State of New York
Supreme Court – County of New York

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

Plaintiffs,

-against-

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' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY INJUNCTION

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PRELIMINARY STATEMENT

The parties are before the Court as a result of a health care emergency created solely by Defendants' inept planning.

Since the COVID-19 pandemic struck the State of New York and the nation, health care leaders have consistently articulated the goal of health equity and stressed the need to reduce disparities in the health care system. The federal 340B drug program ("the 340B Program") underlying this lawsuit is precisely the sort of program that accomplishes those goals. Under the 340B Program, drug manufacturers, as a condition of their participation in Medicaid and Medicare Part B, are required to enter into agreements with the federal Department of Health and Human Services ("HHS") by which they agree to provide front-end discounts to covered outpatient drugs purchased by safety-net providers called "covered entities." The discounts made available to the safety-net providers were specifically intended to enable them to stretch scarce federal resources.

Since its enactment in 1992, the 340B Program has successfully directed money to safety-net providers to ensure that they have the necessary resources to provide and expand uncompensated and under-compensated care programs and to adequately care for their vulnerable patient populations' health and health-related social needs. The 340B Program accomplishes this by allowing covered entities such as Plaintiffs Heritage Health and Housing, Inc. ("Heritage"), and EHS, Inc. d/b/a Evergreen Health ("Evergreen"), to buy covered outpatient drugs at a discounted price, to be reimbursed by insurance companies at standard rates, and then offer their patients treatments that they could not otherwise afford. The safety-net providers generate revenues that enable them to provide critical health care and medications for nearly 2.3 million low-income New Yorkers who are overwhelmingly members of underserved communities.

In 2020, Defendant New York State Department of Health ("DOH") proposed to implement a controversial transition of the pharmacy benefit for New York Medicaid recipients

from a Medicaid managed care model to a Fee-for-Service ("FFS") model ("the Pharmacy Transition"). Notwithstanding the 340B Program's nearly three decades of success, the Pharmacy Transition effectively eliminates the 340B Program revenues on which 340B covered entities and their vulnerable patient populations have come to rely. DOH has never disputed this fact.

Acting at the behest of New York's safety-net providers, at the "eleventh hour" for budget purposes (on March 31, 2021), the State legislature delayed implementation of the Pharmacy Transition for two years. DOH could now implement the Pharmacy Transition no sooner than April 1, 2023, and before doing so, the agency was directed to both address the 340B covered entities' concerns about lost 340B revenues and only proceed with implementation when it is satisfied that "all necessary and appropriate transition planning has occurred." *See* Chapter 56, Laws of 2020, Part FFF.

However, over the next two years, DOH disbanded a 340B Advisory Board whose purpose was to address the providers' anxieties, without meeting that board's statutory mandate. DOH has neither announced nor timely submitted for approval any detailed plan that would replace for 340B covered entities the lost 340B Program revenues eliminated by the Pharmacy Transition. Indeed, one draft ("reinvestment") plan that DOH did float two weeks before implementation of the Pharmacy Transition stunningly failed to include Heritage and approximately one dozen other federally qualified health centers ("FQHCs").

However, DOH's most egregious act has been its consistent efforts to quell the fears and opposition of the State's 340B covered entities to the Pharmacy Transition. DOH has repeatedly told these safety-net providers that, when the Pharmacy Transition is implemented, their funding concerns would be addressed and at no time would they be placed in a position of having to consider staff cuts or reductions in programs. Relying to their detriment on DOH's misrepresentations, many of New York's 340B providers held their proverbial fire despite

mounting evidence that DOH was failing to properly plan for the Pharmacy Transition. DOH then parlayed the dishonestly procured silence of some of its would-be critics to secure the right to implement the Pharmacy Transition on April 1, 2023, the first day allowable under state law. In its zeal to achieve that end, DOH knowingly and fraudulently misrepresented to this Court the true level of opposition to the Pharmacy Transition and how badly it had prepared for the effects the Pharmacy Transition would have on the State's safety-net providers.

While DOH articulates politically correct goals such as reducing health disparities, especially among underserved communities, absent immediate relief for 340B covered entities impacted by the Pharmacy Transition, DOH's program choices will actually enhance those disparities and tear to shreds the health care portion of the State's social safety-net. Defendants' Pharmacy Transition results in illegal, disparate impacts upon Plaintiffs and their disproportionately minority and LGBTQ+ patient populations. Plaintiffs respectfully request that this Court enjoin implementation of that flawed plan (to prevent certain and immediate irreparable harm) for so long as Defendants fail to provide immediate relief to Plaintiffs and all similarly-situated 340B covered entities for the revenues that they previously received under the 340B Program but which were eliminated by virtue of Defendants' rushed and botched implementation of the Pharmacy Transition.

STATEMENT OF FACTS

The Parties:

Formerly known as the Washington Heights-West Harlem-Inwood Mental Health Council, Inc., Plaintiff Heritage Health and Housing, Inc., 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. (Blomberg Aff., ¶ 2.)[1] Today, Heritage operates Heritage HealthCare Center, a federally qualified health center ("FQHC") located in Harlem that 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. (Blomberg Aff., ¶ 3.) Heritage brings this lawsuit on its own behalf, as well as those Heritage patients whose receipt of health care and medications will be adversely impacted by the Pharmacy Transition.

Plaintiff EHS, Inc. d/b/a Evergreen Health 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. (Complaint, ¶¶ 7-8) (Gbadamosi Aff., ¶ 6).

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[1] References herein to "Complaint, ¶__" are to Plaintiffs' Amended Complaint. *See* Culnan Aff., Ex. A. References to "___ Aff." are to affidavits submitted in support of Plaintiffs' application for a preliminary injunction.

Today, Evergreen is a federally qualified health center look-alike organization with over 500 employees, 10 service locations in two counties, and approximately 24,000 patients. With its affiliates, Community Access Services, Inc., and the Pride Center of Western New York, Inc., Evergreen operates as a comprehensive healthcare delivery system where anyone can receive unconditionally non-judgmental and affirming medical, dental, pharmacy, supportive and behavioral health services. 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 of New York State. (Complaint, ¶¶ 9-10) (Gbadamosi Aff., ¶ 8). Evergreen also brings this lawsuit on its own behalf, as well as those Evergreen patients whose receipt of health care and medications will be adversely impacted by the Pharmacy Transition.

Defendant New York State Department of Health is an agency of the State of New York. DOH serves as the single state agency for medical assistance ("Medicaid"), with responsibility for supervising the State's plan for Medicaid. (Complaint, ¶ 11.)

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. (Complaint, ¶ 17.)

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

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." (Blomberg Aff., ¶ 7.)

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. The 340B Program requires, as a condition of a drug manufacturer's 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"[2] that serve the nation's most vulnerable patient populations. More than 700 drug manufacturers have elected to participate in the 340B Program. (Blomberg Aff., ¶¶ 8-9.)

Once admitted into the 340B Program, covered entities are entitled to receive discounts on all eligible covered outpatient pharmaceuticals. However, they 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. This precludes individuals who only receive prescription drugs from the

[2] 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. (Blomberg Aff., ¶ 10.) There are also ten categories of non-hospital entities that fall within the definition of a "covered entity," including but not limited to 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. (Blomberg Aff., ¶ 11.)

covered entity (but no other health care services) from receiving drugs purchased with 340B Program discounts. (Blomberg Aff., ¶ 12.)

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." 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. (Blomberg Aff., ¶ 13.) 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). The 340B Program discounts allow health care facilities to buy medications at a discounted price, get reimbursed by insurance companies at standard rates, and then offer their patients treatments and medications that they otherwise could not afford. (Milano Aff., ¶ 8.)

Examples of the types of programs for which safety-net providers use 340B Program savings include 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. (Blomberg Aff., ¶ 16.)[3] *See also* Gbadamosi Aff., ¶¶ 12-17 (listing programs at Evergreen benefitted by 340B Program revenues).

Implementation of The Pharmacy Transition Proposed By DOH Is Delayed for Two Years:

In 2020, during the administration of former Governor Andrew Cuomo, DOH announced its plan to implement the Pharmacy Transition. Under Medicaid FFS, 340B Program providers must bill at the acquisition cost for the drug in question (with a dispensing fee added on). Because 340B Program safety-net providers under the Pharmacy Transition would be required to bill at their acquisition cost for all drugs, the revenues that they 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. (Blomberg Aff., ¶¶ 18-19.)

When the Pharmacy Transition became a focal point during state budget negotiations in 2021, a statewide coalition of 340B Program covered entities, including Evergreen and other FQHCs, hospitals serving low-income communities, and Ryan White services providers came together to fight the proposed change. With the help of the state legislature, they were successful in getting implementation of the Pharmacy Transition delayed for two years. The Pharmacy Transition could be executed no sooner than April 1, 2023, and not until "all necessary and appropriate transition planning has occurred." (Blomberg Aff., ¶ 20) (Kilmer Aff., ¶ 15).

As part of the delayed implementation, DOH was required to establish a 340B Advisory Group to address the concerns expressed by safety-net providers who would lose 340B Program revenues because of the Pharmacy Transition. Although the 340B Advisory Group did hold some

[3] 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 needed health-related services), covered entities can direct the 340B Program revenue to areas where it is most needed. (Blomberg Aff., ¶ 17.)

initial public meetings with concerned stakeholders, it was disbanded after Governor Cuomo's resignation in August 2021, without meeting its statutory mandate. (Blomberg Aff., ¶ 21.)

Furthermore, DOH has not announced any detailed plan that would replace the lost 340B Program revenues eliminated by virtue of the Pharmacy Transition. In fact, one draft ("reinvestment") plan that DOH did put forward remarkably failed to include Heritage and approximately one dozen other FQHCs. (Blomberg Aff., Ex. A.) And DOH has further heightened providers' anxieties by dawdling with respect to its submission to the federal Centers for Medicare and Medicaid Services ("CMS") a State Plan Amendment ("SPA") that would allow the state agency to modify the terms of its previously-approved State Medicaid Plan to address the lost 340B revenues.[4]

While DOH was failing to take these actions, its leaders were reassuring the State's 340B covered entities that they had nothing to worry about. They advised providers that they would not be placed in the position of having to consider layoffs or cuts to needed and vital programs. (Milano Aff., ¶ 16) (Kilmer Aff., ¶¶ 24-25) (Bernardo Aff., ¶ 20) (Pease Aff., ¶ 20) (Gbadamosi Aff., ¶ 29, Ex. A). However, because of DOH's incompetent planning for the Pharmacy Transition, that is precisely the position in which 340B providers will find themselves if immediate relief for the lost 340B revenues is not forthcoming.

The Present Action and Application:

Heritage and Evergreen have commenced this action on their own behalf, as well as their patients who will be harmed by the Pharmacy Transition, seeking an order declaring that it results

[4] In 2022, California implemented a similar transition of the pharmacy benefits for its Medicaid recipients from a Medicaid managed care model to a FFS model. CMS did not approve California's SPA (to create a pool of money to reimburse 340B providers for lost 340B revenues) for over ten months, and dollars did not start flowing to providers until 15 months after the SPA had been submitted to CMS. Unlike its California counterpart, not only did DOH fail to submit a SPA to CMS before implementation of the Pharmacy Transition, but to date, it has still not submitted such an application. (Culnan Aff., ¶¶ 11-12.)

in illegal, discriminatory impacts on various statutory and constitutional grounds: (1) it constitutes an improper impingement upon the proper and intended functioning of the federal 340B Program; (2) it violates the non-discrimination provision (42 U.S.C. § 18116) of the Affordable Care Act; (3) it violates the rights of Heritage, Evergreen and their patients under the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution; and (4) it violates the rights of Heritage, Evergreen and their patients under the equal protection and non-discrimination provisions of Article I, Section 11 of the New York State Constitution. *See* Complaint (Culnan Aff., Ex. A).

Plaintiffs thereafter made an application for a preliminary injunction via a proposed Order to Show Cause. Plaintiffs also included an application for a temporary restraining order ("TRO") by which they asked the Court to enjoin and restrain Defendants from implementing the Pharmacy Transition until their preliminary injunction application had been decided. *See* Docket No. 9.

On March 30, 2023, Plaintiffs' application for a TRO was considered by the Hon. Margaret Chan. Minutes before the TRO hearing, Defendants submitted papers that contained misrepresentations (most of which are addressed in the accompanying affidavits) aimed at defeating the TRO and preserving their plan to move forward with an April 1 implementation date for the Pharmacy Transition. *See* Docket No. 18 (Bassiri Aff.). Primarily finding that the balance of the equities rested with Defendants, Justice Chan denied Plaintiffs' application for a TRO. *See* Docket No. 19. Defendants thereafter proceeded to implement the Pharmacy Transition on April 1, 2023.

On April 7, 2023, the Parties entered into a Stipulation by which Plaintiffs withdrew without prejudice their initial application for a preliminary injunction. *See* Docket No. 20. The Parties agreed that, should Plaintiffs wish to bring a second application for a preliminary injunction, they shall file such application via Notice of Motion on or before April 26, 2023. It is

pursuant to that Stipulation that Plaintiffs timely bring the current application for a preliminary injunction that would enjoin Defendants from implementing a Pharmacy Transition that does not provide immediate relief for the 340B Program revenues that Plaintiffs and all similarly-situated 340B covered entities have lost, and will lose, as a result of Defendants' rushed implementation of the Pharmacy Transition.

ARGUMENT

A party seeking a preliminary injunction must demonstrate: (1) a probability of success on the merits; (2) danger of irreparable harm in the absence of an injunction; and (3) a balance of the equities in the moving party's favor. *Aetna Ins. Co. v. Capasso*, 75 N.Y.2d 860, 862 (1990); *Doe v. Axelrod*, 73 N.Y.2d 748, 750 (1988); *W. T. Grant Co. v. Srogi*, 52 N.Y.2d 496, 517 (1981).

It is respectfully submitted that, if Defendants do not afford prompt and timely relief to Plaintiffs and other similarly-situated 340B covered entities for the lost 340B revenues caused by the Pharmacy Transition, Plaintiffs and their patients will suffer immediate and irreparable harm that cannot be cured by either a "make whole" payment from Defendants or a judgment rendered by the Court a year or more from now. By then, any such resolution would be rendered ineffectual. The Court should grant Plaintiff's application for a preliminary injunction requiring Defendants to provide immediate relief to Plaintiffs and all other similarly-situated for the 340B Program revenues that were eliminated by virtue of Defendants' April 1 implementation of the Pharmacy Transition.

POINT I

HERITAGE AND EVERGREEN HAVE STANDING TO PURSUE CONSTITUTIONAL AND STATUTORY CLAIMS ON BOTH THEIR OWN BEHALF AND THAT OF THEIR PATIENTS

In *Singleton v. Wulff*, 428 U.S. 106, 108-09 (1976), the United States Supreme Court held that physicians had standing to challenge a Missouri statute that excluded from Medicaid funding all abortions except those "medically indicated." Since *Singleton*, "[c]ourts have generally recognized physicians' authority to pursue the claims of their patients." *Pennsylvania Psychiatric Soc. v. Green Spring Health Servs., Inc.*, 280 F.3d 278, 289 n.12 (3d Cir.), *cert. denied*, 537 U.S. 881 (2002) (collecting cases). In a case with facts similar to those presented here, *Innovative Health Systems, Inc. v. City of White Plains*, 117 F.3d 37 (2d Cir. 1997), the court held that the plaintiff drug and alcohol rehabilitation center that alleged it had been injured by discrimination against its disabled patients possessed standing to sue on its clients' behalf under the Americans With Disabilities Act and the Rehabilitation Act. Finding that the enforcement provisions of those statutes extended relief to "*any person* alleging discrimination on the basis of disability," the use of such broad language in the enforcement provisions evinced a Congressional intent to define standing "as broadly as is permitted by Article III of the Constitution." *Id.* at 47 (emphasis in original). *See also Kalliope R. v. New York State Department of Education*, 827 F. Supp.2d 130, 142-43 (E.D.N.Y. 2010) (school had standing to sue state agency for alleged violations under the Rehabilitation Act).[5]

Given the broad construction of the ability of aggrieved providers to assert constitutional and statutory claims of discrimination on behalf of their patients, Plaintiffs possess standing to

[5] In addition to the constitutional claims asserted in Plaintiffs' Amended Complaint, the non-discrimination provision of the Affordable Care Act, 42 U.S.C. § 18116, provides that "[n]othing in this title . . . shall be construed to invalidate the limit the rights, remedies, procedures or legal standards available to individuals aggrieved" under four civil rights statutes cited therein.

assert Equal Protection and statutory claims protecting those patients from discrimination in the provision of their health care.

POINT II

PLAINTIFFS ARE ABLE TO SHOW A LIKELIHOOD OF SUCCESS ON THE MERITS

New York courts have consistently held that where, "the denial of injunctive relief would render the final judgment ineffectual, the degree of proof required to establish the element of likelihood of success on the merits should be reduced." *State of New York v. City of New York*, 275 A.D.2d 740, 741 (2d Dept. 2000). Even where the court may have "grave doubts" regarding the likelihood of the plaintiff's success on the merits, an injunction should be granted where the moving party has demonstrated that, if a preliminary injunction is not granted, any subsequent judgment may be rendered ineffectual. *Schlosser v. United Presbyterian Home at Syosset, Inc.*, 56 A.D.2d 615 (2d Dept. 1977). *See also Valdez v. Northeast Brooklyn Housing Development Corp.*, 8 Misc.3d 1008(A), 801 N.Y.S.2d 782 (Sup. Ct., Kings Cty. 2005) ("a preliminary injunction is granted where injunctive relief will prevent the potential dissolution of an existing valuable asset or some comparable potential irreparable harm").

In the absence of immediate relief for the lost 340B revenues eliminated by the Pharmacy Transition, Plaintiffs and other 340B providers will soon have to engage in layoffs and program cuts. Plaintiffs cannot wait for a "make whole" payment from Defendants a year from now, or to receive a judgment in their favor at the conclusion of this action. Because Plaintiffs and the patients who rely upon them for needed care will suffer immediate harm that would likely render a final judgment ineffectual, it is respectfully submitted that Heritage and Evergreen can make a sufficient showing that they are entitled to a preliminary injunction.

A. Heritage and Evergreen Have Made a Proper Request For a Declaratory Judgment Because the Pharmacy Transition Impinges Upon and Reduces the Effectiveness of the Federal 340B Program.

Article VI, paragraph 2 of the United States Constitution, commonly known as the Supremacy Clause, provides: "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."

The Pharmacy Transition all but eliminates the savings that Congress intended safety-net providers to realize through the 340B Program. This is not in dispute. There will be a dramatic reduction in the scope and reach of services presently available to Medicaid recipients and other uninsured individuals who rely upon safety-net providers for their health care. In short, the Pharmacy Transition impinges upon, and reduces the effectiveness of, both the federal Medicaid and 340B Programs because it reduces the amount of money available to 340B covered entities to fulfill their non-profit missions and to provide uncompensated and under-compensated medical and other services to millions of New Yorkers. Therefore, it runs afoul of federal law and should be declared illegal.

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 . . . ." Plaintiffs have properly invoked that vehicle for relief, and this Court may render a judgment declaring the Pharmacy Transition invalid.

B. Heritage and Evergreen Have Asserted a Viable Claim That Defendants Have Violated the Non-Discrimination Provision of the ACA.

The Affordable Care Act ("ACA") contains a provision that prohibits any federally funded or administered benefits program or activity from engaging in discrimination. 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). Discrimination in health care is prohibited 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.*) (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).

Because each of the four civil rights statutes referenced in Section 1557 provide for a private right of action, this provision allows aggrieved persons to bring a private right of action for damages and attorneys' fees. *See, e.g.*, *Callum v. CVS Health Corp.*, 137 F. Supp.3d 817, 847-48 (D.S.C. 2015). Furthermore, 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). The New York Medicaid program is a "health program or activity" which is "receiving federal financial assistance" and, therefore, is subject to Section 1557's non-discrimination provision.

Implementation of the Pharmacy Transition will significantly, adversely and disproportionately impact low-income persons, including New York Medicaid recipients, on the

basis of sex, disability, race, color and/or national origin. Of the 2.3 million New Yorkers who receive critical care from 340B covered entities within the State, 71% are persons of color, and 89% are classified as being low-income. (Complaint, ¶ 55.) At Heritage, of the patients who reported their race upon intake, 40% identified as being Hispanic, and another 33.5% identified as being Black. (Milano Aff., ¶ 6.) At Evergreen, over one-third of its patient population identifies as LGBTQ+, and over 1,900 individuals receive treatment for HIV/AIDS. Furthermore, 13% of its patients identified as being Hispanic, while 23% identified as being Black. (Gbadamosi Aff., ¶¶ 9-10.)

These (disproportionately minority) demographic numbers are similar to those at the other 340B entities submitting affidavits in support of Plaintiffs' application for a preliminary injunction: at Harlem United, 71% of its clients identify as being Black, 25% identify as being Latino, and 13% identify as being members of the LGBTQ+ community (Kilmer Aff., ¶ 4); at Housing Works, 48% identify as Black, 26% are Hispanic, and 34% are members of the LGBTQ+ community, with 8% identifying as transgender, non-binary, non-conforming, or gender queer (Bernardo Aff., ¶ 7); at the Alliance of Positive Change, 52% identify as Black, 38% identify as Hispanic, and 46% identify as LGBTQ+ (Duke Aff., ¶ 6); and at the Neighborhood Health Center of WNY, 35% are Hispanic, and 22% are African-American. (Haefner Aff., ¶ 8.)

The Pharmacy Transition will have the disparate impact of denying to the 340B covered entities and their disproportionately minority patient populations 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 sex (including sexual orientation), disability, race, color and/or national origin. Consequently, Defendants have violated Section 1557 of the ACA.

C. The Pharmacy Transition Violates the Rights of Heritage and Evergreen and Their Patients Under the U.S. and New York State Constitutions.

Constitutional guaranties of equal protection are intended to keep "governmental decision makers from treating differently persons who are in all relevant aspects alike." *Nicholas v. Tucker*, 114 F.3d 17, 20 (2d Cir. 1997), *cert. denied*, 523 U.S. 1126 (1998); *Great Atlantic & Pacific Tea Co. v. Town of East Hampton*, 997 F. Supp. 340 (E.D.N.Y. 1998). Where the challenged decision is not drawn on a distinction based on a suspect classification, the decision will be upheld if rationally related to a legitimate government purpose. *Nicholas*, 114 F.3d at 20.[6]

Under the Equal Protection Clauses of the federal and state constitutions, a statute that causes disparate treatment is subject to rational basis scrutiny. *D'Amico v. Crosson*, 93 N.Y.2d 29, 31 (1999); *Gomez v. Evangelista*, 290 A.D.2d 351, 352 (1st Dept. 2002). The New York Court of Appeals has recognized that, under equal protection analysis, any classification which denies to one class of needy persons public assistance available to all others cannot be justified unless it is rationally related to a legitimate state interest. *Lee v. Smith*, 43 N.Y.2d 453, 460 (1977). *See also Matter of Aliessa v. Novello*, 96 N.Y.2d 418 (2001); *Aumick v. Bane*, 161 Misc. 2d 271 (Sup. Ct., Monroe Cty. 1994) (amendment to Social Services Law imposing certain durational requirements for receipt of Medicaid unconstitutional because it "arbitrarily den[ied] full benefits to one class of persons, which are available to all other residents").

Under the Pharmacy Transition, 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 those revenues. Similarly, their patients will be deprived of the full range of benefits

[6] The reach of the Equal Protection Clause of the New York State Constitution (Article 1, Section 11) is co-extensive with its federal counterpart (14th Amendment to the U.S. Constitution). *See Brown v. State,* 89 N.Y.2d 172 (1996); *Under 21 v. City of New York*, 65 N.Y.2d 344 (1985).

available under both Medicaid and the 340B Program, while similarly situated persons in other states would not be so adversely impacted. Defendants know this will occur but, to date, they have taken no definitive action to ameliorate the impacts of the Pharmacy Transition on the 340B covered entities.

While Defendants have tried to justify the Pharmacy Transition by contending that it will generate savings for the Medicaid program, outside studies have questioned those savings. In 2020, the Menges Group calculated that the State would actually lose $154 million in the first year of the Pharmacy Transition and a total of $1.5 billion over five years, in large part due to the costs arising from avoidable inpatient and emergency care. (Complaint, Ex. A.) Similarly, a 2022 report authored by the Wakely Consulting Group estimated that not only are savings from the Pharmacy Transition illusory but that the transition will actually increase annual New York State-specific Medicaid pharmacy benefit expenditures by more than $235 million in Fiscal Year 2023. (Complaint, Ex. B.)

For these reasons, Plaintiffs respectfully submit that there is no rational basis justifying Defendants' adverse treatment of New York's safety-net providers and the patients who rely upon them for vital health care and medications. Therefore, the Pharmacy Transition, as implemented by Defendants, violates the Equal Protection Clauses of the federal and state constitutions.

POINT III

HERITAGE, EVERGREEN AND THEIR PATIENTS WILL BE IRREPARABLY HARMED IF DEFENDANTS DO NOT PROVIDE IMMEDIATE RELIEF FOR LOST 340B REVENUES

"Irreparable injury, for purposes of equity, has been held to mean any injury for which money damages are insufficient." *McLaughlin, Piven, Vogel v. W.J. Nolan & Co.*, 114 A.D.2d 165, 174 (2d Dept.), *appeal denied*, 67 N.Y.2d 606 (1986). Stated another way, irreparable harm exists "where, but for the grant of equitable relief, there is a substantial chance that upon final resolution of the action the parties cannot be returned to the positions they previously occupied." *Brenntag Int'l Chem., Inc. v. Bank of India*, 175 F.3d 245, 249 (2d Cir. 1999).

A. Absent Immediate Relief, Heritage and Evergreen Will Be Irreparably Harmed By the Defendants' Implementation of the Pharmacy Transition.

In 2022, Heritage generated approximately $3.1 million in 340B Program revenue. If immediate relief is not forthcoming, the Pharmacy Transition will be devastating to Heritage and the patients who rely upon the FQHC for their health care. It has already led to a hiring freeze and layoffs, and it could lead to the elimination of many programs that Heritage offers to the most needy of its patients, including a school-based health program. Given the narrow margins on which Heritage operates, it could also hasten the closure of a facility desperately needed in Harlem. (Blomberg Aff., ¶¶ 27-30.)

Similarly, in 2022, Evergreen generated $14 million in 340B Program revenue from Medicaid managed care. (Gbadamosi Aff., ¶ 19.) The Pharmacy Transition has already led to staffing cuts, and absent immediate relief for lost 340B revenues, it will cause elimination of many programs that Evergreen offers to the most needy of its patients. Because Evergreen also operates under narrow margins, implementation of the Pharmacy Transition will likely hasten the closure

of one or more of the (six) Evergreen locations desperately needed in the Buffalo metropolitan area or in the Southern Tier of New York. *Id.* at ¶¶ 21-24.

Courts have consistently held that the potential loss of a plaintiff's entire business constitutes irreparable harm. *See, e.g., Vapor Technology Ass'n v. Cuomo*, 66 Misc.3d 800, 809 (Sup. Ct., Albany Cty. 2020) (preliminary injunction proper to "stave off shuttering of [petitioners'] businesses"). Similarly, when the challenged act threatens a plaintiff's very ability to continue business, irreparable injury exists. *Semmes Motors Inc. v. Ford Motor Co.*, 429 F.2d 1197, 1205 (2d Cir. 1970) ("[T]he right to continue a business in which [Plaintiff] had engaged for twenty years . . . is not measurable in monetary terms"); *Sarwari v. BP Prods. N. Am., Inc.*, 2006 WL 8417396 at *5-6 (D.N.J., Sept. 15, 2006) ("the potential loss or destruction of one's business constitutes irreparable harm" especially where the defendants "can stall and outlast these Plaintiffs"); *Reuschenberg v. Town of Huntington*, 16 A.D.3d 568, 570 (2d Dept. 2005).

Of course, the harm needed to establish irreparable harm need not rise to the level of the destruction of a business concern (although that is what could occur if Defendants do not immediately address Plaintiffs' lost 340B revenues). For example, in *Fairfield Presidential Apartments v. Pollins*, 85 A.D.2d 653 (2d Dept. 1981), the plaintiff landlord sought an injunction to restrain defendants from collecting rents from its tenants during a rent strike. The court held that, where the landlord's loss of rental income would jeopardize its ability to maintain services for the premises, it had satisfied the irreparable harm element (and the trial court erred in denying the landlord's preliminary injunction application). Similarly, because Defendants have implemented the Pharmacy Transition without providing immediate relief for lost 340B revenues, Heritage and Evergreen will no longer be able to provide numerous services needed by the vulnerable patient populations that they serve. Consequently, like the plaintiff in *Fairfield*

Presidential Apartments, Plaintiffs are able to establish that they will experience irreparable harm (failure to provide needed services).

B. Absent Immediate Relief, the Patients of Heritage and Evergreen Will Be Irreparably Harmed By the Pharmacy Transition.

In the supporting affidavit of Heritage's Chief of Medical Affairs, Danielle Milano, M.D., she summarizes the impacts that the Pharmacy Transition would have upon a representative sample of the FQHC's patients who are dependent upon the revenues that Heritage is able to generate from the 340B Program. *See* Milano Aff., ¶ 20. Without 340B Program revenues, Heritage would not be in a position to provide a whole range of expensive, needed medications to its uninsured or underinsured patients. The consequence to the patients would be adverse health effects or outcomes, such as elevated risk of stroke, increased risk of diabetes, and the increased risk of spreading disease to others. These adverse impacts clearly constitute irreparable harm to those patients. *See Innovative Health Systems, supra*, 117 F.3d at 43-44 (where physician affidavit illustrated that alcohol or drug dependent persons risk relapse or other physical harm by relocation of treatment center, irreparable harm had been shown). Similarly, absent immediate relief, Heritage will close its school-based health program (Milano Aff., ¶ 21), and the project by which its Health Center will be moved could be placed in jeopardy. (Blomberg Aff., ¶ 30.)

Fatai A. Gbadamosi, M.D., Evergreen's Chief Medical Officer, discusses the devastating impact that the Pharmacy Transition will have upon Evergreen and its patients. *See* Gbadamosi Aff., ¶¶ 15-18, 23 (specific program impacts, plus delay of plans to construct health center in East Buffalo.) And officials from the other 340B entities submitting supporting affidavits have largely stated that they can only continue "business as usual" for a few months before layoffs and/or program cuts will have to be made. *See* Pease Aff., ¶¶ 16-18; Haefner Aff., ¶ 18; Kilmer Aff., ¶¶

16-22; Duke Aff., ¶¶ 9-11; Bernardo Aff., ¶¶ 16-17. Absent immediate relief, the patients of the 340B covered entities will suffer irreparable harm.

POINT IV

A BALANCE OF THE EQUITIES CLEARLY LIES IN FAVOR OF PLAINTIFFS AND THE VULNERABLE PATIENTS WHO DEPEND UPON THEIR SERVICES

When conducting a balance of the equities in connection with an injunction application, the court compares the hardship that the moving party would face if the injunction were denied against the hardship the defendant would suffer if the injunction were granted. A balance of the equities decidedly falls in favor of Heritage and Evergreen and the low-income, primarily minority (or LGBTQ+) patient populations dependent on the care and services that they provide.

If the Pharmacy Transition is implemented without providing immediate relief to 340B covered entities for lost 340B revenues, it will lead to significant losses in 340B Program revenue that has been reinvested in care and services for New York's sickest and poorest residents and cause severe disruption to New York's safety-net providers and the vulnerable populations that they serve. It also undermines the fiscal stability of critical front-line community providers; and it will devastate a safety-net system within New York that is vital if the State truly wishes to address longstanding health disparities.

On the other hand, Defendants have repeatedly made representations to 340B providers, trade associations and lobbyists (many of whom relied on these representations to their detriment) about their alleged intention that 340B covered entities will be "made whole" for lost 340B Program revenues. Indeed, Medicaid Director Bassiri has already made a representation to that effect to this Court. *See* Bassiri Aff., ¶ 28. Unfortunately, Defendants' lack of planning (no detailed plan to address lost funding, no SPA to CMS) has created a health emergency. DOH had two years to get things right in connection with implementation of the Pharmacy Transition, but it failed miserably. As the old adage goes, "If you break it, you own it."

Through their reasonable request for immediate relief from the impacts of Defendants' Pharmacy Transition, Plaintiffs are only seeking payments that Defendants have promised they would make anyways.[7] For all these reasons, Heritage and Evergreen respectfully submit that a balancing of the equities weighs in their favor.

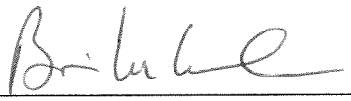
[7] In *Vapor Technology Association, supra*, the court noted that one other practical benefit of an injunction is that it might afford more time for the state legislature to take action to address the important issues raised in the litigation. 66 Misc. 3d. at 809. The same principle applies here.

CONCLUSION

For the foregoing reasons, Plaintiffs Heritage Health and Housing, Inc., and EHS, Inc. d/b/a Evergreen Health respectfully request that this Court should enter an Order granting their application for a preliminary injunction that enjoins Defendants from implementing a Pharmacy Transition that does not provide immediate relief to Plaintiffs and all similarly-situated 340B Program covered entities for the revenues that they previously received under the 340B drug discount program but which were eliminated by Plaintiffs' implementation of the Pharmacy Transition on April 1, 2023.

DATED: April 26, 2023

O'CONNELL & ARONOWITZ, P.C.

By: 

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CERTIFICATE OF WORD COUNT

Pursuant to Rule 202.8-b of the Uniform Rules for New York State Trial Courts, I certify that the foregoing Memorandum of Law contains 6,905 words, excluding the parts of the document permitted to be excluded by the Rule, and therefore, complies with the word count limit. This certificate was prepared in reliance on the word-count function of the word-processing system (Microsoft Word) used to prepare the document.

Dated: April 26, 2023

Brian M. Culnan, Esq.