IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

Genesis Health Care Inc., Plaintiff, vs. 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, 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, Defendants.	Civil Action Number: 4:19-cv-01531-RBH **PLAINTIFF'S MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

Plaintiff Genesis Health Care, Inc. ("Genesis") hereby respectfully submits this Memorandum in Support of its Motion for Summary Judgment. Genesis is entitled to judgment as a matter of law and there are no genuine issues of dispute as to any material fact.

As noted in the Court's Order denying Genesis' Motion to Compel, "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)."

The statutory provision in question, 42 U.S.C. § 256b(a)(5)(B), states simply that "[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**." (emphasis added). This action involves Genesis' objection to the Health Resources

and Services Administration's ("HRSA") embellishment of the statute by which HRSA defines the term "patient" as not only a "patient of the entity" as the statute states, but adds that the patient must also be an individual who has had an encounter with a covered entity that resulted in the prescription being filled with 340B priced drugs. Dkt. No. 33-10 at ¶ 2.

Genesis maintains that the clear and unambiguous language of 42 U.S.C. § 256b(a)(5)(B) says nothing about the origin of the prescription being filled by a 340B covered entity. The statute only requires that a person be a patient of the covered entity. HRSA's addition of a requirement for the covered entity to have also generated the prescription in question is unlawful and an improper reading of 42 U.S.C. § 256b(a)(5)(B). As noted in *Sanofi Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.,* 58 F.4th 696, 699 (3d Cir. 2023), a statutory silence (here the absence as to where the prescription is generated) "tempts speech." "But courts must resist the urge to fill in words that Congress left out." *Id.*

I. INTRODUCTION

Genesis originally commenced this action to set aside HRSA's decision to remove Genesis from the 340B Drug Pricing Program ("340B Program") for allegedly failing to retain auditable records and diverting 340B priced drugs to persons who were not patients of Genesis. Dkt. No. 1. On September 24, 2018, after this action was filed, HRSA amended its Final Agency decision and vacated its decision to remove Genesis from the 340B Program. Genesis was promptly reinstated into the 340B Program. *See* Dkt. No. 33-9. HRSA, however, did not vacate its findings that Genesis violated the program requirements. As a result, Genesis did not dismiss this action but rather sought and obtained stays from this Court while HRSA considered Genesis' Corrective Action Plan (CAP) submitted in response to the amended Final Agency decision.

On March 20, 2019, HRSA notified Genesis that it would accept Genesis' revised CAP with conditions. *See* Dkt. No. 33-10. However, HRSA also stated it was restricting Genesis' ability to provide 340B program drugs to the following "eligible" patients:

> While GHI's CAP has satisfactorily addressed the audit finding with respect to future implementation of the 340B Program, **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.** A covered entity may refer one of its patients to an outside provider and receive documentation of that episode of care that results in a 340B eligible prescription. However, a referral that begins at a private practice to the covered entity, would not qualify a prescription written by the private practitioner as 340B eligible. **GHI must be able to demonstrate that the individual first receives a health care service from a health care professional who is either employed by GHI or provides health care under contractual or other arrangements such as referral for consultation, which demonstrates responsibility for care remains with GHI, in order to meet the patient definition guidelines.**

Id. at ¶ 2 (Emphasis added). This is in direct contradiction to the plan language of the statute, 42 U.S.C. § 256b(a)(5)(B) which provides:

> With 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.**

U.S.C. § 256b(a)(5)(B). By this plain language, Genesis may fill prescriptions for any person who is a Genesis patient. HRSA's interpretation that it seeks to enforce, requiring that the prescription in question to have originated from healthcare services provided by Genesis, clearly adds an additional element that is not within the plain language of the statute.

II. STATEMENT OF FACTS

Genesis is a nonprofit Federally Qualified Health Center ("FQHC"), as defined in 42 U.S.C. § 1396d(l)(2)(B). Genesis provides comprehensive primary and preventive healthcare to patients, regardless of their health insurance status and ability to pay, at its facilities throughout

South Carolina's Pee Dee Region and in Walterboro, South Carolina.[1] HRSA is an agency of the United States Department of Health and Human Services ("DHHS") and "the primary federal agency for improving health care to people who are geographically isolated, economically or medically vulnerable." *About HRSA*, Health Res. & Servs. Admin., https://www.hrsa.gov/about/index.html. HRSA administers the "340B Program." *See 340B Drug Pricing Program*, Health Resource & Services Administration, https://www.hrsa.gov/opa/index.html.

The 340B program (42 U.S.C. § 256b) was first enacted by Congress as part of the Veterans Health Care Act of 1992. *See Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.,* 43 F.Supp.3d 28, (D.D.C.2014). Codified pursuant to the Public Health Services Act, the 340B program establishes maximum, or "ceiling," prices (see https://www.hrsa.gov/opa/updates/2015/may.html) for covered drugs to "stretch scarce Federal resources as far as possible, reaching more *patients* of the covered entities such as Genesis and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see* 2018 OPPS Rule, 82 Fed. Reg. at 52493 & m.18 (acknowledging this legislative intent and quoting house report).

Since January 2011, Genesis has participated in the 340B Program, a drug pricing program by which the DHHS Secretary enters into agreements with manufacturers of covered outpatient drugs to obtain discounts for covered entities purchasing those drugs. *See* 42 U.S.C. § 256b(a)(1). As an FQHC, Genesis is eligible to participate in the 340B Program and obtain certain prescription drugs at a discount for the benefit of its patients. *Id.* at § 256b(a)(4)(A). Entities like Genesis that

[1] Genesis's network of locations includes such registered sites as Pee Dee Health Care in Darlington; Olanta Family Care in Olanta; Lamar Family Care in Lamar; Brent J. Baroody, MD (OB/GYN) in Florence; and Walterboro Family Care in Walterboro. Genesis also operates pharmacies based in Darlington. Genesis manages these locations from its executive office located in Columbia.

participate in the 340B Program are referred to as "covered entities." *Id.* at § 256b(a)(4). Genesis purchases covered outpatient drugs from manufacturers through wholesalers, and dispenses these drugs at its wholly-owned and contract pharmacies to individuals who qualify as Genesis' patients under the 340B Program.

As noted previously, in correspondence dated March 20, 2019, HRSA restricts Genesis ability to provide 340B program drugs to the following "eligible" patients:

> While GHI's CAP has satisfactorily addressed the audit finding with respect to future implementation of the 340B Program, **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.** A covered entity may refer one of its patients to an outside provider and receive documentation of that episode of care that results in a 340B eligible prescription. However, a referral that begins at a private practice to the covered entity, would not qualify a prescription written by the private practitioner as 340B eligible. **GHI must be able to demonstrate that the individual first receives a health care service from a health care professional who is either employed by GHI or provides health care under contractual or other arrangements such as referral for consultation, which demonstrates responsibility for care remains with GHI, in order to meet the patient definition guidelines.**

See Dkt. No. 33-10 at ¶ 2 (Emphasis added).

After Defendants voided its audit findings, this Court granted the Defendants' motion to dismiss. *See* Dkt. No. 49. However, on July 1, 2022, the United States Court of Appeals for the Fourth Circuit reversed the district court's judgment, and the case was remanded for further proceedings. *Genesis v. Becerra*, No. 20-1702 (4th Cir. 2022). Genesis subsequently filed an Amended Verified Petition for Judicial Review maintaining that HRSA's definition of the term "patient" is in direct contradiction to the plain language of the statute, 42 U.S.C. § 256b(a)(5)(B) ("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).

III. ARGUMENT

A. Summary Judgment Standard

Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-24 (1986). Summary judgment is an integral part of the Federal Rules designed "to secure the just, speedy and inexpensive determination of every action." *Celotex* at 327.

"[T]he burden on the moving party may be discharged by showing that there is an absence of evidence to support the non-moving party's case." Id. at 325. As the Fourth Circuit has held, "the moving party on a summary judgment motion need not produce evidence, but simply can argue that there is an absence of evidence by which the nonmovant can prove his case." *Cray Communications, Inc. v. Novatel Computer Systems, Inc*., 33 F.3d 390, 393 (4th Cir.1994). This point was reiterated by the Supreme Court in *Lujan v. National Wildlife Fed'n*, 497 U.S. 871, 885 (1990), wherein the Court held that "*Celotex* made clear that Rule 56 does not require the moving party to *negate* the elements of the nonmoving party's case: ...." *Cray* at 394 (emphasis in original).

Once the moving party has made such a showing, the burden shifts to the nonmoving party to "come forward with `specific facts showing that there is a *genuine issue for trial*.' Fed. R. Civ. P. 56(e)" *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio*, 475 U.S. 574, 585 (1986)(emphasis in original). "[I]ts opponent must do more than simply show that there is some metaphysical doubt as to the material facts." *Id.* at 586. The nonmoving party may not rest upon the mere allegations or denials of his pleading, but his response, by affidavits or as otherwise provided in Rule 56, must set forth specific facts showing that there is a genuine issue for trial. Fed.R.Civ.P. 56(e).

To successfully resist a motion for summary judgment, the non-moving party must specifically set forth evidence which is sufficient for a jury to return a verdict for him at trial in accordance with the substantive evidentiary standard of proof. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252, 106 (1986). Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no "genuine issue for trial." *First National Bank of Arizona v. Cities Service Co.,* 391 U.S. 253, 288–289 (1968).

B. The Language of 42 U.S.C. § 256b(a)(5)(B) Is Plain and Unambiguous and Must Be Construed According to Its Terms

The Supreme Court has long held that if the language of the statute is plain and unambiguous, then it must be applied according to its terms. *Sebelius v. Chloer*, 569 U.S. 369, 376 (2013). Unless otherwise defined, statutory terms are generally interpreted in accordance with their ordinary meaning. *Id*. This foundational rule of statutory interpretation has been applied where DHHS implemented rules that changed the plain meaning of a federal statute. *See Am. Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896 () (2022)(rejecting DHHS' variance in hospital rates when the statute did not authorize such a variance).[2]

Under the 340B Program, the only statutory restrictions placed upon transfer of *any* drug purchased by a covered entity, such as Genesis, are:

a) that the drug be purchased and sold by a "a covered entity" and

b) the covered entity "shall not resell or otherwise transfer the drug to a person who is not a *patient* of the entity."

[2] On June 14, 2023 the Fourth Circuit affirmed the bankruptcy court's decision to confirm a debtor's proposed Chapter 13 plan over the bankruptcy trustee's objection. *Bledsoe v. Cook,* No. 22-1328 (4th Cir. 6/14/2023)(available at 221328.P.pdf (uscourts.gov)). The court found that the statutory provisions under review, related to the debtor's claim for their Mortgage/Rent deduction on Form 122C-2 (for calculation of disposable income) "although intricate," were straightforward and allowed the debtors to claim the Mortgage/Rent deduction as proposed. The trustee objected, advancing various statutory construction and policy arguments, but court rejected the Trustee's "flurry of arguments," because a "straightforward reading" of the statutes upheld the bankruptcy court's decision.

42 U.S.C. § 256b(a)(5)(B) (emphasis added).

The statute does not define the term "patient" or "patient of the entity." 42 U.S.C. § 256b(a)(4). Importantly, the section of the statute requiring that a covered entity only provide 340B priced drugs to its patients is under the heading "Prohibiting resale of drugs." Statutory titles and section headings are tools available for the resolution of a doubt about the meaning of a statute. *Fla. Dep't of Revenue v. Piccadilly Cafeterias, Inc.*, 554 U.S. 33, 47 (2008). The term "patient" as used in Section 256b(a)(5)(B) must be interpreted within the context of the statutory provision's purpose of prohibiting a covered entity from reselling the 340B drugs for profit in the open market. *See* 138 Cong. Rec. S16117-01, 138 Cong. Rec. S16117-01, S16126, 1992 WL 251277 (The bill also includes important administrative safeguards, such as a prohibition against resale of discounted drugs, a provision to prevent multiple discounts under other Federal or State programs, and an audit and dispute-resolution provision); 138 Cong. Rec. S17872-02, 138 Cong. Rec. S17872-02, S17885, 1992 WL 279559 (required a covered entity to permit the Secretary of DHHS and the manufacturer of a drug subject to a rebate or discount agreement to audit, at the Secretary of manufacturer's expense, the records of the entity that directly pertain to the entity's compliance with the prohibitions against duplicate rebates and resale of covered drugs). Congress used the term "patient" to prevent a covered entity from profiting from the program by reselling 340B drugs into the marketplace.

HRSA, however, seeks to enforce a definition of "patient" that improperly embellishes the plain language of the statute to add the concept that the term "patient" should be narrowed to only a subset of patients for whom the covered entity initiated the healthcare service that resulted in the prescription, and excluding patients who have an unrelated encounter. The plain language of 42

U.S.C. § 256b(a)(5)(B) does not support HRSA's interpretation, as it only requires the existence of a patient relationship with Genesis (or any other covered entity). 42 U.S.C. § 256b(a)(5)(B)). Of note is the fact that HRSA defines the term "patient" in its manuals differently than in its enforcement against Genesis. In its Health Center Program Compliance Manual, HRSA defines a patient as an "an individual who has received at least one service in the past 24 months that generated a health center visit, where both the service and the site where the service was received are within the HRSA scope of project." *See* bphc.hrsa.gov /compliance/compliance-manual/introduction, at. 9. Then, in its Health Center Data Reporting Requirements Manual, HRSA defines patient as "an individual who has at least one countable visit during the calendar year in one or more categories of services: medical, dental, mental health, substance use disorder, vision, other professional, or enabling." See bphc.hrsa.gov/sites/default/files/bphc/data-reporting/2022-uds-manual.pdf, pg. 19.

Sanofi Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs., 58 F.4th 696 (3d Cir. 2023), involved DHHS's interpretation of a 340B statute that would require drug makers to deliver discounted drugs to an unlimited number of contract pharmacies per year. The Third Circuit found that nothing in the plain text of the statute or the legislative history supported DHHS's interpretation of the 340B statute's delivery requirements. *Id.* at 699. Specifically, where the relevant law said nothing about such duties (to deliver discounted drugs to an unlimited number of contract pharmacies per year), the Court found DHHS's efforts to enforce its interpretation unlawful. *Id.* Similarly, here, where 42 U.S.C. § 256b(a)(5)(B)) is silent as to the origin of the prescription in question, DHHS's efforts to enforce its interpretation is unlawful.

C. HRSA Does Not Have the Authority to Issue Interpretations of Section 256b(a)(5)(B)

To determine if an agency's action is contrary to the law, the Court must first look to determine if the agency has the legal authority to take such action. *Pharm. Research v. Dept. of Health & Human ServsServ.*, 43 F.Supp.3d 28, 35 (D.D.C. 2014) ("*2014 Decision*"). As noted earlier, HRSA is an agency of DHHS. *See* https://www.hrsa.gov/about/index.html (HRSA Facts). As an administrative agency, HRSA and DHHS only possess power to interpret a statute within the bounds of its statutory authority. *2014 Decision* at 35. In terms of the 340B Program, DHHS has not been granted broad rulemaking authority to carry out the provisions of the 340B Program. *See 2014 Decision*; *Pharm. Research v. U.S. Dept. of Health*, 138 F.Supp.3d 31 (D.D.C. 2015).

In the *2014 Decision*, the Court examined DHHS's interpretation of a statutory provision exempting orphan drugs from 340B pricing. DHHS had issued a final rule limiting the exemption to only instances when the orphan drug was sold for use for the rare condition for which it was designated (*e.g.* not imposing the exemption when the drug was prescribed for other non-orphan indications). *2014 Decision* at 31. In holding that the DHHS rule-making was invalid, the court found that DHHS did not have the broad rule-making authority necessary to implement the orphan drug rule. *Id.* at 39. The Court concluded "[t]he rulemaking authority granted DHHS by Congress under the 340B program has thus been specifically limited, and DHHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program." *Id.* at 42.

Congress' limitation of DHHS' rulemaking authority is evident in the 340B statute. References to HRSA's ability to develop a regulation only appears in section 42 U.S.C. § 256b(d)(1)(B)(vi) related to the creation of standards by which the agency will impose civil

monetary penalties on manufacturers, and in 42 U.S.C. § 256b(d)(3) related to the creation of a system for resolving disputes between covered entities and manufacturers. There is otherwise no provision for broad rulemaking authority to carry out the provisions of the 340B Program. HRSA, therefore, does not have the authority to develop regulations establishing further requirements related to the plain language of 42 U.S.C. § 256b(a)(5)(B).

D. HRSA's Publications of Definitions of the Term "Patient" Are Not Enforceable

Even though HRSA does not have the authority to develop regulations concerning the plain language of 42 U.S.C. § 256b(a)(5)(B), HRSA has attempted to narrow the simple definition of the term "patient" on several occasions. In 1993, HRSA first published a proposed notice of entity "guidelines," but there was no attempt to define the term "patient" of a covered entity. 58 Fed. Reg. 68,923 (December 29, 1993). Specifically, a section titled "Diversion to Nonpatients of the Covered Entity" stated "Covered entities are required not to resell or otherwise transfer drugs purchased at the statutory discount to an individual who is not a patient of the entity." *Id.*

Subsequently, HRSA defined the term "Patient" in a resource titled "HRSA Health Center Program Terms and Definitions" that narrowed the term to include only patients who have at least one encounter within the scope of activities supported by a section 330 (340B) grant. https://www.hrsa.gov/sites/default/files/grants/apply/assistance/Buckets/definitions.pdf (accessed 5/22/2019 and attached as Dkt. No. 33-11.

Then, in 1996, HRSA issued a final guidance *notice* (as opposed to a regulation) transforming the phrase "patient of the entity" into a three-pronged "definition":

> 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 health care; 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.

61 Fed. Reg. 55157-58 (Oct. 24, 1996) (emphasis added).

HRSA provided no further guidance related to the 340B program until 2015, when HRSA filed notice of a 340B Drug Pricing Program Omnibus Guidance. *See* 80 Fed. Reg. 52300-01 (Aug 28, 2015) (withdrawn). This 2015 Omnibus Guidance, however, was officially withdrawn by HRSA on January 30, 2017 and has not been re-issued. *See* OIRA Conclusion of EO 12866 Regulatory Review, https://www.reginfo.gov/public/do/eoDetails?rrid=126712. The withdrawn 2015 Omnibus Guidance defined "Individuals Eligible to Receive 340B Drugs" as follows:

> Section 340B(a)(5)(B) of the PHSA prohibits covered entities from reselling or otherwise transferring a 340B drug to a person who is not a patient of the entity. HHS interprets this section to include all patients that meet all of the following criteria on a prescription-by-prescription or order- by-order basis:
>
> (1) The individual receives a health care service at a covered entity site which is registered for the 340B Program and listed on the public 340B database;
>
> (2) The individual receives a health care service from a health care provider employed by the covered entity or who is an independent contractor of 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). An individual will not be considered a

> patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug.
>
> (4) The individual receives a health care service that is consistent with the covered entity's scope of grant, project, or contract;
>
> (5) The individual is classified as an outpatient when the drug is ordered or prescribed. The patient's classification status is determined by how the services for the patient are billed to the insurer (e.g., Medicare, Medicaid, private insurance). An individual who is self-pay, uninsured, or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently; and (6) The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records which demonstrate that the covered entity has a provider-to-patient relationship, that the responsibility for care is with the covered entity, and that each element of this patient definition in this section is met for each 340B drug.

80 Fed. Reg. 52319 (Aug 28, 2015)(withdrawn).

Despite the 2015 Omnibus Guidance having been withdrawn, it is clear that HRSA has incorporated this even narrower definition of "patient" into its current audit approaches, as evidenced by the HRSA March 20, 2019 correspondence. *See* Dkt. No. 33-10. Therefore, as the wording of the withdrawn guidance and HRSA's correspondence to Genesis state, HRSA is substituting a covered entity's compliance with § 256b(a)(5)(B)'s simple and plain requirement of a person being a patient of a covered entity, such as Genesis, with its requirement that compliance with § 256b(a)(5)(B) be determined on a prescription-by-prescription or order-by-order basis only when written by a provider employed by or contracted with the covered entity or if the covered entity makes a specific referral to another provider.

As noted in Section III.C of this Memorandum, HRSA does not have the authority to develop regulations establishing requirements, conditions, and limitations related to the plain language of 42 U.S.C. § 256b(a)(5)(B). Therefore, HRSA's reliance on the 2015 Omnibus Guidance is improper not only because this Guidance was withdrawn, but also because HRSA did not have the authority to issue the Guidance in the first place.

E. HRSA's Interpretation of the Term "Patient" Is Not Entitled to *Chevron* Deference

Under the *Chevron* doctrine established in 1984, when a court reviews an agency's formal interpretation of a statute that the agency administers, and when the statute has not removed agency discretion by compelling a particular disposition of the matter at issue, courts may defer to any reasonable agency interpretation. *Pereira v. Sessions*, 138 S. Ct. 2105, 2118 (2018) (holding "[b]ut as this Court has long made plain, pleas of administrative inconvenience and self-serving regulations never 'justify departing from the statute's clear text.'"); *see also Helix Energy Solutions Group, Inc. v. Hewitt,* 143 S. Ct. 677, 678 (2023)('. . . even the most formidable policy arguments cannot overcome a clear textual directive"). The Supreme Court has long held that an administrative agency's implementation of a particular statutory provision qualifies for *Chevron* deference only when it appears that: 1) Congress delegated authority to the agency carrying the force of law; and 2) the agency interpretation claiming deference was promulgated in the exercise of that authority. *United States v. Mead Corp*., 533 U.S. 218 (2001).

1. HRSA Does Not Have Authority to Interpret the Meaning of the Word "Patient" in § 256b(a)(5)(B) of the 340B Statute

The first step of the *Chevron* analysis is to determine if the agency in question had rule-making authority. As explained previously, DHHS, and in turn HRSA, have not been granted broad rulemaking authority by Congress to carry out all the provisions of the 340B program. Congress limited DHHS's rule-making authority under the 340B statute to two areas: (1) establishing an adjudication procedure to resolve disputes between covered entities and manufacturers; and (2) setting the amount of civil monetary penalties that can be imposed against manufacturers. HRSA did not have Congressional authority to issue the 1996 and 2015 Final

Rules in the Federal Register regarding the meaning of the term "patient of a covered entity" in § 256b(a)(5)(B) of the 340B statute.

2. Congress' Intent Was Clear Regarding the Word "Patient" in the 340B Statute

If this Court finds that HRSA does have Congressional authority for its interpretation of the rules, the first prong of the second step of the *Chevron* analysis requires the Court to use traditional tools of statutory interpretation to determine if Congress addressed the precise issue before the Court. *See 2014 Decision* at 44. And in this case, Congressional intent is clear and the statutory language is plain and unambiguous.

The plain language of the word "patient," in conjunction with the evidence of Congressional intent, clearly shows that Congress did not intend to place the restrictions on the term "patient of a covered entity" that HRSA seeks to impose. First, the relevant Congressional History for Bill H.R. 2890 (related to the "Medicaid and Department of Veterans Affairs Drug Rebate Amendments of 1992 which added § 256b(a)(5)(B) of the 340B statute) simply states that covered entities will "refrain from reselling such purchased drug to a person who is not a patient of such entity" without defining the term "patient." *See* H.R. 2890, 102d Cong. (1992), https://www.congress.gov/bill/102nd-congress/house-bill/2890.

In addition, looking at the text of 42 U.S.C. § 256b, other terms were defined in the statute, including the terms "Covered entity," "Covered outpatient drug," "Manufacturer," etc., but the term "Patient" is not defined. Therefore, if Congress wanted to include a definition of patient that added additional restrictions and requirements such as the definition HRSA seeks to impose, then Congress could have done so. However, Congress did not restrict the statute in that way.

3. HRSA's Interpretation of the Term "Patient" Is Not Reasonable

If this Court were to find that Congressional intent is not clear as to the use of the word "patient," the second prong of the *Chevron* analysis requires the Court to determine if the agency interpretation is reasonable. *Pharm. Research & Mfrs. of Am.*, 43 F.Supp.3d at 44. An examination of the term "patient" as compared to HRSA's definition in the withdrawn 2015 Omnibus Guidance necessitates the conclusion that HRSA's definition is far from reasonable.

The term "patient" is commonly defined as "an individual awaiting or under medical care and treatment." Merriam-Webster Dictionary at https://www.merriam-webster.com/dictionary/patient. This definition makes sense in the context of 42 U.S.C. § 256b(a)(4): the covered entity shall not "shall not resell or otherwise transfer the drug to a person who is not a *patient* [an individual under medical care and treatment] of the entity." (emphasis added).

In this light, the first prong of the withdrawn 2015 Omnibus Guidance also makes sense: "[t]he individual receives a health care service at a covered entity site which is registered for the 340B Program and listed on the public 340B database." 80 Fed. Reg. 52319 (Aug 28, 2015) (withdrawn). However, HRSA's attempt to further read into the simple term "patient" that the individual *also* must have received a drug that is ordered or prescribed by the covered entity at a specific appointment is unjustifiable and a tortured interpretation of the term "patient." *See id.*

There is nothing in the text of 42 U.S.C. § 256b(a)(4) and the term "patient" that says anything about the origin of the patient's prescription. This is similar to the interpretation examined in *Sanofi*, where the relevant law said nothing about the term "delivery." *See* 58 F.4th at 699 (rejecting DHHS' position that drug makers must deliver certain discounted drugs wherever and to whomever a buyer demands because "the relevant law says nothing about such duties.") The court in *Sanofi* noted that "[l]egal duties do not spring from silence" and held DHHS overstepped

the bounds of 340B by trying to add a requirement tied to an individual's prescription's origin. *Id.* at 707.

As noted previously, the 340B program (42 U.S.C. § 256b) was first enacted by Congress as part of the Veterans Health Care Act of 1992. At that time, Congress choose not to define the term "patient," and did not add a requirement for the covered entity to have also generated the prescription in question. Furthermore, in 2010, the statute (42 U.S.C. § 256b) was amended in Public Law 111-152 (SEC. 2302)(striking the terms "covered drug" and "covered drugs" and replacing the terms with "covered outpatient drug" and "covered outpatient drugs"), Public Law 111-309 (SEC. 204)(amending the definition of "covered outpatient drugs), and Public Law 111-148 (SEC. 7101 and 7012)(expanded participation in the 340B program and improvements to the 340B program). Congress did not revise or further define the term "patient" in 2010, nor did Congress add language to refer to specific prescriptions tied to specific visits to a covered entity.

F. Deference Should Not Be Extended to HRSA When It Disclaimed the Guidance It Relies Upon to Define the Term "Patient"

In addition, HRSA withdrew the 2015 Omnibus Guidance that contains the definition of the term "patient" HRSA seeks to impose on covered entities (as discussed previously, the 2015 Omnibus Guidance was officially withdrawn on January 30, 2017 and has not been re-issued). For this reason, as well, the Court should decline to extend deference to HRSA where HRSA has disclaimed the guidance upon which it relies. *Exelon Generation Co. LLC v. Local 15, Int'l Brotherhood of Elec. Workers, AFL-CIO,* 676 F.3d 566, 576-578 (7th Cir. 2012) (declining deference when the agency had itself "disclaimed the use of regulatory guides as authoritative").

G. The Structure of the 340B Statute Does Not Support HRSA's Interpretation That the Patient's Prescription Must Originate from a Specified Covered Entity Visit

HRSA's narrow restriction on the plain language of 42 U.S.C. § 256b(a)(5)(B) is also against Congressional intent when examined in context with the heading of subsection 256b(a)(5)(B). *See* Fla. Dep't of Revenue v. Piccadilly Cafeterias, Inc., 554 U.S. 33, 47 (2008) (holding statutory titles and section headings are tools available for the resolution of a doubt about the meaning of a statute). The heading of subsection 256b(a)(5)(B), "Prohibiting resale of drugs", states:

> **(B) Prohibiting resale of drugs**
> With 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.

42 U.S.C. § 256b(a)(5)(B)(emphasis added). The clear intent of this subsection is to prevent the reselling of drugs purchased by a covered entity to individuals who are not patients of the covered entity. There is nothing pertaining to the origin of the prescription being filled by the patient. Congress knew how to add such a restriction but did not. *See Sanofi Aventis U.S., LLC,* 58 F.4th at 704. This omission related to the origin of patient prescriptions should be presumed to be intentional. *Id.* at 705.

H. HRSA's Interpretation of the Term "Patient" Puts Genesis in an Inappropriate "Legal Bind" and Foreseeably Results in Patients Forgoing Needed Medications

HRSA's interpretation of the term "patient" to narrow it to only patients who also obtain an order or prescription from a specific visit to Genesis puts Genesis in a "legal bind." As noted in the *Sanofi* case, had the government's interpretation of the 340B statute's delivery requirements been expanded to any and all contract pharmacies, drug makers would have been put in a legal

bind, as the drug makers often comply with FDA safety requirements by limiting distribution to pharmacies that are specially trained to educate and monitor patients. *See* 58 F.4th at 705.

Here, HRSA's interpretation of the definition of "patient," if upheld, would similarly put Genesis in a "legal bind." The intent of the 340B statute is to ensure that 340B patients have access to the care and medications they need from covered entities. Genesis would be in a "legal bind" as it could not assist patients with access to discounted 340B drugs if they obtained a prescription from a non-Genesis provider. Not allowing 340B patients access to discounted drugs (these would usually be specialty drugs generated by provider specialists) would endanger the health of the most vulnerable patient population, as the patients may very well forgo filling prescriptions due to the expense if they are unable to access Genesis' 340B discounted pricing. The patients would also not have access to the patient counseling services Genesis provides to patients filling prescriptions at its pharmacies. Revenue from 340B sales also assists covered entities like Genesis in providing high-quality, affordable care to underserved populations. *See* Karen Mulligan, PhD, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments* (Oct. 14, 2021) *https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/*.

HRSA may argue that it added the requirement for prescriptions to originate from a covered entity for a policy reason, although what that policy concern might be is unclear. HRSA states in the withdrawn 2015 Omnibus Guidance that its definition of patient was developed to "address the diverse set of 340B covered entities" but this is inscrutable and unpersuasive at best. *See* 80 Fed. Reg. 52319, 52306 (Aug 28, 2015) (withdrawn). HRSA also states that an individual who does not meet the criteria in the with withdrawn Guidance is considered a "diversion." *Id.* But again, this does not make sense when the overarching goal of the 340B Program is to provide access to

healthcare and affordable prescriptions to the county's most vulnerable citizens. Moreover, even if HRSA articulated a sound policy argument for its interpretation, such argument still cannot justify a departure from the plain meaning of a statute, here the plain meaning of 42 U.S.C. § 256b(a)(5)(B). *Pereira,* 138 S. Ct. 2105 at 2118 (holding "[b]ut as this Court has long made plain, pleas of administrative inconvenience and self-serving regulations never 'justify departing from the statute's clear text.'"); *see also Helix Energy Solutions Group, Inc.,* 143 S. Ct. at 678)('. . . even the most formidable policy arguments cannot overcome a clear textual directive"); *Bledsoe v. Cook,* No. 22-1328 (4th Cir. 6/14/2023)(available at 221328.P.pdf (uscourts.gov)(although there were at least two sides to the policy question, a rational Congress could reach the policy judgment the statutory text suggests it did).

IV. CONCLUSION

For the foregoing reasons, Genesis respectfully requests that this Court rule that Genesis is entitled to Summary Judgment with respect to the following claims as set forth in its Amended Verified Petition for Judicial Review that stem from the plain language of 42 U.S.C. § 256b(a)(5)(B):

1. 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. 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. Any and all interpretations or guidance of HRSA in contradiction of the plain wording of 42 U.S.C. § 256b(a)(5)(B) are unlawful and unenforceable as a matter of law.

4. 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).
5. 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.
6. HRSA does 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).

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