IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

JANE DOE et al., Plaintiffs, v. JOSEPH A. LADAPO et al., Defendants.	Civil No. 4:23-cv-00114-RH-MAF

PLAINTIFFS' MEMORANDUM OF LAW

REQUEST FOR ARGUMENT

Pursuant to Local Rule 7.1(K), Plaintiffs respectfully request oral argument on this motion, estimating up to two hours for a non-evidentiary hearing.

MEMORANDUM OF LAW

I. Introduction

Adult Plaintiffs, Kai Pope, Lucien Hamel, Olivia Noel, and Rebecca Cruz Evia, make this motion against Defendant Joseph A. Ladapo, in his official capacity as Florida's Surgeon General and Defendant members of the Florida Board of Medicine and the Florida Board of Osteopathic Medicine in their official capacities,

and the State Attorney Defendant in the official capacity challenging the constitutionality of SB 254.

Adult Plaintiffs seek an order enjoining Defendants from enforcing the provisions of SB 254 that prevent transgender adults in Florida from obtaining established medical care because they are transgender and, therefore, because of their sex. *See* attached as Exhibit A, Proposed Preliminary Injunction Order. SB 254 violates the Adult Plaintiffs' freedom from discrimination based on their sex and transgender status under the Equal Protection provisions of the Fourteenth Amendment.

II. Statement of Facts

A. SB 254 Prevents Adult Plaintiffs from Obtaining Safe and Necessary Medical Care to Maintain their Health and Well-Being

i. Plaintiff Kai Pope

Plaintiff Kai Pope is a 51-year old transgender man. Kai has been a practicing hospice physician for 20 years and has lived and worked in Florida for the past 11 years. (Declaration of Kai Pope, ("Pope Decl.") ¶¶ 2–4). Kai was diagnosed with gender dysphoria many years ago and is on hormone therapy that helps bring his body in alignment with his male gender identity. (*Id.* ¶¶ 4, 6). In December of 2021, he underwent a bilateral mastectomy, often referred to as chest surgery or top surgery. (*Id.* ¶ 7). In March of 2023, he underwent a hysterectomy. (*Id.* ¶ 8). The hysterectomy was part of his treatment for gender dysphoria and also in preparation

for genital surgery. His genital surgery was scheduled for September 14, 2023. (*Id.* ¶ 10). However, on July 13, 2023, he was informed by his surgeon during a phone call that his surgery was cancelled because of SB 254. (*Id.* ¶¶ 9–11).

The cancellation of his surgery has devastating consequences for Kai. It means that he will not be able to obtain a procedure that his medical providers, including mental health providers, determined is essential to his health and well-being. (*Id.* ¶¶ 10–12). The efforts to schedule the surgery took over a year—including getting the required medical documentation and the preparatory medical work that he needed, obtaining prior authorization through his insurance provider for the medically necessary procedure, as well as clearing his own schedule to have the time for the procedure and recovery. (*Id.*). If Kai cannot get the scheduled surgery, he will continue to suffer the effects of untreated gender dysphoria. (*Id.* ¶¶ 11–13).

ii. Plaintiff Lucien Hamel

Lucien Hamel is a 27-year old transgender man who lives and works in Florida with his wife and child. (Declaration of Lucien Hamel, ("Hamel Decl.") ¶¶ 2–3). He has known that he is a man since he was very young. (*Id.* ¶¶ 4–5). He was diagnosed with gender dysphoria and started treatment with hormone therapy 4 years ago. (*Id.* ¶¶ 5–6). While he initiated care with a pediatric endocrinologist, he later transitioned care to an adult provider. (*Id.* ¶¶ 6–7).

The medical provider from whom he currently gets his hormone therapy is an autonomous-practice certified Advanced Practice Registered Nurse -- Nurse Practitioner (APRN-NP). (*Id.* ¶ 7). Lucien received his last testosterone shot on June 28 and has been without medication since that time. (*Id.* ¶¶ 9–10). Because of SB 254, he cannot receive continued care for his gender dysphoria from his medical provider. (*Id.* ¶¶ 9–14). Lucien has been searching for a physician to whom he could transfer his care for gender dysphoria but has not been able to find one. (*Id.*). And even at a point if and when he can, he will face a disruption to his ongoing medical care with a provider with whom he has a trusted relationship. (*Id.* ¶ 13). Being forced to go without testosterone has had, and will continue to have, devastating consequences for Lucien physically, emotionally, and psychologically. (*Id.* ¶¶ 12–14).

iii. Plaintiff Olivia Noel

Olivia Noel is a transgender woman who resides in Florida. (Declaration of Olivia Noel, ("Noel Decl.") ¶¶ 2–3). She began receiving transition-related care in May 2016 at the age of 19. (*Id.* ¶ 4). She initiated care at the UF Health multi-disciplinary youth gender clinic after a full multidisciplinary evaluation and assessment. (*Id.* ¶¶ 4–5). At age 21, Oliva was referred to an adult endocrinologist for continued care. (*Id.* ¶ 6). In 2022, Oliva moved to Seattle for a short period of time and established care with a doctor there. (*Id.* ¶ 7). She moved back to Florida

in March 2023. (*Id.* ¶ 8). She has had continuous medical support for treatment of gender dysphoria since she started treatment, including now having been on hormones for 7 years. (*Id.* ¶ 8).

Most recently, she has been receiving medical care through a physician's assistant (PA) at Planned Parenthood. (*Id.* ¶¶ 8–9). Olivia has less than one month left of her estrogen prescription. (*Id.* ¶ 10). She has not been able to find a physician to prescribe her necessary care once that prescription runs out. (*Id.* ¶¶ 10–14). Even if she could find a physician, she is not able to find a psychiatrist or psychologist to perform the evaluation she needs to initiate care with another doctor in a timely way. (*Id.* ¶¶ 16–17). She is also being harmed by SB 254's provisions that prevent her from getting care for her gender dysphoria through telehealth which has been a primary way for her to obtain care.

iv. Plaintiff Rebecca Cruz Evia

Rebecca Cruz Evia is a transgender woman who resides in St. Lucie County, Florida. (Declaration of Rebecca Cruz Evia, ("Cruz Evia Decl.") ¶¶ 2–3). Rebecca has received transition-related care for the treatment of her gender dysphoria, including hormone therapy and breast augmentation surgery, which have allowed her to bring her body into alignment with her female gender identity. (*Id.* ¶¶ 5–8).

Rebecca was scheduled to have surgery at the University of Miami to obtain a vaginoplasty surgery as treatment for her gender dysphoria on August 15, 2023.

(*Id.* ¶ 9). Before the surgery day, she received a phone call from her surgeon who informed her that because of SB 254, the procedure was cancelled. (*Id.* ¶ 10). Upon receiving the call, Rebecca was devastated and shocked, as she was weeks away from obtaining this essential surgery. (*Id.* ¶¶ 9–12). She has sought out alternative providers, but has not been able to access any other option for getting the surgery done. (*Id.* ¶ 11). Without the surgery, Rebecca will continue to suffer harms from the dysphoria she experiences. (*Id.* ¶ 12).

B. Transition-Related Care is the Established Course of Medical Care for the Treatment of Gender Dysphoria in Adults

There are well-established standards of care for treatment of gender dysphoria in adults. These are set out in two publications: the Endocrine Society Clinical Practice Guidelines for the Treatment of Gender Dysphoria and the World Professional Association for Transgender Health ("WPATH") Standards of Care, version 8.[1] These standards are widely followed by well-trained clinicians.[2]

The diagnosis of gender dysphoria in adults can be made by a health care provider with relevant expertise and training in identifying and making mental health care diagnoses. WPATH SOC, at S32. This may include a primary care provider, autonomous-certified advanced practice registered nurse, psychiatrist, psychologist,

[1] *See Dekker v. Weida*, No. 4:22-cv-00325 (N.D. Fla.), ECF Nos. 193-16, 193-24.
[2] *Id.*, Trial Tr., ECF No. 226 at 31 (psychiatrist), *id.* at 198 (pediatric endocrinologist); Trial Tr., ECF No. 227 at 50–52 (surgeon), *id.* at 106, 112–14 (pediatrician, bioethicist, medical researcher); Trial Tr., ECF No. 228 at 15 (physician specializing in pediatrics and adolescent medicine).

or licensed social worker or therapist. Declaration of Vernon Langford ("Langford Decl. ¶ 26; Declaration of Dan H. Karasic ("Karasic Decl.") ¶ 36). The diagnostic criteria require "marked incongruence between one's experienced/expressed gender and assigned gender" of at least six months duration. Diagnostic and Statistical Manual of Mental Disorders, Ed. 5. (DSM-V).

Medical treatment for gender dysphoria in adults consists primarily of hormone therapy--testosterone for transgender men, estrogen and testosterone suppression for transgender women--and surgery.[3] The overwhelming weight of medical authority supports these treatments for gender dysphoria in transgender adults. Organizations that have formally recognized this include the American Academy of Family Physicians, American College of Obstetricians and Gynecologists, American College of Physicians, American Medical Association, American Psychiatric Association, and at least a dozen more.[4] The record in *Dekker* includes statements from hundreds of professionals supporting this care,[5] and shows that not a single reputable medical association has taken a contrary position. As the

[3] *Dekker*, Trial Tr., ECF No. 238 at 72, 74–75; *see also* Trial Tr., ECF No. 228 at 14; Trial Tr., ECF No. 226 at 36, 176.
[4] *See id.*, Pls.' Exs. 36-43, 45–48, ECF Nos. 175-36 through 176-8 (omitting ECF No. 176-4); *see also* Amicus Brief of American Academies and Health Organizations, ECF No. 192-1.
[5] *Id.*, Amicus Brief of American Academies and Health Organizations, ECF No. 192-1; Bruggeman et al., *We 300 Florida health care professionals say the state gets transgender guidance wrong* (Apr. 27, 2022), ECF No. 11-1 at 11–32.

record in *Dekker* demonstrates, there is no credible evidence that rebuts the use of hormone therapy or surgery as standard of care treatment for transgender adults.

Hormone therapies are also routinely used to treat conditions in non-transgender patients in appropriate circumstances, and their safety records and overall effects are well established.[6] The Food and Drug Administration has approved their use, though not specifically to treat gender dysphoria.[7] Even though transition-related medication and surgeries have attendant risks, as any medications or surgeries do, they are also the only effective treatment for gender dysphoria.[8] SB 254 imposes severe restrictions on access to this care that serve no legitimate medical purpose and cause needless irreparable harm to transgender patients, depriving them of medically needed care because they are transgender and putting them at risk of exacerbated gender dysphoria, anxiety, depression, and suicide.

C. SB 254's Informed Consent Requirement Creates Arbitrary, Harmful and Medically Unjustified Restrictions on Access to Transition-Related Medical Care for Adults

SB 254's informed consent requirement creates arbitrary, harmful, and medically unjustified restrictions on transgender patients' abilities to obtain medically necessary transition-related treatment. As set forth in SB 254, patients must provide informed consent while "physically present in the room" with the

[6] *Id.*, Trial Tr., ECF No. 226 at 216.
[7] *See id.*, Trial Tr., ECF No. 226 at 183; Trial Tr., ECF No. 239 at 54–56.
[8] *Id.*, Trial Tr., ECF No. 226 at 218–29.

physician and "in writing on forms adopted in rule by the [Medical Boards]." Fla. Stat. § 456.52(2). While promoting informed consent is in theory a legitimate interest, the arbitrary restrictions and requirements imposed by the statute and forms adopted by the Boards undermine that interest rather than advancing it.

There is widespread national and international agreement that every mature person of sound mind has the right to decide what is done to her or his body with respect to medical care. (Declaration of Kenneth W. Goodman ("Goodman Decl.") ¶¶ 12–13). In the context of medical treatments, the purpose of "informed consent" requirements is to uphold, protect, and foster this important right. *Id.* The point is to ensure that when a patient needs medical care, they can make decisions about that care in an informed way. *Id.* The purpose is not to keep patients from getting needed care or to scare them away from it. *Id.* It is to provide them with accurate medical information. *Id.*

There are three universally accepted components to informed consent: (i) the patient must receive adequate information about the treatment, including its risk, likely benefits, and accepted alternatives; (ii) the patient must have the mental capacity to understand and appreciate the information as provided; and (iii) the patient's agreement to receive the treatment must be voluntary—that is, free of coercion or undue influence. (Goodman Decl. ¶¶ 11–12). Informed consent

requirements are not intended to dissuade patients from receiving treatments whose benefits outweigh the costs to the patient. (*Id.* ¶ 7).

First, the requirement that a doctor be "physically present in the same room" to establish informed consent undermines those goals. A physical presence requirement needlessly prevents the use of telehealth and serves as an insurmountable barrier for patients who do not live in proximity to their provider or who lack access to transportation. (Goodman Decl. ¶ 14). It is also inconsistent with the WPATH Standards of Care which state "assessments may be in person or through telehealth." WPATH SOC at S31.

In addition, the informed consent forms for feminizing hormones, masculinizing hormones, and sex-reassignments surgeries are riddled with false and misleading statements that are harmful to patients, undermine informed consent, and deter or prevent transgender patients from obtaining needed medical care. (Goodman Decl. ¶ 16; Schecter Decl. ¶¶ 20).

All three forms contain the following statement: "Medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative, and the possible psychological benefits may not outweigh the substantial risks of medical treatments and, in many cases, the need for lifelong medical treatments." These statements are

false. (Goodman Decl. ¶ 16). There is a substantial body of research supporting the benefits of hormone therapy and surgeries, which have been provided to transgender adults for more than sixty years. (Declaration of Daniel Shumer ("Shumer Decl.") ¶ 30; Karasic Decl. ¶¶ 25–30). Far from "purely speculative," the provision of these treatments is based on a well-established standard of care and decades of clinical experience. (Shumer Decl. ¶ 30; Karasic Decl. ¶ 31). In addition, it is misleading to say that either hormones or surgery will result in the need for "lifelong medical treatments." In fact, some transition-related procedures reduce the need for certain follow up care. Chest surgery lowers a transgender man's risk of breast cancer and, depending upon the surgical technique, eliminates a need for routine mammography. (Declaration of Loren Schecter ("Schecter Decl.") ¶ 19).

Both cross-sex hormone forms state that the use of hormones to treat gender dysphoria is "considered 'off label' because they are not being used for their intended purpose." This is false. As a rule, medications do not have only a single "intended purpose," and off-label use of medications is both common and appropriate. As the FDA itself explains, "once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient."[9] Many medications are prescribed

[9] *Understanding Unapproved Use of Approved Drugs "Off Label*," *available at* https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-

for off-label uses, which does not mean "they are not being used for their intended purposes." (Shumer Decl. ¶ 29; Karasic Decl. ¶ 42).

Both cross-sex hormone forms also include the following statement: "I know that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT." This is false. In fact, physicians and others who prescribe hormone therapy for transgender patients follow well-established published guidelines and protocols when determining timing, dosing, and type of medications. (Shumer Decl. ¶ 41).

Both cross-sex hormone forms state that "psychological therapy with a mental health provider" is an "option" for patients who do not wish to start or continue hormone therapy. This statement is false insofar as it suggests that psychological therapy is an effective alternative treatment for transgender people for whom hormone therapy is medically indicated. While psychotherapy can be beneficial for many people, including transgender people, there is no evidence that psychotherapy alone can alleviate gender dysphoria. (Karasic Decl. ¶ 32).

label#:~:text=Unapproved%20use%20of%20an%20approved%20drug%20is%20often,it%20to%20treat%20a%20different%20type%20of%20cancer.

Both cross-sex hormone forms state: "Treatment with femininizing [or masculinizing] medications will not prevent serious psychiatric events, including suicide." This statement is false insofar as it suggests that hormone therapy does not have a positive impact on a transgender patient's mental health, including the reduction of suicidality. In fact, substantial research shows that hormone therapy improves gender dysphoria, psychological function, comorbidities (e.g., depression, anxiety, and suicidality), sexual functioning, and overall quality of life. While no treatment can provide an absolute guarantee against "psychiatric events, including suicide," there is no medical basis to suggest that hormone therapy is ineffective in improving psychological health. (Karasic Decl. ¶ 33).

Both cross-sex hormone forms undermine rather than promote informed consent by including information about a laundry list of medications and associated risks, regardless of whether the patient is being prescribed a particular medication. This approach is extremely counterproductive as it is predictably likely to cause confusion, to overwhelm a patient with irrelevant information, prevent a patient from understanding the individualized risks and benefits of the medication that is being recommended or prescribed, and generally make it more difficult for the patient to focus on the information relevant to their health. (Shumer Decl. ¶ 43; Karasic Decl. ¶ 34; Goodman Decl. ¶¶ 18, 22).

These harms are compounded by the fact that both cross-sex hormone forms include information about medications that may never be prescribed for transgender patients in the United States. For example, the form for feminizing hormones includes information about cyproterone acetate. This medication has not been approved by the FDA and is not prescribed in the U.S. Therefore, there is no reason to include it. (Shumer Decl. ¶ 48). Similarly, the form for masculinizing hormones gratuitously mentions testosterone pills, despite noting that testosterone is typically "not given in pill form because the body may not absorb it properly which may cause potentially fatal liver problems." There is no medical reason to convey this information to all transgender male patients, and doing so merely engenders needless fear. (Shumer Decl. ¶ 37).

Both cross-sex hormone forms also contain statements about particular medications that are either false or misleading. For example, the form for masculinizing hormones falsely states that finasteride is a treatment for gender dysphoria in transgender men, whereas in fact is a treatment for baldness in both transgender and non-transgender men. Finasteride is not a treatment for gender dysphoria in transgender men. (Shumer Decl. ¶ 39).

In contrast, finasteride *may* be prescribed to treat gender dysphoria in transgender women. Nonetheless, the form for feminizing hormones misleadingly states that finasteride "is not recommended for routine use in treating populations

with gender dysphoria." In fact, finasteride may be used by transgender women in certain situations when other anti-androgens not effective, and—contrary to the implications of this statement—there is nothing inappropriate or unsafe about such usage. (Shumer Decl. ¶ 50).

Both cross-sex hormone forms also convey medically false or misleading information about risks. For example, the form for masculinizing hormones falsely states that "treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts," and "taking testosterone causes or worsens migraines." In fact, no data supports these assertions. (Shumer Decl. ¶ 46). This form also states that taking testosterone may cause certain changes that "could be permanent," but stating that any of the listed changes could be permanent is incorrect as they are all non-permanent effects of testosterone. (*Id.* ¶ 44). The form for feminizing hormones states: "My risk of breast cancer may significantly increase." A transgender woman receiving estrogen has a higher risk of breast cancer compared to men but not higher than other women. In fact, this risk is lower than that for non-transgender women. Therefore, transgender women are recommended to follow the same breast cancer mammogram screening guidelines as non-transgender women; they do not require stricter monitoring. (*Id.* ¶ 52).

Both cross-sex hormone forms require transgender patients to "undergo a thorough psychological and social evaluation performed by a Florida licensed board-

certified psychiatrist or a Florida licensed psychologist" before beginning hormone therapy and "every two years thereafter[.]" There is no medical basis for these requirements. Neither the WPATH Standards of Care nor the Endocrine Society Practice Guidelines impose any such requirement. As explained by Dr. Shumer: "The health care professional most appropriate to assess a patient's readiness for HRT is one who has clinical expertise and experience working with gender diverse patients. (Shumer Decl. ¶ 31). This may very well be a psychiatrist or psychologist, but may also be a therapist or social worker, a primary care physician, or another health care professional fluent in these topics and available to meet with the patient to have detailed discussion of their experience with gender. (Shumer Decl. ¶ 31; Karasic Decl. ¶¶ 35–36).

Both cross-sex hormone forms state: "HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect your mood. Therefore, you must be under the care of a licensed mental health care professional while undergoing treatment." There is no medical basis for this statement or this requirement, which falsely asserts a medical need for every transgender person using hormone therapy to be under the care of a licensed mental health professional. (Karasic Decl. ¶¶ 35–36). The Standards of Care do not require patients to be under the care of a licensed mental health professional while undergoing hormone therapy, which is a routine treatment for gender dysphoria. In addition, many medications can affect mood, but

none are subject to a similar requirement that an adult patient be under the care of a licensed mental health professional for that reason. Examples of such medications include beta blockers and birth control pills. (Karasic Decl. ¶ 41). Finally, the very same medications used in hormone therapy for transgender patients are prescribed to non-transgender people for other medical conditions with no requirement that they be under the care of a licensed mental health professional. (*Id.* ¶ 40). For example, men with prostate cancer are among the biggest users of anti-androgens, and yet they have no such requirement. (*Id*). Many post-menopausal women receive hormone replacement therapy and yet they have no such requirement. There is no medical reason to single out transgender people for this requirement which, in addition to impeding needed care, falsely stigmatizes transgender people as inherently mentally unstable or mentally ill. (*Id.*)

Both cross-sex hormone forms include a list of potential generic recommendations—untethered to any individualized assessment of a patient's specific medical circumstances and needs—for which there is no medical justification. As Dr. Shumer explains: "Their inclusion serves only to confuse and undermine informed consent and to create unnecessary obstacles to care. Patients receiving care for gender dysphoria are diverse and have different needs. Patients doing very well may need to be seen less frequently than patients who are struggling. Patients with other medical conditions, such as diabetes or hyperlipidemia, may need

lab evaluation more frequently than other patients with no medical problems. Dictating visit frequency, frequency of mental health screening, and laboratory and radiology testing is not an appropriate role for a State Medical Board. These are decisions that medical providers make while thinking critically about each individual patient." (Shumer Decl. ¶ 40).

In particular, the recommendation that patients may be required to undergo annual bone scans has no medical basis whatsoever. As explained in Dr. Shumer's declaration, there is no medical reason for either transgender men or transgender women to undergo annual bone scans. Doing so is not only unnecessary but serves no medical purpose whatsoever. (Shumer Decl. ¶¶ 42, 51).

D. SB 254 Arbitrarily Prevents Qualified Medical Professionals from Providing Medical Care for Transgender Patients

An autonomous-practice certified Advanced Practice Registered Nurse who is a nurse practitioner ("APRN-NP") in Florida is an advanced practice nurse who is authorized to practice autonomously in the field of primary care practice, which is defined by administrative regulation as "physical or mental health promotion, assessment, evaluation, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses, inclusive of behavioral and mental health conditions." Fla. Admin. Code Ann. 64B9-4.001(12) (2021). This authority includes the ability to diagnose, treat, and monitor patients

with gender dysphoria, treatment that is characterized as primary care. (Shumer Decl. ¶ 53; Karasic Decl. ¶ 43; Langford Decl. ¶ 33).

APRN-NPs have completed advanced education and training that includes years of higher medical education beyond the required registered nurse degree and at least 1000 hours of clinical practice. (Langford Decl. ¶ 34). Florida law provides that APRN-NPs may practice medicine independently and without the direct supervision of a physician. Fla. Stat. § 464.0123. The range of tasks they may perform in autonomous practice includes diagnosing illness, ordering and interpreting diagnostic tests, prescribing medications, and managing patient care. (Langford Decl. ¶¶ 25, 28). To the extent there are limits on their ability to prescribe medications, they are the same limitations imposed on physicians. (*Id.* ¶ 28).

Throughout Florida, many transgender patients receive transition-related healthcare from an APRN-NP. The number of APRN-NPs throughout the State is approximately 44,556. The number of licensed physicians is approximately 94,731. The provision in SB 254 that prohibits healthcare practitioners who are not physicians—including APRN-NPs—from providing transition-related medical care to transgender adult patients has left many transgender patients without access to care. (Langford Decl. ¶ 39). APRN-NPs can offer high quality, safe and effective medical care for transgender patients comparable to that provided by physicians. There is no medically valid basis or rationale for preventing them from doing so, and

no evidence supports limiting APRN-NPs' ability to diagnose and treat gender dysphoria. The provisions of SB254 that prohibit APRN-NPs from diagnosing and prescribing care for gender dysphoria are arbitrary and will serve only to bar many patients from getting essential medical care without any justification.

III. Argument

The purpose of a preliminary injunction is to preserve the status quo and thus prevent irreparable harm until the respective rights of the parties can be ascertained during a trial on the merits. *Powers v. Sec., Fla. Dep't of Corrections*, 691 F. App'x 581, 583 (11th Cir. 2017). To obtain a preliminary injunction, a movant must show: "(1) it has a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." *Jones v. Governor of Fla.*, 950 F.3d 795, 806 (11th Cir. 2020) (citing *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc)). "[A]ll of the well-pleaded allegations of [the] complaint and uncontroverted affidavits filed in support of the motion for a preliminary injunction are taken as true." *Elrod v. Burns*, 427 U.S. 347, 350 n.1 (1976). Each of these factors supports granting a preliminary injunction in this case.

A. Plaintiffs Will Likely Succeed on the Merits of their Equal Protection Claim Because SB 254 Singles out Transgender People to Deter Them from Obtaining Medical Care and Lacks Even a Rational Basis, Much Less an Exceedingly Persuasive One.

Plaintiffs are likely to succeed on the merits of their equal protection claim. SB 254 and the Emergency Rules and Informed Consent Forms implementing SB 254 (together, the "Restrictions") single out transgender patients because of their sex and transgender status to prevent them from obtaining medically necessary care. Because the Restrictions discriminate based on transgender status and sex, they are subject to heightened scrutiny—the standard of scrutiny that this Court has already found applies to the provisions of SB254 that ban transition-related care for minors. The State cannot justify denying transgender patients medical care that this Court has already determined to be safe, effective, and necessary for many transgender individuals; accordingly, Plaintiffs are likely to prevail on this claim.

1. The Challenged Restrictions are Subject to Heightened Scrutiny

The Restrictions seek to deny essential medical care to transgender patients because they are transgender and, therefore, because of their sex. As this court has already held, SB 254's ban on healthcare for transgender minors classifies minor patients on the basis of sex and transgender status and is, accordingly, subject to heightened scrutiny. (Prelim. Injunct. Order (Dkt. No. 90) at 19–25). The same analysis applies to SB 254's restrictions on healthcare for transgender adults, which

rely on exactly the same statutory language to describe the restricted care and to whom the restrictions apply.

As this Court has already explained: "[I]f one must know the sex of a person to know whether or how a provision applies to the person, the provision draws a line based on sex." (*Id.* at 19). As with the ban on medical treatment for transgender minors, in order to know whether the restrictions on adult transgender patients apply, one must know whether the patient is transgender and, therefore, must know the patient's sex at birth. If the patient is not transgender, the Restrictions do not apply. If the patient is transgender, the Restrictions do apply. Accordingly, these Restrictions require the same heightened scrutiny applied to all other sex-based laws. *Sessions v. Morales-Santana*, 582 U.S. 47, 57 (2017) (cleaned up) ("[H]eightened scrutiny now attends all gender-based classification.").

2. The Restrictions Cannot Withstand Heightened Scrutiny

Heightened scrutiny requires a state to show that its classification is substantially related to a sufficiently important interest. *Id*. at 58. This standard demands an "exceedingly persuasive justification" for discrimination. *Id*. A justification based on overbroad generalizations is not sufficient, *Virginia*, 518 U.S. at 533, and any asserted justification must reflect the law's "actual purpose" when enacted, not a hypothetical rationale or one "invented *post hoc* in response to litigation," *Miss. Univ. for Women v. Hogan*, 458 U.S. 718, 730 (1982).

The restrictions under SB 254 cannot withstand this test. Preventing transgender patients from receiving necessary medical care does not serve an important governmental interest. In *Dekker v. Weida*, 2023 U.S. Dist. LEXIS 107421 (N.D. Fla. June 21, 2023), Defendants failed to demonstrate that hormone therapy and surgeries provided to treat gender dysphoria are ineffective, unsafe, or experimental. This Court in *Dekker* heard two weeks of testimony establishing the safety and efficacy of medications and procedures for treating gender dysphoria. *Id.* at *7, 23–27. The Court also heard from witnesses for the Defendants seeking to establish the contrary. *Id.* at *25–26.

After hearing the testimony, this Court found as a factual matter: "The great weight of medical authority supports these treatments…[T]he widely accepted standards of care support their use in appropriate circumstances." *Dekker*, 2023 U.S. Dist. LEXIS 107421, at *51. The medical research supporting the use of hormone therapy and surgery for adult patients is substantial. This Court rejected Defendants' justifications for denial of Medicaid funding for gender transition-related health care. Those justifications fare no better here.

This Court did not make factual findings on the medical efficacy and safety of surgery for transgender adults because the *Dekker* plaintiff who required surgery was able to access the needed procedure during the pendency of the case, thus

precluding any need for the Court to address surgeries in its order. The Court did, however, hear fulsome testimony on the topic.

The *Dekker* record reflects that gender transition surgeries may be medically essential for some transgender adults. (*Dekker*, Pltfs.' Tr. Br. (ECF 199) at 25). These surgeries use accepted techniques that are well-established; the risks of such procedures are well-known and well-documented in the literature and are no different when used to treat gender dysphoria rather than other health conditions. *Id.* at 48. The medical literature shows that surgery is a highly effective treatment for gender dysphoria. *Id.* at 48–50.

Decades of research demonstrate that transition-related surgeries lead to positive outcomes for patients and that people whose gender dysphoria is surgically treated experience positive health outcomes, including improvements to mental health, sexual function, and psychosocial wellbeing and quality of life. *Id.* at 50–52.

The scientific literature also establishes that surgery to treat gender dysphoria is safe. *Id.* at 52–53. For example, one study found that transgender men who received chest reconstruction experienced few clinical complications. Michael J. Frederick et al., *Chest Surgery in Female to Male Transgender Individuals*, 78 Ann. Plastic Surg. 249, 253 (2017). A study of over 1000 gender-transition surgeries in the United States found that "[c]omplications of all gender-affirming procedures was

5.8%." Megan Lane et al., *Trends in Gender- affirming Surgery in Insured Patients in the United States*, 6 Plast. Surg. Global Open e1738 (2018). Further, the evidence that shows that surgical interventions are safe to treat gender dysphoria is the same evidence that supports these interventions as safe to treat other conditions, such as congenital conditions, cancer, or traumatic injury since they use the same techniques. *Id.* at 52. In addition, the literature establishes that patient satisfaction with transition-related surgery is very high and regret rates are very low. *Id*. at 53.

3. The Restrictions Imposed by SB 254 Undermine Informed Consent and Harm Patients; They Lack Even a Rational Basis and Cannot Possibly Survive Heightened Scrutiny.

SB 254 intentionally restricts medical care for transgender patients. These restrictions turn normal medical practice on its head, forcing providers to violate established standards of care, provide their patients with false and misleading information about medical treatments, and deny their patients needed care unless they undergo invasive and unnecessary psychological evaluations and unnecessary lifelong psychotherapy. (Shumer Decl. ¶¶ 23–26, 34; Karasic Decl. ¶¶ 23–24, 35, 37–38; Schecter Decl. ¶¶ 16, 20; Goodman Decl. ¶¶ 10, 16–17). These restrictions have no medical basis and serve only to harm transgender patients and deter them from obtaining needed care. Rather than promoting informed consent or the wellbeing of transgender patients, the restrictions imposed by SB 154 undermine

them. For these reasons, none of these restrictions can survive even rational basis review, much less heightened scrutiny.

The requirement that a physician must be "physically present in the same room" when obtaining a transgender patient's informed consent has no medical justification and serves only to deter transgender patients from obtaining the information and care they need. As explained by Plaintiffs' experts there is no medical basis for this requirement. (Karasic Decl. ¶ 44). It contradicts the standards of care, which expressly state that "assessments may be in person or through telehealth." WPATH SOC at S31. Requiring a physician to be physically present in the same room does nothing to enhance a patient's understanding of the information presented or to facilitate informed consent. Instead, its sole impact is to prevent or delay care. (Karasic Decl. ¶ 44).

Requiring providers to use the informed consent forms developed by the Boards also fails even rational review. Promoting informed consent is a legitimate goal; however, it is undermined by mandating that all providers use a one-size-fits-all approach that impedes, rather than enhances, a patient's ability to understand the information presented. (Goodman Decl. ¶ 20). To be effective, informed consent must be consent to the treatment a patient is being prescribed. (Shumer Decl. ¶¶ 24–27; Karasic Decl. ¶ 44). Instead, these forms force providers to give patients a laundry list of treatments they are *not* being prescribed, including medications that

are never prescribed for transgender patients in the U.S. or that are not even treatments for gender dysphoria. This approach is inherently confusing and ineffective, making it much more difficult for patients to absorb the information they need to receive. (Karasic Decl. ¶ 34).

In addition, the forms developed by the Boards are rife with false, misleading, and biased information that prevents transgender patients from accurately understanding the transition-related treatment they seek. Contrary to the false statements in the form, there are decades of research on the safety and efficacy of transition-related care; there are well-established written protocols for the timing, dosage, and type of medications prescribed; and the prescription of these FDA-approved medications for an off-label use is fully consistent with medical ethics and standards. (Shumer Decl. ¶¶ 29, 41; Karasic Decl. ¶ 42). These false statements prevent transgender patients from having the accurate information they need to make informed medical decisions and deter them from seeking care. (*Id.*)

The forms also harm transgender patients by providing false information about specific medications and their effects. For example, the forms falsely state that transgender men who take masculinizing hormones are at heightened risk for breast cancer, whereas, in fact, there is no evidence that this is the case. (Shumer Decl. ¶ 52). Similarly, the forms misstate typical recovery times for certain transition-related surgeries, which are significantly *longer* than the forms state. (Schecter Decl. ¶ 26).

There is no legitimate governmental interest in mandating that transgender patients receive inaccurate information about their treatments, which completely defeats the purpose of informed consent.

In addition to impeding informed consent, the forms make it difficult or impossible for transgender patients to obtain needed care by imposing burdensome and unnecessary requirements that contradict the Standards of Care and serve no medical purpose. For example, the forms require transgender patients to undergo repeated unnecessary and invasive mental health evaluations before obtaining hormone therapy, even though the Standard of Care specifically state that no such evaluations are required. (Karasic Decl. ¶ 35). In addition, the forms require that transgender patients undergo ongoing, lifelong psychotherapy regardless of whether they have any individualized need for such therapy or not. (*Id.* ¶ 38). There is no medical basis for this incredibly invasive and burdensome requirement, which will effectively bar any ability to obtain care for many transgender people.

These requirements also stigmatize transgender people as inherently psychologically unstable or mentally ill, despite the consensus of mental health organizations and experts that being transgender is a normal variation of human identity and is not a mental illness or disorder. There is no more reason to require transgender people to undergo repeated mental health evaluations or lifelong psychotherapy than any other group, and doing so serves only to increase the social

stigma and negative stereotypes that transgender people already experience. (Karasic Decl. ¶ 38).

Finally, there is no rational basis—much less "an exceedingly persuasive one"—for prohibiting APRN-NPs from prescribing and administering hormone therapy to transgender patients, even though they are fully qualified to do so under both Florida law and the Standards of Care. The sole impact of this prohibition is to arbitrarily limit the pool of providers who can serve transgender patients. (Karasic Decl. ¶ 43). This will cause real hardship and denial of care. Many transgender people obtain their primary care from APRN-NPs and will not be able to find a physician to do so, given Florida's shortage of physicians, which is projected to worsen over time. There is no medical reason for this prohibition, which will serve only to make the care transgender people need more difficult or possible to obtain.

In sum, SB 254 undermines the health and wellbeing of transgender people by erecting arbitrary barriers that intentionally make it more difficult or impossible to obtain the medical information and care transgender patients need. Far from having an "exceedingly persuasive justification," these restrictions fail even rational basis review.

b. The Restrictions are Causing Irreparable Harm to the Adult Plaintiffs

The Restrictions inflict severe and irreparable harms. The law prevents the Adult Plaintiffs from obtaining established and time-sensitive medical care. Denial

of medically necessary care is sufficient to show immediate and irreparable harm. *See, e.g.*, *Bowen v. City of New York*, 476 U.S. 467, 483–84 (1986) (finding denial of benefits caused irreparable injury by exposing plaintiffs to "severe medical setback[s]" or hospitalization); *Eknes-Tucker*, 603 F. Supp. 3d at 1150; *Gayle v. Meade*, 614 F. Supp. 3d 1175, 1206-07 (S.D. Fla. June 6, 2020) (holding that increased likelihood of serious illness constitutes an irreparable injury); *Flack v. Wis. Dep't of Health Servs.*, 331 F.R.D. 361, 373 (W.D. Wis. 2019) (denying coverage for medical treatment for gender dysphoria is irreparable harm).

Due to the nature of gender dysphoria and its time-sensitive treatments, every day that goes by in which the Adult Plaintiffs are unable to obtain the medical care they need has a detrimental effect on both their immediate and long-term health and well-being. *See Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1342 (S.D. Fla. 2006) ("The denial of medical benefits, and resultant loss of essential medical services, constitutes an irreparable harm . . . ."); *Smith v. Benson*, 703 F. Supp. 2d 1262, 1278 (S.D. Fla. 2010) (denying plaintiff an essential medical service, which was "necessary for her physical and mental health," constituted irreparable harm"); *Haddad v. Arnold*, 784 F. Supp. 2d 1284, 1307 (M.D. Fla. 2010) (action that is detrimental to the plaintiff's health and well-being, constituted irreparable harm); *Mattive v. Healthsource of Savannah, Inc.*, 893 F. Supp. 1559, 1563 (S.D. Ga. 1995) (finding irreparable harm would result from preventing the plaintiff from obtaining

the cancer treatment that would give her the best chance at long-term health and survival); *J.M. v. Crittendon*, 2018 WL 7079177, at *7 (N.D. Ga. May 21, 2018) (holding it would cause irreparable harm to deny medical care to the plaintiff suffering from a complex medical condition which "could easily snowball and become life-threatening").

SB 254 prevents the Adult Plaintiffs from obtaining time-sensitive, essential medical care. Kai Pope had his surgery cancelled because of SB 254 and will not be able to get it completed without an order from this court enjoining SB 254. Lucien Hamel received his last shot of testosterone and will not be able to receive another unless this Court acts. Olivia Noel has less than a month's supply of hormone therapy and will not be able to continue taking the medication she needs without an injunction from this Court. Rebecca Cruz Evia had her long-awaited surgery cancelled and will not be able to get it rescheduled without this Court's action.

These harms are serious, irreparable, and potentially life-threatening. *Melendez v. Sec'y, Fla. Dep't of Corr.*, 2022 WL 1124753, at *4 (11th Cir. Apr. 15, 2022) (affirming grant of injunction where the plaintiff had severe depression, noting that his potential suicide "constituted the ultimate irreparable injury"); *Mental Health Network, Inc. v. Marstiller*, 2022 WL 19330976, at *4 (S.D. Fla. Jan. 14, 2022) (holding that patients' potential for "confusion, anxiety, and trauma" established irreparable harm); *Braggs v. Dunn*, 383 F. Supp. 3d 1218, 1243 (M.D.

Ala. 2019) ("[T]he immediate and substantial risk of suicide, as reflected in the recent wave of suicides, satisfies the irreparable harm inquiry.").

c. The Imminent Threat of Harm to Adult Plaintiffs Outweigh Any Damage to Defendants, Who Lack an Interest in Enforcing Unconstitutional Laws

The serious irreparable harms that Plaintiffs will experience if SB 254 remains in effect outweigh any countervailing government interest. When "the nonmovant is the government, . . . the third and fourth requirements [for an injunction]—'damage to the opposing party' and 'public interest'—can be consolidated." *Otto v. City of Boca Raton*, 981 F.3d 854, 870 (11th Cir. 2020) (internal citations omitted); *Eknes-Tucker*, 603 F. Supp. 3d at 1150–51. In addition, there is no "legitimate interest in enforcing an unconstitutional [law]." *Otto*, 981 F.3d at 870; *Doe v. Ladapo*, p. 40 ("Adherence to the Constitution is always in the public interest.").

Here, the balance of equities strongly favors an injunction. The medical care provided to transgender adults has been available for many years, and Defendants implicitly acknowledge that it is safe by permitting adults to obtain it, just as long as they are willing to run a gauntlet of unnecessary and harmful obstacles. Under these circumstances, it is difficult to see any injury to Defendants or others that would be caused by prohibiting enforcement of SB 254 while the case proceeds. Doing so would merely maintain the status quo before the law took effect.

In sharp contrast, the immediate harms to Adult Plaintiffs if SB 254 is enforced are severe. They must go to great lengths to find a new provider, travel beyond their home communities to get medical care, if they can even obtain it, and navigate informed consent forms that include misinformation. The movants here have strived and failed to obtain the care they need. SB 254 causes them to suffer or soon suffer the consequences of living with untreated gender dysphoria.

d. The Court Should Enjoin Enforcement of SB 254

"[I]n the case of a constitutional violation, injunctive relief must be tailored to fit the nature and extent" of the violation. *Georgia Advoc. Off. v. Jackson*, 4 F.4th 1200, 1209 (11th Cir. 2021), *vacated as moot*, 33 F.4th 1325 (11th Cir. 2022). "Once invoked, the scope of a district court's equitable powers . . . is broad, for breadth and flexibility are inherent in equitable remedies." *Brown v. Plata*, 563 U.S. 493, 538 (2011) (internal citations omitted). Unconstitutional laws, like SB 254, "are ordinarily vacated universally, not simply enjoined in application solely to the individual plaintiffs." *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 485 F. Supp. 3d 1, 64 (D.D.C. 2020).

An order enjoining SB 254 on its face is necessary and proper. SB 254 makes it extremely difficult or impossible for the Adult Plaintiffs to obtain time-sensitive care by restraining qualified medical providers such as APRN-NPs throughout Florida from prescribing the necessary medications while forcing Adult Plaintiffs to

seek care from in-demand physicians with long wait lists. It forces Adult Plaintiffs to comply with arbitrary, harmful, and medically unjustified requirements far above and beyond what is required for valid informed consent to receive care, including undergoing repeated, invasive, and unnecessary psychological evaluations and monitoring that serve no medical purpose. The only remedy that will redress that injury is an injunction that prevents Defendants from enforcing SB 254. Each of the movants needs to be able to find and secure medical treatment from available medical providers to get the care they need.

The Adult Plaintiffs cannot know with certainty the identity of all providers they may need to consult, nor is it feasible to issue an injunction that would apply only to specific patients or providers. In addition, SB 254 is causing confusion among providers and patients, with the latter scrambling to find alternative ways to obtain care. All of those effects will continue and expand without a facial injunction against SB 254.

e. Request for Relief from Requirement to Post Bond

Plaintiffs request an exemption from the requirements of Fed. R. Civ. P. 65(c). "[T]he amount of security required by [Rule 65(c)] is a matter within the discretion of the trial court . . . [and] the court may elect to require no security at all." *BellSouth Telecomm., Inc. v. MCIMetro Access Transmission Srvs., LLC,* 425 F.3d 964, 971 (11th Cir. 2005).

IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court enjoin enforcement of SB 254 while this lawsuit is pending.

Respectfully submitted this 24th day of July, 2023.

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CERTIFICATE OF WORD COUNT

According to Microsoft Word, the word-processing system used to prepare this Motion and Memorandum, there are 493 total words contained within the Motion, and there are 7844 words contained within the Memorandum of Law.

/s/ Simone Chriss

CERTIFICATE OF SATISFATION OF ATTORNEY CONFERENCE REQUIREMENT

Pursuant to Local Rule 7.1(B), counsel for the Plaintiffs conferred with counsel for the Defendants on July 20, 2023 and July 21, 2023. Counsel for Defendants indicated that Defendants oppose the relief sought.

CERTIFICATE OF SERVICE

I hereby certify that, on July 24, 2023 I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system.

/s/ Simone Chriss