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 Director of the Office of Pharmacy Affairs in the Health Resources and Services Administration; Defendants. _____ 340B Health, Amicus Supporting Plaintiff, and, The Janssen Pharmaceutical Companies, AbbVie, Inc., Bristol Myers Squibb Company, Eli Lilly & Company, Merck & Co., Inc., Amici Supporting Defendants. _____	Civil Action No.: 4:19-cv-01531-RBH **ORDER**

This declaratory judgment action was brought by Plaintiff Genesis Health Care, Inc. ("Genesis") against Defendants Xavier Becerra, as Secretary of the United States Department of Health and Human Services ("HHS"), Carole Johnson, as Administrator of the Health Resources and Services Administration ("HRSA"), and Emeka Egwim, as Lieutenant Commander in the

United States Public Health Service and Director of the Office of Pharmacy Affairs in the Health Resources and Services Administration. ECF No. 33.

This case centers on the Health Resource and Service Administration's ("HRSA") interpretation of the term "patient" under the 340B statute, 42 U.S.C. § 256b, and HRSA's attempts to enforce their interpretation of the term "patient" on Genesis. For the reasons set forth below, the Court grants, in part, Genesis's motion for summary judgment and denies Defendants' motion for summary judgment.[1]

Introduction to the 340B Program (42 U.S.C. §256b)

The 340B program, 42 U.S.C. § 256b, was enacted in response to the increase in drug prices that flowed from the Omnibus Budget Reconciliation Act ("OBRA") of 1990, which created the Medicaid Drug Rebate Program. AR 17-20, H.R. REP. 102-384, 7-10. Congress concluded that while OBRA 90 achieved its objective of generating savings for the Medicaid program, the VA, Federally-funded clinics, and public hospitals experienced substantial price increases in their outpatient drugs as drug manufacturers attempted to limit their rebates to Medicaid. AR. 20, H.R. REP. 102-384, 11. The drug manufacturer's price increases in outpatient prescription drugs "reduced the level of services and the number of individuals that these hospitals and clinics [were] able to provide with the same level of resources." *Id*.

The purpose of the 340B program was to enable the Department of Veterans Affairs ("DVA") and certain Federally-funded clinics to obtain lower prices on the drugs they provided to their patients. AR 17, H.R. REP. 102-384, 7. The legislative history indicates that Congress was not

[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.

willing "to continue to allow the DVA, Federally-funded clinics, and their patients to remain unprotected against manufacturer price increases." AR 20, H.R. REP. 102-384, 11. By providing "covered entities" access to price reductions, the 340B program would "enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." AR 21, H.R. REP. 102-384, 12. Put simply, the purpose of the 340B program was to provide a means to make 340B entities profitable in order for those 340B entities to "stretch scarce Federal resources as far as possible." *See id.*

340B entities are able to stretch these scarce Federal resources because they receive their drugs at a discount and are reimbursed by insurers at the non-discounted price of the drug, thereby increasing the 340B entity's profit margin. This allows 340B entities to provide more services to a larger population of under-served patients.

To achieve the stated purpose of the 340B program, Congress enacted the Veterans Health Care Act of 1992 (340B Program - 42 U.S.C. § 256b).

The 340B statutory provision at issue in this case involves the term "patient," which can be found under the subtitle "Prohibiting resale of drugs." 42 U.S.C. § 256b(a)(5)(B). The relevant code section provides: "[w]ith respect to any covered outpatient drug that is subject to an agreement under this subsection, *a covered entity shall not resell or otherwise transfer the drug to a person who is not a* ***patient*** *of the entity*." *Id*. (emphasis added).

Although other terms are defined in the statute, such as: "over the counter drug", "covered entity", "average manufacturer price", "covered outpatient drug", "manufacturer", and "covered drug", Congress chose not to define the term "patient." *See generally*, 42 U.S.C. § 256b.

HHS Public Notices

On September 19, 1994, the Department of Health and Human Services ("HHS") published a Notice to "inform interested parties of final program guidelines concerning the inclusion of outpatient disproportionate share hospital (DSH) facilities in the PHS drug discount program." Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 FR 47884-01. The Notice contained an important comment:

> Comment: There is no definition of the term "patient," thereby permitting a DSH [Disproportionate Share Hospital or "covered entity"] to distribute discounted drugs to virtually anyone it can argue is a patient without running afoul of the drug resale prohibition of section 340B(a)(5)(B) of the PHS Act.

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 FR 47884-01. HHS responded to the comment by stating "PHS will address this issue in a future Federal Register notice which will request public comment. All comments concerning the definition of 'patient' will be addressed at that time." *Id*. This comment was never specifically addressed in any future Federal Register notice. Even though this comment made HHS aware of the potential for a "covered entity" to distribute discounted drugs to virtually anyone it could argue was a patient, HHS declined to address the issue with any specificity or suggest any limitation with respect to the origination of a certain outpatient prescription. Instead, HHS opted for the "flexible" definition of the term "patient" outlined in the October 1996 guidelines.

On October 24, 1996, HHS published a Notice "to inform interested parties of final guidelines regarding a definition of covered entity 'patient.'" Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 FR 55156-01. Notably, this Notice included the following comment: The definition of "patient" is ambiguous and difficult to

administer from a drug diversion standpoint. *Id*. HHS responded:

> The definition of a "patient" was developed in order to identify those individuals eligible to receive 340B drugs from covered entities. Because of the large number of covered entities and the wide diversity of eligible groups (e.g., hemophilia, HIV, black lung, migrant health, and family planning services), *it was essential that we work closely with each Federal program office to* ***develop a definition flexible*** *enough to describe accurately each covered entity's patient while at the same time not excluding eligible patients.* In addition, not only comments received in response to this notice but also comments from prior Federal Register notices (59 FR 25111, May 13, 1994, and 59 FR 47886, September 19, 1994) were incorporated into the definition. By using such input, *we are confident that the definition will assist covered entities and manufacturers in determining which individuals are eligible to receive 340B drugs*.

Id. (emphasis added). HHS's response to the comment underscores a view in 1996 that the term "patient" was intended to have a flexible application to accommodate the large number of covered entities and the wide diversity of eligible patients.

Another noteworthy comment from the 1996 Public Notice stated:

> Comment: The definition would permit a patient to obtain one medical treatment from a covered entity at any time in his or her lifetime and then continue (forever) to purchase drugs through prescription refills by using such services as mail order. The proposed patient definition should require that a covered entity patient be currently receiving care, and an additional section should be added to address the frequency of medical care.

Id. HHS responded by stating:

> Response: All covered entities must establish a relationship with their patients such that the entity will maintain records of the individuals' health care. The entity will document in the record the care provided and, when appropriate, the prescriptions written. It would be inappropriate for the Department to proceed further and dictate to health care providers guidelines regarding the appropriateness of certain prescriptions. We understand that States typically regulate the refilling of prescriptions.

Id. Again, the response from HHS appears to indicate that all that is necessary for an individual to qualify as a patient of a "covered entity" is for the "covered entity" to establish a relationship with their patients such that the entity will maintain records of the individuals' health care. Conspicuously absent from HHS's response is that HHS did not provide any guidance for a suggested time period or look-back period during which the "patient" must have had a health care encounter with the "covered entity."[2]

Another pertinent comment and response that also indicates HHS's understanding in 1996 of the term "patient" in the context of the 340B program provides: "[c]overed entities should be required to restrict purchases to drug products that are directly related to the provision of services for which Federal funding has been provided." *Id*. HHS's response again implies a broad reading of the term "patient":

> Response: We do not consider a limitation on which drug products a covered entity may purchase to be a reasonable component of the definition of covered entity "patient." To the extent that purchasing certain drugs would contravene a Federal or State law or certain PHS grant principles (and this information is brought to the Department's attention), the Department reserves the right to take such action as it deems appropriate.

Id. Notably, none of the responses to the comments reflect a concern that 340B patient eligibility was conditioned on whether a particular outpatient prescription originated from the "covered entity" or was otherwise initiated by the "covered entity."

The comments to the 1996 Notice raised issues such as: 1) spurious claims that "covered entities" may make regarding patient eligibility of certain individuals; and 2) a potential life-long

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[2] In its response to the audit report, Genesis states that in order to limit the definition of a 340B eligible patient, Genesis only permits the resale of outpatient drugs to "patients" who have received a FQHC service from a "covered entity" within the last twenty-four months. AR 219.

ability by a "patient" to obtain prescription drugs from a "covered entity" based on one single encounter, regardless of how long ago the encounter occurred. These concerns are also voiced in the administrative record by various pharmaceutical manufacturers raising concerns over a broad definition of the term "patient." *See* AR 45-55, 62-80, 83-84, 94-98. Although these issues were raised to HHS, HHS either did not address the comment directly, or set aside the comment implying the comment was not of significant concern.

Following consideration of the comments from the October 1996 Notice, and prior notices, HHS developed the following definition of patient as guidance for its 340B stakeholders:

> **October 1996 Guidelines**
>
> (C) Definition of a Patient
>
> An individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:
>
> 1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's healthcare; and
>
> 2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
>
> 3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.
>
> An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs

> for subsequent self-administration or administration in the home setting.
>
> An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program.

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 FR 55156-01. As noted by Defendants in their supplemental filings before the Fourth Circuit Court of Appeals, the October 1996 guidelines defining "patient" provided a "flexible" definition to apply across varied contexts. *Genesis Health Care, Inc. v. Becerra*, Fourth Circuit Court of Appeals, No. 20-1701, ECF No. 45.

On August 28, 2015, HHS issued a notice proposing further guidelines for implementation of the 340B program. 340B Drug Pricing Program Omnibus Guidance, 80 FR 52300-01. While the purpose of this guidance was broad and covered many different aspects of the 340B program, HHS dedicated a section of the 2015 guidance to the definition of "patient" under the 340B statute. *Id.*

HHS stated the "proposed [2015] guidance [was] meant to address the diverse set of 340B covered entities, and was informed by 340B program audits, through which HHS has learned more about how the definition of patient is applied in different health care settings." *Id.* HHS begins by stating the October 1996 guidelines' three-part test to determine whether an individual was a "patient" under the 340B Program. *Id.* For reference, the October 1996 guidelines are set forth above.

In defining the term "patient," HHS's 2015 guidance utilized strikingly different language from the October 1996 guidance and is outlined below:

> **Proposed 2015 Guidelines (Withdrawn January 2017)**
>
> Under this proposed guidance, an individual will be considered a patient of a covered entity, ***on a prescription-by-prescription or order-by-order basis***, if all of the following conditions are met:
>
> (1) The individual receives a health care service at a facility or clinic site which is registered for the 340B Program and listed on the public 340B database.
>
> . . .
>
> (2) The individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity, such that the covered entity may bill for services on behalf of the provider.
>
> . . .
>
> (3) ***An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service*** described in (2).
>
> . . .
>
> (4) The individual's health care is consistent with scope of the Federal grant, project, designation, or contract.
>
> . . .
>
> (5) The individual's drug is ordered or prescribed pursuant to a health care service that is classified as outpatient.
>
> . . .
>
> (6) The individual's patient records are accessible to the covered entity and demonstrate that the covered entity is responsible for care.

340B Drug Pricing Program Omnibus Guidance, 80 FR 52300-01.

The 2015 proposed guidance outlined above unquestionably utilizes different, and more specific language, to define the term "patient." However, the 2015 proposed guidance was withdrawn in January 2017. OIRA Conclusion of EO 12866 Regulatory Review, https://www.reginfo.gov/public/do/eoDetails?rrid=126712 (last visited October 25, 2023). The most notable distinction between the October 1996 guidelines and the 2015 proposed guidelines is the

inclusion of new language: "*an individual will be considered a patient of a covered entity, on* ***a prescription-by-prescription or order-by-order basis****;" and,* ***"[a]n individual must receive a drug that is ordered or prescribed by the covered entity provider as a result of the service.***" 340B Drug Pricing Program Omnibus Guidance, 80 FR 52300-01 (emphasis added).

There is no dispute that the October 1996 guidelines and proposed 2015 guidelines differ in terms of the language used to define "patient." The 2015 proposed guidelines specifically address 340B patient eligibility, the origin of a prescription eligible for resale by a "covered entity," and require the individual to receive a drug that is ordered or prescribed by the covered entity provider as a result of the health care service received by the "covered entity." 340B Drug Pricing Program Omnibus Guidance, 80 FR 52300-01. Further, the 2015 withdrawn guidance places a limit on the resale of outpatient drugs to "patients" on a prescription-by-prescription or order-by-order basis. 340B Drug Pricing Program Omnibus Guidance, 80 FR 52300-01.

The 1996 guidance contains no such language specifically addressing whether a "covered entity" can fill a "patient's" prescription when that prescription did not originate from an encounter with the "covered entity." Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 FR 55156-01.

Present Dispute

There is no dispute that Genesis is a "covered entity" for purposes of the 340B statute. Genesis has participated in the 340B program since approximately 2011. Genesis provides comprehensive primary and preventive health care to patients, regardless of their health insurance status and ability to pay. As a "covered entity" under the program, Genesis is eligible to obtain certain outpatient prescription drugs at a discount. Among providing health care to the indigent, in

order to maintain operations, Genesis's business model involves purchasing drugs from manufacturers at discount prices and then dispensing these medications to individuals who qualify as "patients" under the 340B program. Genesis also passes discounted prices of outpatient drugs on to its indigent patients. AR 9147.

In approximately June 2017, HRSA conducted a one and a half day audit of Genesis and made a preliminary determination that Genesis was no longer eligible to participate in the 340B program and Genesis was also liable to manufacturers of covered outpatient drugs for purchases made while it was ineligible for the 340B program. ECF No. 1 at ¶ 15, AR 192-93. In the final audit letter dated June 26, 2018, HRSA addressed two findings:

> (Finding 1): GHI failed to maintain auditable records for purposes of the 340B Program Audit . .
>
> (Finding 2): ***GHI dispensed 340B drugs to ineligible patients***...HRSA was unable to assess diversion for clinic-administered drugs due to lack of auditable records. However, HRSA was able to assess diversion for 340B drugs dispensed from the in-house pharmacy and contract pharmacy. In addition, the findings are not based upon withdrawn patient definition guidance and do not represent a new HRSA interpretation.

AR 1499-1503 (emphasis added). Genesis was immediately removed from the 340B program based on Finding 1 - its failure to maintain auditable records for purposes of a 340B Program audit. AR 1500, 1502. Interestingly, according to HRSA's June 26, 2018 letter to Genesis, Genesis was not removed from the 340B program because it dispensed 340B drugs to ineligible patients; rather, Genesis was removed from the 340B Program based on its failure to maintain auditable records. AR 1500, 1502. As a result of Genesis's removal from the 340B Program, HRSA declared that Genesis must stop purchasing 340B drugs for all Genesis service locations and contract pharmacies

immediately. AR 1500. As indicated above, under the 340B statute, a "covered entity" such as Genesis is prohibited from "resell[ing] or otherwise transfer[ring] the drug to a person who is not a *patient* of the entity." 42 U.S.C. § 256b(a)(5)(B).

On June 27, 2018, emails sent between HRSA agents confirmed that Genesis was terminated from the 340B Program. AR 9149.

On June 28, 2018, Genesis initiated this lawsuit to set aside HRSA's decision to remove Genesis from the 340B Program for failing to retain auditable records (Finding 1 of Final Audit) and diverting 340B priced drugs to individuals who were not "patients" of Genesis (Finding 2 of Final Audit). ECF No. 1; *See* AR 1525-1533.

On September 24, 2018, while this lawsuit was pending, HRSA vacated its audit findings and reinstated Genesis into the 340B Program. [Final Report, September 24, 2018, ECF No. 33-1].

Based on the voided audit findings, this Court dismissed the matter as moot. ECF No. 50. In an opinion dated July 7, 2022, the Fourth Circuit Court of Appeals disagreed with this Court and found that there was an ongoing disagreement, thus a live controversy, over how the term "patient" is to be defined in the context of the 340B Program, and specifically whether HRSA's interpretation of the term "patient" conflicts with the 340B statute, 42 U.S.C. § 256b.

Even though HRSA voided its audit findings and re-instated Genesis into the 340B Program, HRSA maintains that in order for an individual to qualify as a "patient" of a "covered entity" under the 340B Program, the prescription for the 340B drug must originate from a health care encounter with Genesis or one of its contract health care providers. Genesis disagrees and contends that, pursuant to the plain wording of the 340B statute, the only requirement for an individual to be 340B eligible is for that individual to be a "patient" of a "covered entity." *See* 42 U.S.C. § 256b(a)(5)(B)

("[w]ith respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity").

HRSA's current interpretation of the term "patient" is reflected in its March 20, 2019 letter to Genesis and states: "**HRSA would like to clarify that in order for an individual to qualify as a 340B patient, GHI must have initiated the healthcare service resulting in the prescription, regardless if the patient had an unrelated billable FQHC encounter**." AR 1541; ECF No. 33-2 (emphasis added). The position reflected in HRSA's March 20, 2019 letter is the precise reason the Fourth Circuit Court of Appeals found that this case was not moot. Genesis remains subject to HRSA's enforcement of its interpretation of the term "patient" under the 340B Program and this creates uncertainty as to the viability of Genesis's business model as well as the services that it is able to provide. The definition of "patient" that HRSA presently endorses (reflected in the March 20, 2019 letter, AR 1541-1543) could significantly impact the profitability of Genesis and its ability to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." AR 21, H.R. REP. 102-384, 12.

Summary Judgment Standard

A court may grant summary judgment when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). When assessing a motion for summary judgment in an Administrative Procedures Act ("APA") case, however, "the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). In such cases the complaint "actually presents no factual allegations, but rather only arguments about the legal conclusion to be

drawn about the agency action." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Therefore, "[t]he entire case on review is a question of law, and only a question of law." *Id*. The Court's review is based on the agency record and limited to determining whether the agency acted arbitrarily or capriciously or in violation of another standard set forth in the APA. *See* 5 U.S.C. § 706.

Analysis

The code section at issue in this case is 42 U.S.C. § 256b(a)(5)(B) and provides:

Prohibiting resale of drugs - "[w]ith respect to any covered outpatient drug that is subject to an agreement under this subsection, *a covered entity shall not resell or otherwise transfer the drug to a person who is not a* ***patient*** *of the entity*." *Id*. (emphasis added).

HRSA interprets the phrase "patient of the entity" under the statute to mean that the covered entity must have "initiated the healthcare service resulting in the prescription." Defendants' Combined Opposition to Plaintiff's Motion for Summary Judgment and Cross-Motion for Summary Judgment, ECF No. 101 at 19. Under HRSA's interpretation, if the "covered entity" did not initiate the healthcare service that resulted in the prescription, Genesis may not resell that particular drug to the individual. Genesis disagrees and contends that HRSA's interpretation of the term "patient" is contrary to the plain wording of the statute and that Genesis may resell 340B drugs to its patients even if the prescription did not originate from Genesis or one of its contract providers.

Because this case was brought under the Administrative Procedures Act ("APA"), 5 U.S.C. §§ 551–559, agency deference to HRSA's interpretation of the term "patient" in the 340B statute must first be addressed. Notably, Defendants do not assert that *Chevron* deference applies to this

case.[3] Reply in Support of Defendants' Cross Motion for Summary Judgment, ECF No. 133 at 15 ("Defendants do not assert *Chevron* deference here").

In *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the United States Supreme Court held that a court must give effect to an agency's regulation containing a reasonable interpretation of an ambiguous statute. *Christensen v. Harris Cnty.*, 529 U.S. 576, 586-87 (2000). Under *Chevron*, where Congress has "explicitly left a gap for an agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation, *Chevron*, 467 U.S., at 843–844, and any ensuing regulation is binding in the courts unless procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute." *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001). Again, the parties do not assert that *Chevron* deference applies to this case.

Agency interpretations such as those that appear in opinion letters, policy statements, agency manuals, and enforcement guidelines lack the force of law and do not warrant *Chevron* deference. *Christensen*, 529 U.S. at 587. The parties appear to be in agreement on this point. Agency interpretations, however, are "entitled to respect" under *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944), to the extent they have the power to persuade. *Shipbuilders Council of Am. v. U.S. Coast*

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[3] Defendants also do not assert *Auer* deference. Under *Auer* deference, an agency's interpretation of its own regulation is "controlling unless plainly erroneous or inconsistent with the regulation." *Auer v. Robbins*, 519 U.S. 452, 461 (1997); *see Christensen v. Harris Cnty.*, 529 U.S. 576, 587–88 (2000) (explaining that *Chevron* deference applies to an agency's interpretation of a statute while *Auer* deference applies to "an agency's interpretation of its own regulation"); *see also United States v. Deaton*, 332 F.3d 698, 708–09 (4th Cir. 2003) (applying *Chevron* deference to the agency's construction of the statute in question and *Auer* deference to its interpretation of the regulation issued pursuant to that statute); *Shipbuilders Council of Am. v. U.S. Coast Guard*, 578 F.3d 234, 242 (4th Cir. 2009). Instead, Defendants argue they are merely issuing an interpretation of the statutory term "patient" and their interpretation is entitled to deference under *Mead*. For reference, *Mead* held that *Skidmore* deference survived *Chevron* and *Skidmore* deference was appropriate for "interpretations contained in policy statements, agency manuals, and enforcement guidelines" "proportional to its power to persuade." *Mead*, 533 U.S. at 234-38.

Guard, 578 F.3d 234, 241 (4th Cir. 2009).

Under *Skidmore*, courts consider the rulings, interpretations, and opinions of the Agency, and while not controlling, courts should acknowledge that the rulings, interpretations, and opinions of the Agency "constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." *Skidmore*, 323 U.S. at 140. "The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it ***power to persuade***, if lacking power to control." *Id.*; *Carlton & Harris Chiropractic, Inc. v. PDR Network, LLC*, 982 F.3d 258, 264 (4th Cir. 2020). However, *Skidmore* deference is only warranted if the agency's interpretation of the statute is persuasive. *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703 (3d Cir. 2023); *Sierra Club v. U.S. Army Corps of Eng'rs*, 909 F.3d 635, 643–44 (4th Cir. 2018). To gauge an agency interpretation's persuasiveness under *Skidmore*, courts look to "the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position." *Mead Corp.*, 533 U.S. at 228; *Carlton & Harris Chiropractic, Inc.*, 982 F.3d at 264–65; *Sierra Club*, 909 F.3d at 643–44 (explaining that courts afford interpretive rules "modest *Skidmore* deference, to the extent the agency's reasoning gives it power to persuade, or, in the absence of such reasoning, no deference at all").

Under *Skidmore*, agency interpretations warrant no deference where the agency's interpretation was "completely devoid of any statutory analysis" and made "no effort to explain or justify" the agency's position. *Sierra Club*, 909 F.3d at 645.

Of course,"no deference is due to agency interpretations at odds with the plain language of

the statute itself." *Smith v. City of Jackson, Miss.*, 544 U.S. 228, 267 (2005). Even contemporaneous and longstanding agency interpretations must fall to the extent they conflict with statutory language. *Pub. Emps. Ret. Sys. of Ohio v. Betts*, 492 U.S. 158, 171 (1989) (*superseded by statute on other grounds*).

For the reasons explained below, the Court finds HRSA's interpretation of the term "patient" as set forth in its March 20, 2019 letter to be contrary to the plain language of the 340B statute. Furthermore, applying the *Skidmore* framework, HRSA's interpretation of the term "patient" is unpersuasive and not entitled to deference under *Skidmore*. Nothing in the statute conditions an individual's eligibility as a 340B patient on whether the health care service resulting in the prescription was initiated by the "covered entity." Accordingly, HRSA's restrictive interpretation of the statutory term "patient" is unpersuasive.

Beginning with language of the statute, the relevant provision provides "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." 42 U.S.C. §256b(a)(5)(B). While the statute defines other terms, the statute does not define "patient," nor does it contain a requirement that a prescription originate from a "covered entity" in order for an individual to be consider an eligible 340B patient.

Words that are not defined in the relevant statutory provisions are typically "interpreted as taking their ordinary, contemporary, common meaning." *Johnson v. Zimmer*, 686 F.3d 224, 232 (4th Cir. 2012). The Court "customarily turn[s] to dictionaries for help in determining whether a word in a statute has a plain or common meaning." *Johnson*, 686 F.3d at 232 (citing *Nat. Coalition for Students v. Allen*, 152 F.3d 283, 289 (4th Cir.1998)). Merriam-Webster defines "patient" as "an individual awaiting or under medical care and treatment."

https://www.merriam-webster.com/dictionary/patient (last visited October 26, 2023). The National Library of Medicine defines "patient" as "an individual who interacts with a clinician either because of real or perceived illness or for health promotion and disease prevention." https://www.ncbi.nlm.nih.gov/books/NBK231308/ (last visited October 26, 2023). The Cambridge Dictionary defines "patient" as "a person who is receiving medical care, or who is cared for by a particular doctor or dentist when necessary." https://dictionary.cambridge.org/us/dictionary/english/patient (last visited October 26, 2023). The Oxford English Dictionary defines "patient" as "a person receiving or (in later use) registered to receive medical treatment, esp. at a particular establishment or from a particular practitioner; a person staying in a hospital for medical treatment." https://www.oed.com/dictionary/patient_adj?tab=meaning_and_use#31768443 (last visited October 26, 2023). The American Medical Association defines an established patient as "one who has received professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past three years." https://www.ama-assn.org/system/files/2023-e-m-descriptors-guidelines.pdf (last visited October 28, 2023). The most basic definition of "patient" this Court located was from a website called "dictonary.com," which simply defined "patient" as "a person who is under medical care or treatment." https://www.dictionary.com/browse/patient (last visited October 26, 2023). Generally speaking, these definitions are similar and provide a strong argument that the term "patient" is not ambiguous but instead the term "patient" enjoys a fairly common definition and ordinary understanding. The amici in support of the Defendants cite to many medical definitions of the term

"patient," however, none of those definitions link the care received by a patient to any particular prescription.

The legislative history behind the 340B Program suggests a broad reading of the term "patient." The purpose of the 340B statute was to combat the increase in prescription drug prices following the Medicaid Drug Rebate Program and was intended to enable the Department of Veterans Affairs and certain Federally-funded clinics to obtain lower prices on the drugs they provide to their patients. AR 17, H.R. REP. 102-384, 7. Due to pharmaceutical manufacturer's drug price increases, the VA, Federally-funded clinics, and public hospitals experienced substantial increases in their outpatient drugs, which resulted in reduced services that "covered entities" were able to provide to the indigent. Since the purpose of the 340B Program was to enable "covered entities" to stretch scarce Federal resources as far as possible and reach as many eligible patients as possible, while providing more comprehensive services, the only logical conclusion is that Congress intended to apply the common everyday meaning of the term patient. HRSA's present interpretation of the term "patient," as outlined in its March 20, 2019 letter to Genesis, is at odds with the plain language of the 340B statute, which simply prohibits the resale or transfer of a 340B drug to a person who is not a "patient" of the "covered entity." 42 U.S.C. § 256b(a)(5)(B). Based on the legislative history and purpose of the 340B statute, it is reasonable to conclude that Congress intended patient to have its plain and ordinary meaning: "an individual awaiting or under medical care and treatment." https://www.merriam-webster.com/dictionary/patient (last visited October 26, 2023).

The 340B statute does not mention the origination of a prescription in order for an individual to be an eligible 340B patient, nor does the statute place any requirement that the 340B prescription

be initiated from a "covered entity" or contract provider for that "covered entity." The plain language of the 340B statute does not require a link between a 340B prescription sold by a "covered entity" to a "patient" and the origination of that prescription. All the 340B statute requires is that the "covered entity" limit the resale of 340B drugs to "patients" of the "covered entity." 42 U.S.C. § 256b(a)(5)(B).

Defendants and the Amici pharmaceutical companies argue that Genesis's interpretation of the term "patient" would allow Genesis to resell drugs to individuals who had not had a healthcare encounter with Genesis for years because Genesis could still claim they were a patient. The statute, however, does not state a specific temporal requirement on the term "patient" and HRSA offers no suggestions for a reasonable temporal requirement. This specific issue was raised in the October 1996 comments but HHS did not set a time limit for recent healthcare encounters and responded to the comment as follows:

> All covered entities must establish a relationship with their patients such that the entity will maintain records of the individuals' health care. The entity will document in the record the care provided and, when appropriate, the prescriptions written. It would be inappropriate for the Department to proceed further and dictate to health care providers guidelines regarding the appropriateness of certain prescriptions.

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 FR 55156-01. While the statute does not require a recent healthcare encounter for an individual to be considered a patient, Genesis voluntarily utilizes a two year look back period to determine whether an individual is a patient. The AMA considers an established patient to be an individual who has received a health care service from a provider within the last three years. https://www.ama-assn.org/system/files/2023-e-m-descriptors-guidelines.pdf (last visited October

28, 2023). In any event, the recency of a healthcare encounter with a "covered entity" as a requirement to be considered a "patient" of the "covered entity" is not the issue before the Court. Rather, the issue before the Court concerns the origination of the prescription that is resold to a "patient" of a "covered entity" under 42 U.S.C. § 256b(a)(5)(B).

Defendants argue that Section 256b(a)(5)(B) indicates a requirement that there be an ongoing relationship between the covered entity and the person. ECF No. 101 at 21. Defendants contend that the statute's use of the present tense ("a person who is not a patient of the entity") is significant and HRSA's interpretation of the term patient (that the prescription originate from the covered entity) gives meaning to the statute's use of the present tense because connecting the prescription for the drugs dispensed to the covered entity helps ensure a present relationship. *Id.* at 20-21. As noted above, the language of the statute merely states "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). The Court agrees that the statute does require an ongoing patient relationship between the individual and the "covered entity." However, the Court disagrees with Defendants' position that the 340B drug prescription must originate from the ongoing relationship between the individual and the "covered entity."

In a similar vein, the pharmaceutical companies who filed briefs as amici in support of Defendants, argue that HRSA's interpretation that the prescription originate from the "covered entity" is supported by the statute's definition of the term "covered drug" in 42 U.S.C. § 256b(b)(2). Brief of Abbvie, Inc., Bristol Myers Squibb Company, Eli Lilly & Company, and Merck & Co, Inc., ECF No. 120 at 27. The amici argue the statute defines "covered drug" as "a covered outpatient drug" as defined in the Social Security Act and "a drug used in connection with an inpatient or

outpatient service provided by a hospital that is enrolled to participate in the drug discount program under this section." *Id.*, 42 U.S.C. § 256b(b)(2). The amici conclude that "necessarily, then, 'covered drugs' must be used in connection with a specific episode of outpatient healthcare that the covered entity itself is providing." *Id.* This argument, too, is unpersuasive. The amici conflate two distinct terms under the statute, "covered drug" and "covered outpatient drugs." The definition of "covered drug" makes no attempt to limit "covered outpatient drug" to one used in connection with an inpatient or outpatient service provided by a hospital. Adopting the amici's reading of the statute would render the second clause of § 256b(b)(2) defining "covered drug" superfluous. *See* 42 U.S.C. § 256b(b)(2)(B).

Although the Third Circuit Court of Appeals has cautioned against drawing inferences from un-enacted drafting history, *See Sanofi Aventis U.S. LLC*, 58 F.4th at 705, this Court cannot ignore the reality that similar legislation was being considered at the time the 340B statute was being drafted. The similar legislation addressed with more clarity the very issue before this Court. The rejected similar legislation contained an amendment that provided: "[a] covered entity that receives a discount under this section for the purchase of a drug or biological may not . . . dispense or administer, directly or through a contract, such drug or biological to an individual *who is not receiving the drug or biological as a patient of the covered entity*." S. REP. 102-259, 4 (emphasis added).

Congress rejected this language and instead chose to enact the 340B statute, which placed no such limitation on patient eligibility and omitted the language requiring the individual to receive the drug or biological "as a patient of the covered entity." It is evident that Congress: 1) was aware of the potential issues created by a broad definition of the term "patient," 2) possessed the tools to limit

the definition of the term "patient" to those individuals whose prescriptions originated from the "covered entity," and 3) in spite of those issues, chose not to limit 340B patient eligibility to prescriptions that originated or were initiated from a covered entity or contract provider.

Bearing in mind that the purpose of the 340B statute was, in part, to make "covered entities" profitable so they could stretch Federal resources as far as possible, reach more eligible patients, and provide more comprehensive services, a broad definition of the term "patient" complies with congressional intent in that the more patients a "covered entity" can sell discounted 340B drugs to, the greater the "covered entity's" profit margin, and the greater the ability of the "covered entity" to provide services to the indigent and achieve the purpose of the 340B statute.

To the extent Defendants argue HRSA's interpretation is entitled to "respect" under *Skidmore*, it is only entitled to respect to the extent it has the power to persuade. *See Skidmore*, 323 U.S. at 140; *Shipbuilders Council of Am.*, 578 F.3d at 241. As explained below, HRSA's interpretation of "patient" in its March 20, 2019 audit letter to Genesis is not a persuasive interpretation of the statutory term "patient." Accordingly, HRSA's interpretation of the term "patient," as reflected in its now-voided March 20, 2019 audit letter, is not entitled to *Skidmore* deference. *See Mead Corp.*, 533 U.S. at 228.

To gauge an agency interpretation's persuasiveness under *Skidmore*, courts look to "the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position." *Mead Corp.*, 533 U.S. at 228; *Carlton & Harris Chiropractic, Inc.*, 982 F.3d at 264–65; *Sierra Club*, 909 F.3d at 643–44 (explaining that courts afford interpretive rules "modest *Skidmore* deference, to the extent the agency's reasoning gives it power to persuade, or, in the absence of such reasoning, no deference at all").

The degree of HRSA's care regarding its interpretation of the term "patient" since the enactment of the 340B statute leaves much to be desired. HRSA was on notice that "covered entities" could make spurious claims regarding patient eligibility as early as 1994. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 FR 47884-01. The comments published in September 1994 raised the issue that "covered entities" could potentially resell 340B drugs to anyone it could claim was a patient. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 FR 47884-0. This comment certainly put HRSA on notice of the potential consequences of a broad and flexible definition of the term "patient" under the 340B Program. These concerns were voiced again in later comments published in the October 1996 notice. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 FR 55156-01. Rather than address these issues in a straightforward manner, HRSA issued its October 1996 guidelines wherein HRSA specifically attempted "to develop a definition *flexible enough to describe accurately each covered entity's patient while at the same time not excluding eligible patients*." *Id*. (emphasis added). Even the amicus brief of the Janssen Pharmaceutical Companies recognizes HRSA's failure to address issues created by a flexible definition of the term "patient." Brief of the Janssen Pharmaceutical Companies, ECF No. 121 at 9 ("For years, Janssen has tried (unsuccessfully) to address this problem within the 340B Program - *a problem that the government has repeatedly acknowledged, but failed to address in any meaningful way*.") (emphasis added).

The three-part test set forth in the October 1996 guidelines is stated above and need not be repeated here. Suffice to say, the October 1996 guidelines contained no language requiring that a prescription originate from a "covered entity" or contract provider for an individual to be considered

a 340B patient under the 340B Program, 42 U.S.C. § 256(b)(a)(5)(B). The only provision in the October 1996 guidelines that remotely addresses the situation of an individual using a "covered entity" solely as a pharmacy is the following passage: "[a]n individual will not be considered a 'patient' of the entity for purposes of 340B ***if the only health care service received by the individual from the covered entity*** is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting." Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 FR 55156-01 (emphasis added). This provision illustrates HRSA's view that there must be more than the mere dispensing of drugs for an individual to be considered a "patient" of a "covered entity," but the provision does not address the origination of a prescription for a 340B drug or for 340B patient eligibility.

The October 1996 guidelines remained in place, and as far as this Court can determine from its own research, the definition of the term "patient" under the 340B statute was not the subject of any litigation in the decades that followed. Genesis became a 340B entity in 2011.

HRSA's withdrawn 2015 guidelines, outlined above, squarely address the issue concerning the term "patient" that the pharmaceutical companies complain about in their briefs - 340B drug diversion to individuals whose prescriptions did not originate or were not initiated from "covered entities." The withdrawn 2015 guidance provides: *"an individual will be considered a patient of a covered entity, on* ***a prescription-by-prescription or order-by-order basis****;" and,* ***"[a]n individual must receive a drug that is ordered or prescribed by the covered entity provider as a result of the service.***" 340B Drug Pricing Program Omnibus Guidance, 80 FR 52300-01. When comparing the withdrawn 2015 guidelines to the October 1996 guidelines, the withdrawn 2015 guidelines clearly provide a more restrictive definition of the term "patient" than the October 1996 guidelines.

Although the 2015 guidelines were withdrawn in 2017, HRSA continues to assert that the definition of "patient" set forth in the 2015 guidelines is the correct interpretation of the 340B statute. *See* Letter to Genesis from HRSA, March 20, 2019, AR 1541 ("HRSA would like to clarify that in order for an individual to qualify as a 340B patient, [Genesis] must have initiated the healthcare service resulting in the prescription, regardless if the patient had an unrelated billable FQHC encounter.").

The difference between the October 1996 guidelines and the withdrawn 2015 guidelines demonstrate a lack of consistency within the HRSA regarding its interpretation of the term "patient." Although one could reach a conclusion that the withdrawn 2015 guidelines were merely an elaboration of the October 1996 guidelines and did not alter the definition of the term "patient," that conclusion can only be reached by employing a host of strained mental gymnastics. The necessity of such an effort, again, demonstrates a lack of consistency within the HRSA regarding its interpretation of the term "patient" and negates any argument that HRSA's interpretation of the statutory term "patient" is persuasive.

Defendants do not direct the Court to any attempt by HRSA to reconcile its restrictive definition of the term "patient" with the purpose of the 340B statute. In developing a restrictive definition of the term "patient," HRSA does not appear to have made any attempt to consider the purpose of the 340B statute - the profitability of "covered entities" in light of prescription drug price increases.

Most critically, HRSA's lack of consistency is evident from Defendants' own filings in this case. In an attempt to convince the Fourth Circuit Court of Appeals that this matter was moot, Defendants represented to the Fourth Circuit that "the language Genesis seeks to challenge can only be found in the now-voided audit letter." *Genesis Health Care, Inc. v. Becerra*, Fourth Circuit Court

of Appeals, No. 20-1701, ECF No. 45. In Defendants' supplemental filing in the Fourth Circuit, Defendants were referring to the March 20, 2019 letter from HRSA to Genesis, which stated: "in order for an individual to qualify as a 340B patient, [Genesis] must have initiated the healthcare service resulting in the prescription, regardless if the patient had an unrelated billable FQHC encounter." AR 1541. Defendants' supplemental filing, at the very least, suggests that HRSA's interpretation of the term "patient" is a moving target and has shifted over time. For those reasons, this Court concludes that HRSA's interpretation of the term "patient," as reflected in its March 20, 2019 now-voided audit letter, is unpersuasive and not entitled to deference under *Skidmore*.

The healthcare industry has changed significantly since the 340B statute was passed in 1992. This Court is not ignorant to the challenges faced by the HRSA as it attempts to address the changes in the healthcare industry over the last several decades. Those changes, however, do not empower the HRSA to enforce a new interpretation of an unambiguous statutory term that restricts a program that Congress intended to have broad application. In the context of the 340B statute, HRSA's attempt to restrict the ability of covered entities to increase their profit margin is an impermissible exercise of the power entrusted to executive agencies tasked with implementing statutes.

Congress's intent in enacting the 340B statute was, in part, to protect "covered entities" from prescription drug price increases and allow "covered entities" to increase their profit margins so that they could stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." AR 21, H.R. REP. 102-384, 12. If there is a desire to restrict the 340B Program and limit the ability of "covered entities" to remain profitable in the face of prescription drug price increases, Congress is the appropriate entity to take the necessary action. It is not the role of HRSA to legislate and limit the 340B program by restricting the definition of the

term "patient," thereby frustrating the ability of the 340B statute to accomplish its purpose.

HRSA's restrictive definition of the term "patient" limits the scope of the 340B Program, limits the profitability of "covered entities," and frustrates the goal of the 340B statute, which is to make "covered entities" profitable in the face of the prescription drug price increases that followed the Medicaid Drug Rebate Program and that continue to this day.

Defendants' statutory based textual arguments are unpersuasive and cannot be squared with the intent of the 340B statute and the "flexible" language used to define "patient" in the October 1996 guidelines. Nor can Defendants' arguments be reconciled with Defendants' representation to the Fourth Circuit Court of Appeals that the language Genesis seeks to challenge can only be found in the now-voided March 20, 2019 audit letter. Defendants' short-sighted concession to the Fourth Circuit in an attempt to convince the Fourth Circuit that this matter was moot illustrates that HRSA's interpretation of the term "patient" has shifted over time from the "flexible" definition adopted in 1996 to the more restrictive definition HRSA seeks to enforce today.

Defendants' jurisdiction and waiver arguments also lack merit and were either specifically rejected by the Fourth Circuit Court of Appeals or rejected by implication. The Fourth Circuit Court of Appeals specifically found that the dispute over the term "patient" is an actual controversy between the parties. Genesis did not waive their challenge to HRSA's interpretation of the term "patient" under the 340B statute and their claim is not barred by the statute of limitations.

Declarations Sought by Genesis

At this point, it is necessary to address the declarations sought by Genesis in this action. Genesis requests this Court issue the following declarations:

1) 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);

2) 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;

3) 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; and

4) declare that HRSA did not have the broad rulemaking authority necessary to implement its interpretations and restrictions to the plain language of 42 U.S.C. § 256b(a)(5)(B). ECF No. 33 at ¶¶ 65-70.

As to the first declaration, the Court agrees with Genesis for the reasons stated above and declares 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)."

As to the second declaration, the wording of this declaration is simply too broad for the Court to issue the declaration as written. A more appropriate declaration more narrowly tailored to this action is that "the plain wording of the 340B statute does not require the 'covered entity' to have initiated the healthcare service resulting in the prescription."

As to the third declaration, this declaration is simply a restatement of the law. Agency interpretations in contradiction of the plain wording of a statute are not entitled to deference and are not enforceable. *See Smith v. City of Jackson, Miss.*, 544 U.S. at 267 (citing *Pub. Emps. Ret. Sys. of Ohio v. Betts*, 492 U.S. 158, 171 (1989) (*superseded by statute on other grounds*)); *Pharm. Rsch. & Manufacturers of Am. v. United States Dep't of Health & Hum. Servs.*, 138 F. Supp. 3d 31, 48 (D.D.C. 2015).

As to the fourth declaration, the Court disagrees with Genesis and finds that HRSA does

possess authority to implement its interpretations of the statutory term "patient" in 42 U.S.C. § 256b(a)(5)(B). *See Pharm. Rsch. & Manufacturers of Am.*, 138 F. Supp. 3d at 39 (stating "it is clear that HHS has the authority to advise the public of its interpretation of the [340B statute]"). In order to administer the dispute resolution process Congress instructed HHS to establish under the 340B Program, 42 U.S.C. § 256b(d)(3)(A), the agency necessarily will be obliged to set forth its understanding of various stakeholder's obligations under the 340B Program, including an interpretation of the statutory term "patient." *See id*. However, as stated above, HRSA's interpretation of the term "patient" must be consistent with the plain language of the statute and the intent of Congress. As explained above, HRSA's present interpretation of the term "patient" as reflected in the March 20, 2019 now-voided audit letter is inconsistent with the plain language of the statute and the intent of Congress in passing the 340B statute.

Conclusion

For the reasons stated above, Plaintiff Genesis Health Care, Inc.'s motion for summary judgment is **GRANTED in part**. ECF No. 100. Defendants' motion for summary judgment is **DENIED**. ECF No. 101. Because Defendants have indicated that the language Genesis challenges can only be found in the now-voided March 20, 2019 audit letter and Defendant's interpretation of the term "patient" set forth in that letter is contrary to the plain wording of the 340B statute, Defendants are, hereby, enjoined from enforcing its March 20, 2019 interpretation of the term "patient" against Plaintiff Genesis Health Care, Inc. until further Order of this Court.[4]

[4] Defendants argued that relief should be limited to Genesis. The Court agrees and Genesis does not appear to dispute that point. Enjoining HRSA from enforcing its March 20, 2019 interpretation of the term "patient" against Genesis will provide adequate relief to Genesis and settle the question between Genesis and HRSA regarding HRSA's interpretation of the term "patient" under the 340B statute, 42 U.S.C. § 256b(a)(5)(B); *See Samuels v. Mackell*, 401 U.S. 66, 72 (1971) (recognizing that declaratory relief has virtually the same practical impact as an injunction).

IT IS SO ORDERED.

November 3, 2023
Florence, South Carolina

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