

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

HERITAGE HEALTH AND HOUSING, INC., and
EHS, INC. d/b/a EVERGREEN HEALTH,

Plaintiffs,

-against-

**AMENDED
COMPLAINT**

NEW YORK STATE DEPARTMENT OF HEALTH and
JAMES V. McDONALD, M.D., M.P.H., in his capacity
as the Acting Commissioner of Health,

Defendants.

Index No.: 651441/2023

Plaintiffs Heritage Health and Housing, Inc., and EHS, Inc. d/b/a Evergreen Health, by and through their attorneys, O'Connell & Aronowitz, P.C., as and for their Amended Complaint against Defendants, respectfully allege as follows:

PARTIES

1. Plaintiff Heritage Health and Housing, Inc. ("Heritage"), is a domestic not-for-profit corporation with a principal place of business located at 416 W. 127th Street, New York, New York.
2. Formerly known as the Washington Heights-West Harlem-Inwood Mental Health Council, Inc., Heritage traces its origins to the 1967 assembly of a group of community activists who were concerned about the lack of medical care and mental health services in the Central Harlem, Washington Heights and Inwood neighborhoods of New York City.
3. Today, Heritage is a not-for-profit corporation that, among other things, operates Heritage HealthCare Center, a federally qualified health center ("FQHC") located in Harlem, a distressed area that was the epicenter of the COVID pandemic. The FQHC has a mission to provide innovative, high-quality and comprehensive health care, dental and psychosocial services to medically underserved communities in New York City. Services at the HealthCare Center include Internal Medicine, Family Medicine, Pediatrics, HIV/AIDS, Gastroenterology (including treatment of liver disease and ulcerative

colitis), Dental, Podiatry, Cardiology (including Cardiovascular Risk Reduction and Diabetes testing and treatment), Behavioral Health Services (including Psychiatry and Psychotherapy), and a school-based Health Center.

4. Of the Heritage patients who reported their race upon intake, 40% identified as being Hispanic, while another 33.5% identified as being Black. Approximately 300 individuals out of its total patient population of 5500 persons receive treatment for HIV/AIDS.

5. Fifty-seven percent of Heritage's patient population is eligible to receive medical assistance ("Medicaid").

6. Eighteen percent of Heritage's patients are on Medicare, while another 10% of the persons who treat at Heritage are uninsured.

7. Plaintiff EHS, Inc. d/b/a Evergreen Health ("Evergreen") is a domestic not-for-profit corporation with a principal place of business located at 206 South Elmwood Avenue, Buffalo, New York.

8. Evergreen was originally founded by a group of volunteers in 1983 as Buffalo AIDS Task Force, Inc., to address the HIV and AIDS crisis in Western New York. As breakthroughs in medical therapy were made for HIV and other sexually transmitted infections/diseases, the organization expanded its range of services beyond HIV care to meet the needs of the communities that it serves.

9. Evergreen is an organization with over 500 employees, 6 service locations in two counties, 10 buildings and approximately 24,000 patients. Its roots are in serving those who were rejected by the health care system during the AIDS crisis, and it continues to prioritize caring for the health and wellness of underserved communities. Its stated mission is to foster healthy communities by providing medical, supportive and behavioral services to individuals and families in Western New York and in the Southern Tier of New York – especially those in marginalized populations and/or challenged by chronic or life-threatening diseases and disabilities, including HIV/AIDS.

10. Today, Evergreen and its affiliates, Community Access Services, Inc., and the Pride Center of Western New York, Inc., operate as a comprehensive healthcare delivery system where anyone can receive unconditionally non-judgmental and affirming medical, dental, pharmacy, supportive and behavioral health services under one roof. Among the types of services that Evergreen provides are chronic illness support, HIV treatment and care, HIV prevention, LGBTQ health and transgender specialty care, sexual health care, drug user health care, treatment and pharmacy services for Hepatitis C, and healthcare for rural populations in the Southern Tier.

11. Of the Evergreen patients who reported their race upon intake, 23% identified as Black/African-American, while another 13% identified as being Hispanic. More than 50% of its patients are members of the LGBTQ+ community.

12. Approximately 54% of Evergreen's patient population is eligible for and receives Medicaid.

13. Twenty percent of Evergreen's patients are on Medicare, while another 3% of the persons who treat at Evergreen are uninsured.

14. Upon information and belief, since the United States Supreme Court decision in *Singleton v. Wulff*, 428 U.S. 106 (1976), courts have generally recognized health care providers' standing to pursue constitutional and statutory claims on behalf of their patients.

15. Pursuant to that authority, Heritage and Evergreen are acting on behalf of their patients who will be adversely impacted should Defendants implement what is described herein as "the 340B Carveout."

16. Upon information and belief, Defendant New York State Department of Health ("DOH") is a department/agency of the State of New York. DOH was established pursuant to § 200 of the New York Public Health Law ("PHL"), and it maintains principal offices at Empire Plaza, Corning Tower, Albany, New York.

17. Upon information and belief, DOH maintains a Regional Office at 90 Church Street, 13th Floor, New York, New York.

18. Upon information and belief, pursuant to PHL § 201(1)(v), DOH serves as the single state agency for Medicaid, with responsibility for supervising the State's plan for Medicaid, and for adopting regulations as may be necessary to implement that plan.

19. Upon information and belief, pursuant to PHL § 201(1)(p), DOH shall "receive and expend funds made available for public health purposes pursuant to law."

20. Upon information and belief, the stated mission of DOH is to "protect, improve and promote the health, productivity and wellbeing of all New Yorkers" (emphasis added).

21. Upon information and belief, one of the strategic priorities articulated in DOH's current departmental Strategic Plan is the need to "champion health equity." Through its Office of Minority Health & Health Disparities Prevention, Office of Public Health, and Office of Quality and Patient Safety, DOH asserts that it will meet this strategic priority by "[i]dentify[ing] and mitigat[ing] instances where socioeconomic factors impact health and health care quality."

22. Upon information and belief, in 2022, DOH submitted to the federal Centers for Medicaid and Medicare Services ("CMS") a Medicaid waiver proposal entitled "Strategic Health Equity Reform Payment Arrangements: Making Targeted, Evidence-Based Investments to Address the Health Disparities Exacerbated by the COVID-19 Pandemic." DOH stated that it sought the Medicaid waiver to "lay the groundwork for reducing long standing racial, disability-related, and socioeconomic health disparities, increase health equity through measurable improvement of clinical quality and outcomes, and keep the overall Medicaid program expenditures neutral to the federal government."

23. Upon information and belief, DOH's Medicaid waiver proposal was purportedly structured to advance health equity, with the agency's focus on the following subsidiary goals:

(a) building a more resilient, flexible and integrated delivery system that reduces health disparities, promotes health equity, and supports the delivery of social care; (b) developing and strengthening supportive housing services and alternatives for the homeless and long-term institutional populations; and (c) redesigning and strengthening system capabilities to improve quality, advance health equity, and address workforce shortages.

24. Upon information and belief, on or about January 1, 2023, Defendant James V. McDonald, M.D., M.P.H., was appointed Acting Commissioner of Health, and he presently serves in that official capacity.

25. This lawsuit has been commenced because DOH's laudable but ultimately empty words are belied by its racist, discriminatory actions. While DOH pays lip service to and articulates politically correct goals such as reducing health disparities, especially among underserved communities including communities of color, through the planned conduct underlying this lawsuit, DOH will intentionally enhance those disparities. As discussed more fully herein, by pressing forward with an illegal and discriminatory plan that will radically alter how the Medicaid pharmacy benefit in New York operates, DOH will wreak immeasurable harm upon New York's safety-net health care providers and the largely low-income persons dependent upon those providers for their health care and medications. Heritage and Evergreen respectfully request that this Court declare that plan, known as the 340B Carveout, illegal and permanently enjoin Defendants from implementing it.

RELEVANT FACTS

DOH Is the Single State Agency
Responsible For Administering the
Medicaid Program Within New York State:

26. Upon information and belief, created in 1965, the federal medical assistance (“Medicaid”) program is a joint federal-state program for furnishing and financing health care and services to vulnerable and at-risk Americans.

27. Upon information and belief, Medicaid’s stated purpose is:

[E]nabling each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care. . . .

42 U.S.C. § 1396.

28. Upon information and belief, every state must designate a single state agency responsible for establishing, and complying with, a state Medicaid plan. *See* 42 U.S.C. § 1396a(a)(5). Each state Medicaid plan must be approved by the United States Department of Health and Human Services (“HHS”) and must describe the policies and methods that the state will utilize to set reimbursement rates for each type of Medicaid service provided. *See* 42 C.F.R. § 430.10 and 447.201(b).

29. Upon information and belief, when implementing its Medicaid program, each state is required to “provide such safeguards as may be necessary to assure that . . . care and services will be provided, in a manner consistent with simplicity of administration and the best interest of its recipients.” 42 U.S.C. § 1396a(a)(19).

30. Upon information and belief, DOH is the single state agency responsible for administering the Medicaid program within New York State.

The Federal 340B Program Generates
Needed Revenue for Safety-Net Providers:

31. Upon information and belief, to understand the 340B drug pricing program (“the 340B Program”) underlying this litigation, one must look back to 1990, when Congress created the Medicaid drug rebate program (“MDRP”) to lower the cost of pharmaceuticals reimbursed by state Medicaid agencies. The MDRP requires drug companies to enter into a rebate agreement with HHS as a precondition for their drugs being covered by Medicaid and Medicare Part B. Under the MDRP program, a manufacturer must pay rebates to state Medicaid programs for “covered outpatient drugs,” as defined in the statute. The rebate amount for a brand name covered outpatient drug is based on the manufacturer’s “best price” for the drug in question.

32. Upon information and belief, in 1992, through Section 602 of the Veterans Health Care Act, Congress created the 340B Program. *See* 42 U.S.C. § 256b *et seq.* In doing so, Congress extended to safety-net providers the same kind of relief from high drug costs that Congress provided to the Medicaid program with the MDRP.

33. Upon information and belief, the 340B Program requires drug manufacturers, as a condition of their participation in Medicaid and Medicare Part B, to enter into an agreement with HHS. Under these pharmaceutical pricing agreements (“PPAs”), the manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by “covered entities” that serve the nation’s most vulnerable patient populations. More than 700 drug manufacturers have elected to participate in the 340B Program.

34. Upon information and belief, the definition of “covered entities” includes six categories of hospitals: disproportionate share hospitals (“DSHS”), or hospitals which serve a “disproportionate” share of low-income Medicaid or Medicare patients; children’s hospitals and cancer hospitals exempt from the Medicare prospective payment system; sole community hospitals; rural referral centers; and

critical access hospitals. To be eligible to participate in the 340B Program, hospitals in each of these categories must be (a) owned or operated by a state or local government; (b) a public or non-public non-profit organization which is formally granted governmental powers by a state or local government; or (c) a private non-profit organization that has a contract with a state or local government to provide care to low-income individuals who do not qualify for Medicaid or Medicare.

35. Upon information and belief, the percentage of Medicare patients in 340B Program hospitals that identify as Black is 69 percent higher than in non-340B Program hospitals and 63 percent higher than in physician offices.

36. Upon information and belief, there are also ten categories of non-hospital entities that fall within the definition of a “covered entity.” These non-hospital covered entities include FQHCs; FQHC “look-alikes”; state-operated AIDS drug assistance programs; tribal/urban Indian health centers; Ryan White HIV/AIDS programs; and other federally funded specialized clinics (i.e., hemophilia, tuberculosis) serving low-income patients. Eligibility for these non-hospital entities to participate in the 340B Program is based on whether the facility receives federal funding.

37. Upon information and belief, once admitted into the 340B Program, covered entities are entitled to receive discounts on all eligible covered outpatient pharmaceuticals.

38. Upon information and belief, covered entities may only dispense drugs purchased with 340B Program discounts to “eligible patients.” Although there are no income- or insurance-based requirements for patient eligibility, covered entities may not dispense drugs purchased with 340B Program discounts to patients who do not receive outpatient services at the covered entity. Specifically, patients must have an established relationship with the covered entity, receive health care services from a health care professional employed by the covered entity, and receive a health care service or range of services consistent with the services for which federal funding has been provided to the entity. The definition of an “eligible patient” precludes individuals who only receive prescription drugs from the

covered entity (but no other health care services) from receiving drugs purchased with 340B Program discounts.

39. Upon information and belief, the maximum amount that a drug manufacturer can charge a covered entity for the purchase of a 340B Program covered drug is called the 340B Program “ceiling price.”

40. Upon information and belief, the 340B Program “ceiling price,” which is calculated according to a prescribed statutory formula, is lower than the amount other purchasers would pay for the drug.

41. Upon information and belief, the 340B Program discount for brand name drugs is set at 23.1 percent off the drug’s average manufacturers price (“AMP”); for generic drugs, the 340B Program discount is 13.0 percent off AMP. The discount can be larger if the “best price” that a manufacturer offers for a drug is lower than the minimum discount.

42. Upon information and belief, the 340B Program drug pricing discounts are intended to “enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. Rep. No. 102-384, pt. 2 at 12 (1992) (conf. report).

43. Upon information and belief, because of the 340B Program discounts, health care facilities are able to buy medications at a much cheaper rate and offer their patients treatments that they otherwise could not afford. Furthermore, by turning a profit when insurance companies reimburse them at full price for the pharmaceuticals purchased at the 340B Program discount price, the safety-net providers are able to generate revenues that enable them to stretch scarce federal resources and provide care for vulnerable populations.

44. Upon information and belief, safety-net providers use 340B Program savings to provide critical programs that otherwise might not be fiscally possible. These programs include but are not

limited to providing free or substantially discounted prescriptions to uninsured or low-income patients; providing “wrap-around” support services needed to address social determinants that present barriers to care; improving access to specialized care previously unavailable in underserved areas; establishing and improving neighborhood clinics; bringing mobile units to communities with no local primary care provider or pharmacy; creating multidisciplinary clinics to treat substance use and mental health disorders; offering HIV prevention and care services that cannot be billed to Medicaid or other programs; providing transportation to medical appointments; providing additional nurses for medical care; and providing medical care for children in foster care.

45. In short, the 340B Program is a well-established, long-standing mechanism created by Congress that successfully funnels money to safety-net providers to ensure that they have the necessary resources to expand uncompensated care programs and to adequately care for their patients’ health and health-related social needs.

46. Upon information and belief, 340B Program funding is vital to covered entities because of its predictability and flexibility. The 340B Program has created a reliable funding stream which is not tied to grant cycles or state budgets. Moreover, because there are few restrictions as to how it is used (so long as it is reinvested into health care related services), covered entities can direct the 340B Program revenues where they are needed most.

47. Upon information and belief, use of the 340B Program revenues also leads to better health outcomes for the patients of covered entities. For example, Ryan White clinics provide care for one-half of the nation’s population with HIV/AIDS. One study has found that HIV/AIDS patients who receive their drugs from a 340B Program provider have higher medication adherence rates than patients who do not.

48. Upon information and belief, Heritage is an FQHC and is a “covered entity” as that term is defined under the 340B Program.

49. Upon information and belief, in 2022 alone, Heritage generated approximately \$3.1 million in 340B Program revenues. As a result of those revenues, Heritage has been able to provide uncompensated care and medications to many of its most vulnerable patients.

50. Upon information and belief, FQHCs such as Heritage provide health care to 1 in 11 people in the United States.

51. Upon information and belief, Evergreen is an FQHC “look-alike” and is a “covered entity” as that term is defined under the 340B Program.

52. Upon information and belief, in 2022 alone, Evergreen generated approximately \$14 million in 340B Program revenues from the patients that it billed through Medicaid managed care. As a result of those revenues, Evergreen has been able to provide uncompensated care and medication to many of its most vulnerable patients.

53. Upon information and belief, 340B Program revenues account for an average of 11% of the budgets of primary safety-net providers across New York State, and for some clinics, that number is as high as 40%.

54. Upon information and belief, 340B Program revenues assist covered entities in New York in providing critical health care services to nearly 2.3 million New Yorkers.

55. Upon information and belief, of the 2.3 million New Yorkers who receive critical health care services from covered entities within the State, 71% are persons of color, and 89% are classified as being “low-income.”

DOH Proposes the 340B Carveout:

56. Upon information and belief, in or about 2020, during the administration of former Governor Andrew Cuomo, DOH announced a plan to change the pharmacy benefit for persons participating in the State’s Medicaid program. DOH proposed that the pharmacy benefit afforded to

New York Medicaid recipients would be carved out of the State's Medicaid managed care program, with payment for medications covered under that benefit to be reimbursed on a fee-for-service ("FFS") basis. This plan became known as "the 340B Carveout."

57. Upon information and belief, under Medicaid FFS, 340B Program providers must bill at the acquisition cost for the drug in question.

58. Upon information and belief, because 340B Program providers under the 340B Carveout would be required to bill at their acquisition cost for all drugs, the revenues that 340B Program safety-net providers had been able to generate under the Medicaid managed care model would be eliminated, as would many of the ancillary benefits that they derived from the 340B Program discounts.

If Implemented, the 340B Carveout Will Cause
Severe Disruption to New York Safety-Net Providers
and the Vulnerable Populations That They Serve:

59. Upon information and belief, if the 340B Carveout is implemented, it will all but eliminate the savings that safety-net providers have realized through the 340B Program and the revenues on which covered entities have relied to meet the health care needs of New York's sickest and poorest residents. The 340B Carveout would dramatically curtail the scope and reach of services presently available to low-income medically underserved New Yorkers; it would undermine the fiscal stability of critical front-line community providers; and it would devastate a safety-net system within New York that is vital if the State truly wishes to address longstanding health disparities.

60. Upon information and belief, if the 340B Carveout is implemented, it will lead to an estimated \$250 million loss in 340B Program revenue that has been reinvested in care and services for New York's most vulnerable populations:

- FQHCs alone stand to lose a collective \$100 million in 340B Program revenue;
- A survey of just 15 Ryan White programs and other community health centers focused on HIV prevention and care found that they would lose \$56 million annually; and

- A small subset of hospitals reported that they would lose an additional \$87 million in the first year of the 340B Carveout's implementation.

61. Upon information and belief, if the 340B Carveout is implemented, it will cause severe disruption to New York safety-net providers and the vulnerable populations that they serve. Among the havoc-wreaking impacts that the 340B Carveout will cause include the following:

- the community-based safety-net providers on whom vulnerable New Yorkers depend will collectively lose over \$250 million annually;
- safety-net providers will be forced to cut jobs and services;
- clinics in underserved communities will close, exacerbating inequities in access to care; and
- efforts to prevent the spread of HIV will be compromised, as over \$56 million will be siphoned away from the HIV prevention and treatment efforts of Ryan White HIV/AIDS programs.

62. As noted previously, in 2022 alone, Heritage generated approximately \$3.1 million in 340B Program revenues. Implementation of the 340B Carveout would be devastating to Heritage and the patients who rely upon Heritage for their health care and medications. The 340B Carveout would lead to the elimination of many programs that Heritage offers to the most needy (often uninsured) of its patients, and given the narrow margins on which Heritage operates, implementation of the 340B Carveout could hasten the closure of a facility desperately needed in Harlem.

63. Implementation of the 340B Carveout would cause Evergreen to lose \$14 million in 340B Program revenues, losses which would be devastating to Evergreen and the patients who rely upon Evergreen for their health care and medications. The 340B Carveout would lead to the elimination of many programs that Evergreen offers to the most needy of patients, and given the narrow margins on which Evergreen operates, implementation of the 340B Carveout could hasten the closure of one or more of the (six) Evergreen service locations desperately needed in the Buffalo metropolitan area or in the Southern Tier of New York.

Independent Studies Have Shown That New York
Medicaid Will Not Achieve the Savings That DOH
Expects to Realize Through the 340B Carveout:

64. Upon information and belief, DOH has attempted to justify the 340B Carveout by claiming that the plan would generate \$166 million in savings in the first year of the Carveout, shared among the federal and state governments.

65. Upon information and belief, in 2020, the Menges Group, a Virginia-based consulting firm that studies Medicaid and Medicare programs, issued a report that refuted the savings projected by DOH under the 340B Carveout. Analyzing the likely impact of the 340B Carveout, the Menges Group calculated that the State would actually lose \$154 million in the first year of the 340B Carveout and a total of \$1.5 billion over five years, in large part due to the costs arising from avoidable inpatient and emergency care. A copy of the report issued by the Menges Group is attached hereto as Exhibit A.

66. Upon information and belief, in addition, a 2022 report authored by the Wakely Consulting Group (“the Wakely Report”), a healthcare actuarial consulting firm, estimated that not only are savings from the 340B Carveout illusory but that the shift from Medicaid managed care to Medicaid FFS will actually increase annual New York State-specific Medicaid pharmacy benefit expenditures by more than \$235 million in Fiscal Year 2023. A copy of the Wakely Report is attached as Exhibit B.

67. Upon information and belief, among the Wakely Report’s key findings regarding the financial impact of the 340B Carveout were the following:

- Ingredient Costs and Dispensing Fees: While the State would generate savings from lower ingredient costs paid under the Medicaid FFS model, higher dispensing fees paid to pharmacies would result in a net 7.5% increase in total expenditures.
- Drug Utilization Differences and Rebate Revenue: Wakely anticipates an increase in costs due to a shift in utilization toward brand name drugs (and away from generic drugs). Although the State would generate additional drug rebate revenue under the 340B Carveout, this would be due to increased brand name utilization with rebate revenue unlikely to offset the higher brand name drug prices.

- Administrative Cost Estimates: Wakely concluded that the State's estimates of administrative savings are likely overstated because health plans will still need to manage a broad range of pharmacy-related administrative functions, such as benefit requests, case management and care coordination.

68. Upon information and belief, in addition to not achieving projected cost savings, moving the pharmacy benefit from managed care to FFS will result in more fragmented care for those Medicaid patients, particularly minority and underserved populations and individuals with complex health conditions who rely on having their care integrated and coordinated across the health care spectrum.

69. Upon information and belief, the reduction in safety-net providers' ability to offer needed services will lead to worsened health outcomes in the communities that they serve.

DOH Is Pressing Forward With
Implementation of the 340B Carveout:

70. Upon information and belief, the 340B Carveout was originally scheduled to take effect on May 1, 2021.

71. Upon information and belief, after New York's safety-net providers worked with community leaders and local advocacy groups to warn New York lawmakers about the serious fiscal and social burdens that the 340B Carveout would cause if implemented, in or about April 2021, as part of the 2021 budget legislation, implementation of the 340B Carveout was delayed until April 1, 2023.

72. Upon information and belief, despite the devastating impacts that the 340B Carveout, an ill-conceived relic of the Cuomo era, would inflict upon New York's safety-net providers and the persons who rely upon those providers for needed health care services, DOH is currently pressing forward with plans to implement the 340B Carveout on April 1, 2023.

73. By reason of the foregoing, this Court is presented with a justiciable controversy.

74. Neither Heritage nor Evergreen has previously made an application to any court for the relief sought herein.

**AS AND FOR A FIRST CAUSE OF ACTION
(New York Declaratory Judgment)**

75. Plaintiffs repeat and reiterate the allegations of paragraphs 1 through 74 of this Amended Complaint with the same force and effect as if each had been fully set forth herein.

76. Upon information and belief, CPLR 3001 provides that New York State Supreme Court “may render a declaratory judgment having the effect of a final judgment as to the rights and other legal relations of the parties to a justiciable controversy whether or not relief is or could be claimed. If the court declines to render such a judgment it shall state its grounds . . .”

77. Upon information and belief, Article VI, paragraph 2 of the United States Constitution, commonly known as the Supremacy Clause, provides in pertinent part, “This Constitution, and the laws of the United States which shall be made in pursuance thereof . . . shall be the supreme law of the land; and judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.”

78. Upon information and belief, the 340B Carveout will all but eliminate the savings that Congress intended safety-net providers to realize through the 340B Program and the revenues on which these covered entities have relied to meet the health needs of New York’s most vulnerable and needy residents. The 340B Carveout would result in a dramatic reduction in the scope and reach of services presently available to New Yorkers who rely upon safety-net providers for their health care and medications.

79. Upon information and belief, the 340B Carveout impinges upon and reduces the effectiveness of the federal 340B Program because it reduces the amount of money available to covered

entities to fulfill their non-profit missions and to provide extra (uncompensated) medical and other services to millions of New Yorkers, many of whom participate in the Medicaid program.

80. To the extent that Defendants' conduct impinges upon and reduces the effectiveness of the federal 340B Program, it runs afoul of federal law and should be declared illegal.

81. Upon information and belief, a permanent injunction prohibiting Defendants from implementing the 340B Carveout is necessary to avoid irreparable harm to Heritage, Evergreen and their patients.

82. Upon information and belief, a permanent injunction prohibiting Defendants from implementing the 340B Carveout is necessary to protect the broader public interest, including the 2.3 million New Yorkers who receive vital health care and medications from 340B covered entities within the State.

83. By reason of the foregoing, Plaintiffs respectfully request that this Court issue an Order declaring, pursuant to CPLR 3001, that Defendants' 340B Carveout is illegal because it constitutes an improper impingement upon the proper and intended functioning of the federal 340B Program, and permanently enjoining Defendants from implementing the 340B Carveout.

**AS AND FOR A SECOND CAUSE OF ACTION
(Discrimination in Violation of the Affordable Care Act)**

84. Plaintiffs repeat and reiterate the allegations of paragraphs 1 through 83 of this Amended Complaint with the same force and effect as if each had been fully set forth herein.

85. Upon information and belief, on or about March 23, 2010, the Patient Protection and Affordable Care Act ("ACA") was signed into law, representing the most significant regulatory overhaul and expansion of health care coverage in the United States since the 1965 enactment of Medicaid and Medicare.

86. Upon information and belief, included in the ACA was a non-discrimination provision that prohibits any federally funded or administered benefits program or activity from engaging in discrimination. More specifically, Section 1557 of the ACA provides that “an individual shall not ... be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contents of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).” 42 U.S.C. § 18116(a).

87. Upon information and belief, Section 1557 of the ACA prohibits discrimination in health care on the grounds set forth in four pre-existing civil rights statutes: Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d *et seq.*) (race, color or national origin); Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 *et seq.*) (sex/gender), the Age Discrimination Act of 1975 (42 U.S.C. § 6101 *et seq.*) (age), and the Rehabilitation Act of 1974 (29 U.S.C. § 794) (disability).

88. Upon information and belief, the New York Medicaid program administered by DOH is a “health program or activity” which is “receiving federal financial assistance” and, therefore, is subject to Section 1557’s non-discrimination provision.

89. Upon information and belief, because each of the four civil rights statutes referenced in Section 1557 provides for a private right of action, federal courts have held that Section 1557 allows aggrieved persons to bring a private right of action for damages and attorneys’ fees.

90. Upon information and belief, HHS’s Office of Civil Rights (“OCR”) has interpreted Section 1557 “as authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation.” 81 Fed. Reg. 31440 (2016).

91. Upon information and belief, DOH’s planned implementation of the 340B Carveout will significantly, adversely and disproportionately impact New York Medicaid recipients, including

Heritage and Evergreen patients that participate in Medicaid, on the basis of their race, color and/or national origin.

92. By reason of the foregoing, Defendants' discriminatory action will disproportionately deny Heritage and Evergreen patients of the full and equal enjoyment of the benefits, services, facilities, privileges and advantages available under the federal-state Medicaid and federal 340B Programs on the basis of their race, color and/or national origin.

93. By reason of the disproportionately minority composition of their patient populations, Defendants' discriminatory action will deny Heritage and Evergreen of the full and equal enjoyment of the benefits, services, facilities and advantages available under the federal-state Medicaid and federal 340B Programs on the basis of race, color and/or national origin.

94. Upon information and belief, those individuals diagnosed with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), whether symptomatic or asymptomatic, suffer from a "disability" as that term is defined in the Rehabilitation Act.

95. Upon information and belief, in light of the Supreme Court's decision in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), federal discrimination laws that prohibit discrimination because of sex or gender include discrimination against members of the LGBTQ+ community.

96. Upon information and belief, DOH's planned implementation of the 340B Carveout will significantly, adversely and disproportionality impact members of the LGBTQ+ community and New York Medicaid recipients with HIV/AIDS, including Heritage and Evergreen patients that participate in Medicaid, on the basis of sex and/or disability.

97. By reason of the foregoing, Defendants' discriminatory action will disproportionately deny Heritage and Evergreen patients of the full and equal enjoyment of the benefits, services, facilities, privileges and advantages under the federal-state Medicaid and federal 340B Programs on the basis of sex and/or disability.

98. By reason of the foregoing, Defendants' discriminatory action will deny Heritage and Evergreen of the full and equal enjoyment of the benefits, services, facilities and advantages under the federal-state Medicaid and federal 340B Program on the basis of sex and/or disability.

99. Upon information and belief, Defendants DOH and McDonald knew or should have known that the 340B Carveout would disproportionately impact persons of color, members of the LGBTQ+ community, and persons with HIV/AIDS, including the Heritage and Evergreen patients described herein.

100. Upon information and belief, Defendants DOH and McDonald knew or should have known that the 340B Carveout would disproportionately impact 340B Program providers such as Heritage and Evergreen who provide needed care to New York's communities of color, members of the LGBTQ+ community and persons with HIV/AIDS.

101. By reason of the foregoing, the discriminatory conduct of Defendants DOH and McDonald, in violation of the ACA, is intentional and willful.

102. By reason of the foregoing, Plaintiffs request that the Court issue an Order declaring that Defendants' 340B Carveout violates Section 1557 of the ACA by discriminating against Plaintiffs, their patients, and all similarly situated persons or providers due to sex, disability, race, color and/or national origin, and permanently enjoining Defendants from implementing the 340B Carveout.

AS AND FOR A THIRD CAUSE OF ACTION
(Equal Protection Clause of the United States Constitution)

103. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 102 of this Amended Complaint as if each had been fully set forth herein.

104. The Fourteenth Amendment to the United States Constitution provides:

No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any

person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

105. Upon information and belief, Heritage is a covered entity that participates in the federal-state Medicaid program.

106. Upon information and belief, Evergreen is a covered entity that participates in the federal-state Medicaid program

107. Upon information and belief, Heritage is a covered entity that also participates in the 340B Program and enjoys the benefits, services, privileges and advantages afforded to participants in that federal program.

108. Upon information and belief, Evergreen is a covered entity that also participates in the 340B Program and enjoys the benefits, services, privileges and advantages afforded to participants in that federal program.

109. Upon information and belief, if Defendants' 340B Carveout is implemented, Heritage, Evergreen and other safety-net providers in New York State will be deprived of the revenues that they had been able to generate under the 340B Program, while similarly-situated covered entities in other states will continue to be able to generate 340B Program revenues.

110. Upon information and belief, if Defendants' 340B Carveout is implemented, Heritage, Evergreen and other safety-net providers in New York State will be unable to offer to their patients the ancillary benefits derived from the 340B Program discounts, while similarly-situated covered entities in other states will continue to be able to offer such benefits to their patients.

111. Upon information and belief, if Defendants' 340B Carveout is implemented, patients of Heritage and Evergreen will be deprived of the full enjoyment of the benefits, services, facilities, privileges and advantages available under the federal-state Medicaid and federal 340B Programs.

112. Upon information and belief, if Defendants' 340B Carveout is implemented, patients of Heritage and Evergreen will be deprived of the full enjoyment of the benefits, services, facilities,

privileges and advantages available under the federal-state Medicaid and federal 340B Programs, while similarly-situated persons in other states will not be so adversely impacted.

113. Upon information and belief, DOH has attempted to justify the 340B Carveout by claiming that the plan would generate significant savings which would be shared among the federal and state governments.

114. Upon information and belief, the reports issued by the Menges Group and the Wakely Consulting Group (referenced above) collectively illustrate that not only are the desired savings from the 340B Carveout illusory but that the shift from Medicaid managed care to Medicaid FFS will actually increase annual New York State-specific Medicaid pharmacy benefit expenditures.

115. By reason of the foregoing, Defendants' decision to implement a program that will cause Heritage, Evergreen and their patients to be treated differently from similarly-situated persons in other states is not rationally related to a legitimate governmental purpose.

116. By reason of the foregoing, if Defendants' 340B Carveout is implemented, Defendants will violate the rights of Heritage, Evergreen and their patients under the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

117. By reason of the foregoing, Plaintiffs request that the Court issue an Order declaring that Defendants' 340B Carveout violates the rights of Heritage, Evergreen and their patients under the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution, and permanently enjoining Defendants from implementing the 340B Carveout.

**AS AND FOR A FOURTH CAUSE OF ACTION
(Violation of Equal Protection and Non-Discrimination
Provisions of the New York Constitution)**

118. Plaintiffs repeat and reiterate the allegations of paragraphs 1 through 117 of this Amended Complaint with the same force and effect as if each had been fully set forth herein.

119. Upon information and belief, Article I, Section 11 of the New York State Constitution provides as follows:

No person shall be denied the equal protection of the laws of this state or any subdivision thereof. No person shall, because of race, color, creed or religion, be subjected to any discrimination in his or her civil rights by any other person or by any firm, corporation, or institution, or by the state or any agency or subdivision of the state.

120. Upon information and belief, if Defendants' 340B Carveout is implemented, Heritage, Evergreen and their patients will be deprived of their rights under the Equal Protection Clause of the New York State Constitution.

121. Upon information and belief, if Defendants' 340B Carveout is implemented, Heritage, Evergreen and their patients will suffer discrimination on the basis of sex, sexual orientation, gender identity or expression, disability, race, color or creed in violation of the protections afforded to them under the New York State Constitution.

122. By reason of the foregoing, Plaintiffs respectfully request that this Court enter an Order declaring that Defendants' 340B Carveout violates the rights of Heritage, Evergreen and their patients under the equal protection and non-discrimination provisions of Article 1, Section 11 of the New York State Constitution, and permanently enjoining Defendants from implementing the 340B Carveout.

WHEREFORE, Plaintiffs Heritage Health and Housing, Inc., and EHS, Inc. d/b/a Evergreen Health respectfully request that the Court enter a judgment in their favor and against Defendants as follows:


- (a) on the first cause of action, issuing an Order declaring that Defendants' 340B Carveout is illegal because it constitutes an improper impingement upon the proper and intended functioning of the federal 340B Program, and permanently enjoining Defendants from implementing the 340B Carveout;
- (b) on the second cause of action, issuing an Order declaring that Defendants' 340B Carveout violates Section 1557 of the ACA (42 U.S.C. § 18116), by discriminating against Heritage, Evergreen and their patients on the basis of sex, disability, race, color and/or national origin, and permanently enjoining Defendants from implementing the 340B Carveout;

- (c) on the third cause of action, issuing an Order declaring that Defendants' 340B Carveout violates the rights of Heritage, Evergreen and their patients under the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution, and permanently enjoining Defendants from implementing the 340B Carveout;
- (d) on the fourth cause of action, issuing an Order declaring that Defendants' 340B Carveout violates the rights of Heritage, Evergreen and their patients under the equal protection and non-discrimination provisions of Article 1, Section 11 of the New York State Constitution, and permanently enjoining Defendants from implementing the 340B Carveout;
- (e) awarding to Plaintiffs their reasonable attorneys' fees and costs, as permitted by law; and
- (f) awarding to Plaintiffs such other and further relief as the Court may deem just and proper.

DATED: March 24, 2023
Albany, New York

O'CONNELL & ARONOWITZ, P.C.

By:



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