

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SAGEBRUSH HEALTH SERVICES, a
Nevada nonprofit foundation
8379 West Sunset Road, Suite 210
Las Vegas, NV 89113

Plaintiff,

v.

XAVIER BECERRA, in his official capacity,
and U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, DC 20201

and

CAROLE JOHNSON, in her official capacity,
and HEALTH RESOURCES AND SERVICES
ADMINISTRATION,
5600 Fishers Lane
Rockville, MD 20857

Defendants.

Civil Action No.

VERIFIED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Sagebrush Health Services (“Sagebrush”), a nonprofit foundation, submits the following Verified Complaint for Declaratory and Injunctive Relief against Defendants Xavier Becerra in his official capacity, the United States Department of Health and Human Services (“HHS”), the Health Resources and Services Administration (“HRSA”), and Carole Johnson in her official capacity, and alleges as follows:

NATURE OF CASE

1. This is an action arising out of HRSA’s arbitrary and unlawful actions which, if uncorrected, will have catastrophic, irreparable, and fatal consequences to Sagebrush.

Accordingly, Sagebrush urgently brings this action to obtain immediate relief from the unlawful, arbitrary, and capricious actions of HRSA to terminate Sagebrush-affiliated clinics from the 340B Program without required due process. Absent judicial intervention, HRSA's actions will inevitably cause the imminent destruction of Sagebrush, which relies on the 340B Program to sustain its operations.

2. HRSA's failure to follow its own published regulatory process, and its disturbing deviance from its statutory authority, are violations of both constitutional due process and the Administrative Procedure Act ("APA"). As a result, the agency's actions in this case must be set aside.

THE PARTIES

3. Sagebrush is a Nevada nonprofit foundation that collaborates with specialty care clinics in Nevada, Connecticut, and South Carolina. Its headquarters is located at 8379 West Sunset Road, Suite 210, Las Vegas, Nevada 89113.

4. Defendant Xavier Becerra is the Secretary of HHS. He has ultimate responsibility for oversight of the activities of HRSA, including the administration of the 340B Program and the actions subject to this complaint. He is sued in his official capacity only. Secretary Becerra maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201.

5. Defendant HHS is an executive department of the United States government that is responsible for HRSA and the 340B Program. HHS is headquartered in Washington, D.C.

6. Defendant HRSA is an administrative agency of the United States government within HHS. It is the division of HHS charged with administering the 340B Program. HRSA is headquartered in Rockville, Maryland.

7. Defendant Carole Johnson is the Administrator of HRSA. Administrator Johnson has ultimate responsibility for HRSA's Office of Pharmacy Affairs ("OPA") and its administration of the 340B Program, among other duties. She is sued in her official capacity only. Administrator Johnson maintains an office at 5600 Fishers Lane, Rockville, Maryland 20857.

JURISDICTION AND VENUE

8. This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1331 because this action arises under the United States Constitution and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq.*

9. Venue is proper in this Court under 28 U.S.C. § 1391(b)(1) because this is an action against officers and agencies of the United States headquartered in this District.

STATEMENT OF FACTS

A. The 340B Program

10. The 340B Program, established by Congress in 1992, is a federal drug discount program that allows certain types of health care providers and organizations, referred to as "covered entities," to obtain outpatient drugs from participating manufacturers at substantially reduced prices. *See* 42 U.S.C. § 256b. The purpose of the program, which takes its name from its enabling statute, Section 340B of the Public Health Service Act ("PHSA"), is to empower covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. 102-384(II) at 12 (1992).

11. One category of covered entity eligible to participate in the 340B Program is an “entity receiving funds . . . through a State or unit of local government” under Section 318 of the PHSA “relating to treatment of sexually transmitted diseases” (a “Section 318 Subawardee”). 42 U.S.C. § 256b(a)(4)(K). Such entity may gain access to the 340B Program only after “certification” of eligibility by HRSA. *Id.* § 256b(a)(7)(A). HRSA also must “recertify” the eligibility of a Section 318 Subawardee annually. *Id.* § 256b(a)(7)(E).

12. To enroll in the 340B Program as a Section 318 Subawardee, an entity must register as a covered entity via HRSA’s Office of Pharmacy Affairs Information System (“OPAIS”).¹ Section 340B of the PHSA describes OPAIS as a “single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs” 42 U.S.C. § 256b(d)(2)(B)(iv). Without registration information in OPAIS, a manufacturer or distributor is unable to verify an entity’s eligibility as a covered entity and therefore may decline to sell 340B drugs to the entity.

13. A Section 318 Subawardee must separately register each physical site that purchases 340B drugs to administer or dispense to eligible patients who receive Section 318 Subawardee services at the site. HRSA’s website contains detailed instructions regarding registration.² Once the registration is complete, OPA reviews the submission and “verif[ies] eligibility by conferring with the appropriate granting agency.”³ If OPA

¹ See <https://340bopais.hrsa.gov/home> (last visited Jan. 15, 2025).

² See <https://www.hrsa.gov/opa/registration> (last visited Jan. 15, 2025).

³ See FAQ ID: 1213 at https://www.340bpvp.com/search#tab=faq&cf-p_faq_category_hierarchy=Eligibility%2FRegistration&firstResult=20 (last visited Jan. 15, 2025).

determines that a site is a Section 318 Subawardee and provided all required information, OPA will approve the site's enrollment as a covered entity and issue a 340B identification number — a unique number that drug manufacturers, wholesalers, and others use to verify the covered entity's program enrollment.⁴

B. 340B Program Compliance and Oversight

14. A covered entity is subject to two statutory prohibitions: the “diversion” prohibition and the “duplicate discount” prohibition. The diversion prohibition prevents a covered entity from reselling or transferring a drug purchased through the 340B Program to anyone other than a “patient” of the covered entity. *See* 42 U.S.C. § 256b(a)(5)(B). The duplicate discount prohibition prevents a covered entity from billing fee-for-service Medicaid for a 340B drug if the state Medicaid agency will request a rebate from the manufacturer. *See id.* § 256b(a)(5)(A).

15. Additionally, a covered entity's records directly related to its compliance with the diversion and duplicate discount prohibitions are subject to audit by HRSA and manufacturers. *See id.* § 256b(a)(5)(C). The audit process is conducted according to “procedures established by the Secretary relating to the number, duration, and scope of audits” *Id.* If, “after audit . . . and after notice and hearing,” HRSA determines that the covered entity violated either prohibition, the covered entity may be liable to an affected manufacturer for repayment of an amount equal to the 340B discount. *Id.* § 256b(a)(5)(D).

16. HRSA's covered entity audit procedures are set forth on the “Program Integrity” page of the 340B Program website.⁵ The scope of an audit may include review of the entity's status as a covered entity. Upon completion of the audit, HRSA will issue a final report

⁴ *See* <https://www.hrsa.gov/opa/registration> (last visited Jan. 15, 2025).

⁵ *See* <https://www.hrsa.gov/opa/program-integrity> (last visited Jan 15, 2025).

addressing its findings. The report may be accompanied by a request for a corrective action plan (“CAP”).

17. The covered entity has thirty calendar days from the date of HRSA’s final report to notify the agency of its agreement or disagreement with the final report.

18. If the covered entity agrees with the final report, it must submit a CAP, if required, to HRSA within sixty calendar days. HRSA generally expects full CAP implementation and any settlement with manufacturers to be complete within six months of the CAP approval date. The covered entity may be terminated from the 340B Program for deviating from this expectation.

19. If the covered entity disagrees with the final report, it must provide a written notice of disagreement and supporting documents. HRSA will review the covered entity’s response and may reissue the final report with revisions, as appropriate. At that time, HRSA will request a CAP, if still required, in accordance with the above-described procedures.

20. If, in connection with an audit, HRSA determines that a covered entity’s violation of the diversion prohibition is “systematic and egregious as well as knowing and intentional,” the agency is statutorily authorized to “remov[e] the covered entity from the drug discount program . . . and disqualify[] the entity from re-entry into such program for a reasonable period of time . . .” 42 U.S.C. § 256b(d)(2)(B)(v)(II). According to HRSA’s Program Integrity webpage, “[a] finding of non-compliance with the diversion prohibition *in two or more audits*, depending on the nature of the violation, may be considered systematic and egregious, as well as knowing and intentional” (emphasis

added), and therefore may result in the covered entity's removal and disqualification from re-entry into the 340 Program.

C. Sagebrush

21. Sagebrush is a Nevada nonprofit foundation that is affiliated with specialty care clinics in Nevada, Connecticut, and South Carolina. It is the recipient of two grant subawards focused on the screening, detection, treatment, and prevention of sexually transmitted infections ("STIs"). One was issued by the Nevada Department of Health and Human Services ("NHHS") (the "NHHS Subaward"); the other by the Connecticut Department of Public Health ("CDPH") (the "CDPH Subaward," collectively with the NHHS Subaward, the "Subawards"). The Subawards derive from awards made by the Centers for Disease Control and Prevention ("CDC") to NHHS and CDPH under Section 318 of the PHSA.

D. The NHHS Subaward

22. NHHS awarded the NHHS Subaward for the initial period from January 1, 2023, to December 31, 2023, in a Notice of Subaward identifying CDC as the source of funds under Section 318 grant number 6NH25PS005179-05-03.

23. The Notice of Subaward includes a Scope of Work that details various goals, objectives, and activities required of Sagebrush. The Scope of Work contemplates Sagebrush's affiliation with medical providers to perform the NHHS Subaward activities, listing the name and addresses of nineteen clinic sites. The Scope of Work expressly acknowledges that the NHHS Subaward activities will be directed to patients at "infusion-based specialty clinics, such as Infectious Disease, Rheumatology, Neurology, Nephrology, Cardiology, Gastroenterology, Oncology, and other applicable specialties" and that those patients would be "incorporate[ed] into [Sagebrush's] 340B program."

24. Pursuant to a Subaward Amendment #1 dated July 17, 2023, NHHS and Sagebrush agreed to modify the Scope of Work to include additional provisions relating to development and implementation of a national protocol for STI risk assessment and/or testing, prevention, and/or education focused on short-term visitors and other temporary residents of Nevada.

25. Pursuant to a Subaward Amendment #2 dated November 20, 2023, NHHS and Sagebrush agreed to extend the NHHS Subaward through January 31, 2024.

26. NHHS and Sagebrush agreed to further extend the NHHS Subaward through January 31, 2025. This is memorialized in a new Notice of Subaward that is substantially similar to the original Notice of Subaward.

27. Pursuant to a Subaward Amendment #1 dated July 17, 2023, NHHS and Sagebrush agreed to extend the NHHS Subaward through February 28, 2025, and to modify the Scope of Work to include a list of the nineteen clinic sites where NHHS Subaward activities occur. The amendment also updates the underlying CDC grant number (6 NH25PS005179-05-04) to reflect the new award under which NHHS will continue to receive Section 318 funds.

28. In total, Sagebrush received \$600 from NHHS to cover the costs of STI-related outreach and education materials, as well as condoms provided by NHHS on an in-kind basis, for distribution to target populations.

E. The CDPH Subaward

29. The CDPH Subaward comprises an in-kind contribution of human immunodeficiency virus (“HIV”) and hepatitis C tests that CDPH has provided to Sagebrush with funds from the CDC under Section 318 grant number 6NU62PS924521-

04-02. The CDPH Subaward commenced on or around December 28, 2022, and continues on an ongoing basis, subject to resource availability, consistent with the term of CDPH's grant from the CDC, which on information and belief will expire on July 31, 2029. The terms of the CDPH Subaward are memorialized in communications between CDPH and Sagebrush, copies of which Sagebrush provided to HRSA. CDPH acknowledged and approved all the clinic sites where Sagebrush has administered the tests.

F. Sagebrush's Participation in the 340B Program

30. To ensure effective implementation of its Subawards, Sagebrush developed a comprehensive sexual health care services program (the "Program"). A key component of the Program is care collaboration with medical specialists (the "Providers"), including oncology and rheumatology providers, for example, many of whom treat patients who are immunocompromised or otherwise may be at increased risk of contracting STIs (the "Patients"). These care collaboration models involve the integration of STI education, screening, testing, and treatment services with the medical services in which the Providers specialize. With support from Sagebrush, the Providers carry out programmatic functions and STI-related services within the scope of the Subawards ("Subaward Services") for Patients at the Providers' respective outpatient clinics (the "Sites"). At Nevada Sites, the Subaward Services include sexual health screening and distribution of STI education materials and condoms. At Connecticut Sites, the Subaward Services include sexual health screening and administration of HIV and hepatitis C tests.

31. Sagebrush separately registered multiple Sites as Sagebrush's "subdivisions" or "child sites" in OPAIS, including those Sites listed in the NHHS Notice of Subaward and those sites where Providers administer CDPH-purchased HIV and hepatitis C tests. OPA reviewed and

approved the Sites and issued a unique 340B identification number for each one. With respect to such Sites, Sagebrush purchased 340B drugs that were administered or prescribed to Patients at the Sites.

32. From time to time, Sagebrush has removed from OPAIS Sites where Subaward activities have ceased.

33. Sagebrush's Program is contingent on the availability of financial resources derived from Sagebrush's participation in the 340B Program. The drug discount savings fund many of the Program's activities and other community benefit programs, including STI screening and treatment services that are not directly funded under the Subawards.

G. The Instant Litigation

34. By letter dated February 2, 2024, HRSA notified Sagebrush that the agency was "conducting a review" of fifty-three Sagebrush Sites listed in OPAIS for "compliance with 340B Program requirements with a focus on the site's receipt of grant funding from the Centers for Disease Control and Prevention (CDC), and determinations of patient eligibility." The letter contained eleven inquiries and document requests for which HRSA requested responses by Saturday, March 2, 2024 (subsequently extended to Monday, March 4, 2024).

35. On March 4, 2024, Ms. Dybik, acting as Sagebrush's 340B Program authorizing official, responded to HRSA's requests by letter. The letter included 8,135 pages of responsive documents.

36. On July 3, 2024, HRSA sent a letter to Sagebrush requesting Sagebrush's response to eight additional questions and document requests. Sagebrush responded by letter dated August 2, 2024, and attached ten responsive documents.

37. On September 19, 2024, HRSA sent a letter to Sagebrush asserting that three Sagebrush Sites were not "currently eligible to participate in the 340B Program as an STD covered entity under Section 340B(a)(4)(K) of the PHSA" because the CDPH Subaward allegedly expired on July 31, 2024. HRSA claimed that it "will terminate these sites from the 340B Program on September 27, 2024, if Sagebrush is unable to demonstrate its current eligibility, including the submission of documentation to show compliance."

38. Sagebrush responded by letter on September 25, 2024, enclosing communications from CDPH demonstrating that CDPH continued the CDPH Subaward past July 31, 2024, and that the three Sites at issue remained eligible to participate in the 340B Program.

39. On December 20, 2024, HRSA sent a letter to Sagebrush stating that HRSA determined that fifty-five sites that were currently or previously registered in OPAIS "have not been eligible to participate in the 340B Program as STD covered entities under Section 340B(a)(4)(K) of the PHSA." Notwithstanding that OPA had previously reviewed and approved the OPAIS registration information for each of the Sites and had issued individual 340B identification numbers, HRSA concluded that the Sites "failed to comply with this statutory eligibility requirement and failed to provide documentation to demonstrate receipt of Section 318 funding or support"

40. Based on this determination, HRSA demanded that Sagebrush terminate twenty Sites active in OPAIS by December 27, 2024. Should Sagebrush fail to comply, HRSA would terminate the twenty Sites by December 30, 2024.

41. The effect of HRSA’s determination is that Sagebrush must repay all savings that it realized from the allegedly ineligible Sites’ participation in the 340B Program. This amount totals tens of millions of dollars, repayment of which would force Sagebrush to cease all operations.

42. HRSA further demanded that Sagebrush “provide a statement that Sagebrush has determined the full scope of non-compliance and worked with affected manufacturers regarding repayment.” Only after Sagebrush “is able to demonstrate that it determined the full scope of non-compliance, repaid affected manufacturers, can demonstrate that it meets the covered entity eligibility requirements set forth in Section 340B(a)(4) of the PHSA, and meets all other 340B Program requirements” would HRSA allow Sagebrush to re-register the sites.

43. Sagebrush responded on the same day, emphasizing its disagreement with HRSA’s determination and requesting that HRSA withdraw its demand that Sagebrush terminate the twenty Sites from the 340B Program. Sagebrush included documents showing the current status of the Subawards and requested that HRSA grant Sagebrush an additional thirty days to demonstrate the 340B eligibility of the Sites.

44. Separately, Sagebrush’s legal counsel emailed HRSA on December 20, 2024, to request that HRSA extend its deadline to terminate the Sites to January 31, 2025.

45. Later, on December 20, 2024, HRSA emailed Sagebrush and stated that HRSA would agree to “pause the date that we requested Sagebrush terminate its sites in our letter dated Dec. 20, 2024, until we have had chance to review this information.”

46. On January 9, 2025, Sagebrush’s legal counsel sent HRSA a letter expressing concern that HRSA’s findings, as stated in its December 20, 2024, letter were

“not in compliance with HRSA’s own policies and procedures as stated in its Program Integrity Materials (the “Policy”).” Thus, it was unclear if HRSA’s letter “triggers the dispute resolution process as provided in the Policy,” including the potential submission of a CAP for HRSA’s approval.

47. On January 13, 2025, HRSA notified Sagebrush that it had reviewed the additional materials that Sagebrush provided on December 20, 2024, and reiterated its determination that each of the Sites identified in HRSA’s December 20, 2024, letter be terminated. According to HRSA, the additional materials failed to show Sagebrush’s receipt of Section 318 funding. HRSA also determined that “there are a number of other deficiencies in much of the documentation, such as, not being specific to the sites being terminated and not being specific to the time periods covered.” For these reasons, the letter stated that HRSA would terminate the Sites by close of business on January 13, 2025.

48. HRSA’s determination that the fifty-five Sites referenced in its December 20, 2024, letter are ineligible to participate in the 340B Program has immediate, severe, and permanent adverse consequences for Sagebrush. It effectively puts Sagebrush out of business because Sagebrush is unable to repay applicable manufacturers the millions of dollars in 340B discounts that it received on those manufacturers’ drugs. Further, the termination of the twenty actively registered Sites precludes Sagebrush from purchasing 340B drugs for Patients at those Sites and realizing future 340B savings. As a result, the Program will abruptly cease, along with the Subaward Services to Patients, impairing Patients’ access to health care services, including pre-exposure prophylaxis and post-exposure prophylaxis treatment that Sagebrush provides to Patients to prevent HIV infection, and Sagebrush’s ability to fulfill its Subaward obligations.

COUNT 1 – Violation of 5 U.S.C. § 706(2)(C)

(Exceeding Statutory Authority)

49. 49 Plaintiff repeats and realleges the factual allegations of the preceding paragraphs as if fully set forth herein.

50. Defendants' decision to terminate Sagebrush's Sites from the 340B Program and its determination that the Sites referenced in HRSA's December 20, 2024, letter are ineligible to participate in the 340B Program are final agency actions made reviewable by 5 U.S.C. § 706(2).

51. Sagebrush is adversely affected by Defendants' actions.

52. Defendants' decision to terminate Sagebrush's Sites from the 340B Program and its determination that the Sites referenced in HRSA's December 20, 2024, letter are ineligible to participate in the 340B Program, which Defendants made without affording Sagebrush the notice and hearing required under 42 U.S.C. § 256b(a)(5)(D), constituted activity in excess of Defendants' authority and in violation of 5 U.S.C. § 706(2)(C).

53. Sagebrush has suffered and will continue to suffer irreparable harm, including, without limitation, repayment liability in the millions of dollars, as a result of Defendants' violations of 5 U.S.C. § 706(2)(C).

54. Sagebrush is entitled to injunctive and declaratory relief to remedy Defendants' unlawful conduct, as well as all other relief as set forth in its Prayer for Relief. *See* 5 U.S.C. § 705.

COUNT 2– Violation of 5 U.S.C. § 706(2)(D)

(Failure to Observe Procedure Required by Law)

55. Plaintiff repeats and realleges the factual allegations of the preceding paragraphs as if fully set forth herein.

56. Defendants’ decision to terminate Sagebrush’s Sites from the 340B Program and its determination that the Sites referenced in HRSA’s December 20, 2024, letter are ineligible to participate in the 340B Program are final agency actions made reviewable by 5 U.S.C. § 706(2).

57. Sagebrush is adversely affected by Defendants’ actions.

58. Defendants’ decision to terminate Sagebrush’s Sites from the 340B Program and its determination that the Sites referenced in HRSA’s December 20, 2024, letter are ineligible to participate in the 340B Program, which Defendants made without affording Sagebrush the notice and hearing required under 42 U.S.C. § 256b(a)(5)(D), and provided for by HRSA’s own procedures, published on its own website, are violations of 5 U.S.C. § 706(2)(D).

59. Sagebrush has suffered and will continue to suffer irreparable harm, including, without limitation, repayment liability in the millions of dollars, as a result of Defendants’ violations of 5 U.S.C. § 706(2)(D).

60. Sagebrush is entitled to injunctive and declaratory relief to remedy Defendants’ unlawful conduct, as well as all other relief as set forth in its Prayer for Relief. *See* 5 U.S.C. § 705.

COUNT 3 – Violation of 5 U.S.C. § 706(2)(A)

(Revocation of Site Status Absent Reasonable Explanation)

61. Plaintiff repeats and realleges the factual allegations of the preceding paragraphs as if fully set forth herein.

62. Defendants' decision to terminate Sagebrush's Sites from the 340B Program and its determination that the Sites referenced in HRSA's December 20, 2024, letter are ineligible to participate in the 340B Program are final agency actions made reviewable by 5 U.S.C. § 706(2).

63. Sagebrush is adversely affected by Defendants' actions.

64. Defendants' decision to terminate Sagebrush's Sites from the 340B Program and its determination that the Sites referenced in HRSA's December 20, 2024, letter are ineligible to participate in the 340B Program, which Defendants made without affording Sagebrush the notice and hearing required under 42 U.S.C. § 256b(a)(5)(D), and provided for by HRSA's own procedures, published on its own website, is a violation of 5 U.S.C. § 706(2)(A).

65. Defendants failed to engage in reasoned decision-making; to reasonably (or at all) explain their departure from HRSA's own procedures; or to provide an adequate and reasonable explanation for their actions.

66. Defendants' actions fly in the face of the plain and unambiguous text of HRSA's own procedures and undermine the policy and purpose of those procedures to guarantee due process to covered entities participating in the 340B Program.

67. Sagebrush has suffered and will continue to suffer irreparable harm, including, without limitation, repayment liability in the millions of dollars, as a result of Defendants' violations of 5 U.S.C. § 706(2)(A).

68. Sagebrush is entitled to injunctive and declaratory relief to remedy Defendants' unlawful conduct, as well as all other relief as set forth in its Prayer for Relief. See 5 U.S.C. § 705.

COUNT 4 – Violation of Due Process
(Violation of Sagebrush’s Due Process Rights)

69. Plaintiff repeats and realleges the factual allegations of the preceding paragraphs as if fully set forth herein.

70. Plaintiff further alleges that Defendants’ actions resulted in the deprivation of Plaintiff’s constitutional rights.

71. Sagebrush’s enrollment in the 340B Program constitutes a highly valuable property right. By depriving Sagebrush of this right in an arbitrary and capricious matter, and without all of the requisite notices and hearings as discussed above, Defendants have wrongfully infringed Sagebrush’s right to due process of law, as guaranteed by the Fifth Amendment to the United States Constitution.

72. Sagebrush is entitled to injunctive and declaratory relief to remedy Defendants’ unlawful conduct, as well as all other relief as set forth in its Prayer for Relief. *See* 5 U.S.C. § 705.

WHEREFORE, Sagebrush prays that this Court enjoin Defendants and remand this matter to HRSA for further consideration. Additionally, Sagebrush requests the Court to:

a. Award Plaintiff emergency, preliminary, and permanent injunctive relief preventing implementation of the wrongful, arbitrary, and capricious administrative actions subject to this complaint;

b. Declare that:

- Defendants’ termination of Sagebrush’s Sites from the 340B Program and its determination that the Sites referenced in HRSA’s December 20, 2024, letter are ineligible to participate in the 340B Program, which Defendants made without affording Sagebrush proper

notice and hearing, are in excess of Defendants' statutory jurisdiction and authority, and in violation of 5 U.S.C. § 706(2)(C);

- Defendants' termination of Sagebrush's Sites from the 340B Program and its determination that the Sites referenced in HRSA's December 20, 2024, letter are ineligible to participate in the 340B Program, which Defendants made without affording Sagebrush proper notice and hearing, directly conflict with 42 U.S.C. § 256b(a)(5)(D) and HRSA's published procedures in violation of 5 U.S.C. § 706(2)(D);

- Defendants' termination of Sagebrush's Sites from the 340B Program and its determination that the Sites referenced in HRSA's December 20, 2024, letter are ineligible to participate in the 340B Program, which Defendants made without affording Sagebrush proper notice and hearing, directly conflict with 42 U.S.C. § 256b(a)(5)(D) and HRSA's published procedures and are arbitrary and capricious in violation of 5 U.S.C. § 706(2)(A); and

- Defendants' termination of Sagebrush's Sites from the 340B Program and its determination that the Sites referenced in HRSA's December 20, 2024, letter are ineligible to participate in the 340B Program, which Defendants made without affording Sagebrush proper notice and hearing, violate Sagebrush's right to due process under the Fifth Amendment to the United States Constitution;

c. Award Sagebrush its reasonable attorney's fees and costs, as permitted by law; and

d. Grant such other further relief as this Court deems just, equitable, and proper.

January 16, 2025

SAGEBRUSH HEALTH SERVICES

/s/ James H. Hulme

James H. Hulme (Bar No. 323014)

Douglas A. Grimm (Bar No. 495805)

ArentFox Schiff LLP

1717 K Street, NW

Washington, DC 20006-5344

Ph: 202.857.6000

Fax: 202.857.6395

james.hulme@afslaw.com

douglas.grimm@afslaw.com

Counsel for Plaintiff Sagebrush Health Services