No. 1:21-cv-00027.

[25] Joint Status Report (July 6, 2021), Azar, Docket No. 1:21-cv-00027.

[26] Appointment of Administrative Dispute Resolution Board Members, 86 Fed. Reg. 33,317 (June 24, 2021).

[27] *Three Drug Makers Answer HRSA's 340B Contract Pharmacy Letters Defiantly*, 340B Report (June 29, 2021).

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