UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

Genesis Health Care, Inc., Plaintiff, v. Xavier Becerra, as Secretary of the United States Department of Health and Human Services; Carole Johnson, as Administrator of the Health Resources and Services Administration; Emeka Egwim, as Lieutenant Commander in the United States Public Health Service and Direction of the Office of Pharmacy Affairs in the Health Resources and Services Administration, Defendants.	Civ. Action No. 4:19-cv-01531-RBH **ORDER**

Presently before the Court is Plaintiff Genesis Health Care, Inc.'s motion to compel a privilege log and request for extra-record discovery. ECF No. 95. The government filed a response in opposition on February 13, 2023. Genesis did not file a reply. For the reasons set forth below, the Court respectfully denies Genesis's motion to compel.[1]

This case was on remand from the Fourth Circuit Court of Appeals. *Genesis Healthcare, Inc. v. Becerra*, 39 F.4th 253, 256 (4th Cir. 2022). Plaintiff originally brought this suit seeking injunctive and declaratory relief because Health Resources Services Administration ("HRSA") removed Genesis Healthcare from the 340B program, which is designed to provide drugs to qualified persons at discounted prices. After Genesis filed their complaint, HRSA vacated its order

[1] Under Local Civil Rule 7.08 (D.S.C.), "hearings on motions may be ordered by the Court in its discretion. Unless so ordered, motions may be determined without a hearing." Upon review of the briefs, the Court finds that a hearing is not necessary.

removing Genesis Healthcare from the 340B program, but it continued to insist that Genesis Healthcare comply with its requirement of serving only eligible "patients" as defined by HRSA.

Based on Genesis Healthcare's reinstatement in the 340B program, this court dismissed the matter as moot; however, the Fourth Circuit found that "because Genesis Healthcare continues to be governed by a definition of 'patient' that, it maintains, is illegal and harmful to it, we conclude that there remains a live controversy between the parties" - reversing this Court's finding of mootness. *Genesis Healthcare, Inc.*, 39 F.4th at 257. Thus, the sole issue in this declaratory judgment action concerns the definition of "patient" in the context of the HRSA's 340B program, HRSA's patient definition guidelines, and whether HRSA's reading of the term "patient" is consistent with the statute, 42 U.S.C. § 256b(a)(5)(B).

Genesis's amended complaint specifically seeks the following declarations:

1) Genesis requests this Court declare that the only statutory requirement for 340B eligibility of a person is that the person be a patient of a covered entity, as clearly stated in 42 U.S.C. § 256b(a)(5)(B). ECF No. 33 at ¶¶ 65, 68.

2) Genesis requests this Court declare that the plain wording of 42 U.S.C. § 256b(a)(5)(B) requires that any prescription from any source is available to a patient of a covered entity. *Id*. at ¶¶ 66, 69.

3) Genesis further requests this Court declare any and all interpretations or guidance of HRSA in contradiction of the plain wording of 42 U.S.C. § 256b(a)(5)(B) unlawful and unenforceable as a matter of law. *Id*. at ¶ 67.

4) Genesis further requests this Court declare that HRSA did not have the broad rule-making authority necessary to implement its interpretations and restrictions to the plain language of 42 U.S.C. § 256b(a)(5)(B). *Id*. at ¶ 70.

Clearly, from a review of the pleadings in this case, Genesis seeks nothing more than a

declaration regarding HRSA's reading of the statutory interpretation of the definition of "patient" in the context of HRSA's 340B program. In its opinion remanding the matter, the Fourth Circuit recognized as much, "[t]he real issue thus remains, even after HRSA's final letter, *whether the 1996 Guidelines are inconsistent with the statute*, as Genesis Healthcare has alleged and with respect to which Genesis Healthcare sought a declaratory judgment." *Genesis Healthcare, Inc.*, 39 4th at 261.

In its motion to compel a privilege log and extra record discovery, Genesis states that it "seeks discovery related to its action for declaratory relief challenging HRSA's 1996 Guidelines and HRSA's interpretation of the statutory term 'patient.'" ECF No. 95 at 6. Genesis argues that the Administrative Record is directly and only related to the audit and removal of Genesis from the 340B program and does not contain the materials necessary to develop a record related to HRSA's interpretation of the term "patient." *Id*. Therefore, in essence, Genesis maintains that it requires extra-record discovery and a privilege log to challenge the HRSA's interpretation of the statutory term "patient" under the 340B program.

While Genesis's position is well-taken, this Court cannot ignore the reality that this case involves a question of statutory interpretation, and whether the agency's interpretation of the term "patient" is consistent with the statute. These issues can be addressed by cross-motions for summary judgment and the Court would normally apply the traditional tools of statutory interpretation. *See, e.g. American Hosp. Assoc. v. Becerra*, 142 S. Ct. 1896, 1906 (2022) (stating "after employing the traditional tools of statutory interpretation, we do not agree with HHS's interpretation of the statute" in a case involving question of statutory interpretation in context of reimbursement rates for 340B hospitals).

Although not cited by the parties, in *Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services*, the district court was tasked with, among other things, reviewing the HRSA's reading of statutory terms within the 340B statute. *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 191-207 (D.N.J. 2021), aff'd in part, rev'd in part sub nom. *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023). In that case, HRSA read the 340B statute to require pharmaceutical manufacturers to deliver discounted drugs to an unlimited number of contract pharmacies per "covered entity." *See Sanofi Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th at 706. The district court in New Jersey found in favor of the government and determined that the pharmaceutical companies could not "dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs." *Sanofi-Aventis U.S., LLC* , 570 F. Supp. 3d at 203. The New Jersey district court declined, however, to determine how many contract pharmacies the 340B statute permits for each "covered entity" and remanded the matter to the agency "for additional investigation or explanation." *Id.*

Also not cited by the parties, in a similar case which reached the opposite result, a Delaware district court also reviewed HRSA's interpretation of the 340B statute. *AstraZeneca Pharms. LP v. Becerra*, No. CV 21-27-LPS, 2022 WL 484587, at *1 (D. Del. Feb. 16, 2022), judgment entered, No. CV 21-27-LPS, 2022 WL 18508603 (D. Del. Mar. 11, 2022), *aff'd in part sub nom. Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023). As in *Sanofi-Aventis U.S., LLC*, HRSA took the view that "all covered entities may use an unlimited number of contract pharmacies for dispensing 340B drugs." *AstraZeneca Pharms. LP*, 2022 WL 484587, at *1. The district court in Delaware ruled that nothing in the plain text of the 340B statute

or legislative history supported the government's interpretation of the 340B statute: that pharmaceutical manufacturers were required to deliver 340B drugs to an unlimited number of contract pharmacies of covered entities. *AstraZeneca Pharms. LP*, 2022 WL 484587, at *6-7; *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 61 (D. Del. 2021).

This Court has scoured the district court dockets in the above-mentioned cases and it does not appear that any extra-record discovery was *requested*, *relied on by either party in their cross-motions for summary judgment, or relied upon by the district courts in rendering their decisions*. The dockets reflect the Certified Administrative Record was filed, but beyond that there does not appear to have been any extra-record discovery conducted or pursued. To resolve the merits of the case, the district courts analyzed the text of the 340B statute, legislative history, any pertinent statutory structural clues, and whether other statutory provisions supported HRSA's position. *See, e.g. AstraZeneca Pharms. LP*, 543 F. Supp. 3d at 59-61 (D. Del. 2021); *AstraZeneca Pharms. LP*, 2022 WL 484587, at *6-7; *Sanofi-Aventis U.S., LLC*, 570 F. Supp. 3d. at 194-203.

These cases were consolidated on appeal and the Third Circuit Court of Appeals ultimately resolved the question of whether the 340B statute required pharmaceutical manufacturers to deliver discounted drugs to an unlimited number of contract pharmacies. *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703 (3d Cir. 2023). The Third Circuit started its analysis with the text of the 340B statute, then it considered whether any structural clues confirm whether the statute required unlimited delivery to contract pharmacies. *Sanofi Aventis U.S. LLC*, 58 F.4th at 703–04. Finally, the Third Circuit looked to the drafting and legislative history. *Id*. at 705. In conclusion, the Third Circuit disagreed with HRSA's interpretation of the 340B statute and enjoined the government from enforcing its reading of Section 340B as requiring pharmaceutical

manufacturers to deliver discounted drugs to an unlimited number of contract pharmacies. *Id*. at 706.

In essence, Genesis has not illustrated that the present case differs in any material respect from *Sanofi-Aventis U.S., LLC* or *AstraZeneca Pharms. LP*. Further, Genesis has failed to demonstrate that extra-record discovery or the disclosure of a privilege log is appropriate, necessary to the resolution of this case, or will have any impact on the relevant questions of statutory interpretation.

As alleged by Genesis in its amended complaint, ECF No. 33 at ¶ 6, this action arises under the Administrative Procedures Act, 5 U.S.C. § 500, *et seq*. ("APA"). As a general matter, "claims brought under the APA are adjudicated without a trial or discovery, on the basis of an existing administrative record[.]" *Audubon Naturalist Soc'y of the Cent. Atl. States, Inc. v. U.S. Dep't of Transp.*, 524 F. Supp. 2d 642, 660 (D. Md. 2007); *see also Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 47 (D.C. Cir. 2013) ("[I]t is black-letter administrative law that in an APA case, a reviewing court 'should have before it neither more nor less information than did the agency when it made its decision.' " (citation omitted)). This "reflects the recognition that further judicial inquiry into 'executive motivation' represents 'a substantial intrusion' into the workings of another branch of Government and should normally be avoided." *Dep't of Commerce v. New York*, —— U.S. ——, 139 S. Ct. 2551, 2573, 204 L.Ed.2d 978 (2019) (citation omitted).

Under the APA, "the court shall review the whole record or those parts of it cited by a party." 5 U.S.C. § 706(2). Ordinarily, this inquiry "is limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record." *New York*, 139 S. Ct. at 2573 (citing *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 549, 98

S.Ct. 1197, 55 L.Ed.2d 460 (1978)). Hence, "the focal point for judicial review" under the APA "should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142, 93 S.Ct. 1241, 36 L.Ed.2d 106 (1973) (per curiam).

In an APA case, discovery beyond the record may be appropriate where the record is incomplete; where additional information would provide helpful context; where supplemental information would assist the court in determining whether the agency failed to consider relevant factors; and, where the record's integrity has been impugned. *Mayor & City Council of Baltimore v. Trump*, 429 F. Supp. 3d 128, 137 (D. Md. 2019). These exceptions exist for the purpose of assisting the Court in its judicial review function under the APA, not necessarily to assist the plaintiff in proving their case, particularly when the issue is one of statutory interpretation. As alluded to in the previous paragraphs, the Court is puzzled as to how extra-record discovery could aid the Court in its judicial function of determining whether HRSA's reading of the statutory term "patient" is consistent with the 340B statute.

Whether the plaintiff is seeking to supplement the record, obtain a privilege log, or engage in extra-record discovery, a plaintiff must generally make "a strong showing of bad faith or improper behavior" on the part of the agency in order to be entitled to extra-record discovery. *New York*, 139 S. Ct. at 2574; *Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 514 (D.C. Cir. 2010); *see also Air Transp. Ass'n of Am., Inc. v. Nat'l Mediation Bd.*, 663 F.3d 476, 487 (D.C. Cir. 2011) (extra-record discovery appropriate only where "party makes a significant showing ... that it will find material in the agency's possession indicative of bad faith or an incomplete record"); *Stand Up for California! v. United States Dep't of Interior*, 71 F. Fupp.3 d 109, 123 (D.D.C. 2014) ("[T]o

obtain a log of privileged and deliberative materials excluded from the administrative record, plaintiffs must overcome, with clear evidence, the presumption of regularity in the agency proceedings by showing bad faith or other exceptional circumstances"); *see also Oceana, Inc. v. Ross*, 920 F.3d 855, 865 (D.C. Cir. 2019) ("absent a showing of bad faith or improper behavior, '[a]gency deliberations not part of the record are deemed immaterial' and "[b]ecause predecisional documents are 'immaterial,' they are not 'discoverable'"). The Court does not find the cases cited by Genesis calling *Oceana* into question persuasive or applicable to this case of statutory interpretation. Genesis has failed to make a sufficient showing of bad faith, exceptional circumstances, improper behavior, or that it is otherwise entitled to a privilege log or extra record discovery.

Genesis attempts to show impropriety or bad faith by pointing to discrepancies between the response it got from the government on its FOIA request and the CAR produced in this case. Genesis's arguments, however, are insufficient to warrant extra record discovery. The FOIA documents were provided under a different standard than the CAR and Genesis has failed to show that anything was improperly excluded from the administrative record. It should be noted that Genesis did not bring an action challenging the government's FOIA response. The government asserts on page 2 of its brief that Genesis focuses on a redacted document that it received via FOIA (a blank template audit protocol form), yet that same document *completed specifically for Genesis*, is included in the CAR. *Genesis filed no reply to the government's response and makes no attempt to dispute this important point.*

The Court's prior Text Order permitted Genesis to file a motion for extra-record discovery by February 6, 2023. *See* ECF Nos. 78, 80-81. Genesis, however, was required to identify with particularity the nature of the extra-record discovery needed and demonstrate a particularized need

for such discovery. ECF No. 78. Other than a vague request for a privilege log and an unsupported assertion that the government is withholding its 340B audit program and process materials - *an assertion the Court finds conflicts with the documents actually produced in the CAR*, Genesis has failed to identify with particularity any extra-record discovery needed and they have failed to demonstrate a particularized need for any discovery beyond the CAR.

As a final argument, Genesis acknowledges that this Court must "decide all relevant questions of law, interpret . . . statutory provisions, and determine the meaning . . . of the terms of an agency action." 5 U.S.C. § 706. *See* Genesis Motion to Compel, ECF No. 95 at 16. Genesis goes on to cite a version of Fed. R. Civ. P. 26(b)(1) that has not been in effect since December 1, 2007. The current version of Fed. R. Civ. P. 26(b)(1), which has been in effect since December 1, 2015, provides:

> Parties may obtain discovery regarding any nonprivileged matter that is *relevant to any party's claim or defense and proportional to the needs of the case*, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

Fed. R. Civ. P. 26(b)(1) (emphasis added). Proportionality requires courts to consider, among other things, "the importance of the discovery in resolving the issues" and "whether the burden or expense of the proposed discovery outweighs its likely benefit." *Id*. This relieves parties from the burden of taking unreasonable steps to ferret out every relevant document. *Virginia Dep't of Corr. v. Jordan*, 921 F.3d 180, 188–89 (4th Cir. 2019). Here, Genesis has failed to show how extra-record discovery is proportional to the needs of a case which is limited to the Court's review of HRSA's reading of the

statutory term "patient" and whether HRSA's reading is consistent with the 340B statute. Genesis has not demonstrated that extra-record discovery is required under Fed. R. Civ. P. 26(b)(1).

Conclusion

In the absence of a showing of bad faith, exceptional circumstances, or a particularized request establishing exactly what extra record discovery is needed and why it is needed in this case of statutory interpretation, Plaintiff Genesis Health Care, Inc.'s [95] motion to compel privilege log and request for extra record discovery is **DENIED**.

IT IS SO ORDERED

April 24, 2023
Florence, South Carolina

s/ R. Bryan Harwell
R. Bryan Harwell
Chief United States District Judge