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

AUGUST DEKKER, *et al.*, *Plaintiffs*, v. JASON WEIDA, *et al.*, *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

While Defendants correctly acknowledge that a primary question in this case is whether, "based on current medical opinion," Florida's Exclusion and "determination" that medical treatments for gender dysphoria are "experimental is reasonable," *Rush v. Parham*, 625 F.2d 1150, 1157 n.13 (5th Cir. 1980), Defendants' Motion is otherwise a masterclass in misinformation and disinformation.

In addition to misstating facts, Defendants ignore that single most material fact in this case—whether medical treatment for gender dysphoria is experimental—is genuinely disputed, particularly given the overwhelming record evidence that such medical treatment is *not* experimental or investigational, but rather *necessary*, *safe*, and *effective*. This alone warrants denying Defendants' Motion, as "[t]he party

seeking summary judgment bears the exacting burden of demonstrating that there is no dispute as to any material fact in the case." *Warrior Tombigbee Transp. Co. v. M/V Nan Fung*, 695 F.2d 1294, 1296 (11th Cir. 1983).

Take Defendants' opening paragraph. Defendants reference a handful of countries that have purportedly restricted the provision of gender-affirming care in a manner that is both misleading and false.[1] Defendants "ignore European countries where access to trans care has recently expanded (Spain, Portugal, and France)." (Opp. Ex. A.)[2] Indeed, "in France, the use of hormone blockers or hormones of the opposite sex is possible with parental authorization at any age," and surgical treatment for gender dysphoria is likewise available, including "mastectomy, which is authorized … from the age of 14."[3] New Zealand also has not restricted the provision of gender-affirming medical care. (Opp. Ex. B; Opp. Ex. C.)

Defendants argue that because some outlier doctors go against the grain, the Exclusion and their determination is "reasonable" under *Rush*. Not so. Under *Rush*, "whether the state's determination 'is' reasonable, [is] controlled … by 'current

[1] How countries with nationalized health care systems provide medical care has little bearing here.

[2] Exhibits referred to as "Ex.#" refer to Plaintiffs' trial exhibits filed at ECF 175-184. Exhibits referred to as "Opp. Ex. [letter]" are exhibits attached to this memorandum.

[3] https://www.academie-medecine.fr/wp-content/uploads/2022/03/22.2.25-Communique-PCRA-19-Gender-identity-ENG.pdf.

medical opinion.'" Doc.64 (quoting *Rush*, 625 F.2d at 1157 n.13). "Defendants attempt to create scientific controversy in [an otherwise] uniform agreement through experts who mix their scientific analysis with hypothetical speculation and political hyperbole." *Kadel v. Folwell*, 2022 WL 3226731, at *32 (M.D.N.C. 2022). But "Defendants' belief that gender affirming care is ineffective and unnecessary is simply not supported by the record." *Id.*

Here, Plaintiffs have presented copious evidence demonstrating that gender-affirming care is *not* experimental or investigational, but *necessary*, *safe*, and *effective* medical care that has been provided and studied *for decades*. Each of Plaintiffs' experts completely undermine the State's position, and at minimum, create a genuine issue of material fact. And unlike Defendants' experts (with one exception), Plaintiffs' experts *all* have experience treating or studying gender dysphoria, and its medical treatment. Their testimony shows that gender-affirming care is safe, effective, and widely accepted. Defendants ignore this evidence.[4]

Defendants also fail to contend with the plethora of case law showing that exclusions of medical treatments for gender dysphoria from coverage are unlawful

[4] Defendants reference an expert report from Dr. Brignardello-Petersen, one of AHCA's consultants on the GAPMS Report. Defendants never disclosed Dr. Brignardello-Petersen as an expert in this case and refused to accept service of Plaintiffs' subpoena for her as she is based in Canada. To the extent Defendants seek to introduce Dr. Brignardello-Petersen's report in support of the GAPMS Report or to reference it as expert opinion, Plaintiffs move to strike such references.

and violate the Medicaid Act's comparability and EPDST requirements, Section 1557 of the ACA, and the Fourteenth Amendment's Equal Protection Clause.

Because there are material facts genuinely in dispute and a barrage of case law supports Plaintiffs' claims, the Court should deny Defendants' Motion.

II. STATEMENT OF THE CASE AND FACTS

Correcting every misstatement in Defendants' statement of the case and facts would exceed permitted word limits, so Plaintiffs refer the Court to their Trial Brief and present the following facts.

A. Gender Dysphoria

Gender dysphoria is a serious medical condition, experienced only by transgender people, characterized by the significant distress caused by the incongruence between their sex assigned at birth and their gender identity. (Ex.8, at 10 ¶7; Ex.10, ¶20; Ex.7, ¶24.) Without appropriate treatment, gender dysphoria can cause debilitating anxiety, severe depression, self-harm, and even suicidality. (Ex.7, ¶¶26, 36, 68; Ex.9, ¶41; Ex.10, ¶21.)

B. Treatment for Gender Dysphoria

Gender dysphoria is treatable, and interventions are supported by well-established evidence-based guidelines, for which decades of research and clinical practice provide support. (Ex.9, ¶ 41; Ex.5, ¶ 17; Ex.8, at 12-13 ¶¶ 10-12; Ex.10, ¶¶24-26; Ex.7, ¶¶27-28, 33, 56-59; Ex.142.)

Treatment seeks to eliminate the distress of gender dysphoria by aligning an individual's body and presentation with their internal sense of self. (Ex.7, ¶36; Ex.10, ¶22.) The medical community does not consider these treatments to be experimental or investigational. (Ex.5, ¶¶32-33; Ex.14, ¶¶21-36; Ex.17, ¶23; Ex.8, ¶73; Ex.10, ¶¶ 44-46; Ex.9, ¶89.).

1) The treatment protocols for gender dysphoria

Gender-affirming medical care dates back almost a century. (Ex.5, ¶32, Ex.10, ¶46.) The first gender-confirming surgeries were performed in the 1920s. (Ex.143, at 48-49.) Hormone treatment for gender dysphoria began after estrogen and testosterone became commercially available in the 1930s. (Ex.5, ¶32; Ex.11, ¶32; Ex.2, ¶ 27; Ex.143, at 49.) Puberty-delaying medications have been used to treat gender dysphoria since the late 1990s. (Ex.5, ¶32; Ex.8, ¶24; Ex.142, at 364.)

WPATH first established standards of care for the treatment of gender dysphoria in 1979, which have been continuously maintained and are now in their eighth version ("WPATH SOC8") (Ex.7, ¶27; Ex.8, at 12 ¶10; Ex.9, ¶48; Ex.10, ¶ 24; Ex.17, ¶55; Ex.142, at 361; *see also* Ex.34.) The WPATH SOC8 are based on the best available evidence and professional consensus. (Ex.5, ¶29; Ex.7, ¶28; Ex.8, at 12 ¶10; Ex.9, ¶48; Ex.10, ¶¶ 8, 24; Ex.17, ¶56; Ex.142, at 361; *see also* Ex.34, at S8, S247-S251.)

The Endocrine Society's Clinical Practice Guidelines are largely consistent with the WPATH SOC8 and were developed using rigorous scientific methods. (Ex.5, ¶¶17-18; Ex.7, ¶¶31-33; Ex.8, at 13 ¶12; Ex.9, ¶53; Ex.10, ¶26; Ex.17, ¶¶57-58; Ex.142, at 361; *see also* Ex.123; Doc.193-24.)

The WPATH SOC8 and the Endocrine Society Guidelines provide for medical interventions that are individualized based on patient needs and may include puberty-delaying medications, hormone therapy, or surgeries. (Ex.8, at 12 ¶10; Ex.7, ¶40; Ex.9, ¶57; Ex.10, ¶ 25; *see generally* Ex.34; Ex.123; Doc.193-24.) Treatment protocols differ for adolescents (minors who have started puberty) and adults. (Ex.17, ¶59; *see also* Ex.34, at S32, S48, S111, S129; Ex.123, at 3878, Table 5.) No medical or surgical treatments are provided to any patient until *after the onset of puberty*. (Ex.8, at 17 ¶18; Ex.7, ¶41; Ex.9, ¶44; Ex.17, ¶¶25, 59; *see also* Ex.34, at S69; Ex.123, at 3870.)

America's major medical organizations agree gender-affirming medical care is necessary for people with gender dysphoria. (Ex.5, ¶30; Ex.7, ¶34; Ex.8, at 12 ¶¶10-11, ¶48; Ex.9, ¶¶54-55; Ex.10, ¶27; Ex.17, ¶60; Ex.142, at 361.)

a) Puberty-delaying medications

For adolescents with gender dysphoria who experience severe distress with the onset of puberty, puberty-delaying medications may be indicated. (Ex.7, ¶42; Ex.8, ¶¶22-23; Ex.9, ¶46; Ex.17, ¶89.) Such interventions afford the adolescent time

to better understand their gender identity while delaying the development of secondary sex characteristics, which can cause severe distress when incompatible with an adolescent's gender identity. (Ex.8, ¶¶23-24; Ex.12, ¶81; Ex.9, ¶66; Ex.17, ¶92.) The treatment is reversible if an adolescent discontinues the treatment, puberty will resume. (Ex.7, ¶42; Ex.8, ¶¶24; Ex.9, ¶65.)

Puberty-delaying medications do not have any long-term implications on fertility or sexual function, and there is no evidence that they impact brain development, emotional regulation, or cognition. (Ex.15, ¶¶21-33; Ex.12, ¶¶17-23; Ex.9, ¶73.) The medical and scientific literature has established that puberty-delaying medications are safe and effective to treat gender dysphoria in adolescents. (Ex.5, ¶32; Ex.9, ¶¶63, 78-82; Ex.8, ¶¶25-29, 99-101; Ex.16, ¶¶51-54; Ex.12, ¶¶73-74; *see also, e.g.*, Exs. 141, 163, 165, 167, and 168.)

b) Hormone therapy

For some adolescents and adults with gender dysphoria, hormone therapy may be medically necessary. (Ex.17, ¶96; Ex.8, ¶32; Ex.7, ¶43, Ex.9, ¶¶46, 72.) Gender-affirming hormone therapy is a partially reversible treatment, meaning some of the hormones' effects are reversible, while others are not. (Ex.7, ¶43; Ex.8, ¶32.) Hormone therapy allows for a physical development more closely aligning with a person's gender identity, helping alleviate gender dysphoria. (Ex.9, ¶¶60, 71.)

The scientific literature shows that hormone treatment is safe and effective to treat gender dysphoria in adolescents and adults. (Ex.9, ¶¶86-88; Ex.8, ¶¶ 34-40; Ex.17, ¶¶101-102; *see also, e.g.*, Ex.166; Ex.180; Ex.221; Ex.156; Ex.197; Ex.176; Ex.195; Ex.164; Ex.212.)

c) Surgery

Gender-confirming surgery may be indicated for some transgender adults and older adolescents to align their primary and secondary sex characteristics with their gender identity. (Ex.8, ¶42; Ex.10, ¶22.) Surgeons regularly perform these procedures to treat conditions other than gender dysphoria. (Ex.10, ¶38.) The scientific literature shows that surgery is a safe and effective treatment for gender dysphoria. (Ex.10, ¶¶40-42, 46; Ex.8, ¶¶44-45; Ex.5, ¶32; *see also, e.g.*, Ex.202, Ex.208; Ex.178; Ex.192; Ex.198; Ex.193.)

2) <u>The quality of the evidence</u>

The quality of the evidence supporting these gender-affirming medical interventions is comparable to studies supporting other, well-established treatments and procedures. (Ex.8, ¶¶70-90; Ex.5, ¶¶18-28; Ex.11 ¶¶55, 83; Ex.10, ¶52-54; Ex.17, ¶106.) Scientific ratings of evidence generally employ stringent standards that are not satisfied for many commonly prescribed treatments. As one recent scientific article concluded, "only a minority of outcomes for health care interventions are supported by high-quality evidence." (Ex.182.) The fact that a

treatment is not supported by "high-quality" evidence does not mean that the treatment is unsupported in the literature and clinical practice, that it is experimental or investigational, or that it is not medically necessary. (Ex.14, ¶75.) That is because "[t]o determine whether a treatment is safe and effective, and whether it is experimental or investigational, we look at the whole body of research and clinical experience." (Ex.12, ¶73.) "By this measure, gender-affirming medical care as treatment for gender dysphoria has been shown to be safe, effective, and is not experimental or investigational." (*Id.*)

3) Psychotherapy alone is not an effective treatment for gender dysphoria.

There is no established safe and effective alternative to gender-affirming medical care for treating gender dysphoria. (Ex.10, ¶58; Ex.7, ¶37; Ex.11, ¶¶23-24, 47.) Defendants present psychotherapy alone as an alternative but have offered no evidence to support that claim. (Opp. Ex. D (Weida), 88:18-22.) None exists. While behavioral health interventions are an important component of gender-affirming care for many, the literature has established for decades that mental health interventions alone are insufficient to treat gender dysphoria. (Ex.7, ¶37; Ex.11, ¶48; Ex.17, ¶91; Ex.8, ¶112; Ex.10, ¶58; Ex.158, at 13.)

III. ARGUMENT

A. Defendants' determination that gender-affirming medical treatments are experimental is unreasonable, or at least, genuinely disputed.

This Court, relying on *Rush*, 625 F.2d 1150, articulated as a controlling question in this case "whether, based on current medical knowledge, the state's determination that these treatments are experimental is reasonable."[5] Here, AHCA's determination was not reasonable, or at minimum, there is a genuine issue of material fact on that point.

Defendants' own Medicaid regulations set forth six specific criteria that govern whether a service is consistent with generally accepted professional medical standards, as opposed to experimental or investigational. Fla. Admin. Code ("FAC") 59G-1.035(4); *see also K.G.*, 864 F.Supp.2d at 1321. These GAPMS factors show that the excluded services are not experimental. AHCA's skewed and incomplete

[5] Of note, *Rush* turns on the "reasonable standards" provision of the Medicaid Act, 42 U.S.C. §1396a(a)(17), whereas Plaintiffs claim that the Exclusion violates the EPSDT and comparability provisions. (Doc.1, at ¶¶275-80). Nevertheless, Plaintiffs agree that if the treatments are experimental, the Exclusion does not violate EPSDT requirements. Ex.62; *K.G. ex rel. Garrido v. Dudek*, 864 F.Supp.2d 1314, 1321 (S.D. Fla. 2012), *aff'd in part, rev'd in part sub nom. Garrido v. Dudek*, 731 F.3d 1152 (11th Cir. 2013). Regardless, Plaintiffs contend the Exclusion could violate the Medicaid Act's comparability requirement, Section 1557, and the Equal Protection Clause even if Defendants' conclusion was reasonable. The Court has acknowledged that possibility. (Doc.64, at 4.)

consideration thereof underscores that its determination was not reasonable.[6] *See K.G.*, 864 F.Supp.3d at 1322.

1) Evidence-based clinical practice guidelines

Two professional medical associations – WPATH and the Endocrine Society – have published clinical practice guidelines recommending gender-affirming care for the treatment of gender dysphoria in persons meeting specific criteria. (Ex. 34; Ex.123; Doc.193-24.) These guidelines establish the authoritative protocols for health care providers working with transgender patients. (Ex.7, ¶39; Ex.9, ¶¶48-49, 56; Ex.10, ¶24; Ex.324, at 4.) And no published clinical practice guidelines recommend the use of psychotherapy alone to treat gender dysphoria. (Ex.9, ¶14.)

Defendants' argument that the WPATH and Endocrine Society guidelines are biased and not evidence-based is without merit. First, it is *de rigeur* for professional medical associations to advocate on behalf of health care providers and patients. (Ex.14, ¶¶54-56.) That does not undermine—let alone, invalidate—their published clinical practice guidelines. Second, the fact that WPATH members drafted the Standards of Care reflects not bias or a conflict of interest, but that clinicians and researchers with the requisite expertise in transgender medicine drafted them. (Ex.12, ¶42; Ex.5, ¶¶9-11.) Third, the WPATH and Endocrine Society guidelines

[6] That AHCA even initiated the GAPMS process for these services reveals that the process was a sham, as it is not used for already-covered services. (Ex.30; Doc.120-6, 93:13-93:21.)

are based on rigorous reviews of the peer-reviewed scientific literature, as well as extensive clinical experience. (Ex.34, at App'x A; Ex.123, at 3872-73; Ex.17, ¶¶55-58; Ex.5, ¶¶18-24, 29; Ex.7, ¶¶28, 33.)

Moreover, the guidelines themselves were peer-reviewed and published in medical journals. "That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995).

Defendants' attempt to discredit these clinical practice guidelines is even more remarkable considering AHCA's prior reliance on these very guidelines during GAPMS processes. For example, the 2016 GAPMS report on puberty suppression therapy included the Endocrine Society guidelines without any suggestion that they were somehow invalid. (Ex. 240.)

2) Published reports and articles in the authoritative medical and scientific literature

Abundant "peer-reviewed scientific literature generally recognized by the relevant medical community or practitioner specialty associations" examines the use of puberty delaying medications, hormone therapy, and surgery to treat gender dysphoria. FAC 59G-1.035(4)(b).

In drafting the GAPMS Report, AHCA ignored most of the body of peer-reviewed literature on gender-affirming care. (Doc.120-6, at 147:12-147:25; Doc.84-1, ¶4.) The "assessment" by Dr. Brignardello-Peterson and Dr. Wiercioch included just 27 studies published between 2020 and 2022 (Ex.324, at 10-11.)—hardly a comprehensive review. (Ex.324, at 10-11; Ex.7, ¶¶80-81.)

The GAPMS Report and Defendants' experts attempt to discount the supportive literature they did consider as "low quality." That claim is highly misleading and at minimum surfaces a factual dispute. (Ex.324, at 11-12; Ex.5, ¶¶19-22.) While randomized trials are rated as high-quality evidence and observational studies as low-quality evidence (Ex. 5, ¶20), for ethical and practical reasons, it is not possible to conduct randomized trials involving medical treatments for gender dysphoria. (Ex.8, ¶¶74-85; Ex.10, ¶¶52-53; Ex.5, ¶¶27-28; Ex.9, ¶17; Ex.7, ¶83.) The lack of randomized trials does not render the existing research insufficient to inform clinical decision making. (Ex.324, at 13; Ex.14, ¶30; Ex.10, ¶56; Ex.13, ¶8; Ex.8, ¶¶73, 88-90.)

3) Effectiveness in improving prognosis or health outcomes

The peer-reviewed literature shows that puberty-delaying medications, hormone therapy, and surgery are: 1) safe and effective for the treatment of gender dysphoria; and 2) when used for that purpose, correlated with additional positive

health outcomes, including improved quality of life, mental health, and psychosocial functioning. (Section II.B, *supra*.)

4) Utilization trends

The GAPMS Report makes no mention of this factor. There has been a notable increase in the utilization of gender-affirming medical care over the last three decades, and AHCA's own data reflects this increase. (Ex.5, ¶¶39-40; Ex. 317; *see also* Ex.6, at ¶59.) Paradoxically, AHCA appears to view that rise in utilization as a reason to implement the Exclusion. (Ex.335.) But what it shows is that the services are commonly used and not experimental. *See Rush*, 625 F.2d at 1156, n.11 (contrasting service that is "generally accepted by the professional medical community as an effective and proven treatment for the condition for which it is being used" with a one that "is rarely used, novel, or relatively unknown").

5) Other coverage policies

AHCA's coverage exclusion is an outlier among health insurance plans. Most health plans, in Florida and elsewhere, do not have categorical transgender-specific exclusions. (Ex.6, ¶¶40-46; *id.* ¶35 (highlighting that 25 states and D.C. prohibit such exclusions in state-regulated individual and group plans); Ex.5, ¶42.) In drafting the GAPMS report, AHCA did not even review private insurance policies. (Doc.120-6, at 149:2-152:6.)

Only 9 of the 56 states and territories operating a Medicaid program exclude coverage of gender-affirming medical care. (Ex.6, ¶¶54, 57.) Even among those jurisdictions, Florida's exclusion stands apart for its breadth and scope. (Ex.6, ¶¶ 55-57.) And Florida Medicaid itself covered this care until the Exclusion was adopted. (Doc.120-6, at 66:25-68:17, 74:18-75:9, 84:2-18, 243:7-15; Ex.257; Ex.317.)

While other nations' coverage policies have never factored into the GAPMS process, Defendants argue that their determination regarding puberty-delaying medications, hormone therapy, and surgery reflects an "international consensus" on the issue. (Mot. at 24-25.) That is wrong and misleading. Defendants have not conducted a comprehensive review of other countries' policies regarding gender-affirming care. And Defendants have misrepresented those nations' policies. (Ex.14, ¶¶73-82; Doc.142-11.)

6) Recommendations or assessments by clinical or technical experts on the subject or field

Recognized clinical and technical experts in the field of transgender medicine agree that puberty-delaying medications, hormone therapy, and surgery are safe and effective treatments for gender dysphoria. (Ex.8, ¶121; Ex.9, ¶89; Ex.11, ¶¶53-54, 100; Ex.17, ¶¶23, 133; Ex.10, ¶¶23, 43, 81; Ex.324, at 4-5.) But AHCA did not seek recommendations or assessments from recognized experts; it consulted a handful of vocal opponents of gender-affirming care.

B. Plaintiffs' Medicaid Act Claims Are Viable.

1) The EPSDT and Comparability Provisions of the Medicaid Act Are Enforceable Pursuant to 42 U.S.C. § 1983.

The Court should reject Defendants' argument that Plaintiffs have no private cause of action to enforce their Medicaid Act claims. For more than 20 years, the Supreme Court has required lower courts to apply a three-prong test to determine whether a statutory provision gives rise to a federal right under 42 U.S.C. § 1983. *See Gonzaga Univ. v. Doe*, 536 U.S. 273 (2002); *Blessing v. Freestone*, 520 U.S. 329 (1997). Under *Blessing*, courts must evaluate three elements: first, Congress must intend the provision in question to benefit the plaintiff; second, the right contained in the provision must not be so "vague and amorphous" that its enforcement would strain judicial competence; third, the statute must unambiguously impose a binding obligation on the state. 520 U.S. at 340-41 (citations omitted). *Gonzaga* clarified the first prong of the test, instructing that the provision in question must contain unambiguous "right- or duty-creating language," as opposed to language with an aggregate, rather than individual, focus. 536 U.S. at 284 n.3; *see also* 42 U.S.C. §§ 1320a(2), (10) (congressional intent that provisions of the Social Security Act, of which Medicaid is a part, are privately enforceable).[7]

[7] Citing *Collins v. City of Harker Heights*, 503 U.S. 115, 119 (1992), Defendants argue that the EPSDT and comparability provisions do not create enforceable rights because § 1983 "does not provide a remedy for abuses that do not violate federal law." (Mot. at 28.) *Collins*, which did not involve a federal law, is inapposite. There,

Blessing also instructs plaintiffs to plead their complaints in "manageable analytic bites" and courts to determine whether "each separate claim" satisfies the test. *Blessing*, 520 U.S. at 342; *id*. at 340. Here, Count III of Plaintiffs' complaint alleges that the Exclusion violates the EPSDT provisions, 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B), 1396d(r)(5), and 1396a(a)(43)(C), and Count IV alleges that the Exclusion violates the comparability requirements, 42 U.S.C. § 1396a(a)(10)(B). (Doc.1, at ¶¶275-80.)

Every federal appellate court to have considered whether the EPSDT provisions are enforceable by Medicaid beneficiaries through section 1983 has concluded that they are. *See S.D. ex rel. Dickson v. Hood*, 391 F.3d 581, 602-07 (5th Cir. 2004); *Pediatric Specialty Care, Inc. v. Ark. Dep't of Human Servs.*, 293 F.3d 472, 477-79 (8th Cir. 2002); *Miller v. Whitburn*, 10 F.3d 1315, 1319-20 (7th Cir. 1993); *see also Waskul v. Washtenaw Co. Cmty. Mental Health*, 979 F.3d 426, 445-48 (6th Cir. 2020) (finding § 1396a(a)(10)(A) enforceable in non-EPSDT case); *Bontrager v. Ind. Fam. & Soc. Servs. Admin*, 697 F.3d 604, 606-07 (7th Cir. 2012) (same); *Watson v. Weeks*, 436 F.3d 1152, 1159-62 (9th Cir. 2006) (same).

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the Supreme Court held that even if the allegations in the complaint were true, there was no constitutional violation. *Id*. at 125-30. Defendants make no such argument, and this Court has found that if Defendants' determination that the excluded treatments are experimental was unreasonable, Defendants have violated the Medicaid Act. (Doc.64, at 3-6.)

Defendants' argument that these courts failed to grasp the nature of a federal right under *Gonzaga* is unfounded. Take, for example, *S.D. ex rel. Dickson v. Hood*, in which a Medicaid beneficiary sought to enforce the EPSDT provisions. Assessing the first *Blessing*/*Gonzaga* prong, the Fifth Circuit concluded that section 1396a(a)(10)(A)—which requires that the State "must provide for making medical assistance available, including at least the care and services listed in paragraph (1) through (5), (17) and (21) of section 1396d(a) of this title, to all individuals" who meet the eligibility criteria—contains "precisely the sort of 'rights-creating' language identified in *Gonzaga* as critical to demonstrating a congressional intent to establish a new right." *S.D.*, 391 F.3d at 603. The Court also found that the EPSDT provisions do not have an aggregate focus but rather are "'concerned with whether the needs of [particular individuals] have been satisfied.'" *Id*. at 604 (quoting *Gonzaga*, 536 U.S. at 275). Turning to the second prong, the Court found that enforcement of the EPSDT provisions does not "strain judicial competence; it is the sort of work in which courts engage every day." *S.D.*, 391 F.3d at 605 (quotations omitted).[8] And third, the Court concluded that the provisions impose binding requirements on participating states. *Id*. at 605-06.

[8] While Defendants claim otherwise, district courts are clearly capable of determining whether health care services are "necessary" under section 1396d(r)(5). *See, e.g.*, *K.G.*, 981 F.Supp.2d at 1291-92; *C.R. ex rel. Reed v. Noggle*, 559 F.Supp.3d 1323, 1337 (N.D. Ga. 2021).

Similarly, two circuits have concluded that the comparability provision is enforceable through section 1983.[9] *See Waskul*, 979 F.3d at 446-48; *Davis v. Shah*, 821 F.3d 231, 255 n.12 (2d Cir. 2016).[10] In *Waskul*, the Sixth Circuit found that the comparability provision – which requires that "the medical assistance made available to any individual described" must "not be less in amount, duration, or scope than the medical assistance made available to any other such individual," 42 U.S.C. § 1396a(a)(10)(B) – contains "the kind of individually focused terminology that unambiguously confers an individual entitlement under the law." *Id*. at 447 (cleaned up). The Court further determined that the provision is "amenable to judicial remedy," as it "sets forth criteria for determining whether . . . services are equitably provided," and that the provision is "couched in mandatory rather than precatory language." *Id*. at 448 (cleaned up).

These cases establish that the EPSDT and comparability provisions create individual federal rights for Medicaid beneficiaries and are thus "presumptively

[9] In *Harris v. James*, 127 F.3d 993 (11th Cir. 1997), the Eleventh Circuit held that a federal regulation itself cannot create an enforceable right under section 1983. *Id.* at 1008. The Court made clear that it was not deciding whether the statutory comparability provision could give rise to a federal right. *Id*. at 1011. Thus, *Harris* has no bearing on the issue before this Court. *See Doe v. Chiles*, 136 F.3d 709, 714-15 (11th Cir. 1998).

[10] Multiple district courts have reached the same conclusion. *See, e.g.*, *Cruz v. Zucker*, 116 F.Supp.3d 332, 345-46 (S.D.N.Y. 2015); *Women's Hosp. Found. v. Townsend*, 2008 WL 2743284 (M.D. La. July 10, 2008); *Michelle P. v. Holsinger*, 356 F.Supp.2d 763, 767-68 (E.D. Ky. 2005).

enforceable by § 1983." *Gonzaga*, 536 U.S. at 284. Defendants cannot make the "difficult showing" that Congress expressly prohibited reliance on section 1983 or that it provided a comprehensive remedial scheme intended to preclude individual suits to rebut this presumption. *Blessing*, 520 U.S. at 346. Congress has not done so. *See Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 521-22; *see also City of Rancho Palos Verdes v. Abrams*, 544 U.S. 113, 121-22 (2005).

Finally, *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320 (2015), does not implicate the enforceability of Medicaid's EPSDT and comparability provisions pursuant to section 1983. *Armstrong* concerned a Medicaid payment provision (not EPSDT or comparability) that health care providers (not Medicaid enrollees) were seeking to enforce under the Supremacy Clause (not section 1983). 575 U.S. at 323-34. Unlike the provisions at issue here, the provision at issue in *Armstrong*, 42 U.S.C. § 1396a(a)(30)(A), had been found unenforceable pursuant to section 1983 by most courts, including this one. *See Fl. Pharmacy Ass'n v. Cook*, 17 F.Supp.2d 1293 (N.D. Fla. 1998). The plurality's reasoning in *Armstrong* did not involve and certainly did not overrule the section 1983 enforcement test. *See, e.g., BT Bourbonnais Care, LLC v. Norwood*, 866 F.3d 815, 820 (7th Cir. 2017); *Legacy Cmty. Health Servs., Inc. v. Smith*, 881 F.3d 358, 373 (5th Cir. 2018).

2) The Exclusion Violates the Medicaid Act's EPSDT Requirements.

The EPSDT requirements' fundamental purpose is to ensure that Medicaid recipients under age 21 receive the "health care they need when they need it." *M.H. v. Berry*, 2021 WL 1192938, *6 (N.D. Ga. 2021) (cleaned up). Specifically, they require each state Medicaid program to cover any service allowable under § 1396d(a) if "necessary . . . to correct or ameliorate" health conditions regardless of whether the state covers the service for adults. 42 U.S.C. §§ 1396d(r)(5), 1396a(a)(10)(A), 1396d(a)(4)(B); *see, e.g.*, *Moore ex rel. Moore v.* Reese, 637 F.3d 1220, 1233-34 (11th Cir. 2011); *S.D*, 391 F.3d at 589-93. "The EPSDT obligation is thus extremely broad." *Katie A., ex rel. Ludin v. L.A. County*, 481 F. 3d 1150, 1154 (9th Cir. 2007); *see also Smith v. Benson*, 703 F.Supp.2d 1262, 1269-70 (S.D. Fla. 2018). And "there is a very strong inference to be inclusive rather than exclusive" when determining the meaning of "correct or ameliorate." *Ekloff v. Rodgers*, 443 F.Supp.2d 1173, 1180 (D. Ariz. 2006). Further, states must take the proactive step of ensuring that services determined to be medically necessary for a particular beneficiary are actually arranged for. 42 U.S.C. § 1396a(a)(43)(C); *Katie A.*, 481 F. 3d at 1158-59.

Here, the EPSDT provisions require Defendants to cover the gender-affirming services barred by the Exclusion. Puberty-delaying medications, hormone therapy, and surgery fall within the scope of benefits listed in § 1396d(a). *See* 42 U.S.C. §

1396d(a)(1) (inpatient hospital services), (2)(A) (outpatient hospital services), (5)(A) (physicians' services), (12) (prescribed drugs). And, for many transgender young people, the services are "necessary . . . to correct or ameliorate" their gender dysphoria. *Id*. § 1396d(r)(5).

Broad consensus within the medical community recognizes that these treatments can be medically necessary for transgender adolescents and young adults, based on their individual needs. Prior to implementing the Exclusion, AHCA reached the same conclusion, covering each of these services for a significant number of transgender Medicaid beneficiaries under age 21. (Ex.317.) Indeed, AHCA covered puberty-delaying medications for K.F. and S.D. (Doc.120-6, at 247:9-247:20), and hormone therapy for Mr. Rothstein (*id*. at 246:15-247:6).

3) The Exclusion Violates the Medicaid Act's Comparability Requirement.

The Medicaid Act requires AHCA to ensure that the "medical assistance made available to any [categorically needy] individual . . . shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual." 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. § 440.240. Federal regulations make clear that states "may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c).

Courts regularly hold that the comparability requirement "prohibits discrimination among individuals with the same medical needs stemming from different medical conditions." *Davis*, 821 F.3d at 258; *see also White v. Beal*, 555 F.2d 1146, 1148 (3d Cir. 1977); *Cota v. Maxwell-Jolly*, 688 F.Supp.2d 980, 993 (N.D. Cal. 2010).

While AHCA refuses to cover various surgical procedures necessary to treat gender dysphoria, the agency covers the same surgeries when necessary to treat other conditions. (Ex.4 at Definitions ¶ 13; Ex.1, at ¶¶ 8-12.) Multiple federal courts have held that such a policy violates the comparability requirement by discriminating based on diagnosis.[11] *See*, *e.g.*, *Flack v. Wis. Dep't of Health Servs.*, 395 F.Supp.3d 1001, 1019 (W.D. Wis. 2019); *Fain v. Crouch*, 2022 WL 3051015, *13 (S.D. W. Va. 2022).

The same reasoning applies to the categorical exclusion of hormone therapy. AHCA does not cover testosterone or estrogen when necessary to treat gender dysphoria but covers the same prescription drugs when necessary to treat other conditions. (Ex.4, ¶13; Ex.1, ¶8.) While Defendants argue that these uses are not

[11] Defendants argue that there is no "equivalence between" a mastectomy performed to treat gender dysphoria and a mastectomy performed to treat breast cancer because in the breast cancer context, "diseased breast tissue is removed from the body." (Mot. at 28.) Defendants do not explain why that distinction is meaningful and ignore that a mastectomy is routinely performed (and covered by AHCA) in patients whose breast tissue is not "diseased." (Ex.10, ¶¶14, 24.)

equivalent for purposes of Medicaid coverage, the prescription drug provision of the Medicaid Act indicates otherwise. The statute requires states to cover all FDA-approved drugs when they are prescribed for a "medically accepted indication," subject to certain limited inapplicable exceptions.[12] 42 U.S.C. §§ 1396r-8(k)(2), 1396r-8(d)(1)(B); Ex.63, at 2; *see also Edmonds v. Levine*, 417 F.Supp.2d 1323, 1338 (S.D. Fla. 2006). A "medically accepted indication" is a use that is FDA-approved or "supported by one or more citations included or approved for inclusion in any of the compendia" listed in the Medicaid Act. 42 U.S.C. § 1396r-8(k)(6); *see also id*. § 1396r-8(g)(1)(B)(i) (listing three compendia, including DRUGDEX). Thus, under the Medicaid Act, a use that is FDA-approved stands on equal footing with a use that is supported by citation in a compendium. *See Edmonds*, 417 F.Supp.2d at 1337 (holding that AHCA cannot "substitute its own judgment for that of Congress" and deny coverage for uses of a prescription drug that are supported by citation in a compendium).

Here, citations in DRUGDEX support the use of various forms of testosterone and estrogen to treat gender dysphoria. Ex.25, at 18-21, 23-26, 29-36; Ex.26at 23-25, 27-28, 34-35. *See Dobson v. Sec'y of Health & Hum. Servs.*, 2022 WL 424813 at *7 (11th Cir. 2022) (interpreting the phrase "supported by one or more citations"

[12] Conversely, nothing in the Medicaid Act prohibits states from covering FDA-approved drugs when they are prescribed for a use that is not FDA-approved or supported by citation in a compendium.

in § 1396r-8(k)(6) to mean a citation "tend[s] to show or help[s] prove the efficacy and safety of the prescribed off-label use"). But while that use is on par with any FDA-approved use for purposes of Medicaid coverage, Florida only covers testosterone for FDA-approved indications. (Ex.27; Ex.25, at 10-11.) Moreover, as a matter of practice, AHCA covers testosterone cypionate, testosterone enanthate, and estrogen for ***absolutely any use*** – whether the use is FDA-approved, supported by citation in a compendium, or not – other than to treat gender dysphoria. (Ex.28.)[13] Thus, AHCA is excluding coverage for only one "medically accepted indication" (gender dysphoria) and providing coverage for every other indication, even those that are not medically accepted.

C. The Exclusion Violates Section 1557 of the ACA.

Section 1557 creates "an affirmative obligation not to discriminate in the provision of health care." *Schmitt v. Kaiser Found. Health Plan of Wash.*, 965 F.3d 945, 955 (9th Cir. 2020). Section 1557 requires, in relevant part, that "[a]n individual shall not, on the ground prohibited under … title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), … 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." 42

[13] https://ahca.myflorida.com/content/download/8681/file/PDL.pdf.

U.S.C. § 18116(a). Title IX prohibits discrimination "on the basis of sex." 20 U.S.C. § 1681.

"To state a claim under [Section 1557], a plaintiff is required to show that he or she (1) was a member of a protected class, (2) qualified for the benefit or program at issue, (3) suffered an adverse action, and (4) the adverse action gave rise to an inference of discrimination." *Griffin v. Gen. Elec. Co.*, 752 F.App'x 947, 949 (11th Cir. 2019). Plaintiffs address each element in turn.

1) The Exclusion discriminates against Plaintiffs based on sex.

The Exclusion discriminates based on sex in three distinct ways. First, the Exclusion speaks in explicit gendered terms and *facially discriminates* based on sex. Second, the Exclusion discriminates based on sex stereotypes relating to a person's sex assigned at birth. And third, the Exclusion discriminates based on sex because it discriminates based on transgender status.

a) The Exclusion facially discriminates based on sex.

On its face, the Exclusion discriminates based on sex. The Exclusion explicitly precludes Medicaid coverage for "services for the treatment of *gender* dysphoria," including "*[s]ex* reassignment surgeries" and any "procedures that alter primary or secondary *sexual* characteristics." FAC 59G-1.050(7). "A facial inquiry is what it sounds like: a review of the language of the policy to see whether it is facially neutral or deals in explicitly racial or gendered terms.'" *Kadel*, 2022 WL

3226731, at *18 (cleaned up).

Here, one cannot "'try writing out instructions' for which treatments are excluded 'without using the word[] … sex (or some synonym).'" *Kadel*, 2022 WL 3226731, at *19 (quoting *Bostock*, 140 S. Ct. at 1746). "It can't be done." *Bostock*, 140 S. Ct. at 1746. It is impossible to determine whether a particular treatment is for "*gender* dysphoria,"[14] leads to ""*[s]ex* reassignment," or "alter[s] primary or secondary *sexual* characteristics"—and thus, whether the Exclusion applies—without comparing the member's sex assigned at birth to how it might be impacted by the treatment. *Kadel*, 2022 WL 3226731, at *19.

A barrage of case law examining similar exclusions supports this conclusion. *See, e.g.*, *Fain*, 2022 WL 3051015, at *8; *Fletcher v. Alaska*, 443 F.Supp.3d 1024, 1027, 1030 (D. Alaska 2020); *Flack v. Wisconsin Dep't of Health Servs.*, 395 F.Supp.3d 1001, 1019-22 (W.D. Wis. 2019); *Boyden v. Conlin*, 341 F.Supp.3d 979, 1002-03 (W.D. Wis. 2018).

The Eleventh Circuit's decision in *Adams by & through Kasper v. Sch. Bd. of St. Johns Cnty.*, 57 F.4th 791 (11th Cir. 2022) (en banc), does not affect this straightforward analysis. In *Adams*, the Eleventh Circuit was concerned not with whether the policy at issue discriminated based on sex but "whether discrimination based on biological sex necessarily entails discrimination based on transgender

[14] Gender dysphoria necessarily considers an individual's sex assigned at birth.

status." *Id.* at 809. Indeed, the court found that a "bathroom policy requir[ing] 'biological boys' and 'biological girls'—in reference to their sex determined at birth—to use either bathrooms that correspond to their biological sex or sex-neutral bathrooms," *id.* at 801, facially "classifie[d] on the basis of biological sex." *Id.* at 803.[15]

Because a beneficiary's sex (however, one defines it) plays "an unmistakable and impermissible role in the" decision to deny Medicaid coverage under the Exclusion, the Exclusion facially discriminates based on sex. *Kadel*, 2022 WL 3226731, at *28.[16]

b) The Exclusion discriminates based on sex because it discriminates based on sex stereotypes.

Excluding coverage for gender-affirming medical care because it "*alter[s]* primary or secondary *sexual* characteristics," FAC 59G-1.050(7), "entrenches" the sex-stereotyped "belief that transgender individuals must preserve the genitalia and other physical attributes of their [sex assigned at birth] sex over not just personal preference, but specific medical and psychological recommendations to the

[15] Section 1557 only incorporated the grounds and enforcement mechanisms of Title IX, not any of its exemptions or carve-outs. *See Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 485 F.Supp.3d 1, 43 (D.D.C. 2020).

[16] The holding in *Lange v. Houston County, Georgia*, 499 F.Supp.3d 1258, 1275 (M.D. Ga. 2020) ("*Lange I*"), is unavailing. (Doc.137 at 2-3.) *Lange I* is particularly unpersuasive for Plaintiffs' statutory claims, where Congress has directly renounced *Geduldig*'s reasoning.

contrary." *Boyden v. Conlin*, 341 F.Supp.3d 979, 997 (W.D. Wis. 2018). This is a "form of sex stereotyping where an individual is required effectively to maintain his or her natal sex characteristics." *Id.*; *see also Flack*, 328 F.Supp.3d at 951. It "is textbook sex discrimination." *Kadel*, 2022 WL 3226731, at *19.

Accordingly, courts throughout the country have found similar discrimination against transgender people to be rooted in impermissible sex stereotyping. *See, e.g.*, *Kadel v. Folwell*, 446 F.Supp.3d 1, 14 (M.D.N.C. 2020); *Toomey v. Arizona*, 2019 WL 7172144, at *6 (D. Ariz. Dec. 23, 2019).

This principle accords with longstanding Eleventh Circuit precedent that "[a]ll persons, whether transgender or not, are protected from discrimination on the basis of [a sex stereotype]." *Adams*, 57 F.4th at 813 (quoting *Glenn v. Brumby*, 663 F.3d 1312, 1318-19 (11th Cir. 2011)). *Adams* does not change this result. Unlike in *Adams*, the Exclusion hinges on prohibiting coverage for procedures that "*alter* primary or secondary *sexual* characteristics," FAC 59G-1.050(7), and "services for the treatment of *gender* dysphoria," FAC 59G-1.050(7), which by definition refers to the psychological distress that results from an *incongruence between one's sex assigned at birth and one's gender identity*. (Ex.33).

c) The Exclusion discriminates based on sex because it discriminates based on transgender status.

In *Bostock*, the Supreme Court explained that "it is impossible to discriminate against a person for being … transgender without discriminating against that

individual based on sex." 140 S.Ct. at 1741. And it is settled law that a policy that discriminates based on conduct or characteristics that either define or are closely correlated with a particular group facially discriminates against that group. *See, e.g.*, *Christian Legal Soc'y v. Martinez*, 561 U.S. 661, 689 (2010); *Lawrence v. Texas*, 539 U.S. 558, 583 (2003) (O'Connor, J., concurring).

Here, only transgender people have gender dysphoria. *See Fain*, 2022 WL 3051015, at *6; *see also C.P.*, 2022 WL 17788148, at *6; *Kadel*, 2022 WL 11166311, at *4; Section II(A), *supra*. Thus, the medical care singled out by the Exclusion is medical care that only transgender people need or seek. *See Fain*, 2022 WL 3051015, at *8; *Toomey*, 2019 WL 7172144, at *6; *Flack*, 328 F.Supp.3d at 950.

2) Plaintiffs have suffered an adverse action giving rise to an inference of discrimination.

Plaintiffs suffered an "adverse action" due to the Exclusion. Because of the Exclusion, Plaintiffs have lost Medicaid coverage for necessary medical treatment recommended by their doctors that would otherwise be covered. Defendants promulgated the Exclusion with discriminatory intent to achieve a discriminatory effect. The Exclusion bans coverage of medically necessary care for the treatment of gender dysphoria, which only transgender persons need. *See also Kadel*, 2022 WL 3226731, at *20.

Moreover, where the state "intentionally penalizes a person identified as male

at birth for . . . actions that it tolerates in [someone] identified as female at birth"—here, pursuing medical intervention to affirm a female identity—"sex plays an unmistakable and impermissible role." *Bostock*, 140 S.Ct. at 1741-42. Put another way, whether coverage is prohibited turns explicitly on a person's sex assigned at birth.

D. The Exclusion Triggers Heightened Scrutiny Under the Equal Protection Clause and Defendants Have Not Met Their Burden.

None of Defendants' arguments undermine the triable issue that Defendants' Exclusion violates Equal Protection because it discriminates based on sex and transgender status. And because the Exclusion discriminates based on sex and transgender status, Defendants must show that an "exceedingly persuasive justification" supports the Exclusion. *United States v. Virginia*, 518 U.S. 515, 531 (1996).

1) The Exclusion discriminates based on sex, triggering heightened scrutiny.

As outlined above, the Exclusion (1) *facially discriminates* based on sex; (2) discriminates based on sex stereotypes relating to a person's sex assigned at birth; and (3) discriminates based on sex because it discriminates based on transgender status.

Defendants argue that *Adams* held that "sex-based discrimination is discrimination based on biological sex" and that the Exclusion "does not make a

distinction based on biological sex." (Mot. at 32.) Not so, *see supra*. But even viewed in that (incorrect) framing, the Exclusion discriminates based on sex because the Exclusion prohibits coverage of procedures that ""*alter* primary or secondary *sexual characteristics*." FAC 59G-1.050(7). Such characteristics are biological.

Defendants further argue that rational basis applies because the Exclusion purportedly discriminates not based on sex, but on "medical diagnosis." (Mot. at 32.) But this does not save the Exclusion, either. Federal courts have rejected identical arguments. *Kadel*, 446 F.Supp.3d at 18. Only transgender people need coverage for "services and treatment for *gender dysphoria*" because only transgender people are diagnosed with gender dysphoria.

Defendants also argue that because the Exclusion is applied to both transgender people who were assigned female at birth and those who were assigned male at birth, it does not discriminate "based on sex." (Mot. at 32.) But that one group of transgender people are not treated worse than another does not change the fact that the Exclusion discriminates based on sex. "[T]he Equal Protection Clause, extending its guarantee to any person, reveals its concern with rights of individuals, not groups." *J.E.B. v. Alabama ex rel. T.B.*, 511 U.S. 127, 152 (1994) (Kennedy, J., concurring) (cleaned up); *see also Loving v. Virginia*, 388 U.S. 1, 8 (1967).

Finally, Defendants' reliance on *Geduldig v. Aiello*, 417 U.S. 484 (1974), is unavailing.

First, the Exclusion explicitly and facially classifies based on sex. *See Fletcher*, 443 F.Supp.3d at 1027, 1030; *see also Whitaker v. Kenosha Unified Sch. Dist. No.1 Bd. of Educ.*, 858 F.3d 1034, 1051 (7th Cir. 2017). Every person to whom the Challenged Exclusion applies is therefore discriminated against because of sex.

Second, *Geduldig* only held that an exclusion of pregnancy from a disability benefits program with no showing of "pretext" is not *per se* "discrimination against the members of one sex." 417 U.S. at 496 n.20. But "[s]ome activities may be such an irrational object of disfavor that, if they are targeted, and if they also happen to be engaged in exclusively or predominantly by a particular class of people, an intent to disfavor that class can readily be presumed." *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993). Here, the Exclusion categorically excludes gender-affirming care from coverage, "which is only sought by transgender individuals." *Brandt v. Rutledge*, 2021 WL 3292057, at *2 (E.D. Ark. Aug. 2, 2021). That is precisely what *Geduldig* and *Bray* prohibit.

Third, the centrality of gender transition to transgender identity distinguishes this case from *Geduldig*. Unlike the pregnancy exclusion in *Geduldig*, the Exclusion here is based on a characteristic that defines membership in the excluded group. Pregnancy is not the defining characteristic of a woman. Living in accord with one's gender identity rather than birth-assigned sex is the defining characteristic of a transgender person. *See*, *e.g.*, *Glenn*, 663 F.3d at 1316.

2) The Exclusion discriminates based on transgender status and therefore independently triggers heightened scrutiny.

Defendants misconstrue the reach of the *Adams* case again in their assertion that the court "explained what constitutes unconstitutional discrimination based on transgender status." (Mot. at 32.) But the *Adams* court did no such thing. True, the *Adams* court expressed in *dicta* "doubt that transgender persons constitute a quasi-suspect class" because "the Supreme Court has rarely deemed a group a quasi-suspect class." 57 F.4th at 803 n.5. But that does not mean that "[t]ransgender individuals [] aren't entitled to heightened constitutional review per se." (Mot. at 33.)

Discrimination based on transgender status is separately entitled to, at least, heightened scrutiny because transgender people meet all of the indicia required. *See Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 607 (4th Cir. 2020); *see also Karnoski v. Trump*, 926 F.3d 1180, 1200 (9th Cir. 2019). "[T]ransgender people as a class have historically been subject to discrimination or differentiation; … they have a defining characteristic that frequently bears no relation to an ability to perform or contribute to society; … as a class they exhibit immutable or distinguishing characteristics that define them as a discrete group; and … as a class, they are a minority with relatively little political power." *Evancho v. Pine-Richland Sch. Dist.*, 237 F.Supp.3d 267, 288 (W.D. Pa. 2017).

3) There is a genuine dispute of material fact as to whether Defendants engaged in purposeful discrimination.

Defendants must "treat all persons similarly situated alike" or "avoid all classifications that … that reflect a bare desire to harm a politically unpopular group." *Glenn*, 663 F.3d at 1315 (cleaned up). That said, because the Exclusion is facially discriminatory, a showing of intentional discrimination is unnecessary. *See Cmty. Servs., Inc. v. Wind Gap Mun. Auth.*, 421 F.3d 170, 177 (3rd Cir. 2005).

Determining discriminatory intent is guided by an eight-factor test. *See League of Women Voters of Fla., Inc. v. Fla. Sec'y of State*, 32 F.4th 1363, 1373 (11th Cir. 2022) (cleaned up). Here, these factors are met.

- *The impact of the challenged law*: "[T]he Exclusion impacts only transgender individuals—that provides some circumstantial evidence of intentional discrimination." *Lange v. Houston Cnty., Georgia*, 608 F.Supp.3d 1340, 1355 (M.D. Ga. 2022) ("*Lange II*"). *See also supra*.
- *The historical background:* Here, Florida Medicaid covered medical treatment for gender dysphoria, until 2022, when Florida's government adopted a blizzard of anti-LGBTQ laws. This includes restrictions on the coverage and provision of gender-affirming care, "Don't Say or Trans" laws, banning of books discussing LGBTQ identities, bans on drag performances, and more. (Opp. Ex. E; Doc.1, ¶¶126(a)-(f).)

- *The specific sequence of events leading up to its passage:* Plaintiffs have laid out circumstantial evidence concerning this factor, including the coordination with the Governor's Office, FDOH, and anti-transgender activists.
- *Procedural and substantive departures:* Plaintiffs have documented a litany of procedural and substantive departures, including AHCA's: (1) hiring of outside consultants, which AHCA had never done for a GAPMS (Doc.120-6, at 137:10-12, 139:17-138:3), all of whom opposed gender-affirming care (Ex.324, at 7-9); (2) not enlisting or even considering any consultant supporting the provision of gender-affirming care (Doc.120-6, 135:10-15; Doc.120-9, 112:5-23); (3) employing an unprecedented GAPMS process for a treatment already covered (Doc.120-6, 93:13-21); (4) bypassing the employees typically tasked with conducting GAPMS processes (Doc.120-9, 85:16-19); and (5) closely coordinating with and having the process originate from other agencies like FDOH and the Governor's Office, (Doc.120-6, at 89:18-19, 90:25-91:1, 92:2-4; Opp. Ex. D (Weida), 15:2-18:3; Ex.302).
- *The contemporary statements and actions of key legislators:* Plaintiffs have pointed to some of these demeaning and offensive statements. (Doc.1, ¶126(g).)

- *The foreseeability of the disparate impact and knowledge of that impact:* The impact on transgender Medicaid beneficiaries was both foreseeable and communicated to Defendants during the notice-and-comment process. (Ex. 323, at 6; Ex. 324, at 2; Ex. 325, at 3-4).
- *The availability of less discriminatory alternatives*: "There is no evidence [Defendants] considered less discriminatory alternatives." *Lange II*, 608 F.Supp.3d at 1356.

When it comes to whether Defendants engaged in purposeful discrimination, "the facts are hotly disputed," at least. *Lange II*, 608 F.Supp.3d at 1356.

IV. CONCLUSION

For the foregoing reasons, the Court should deny Defendants' Motion.

Respectfully submitted this 28th day of April 2023.

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CERTIFICATE OF WORD COUNT

As required by Local Rule 7.1(F), I certify that this Motion contains 7,999 words.

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of April 2023, a true copy of the foregoing has been filed with the Court utilizing its CM/ECF system, which will transmit a notice of electronic filing to counsel of record for all parties in this matter registered with the Court for this purpose.

/s/ Omar Gonzalez-Pagan
Counsel for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, *et al.*, *Plaintiffs*, v. JASON WEIDA, *et al.*, *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

DECLARATION OF OMAR GONZALEZ-PAGAN

Pursuant to 28 U.S.C.§ 1746, I, Omar Gonzalez-Pagan, do hereby declare as follows:

1. I am over 18 years of age.

2. I am Counsel at Lambda Legal Defense and Education Fund, Inc. and serve as counsel of record for the plaintiffs in the above-captioned matter.

3. I have personal knowledge of the stated herein, except those stated on information and belief, and if called upon, could and would testify competently to them.

4. I submit this declaration in support of Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion for Summary Judgment.

5. Attached as **Exhibit A** is a true and accurate copy of an email with the subject line "A Message from your WPATH President, Dr. Marci Bowers" sent to WPATH members on April 21, 2023, as publicly posted on https://listloop.com/wpath/mail.cgi/archive/adhoc/20230421130649/.

6. Attached as **Exhibit B** is a true and correct copy of article "Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand," published in the peer-reviewed academic Journal of New Zealand Medical Journal in December 2018.

7. Attached as **Exhibit C** is a true and correct copy of the publication "Primary Care Gender Affirming Hormone Therapy Initiation Guidelines: Aotearoa New Zealand guidelines for commencing GAHT for adults in primary care," published in March 2023.

8. Attached as **Exhibit D** is a true and correct copy of excerpts of the transcript of the deposition of Jason Weida on April 24, 2023 taken in relation to the above-captioned matter.

9. Enclosed as **Exhibit E** is a true and correct copy of the press release issued by Equality Florida on April 11, 2023 announcing their "TRAVEL ADVISORY: FLORIDA MAY NOT BE A SAFE PLACE TO MOVE OR VISIT."

I declare under the penalty of perjury that the foregoing is true and correct.

Dated this 28th day of April 2023.

/s/ Omar Gonzalez-Pagan
Omar Gonzalez-Pagan

A Message from your WPATH President, Dr. Marci Bowers

From: "WPATH" <wpath@PROTECTED>
Subject: A Message from your WPATH President, Dr. Marci Bowers
Date: April 21st 2023

WPATH
WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

April 21, 2023

Dear Colleagues,

In the United States, 2023 has been a difficult year thus far for trans rights, to say the least. Although anti-trans sentiment has simmered for years, the exponential rise in TGD identification among adolescents has triggered unprecedented attacks against all things trans. More than 400 anti-transgender bills, particularly in conservative states, see anti-transmessaging as a winning political posture for some. Eleven (11) states alone have already banned or restricted gender affirming care for gender diverse adolescents. Last week, Missouri became the first state to attempt gender enforcement on *adult* populations when attorney general, Andrew Bailey, issued an 'emergency declaration' that added draconian new hurdles for adult trans care to its adolescent ban. It is already probable that gender affirming care will be a wedge issue in the 2024 US election cycle.

Globally, many of the arguments used here in the US to ban transgender care have been cherry-picked or use narrowly excerpted language for restrictions that have been implemented in gender

services policies in Sweden and the UK---'lack of evidence', 'experimental' and 'focus on mental health'. They also ignore European countries where access to trans care has recently expanded (Spain, Portugal, and France). And unlike Swedish and British restrictions---which do not end treatment but rather, make research participation compulsory in order to answer remaining questions---conservative US policy makers have no interest in research on TGD medical therapy; they only care about shutting it down. Rather than safeguard young people by outlawing automatic weapons and high-capacity munitions, conservatives feel that banning trans care and removing LGBTQ-themed books will better protect society.

Caught in the middle are TGD individuals, providers, and families, who are now in anguish here in US-affected states. WPATH membership continues to receive stories of growing despair, clinics closing, families moving or seeking healthcare out of state [see link]. (https://www.vice.com/en/article/wxj5pw/florida-lgbtq-clinics-anti-trans-laws) Suicidality and desperation are again, needlessly in play.

Telemedicine and the emergence of sanctuary US states (California, Minnesota, and Colorado) that have chosen to defend access to trans care, provide some hope. But real progress on the road back will be difficult until the flow of anti-trans legislation slows and then stops. If there is one reductionist word that WPATH does not deserve, it is advocacy--all scientific organizations participate in some form of advocacy.

That said, the scientific and biological arguments can all be won and should continue to be argued. In a recent interview, Dr. Eli Coleman responded "*WPATH followed a rigorous, multi-year process and was based on the best available scientific evidence and weighing all risks and benefits to arrive at the recommendations in our Standards of Care 8 guidelines. Our multi-step methodology is clearly set forth in the guidelines themselves. When you compare the process we followed, the SOC8 has by far the more robust methodology than any other trans health related guidelines. We had 119 experts from around the world involved, developed PICO questions which formed the basis of systematic reviews, used a consensus-based approach (Delphi) involving all committee members to arrive at our conclusions and then graded the strength of our recommendations. We had an extensive period of public comment on a draft of the SOC8 and this input was checked against the available evidence resulting in the final version of the SOC8. The rationale for our recommendations is clearly explicated in the SOC8 referencing the extant research. WPATH stands behind our process and conclusions.*"

The recent New York Times opinion piece, "*What Decades of Providing Trans Care Have Taught Me*", was my take on the situation and can be read here (https://wpath.org/media/cms/Documents/NYT%20OpEd%20M%20Bowers%20Apr%201%202023.pdf).

The **first step** on the road back, in my opinion, will be to allow the public to hear the anguish and the stories of those in pain as a direct result of anti-trans legislation, difficult as this will be to watch---and to pin this pain upon those legislators and policy makers who have inflicted the agony. In my interview

with CBS Evening News to be aired any day, I called it 'legislative cruelty'. The moment we are in reminds me of San Francisco's Harvey Milk and his plea to gay persons to come out. We need to be heard—trans persons, allies, parents, families, politicians, clergy---those who have been hurt and those who know us.

The **second step** on the road back will be to unite disparate causes in our fight against a common foe. An attack on trans care is an attack on women. It is an attack on black people, brown people, and Asian people. It is an attack on Jewish, Muslim, Hindi, Sikh, and true Christian communities. It is an attack on diversity and all of the ideals that diversity holds. It is an attack on us all. A majority of Americans favor access to adolescent trans care see link to NPR-Marist poll (https://maristpoll.marist.edu/polls/npr-pbs-newshour-marist-poll-transgender-rights-april-2021/) but the support is regional and it is thin. We need to better explain what adolescent TGD care looks like, why it is effective and indicated and who these patients really are. Anti-trans legislation needs to be fought with every voice, every thought, every inclination by all who know it. We need to make anti-trans legislation a *losing political issue*.

Already lost in this debate is the deplorable state of health and sex education throughout the Southern US. Furthering this ignorance, books are now banned, especially and specifically those with LGBTQI themes. It is of little surprise to many that persistent rates of new HIV infection, incest, and STDs remain highest where sex education is lowest, most in states where anti-trans legislation has been proposed.

And finally, '*What is a Woman?*', the title to a trite and condescending 2022 American movie produced by conservative Matt Walsh, whose edits left out any answer to the question, as though the answer was obvious. What was cut from the piece was reality; that nature lacks a definitive answer to the question. Because there is no biological measure----not chromosomes, not hormones, not anatomy nor any of the six other biological markers of sex---a woman is what society sees based upon the gender identity the individual projects. No measure in biology gets it right every time. For every rule, there is an exception. Sex and gender are complicated and diverse---but let us explain the phenomena, not allow the issues to be put back in the societal closet. Ultimately, what terrifies conservatives most is that gender diversity is a force of nature that can no longer be contained by religious conscription or enforcement of a gender binary.

Killarney, Ireland and EPATH will again surely exceed expectations as we meet April 26-28, 2023.

Until we all dance once more….

Marci L Bowers, MD

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Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand

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ABSTRACT

Internationally and within Aotearoa, New Zealand, there has been a substantial increase in the demand for gender affirming healthcare over the past decade. It is likely that this level of referrals to health services will continue in the foreseeable future. The Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand were developed following the recognition that the previous good practice guide required updating to be in step with current practice and international standards. This article presents a summary of the guideline focusing on puberty blockers, hormonal therapies, access to surgery and other gender affirming healthcare. We hope these guidelines will support the development and provision of services providing gender affirming healthcare around the country and provide helpful guidance to all health professionals involved in the care of trans people.

Internationally and within Aotearoa, New Zealand, there has been a substantial increase in the demand for gender affirming healthcare over the past decade. The Youth'12 survey estimated that approximately 1.2% of adolescents in Aotearoa, New Zealand identify as transgender.[1] As societal acceptance for trans people grows, it is likely that this level of referrals to health services will continue in the foreseeable future.[1,2]

Transgender healthcare is rapidly evolving. Table 1 includes some of the terminology healthcare professionals may encounter. The World Professional Association of Transgender Health (WPATH) is the international body responsible for producing standards of care (SOC) for transgender health based on international clinical consensus.[3] These are currently being revised and version 8 will inform practice internationally and in Aotearoa, New Zealand.

The Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand[4] were developed following the recognition that the previous good practice guide required updating to be in step with current practice and international standards. This guideline is not intended to replace the WPATH SOC but to present additional guidance for the provision of gender affirming healthcare in Aotearoa, New Zealand. This article presents a summary of gender affirming healthcare discussed in the larger document.

Methods

This guideline was produced in collaboration with trans community members and after consultation with many services and health professionals throughout Aotearoa, New Zealand, who work professionally

Table 1: Terminology.

Gender identity
A person's concept of their self as male, female, a blend of both or neither. Gender identity can be the same as, or different to, the sex assigned at birth.
Gender expression
The external presentation of one's gender. This can be expressed through one's name, clothing, behaviour, hairstyle, voice or any other way. A person's gender expression may or may not conform to socially defined behaviours and characteristics typically associated with being either solely masculine or feminine.
Gender diverse
A term to describe people who do not conform to their society or culture's expectations for males and females. Being transgender can be one way of being gender diverse, but not all gender diverse people identify as being transgender and vice versa. Gender creative or gender expansive are other similar terms that are used when referring to children.
Assigned male at birth
A person who was thought to be male when born and initially raised as a boy.
Assigned female at birth
A person who was thought to be female when born and initially raised as a girl.
Trans or transgender
A term for someone whose gender identity does not align with their sex assigned at birth. This term is often used as an umbrella term, recognising that people may describe themselves in many ways including the use of indigenous terms such as; whakawāhine, tangata ira tāne, tāhine (Māori), mahu (Hawai'i and Tahiti), vakasalewalewa (Fiji), palo- pa (Papua New Guinea), fa'afafine (Samoa), akava'ine (Rarotonga), fakaleiti or leiti (Tonga), fakafifine (Niue).
Cis or cisgender
A term for someone whose gender identity aligns with their sex assigned at birth.
Trans boy/male/man
A term to describe someone, assigned female at birth, who identifies as a boy/male/man.
Trans girl/female/woman
A term to describe someone, assigned male at birth, who identifies as a girl/female/woman.
Non-binary
A term to describe someone who doesn't identify exclusively as a man or a woman. There are many different ways that people may be non-binary male or female.
Gender dysphoria
A term that describes the distress experienced by a person due to the incongruence between their gender identity and their sex assigned at birth.
Social transition
The process by which a person changes their gender expression in social situations to better align with their gender identity.
Gender affirming healthcare
Healthcare that is respectful and affirming of a person's unique sense of gender and provides support to identify and facilitate gender healthcare goals. These goals may include supporting exploration of gender expression, support around social transition, hormone and/or surgical interventions. This may also involve providing support to whānau, caregivers or other significant supporting people.
Pronoun
A word used in place of a noun (or name). Pronouns include: he/him, she/her or they/them. Other gender neutral pronouns in use include ze and hir.

to advance healthcare for trans people. While regional differences in practice exist, the document describes principles and approaches that encompass this diversity. The gender affirming hormonal therapy guidelines in this document draw significantly on those published by the Endocrine Society.[5]

Principles of gender affirming healthcare

These guidelines are based on the principle of Te Mana Whakahaere; trans people's autonomy of their own bodies, represented by healthcare provision based on informed consent.[6] The informed consent process involves several conversations between the trans person and clinician(s) before starting treatments that have an irreversible component to increase certainty that they are adequately prepared and are making a fully informed decision.[7]

The use of Sir Mason Durie's Te Whare Tapa Whā as a framework highlights the equal importance of spiritual, family, mental and physical health.[8] Health providers have a duty to approach care holistically and in partnership.[4] Involving practitioners with expertise in mental health is important for two reasons. Firstly, mental health professionals with the appropriate skills can assist with the informed consent process. Secondly, it is increasingly recognised that discrimination and marginalisation experienced by trans people contributes to high rates of anxiety and depression.[9–11] The Youth'12 survey highlighted the mental health disparities experienced by trans young people compared to their cisgender peers with 41% vs 12% experiencing significant depressive symptoms and 20% vs 4% reporting an attempted suicide, respectively, in the past 12 months.[1] While there is no New Zealand data for older trans people it is likely that they also experience elevated rates of anxiety and depression as overseas studies have found.[9] Because of this, health services that have good links with peer support groups and mental health professionals will be more responsive to the needs of trans people accessing gender affirming healthcare.

Each person presenting to a health service has their own unique clinical presentation and needs. While many trans people will benefit from hormone therapies and surgical interventions, some may require only one or neither of these options.[12] Clinicians should not assume that everyone wants to conform to binary (male or female) gender norms and be open to gender affirming healthcare that aligns with non-binary identities.[3] When outer gender expression is congruent with an inner sense of self, most trans people will find increased comfort, confidence and improved function in everyday life.[13] Avoiding harm is a fundamental ethical consideration for health professionals when considering healthcare. Withholding or delaying gender affirming treatment is not considered a neutral option, as this may cause harm by exacerbating any gender dysphoria or mental health problems. This is no different from harm that can be caused by withholding or delaying other medically necessary care.

Gender affirming healthcare

Gender affirming healthcare may include provision of puberty blockers in children and adolescents, and hormone therapy in older adolescents and adults. The criteria for access to gender affirming hormones are persistent well-documented gender dysphoria, the capacity to make a fully informed decision and to consent for treatment, 16 years of age or older, and significant medical or mental health concerns must be reasonably well controlled. However, it is increasingly recognised that there may be compelling reasons, such as final predicted height, to initiate hormones prior to the age of 16 years for some individuals, although there is as yet little published evidence to support this.[5] There is no upper age limit to starting gender affirming hormone therapy. These criteria reflect the WPATH SOC which emphasise that having medical or mental health concerns does not mean gender affirming care cannot be commenced, rather that these need to be managed as part of an informed consent process.[3] This readiness can be assessed by a prescribing provider or mental health professional who is experienced and competent at working with trans people.

The informed consent process for readiness for puberty blockers, gender affirming hormones or surgery are detailed in the WPATH SOC.[3] The main components include assessing gender dysphoria, discussing social transition, gender expression and physical transition options, and providing a space to consider the implications of these options, with regard to safety, expectations

and impact on social, emotional, academic/occupational functioning. For all trans, particularly children and young people, consideration of psychosocial supports, especially family/whānau support is essential. Provide support to families and additional guidance if this support is absent. If this aspect of the assessment is not completed by a medical professional, then communication between the mental health professional and the prescriber/surgeon should occur to ensure a holistic approach to assessment.

Fertility preservation should be discussed prior to starting puberty blockers, gender affirming hormone therapy or gonadectomy.[5] Refer to local fertility services for access to funded cryopreservation of gametes. For those starting feminising hormones, who have reached at least Tanner stage 3, it is recommended that cyropreservation of sperm be considered.[5] For those in early adolescence (Tanner stage 2–3), collection of mature sperm will not usually be possible as mature sperm are produced from mid puberty (Tanner stage 3–4).[7] For those starting masculinising hormones, the option of egg or ovarian tissue storage should be discussed, recognising however, that this involves invasive procedures that are not currently funded where reproductive organs remain. There is no current evidence to suggest that testosterone exposure affects the likelihood of future healthy egg harvesting, and there are many reports of trans men who have ceased testosterone, for the purposes of achieving conception, having successful pregnancy outcomes.[14] However, it is unknown what effect the duration of testosterone therapy has on ovarian function.

Testosterone therapy does not provide a guarantee of adequate contraception and is contraindicated in pregnancy because of potential harm to the fetus from the androgenising effects of treatment.[15] Provide contraceptive advice prior to starting testosterone. Progesterone based Long Acting Reversible Contraception (LARCs) such as (Depo provera®, Jadelle®) or Intrauterine Devices (IUDs) such as Mirena®/ IUCDs are suitable options. Note that IUD insertion may be technically more challenging in those with a degree of cervical atrophy from testosterone therapy.

Puberty suppression using gonadotropin releasing hormone (GnRH) agonists

Puberty blockers can be prescribed from Tanner stage 2 to suppress the development of secondary sex characteristics and may be still beneficial when prescribed later in puberty to prevent ongoing masculinisation/feminisation.[5] Puberty blockers are considered to be fully reversible and allow the adolescent time prior to making a decision on starting hormonal therapies. Monitoring of height is recommended as adult height may potentially be increased if prolonged puberty suppression delays epiphyseal fusing.[5] A bone age may be helpful to assess whether epiphyseal closure has occurred when considering what rate of hormonal induction to use. Concern has been raised regarding the long-term impact of puberty suppression on bone mineral density.[5] It is therefore advisable to encourage young people on puberty blockers to have an adequate calcium intake, provide vitamin D supplementation where needed and encourage weight bearing exercise.[7] Bone density measurements (DEXA) can be considered in those requiring a prolonged period on puberty blockers or have significant additional risks for reduced bone density.

Puberty blockers halt the continuing development of secondary sexual characteristics, such as breast growth or voice deepening, and relieve distress associated with these bodily changes for trans young people.[16,17] For trans men and others assigned female at birth, the puberty blockers will induce amenorrhoea, reducing distress associated with menstruation.

Currently goserelin (Zoladex®) implants have sole subsidy status, although leuprorelin (Lucrin®) injections are fully funded for children and adolescents who are unable to tolerate administration of goserelin.[18] Table 2 presents clinical recommendations for puberty blockers, and standard dosing schedules. Puberty blockers should be continued until further treatments such as initiating other anti-androgens, accessing orchiectomy or other surgical interventions are decided on.

Table 2: Clinical recommendations and dosing schedules for puberty blockade.

Medical examination and investigations during suppression of puberty	
Examination	Every 3–6 months: height, weight, consider sitting height, BP, Tanner stage to ensure complete suppression
Blood tests	Every 6–12 months: LH, oestradiol or testosterone. LH should be suppressed <2.0 units/L along with clinical features of puberty arrest.
X-rays	Bone age on left hand if clinically indicated
If major risk factors for osteoporotic # or prolonged time on puberty blockers	Consider DEXA imaging and Vitamin D treatment.
Leuprorelin (Lucrin®)	11.25mg IM every 12 weeks*
Goserelin (Zoladex®)	10.8mg SC implant insertion into lower abdomen every 12 weeks*

*Frequency can be reduced to 10 weeks if incomplete LH suppression, puberty progression, or ongoing menses.

Gender affirming hormonal therapy

Adults should undergo a medical examination and investigations prior to starting hormones (Table 3). It is important to evaluate and address any medical conditions that could be exacerbated by treatment.[5] As with the use of oestrogen or testosterone in any context, clinicians should consider whether patients are; smokers, have a history of heart failure, cerebrovascular disease, coronary artery disease, atrial fibrillation, or personal risk factors for cardiovascular disease, history or family history of venous thromboembolism (VTE), migraine, history of sleep apnoea or hormone-sensitive cancers (eg, breast, prostate, uterine or testicular). Prescribers are advised to not consider any of the above conditions as absolute contraindications, but to consider and discuss any risks presented as part of the informed consent process.

Feminising hormonal therapy (Table 4)

Oestradiol valerate can be started in conjunction with an anti-androgen agent or added to a GnRH agonist (leuprorelin/goserelin). Goserelin (Zoladex®) is an option where oral anti-androgen agents are not tolerated. Anti-androgens are no longer required following orchiectomy or genital gender reassignment surgery. Start a low dose of oestradiol valerate (Progynova®/Estradot®) and increase the dose every 6–12 months depending on the clinical effect.

Table 3: Medical examination and investigations prior to commencing gender affirming hormonal therapy.

Physical examination	**Investigations**
Blood pressure	Electrolytes if starting spironolactone
Height	HbA1c if risk factors suggest indicated
Weight	Lipids if risk factors suggest indicated
BMI	Prolactin if starting oestrogen
Tanner stage (in adolescents)	LH
	Testosterone level
	Oestradiol level
	Urine/serum HCG if commencing testosterone

Table 4: Feminising gender affirming hormonal therapy dosing regimen and expected effects.[5]

Medication	**Dose (adults and older adolescents)**		
Anti-androgen agent options (not required post gonadectomy)			
Cyproterone	Starting dose: 25–50mg po daily Usual maintenance dose: 25–50mg po daily, although smaller doses (12.5mg) may be effective		
Spironolactone	Starting dose: 50–100mg po daily Usual maintenance dose: 100–200mg po daily		
Oestrogen options			
Oestradiol valerate (Progynova®)	Starting dose: 1mg po daily* Usual maintenance dose: 2–4mg, maximum 6mg po daily		
Oestradiol patch (Estradot®)	Starting dose: 25mcg patch twice weekly Usual maintenance dose: 100–200mcg patch twice weekly		
Effect of oestrogen	**Expected onset**	**Expected maximum effect**	**Reversibility**
Redistribution of body fat	3–6 months	2–3 years	Likely
Decrease in muscle mass and strength	3–6 months	1–2 years	Likely
Softening of skin/decreased oiliness	3–6 months	unknown	Likely
Decreased sexual desire	1–3 months	3–6 months	Likely
Decreased spontaneous erections	1–3 months	3–6 months	Likely
Breast growth	3–6 months	2–3 years	Not possible
Decreased testicular volume	3–6 months	2–3 years	Unknown
Decreased sperm production	unknown	>3 years	Unknown
Thinning and slowed growth of body and facial hair[a]	6–12 months	>3 years	Possible
Male pattern baldness	Variable	b	
Voice changes	None	c	

a - Complete removal of hair requires laser treatment;
b - Familial scalp hair loss may occur if estrogens are stopped;
c - Treatment by speech-language therapists for voice training is most effective.

Potential complications for feminising oestrogen therapy include VTE particularly if aged >40 years and within the first two years of treatment.[5] Transdermal oestrogen has lower risks for thromboembolism than oral oestrogen and should be considered particularly if increased risks are present. It is unclear whether oestrogen therapy may adversely affect the lipid profile and blood pressure, but any effect is likely to be modest.[19,20] Liver dysfunction and gallstones are occasionally seen, although a clinically significant rise in the prolactin level is an uncommon occurrence.[21] There may be alterations in mood and libido.

Table 5: Masculinising gender affirming hormonal therapy dosing regimen and expected effects.[5]

Medication	**Dose (adults and older adolescents)**		
Androderm® patches	7.5mg daily (local irritation common)		
Sustanon® (testosterone esters)	250mg/ml IM every 3 weeks[a]		
Depo T (testosterone cypionate)	100–200mg IM every two weeks or, 100mg SC weekly–200 mg SC every 2 weeks		
Reandron® (testosterone undecylate)	1,000mg IM every 10–12 weeks (second dose at six weeks to achieve steady state)		
Effect of testosterone	**Expected onset**	**Expected maximum effect**	**Reversibility**
Skin oiliness/acne	1–6 months	1–2 years	Likely
Facial body/hair growth	6–12 months	4–5 years	Unlikely
Scalp hair loss	6–12 months[b]	variable	Unlikely
Increased muscle mass/strength	6–12 months	2–5 years	Likely
Redistribution of body fat	1–6 months	2–5 years	Likely
Cessation of periods	1–6 months		Likely
Clitoral enlargement	1–6 months	1–2 years	Unlikely
Vaginal atrophy	1–6 months	1–2 years	Unlikely
Deepening of voice	6–12 months	1–2 years	Not possible
Increased sexual desire	variable	variable	Likely

a - Sustanon contains peanut oil (arachis oil) and should be potentially avoided in those with peanut allergies.
b - Highly dependent on age and inheritance; may be minimal.

Masculinising hormonal therapy (Table 5)

Testosterone can be added to a GnRH agonist or started on its own. Start a low dose of testosterone and increase gradually. Potential complications include polycythemia, which if severe, increases the risk of a thrombotic event. Periods will usually cease within the first 3–6 months of therapy. For those moving from GnRH agonists to testosterone, continue the blocker until the person is on the full testosterone dose and well virilised to avoid any undesired bleeding. For those not started on a GnRH agonist and not ready to start testosterone other interventions to achieve bleeding cessation include:

- Primolut® (norethisterone) po 5mg bd to 10mg tds. Note: Norethisterone is partially metabolised to ethinylestradiol, which at these high doses is equivalent to levels in the combined oral contraceptive.
- Provera® (medroxyprogesterone) po 10mg tds or 20mg nocte
- Combined Oral Contraception—continuous active pill taking to avoid menstruation
- Depo-provera® (medroxyprogesterone acetate) 150mg IM every 12 weeks
- Mirena® (levonorgestrel)—intrauterine device

The additional consideration of need for adequate contraception may affect the choice made.

Trans people receiving maintenance hormonal therapy should have ongoing medical assessments and investigations as illustrated in Table 6.

Table 6: Maintenance surveillance for gender affirming hormone therapy.[5]

	Investigation	Frequency
All persons	HbA1c—if risk factors suggest indicated	Annual
	Lipids—if risk factors suggest indicated	Annual
	Consider DEXA imaging if major risk factors for osteoporosis	
Feminising gender affirming hormone therapy	Electrolytes if on spironolactone and after a change in dose	Annual
	Liver function tests	Annual
	Testosterone—aim for <2nmol/L	3 monthly during first year, then annually
	Oestradiol – avoid supraphysiological levels (target <500pmol/L)	3 monthly during first year, then annually
	Prolactin	2 yearly
Masculinising gender affirming hormonal therapy	Testosterone – aim for male reference range[a]	3 monthly during first year, then annually
	Full blood count[b]	Every 3 months for first year, then 1–2 yearly
	Liver function tests	3 monthly during first year, then annually

a – testosterone should be measured midway between Depo T and Sustanon injections, immediately prior to a Reandron injection, and at least two hours after application of a testosterone patch.
b-consider testosterone dose reduction if Hct >0.54.

Gender affirming surgery

While many trans people are comfortable without, for others surgery is essential to alleviate their body dysphoria and live fully and authentically in their gender. Availability and funding are significant issues within Aotearoa, New Zealand. District health boards (DHBs) have expertise around provision of chest surgery (chest reconstruction to masculinise/breast augmentation to feminise where there has been no response to oestrogen), hysterectomy, oophorectomy and orchiectomy. Some DHBs have expertise in plastic surgical techniques such as laryngeal shaves and facial feminisation. Clinicians should be aware of local services and referral pathways. Currently access to genital reconstruction surgery (metoidioplasty or phalloplasty (masculinising) and vaginoplasty (feminising)) is via the Ministry of Health high-cost treatment pool (see website[23]).

Table 7 presents the surgical criteria recommended in the Aotearoa, New Zealand guidelines. These are the same as the current WPATH SOC.[3]

Other gender affirming care

Laser hair removal is important, particularly as feminising therapies will not completely halt facial hair growth that is already established. Be aware of local providers and support access where possible. Wearing a chest binder to achieve a more masculine chest appearance may be important; discuss safe use to prevent health risks associated with prolonged use.[24] Speech and communication are fundamental to people's genders. The goal of speech-language therapy is to help trans people develop voice and communication that reflects their gender.

General healthcare

All New Zealanders have the right to healthcare that is respectful and non-discriminatory. Ensuring healthcare services

Table 7: Aotearoa, New Zealand Guidelines and WPATH SOC v7 criteria for access to gender affirming surgery.[3]

- Criteria for access to chest reconstruction surgery:
  - Persistent, well-documented gender dysphoria.
  - Capacity to make a fully informed decision and to consent for treatment.
  - Age of majority.
  - If significant medical or mental health concerns are present, they must be reasonably well controlled.

Hormonal therapy is not a prerequisite for masculinising chest surgery but is recommended for a minimum of 12 months prior to consideration of feminising chest surgery.

- Criteria for access to hysterectomy, salpingo-oophorectomy and orchidectomy:
  - Persistent, well documented gender dysphoria.
  - Capacity to make a fully informed decision and to consent for treatment;
  - Age of majority.
  - If significant medical or mental health concerns are present, they must be well controlled.
  - 12 continuous months of hormone therapy as appropriate to the patient's transition goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones).
- Criteria for access to metoidioplasty or phalloplasty (masculinising) and for vaginoplasty (feminising):
  - Persistent, well documented gender dysphoria.
  - Capacity to make a fully informed decision and to consent for treatment.
  - Age of majority.
  - If significant medical or mental health concerns are present, they must be well controlled.
  - 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones).
  - 12 continuous months of living in a gender role that is congruent with their gender identity (note that this can include gender identities other than male and female).

In New Zealand, current practice is that the person must be 18 years or older to access publicly funded surgeries as above and in addition to the referral letter from the prescribing clinician, a letter of support from a mental health professional should be provided. The role of the mental health professional is to ensure that the person is psychologically prepared for the surgery (for example, has made a fully informed decision with clear and realistic expectations and is practically prepared for the event).

are inclusive of gender diversity is fundamental to good health care for trans people. Apart from gender affirming healthcare, trans people experience the same health needs as others. Those who have not undergone surgical removal of their breasts, cervix, uterus, ovaries, prostate or testicles remain at risk of cancer in these organs and should undergo screening as recommended. Manage sensitively, as many trans people find cancer screening extremely challenging, both physically and emotionally. Refer trans women for mammograms as per the National Breast Screening programme. Use of internal oestrogen cream prior to cervical smears in trans men may reduce discomfort and reduce the risk of inadequate smear tests.

General recommendations

Based on the guidelines outlined above, to best support the needs of transgender people in Aotearoa, New Zealand, we recommend that:

1. All health services provide equitable and accessible gender affirming healthcare services that align with international standards, evidence-based literature and community feedback.

2. DHBs enable flexible and responsive pathways on the basis of informed consent and self-determination.
3. Health services enable the involvement of trans people, including Māori trans people, in decisions that affect them regarding the development and provision of services.
4. Health services must support the development of culturally appropriate practice within clinical settings that acknowledges kaupapa Māori health frameworks.
5. DHBs provide clear information about pathways to access gender affirming healthcare services. This is inclusive of health services delivered by DHBs and primary healthcare.

Conclusion

The Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand have been developed in acknowledgement of the substantial increase in demand and significant evolution that has occurred in the period since the publication of currently used documents. The above summary provides an overview of gender affirming healthcare, while the full guideline details the role of the healthcare workforce in the provision of holistic healthcare for transgender people. We hope these guidelines will support the development of health services around the country, and provide helpful guidance to all health professionals involved in the care of transgender people.

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Nil.

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Primary Care Gender Affirming Hormone Therapy Initiation Guidelines

Aotearoa New Zealand guidelines for commencing GAHT for adults in primary care.

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Contents

Glossary of terms

In the field of transgender health, language continues to change and evolve. When in doubt about what language to use with patients, clarify the patient's preferred terminology and use their preferred language.

Transgender (or trans)

People whose genders differ from societal expectations based on their sex assigned at birth; in this document we use this term to include transgender men, transgender women, non-binary people (who do not solely identify as a man or a woman), tangata ira tāne, whakawāhine, irawhiti, and some takatāpui and MVPFAFF+[a] people.[1]

Cisgender (or cis)

A term for someone whose gender identity aligns with their sex assigned at birth.

Gender dysphoria

The distress or discomfort some trans people experience when their gender and body do not feel connected or congruent. Not all trans people experience gender dysphoria.

Gender euphoria

Feeling comfortable in your body. Some people experience this as joy and happiness.

Gender incongruence

A marked and persistent incongruence between an individual's presumed and experienced gender. Often referred to as a diagnostic code from the ICD-11 as outlined in Appendix A.

Gender affirming hormone therapy (GAHT)

The hormone therapy taken by some transgender people to embody and affirm their gender, often leading to improved psychological wellbeing and quality of life.

E-GAHT is used to abbreviate oestrogen-based gender affirming hormone therapy, and T-GAHT to mean testosterone-based gender affirming hormone therapy.

[a] MVPFAFF+ is an acronym to describe Pasifika gender identities: Mahu (Hawai'i and Tahiti), Vaka sa lewa lewa (Fiji), Palopa (Papua New Guinea), Fa'afafine (Samoa), Akava'ine (Rarotonga), Fakaleiti (Tonga) and Fakafifine (Niue).

Purpose and scope

This guideline aims to facilitate a primary care-based approach and to give general practitioners (GPs) and nurse practitioners (NPs) tools and information to safely initiate gender affirming hormone therapy (GAHT) in collaboration with their patients. They remove a standard requirement for a mandatory mental health assessment, instead encouraging an individualised approach which utilises psychological support and input only when needed.

Referral to secondary care is only initiated when needed and the primary care prescriber remains the primary or sole treating clinician for the majority of people. This aims to reduce unnecessary barriers and improve access to GAHT, in turn improving health outcomes for transgender adults in Aotearoa New Zealand (NZ).

All transgender people have a right to self-determination, autonomy and dignity when accessing healthcare, including gender affirming healthcare. This guideline aims to outline an open and transparent, person-centred approach to commencing GAHT which views the patient as a competent adult who has the capacity to make their own decisions about their body and health.

By working in partnership with the patient, this approach aims to empower patients by helping them to understand the benefits and risks of GAHT, enabling them to make an informed decision about starting GAHT.

Many transgender people will be well informed about their healthcare and patients will arrive with a wide range of levels of knowledge about GAHT. The prescriber's role is to ensure safety by following prescribing and dosing guidelines, assessing medical risk, providing education about expected outcomes, and monitoring treatment, in collaboration with their patient.

This document describes an approach to care for adults. Whilst the principles of self-determination, autonomy and informed consent remain the same in adolescents, there are added considerations and complexities in working with a younger population which were felt to be beyond the scope of this guideline. These considerations include the importance of youth development, family support, safety and the potential differences in both medications used and dosing. We recommend healthcare providers refer to the latest Standards of Care version 8 (SOC-8), released by the World Professional Association for Transgender Health (WPATH), for guidance for working with transgender children and adolescents.[2]

It is intended that these guidelines are used in conjunction with the *Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa New Zealand* [3] and local health pathways. They sit within the context of these national guidelines, which have a broader scope of all types of gender affirming care for people of all ages. These national guidelines were informed by Tā Mason Durie's models of health: Te Pae Māhutonga, using guiding principles of te mana whakahaere (autonomy) and ngā manukura (community leadership),[4] and Te Whare Tapa Whā, considering physical health, spiritual health, whānau health, and mental health.[5]

Importantly, GAHT is only one aspect of the wider process of gender affirmation, which may include medical, legal and social steps. Every transgender person is unique, and so may want to undertake some, none, or all of these steps to affirm their gender. Similarly, they may place different weight upon each of these and so pursue these in different orders. How to affirm one's own gender is a very individual decision, and there is no right or wrong way to do so.

Introduction

GAHT refers to the hormone therapy taken by some transgender people to embody and affirm their gender, often leading to improved psychological wellbeing and quality of life.[6] As outlined in the national guidelines,[3] gender affirming care, including GAHT, is a key part of transgender people's lives, and should be considered holistically in the context of their social and whānau relationships and spiritual wellbeing.[5]

Historically, the provision of GAHT has been limited to specialised secondary care services, which has contributed to restricted access to gender affirming care. Transgender people continue to face many barriers to accessing appropriate care in a timely manner, including cost, travel (particularly for patients in rural areas) and waiting times, partly due to increasing numbers of people accessing this type of care.[7] The increase in numbers of people seeking GAHT is thought to be due to greater awareness and reduced societal stigma when compared with previous decades. In the 2018 Counting Ourselves transgender health survey, 19% of participants reported an unmet need for GAHT.[8] The most commonly reported barriers were not knowing where to go (40%), cost (28%) and fear (26%). An informed consent model of care (further explained below), distributed among primary care providers, is the best model of care to reduce the current unmet need for GAHT.

In NZ, GAHT is currently initiated by a variety of health professionals in different clinical settings. This can include GPs, NPs, endocrinologists, sexual health physicians, adolescent health physicians and paediatricians. At the time of writing, pathways to access GAHT vary depending on locality. However, initiation of GAHT is increasingly being provided in primary care settings due to increasing demand and greater recognition of the barriers that transgender people, particularly those living outside of main cities, face when accessing secondary care services. Patients have a right to access GAHT in a timely manner within their local communities. To work towards this, these guidelines have been developed to assist all primary care providers by providing the information they need to initiate and provide repeat prescriptions of GAHT, with the aim of supporting their patients' gender affirmation and removing barriers for transgender adults accessing hormones. These guidelines are informed by the *Aotearoa Guidelines for Gender Affirming Health Care*[3] and overseas guidelines which have been adapted for local use.[9-13]

This document is a partnership between transgender and cisgender professionals; its authors include general practitioners, a primary care nurse, endocrinologists, a sexual health physician, an adolescent health physician, psychologists, academics and peer supporters. Whilst we appreciate that not all GPs and NPs will choose to initiate GAHT, this guideline has been written for those who do want this guidance.[b]

Many of the current pathways to access GAHT in NZ include the requirement of a psychosocial assessment by a mental health professional. These are often performed by psychologists and psychiatrists, resulting in long wait times for clients or a high cost barrier if more timely care is sought in the private system (which is not available or affordable to many people). Many transgender people experience this approach as pathologising, and may worry they have to prove they are 'transgender enough' or say the right thing in order to access the treatment they know they need to affirm their gender.[14] It is not the role of a health professional to make a judgement on whether a patient's gender (e.g. a non-binary gender) is valid or whether a patient is male or female enough. In some parts of NZ, it can be challenging to find a mental health professional to conduct this assessment at all.

[b] We recognise that not all primary care prescribers will want to initiate GAHT, and that challenges such as funding, appointment length and availability, increasing workloads and burnout all exist in NZ at this time. However, we feel it is important that those who wish to provide this care have access to practical guidance as provided in this document and are supported to prescribe GAHT for their patients. Supporting transgender patients to access GAHT in a timely manner which recognises their autonomy is very rewarding work, and we encourage primary care to get involved.

These guidelines outline an approach where the primary care team works in collaboration with patients to meet their gender goals, provides education about GAHT and general health, and helps to support patients' understanding of the risks and benefits of GAHT to make well-informed decisions about their health. This is often referred to as an 'informed consent model' and is the approach used in this document (see 'Informed consent' below for more detail).

Being transgender is not a mental illness.[15] Societal stigma and prejudice can lead to transgender people experiencing disproportionately high levels of discrimination, harassment, homelessness, unemployment, abuse and violence. The resulting gender minority stress can lead to the inequitable rates of poor mental health experienced by transgender people as a population.[16-18]

As a result, some transgender people will present with mental health conditions which require input from secondary care. As with any patient seen in primary care, psychologists, psychiatrists or secondary mental health services only need to be involved for those who are experiencing moderate to severe mental illness. Everyone else can, in theory, be managed in the community with their regular primary care team, which could include support from counsellors, health improvement practitioners or other mental health providers as needed.

For those who request it, counselling or psychotherapy can be of benefit, not as an assessment tool or mandatory part of accessing GAHT, but instead to provide psychological support during a time of change which can be stressful due to both personal and societal factors. For example, people may find it helpful to have support with exploring their gender or sexuality (particularly adolescents), the 'coming out' (or disclosure) process (especially to family or their workplace), and navigating experiences and concerns around transphobia, social stigma and other aspects of adjusting to this time of change. Ideally this support would be provided by mental health professionals such as counsellors or psychologists (or peer supporters where appropriate) who have high levels of transgender cultural safety.

Primary care is the ideal place for meeting most of the healthcare needs of transgender people, including hormone initiation, as primary care teams are part of patients' local communities, and are experts in whole life experience, including normal life events which may require their input. GPs and NPs take a holistic approach which considers a patient's physical health, mental health, culture, social supports, environment and lifestyle factors, which is well suited to providing gender affirming healthcare.

Primary care practitioners are able to work together with each transgender person to understand their gender embodiment goals, discussing options and together finding the most appropriate care for the individual. A patient with more complex mental health issues can still be referred to a psychologist or mental health team as needed, but there is no good reason for this to be the default approach. Likewise, a patient with more complex physical health issues can still be referred to an endocrinologist or sexual health physician. The Counting Ourselves survey[8] found that 48% of respondents felt that their doctor did not know enough about transgender healthcare, so health provider education is an important aspect of ensuring health needs can be adequately met.

The authors recognise that this is a rapidly evolving field of medicine. The guidelines were written in February 2023 and will require review in three years' time. We welcome and encourage research to evaluate the impact and outcomes of these guidelines, as well as the experiences of patients and providers.

Informed consent

The informed consent model of care views treatment as collaborative between the patient and healthcare provider. It is a term commonly used in medical practice to describe the interactive process of a health practitioner providing a patient with information and the patient using this to make an informed decision about their healthcare. In gender affirming healthcare, the term acknowledges that transgender people are the experts on their own gender, and the experiences, goals and needs that are related to their gender, while also acknowledging that healthcare providers have the expertise to provide this care in a way that maximises safety and efficacy.[19]

Informed consent is a process that respects patient autonomy and dignity and assumes capacity. As such it does not require a routine referral to secondary services or the private equivalent for a psychosocial assessment prior to initiating GAHT. We acknowledge the varied interpretations of the term 'informed consent' within transgender healthcare, and so have described here what is meant by informed consent in this guideline.

The use of 'informed consent' in this guideline reflects that used by the Medical Council of New Zealand (MCNZ)[20] to describe the process of providing information, including risks and benefits about a treatment, in a way that the patient can understand, as part of a trusting clinician–patient relationship, so that the patient can make a fully informed decision about care. In the case of a patient-centred approach to GAHT, the patients bring their own individualised gender embodiment goals and are active participants in the process.

Informed consent is an important component of the biomedical ethics principle of respect for patients' autonomy; this respect for autonomy should be balanced against the principles of beneficence and nonmaleficence.[21] This is reflected in *Cole's Medical Practice in New Zealand*, which states that the principle of informed consent serves to protect patient autonomy and a patient's right to determine what they want to do with their body, but that patients do not have a right to be provided treatment that is not clinically indicated.[22]

Primary care is the ideal place to create a safe and affirming space for gender affirming care. Primary care clinicians work as collaborative partners to establish lifelong relationships with the patient as the primary decision-maker. This partnership supports patient understanding of the risks and benefits of GAHT, including the impact on other areas of life such as work or education, relationships, sexual function and fertility, and works to promote general health and wellbeing. These guidelines serve as a starting point for patients and clinicians to develop a care plan appropriate to each individual's needs. Peer supporters, primary care nurses, primary mental health services, counsellors, psychologists and social workers may be involved in the delivery of hormones and GAHT health education. A multi-disciplinary approach is useful, although we recognise this is not always possible.

Like other medical interventions with similar risks, an external mental health assessment is not mandatory before accessing GAHT for adult patients. Providers should be aware that GAHT is often associated with improvements in a patient's mental health.[23] A patient who has severe mental health difficulties will likely still be able to provide informed consent, but may require support and treatment from a mental health professional alongside starting GAHT. For adults with a complex presentation or those who are requesting less common treatments or treatments with limited research evidence, further advice or assessment from different health professionals is likely to be required.[2] Remember that gender affirming healthcare may reduce mental distress, and that withholding or delaying care unnecessarily is unethical and could worsen a person's mental health. See FAQ 2 for more details.

The starting point when assessing capacity is always to presume that an adult has capacity to make the decision.[22] A patient has capacity to make a decision if they understand the nature and effects of the treatment; can weigh up options; balance risks and benefits; foresee consequences of consenting (or not consenting); demonstrate consistency in their decision-making; have no undue influence from a third party and can communicate their decision. In most cases for patients with diminished capacity to consent, external support may be required to assess capacity.

Examples of situations where capacity to consent may be diminished include cognitive impairment, intellectual disability, dementia, psychosis, or mania of a degree that it may be impacting on their ability to adequately understand and balance necessary information. In these cases only, a formal capacity assessment is an essential part of the informed consent process, ideally conducted by a health professional who knows the patient well.[24] A mental health professional may be able to assist with a capacity assessment. Providers should be aware that patients with diminished capacity still have a right to timely access to care, and this may involve the use of a supported decision-making process; see the section on diminished capacity in the Frequently Asked Questions section (FAQ 4) for more details.

We encourage prescribers to take a harm reduction approach to the initiation of GAHT, particularly when a patient is self-sourcing GAHT. If a patient is taking GAHT formulations which are unavailable in NZ or outside of recommended dose ranges, a plan to transfer onto NZ medications and doses in line with these guidelines should be negotiated in partnership with your patient.

WPATH Standards of Care Version 8

These guidelines align with the GAHT recommendations from the WPATH Standards of Care version 8.[2] Full details of the SOC-8 criteria for GAHT can be found in Appendix A, and these have been incorporated throughout this guideline. The SOC-8 recommendations refer to the International Classification of Diseases and Related Health Problems (ICD-11)[25] coding for Gender Incongruence, the details of which can also be found in Appendix A.

Stages of gender affirming hormone therapy initiation

These guidelines are based on providing individualised care in a staged format with a new patient. There is no set number of appointments that a patient must be seen for prior to starting GAHT, and this will vary depending on complexity, practitioner experience and appointment length. In some situations, several stages could be completed in one longer appointment, whilst in other situations it might take multiple appointments to work through one stage. Similarly, each person's body and gender embodiment goals are different, and it may take more appointments, working with your patient, for you both to understand what works best for them. This may require trialling different dosages and types of hormones and making changes where needed.

When patients consent to treatment it is good practice to allow reasonable time for the patient to make their decision. The MCNZ states that a key principle of informed consent is that it is an interactive process and not a one-off event.[20] For this reason, prescribers may wish to separate stages 3 and 4 into separate appointments, to allow patients time to consider the information provided, and to provide an opportunity to ask further questions.

The stages outlined below help to ensure that GAHT is prescribed as safely as possible, and help to ensure the best outcome for the patient's overall wellbeing. Stages 1 to 3 should be completed prior to prescribing hormones. These can be undertaken by a GP, NP, primary care nurse, or a combination of these colleagues working together in one practice.

Terminology used in this guideline

E-GAHT is used to abbreviate *oestrogen-based GAHT* (previously known as feminising GAHT).

T-GAHT is used to abbreviate *testosterone-based GAHT* (previously known as masculinising GAHT).

Stages in starting GAHT	
Stage 1	Introduction, relationship building, information gathering
Stage 2	Medical review (including fertility discussion)
Stage 3	Hormone information and education
Stage 4	Hormone initiation (first prescription)
Stage 5	Maintenance prescribing and long-term follow-up

Stage 1:

Introduction, relationship building, information gathering

Stage 1

Introduction, relationship building, information gathering

- General introduction to the service and how the process of getting started on GAHT will work.
- Check patient's name, gender and pronouns and ensure they are recorded accurately on the Practice Management System (PMS). Check which name your patient would like you to use when calling them from the waiting room. Adding this information as an alert or a 'post-it note' on the PMS may be helpful.
- Explore gender embodiment goals for gender affirming care.
  - You could ask: Think about your body as it is now, what would you like to stay the same? What would you like to change?
  - See Tables 1 and 2 for physical effects of GAHT. Sometimes people's goals may not require or be achievable with GAHT, so it is important to explore this with your patient.
  - People's goals are individual and may change over time. Work together with your patient over time, adjusting medication as needed in response to their needs and goals.
- Current and recent past gender experiences (see example questions in Appendix B).
- Give information about other supports. These may be available on your health pathways. Some examples can be found here:

  Gender diversity support services – Health Navigator

  Rainbow organisations – Te Ngākau Kahukura
- Give hormone information sheet (Appendix E) if appropriate at this stage (this will be explained to patient fully at Stage 3, but this gives the patient an opportunity to take it home and read it).
- HEeADSSS[26] or similar psychosocial assessment, including asking about patient supports.

Stage 2:

Medical review (includes fertility discussion)

Stage 2

Medical review (includes fertility discussion)

- Past medical and surgical history – for E-GAHT ask specifically about breast cancer, venous thromboembolism (VTE), cardiovascular disease (CVD), migraines, liver disease.
- Review mental health including current supports and strengths (consider PHQ-9 and GAD-7 if relevant) – arrange any extra support or referrals if indicated.
- Social history – including alcohol, drugs, and smoking/vaping. Discuss risk reduction, e.g. smoking cessation.
- Family history – ask specifically about VTE, CVD, breast cancer and liver disease.
- Medications and allergies – you may wish to check if the patient is 'self-medicating' with hormones (e.g. self-sourcing hormones online).
- Sexual health review (including discussion about the need for any STI testing, contraception and/or HIV PrEP where relevant).
- Any increased risks from hormonal therapy to manage – there are very few, if any, medical contraindications.
  - For E-GAHT consider discussion with secondary care if there is migraine with aura, CVD, VTE history or significant liver disease. (See E-GAHT section and FAQ 5 for more detail.)
  - Pregnancy is an absolute contraindication for T-GAHT (consider checking a Beta hCG level). Relative contraindications include severe hypertension, sleep apnoea and polycythaemia since these conditions can be exacerbated by testosterone.[2]
- Recommend cervical screening for patients who are over 25 years old and have a cervix.
- Update or establish baseline observations – blood pressure and weight.
- Offer trans culturally safe counselling or peer support – this can be very useful alongside GAHT.
- For those starting E-GAHT offer speech and language therapy referral for voice therapy (in some regions this may be available for those starting T-GAHT, but as T-GAHT lowers the voice this is less often required).

Note: There is no need for a routine genital or breast examination.

Stage 2

Medical review (includes fertility discussion)

Baseline bloods

- E-GAHT – LFT, lipids, FSH, LH, oestrogen, testosterone. Electrolytes if starting spironolactone. HbA1c if indicated by risk factors.
  - If referring for fertility preservation include HIV, syphilis, hepatitis B&C.
- T-GAHT – LFT, lipids, FSH, LH, oestrogen, testosterone FBC and Beta hCG. HbA1c if indicated by risk factors.
- Prolactin measurement is not usually required, see FAQ 6.

Fertility (reproductive options)

You will need to assess your patient's capacity to understand the effect of GAHT on reproduction and explore reproductive options with the individual prior to the initiation of gender affirming treatment. This is discussed in more detail at Stage 3 (hormone information) but is also included here so that relevant blood tests can be included in the baseline bloods if required for those starting E-GAHT.

A pamphlet about fertility preservation for transgender people can be found here: Transgender fertility: Preservation and treatment (PDF, 813KB)

- E-GAHT (assigned male at birth): E-GAHT may result in permanent loss of fertility.[27] There is funding available for fertility preservation (check with your local service for current eligibility criteria).

  Fertility preservation is not a requirement for GAHT, but it is essential to discuss this with your patient. If referral for fertility preservation is desired, include HIV, Syphilis and Hepatitis B & C on baseline bloods.
- T-GAHT (assigned female at birth): T-GAHT usually causes ovarian suppression. This may be reversible on stopping testosterone (which may result in a return of spontaneous fertility) but may also be irreversible.[28-30] Patients should be aware that if they wish to become pregnant in the future, they will need to stop testosterone (as it is a teratogen) and that they may require fertility assistance in the form of egg harvesting. Egg harvesting can usually be undertaken at the time of desired pregnancy (and egg quality is unaffected by testosterone), so is not necessarily required prior to starting GAHT.[30] For this reason, egg harvesting is currently only funded for those having a surgical removal of reproductive organs. A funded assessment with a fertility specialist to discuss options prior to starting T-GAHT may be available if your patient wishes to discuss this in more detail.

Menstrual cessation

Many transgender and non-binary people assigned female at birth experience dysphoria with menstruation. This can be significant, and for some may contribute to poor mental health or even suicidality. It is important to discuss this and to offer menstrual cessation options if this is desired. Although testosterone usually results in amenorrhoea, starting menstrual cessation sooner is often welcomed and desired by patients.

When considering which option to use it is important to take into account whether contraception is required. Table 1 outlines options for menstrual cessation. Medication used for menstrual cessation can usually be stopped (if not needed for contraception) once the patient is established on testosterone and menstruation has ceased. Menstruation may persist despite adequate testosterone levels in 5–10% of people,[31] in which case progesterone therapy could be continued.

Table 1: **Menstrual cessation options**

Contraceptive	Depo-provera Mirena Combined contraceptive pill	Usual contraception dose	Oestrogen containing medication may not be desired by trans masculine people.
Not contraceptive	Norethisterone (Primolut)	5mg BD	Can increase to 10mg BD for 1 week if breakthrough bleeding then reduce slowly. Occasionally need to stay at higher doses.
	Medroxyprogesterone (Provera)	10–20mg once daily – up to 10mg TDS	
	Utrogestan	100–200mg daily	

Note: Testosterone is NOT a contraceptive.

Stage 3:

Hormone information and education

Stage 3

Hormone information and education

Check blood results and discuss these with the patient as necessary.

Address any remaining concerns or questions.

Ensure referrals are completed and that the patient is linked to appropriate supports.

Prior to starting E-GAHT: check that fertility preservation has been organised (if desired).

Go through hormone information and education (detailed in the following pages), including gender embodiment goals, side effects, risks, permanent effects, and time frame for changes. Some people may decide not to continue with GAHT in the future, so it is important to discuss the permanent and non-permanent changes. (See also FAQ 1.)

Highlight that changes will be gradual, occurring over years. Explain the need for regular review and monitoring in the first year and ongoing need for bloods and clinical review thereafter.

Provide written information and a copy of the consent form.[c] These forms can be found in Appendices E and F.

Document whether the patient has capacity to provide informed consent to commence GAHT, whether they meet the SOC-8 criteria for hormone treatment (see Appendix A) and that you have discussed fertility (see PMS shortcuts in Appendix C).

The checklist in Appendix D can be used to ensure all steps have been completed prior to prescribing.

[c] A consent form can be a useful addition and may act as a guide to the clinician to check all of the relevant points have been discussed, but is not a requirement. We have included it here as an option. By far the most important aspect of informed consent is the conversations between the patient and clinician outlined here. If these are well documented and the patient has had time to consider the information and ask questions, this is more important than a written consent form. See the MCNZ statement on informed consent for more detail.

Stage 3

Hormone information and education

T-GAHT — Information to cover in the consent process

We recommend using the patient information sheet in Appendix E to make it easier to cover this information with the patient. This will provide a handy reminder and prompt of what you need to cover when providing information about GAHT.

- Explain which preparations of testosterone are available (and check patient preferences for which to use), frequency of administration and the option of self-injecting (full medication details can be found below in 'GAHT initiation protocol').
- Recommended monitoring for T-GAHT:
  - Bloods and blood pressure (BP) 3–6-monthly in the first year, thereafter annually or as clinically indicated. Note the timing of the blood test when measuring testosterone levels (see below).

Discuss the changes expected with T-GAHT

Changes occur gradually over months to years (see Table 2). Physical examinations are not necessary. Often reassurance is required, especially in the first 6 months.

The following infographic can be helpful: Effects and expected time course of a regimen consisting of testosterone

Note – your patient may prefer the use of non-gendered language when describing their genitals, so we recommend asking them what words they prefer and then using those. Commonly used terms (at the time of writing) include 'front hole' or 'internal genitals'.

- Permanent effects:
  - Deepening of the voice,
  - Increased body hair growth including facial hair,
  - Androgenetic alopecia,
  - Genital changes: clitoral enlargement (may be up to 1–3cm) and this can feel uncomfortable and even painful initially. Vaginal dryness can be relieved with oestrogen cream or an over-the-counter product for vaginal dryness and ensuring use of extra lubrication for vaginal sex.
- Sex – vaginal dryness increases the risk of STIs including HIV, so it is advisable to use condoms if having sex using this part of the body. Lubrication can help with any associated discomfort. Testosterone is not a contraceptive.
- Effects which are likely reversible: acne/oily skin, increased muscle mass/ strength, redistribution of body fat, increased libido. Irritability and frustration may be variably present.
- Menstruation stops in most people (around 90%) after 1–6 months.[31] *(Many patients prefer the term 'monthly bleeding'.)*
- Fertility – You may have already discussed this in Stage 2, but it is repeated here to ensure it isn't missed. T-GAHT usually causes ovarian suppression. This may be reversible on stopping testosterone (which may result in a return of spontaneous fertility) but may also be irreversible.[28-30] Patients need to understand that if a future pregnancy is desired it will mean stopping testosterone (as it is a teratogen) and may require fertility assistance in the form of egg

harvesting. Egg harvesting is more effective at the time of desired pregnancy (and egg quality is unaffected by testosterone), so is not required prior to starting GAHT.[28]

It is possible to become pregnant while taking testosterone even if menstruation has stopped, so **contraception is essential if there is any sexual contact that would put someone at risk of pregnancy**. Testosterone is likely to be harmful to a developing fetus and should not be used during pregnancy.

- Risks – Polycythaemia, liver dysfunction, pelvic pain, raised cholesterol and raised blood pressure.[32-34] Studies in cisgender men indicate a slight increased VTE risk in the first 6 months on testosterone therapy.[35]
- Cancer screening
  - Discuss the importance of cervical screening for anyone with a cervix.
  - Breast screening is recommended from age 45 years for anyone who has breasts. Those who have had 'top surgery' (this commonly used term refers to chest reconstruction surgery or bilateral mastectomy) should follow the advice of their surgeon, as this may depend on the extent of the surgery performed. Some people may be advised to have clinical examinations and possibly ultrasound screening.
  - Ensure recalls are not removed if gender is changed on the PMS.
- Gender affirming surgery – provide information on local pathways for surgery. Your patient may be especially interested in accessing top surgery. Availability varies between localities; check your local health pathways. A stocktake of availability as of 2021 can be found here: An update for the provision of gender affirming healthcare across the district health boards of Aotearoa New Zealand – PATHA. Gender affirming genital surgery referral forms can be found here: The Gender Affirming (Genital) Surgery Service – Ministry of Health.

Table 2: **Effects of testosterone-based hormones (T-GAHT)**

Effect of testosterone	Expected onset	Expected maximum effect	Reversibility
Skin oiliness/acne	1–6 months	1–2 years	Likely
Facial body/hair growth	6–12 months	4–5 years	Unlikely
Scalp hair loss	6–12 months[a]	Variable	Unlikely
Increased muscle mass/strength	6–12 months	2–5 years	Likely
Redistribution of body fat	1–6 months	2–5 years	Likely
Cessation of periods	1–6 months		Likely
Clitoral enlargement	1–6 months	1–2 years	Unlikely
Vaginal atrophy	1–6 months	1–2 years	Unlikely
Deepening of the voice	6–12 months	1–2 years	Not possible
Increased sexual desire	Variable	Variable	Likely

[a] Highly dependent on age and inheritance; may be minimal.

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Stage 3

Hormone information and education

E-GAHT — Information to cover in the consent process

We recommend using the patient information sheet in Appendix E to make it easier to cover this information with the patient. This will provide a handy reminder and prompt of what you need to cover when providing information about GAHT.

- Explain that E-GAHT involves using two medications – an oestrogen and a testosterone blocker:
  - — Oestrogen:

    Explain which preparations of oestrogen are available (tablets or patches). Explain that there is no good evidence yet that one form of oestrogen is better than another in terms of effects, but that oestrogen patches are likely to carry a lower risk of VTE and LFT dysfunction than tablets.[36, 37]
  - — Testosterone blocker:

    Discuss options for androgen blockade (spironolactone or cyproterone). There are no studies yet that compare efficacy in E-GAHT, therefore patients can select their preferred approach, in discussion with their prescriber and taking into account potential side effects and risks, and any relevant health conditions or medications.
    - o Spironolactone is a blood pressure tablet at low doses but works as a weak anti-androgen at higher doses. It will not suppress testosterone levels but will block the effects of testosterone in the body, promoting breast growth and slowing down body hair. Common side effects include dizziness and urinary frequency.
    - o Cyproterone in very small doses (12.5mg daily or less) will suppress testosterone to < 2 nmol/L but does not suit everyone. Side effects can include fatigue and low mood. Shortness of breath is an uncommon side effect but should be counselled for. Larger doses have been associated with liver function abnormalities and there is a dose-dependent and cumulative risk of meningioma thought to be related to doses of 25mg daily or greater.[38-40] Evidence in other areas of healthcare shows the risk of VTE is increased with cyproterone use.[41]
- Recommended monitoring for E-GAHT
  - — Bloods and blood pressure 3–6-monthly in first year, thereafter annually or as clinically indicated.

Discuss the changes expected with E-GAHT

- Changes occur gradually over months to years (see Table 3). Physical examinations are not necessary. Often reassurance is required, especially in the first 6 months. The following infographic can be helpful: Effects and expected time course of a regimen consisting of an anti-androgen and estrogen.
- Permanent effects:
  - — Fertility is thought to be permanently affected by E-GAHT.[27, 42] Fertility preservation is recommended in young people and is usually funded. It is essential to have and document this discussion prior to prescribing E-GAHT.

  - Breast development is gradual over 2–years.[32] It can be helpful to manage expectations as many people develop an A cup or smaller after 1 year on E-GAHT.[43] This can be a common source of dissatisfaction.[44]
- Effects which are likely reversible: softer skin, decreased muscle mass, thinning of body hair, fat redistribution to buttocks, hips and thighs.
- Libido usually reduces when taking androgen blockers. Erections usually reduce in frequency and may be less firm and shorter lasting (Sildenafil can be helpful for some people). Testicles can shrink to less than half their original size.
- E-GAHT does NOT change:
  - Voice pitch (voice therapy may be available via a speech and language therapist depending on local pathways)
  - Facial bone structure
  - Prominence of the tracheal cartilage (Adam's apple)
  - Growth of facial and body hair, which slows but does not stop completely (laser hair removal if desired can be funded by a WINZ disability allowance if the patient has a community service card or is on a low income.
- Side effects – breast tenderness and weight gain. In the first few days to weeks there may be nausea and headaches which usually settle.
- Risks – VTE (risk can be lowered, see FAQ 5), raised cholesterol, gallstones, raised BP, possible increase in breast cancer risk.[32] We recommend explaining the symptoms of deep vein thrombosis and pulmonary embolism and advising patients to seek urgent medical help if these occur.
- Cancer screening – Breast screening is recommended from age 45 years for anyone who has breasts.
- Gender affirming surgery – provide information on local pathways for surgery. Availability varies between localities; check your local health pathways. A stocktake of availability as of 2021 can be found here: An update for the provision of gender affirming healthcare across the district health boards of Aotearoa New Zealand – PATHA. Gender affirming genital surgery referral forms can be found here: The Gender Affirming (Genital) Surgery Service – Ministry of Health.

Table 3: **Effects of oestrogen-based hormones (E-GAHT)**

Effect of testosterone	Expected onset	Expected maximum effect	Reversibility
Redistribution of body fat	3–6 months	2–3 years	Likely
Decrease in muscle mass and strength	3–6 months	1–2 years	Likely
Softening of skin/decreased oiliness	3–6 months	Unknown	Likely
Decreased sexual desire	1–3 months	3–6 months	Likely
Decreased spontaneous erections	1–3 months	3–6 months	Likely
Breast growth	3–6 months	2–3 years	Not possible
Decreased testicular volume	3–6 months	2–3 years	Unknown
Decreased sperm production	Unknown	>3 years	Unknown
Thinning and slowed growth of body and facial hair	6–12 months	>3 years[a]	Possible
Male pattern baldness	Variable	[b]	
Voice changes	None	[c]	

[a] Complete removal of hair requires laser treatment. [b] Familial scalp hair loss may occur if oestrogens are stopped.
[c] Treatment by speech-language therapists for voice training is most effective.

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Stage 4:

Hormone Initiation

Stage 4

Hormone Initiation

- Ensure Stages 1–3 are complete and that patient is happy to start GAHT (see checklist in Appendix D). If using the consent form, ensure this has been signed by the patient.
- Document patient's capacity to provide informed consent, whether they meet the SOC-8 criteria for GAHT (see Appendix A) and that you have discussed fertility (see Appendix C for PMS shortcut suggestions).
- Inform the patient that using these medications for gender affirmation is an unapproved use of an approved medication.[45] These medications are widely used around the world for this purpose and there is a recognised clinical justification for their use. This is also known as 'off-label' use.

  As a prescriber you must explain what is being prescribed, and why, and obtain informed consent from your patient. It is acknowledged, however, that when off-label use of a medicine is so common that it is regarded as usual practice, obtaining separate consent (for off-label use) may not be considered necessary, and this is at the clinician's discretion.[46]
- Give GAHT prescription as per GAHT initiation protocol below. Arrange to follow up in 3 months.
- T-GAHT: arrange a nurse appointment for ongoing injections.

Stage 5:

Maintenance prescribing and long term follow up

Stage 5

Maintenance prescribing and long term follow up

In the first year, follow up every 3 months, or more often if needed; thereafter as needed depending on individual needs. Generally, an annual review is recommended, but for patients who have been stable on GAHT for a significant time it may be appropriate to extend this.

- Review effects of medications and check the patient is happy to continue taking GAHT.
- Adjust doses as per hormone protocol.
- Monitor BP and bloods 3–6-monthly in the first year (or more often if necessary) then annually or as clinically indicated. Monitoring is primarily with dose changes, which is likely to be every 3 months, but flexibility may be needed. Monitor weight as appropriate.
- Monitor mental and physical health. Encourage lifestyle/health behaviours which reduce the risks associated with GAHT, e.g. smoking cessation, cholesterol reduction, moderate alcohol use.
- If needed, connect to mental health and peer support.
- Make referrals for other gender affirming care as desired by your patient.
  - Gender affirming genital surgery referrals are via the Ministry of Health. For further detail see 'Gender affirming (genital) surgery service forms' here: The Gender Affirming (Genital) Surgery Service – Ministry of Health
  - For other gender affirming surgeries refer to your locality health pathways.

GAHT Initiation Protocol

GAHT Initiation Protocol

This protocol relates only to the initiation of gender affirming hormone therapy in adults and is to be used by prescribers after following GAHT Stages 1–3 described above.

The starting protocols below are for adults who have NOT been on gonadotropin releasing hormone (GnRH) agonists (also known as puberty blockers) from a young age (Tanner stage 2–3). For those who have been on puberty blockers from Tanner stage 2–3, GAHT initiation should progress more gradually.[32]

This section outlines the medications used in GAHT, dosage guidance, recommended monitoring, and a protocol for initiating GAHT.

Oestrogen-based Gender Affirming Hormones (E-GAHT)

Table 4: **Overview of E-GAHT**

Oestrogen formulation	Starting dose	Maximum (usual maintenance dose)	Notes
Oestradiol valerate (Progynova)	1–2mg daily	4–6mg daily	Increasing by 1–2mg every 3–6 months is generally recommended.
Oestradiol patch (Estradot)	25–50mcg patch twice weekly	100-200mcg patch twice weekly	Increasing by 25–50mcg every 3–6 months is generally recommended. Lower VTE risk than oral oestrogen. Recommended if liver or lipid dysfunction or >45 years old.
Androgen blocker*	**Starting dose**	**Maximum (usual maintenance dose)**	**Notes**
Spironolactone	50–100mg daily	200mg daily	Unable to use serum testosterone for clinical guidance as spironolactone blocks the effect of testosterone on the tissues rather than its production. Monitor potassium level.
Cyproterone	12.5mg daily (or 12.5-25mg on alternate days)	12.5mg once daily (or 12.5-25mg on alternate days)	Use lowest effective dose. Use of higher doses long-term has been linked to meningioma. Consider review and discussion every 5 years if remaining on this long term. Contra-indicated in history of thromboembolic disorders as increases VTE risk. Monitor liver function.
Goserelin	10.8mg SC implant insertion into lower abdomen every 12 weeks		Not first line in adults due to high cost and good availability of alternative options.

***The androgen blocker is no longer required if the patient has had an orchiectomy.**

For guidance on E-GAHT in individuals with increased cardiovascular or VTE risk, see FAQ 5. For a comment on Progesterone use See FAQ 8.

Table 5: **E-GAHT recommended monitoring**

Investigation	Comment
Electrolytes	If patient is on spironolactone.
Liver function tests	If abnormal, use transdermal oestrogen as first choice. Monitor if on cyproterone.
Lipids	
Oestrogen	Only checked to ensure levels are not supraphysiological. Some guidelines would recommend an upper limit of 700–750 pmol/L[32] but there is insufficient evidence to definitively recommend any target range. Experience suggests that oestrogen levels or dose do not correlate well with physical effects or self-reported satisfaction with E-GAHT, and exogenous oestrogen is not well measured in the serum.
Testosterone	On cyproterone – levels would typically be <2nmol/L (or higher if wanting to maintain erectile function). On spironolactone – no need to measure as it doesn't usually suppress (see above); instead, be guided by clinical response.

E-GAHT
Starting Protocol

Prior to first prescription	Complete Stages 1–3 in the primary care protocol for starting GAHT. This includes a psychosocial assessment, medical review, baseline blood tests, blood pressure, weight, fertility preservation (if desired), and informed consent outlining effects (including permanent changes) and risks of GAHT by a knowledgeable healthcare provider. Provide the patient with information sheet and document consent.
Commence GAHT – first prescription	**Oestrogen** – *one of*: Estradiol (Progynova) 1–2mg OD *or* Estradot patches 25–50mcg twice weekly ***AND*** **Testosterone blocker** – *one of*: Spironolactone 50–100mg OD *or* Cyproterone 12.5mg OD (or 12.5–25mg on alternate days)
3 months after commencing hormones	If no concerns, adjust androgen blocker to maintenance dose and commence gradual increase in oestrogen dose: • Oestrogen can be increased: — Progynova by 1–2mg every 3–6 months up to maximum of 6mg — Estradot by 25–50mcg every 3–6 months up to maximum of 100–200mcg twice weekly. • Spironolactone – consider increasing to 200mg OD (if potassium level is normal). • Cyproterone – continue 12.5mg OD (or 12.5–25mg on alternate days). • Bloods for potassium (if taking spironolactone), liver function, lipids. • Check blood pressure.
3-monthly appointments in first year, can be 12-monthly thereafter if stable	At each follow-up visit: • Review progress and discuss any issues or questions. • Check on physical and mental health and social supports. • If your patient has an orchiectomy the androgen blocker can be stopped. • Ensure monitoring is up to date: — Check blood pressure 3–6-monthly in the first year, thereafter 12-monthly. — Monitor blood tests 3–6-monthly in the first year, thereafter 12-monthly or as clinically indicated (see Table 5 for details).

Testosterone-based Gender Affirming Hormones (T-GAHT)

Table 6: **Overview of T-GAHT**

Testosterone formulation	Standard starting dose	Maximum (usual maintenance) dose	Notes
Depo-testosterone (testosterone cypionate)	100mg IM/SC* every 2 weeks or 50mg SC weekly	200mg IM/SC* every 2 weeks or 100mg SC weekly	Testosterone level should be measured mid-way between injections. Patient can be taught to self-inject.
Sustanon (testosterone esters)	125mg (0.5ml) IM* every 3 weeks	250mg (1ml) IM* every 3 weeks	Testosterone level should be measured mid-way between injections. Patient can be taught to self-inject.
Reandron (testosterone undecylate)	Less commonly used as a starting testosterone, but can be started at 500mg IM The second dose can be given after 6 weeks to achieve steady state and thereafter continue 12-weekly	750–1000mg IM every 10–14 weeks	Testosterone level should be checked immediately prior to injection. Injection must be given by a health professional (due to risk of oil embolism).
Androderm patches	5mg daily	5–10mg daily	Testosterone level should be measured in the morning. Skin irritation is common.

* Depo-testosterone is licensed for IM use. It is not licensed for subcutaneous administration in NZ but can be administered this way if preferred, with weekly dosing appearing to be most commonly used.[47]

Low dose testosterone is discussed in FAQ 7.

Table 7: **T-GAHT recommended monitoring**

Investigation	Comment
Full blood count	If the haematocrit > 0.52 reduce the dose of testosterone and/or discuss with an endocrinologist or haematologist.
Liver function tests	
Lipids	
Testosterone	• Aim for usual male reference range for standard doses. • Check 6–12-monthly once patient has been on testosterone for around 6–9 months (it takes time for levels to stabilise initially). • Timing of blood test is dependent on testosterone formulation – see Table 6 above. • If raised, reduce testosterone dose and repeat level in 3 months.

T-GAHT
Starting Protocol

Prior to first prescription	Complete Stages 1–3 in the primary care protocol for starting GAHT. This includes a psychosocial assessment, medical review, baseline blood tests, blood pressure, weight, and informed consent, outlining effects (including permanent changes) and risks of hormones by a knowledgeable healthcare provider. Provide the patient with an information sheet and document consent.
Commence GAHT – first prescription	Depo-testosterone 100mg IM/SC fortnightly (or 50mg SC weekly) *or* Sustanon 125mg (0.5ml) IM every 3 weeks *or* Reandron 500mg IM with 750–1000mg IM at 6 weeks (thereafter 3-monthly) *or* Testosterone patch 5mg daily
3 months after commencing hormones	• Review progress and discuss any issues. • Bloods for complete blood count (monitor haematocrit), liver function, lipids. • Blood pressure. • If no concerns, increase hormones to maintenance therapy. If patient wishes to switch testosterone preparation, the preferred testosterone can be administered at the time the next dose of the previously used testosterone is due. • Plan for testosterone level measurement at the appropriate time (after at least 6 months on GAHT. See Table 6 for timing of blood test).
3-monthly appointments in first year, can be 12-monthly thereafter if stable	At each follow-up visit: • Review progress and discuss any issues or questions. • Check on physical and mental health and social support. • Ensure monitoring is up to date: — Blood pressure 3–6-monthly in first year, thereafter 12-monthly. — Bloods 3–6-monthly in first year, thereafter 12-monthly or as clinically indicated (see Table 7 for details, including timing of testosterone measurements). • Provide education about self-injection if appropriate.

Frequently Asked Questions

(FAQs)

1. What if my patient stops taking hormones?

Affirming one's gender is not necessarily a linear process and may take place over a lifetime. Some people experience their gender more fluidly than others and it is common for someone's understanding of, and comfort with, their gender identity and gender expression to evolve throughout their lives. Someone's decision to start GAHT and a later decision to stop GAHT can both be the right decision for them at that stage of their lives. This is not – and should not – be viewed as a mistake or a failure. Similarly, some patients may shift from identifying with a binary gender to non-binary gender (or vice versa), and their goals from their transition may change accordingly. Stories of this nature are common, and often referred to as 'non-linear transitions'. They are simply reflective of the variety of human experience.

Some providers may feel anxious about 'getting it wrong' or worry that their patient may later regret their decision. The informed consent process outlined in this document respects the autonomy of the patient as a competent adult who has the capacity to make their own decisions about their body and health once they have been given the necessary information. Patients accessing GAHT have an equal right to receive support from health professionals and from family/friends/whānau where needed. By working in partnership, this approach seeks to enhance a given patient's understanding of the potential benefits and risks of GAHT. The provider's role is to provide support and information, and to ensure safety by following prescribing and dosing guidelines, monitoring treatment and monitoring for potential risk. As part of a patient-centred approach, the patient should be an active partner in decisions about GAHT based on their own gender embodiment goals, and information provided to them about likely changes to them (both reversible and irreversible) and risks.

We are beginning to understand more about non-linear transitions (sometimes discussed in the context of 'retransition' or 'detransition') and the reasons people's goals, gender identities, gender expressions, or engagement with treatment change. Frequently, people who have stopped affirming their gender (whether temporarily or permanently) do so due to external factors, including pressure from family, discrimination and social stigma.[48] Detransition is not the same as regret. Social connections and support can be a preventative factor by allowing people to be themselves despite external pressures. Trying to ensure that patients have relational support for their decision-making –for example, from family, friends, whānau and health professionals – where this is requested or needed is important. It is essential that healthcare providers are available to support patients with non-linear transitions, and it can be useful to make this support clear when initiating GAHT. If hormones are stopped, it is important to ensure restoration of physiological sex hormone levels to remove risks of longer-term hypogonadism.

2. Can I still prescribe GAHT where there are significant mental health concerns?

Many (but not all) transgender people experience mental health conditions, often due to gender minority stress.[49] This is caused by negative social attitudes, discrimination, prejudice and violence. Discomfort between a person's intrinsic sense of identity, their body and how they are perceived by others also contribute to distress, as can difficulty in accessing gender affirming services (including GAHT) in a timely manner.[50] Symptoms of anxiety, low confidence, depression, anxiety, disordered eating and trauma are common.

Where a patient has severe mental health concerns that meet the criteria for secondary mental health services, then refer them to these services. However, if a patient's mental health concerns *do not* affect their capacity to provide informed consent for GAHT, then you can concurrently commence GAHT. If you are concerned about your patient's capacity to give consent to GAHT due to their mental health, then this may need to be addressed first and onward referral may be recommended (refer to FAQ 4 on diminished capacity below for more detail). If you are unsure, you can seek consultation from secondary services to see if an onward referral would be recommended. If secondary mental health input is not required,

give your patient advice, support, and treatment for mental health as with any other patients.

Gender affirming healthcare may reduce mental distress, so withholding or delaying care unnecessarily is unethical and could worsen a person's mental health. It is important to weigh up the risks and benefits of these decisions, noting that onward referral may at times come with barriers for patients such as long wait times, transport issues or cost. Doing nothing is not a neutral option and can result in harm to your patient. There should always be the option to refer more complex situations to secondary care for input if a GP or NP feels it is outside of their scope or experience.

3. My patient is autistic. Does this impact on their capacity to give informed consent to start GAHT?

It has been consistently shown that transgender or non-binary people are more likely to be autistic than cisgender people, although there is no consensus as to why.[51] Autism is a neurodevelopmental phenomenon that manifests in a wide variety of ways dependent on the individual. Autistic people may have different cognitive, sensory or social processing, and as a result they may see the world and interact with others differently.

Being neurodivergent does not routinely impact on an individual's capacity to give informed consent. However, some autistic people may need more time to provide information about themselves or may need questions to be asked in a different way, so they are able to communicate their gender identity, embodiment goals for GAHT, and/or demonstrate their understanding of the risks and benefits. It is important to recognise these differences and to create an environment where autistic patients are supported to communicate and engage in a way which feels more comfortable to them, to share the cognitive load, increase their overall comfort, and reduce their feelings of stress. Where a patient is not able to provide you with the information you need, or demonstrate understanding, then it is hard for them to show capacity. It is the job of providers to reduce barriers in any way we can to maximise their ability to demonstrate this.

For patients whose social communication difficulties impair their ability to demonstrate their understanding, in a way required to give informed consent, additional support may be required. This could include referral to communication, mental health or Autism support services (if timely access to these services is available locally).

4. When does a patient have diminished capacity to provide consent?

In Aotearoa New Zealand, adult patients have the right to be presumed to have capacity to give informed consent, unless there are reasonable grounds to believe otherwise.[52] Reasons for diminished capacity might include intellectual disability, brain injury or cognitive impairment, e.g. dementia, psychosis and mania. Some people may have capacity but have difficulty in communication and may need support to aid this process.

If a patient can retain information that they need about GAHT (i.e. risks and benefits), demonstrate understanding of how this will affect their lives (e.g. changes to their body, including permanent changes), weigh the information to come to a decision and clearly communicate a decision based on this understanding and reasoning, then they have capacity to give informed consent to GAHT.

Patients without full capacity still have a right to access care in a timely manner and to have a supported role in decision-making for their care, as indicated under Right 7(4) HDC Code of Rights:[52] The usual procedure for this is for the GAHT prescriber to come to a decision that is in the patient's best interest based on:

(1) the patient's views, level of capacity, wishes and assent.

(2) the views of a suitable person suitable person who is interested in the welfare of the patient, such as a caregiver or family member who knows the person well, or a wider circle of people that includes friends and whānau. This may include an enduring power of attorney or a welfare guardian if one is appointed.

(3) the prescriber's and other

health professionals' expertise of the risks and benefits to the patient.[53]

Prescribers should take care to ensure to provide information to patients in a way that is accessible and appropriate to their level of understanding. Referral to a colleague or appropriate secondary service may aid the decision-making process for patients with diminished capacity.

5. What if my patient starting E-GAHT has a heightened risk of thrombosis or cardiovascular disease?

Patients need to be informed that oestrogen increases the risk of thrombosis and cardiovascular disease. Smoking cessation should be strongly supported. However, it would be unethical to withhold E-GAHT on these grounds. Instead, clinicians should discuss both benefits and risks of E-GAHT with their patients and mitigate any increased risk as much as possible.

In someone with risk factors for thrombosis and/or increased cardiovascular risk (e.g. smoking, ischaemic heart disease, migraine with aura, older age) it is recommended:

- To use transdermal rather than oral oestrogen, as evidence suggests the risk of VTE with transdermal use is similar to population risk.[36, 37] It is sensible to use the lowest effective dose.
- Cyproterone at higher or contraceptive doses (Ginet) increases the risk of VTE[41] and is contraindicated in those with a history of thromboembolic disorders.[54] There are insufficient data to be certain as to whether these risks are removed through the use of lower doses (12.5mg daily). Clinicians should consider alternative androgen blockade options (spironolactone or Gosarelin) in those with an increased VTE risk.

6. Do I need to measure prolactin?

Several guidelines recommend measuring prolactin at baseline and during follow-up in those on E-GAHT, but at present there is no compelling evidence to suggest that E-GAHT increases the risk of pathological hyperprolactinaemia outside of cyproterone use at higher than contemporary recommended doses.[55] There is no such recommendation for cisgender women using contraceptive doses of oestrogen, oestrogen for menopausal therapy, or during pregnancy when oestrogen levels would be expected to be similar or higher to those achieved with E-GAHT. Indeed, oestrogen therapy is frequently used in women with known prolactinomas who are intolerant of dopamine agonist therapy. Furthermore, mildly elevated prolactin measurements that are unlikely to be significant are very common, and the routine measurement of prolactin therefore raises the risk of unnecessary further investigations. We suggest clinicians use clinical judgement when determining if prolactin measurements are required.

7. My patient is requesting low-dose testosterone.

Some people, often those who are non-binary, choose to start on lower doses of testosterone (sometimes referred to by patients as 'micro-dosing'). There is a lack of any evidence to guide low-dose hormone regimens. Patients may choose to remain on a low dose long term, or more slowly increase up to standard maintenance doses over time. A more gradual increase may give some control over the speed of onset of the experienced effects, although this is not guaranteed. When obtaining consent, it is essential to inform the patient about all the same effects, including the permanent changes, as standard testosterone dosing, as all of these occur at lower doses.

There is a lack of evidence to support an optimum testosterone level in this context. Testosterone supplementation is indicated in hypogonadal cisgender men to reduce an increased cardiovascular and bone health risk that is otherwise seen. However, there is currently no literature to indicate an absolute testosterone level below established local reference ranges at which this increased risk becomes apparent. Acknowledging this, and the lack of data in the context of T-GAHT, it is not yet possible to define a minimum testosterone

level when using T-GAHT and patients should be aware of this. In practice, many clinicians would recommend a minimum testosterone level of 6–8 nmol/L.

8. My patient is requesting a medication that is either not in these guidelines or not licensed in New Zealand.

In these guidelines, we recommend the use of medications that either have an established evidence base in the use of GAHT, have a long history of use in GAHT, or are widely used in other populations and risk profiles are therefore well understood. These guidelines align with and support many other guidelines in this area. However, overseas practice may differ, and patients may ask about the use of medications not included in these guidelines. The following are frequently encountered enquiries:

T-GAHT

Oral testosterone

Andriol capsules are not licensed in Aotearoa New Zealand for GAHT, and at the time of writing are not funded. Oral testosterone is not used as a first-line option in T-GAHT due to the fluctuation in testosterone levels throughout the day and the need for frequent dosing, as well as being less effective at stopping menstruation.[12] They can be used on a case-by-case basis, particularly in someone who is needle-phobic and is unable to tolerate transdermal testosterone. They should be avoided if liver disease is present[54] and LFTs should be monitored as with other testosterone regimes. If this option is used, Andriol can be started at 40mg daily and be increased up to 120mg daily in 2 divided doses. When measured, testosterone levels should be checked prior to the morning dose.

E-GAHT

Progesterone

Progesterone is occasionally prescribed as part of gender affirming care. Anecdotally, some people who take E-GAHT have reported benefits of using progesterone on breast development, sleep, mood, and other physical changes. Micronised progesterone (utrogestan) is prescribed for menopausal hormone therapy in many cisgender women and is now funded in Aotearoa New Zealand.

However, there are no current high-quality data to indicate any effect of progesterone for gender affirmation,[56, 57] and no data on safety. It is therefore not included in the majority of international guidelines for gender affirming hormone therapy.[2, 3, 10, 32] Authors of the WPATH SOC-8 attempted to complete a systematic review on this issue but failed to identify enough data to make any recommendations for or against the use of any progesterone in this context, and noted 'existing data suggest harm is associated with extended progestin exposure'.[2] Progesterone treatment in other contexts is associated with weight gain, mood disturbance, fatigue, an increased risk of breast cancer, and venous thromboembolism (VTE).[2, 58] It is not clear how generalisable the data from cisgender women is to transgender populations, who tend to be younger and less likely to use equine oestrogen.[2, 59] Utrogestan is likely to have a lower risk of side effects than older progesterones,[60, 61] and emerging evidence suggests a lower associated risk of breast cancer. Further studies in cisgender and transgender people are required however to confirm this.

This guideline is therefore unable to make a recommendation for or against progesterone use in GAHT at this stage, and we await the outcome of research trials designed to address these questions with interest.

Clinicians may be asked to prescribe progesterone as part of E-GAHT. This should prompt a discussion about expectations and outcomes, potential risk, and current evidence. This discussion may reveal other ways in which doses of existing medications can be adjusted to support your patient's gender embodiment goals. Prescribing decisions ultimately rest with the clinician, but patient autonomy, gender embodiment goals and self-determination for patient choice should be considered and respected.

Anti-androgens

There are no high-quality data to indicate that the use of any particular anti-androgen is superior to any other. We support the use

of spironolactone or cyproterone as both have been used widely in E-GAHT for several decades, and experience with both medications is now extensive in both transgender and other populations. Both are funded for use in GAHT. Cyproterone is associated with an increased risk of liver dysfunction, VTE[41] and meningioma,[38, 39] however, and the lowest effective dose (12.5mg daily or on alternate days) should be used if this is chosen. GnRH agonists (Goserelin) are licensed for use in GAHT and are an option if oral options are not tolerated, with the available evidence suggesting a comparable effect.[62]

Flutamide is recommended by some overseas guidelines on E-GAHT, but is associated with hepatotoxicity, and its use is recommended against by many guidelines on the management of hirsutism in cisgender women for this reason.[63] 5α-inhibitors (often termed dihydrotestosterone blockers) are less effective than other anti-androgens but are occasionally used to reduce androgenic hair loss. Bicalutamide is a potent anti-androgen but is associated with hepatotoxicity and reported cases of fulminant hepatitis.[64] While there remains a lack of any evidence to indicate superiority of Flutamide, 5α-inhibitors or Bicalutamide as anti-androgens in E-GAHT, we recommend against their use because of likely increased treatment risks.[62]

Oestrogen

The goal of GAHT is to provide physiological hormone levels. To achieve this with E-GAHT, oestrogen must be administered, and testosterone must be blocked or lowered, and neither approach is effective in isolation. Unfortunately, many of the physical effects of having progressed through a testosterone-based puberty are not reversed through hormonal therapy alone, and the effect of E-GAHT commenced beyond this age may therefore be less than optimal.

— Higher doses of oestrogen

There is currently no evidence to suggest that a dose of oestrogen higher than 200mcg/24 hours via patch or 6mg daily orally is helpful, and, indeed, poor evidence to suggest any strong correlation between oestrogen doses at recommended levels and outcomes at all.[65] The recommended upper limits of oestrogen dosing in these guidelines align with SOC-8 and the Endocrine Society.[2, 32] While some guidelines recommend a target oestrogen level, there are few available data to definitively specify any target range, and those guidelines that do incorporate such a target generally acknowledge this.

— Oestrogen use without anti-androgen therapy

Some patients advocate for the use of oestrogen therapy alone at higher doses to suppress testosterone production in lieu of additional anti-androgen therapy. By definition, however, this requires the use of oestrogen at supraphysiological levels, with high circulating levels of oestrogen required to suppress pituitary gonadotrophin output and therefore lower testosterone levels to the desired target. There is no evidence to suggest this approach results in improved physical outcomes, and, while there is little evidence specifically on this approach, the use of oestrogen at higher than physiological levels is likely to increase the risks associated with oestrogen use.[65] Aligning with most guidelines on this subject,[32] we therefore recommend against this approach.

— Intramuscular oestrogen

Some international guidelines include IM oestrogen alongside oral and transdermal options,[10, 32] but it is neither licensed nor funded in Aotearoa New Zealand. There is no evidence to suggest that IM oestrogen is any more effective than transdermal oestrogen, and both are likely to be associated with a lower risk of liver dysfunction than oral oestrogen. It is unclear whether the VTE risk may also be lower than seen with oral oestrogen. However, in contrast to transdermal oestrogen, significant variation in oestrogen levels is noted with IM oestrogen, with levels far in excess of those recommended by most guidelines often seen shortly after administration in particular.[32] There are no high-quality data to advise on whether this may increase oestrogen-related risks. There is little guidance on monitoring levels in patients on intramuscular oestrogen as part of GAHT but dosing guidance can be found in the Endocrine Society guidelines.[32]

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Appendix A:

WPATH SOC-8 hormone criteria and ICD-11 gender incongruence

The statements below outline a summary of the SOC-8 criteria for GAHT. However, there are a lot of nuances around each point, which are discussed in more depth in the full SOC-8 document, which can be found here: Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

SOC-8 Summary Criteria for hormonal treatment for adults and adolescents[2]

- Gender incongruence is marked and sustained;
- Meets diagnostic criteria for gender incongruence prior to gender-affirming hormone treatment in regions where a diagnosis is necessary to access health care;
- Demonstrates capacity to consent for the specific gender-affirming hormone treatment;
- Other possible causes of apparent gender incongruence have been identified and excluded;
- Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
- Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options.

ICD-11 description of Gender Incongruence[25]

Gender Incongruence of Adolescence and Adulthood is characterised by a marked and persistent incongruence between an individual´s experienced gender and the assigned sex, which often leads to a desire to 'transition', in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual´s body align, as much as desired and to the extent possible, with the experienced gender. The diagnosis cannot be assigned prior to the onset of puberty. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.

Appendix B:

Sample questions for gender history and embodiment goals

- How would you describe your gender?
- How did you come to learn your gender as it is now?
- What steps have you taken to feel more comfortable in your gender? For example, changed your name or pronouns, dressing differently? How does that feel for you?
- Are you hoping to take any other steps in your transition? What are your current goals? How would you like to embody your gender?
  - *Thank you for sharing that with me. I'm going to make a note of your goals – please let me know if these goals ever change so I can continue to recommend the best care for you.*
- Have you thought about how you will manage a change in appearance at school/work/study/home?
- Who is/are your support/s with this process?
- Have you talked to anyone about your gender identity and your plans to affirm your gender through medical treatment?

  (Of course, there is no requirement for a person to discuss this with others, but this question can help to identify support – or lack of it – and thereby facilitate conversations around this. For example, if a younger person hasn't got parental support, it might be worth having a conversation about how they plan to approach this when there are noticeable physical changes. Family support is important and if not available then other supports should be identified.)
- When did you start thinking about taking hormone therapy?
- What do you think will be the main benefits of hormone therapy? What are you looking forward to?
- Think about your body as it is right now:
  - What would you like to stay the same?
  - What would you like to change?
- How do you imagine your life will change if you start hormone treatment?
- Are there any changes that you are not sure about?
- Do you foresee any concerns or challenges?
- Are you aware of the impacts of hormones on your fertility/ability to have children in the future? Would you consider a referral to a fertility service to store gametes?
  - *Lots of people find it quite difficult to think about how our fertility might affect us in the future, so I'd really encourage you to take your time when you're thinking about this. You don't have to answer now but we should talk about this again before you start hormones.*
- Some people find it useful to have the support of a peer support worker or talk therapist to help with decisions or support. Would you like a referral to a talk therapist with experience around this?
- Some people change their minds about taking hormones, often because of family or society pressures. Have you thought about this at all? (You can emphasise that this does not worry you and encourage them to talk to you, let them know that you are available for support whatever decisions they make in the future.)

Appendix C:

Examples of Practice Management System shortcuts

These can be added to your practice management system (PMS) to use as personal shortcuts to save time when writing your notes.

Capacity

Patient has the capacity to provide informed consent to start gender affirming hormone therapy.

WPATHSOC-8

Patient meets the criteria for hormonal treatment from the WPATH Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (SOC-8).

T-GAHT

We have discussed the information on the consent form and patient information sheet, and I have provided copies of both. Discussed effects of hormones, time taken to see changes, which changes are permanent, risks, side effects, medication options and monitoring, cervical screening, and importance of not getting pregnant on testosterone and need for contraception even if periods have stopped. Discussed potential impact on future fertility including that testosterone needs to be stopped if wishing to conceive and that egg harvesting may be required to achieve a pregnancy.

E-GAHT

We have discussed the information on the consent form and patient information sheet, and I have provided copies of both. Discussed effects of hormones, time taken to see changes, which changes are permanent, risks, side effects, medication options and monitoring.
I have explained that GAHT does not change voice, bone structure or Adam's apple.
Discussed permanent effect on loss of fertility and fertility preservation has been offered.

Appendix D:

Checklists which can be used prior to first GAHT prescription

T-GAHT Checklist

- ☐ Discussed gender embodiment goals and expectations of GAHT
- ☐ PMH, DH, FH, SH, HEeADSSS
- ☐ MH review – offer support options as needed
- ☐ Check on family/community support
- ☐ Fertility/reproductive options discussed
- ☐ Information on consent form and info sheet explained and copy provided to patient
- ☐ Offered menstrual cessation options
- ☐ Discussed contraception
- ☐ Discussed cervical screening and set recall
- ☐ Baseline bloods (FBC, LFT, LH, FSH, oestrogen, testosterone, lipids and consider HbA1c & Beta hCG)
- ☐ Baseline BP & Wt
- ☐ Document capacity to provide informed consent and whether they meet the SOC-8 criteria for hormone treatment
- ☐ Consent form signed (if using)
- ☐ Arrange for nurse appointment for injection, GP appointment for follow-up in 3 months and set recall for 3–6-monthly bloods and plan to measure testosterone after 6–9 months

E-GAHT Checklist

- ☐ Discussed gender embodiment goals and expectations of GAHT
- ☐ PMH, DH, FH, SH, HEeADSSS
- ☐ MH review – offer support options as needed
- ☐ Check on family/community support
- ☐ Discuss likely infertility and offer fertility preservation
- ☐ Information on consent form and info sheet explained and copy provided to patient
- ☐ Discussed – voice therapy, other supports
- ☐ Baseline bloods (LFT, lipids, electrolytes, LH, FSH, testosterone, oestrogen, consider HbA1c & HIV, syphilis, hep B & C if preserving fertility)
- ☐ Baseline BP & Wt
- ☐ Document capacity to provide informed consent and whether they meet the SOC-8 criteria for hormone treatment
- ☐ Consent form signed (if using)
- ☐ Arrange for follow-up in 3 months and set recall for 3–6-monthly bloods

Appendix E:

Patient information sheets

Oestrogen-based gender affirming hormone therapy

The person prescribing your hormones should go through and discuss all of this information with you. If you have any questions or anything is unclear, please discuss this with your health provider.

Which medications are used?

Two medications are used as part of oestrogen-based hormone therapy:

- Oestrogen to provide the hormone oestrogen.
- Testosterone blockers (or anti-androgens) are given alongside this to block the hormone testosterone. If you have an orchiectomy (removal of external gonads or testicles) this medication is no longer needed.

Oestrogen comes in tablets or patches. There is no evidence of a difference in feminising outcomes or effects between these, so you can choose which you prefer, in discussion with your prescriber and taking into account your medical history. Patches are likely to carry a lower risk of blood clots. Taking high doses does not cause changes to happen more quickly and can put your health at risk. There is no evidence to support higher doses or regimes outside of standard guidelines.

Oestrogen tablets are taken every day. Oestrogen patches are applied to the lower abdomen and changed twice a week.

Testosterone blocker options are spironolactone or cyproterone. Both are a tablet taken every day or every other day. There is no evidence of a difference in feminising effects between these.

Spironolactone is a blood pressure tablet at low doses but works as an anti-androgen at higher doses. It will not suppress testosterone levels but will block the effects of testosterone in the body, promoting breast growth and slowing down body hair. Side effects can be low blood pressure, dizziness and passing urine more often.

Cyproterone in very small doses (12.5mg daily or less) will suppress testosterone but it does not suit everyone. Side effects can include fatigue/tiredness and low mood. Shortness of breath is an uncommon side effect but is possible. Larger does have been associated with liver function abnormalities and with a benign brain tumour called a meningioma, but this is thought to be related to long-term use of doses greater than 25mg daily. Evidence in other areas of healthcare shows the risk of blood clots is increased with cyproterone use.

These hormones are fully funded by PHARMAC, which means they cost the same as other routine prescriptions.

What blood tests do I need?

A baseline blood test is often performed before starting hormone therapy, then ongoing monitoring blood tests are usually 3–6-monthly for the first year and 6–12-monthly thereafter (or as agreed with your healthcare provider). You will usually also need to have your blood pressure and weight checked every year.

The blood test will check your liver function and cholesterol levels, as well as monitoring hormone levels. If you are taking spironolactone your potassium level will be monitored.

When taking spironolactone, the testosterone level measured in your blood test may remain raised, as spironolactone mostly acts to blocks testosterone's effect on the tissues in the body, rather than reducing the release of testosterone. For this reason, there is no need to check testosterone levels on a blood test if you are taking spironolactone.

Oestrogen levels are only checked to ensure levels are not too high as this can lead to health risks. Oestrogen levels do not correlate well with physical effects or reported satisfaction, and there isn't enough evidence to suggest a target range. Instead your oestrogen dose will be adjusted in line with standard dose ranges and your experiences of the effects.

Expected effects

Effects are gradual and timing varies, but it can take years for the full effects to be seen. The effects are largely dependent on genetics and the age you start hormones, rather than the dose or type of medication you take. It is important to have realistic expectations about the effects of hormones. The table below outlines the expected timing of the effects, and this link shows the expected effects in a picture: Effects and expected time course of hormone therapy consisting of an anti-androgen and oestrogen

The following changes are permanent (these will not reverse if you stop taking hormones):

- Breast growth – breast growth is gradual over 2–3 years. Most people starting oestrogen-based hormone therapy after puberty can expect to develop an A cup or smaller. As with all people who develop breasts, these vary in size and shape.
- Loss of fertility – your external gonads (testicles) may shrink and eventually stop producing sperm. This may lead to a permanent loss of fertility. Fertility preservation is usually available free of charge. Your GP or nurse practitioner can refer you for this before you start hormones.

The following changes are not permanent (these may reverse if you stop hormones):

- Softer skin
- Decreased muscle mass and strength
- Less body hair – decreases in thickness and grows more slowly but it doesn't go away completely. Some people choose electrolysis or laser treatment for a more permanent solution.
- Redistribution of fat (more on hips, bum, thighs)

Things that don't change:

- Facial hair growth slows down but doesn't stop completely.
- Voice stays the same (voice therapy may be available in your region).
- Bone structure of your face and Adam's apple doesn't change.

Effect of oestrogen	Expected onset	Expected maximum effect	Reversibility
Redistribution of body fat	3–6 months	2–3 years	Likely
Decrease in muscle mass and strength	3–6 months	1–2 years	Likely
Softening of skin/decreased oiliness	3–6 months	Unknown	Likely
Decreased sexual desire	1–3 months	3–6 months	Likely
Decreased spontaneous erections	1–3 months	3–6 months	Likely
Breast growth	3–6 months	2–3 years	Not possible
Decreased testicular volume	3–6 months	2–3 years	Unknown
Decreased sperm production	Unknown	>3 years	Unknown
Thinning and slowed growth of body and facial hair	6–12 months	>3 years[a]	Possible
Male pattern baldness	Variable	[b]	
Voice changes	None	[c]	

[a] Complete removal of hair requires laser treatment.
[b] Depending on your family history, balding may occur if oestrogens are stopped.
[c] Treatment by speech-language therapists for voice training is most effective.

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Sex

A baseline blood test is often performed Your sex drive is likely to be lower. You will soon notice that you get hardening or stiffening of your erectile tissue (erections) less often and when this does occur, it may be more difficult to sustain. If this is causing issues with sex, you can ask your GP for medication to help this. Lowering the dose of your testosterone blocker may also help. Your external gonads (testicles) will usually shrink to less than half of their original size. Although your sperm count is likely to be lowered (see below), it isn't always, and so if you have sex with someone who is able to become pregnant, you should use contraception.

Fertility

The impact on fertility is unclear but it is safest to assume that within a few months of starting oestrogen-based hormone therapy you could permanently and irreversibly lose the ability to create sperm. Fertility preservation is usually fully funded and your GP or nurse practitioner can refer you for this.

Side effects and risks

- Common side effects include breast tenderness and weight gain. Nausea and headaches can occur when starting oestrogen and usually settle in the first few days or weeks.
- Please tell your healthcare provider if you develop migraine headaches.
- Full medical effects and long-term safety are not known. For most people, benefits outweigh risks, but it depends on other risk factors you may have (such as family history, body size, smoking and blood pressure level).
- There is a small increased risk of liver problems and raised cholesterol (these are both monitored on the blood tests).
- There is an increased risk of blood clots. Using oestrogen patches instead of tablets reduces this risk.
- Risk of health problems are higher if you smoke or are overweight or are over the age of 45 years.
- There may be a slight increased risk of breast cancer compared with cisgender men.

Emotional health

You may feel more emotional. It is not known exactly how hormones will impact your mental health and this varies between individuals. It is a bit like going through a second puberty, so you may experience a rollercoaster of emotions, or you may notice no change. Some people experience mood swings or a worsening of anxiety or depression. You may prefer to start the hormones when you have an upcoming period without big life stressors. We know that gender affirmation can also be a stressful time and many people benefit from extra support through this. Please discuss this with your health provider who can give you options for counselling or peer support. Many people find it very helpful to talk to someone who understands gender affirmation, and it can be helpful to explore concerns around coming out (disclosure), stress with family, social and internalised transphobia, anxiety, uncertainty, acceptance etc. You can find details about support options here:

Gender diversity support services – Health Navigator

Rainbow organisations – Te Ngākau Kahukura

Cancer screening

Breasts – breast screening (mammograms) from the age of 45 years as per national screening guidelines is recommended for anyone with breasts. This is a free service. You can find out more about breast screening and mammograms here: Breast screening – Time to Screen

Prostate – the prostate is a small gland which surrounds the opening of the bladder. If you have a prostate gland it is possible to develop cancer in this. Prostate cancer is most common over the age of 50 years. If you develop trouble with peeing, such as poor flow, dribbling, trouble starting or stopping peeing, peeing more often or blood in your pee, you should speak to your health provider.

Appendix E:

Patient information sheets

Testosterone-based gender affirming hormone therapy

The person prescribing your hormones should go through and discuss all of this information with you. If you have any questions or anything is unclear, please discuss this with your health provider.

Testosterone

Testosterone comes in injections and patches. The most common form is injectable testosterone, as patches commonly cause skin irritation. These hormones are fully funded by PHARMAC, which means they cost the same as other routine prescriptions. There is no evidence of any difference in outcomes or effects between the different forms of testosterone.

There are three forms of injectable testosterone:

- Depo-testosterone is given every 2 weeks.
- Sustanon is given every 3 weeks.
- Reandron is given approximately every 3 months.

Depo-testosterone and Sustanon can be self-injected at home if you wish to do so (but can also be given in clinic by a nurse). The nurse can teach you how to safely self-inject if this is your preferred option. You can also find useful information about this here: Transgender health injection guide

Reandron must be given by a health professional, and you will be seen in clinic for these injections.

Monitoring

Monitoring blood tests are usually needed before starting hormone therapy, then usually 3–6-monthly for the first year and 6–12-monthly thereafter (or as agreed with your healthcare provider). You will usually need to have your blood pressure and weight checked every year. The blood test will check your liver function and cholesterol levels, as well as monitoring hormone levels.

While most monitoring is started at baseline and then 3-monthly, the exception to this is your testosterone level. It takes time for this to stabilise, so it is not usually measured until 9–12 months after starting testosterone. When having a blood test for testosterone, the timing of your blood test is important and depends on which formulation of testosterone you are on:

- Depo-testosterone and Sustanon – check testosterone level mid-way between injections.
- Reandron – check testosterone level just before next injection.

Expected effects

Everyone is different in how quickly they respond to testosterone, but you will start to notice changes in your body gradually over the first few months (see table below). It takes years for the full effects to be seen. This link shows this in a picture: Effects and expected time course of testosterone hormone therapy

The following changes are permanent (these will not reverse if you decide to stop taking testosterone):

- Deeper voice (this can start with a scratchy feeling in the throat)
- Increased hair growth on your body (chest, back, arms)
- Facial hair (the amount varies from person to person)
- Hair loss at temples, possibly becoming bald with time depending on your age and family history.
- Genital changes: Erectile tissue (clitoris) growth around 1–3cm. This can feel uncomfortable or even painful initially.

The following changes are not permanent (these may reverse if you stop testosterone):

- Skin oiliness and acne (acne is usually worst in the first year then gradually improves. You can discuss acne medications with your health provider if needed.)
- Redistribution of body fat (less fat on hips, bum and thighs)
- Increased muscle mass and upper body strength
- Increased sex drive
- Monthly bleeding (periods) usually stops after 1–6 months (for most people but not all. Your prescriber can give you medication to stop monthly bleeding in the meantime if you need this.) Please let us know if you experience any bleeding after your monthly bleeding has stopped.

Effect of testosterone	Expected onset	Expected maximum effect	Reversibility
Skin oiliness/acne	1–6 months	1–2 years	Likely
Facial body/hair growth	6–12 months	4–5 years	Unlikely
Scalp hair loss	6–12 months[a]	Variable	Unlikely
Increased muscle mass/strength	6–12 months	2–5 years	Likely
Redistribution of body fat	1–6 months	2–5 years	Likely
Cessation of periods	1–6 months		Likely
Clitoral enlargement	1–6 months	1–2 years	Unlikely
Vaginal atrophy	1–6 months	1–2 years	Unlikely
Deepening of the voice	6–12 months	Variable	Not possible
Increased sexual desire	Variable	Variable	Likely

[a] Highly dependent on age and inheritance; may be minimal.

(Reproduced with permission from the *Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand*)

Fertility and contraception

Long-term effects on fertility are not clear. Testosterone stops the ovaries from working and it is not known whether this is reversible or not. If you wish to carry a pregnancy in the future, you will need to stop testosterone as it is harmful to a developing fetus (the exact length of time it needs to be stopped before getting pregnant is not known, so make sure you discuss this with your doctor).

After stopping testosterone your fertility could return allowing you to become pregnant without assistance. However, it may not return, and you may not be able to become pregnant without fertility assistance. This assistance usually involves egg harvesting which is an invasive procedure where eggs are removed using a needle. Testosterone does not usually affect the quality of the eggs, so if it is desired this procedure can be carried out at the time it is needed and is not usually recommended before starting hormone therapy.

If you have surgery which involves removing your reproductive organs, you may be able to access funded egg storage and can discuss this with your health provider. If you would like to discuss fertility options in more detail you can request a referral to a fertility specialist.

Testosterone is NOT a form of contraception. If you are having sex which could result in pregnancy (front hole (vaginal) sex with someone whose body produces sperm), you should use contraception even if your periods have stopped.

Sex

Your libido (sex drive) may increase and your genitals, especially your erectile tissue (clitoris), will grow. This can lead to sex and orgasms feeling different. Testosterone can cause the internal genitals (vagina) to become dry, which can cause sex to feel uncomfortable. This can be eased by using additional lubrication (lube). If you have ongoing problems with discomfort in this area, an oestrogen cream can make the internal genital area feel much more comfortable. Your GP or nurse practitioner can prescribe oestrogen cream, or you can try an over-the-counter cream for dryness such as the Vagisil range.

Side effects and risks

- Increased red blood cells (this can thicken the blood increasing risk of stroke or heart attacks. Red blood cells are monitored on your blood tests.)
- Possible risk of liver problems or raised cholesterol (these are monitored on your blood tests).
- There may be an increased risk of blood clots.
- Risk of health problems are higher if you smoke or are overweight.
- Full medical effects and risks are not known.
- Potential risk of testosterone injections include pain at the site and infection. Steps are taken to reduce this risk. Reandron can rarely cause an oil embolism which is when a tiny amount of oil gets into the blood stream. This is why Reandron should be given by a health professional.

Emotional health

It is not known exactly how it will impact on your mental health and this varies between individuals. It is a bit like going through a second puberty, so you may experience a rollercoaster of emotions, or you may notice no change. You may prefer to start the hormones when you have an upcoming period without big life stressors. You may find your mental health improves, but we know that gender affirmation can also be a stressful time and many people benefit from extra support through this. Please discuss this with your health provider who can give you options for counselling or peer support. Many people find it very helpful to talk to someone who understands gender affirmation, and it can be helpful to explore concerns around coming out, stress with family, social and internalised transphobia, anxiety, uncertainty, acceptance, etc. You can find details about support options here:

Gender diversity support services – Health Navigator

Rainbow organisations – Te Ngākau Kahukura

Cancer screening

Cervical screening – this is recommended for anyone aged 25–69 years old who has a cervix. From July 2023 this can be done using a simple swab (which you can choose to do yourself in private). More details here: Cervical screening – Time to Screen

It is possible that changing your gender marker on your primary care practice computer system could result in you not getting a reminder when you are due for this test, so please discuss with your GP or nurse if you think this could be the case. The HPV vaccine greatly reduces your risk of cervical cancer. If you have not had this vaccine, please discuss this with a nurse or GP.

Breast screening – if you have breasts, screening mammograms are recommended from age 45 years. If you've had top surgery, you will need to follow the advice of your surgeon, which may be to perform regular self-exams and ask your GP about annual chest wall examinations with possible ultrasound scans. More information here: Breast screening – Time to Screen

Appendix F:
Consent forms

Consent form for starting oestrogen-based hormone therapy

This consent form outlines important information you might want to talk to your health team about before starting hormones to feminise the body.

Progynova (oestradiol valerate) tablets or **Estradot** (oestradiol hemihydrate) patches provide the feminising hormone oestrogen. Testosterone blockers are needed as well unless orchiectomy surgery has occurred.

Oestrogen tablets/patches will gradually feminise the body.

Permanent body changes (even if you stop taking the tablets):

- Gradual increase in breast size over 2–3 years.
- Your oestrogen dose is increased slowly for best breast development.
- It is not known if taking oestrogen increases the risk of breast cancer. Take care of your breasts – it is recommended to follow the normal breast screening guidelines for women.

Non-permanent body changes (that may reverse if you stop the oestrogen):

- Softer skin
- Decreased muscle mass
- Less body hair
- More fat on buttocks, hips and thighs

Things that don't change much:

- Facial hair slows down but doesn't stop completely
- Voice stays the same
- Bone structure of your face and Adam's apple doesn't change

If you stop taking your hormones some body changes stay but you may find that your body will slowly masculinise.

Fertility

Taking the hormones stops your testicles producing testosterone. Your testicles may shrink by up to 50% and may eventually stop sperm production. If it is important for you to preserve your fertility you might want to freeze your sperm before you start treatment. Your health team will talk to you about this.

Sex

Taking the blocker tablets may lower your sex drive so that you are not as interested in having sex any more. You may find that you get erections less often and that your penis doesn't get as hard any more. If you want to be able to use your penis for sexual pleasure talk to your health team and they will review your medications.

Mental health

Some people may feel more emotional taking oestrogen. Some people find their mental health improves – the effects of hormones on the brain are not fully understood. Transitioning can be a stressful time and many people need some help adjusting to the physical and emotional changes. It is really important that you let your health team know if you are having problems so that they can help you access the support you need.

Common side effects

- Nausea
- Headaches
- Tender breasts
- Weight gain

Most side effects should settle within a few days to weeks of starting the medications. Please tell your health team if you have any side effects, especially headaches or migraines.

Potential risks of oestrogen

The full medical effects and safety of taking hormones are not fully known. The potential risks of taking oestrogen must be weighed against the benefits that hormones can have on your health and quality of life.

Likely increased risk

- Blood clots – deep vein thrombosis (DVT), pulmonary embolism (blood clot in the lung), stroke, heart attack
- Changes to cholesterol (may increase risk of pancreatitis and heart disease)
- Gallstones

Possible increased risk

- Increased blood pressure
- Liver problems
- Increased prolactin and possibility of benign pituitary tumours

Possible increased risk if you have extra risk factors

- Heart disease
- Diabetes

No increased risk or unknown

- Breast cancer

Some of these risks are reduced by using oestrogen patches instead of tablets.

Go to the emergency department or seek medical help urgently if you have:

- A swollen painful leg
- Chest pain or difficulty breathing
- Vision or speech problems.

These symptoms might mean you have a serious problem like a blood clot.

The risk of having a blood clot is much higher if you smoke or are overweight.

Blood clots are more common as you get older. Stopping oestrogen before and after surgery can help reduce the risks of blood clots around this time.

Keeping in touch with your health team for regular check-ups and blood tests is an important part of your care and will reduce the risks of taking hormonal therapy.

Are there any other questions you want to ask?

It is your health team's responsibility to best support you to make the decisions that are right for you and to keep ourselves up to date so that we can best inform you.

For many different reasons people question whether or not they want to continue to take hormones. This can be a normal part of your journey. Please feel free to discuss this with your prescriber before you stop your medication. Come and talk – your health team is always ready to listen.

I wish to start feminising hormone therapy:

Name .....

Date .....

Prescribed by:

Name .....

Date .....

Appendix F:
Consent forms

Consent form for starting testosterone-based hormone therapy

This consent form outlines important information you might want to talk to your health team about before starting hormones to masculinise the body.

There are different types of testosterone that are taken to masculinise the body. Everyone is different in how quickly they respond to testosterone but you will start to notice changes in your body gradually over the first few months. It may take several years before the full effect is felt. While there are different ways of getting testosterone into the body most people are on injections.

Permanent body changes (even if you stop taking testosterone):

- Deeper voice
- Increased growth of hair – with thicker hairs on arms, legs, chest, back and abdomen
- Gradual growth of moustache/beard hair
- Hair loss at the temples – possibly becoming bald with time
- Genital changes – clitoral growth (typically 1–3 cm) and vaginal dryness.

Non-permanent body changes (that may reverse if you stop the testosterone):

- Skin changes – increased oil and acne
- Change in body shape – less fat on buttocks, hips and thighs
- Increased muscle mass and upper body strength
- Increased sex drive
- Periods usually stop after 1–6 months

Things that don't change much:

- Breast tissue looks a bit smaller due to fat loss
- Possible weight gain or loss

Fertility

While it is not known what the long-term effects are of taking testosterone some trans men find that if they stop their testosterone they will become fertile again and can get pregnant. There are no guarantees for anyone and it is probably harder to get pregnant the older you are and the longer you have been on testosterone.

Testosterone is dangerous for the developing fetus – you must not get pregnant while you are on testosterone. Even after your periods stop you might still be at risk of getting pregnant. If you are having any sexual contact that puts you at risk of pregnancy you must talk to your health team about contraception options.

Sex

Taking testosterone causes your vagina to become dryer and more fragile. This increases the risk of sexually transmitted infections (STIs), including HIV if you are having any sexual contact with this part of the body. Condoms provide good protection against STIs and lubricant helps to prevent any discomfort.

Mental health

Some people find that testosterone can cause emotional changes such as increased irritation, frustration and anger. Some people find their mental health improves – the effects of hormones on the brain are not fully understood.

Transitioning can be a stressful time and many people need some help adjusting to the physical and emotional changes. It is really important that you let your health team know if you are having problems so that they can help you access the support you need.

Potential risks of testosterone

The full medical effects and safety of taking hormones are not fully known. The potential risks of taking testosterone must be weighed against the benefits that hormones can have on your health and quality of life.

Likely increased risk

- Increased red blood cells (polycythemia) – might thicken the blood and increase the risk of a stroke or heart attack
- Sleep apnoea (sleep disorder)

Possible increased risk

- Increased blood pressure
- Liver problems
- Increased prolactin and possibility of benign pituitary tumours

Possible increased risk if you have extra risk factors

- Diabetes
- Increased blood pressure

No increased risk or unknown

- Breast cancer
- Cervical, ovarian, uterine cancer
- Blood clots – deep vein thrombosis (DVT)

The risk of health problems is higher if you are a smoker or overweight.

Keeping in touch with your health team for regular check-ups and blood tests is an important part of your care and will reduce the risks of taking hormonal therapy.

Are there any other questions you want to ask?

It is your health team's responsibility to best support you to make the decisions that are right for you and to keep ourselves up to date so that we can best inform you.

For many different reasons people question whether or not they want to continue to take hormones. This can be a normal part of your journey. Please feel free to discuss this with your prescriber before you stop your medication. Come and talk – your health team is always ready to listen.

I wish to start masculinising hormone therapy:

Name .....

Date .....

Prescribed by:

Name .....

Date .....

Appendix G:

Testosterone administration

Practical tips for health professionals

Visual overview of available formulations of injectable testosterone

NB: this is not patient information. Useful resources for patients wishing to self-administer Sustanon or Depo-testosterone can be found here: Transgender health injection guide

Reandron
(testosterone undecanoate)

Comes in a vial. Usually given 12-weekly. Single use vial, dose up to 4ml.

Sustanon
(testosterone esters)

Comes in a glass ampoule. Single use, usually given 3-weekly. Can be self-administered.

Depo-testosterone
(testosterone cypionate)

Comes in a vial, each vial contains 5-10 doses. Usually given fortnightly. Can be self-administered.

General advice for all formulations:

- The first injection can be very significant for people – they may have waited a long time to start. Important not to rush; ensure privacy.
- Obtain and document consent, ensure person is aware of potential side effects.
- All formulations should be administered slowly.
- 20-minute wait after the first injection is recommended in case of allergy.

Storage

- All formulations need to be stored below 30°C (e.g. in a cool cupboard away from direct sunlight). Do not refrigerate or freeze.
- Sustanon should be used immediately once the ampoule is open as it cannot be resealed.

Preparation

- As with all medicines, check expiry date first, and '5 rights of medication administration' (the right person, drug, dose, route, time).
- Slightly warming the formulation beforehand in one's hands it easier to prepare and administer.
- Injecting the same volume of air as the dose required into the vial for Reandron and Depo-T can break the vacuum and make it easier to draw up the liquid, but this is not essential. This will not be possible with Sustanon.
- Always check for air bubbles in the syringe and remove prior to administration.

Administration

- As with any deep intramuscular injection the ***ventrogluteal*** site is the best administration site for all formulations: reported to be less painful, less risk of injury to underlying nerve structures, less risk of oil embolism as no major blood vessels, and usually less adipose tissue and more muscle. However, it can be given in the ***dorsogluteal*** site. The same site should not be used every time, so rotate between left and right side each injection.
- Can be given standing or supine per personal preference (supine recommended for Reandron). People self-administering their testosterone usually use the vastus lateralis or rectus femoris sites as better access.
- All formulations are given as a deep intramuscular injection so best use a 38mm (1.5”) 22 G needle to administer. Important to inject into deep muscle as testosterone can cause necrosis or abscess formation if given too superficially/into adipose tissue.
- Depo T can also be given subcutaneously but there is not yet enough evidence around the safety and efficacy of giving Sustanon via this route. Note that the dose and regime for subcutaneous administration of Depo T is not the same as for the intramuscular route.
- As with all intramuscular injections, Z-track technique is recommended to prevent tracking of the medication into the subcutaneous tissue.
- Always aspirate first before injecting solution to ensure the needle is not in a blood vessel.
- All formulations should be administered ***slowly*** and at a steady, controlled pace.

Disposal

- Some people like to keep their ampoules/ vials so check first before disposal.
- Dispose of all syringes per usual protocol, e.g. via a sharps bin.
- Local needle exchanges often have facilities for safe sharp disposal for self-administration.

Reandron

- Ideally given over 4 minutes, very thick solution so takes time, be patient!
- Doses should not be split (i.e. needs to be given as 4ml dose not 2 x 2ml).
- Use an 18G needle to draw up medication then change to 38mm 22G or 21G needle to administer.
- For dose of 3ml or less, use a 3ml syringe as resistance will be less. For a dose of 4ml use a 5ml syringe.

Sustanon

- Contains arachis oil – check no peanut allergies first.
- When breaking the top, have the 'small blue dot' facing away from you. This indicates the weakest point of the vial. You can then break the vial by snapping the top off towards you. Use a gauze or tissue to do this to protect your fingers from the glass – can be sharp.
- Use a blunt filter needle in case of glass fragments to withdraw solution into the syringe.
- Change to 38mm 22G needle when ready to administer.
- Use a 1ml tuberculin syringe or 3ml syringe, depending on dosage. For a dose of 1ml, a 3ml syringe is usually easier to prepare.

Depo-testosterone

- Use within 28 days.
- Use alcohol swab to clean the rubber bung each time before drawing up (allow time to dry).
- Replace lid and secure until next visit.
- Can use 18G needle to draw up medication then change to 38mm 22G needle to administer.
- Can use 1ml tuberculin syringe or 3ml syringe, depending on dose.

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United States District Court
Northern District of Florida

Case Number: 4:22-cv-00325-RH-MAF

August Dekker, et al.
Plaintiffs,
vs.
Jason Weida, et al.
Defendants:
_____/

VIDEOCONFERENCE DEPOSITION OF
JASON WEIDA

DATE: April 24, 2023
TIME: 3:00 p.m. - 6:31 p.m.
LOCATION: 119 South Monroe Street, Suite 500
Tallahassee, Florida 32301
REPORTED BY: John Bilich, Notary Public
JOB NO.: 5884626

A P P E A R A N C E S

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A No.

Q Do you recall being in attendance at a meeting with officials from the governor's office and people from the Florida Department of Health, as well as people from AHCA prior to April 20th of 2022?

A Not -- may I ask you a clarifying question?

Q Yes, of course.

A Okay. Regarding gender-related issues?

Q Correct. Well, gender dysphoria and transgender issues in particular, not gender issues generally.

A Right, I just want to make sure, because we have a lot of meetings and I have met with the Department of Health in the past on a range of topics. But with respect to the topics at issue in this lawsuit, I do not recall being at a meeting with all of those individuals.

Q Do you recall being in a meeting with some subset of those individuals?

A Yes, I do.

Q Okay. When was that?

A I don't have an exact date, but I believe it would have been early April.

Q Who was present in the meeting?
A So in addition to myself -- well, I want to be -- I just want to be clear here. So I remember two such meetings, and I don't remember exactly who was at one meeting versus the other, but I can tell you who I remember being at both of those meetings cuz I know that there was at least one person and possibly more who was at one, but not both, and I just don't remember which ones those were. But I can just tick through the whole list if that's okay with you?
Q Fair enough. Before you do that, was the other meeting -- you mentioned that one meeting was early April. Was the other meeting in March, or was the other meeting after the meeting in early April?
A I believe it was after the meeting in early April.
Q So, as you recall today, you had a meeting in early April and then a meeting after that meeting, correct?
A That's correct.
Q All right. So let's start with, tell me everyone that you can remember that was in those meetings collectively, since you can't remember who was in which one.

A Right. So, collectively, obviously without representing that they were all there for both, the people that I remember being at one or the other, or possibly both of those meetings, were secretary Marstiller, who was the secretary of the Agency for Healthcare Administration at the time. Cody Farrill, who was the chief of staff at the Agency for Healthcare Administration at the time, Josie Tamayo, who was the General Counsel for the Agency for Healthcare Administration at the time. Andrew Sheeran, who at the time was the chief litigation counsel. He worked for Josie Tamayo. He's our current General Counsel, but at the time he was the chief litigation counsel. I recall Ryan Newman being present. Ryan is and was at the time the governor's General Counsel. And at one or both of those meetings, Katie Strickland, who is the deputy chief of staff for the governor, one of the deputy chiefs of staff. And I also recall Maureen Furino, although I don't remember if she was present or just called in. I think she might have called into the meeting. So I don't think she was technically present.

Q And who is she?

A She is a deputy General Counsel. She

worked for Mr. Newman.

Q Okay. Anyone else you recall being there?

A Not that I can recall.

Q Who called the meeting?

A I don't know who --

Q -- organized -- (Talking simultaneously.) [Inaudible].

A I don't know.

Q How did you find out you were going to be there, or needed in the meeting?

A I believe I was invited by somebody from the agency management team at the Agency for Healthcare Administration. I just don't remember who that would've been.

Q What were you told the meeting was going to be about?

A I was told the meeting was going to be about recent guidance that had been issued by the United States Department of Health and Human Services regarding treatments for gender dysphoria.

Q And do you recall who told you that?

A No, I don't.

Q Do you recall, did you get a calendar invitation for the meeting?

A I don't recall. It was about a year ago,

Q Yes.

A So, I don't have the full list in front of me, but my understanding is that there are, I don't know exactly how many, but several coverage policies in the Bureau of Medicaid policy that provide for various mental health and behavioral health services for the treatment of gender dysphoria.

Q What analysis was done to determine whether or not there's any evidence that psychotherapy or behavioral health therapy on its own is an appropriate treatment for gender dysphoria?

A Well, the GAPMS report focused on the procedures that are described in the current rule. The GAPMS report did not focus on, directly at least behavioral health services. So that was not part of the GAPMS process or the review.

Q Has any analysis been done to determine whether or not psychotherapy or behavioral health therapy alone is an appropriate treatment for gender dysphoria?

A I don't know the answer to that question.

Q Shouldn't you know the answer to that question? Is if that's the only thing that's covered for gender dysphoria, shouldn't you know, as

Posted on 04/11/2023 by **brandon (/user/730)**

Equality Florida Issues Advisory Warning For Travel

ST. PETERSBURG, FL -- Today, Equality Florida took the extraordinary step of issuing a travel advisory, warning of the risks posed to the health, safety, and freedom of those considering short or long term travel, or relocation to the state. The move comes in response to a wave of safety inquiries Equality Florida has received following the passage of laws that are hostile to the LGBTQ community, restrict access to reproductive health care, repeal gun safety laws, foment racial prejudice, and attack public education by banning books and censoring curriculum.

“As an organization that has spent decades working to improve Florida’s reputation as a welcoming and inclusive place to live work and visit, it is with great sadness that we must respond to those asking if it is safe to travel to Florida or remain in the state as the laws strip away basic rights and freedoms,” said **Nadine Smith, Equality Florida Executive Director**. “While losing conferences, and top students who have written off Florida threatens lasting damage to our state, it is most heartbreaking to hear from parents who are selling their homes and moving because school censorship, book bans and health care restrictions have made their home state less safe for their children. We understand everyone must weigh the risks and decide what is best for their safety, but whether you stay away, leave or remain we ask that you join us in countering these relentless attacks. Help reimagine and build a Florida that is truly safe for and open to all, and where freedom is a reality, not a hollow campaign slogan.”

Governor Ron DeSantis, who has made the extremist policies the centerpiece of his presidential campaign strategy, has weaponized state agencies to silence critics and impose sanctions on large and small companies that dissent with his culture war agenda or disagree with his attacks on diversity, equity, and inclusion.

Already, the adopted and proposed policies detailed in the travel advisory have led Florida parents to consider relocating (https://19thnews.org/2023/02/queer-florida-parents-leaving-state-dont-say-gay/), prospective students to cross Florida colleges and universities off their lists (https://www.forbes.com/sites/petergreene/2023/03/31/survey-1-in-8-florida-incoming-freshmen-plan-to-flee-desantiss-education-policies/?sh=c2cc6f42dfda), events and conferences to cancel future gatherings (https://www.lgbtqnation.com/2022/09/large-gaming-event-set-florida-canceled-dont-say-gay-law/), and the United States military to offer redeployment for service members whose families are now unsafe in the state. Businesses have spoken out against the governor’s abuse of state power to punish dissent, with Disney CEO Bob Iger calling DeSantis “anti-business and anti-Florida (https://www.theguardian.com/us-news/2023/apr/04/disney-bob-iger-ron-desantis-florida).” The worsening attacks, especially those targeting transgender youth, have also led to the proposal of policies around the country (https://thehill.com/homenews/3861492-amid-tidal-wave-of-anti-trans-legislation-democratic-states-race-to-become-refuges-for-gender-affirming-care/) to provide refuge for those fleeing states like Florida.

The Florida Immigrant Coalition, a statewide immigrant rights coalition of 65 member organizations and over 100 allies, also issued a travel advisory today (https://floridatraveladvisory.com/), urging reconsideration of travel to Florida and providing critical information about where immigrant travelers can learn more about their constitutional rights. And just weeks ago, Florida chapters of the NAACP voted unanimously (https://naacp.org/articles/naacp-florida-state-conference-recommends-travel-advisory-state-response-african-american) to request similar warnings to the Black community about the risk of traveling or relocating to the state.

Equality Florida's full travel advisory follows.

MEMORANDUM

To: Interested Parties

From: Equality Florida

Subj.: TRAVEL ADVISORY: FLORIDA MAY NOT BE A SAFE PLACE TO MOVE OR VISIT

Date: April 12, 2023

Today, Equality Florida took the unprecedented step of issuing a travel advisory to individuals, families, entrepreneurs, and students warning that Florida may not be a safe place to visit or take up residence. The advisory comes after passage of laws that are hostile to the LGBTQ+ community, restrict access to reproductive health care, repeal gun safety laws and allow untrained, unpermitted carry, and foment racial prejudice. The Governor has also weaponized state agencies to impose sanctions against businesses large and small that disagree with his attacks on diversity, equity, and inclusion.

Florida has recently adopted a slate of hateful laws, and is fast-tracking additional measures that directly target the rights of LGBTQ+ individuals and basic freedoms broadly. Already, those policies have led Florida parents to consider relocating (https://19thnews.org/2023/02/queer-florida-parents-leaving-state-dont-say-gay/), prospective students to cross Florida colleges and universities off their lists (https://www.forbes.com/sites/petergreene/2023/03/31/survey-1-in-8-florida-incoming-freshmen-plan-to-flee-desantiss-education-policies/?sh=c2cc6f42dfdahttps://www.forbes.com/sites/petergreene/2023/03/31/survey-1-in-8-florida-incoming-freshmen-plan-to-flee-desantiss-education-policies/?sh=c2cc6f42dfda), events and conferences to cancel future gatherings (https://www.lgbtqnation.com/2022/09/large-gaming-event-set-florida-canceled-dont-say-gay-law/), and the United States military to offer redeployment for service members whose families are now unsafe in the state. These laws and policies are detailed below.

Assaults on Medical Freedom

- Florida's Boards of Medicine and Osteopathy have adopted policies banning access to lifesaving medical care for transgender youth and the Agency For Health Care Administration has eliminated Medicaid coverage for transgender adults accessing that care
- Florida is poised to pass laws creating criminal penalties for medical providers who provide medically necessary care for transgender youth, weaponizing the courts to shred existing child custody agreements and reassign transgender youth to an unsupportive parent, and severely restricting access to prescribed medical care for transgender adults
- Florida has passed or is poised to pass bills that restrict access to reproductive health care, including a near-total abortion ban, which threatens to force people to travel out of state or seek unsafe, illegal abortions.

These policies disproportionately harm marginalized communities, including the direct impacts on the transgender community and communities of color, and could lead to serious health consequences. Transgender people in Florida are facing the immediate threat of loss of lifesaving, medically necessary care and families risk interference in child custody arrangements at the hands of an unsupportive parent and a weaponized state court system. These attacks pose an imminent threat to the health and safety of all in Florida and potential travelers should be aware of the risks.

Assaults on Academic Freedom

- The Florida legislature has sought to strip Diversity, Equity, and Inclusion (DEI) programs from colleges and universities, that help LGBTQ and minority students thrive
- The Governor has initiated a hostile, right-wing takeover of higher education, and installed partisan allies to implement a conservative overhaul of public universities
- His administration has taken aim at AP African American studies, threatening to sever ties with the College Board over the inclusion of queer history and intersectionality in the course, and college majors, including gender studies

These actions by the Governor pose a serious threat to academic freedom, free speech, and the pursuit of knowledge. DEI departments play a crucial role in promoting diversity and inclusion on campus, and their removal undermines the ability of students and faculty to engage in critical discussions about issues of race, gender, and identity.

Furthermore, the replacement of university presidents with political appointees threatens the independence of higher education institutions, and undermines the ability of these institutions to make decisions that are in the best interest of their students, faculty, and staff. These attacks on public education are deeply concerning, and further reinforce the message that Florida is not a welcoming state for people from all backgrounds. We urge individuals, families, entrepreneurs, and students to consider the implications of traveling to or residing in Florida, and to support efforts to defend public education and academic freedom in the state.

Censorship and Erasure of the LGBTQ Community

- Florida has passed a prohibition on classroom instruction on sexual orientation and gender identity in public schools
- This law has already precipitated a raft of damaging impacts in school districts across the state, including
    - Hundreds of book challenges and bans targeting titles written by LGBTQ authors and/or including LGBTQ characters
    - The refusal of districts like Miami-Dade to recognize LGBTQ History Month
    - The removal of rainbow Safe Space stickers
    - The censorship of graduation speech content to remove references to LGBTQ identities
    - Warnings to educators and administrators to hide family photos
- Lawmakers are currently considering a bill to extend that prohibition through 8th grade, while the Department of Education is set to decide on a policy proposal that would expand it to all grades and revoke teacher licenses over violations
- Florida is poised to pass a bill that would ban transgender people from updating their birth certificates to reflect their gender identity

The infamous Don’t Say LGBTQ law has made Florida synonymous with the anti-LGBTQ movement to empower government censorship and book banning across the nation. That law, along with additional proposals being considered, has turned the state’s classrooms into political battlefields and is telegraphing to LGBTQ families and students that they are not welcome in Florida.

Assaults on Arts, Entertainment, and Sports Participation

- Florida has passed a ban on transgender women and girls from participating in school sports consistent with their gender identity
- Lawmakers are poised to pass restrictions on certain live drag performances, stage shows, and local pride celebrations, limiting parents’ ability to determine what content may be suitable for their families

The far-right's obsession with drag queens has put LGBTQ people in physical danger across the country, but especially in Florida. In 2022 alone, the LGBTQ media organization GLAAD found 141 incidents of anti-LGBTQ protests and threats targeting drag events. Right-wing media like Fox News and Libs Of TikTok have misrepresented what occurs at drag events and taken examples out of context to create fear and misunderstanding. This has had real world consequences, with protests and threats of violence against venues hosting drag shows.

In Florida, Orlando organizers were forced to cancel Drag Queen story hour due to threats from Neo-Nazis (https://www.orlandoweekly.com/news/orlando-area-drag-queen-story-hour-canceled-due-to-neo-nazi-threats-32762594). This last December in Lakeland (https://www.fox13news.com/news/demonstrators-wearing-nazi-gear-show-up-outside-lakeland-charity-event-that-included-drag-performers), masked individuals in Nazi gear, waving Nazi flags ambushed a charity event hosted by drag queens while projecting hateful messages onto local buildings.

Assaults on Business

- DeSantis has recently signed a bill that restricts businesses from providing diversity and inclusion training to their employees, a blatant attempt to dictate to businesses what they can and cannot do, and to prevent them from training their employees to be better prepared for a diverse workforce and customer base
- The Florida legislature is expected to pass SB 1438, which weaponizes state agencies with more power to politically target LGBTQ-friendly businesses who open their doors to live drag performances, with threats of fines, license revocation, and jail time. Individuals that admit minors with an accompanying parent would be charged with first degree misdemeanor crimes.
- The governor has weaponized the state legislature against businesses that stand with their LGBTQ employees and clients and against his agenda, most notably wielding two special sessions of the legislature to punish Disney, the state's largest single-site employer

The Miami Herald recently reported (https://www.miamiherald.com/news/politics-government/state-politics/article273247175.html) that DeSantis-controlled agencies sought to punish and revoke the liquor license of an Orlando establishment that hosted a live drag performance even after the state's own investigators reported that they saw nothing "lewd". The discriminatory targeting of LGBTQ-friendly businesses by the state will have a broader chilling effect over drag performances, an intended consequence of this type of censorship.

Disney has also recently denounced the governor's actions against them, with CEO Bob Iger calling the state's policies "anti-business and anti-Florida (https://www.theguardian.com/us-news/2023/apr/04/disney-bob-iger-ron-desantis-florida)."

These laws and actions are harmful to businesses and their employees, as they undermine efforts to create inclusive workplaces and hinder the ability to effectively engage with diverse customers and clients. It also sends a message that Florida is not a welcoming state for people from all backgrounds and that discrimination is acceptable.

Efforts to Foment Racial Prejudice

- Florida has passed a bill that would limit the honest teaching of history and systemic racism in schools
- The state passed another that restricts voting access for people of color and is currently considering additional voting restrictions
- DeSantis' new elections police have abused their power to aggressively target and prosecute returning citizens, mostly Black Floridians, for voting after official government entities told them they were eligible to vote (https://www.politico.com/news/2022/08/26/desantis-voter-fraud-defendants-florida-00053788)

These laws create an unsafe and unwelcoming environment for LGBTQ+ individuals, women, people of color, and other marginalized communities. They send a message that discrimination and prejudice are acceptable in Florida, and we cannot in good conscience encourage people to visit or move to a state that is openly hostile to their basic human rights.

As a result of these dangerous and discriminatory laws, we urge individuals, families, entrepreneurs, and students to reconsider travel plans to Florida and to consider the impact that their travel and economic choices can have on promoting equality and justice for all.

Repealing of Gun Safety Laws

The passage of deadly permitless carry makes Floridians less safe (https://everytownresearch.org/solution/strong-standards-for-carrying-concealed-guns-in-public) and signals the reversal of the progress made after Pulse and Parkland. Coupled with the state's infamous Stand Your Ground law, Permitless Carry threatens to exacerbate Florida's violent crime rate at a time when the state's homicide rate ranks 20th in the nation, exceeding both California and New York.

LGBTQ Floridians know all too well that the gun lobby's obsession with easy access to deadly weapons can make hatred and bigotry lethal (https://www.hsph.harvard.edu/news/hsph-in-the-news/do-guns-make-us-safer-science-suggests-no/). Gun violence is not abstract or hypothetical -- it is stealing our loved ones. Those considering travel to Florida should weigh the potentially deadly consequences of the DeSantis Administration's decision to eliminate basic training and permitting requirements in order to concealed carry a firearm.

Attacks on Immigrant Communities

Florida has passed and is poised to pass legislation targeting immigrant communities, with consequences that could include arrest for operating a vehicle, no matter the state you are from, reduced access to health care services, and compromised safety. A bill currently being considered by the Florida legislature could impose criminal penalties on any who shelter, support, or provide transportation to undocumented immigrants. And these moves come just months after Governor DeSantis trafficked migrants from Texas to Massachusetts in a cruel scheme to use their suffering as campaign marketing material.

The threats posed to immigrants in Florida led the Florida Immigrant Coalition to issue its own advisory urging reconsideration of any travel to the state. That advisory can be found here (https://floridatraveladvisory.com/).

Conclusion

Taken in their totality, Florida's slate of laws and policies targeting basic freedoms and rights pose a serious risk to the health and safety of those traveling to the state. We regret that these attacks have already led many to flee the state and are driving others to consider relocation. And, in a state whose economy is fueled by visitors from around the world, it is with great sadness that Equality Florida has had to take the extraordinary step of responding to inquiries by issuing an official advisory warning about the risks of travel to the state.

Equality Florida will continue providing information and resources to those impacted by these laws and policies. Visit our Open Doors Florida directory (https://opendoorsflorida.com/) to find businesses with nondiscrimination policies and procedures. And if you experience discrimination, report it to our team here (https://eqfl.org/lgbtq-protections) or call our Main Office at 813-870-3735.

It is our hope that those Floridians who can, will stay and engage more deeply in the fight against the state's all-out assaults on democracy and freedom. This moment calls for a grassroots movement in defense of justice and equality for all -- so that we can turn back the tide of right wing authoritarianism, recommit to building a state that is safe and open to all, and once again celebrate Florida as a free state.

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