

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

Genesis Health Care Inc.,)	Civil Action Number: 4:19-cv-01531-RBH
)	
Petitioner,)	
)	
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,)	
)	
Respondents. ¹)	

**ANSWER TO AMENDED VERIFIED PETITION
 FOR JUDICIAL REVIEW**

Defendants Xavier Becerra, in his official capacity as the Secretary of the United States Department of Health and Human Services (“HHS”); Carole Johnson, in her official capacity as Administrator of the Health Resources and Services Administration (“HRSA”); and Emeka Egwim, in his official capacity as Director of the Office of Pharmacy Affairs (“OPA”), hereby answer the Amended Verified Petition for Judicial Review as follows.

The text preceding the section entitled “Introduction and Parties” consists of five unnumbered paragraphs. The first paragraph consists of Petitioner Genesis Health Care’s (“Genesis”) characterization of this action, not allegations of fact to which a response is required.

¹ Pursuant to Federal Rule of Civil Procedure 25(d), Secretary Becerra, Administrator Johnson, and LCDR Egwim are substituted for the original named defendants in this action.

As to the first and second sentence of the second unnumbered paragraph, HRSA admits that it issued a revised final audit report to Genesis dated September 24, 2018, vacated its decision to remove Genesis from the 340B Program, and reinstated Genesis into the 340B program. But Genesis's characterization of HRSA's previous determination as a "Final Agency decision" is a conclusion of law, to which no response is required. As to the third sentence, Defendants admit that the September 24, 2018, revised final audit report did not vacate the findings that Genesis violated program requirements, but Defendants state further that these findings were subsequently voided in full on June 6, 2019. The remainder of this paragraph consists of characterizations of this action, to which no response is required.

As to the first sentence of the third unnumbered paragraph, HRSA admits only that it notified Genesis on March 20, 2019, that HRSA would accept Genesis's revised Corrective Action Plan (CAP). The remainder of the paragraph consists of a characterization of the March 20, 2019 notice, which speaks for itself, and of legal argument to which no response is required. To the extent a response is required, Defendants deny the remainder of the paragraph.

The fourth and fifth unnumbered paragraph consists of characterizations of this action, to which no response is required. Furthermore, Defendants deny that Genesis is entitled to any relief.

INTRODUCTION AND PARTIES

1. Admit that Genesis is a Federally Qualified Health Center pursuant to 42 U.S.C. § 1396(l)(2). Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of Paragraph 1 and the accompanying footnote.
2. Admit.

3. Defendants admit that Alex M. Azar II was HHS Secretary at the time the Amended Verified Petition was filed, and state further Secretary Becerra has been substituted as defendant pursuant to Federal Rule of Civil Procedure 25(d).
4. Defendants admit that George Sigounas was HRSA Administrator at the time the Amended Verified Petition was filed, and state further that Administrator Johnson has been substituted as defendant pursuant to Federal Rule of Civil Procedure 25(d).
5. Defendants admit that Krista Pedley was Director of OPA at the time Amended Verified Petition was filed, and state further that LCDR Egwim has been substituted as defendant pursuant to Federal Rule of Civil Procedure 25(d).

JURISDICTION AND VENUE

6. Paragraph 6 contains a jurisdictional statement, and thus no response is required.
7. Paragraph 7 contains a jurisdictional statement, and thus no response is required.
8. Paragraph 8 contains a jurisdictional statement, and thus no response is required.

FACTUAL BACKGROUND

9. Admit, with the following exceptions. The U.S. Public Health Service (USPHS) consists of more than 6,000 professionals and the Public Health Services Act is administered by various parts of HHS.
10. Admit.
11. Defendants are without knowledge or information sufficient to form a belief as to the truth of Paragraph 11.
12. Defendants are without knowledge or information sufficient to form a belief as to the truth of Paragraph 12.
13. Admit.

14. Admit.
15. Admit that OPA sent a final audit report to Genesis on February 14, 2018, and that it contains the quoted text. Otherwise, Defendants deny any characterization of that document, which speaks for itself.
16. Admit that OPA sent a final audit report to Genesis on or about February 14, 2018, and that it contains the quoted text. Otherwise, Defendants deny any characterization of that document, which speaks for itself.
17. Admit.
18. Admit.
19. Admit that OPA sent a response to Genesis on or about June 26, 2018. Defendants deny any characterization of that document, which speaks for itself.
20. Admit the first sentence of Paragraph 20. Admit further that, at the time Genesis filed its petition on June 28, 2018, Defendants had not notified Genesis of any change to the June 26, 2018 audit report.
21. Admit.
22. HRSA admits that it issued a revised final audit report to Genesis dated September 24, 2018, vacated its decision to remove Genesis from the 340B Program, and reinstated Genesis into the 340B program. Genesis's characterization of this document as an "amended Final Agency action" is a legal conclusion to which no response is required.
23. Denied.
24. Denied.
25. Admit.
26. Admit.

27. Admit the document contains the quoted language, but deny any characterization of the document, which speaks for itself.
28. Paragraph 28 and the accompanying footnote references and characterizes 42 U.S.C. 256b and Section 1927(k) of the Social Security Act. Such allegations require no response because the provisions speak for themselves.
29. Paragraph 29 consists of argument and conclusions of law, not allegations of fact to which a response is required; to the extent a response is deemed required, Defendants deny this paragraph.
30. Deny that HRSA has never issued regulations on the administration of the 340B program. Otherwise, Paragraph 30 and the accompanying footnote consists of argument and conclusions of law, not allegations of fact to which a response is required; to the extent a response is deemed required, Defendants deny this paragraph.
31. Paragraph 31 consists of argument and conclusions of law, not allegations of fact to which a response is required; to the extent a response is deemed required, Defendants deny this paragraph.
32. Admit only that HRSA published a “Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines” in the Federal Register on December 29, 1993. Otherwise, Paragraph 32 references and characterizes that document; Defendants deny such characterization of the document, which speaks for itself.
33. Admit only that “Genesis, as a nonprofit FQHC, has applied for and receives a grant under Section 330.” Otherwise, the paragraph references and characterizes a Grants Policy Statement issued by HHS and a set of Program Terms and Definitions issued by HRSA.

Admit that the HRSA document contains the quoted language, but deny any characterization of the document, which speaks for itself.

34. Admit only that HRSA published a “Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility” in the Federal Register on October 24, 1996, and that the document contains the quoted language. Otherwise, paragraph references and characterizes the document; Defendants deny any characterization of the document, which speaks for itself.
35. Deny that HRSA provided “no further guidance on any issue related to the 340B program” between 1996 and 2015. Admit that HRSA published a notice in the Federal Register entitled “340B Drug Pricing Program Omnibus Guidance” on August 28, 2015, that HRSA withdrew the notice on January 30, 2017, and that the notice has not been re-issued. Admit that the notice has language substantially similar to what is quoted in the Amended Verified Petition (it appears that the Amended Verified Petition takes language from different sections of the notice without using ellipses). The remainder of the paragraph references and characterizes HRSA’s letter to Genesis, sent on or about March 20, 2019; Defendants deny any characterization of the document, which speaks for itself.
36. Admit only that HRSA does not publish audit letters on its website. Most of the remainder of the paragraph consists of argument and conclusions of law, not allegations of fact to which a response is required. To the extent a response is deemed required, Defendants deny this paragraph. The third-to-last and second-to-last sentences reference and characterize documents attached to the Amended Verified Petition; Defendants deny any characterization of these documents, which speak for themselves. The final sentence is a request for relief and Defendants deny that Genesis is entitled to any relief in this case.

37. Paragraph 37 consists of argument and conclusions of law, not allegations of fact to which a response is required. To the extent a response is deemed required, Defendants deny this paragraph.

38. Paragraph 38 consists of argument and conclusions of law, not allegations of fact to which a response is required. To the extent a response is deemed required, Defendants deny this paragraph.

**HRSA’S FINDING THAT GENESIS FAILED TO COMPLY WITH 340B
PROGRAM REQUIREMENT IS ARBITRARY, CAPRICIOUS,
AND NOT IN ACCORDANCE WITH LAW²**

39. Paragraph 39 references and characterizes 5 U.S.C. § 702. No response is required because the provision speaks for itself.

40. Paragraph 40 references and characterizes case law. No response is required because the cited case law speaks for itself.

41. Paragraph 41 quotes 5 U.S.C. § 706(2)(A). No response is required because the provision speaks for itself.

42. Admit only that the quoted language appears in the March 20, 2019 correspondence. Otherwise, the paragraph consists of argument or characterizes documents that speak for themselves, not allegations of fact to which a response is required. To the extent a response is deemed required, Defendants deny the remainder of this paragraph.

43. The first three sentences of Paragraph 43 consist of argument and conclusions of law, not allegations of fact to which a response is required. To the extent a response is deemed

² Headings from Genesis’s Amended Verified Complaint are included only for easy of reference. Defendants do not construe them to be allegations of fact to which a response is required. To the extent a response is deemed required, Defendants deny all allegations contained within the section headings of the Amended Verified Petition.

required, Defendants deny this paragraph. The remainder of the paragraph references and characterizes case law. No response is required because the case law speaks for itself.

44. Admit only that HRSA is an agency of HHS. The first sentence of this paragraph consists of argument and conclusions of law, not allegations of fact to which a response is required. The remainder of the paragraph references and characterizes case law. No response is required because the case law speaks for itself.

45. Paragraph 45 consists of argument and conclusions of law, not allegations of fact to which a response is required. To the extent a response is deemed required, Defendants deny this paragraph.

46. Paragraph 46 consists of argument and conclusions of law, not allegations of fact to which a response is required. To the extent a response is deemed required, Defendants deny this paragraph.

HRSA'S REQUIREMENT THAT GENESIS REPAY DRUG MANUFACTURERS IS ARBITRARY, CAPRICIOUS, AND NOT IN ACCORDANCE WITH LAW

47. Paragraph 47 consists of argument and conclusions of law, not allegations of fact to which a response is required. To the extent a response is deemed required, Defendants deny this paragraph.

48. Paragraph 48 quotes 42 U.S.C. § 256b(a)(5)(D). No response is required because the provision speaks for itself.

49. Paragraph 49 references and quotes the March 20, 2019 correspondence. No response is required because the document speaks for itself.

50. Paragraph 50 consists of argument and conclusions of law, not allegations of fact to which a response is required. To the extent a response is deemed required, Defendants deny this paragraph.

51. Paragraph 51 consists of argument and conclusions of law, not allegations of fact to which a response is required. To the extent a response is deemed required, Defendants deny this paragraph.

**HRSA'S DETERMINATION REGARDING THE SCOPE OF PATIENT
ELIGIBILITY MUST BE STAYED PENDING JUDICIAL REVIEW**

52. [This paragraph concerns Genesis's request for a stay, which the Court has already denied. Order, Dkt. 44 (June 26, 2019).]

53. [This paragraph concerns Genesis's request for a stay, which the Court has already denied. Order, Dkt. 44 (June 26, 2019).]

54. [This paragraph concerns Genesis's request for a stay, which the Court has already denied. Order, Dkt. 44 (June 26, 2019).]

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60. [This paragraph concerns Genesis's request for a stay, which the Court has already denied. Order, Dkt. 44 (June 26, 2019).]

61. [This paragraph concerns Genesis’s request for a stay, which the Court has already denied. Order, Dkt. 44 (June 26, 2019).]
62. [This paragraph concerns Genesis’s request for a stay, which the Court has already denied. Order, Dkt. 44 (June 26, 2019).]
63. [This paragraph concerns Genesis’s request for a stay, which the Court has already denied. Order, Dkt. 44 (June 26, 2019).]
64. [This paragraph concerns Genesis’s request for a stay, which the Court has already denied. Order, Dkt. 44 (June 26, 2019).]

DECLARATORY JUDGMENT CONCERNING PLAIN LANGUAGE OF 42 U.S.C. § 256b(a)(5)(B)

65. This paragraph consists of a request for relief. Defendants deny that Genesis is entitled to any relief in this case.
66. This paragraph consists of a request for relief. Defendants deny that Genesis is entitled to any relief in this case.
67. This paragraph consists of a request for relief. Defendants deny that Genesis is entitled to any relief in this case.

DECLARATORY JUDGMENT CONCERNING HRSA’S LACK OF AUTHORITY TO INTERPRET THE LANGUAGE OF 42 U.S.C. § 256b(a)(5)(B) CONTRARY TO THE PLAIN LANGUAGE OF THE STATUTE

68. This paragraph consists of a request for relief. Defendants deny that Genesis is entitled to any relief in this case.
69. This paragraph consists of a request for relief. Defendants deny that Genesis is entitled to any relief in this case.
70. This paragraph consists of a request for relief. Defendants deny that Genesis is entitled to any relief in this case.

PRAYER FOR RELIEF

This unnumbered section consists of a request for relief. Defendants deny that Genesis is entitled to any relief in this case.

GENERAL DENIAL

The Defendants deny each and every allegation of the Amended Verified Petition not otherwise expressly admitted, qualified, or denied herein.

AFFIRMATIVE DEFENSES

1. The Amended Verified Complaint fails to state a claim upon which relief can be granted.
2. The Plaintiff lacks standing as to some or all of their claims.
3. Some or all of the Plaintiff's claims are moot.
4. Some or all of the Plaintiff's claims are barred by the doctrines of ripeness, laches, or failure to exhaust administrative remedies.
5. Some or all of the Plaintiff's claims are barred by the statute of limitations.
6. Some or all of the Plaintiff's claims are barred by the doctrine of unclean hands.
7. Defendants reserve their right to assert additional affirmative defenses during the course of this litigation.

WHEREFORE, Defendants deny that Plaintiff is entitled to the relief requested or to any relief whatsoever, and request that the Amended Verified Complaint be dismissed with prejudice, that judgment be entered in favor of Defendants, and that the Court order such other and further relief as it may allow.

[SIGNATURE PAGE FOLLOWS]

Respectfully submitted,

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