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.

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