- It is already known that almost all children who use puberty blockers go on to progress with more damaging gender transition treatments, whereas those that do not use puberty blockers are much more likely to see their gender confusion resolve at the onset of puberty.

Response produced by Katy Montgomerie

Question 3A

All new clinical staff should be specialists in trans healthcare and dealing with trans and gender diverse youth, or have been trained in this. It is not good enough to just have an expert in autism or neurodisability, etc who has no experience or expertise working with trans kids.

Adding support for trans kids with other intersecting conditions is very good, however it must not be used as an excuse to deny trans kids healthcare on the flawed premise that autistic kids cannot be trans or that they don't know who they are for example.

A multidisciplinary team being available when necessary is a good thing for those in need of it, but it should not be required for every patient to waste time having to talk to all of these specialists. This should be about providing extra support, not about adding in new gatekeeping or excuses to deny trans children healthcare.

Question 3B

The person overseeing trans healthcare for trans kids in the UK should be a trans person. We wouldn't accept it if the people in charge of women's healthcare from top to bottom were men, women must have a say in their healthcare, and so must trans people.

Moving towards depathologising NHS help for trans kids is good.

Any expert who is in this role must have expertise working with trans people before starting this role. No cis people learning on the job.

Question 3C

Any interim service should be there to support referrals and not just add an extra step of gatekeeping to slow trans kids down from accessing the care they need.

Local support is good in principle, however it is a reality that many trans people have unsupportive or even hostile GPs towards their care. Any change in this regard must acknowledge this and ideally should provide a route around transphobic service providers and should make it so that hostile attitudes towards trans healthcare are not accepted in the NHS.

This local support must be available to new patients and not just those already on the offensively long waiting lists already.

The goal of local services should be to support trans kids in parallel, helping them while they wait for specialist services, not as just an extra step to hold them back from accessing care.

I am well aware that the NHS has completely failed to keep to its own guide of 18-week waiting times when it comes to all trans people, but I think that anyone building a new improved service must commit to these times and make that clear

Question 3D

It is essential that if a patient has an unsupportive or openly hostile GP that they are able to have a route around this. I think it is unreasonable to just assume that a teenager or even a parent will be able to shop around for GPs, there must be other routes. It is naïve and frankly ignorant to assume that every GP has the best intentions for trans people at heart.

Seeing as you acknowledge that only 5% of referrals come from outside the NHS today this move seems pointless as it is clearly not a large burden on the service and is likely just from kids who feel that the person they told is the most supportive adult in their life.

Question 4

Social transition includes some or all of changing clothes, hairstyle, makeup use, name and pronouns. It is beyond ridiculous that the NHS thinks that it can mandate what clothes someone would wear or how they would want to be referred to.

Kids should be allowed to explore who they are and how they want to present without being forced to adhere to outdated gender roles. There is no reason why any child should be forced to wear certain clothes. There is no evidence at all to show that letting a child express themselves is more or less likely to result in them being trans when they hit adolescence.

It is inappropriate for a GP or any healthcare professional to try and dictate how a child or anyone live their lives. To me this seems like an attempt to allow the pushing of conversion therapy onto trans kids. As you well know conversion therapy of all LGBT people is often largely focussed on controlling things such as expression and presentation.

Question 5

Describing HRT and blockers as “unregulated drugs“ is false, these medicines are very regulated in the UK. Describing them like this gives the impression that they are either black market or illegal. This comes across as fearmongering about medicine that cis people are able to access over the counter.

The goal of the NHS should be making it so private healthcare is not needed at all by anyone. If private healthcare options exist it is a sign that the NHS is already failing. In the case of trans healthcare the NHS has been failing so badly for so long for so many people that private options are absolutely essential. This of course excludes those unable to afford them, which is discriminatory, but pressuring

or closing down these services will not help anyone and will just force people to buy from the black market or move abroad. There is no reason at all that private services would provide lesser or inadequate care. In fact what we have seen historically is that private options provide care much closer to that of the international guidelines than the disgraceful level of healthcare the NHS has provided trans people.

I personally have had to rely on private healthcare for my own transition for almost every step of the way because the NHS has totally failed trans adults like me, and for trans kids it is currently even worse.

If the NHS wants to create a system without private healthcare options then they should just meet the international guidelines for trans healthcare in a timely fashion.

Question 6

There should be explicit commitment to wipe out conversion practices in all forms.

Forcing all patients to participate in research in order to get healthcare is unethical. It prevents people having autonomy over their own lives and may prevent some people accessing care. Many trans people would be more than happy to voluntarily sign up to being part of studies on trans healthcare, there is no need to treat us as lab mice.

This document makes no reference to NHS fertility services for young trans people. These should be included.

HRT is an essential part of trans healthcare, this document fails to mention them and it is likely that local services will want to prescribe them and they should be given guidance on how to.

This service should be constantly evolving to meet the new best practices and should have constant involvement from patients and the community.

Question 7

The document claims that most prepubescent children grow out of gender dysphoria but does not provide any evidence for this claim.

The document incorrectly describes the Equality Act 2010 protected characteristic of Gender Reassignment. It is hard to read this as not a bad faith attempt to remove legal protections from young trans people. Anyone who proposes to undergo transition has this characteristic.

The equality impact assessment does not address how to mitigate the extra hurdles that disabled trans people and trans people of colour will face in accessing healthcare and support.

This document completely fails to acknowledge the fact that some young trans people may be pregnant. There is no reason why trans people would be less likely than cis people to undergo teen pregnancies.

Response from Gay Men's Network

Question 3: To what extent do you agree with the four substantive changes to the service specification explained above?

A: Composition of the clinical team

We welcome the decision to extend the clinical team to include specialists in areas other than gender dysphoria to allow co-existing mental health conditions to be assessed alongside a patient's gender incongruence. Specialists should have a clear understanding of how young people's mental health, including feelings of anxiety and depression, can be affected by the manifestation of their sexual orientation and that homophobia – both external and internal – can be a major driver for referral to The Service. It is vital that clinical teams are aware of homophobia as a safeguarding risk and can assess if patients are being driven to The Service as a means of escape or through parental or other coercion/peer pressure. We would suggest that this is also integrated into the ongoing training regime that NHS England proposes elsewhere in the ISS.

We agree that a multidisciplinary team using standardised assessment and diagnostic criteria creates a robust and auditable treatment approach which can guard against the "diagnostic overshadowing" identified in the Interim Cass Report. We would urge The Service to include experience of homophobia and, where appropriate, feelings towards sexual orientation as an integral part of the assessment criteria to be developed.

We applaud the recognition that autism spectrum conditions were overrepresented in GIDS patients. This recognition represents a marked and welcome shift from the lack of critical inquiry demonstrated by GIDS in the face of the evidence before them. The complete lack of clinical curiosity or inquiry into the overrepresentation of autistic spectrum disorder patients among referrals to GIDS represented a fundamental failing of GDIS to protect vulnerable young people. The proposed multidisciplinary team should, therefore, include psychiatrists and psychologists or psychotherapists with specialist clinical training and experience of working with ASD patients.

B: Clinical leadership

We agree with the decision to make the clinical lead for the service a medical doctor. Doing so would create a single, expert locus for accountability, coordination and decision making.

Medical doctors are professionally accountable to their Regulators and professional disciplinary bodies and liable for damages where negligent practice is proved. In an area where questions as to Gillick competence and ideological malpractice have arisen, the opportunity of recourse to a

professional regulator offers further assurances of and clear mechanisms for accountability. It is also consistent with the professional regulation of other NHS services.

We welcome the reference in the ISS that the clinical lead be those with significant experience in child development. Such experience will be necessary to provide effective clinical oversight of the multidisciplinary team being proposed. We would strongly urge that clinical leads be alive to and are trained as to the risks of internalised and external sources of homophobia in prompting referrals to the service.

C: Collaboration with referrers and local services

We welcome this measure which it is hoped will relieve pressure on the GIDS waiting lists.
Long waiting times were often used to criticise GIDS and left patients without assessment or treatment for significant periods. We support increased collaboration between The Service
and local professionals to properly assess young people and that the ISS explicitly states that not all children may reach the criteria for access to The Service. In particular, we commend the specific mention of "watchful waiting" as a valid treatment pathway. It is clear from the research that has been done that up to 80% of young people presenting with gender incongruence will desist after puberty. The majority of those will grow up to be gay or lesbian. It is important that this fact is recognised, and those young people are supported, given the time and opportunity to grow rather than placed on an irreversible medical pathway.

We support the revised model whereby The Service provides specialist support to local professionals in developing individual care plans for patients and the focus on awareness of co-existing mental health and other conditions. These care plans must include therapeutic interventions to address any co-existing conditions and, in particular, assess their contribution to the patient's sense of gender incongruence. The ISS also highlights working with local networks to ensure safeguarding and the involvement of child services where concerns are raised. We hope that service providers recognise homophobia as a safeguarding risk since this has so unequivocally been demonstrated as a key motivator for many young people and some families who engage with The Service in the first place. The ISS recognises "co-existing mental health, neurodevelopmental and/or family or social complexities" as sources of distress for young people presenting with gender incongruence. We would urge The Service to include homophobia as an additional source of distress these young people may experience on the basis that the evidence for this is overwhelming (Appendix 1).

D: Referral Sources

We support the proposed change. While only affecting 5% of referrals, it is an important signal that non-medical groups are no longer part of the referral process, and that only medical or other statutory bodies will be involved. Indeed, the interim Cass Review noted that it was unusual for a specialist service such as GIDS to accept referrals from non-medical sources. We know from previous evidence that the GIDS service had been unduly influenced by external lobby groups and that clinicians were, in some cases, overly concerned with placating these groups. The involvement of these groups has

presented a serious lapse in safeguarding. It is vital that services for vulnerable young people be rooted in sound, clinical practice and not subject to the political or ideological positions of lobby groups.

Question 4: To what extent do you agree that the interim service specification provides sufficient clarity about approaches towards social transition?

We welcome the acknowledgement in the ISS that gender incongruence in most prepubertal children does not continue into adolescence and the marked shift from “affirmation“ to “careful observation“ as the clinical focus. Furthermore, the ISS recognises that, as expressed in the interim Cass Review, social transition is not a “neutral act“ and that social transition carries with it the risk that the child will experience further difficulties reversing the behaviour if their gender incongruence resolves in adolescence.

We would further point out that social transition, like most ideas of gender, relies upon societal stereotypes of male and female behaviour. It is important to recognise that homophobia from parents or guardians and social media can also play a significant and detrimental role in inappropriate social transitioning. We would recommend that, in addition to the deeper consideration of social transition in the ISS, it go further and make specific reference to familial and social/peer pressure as a safeguarding concern, with respect to social transition and the temporary nature of most gender incongruence.

Question 5: To what extent do you agree with the approach to the management of patients accessing prescriptions from un-regulated sources?

We fully support the recommendation in the ISS that The Service will not accept clinical responsibility for patients who have obtained masculinising or feminising hormones from unregulated sources. The NHS should not be a party to young people taking drugs provided to them by unregulated, online sources or ideologically driven lobby groups. We also welcome the increased clarity in the ISS in its advice to GPs to engage local safeguarding services where there is evidence that a patient has accessed these drugs from un-regulated sources. Where such medicines are obtained and safeguarding referrals under the proposed ISS are made, we would recommend those referrals fully capture any third-party activity by lobby groups or practitioners facilitating or encouraging this process. This step would ensure a policy that deals with causes as well as symptoms.

Question 6. Are there any other changes or additions to the interim service specification that should be considered in order to support Phase 1 services to effectively deliver this service?

We believe the ISS ought to explicitly acknowledge that a significant proportion of young people who present as gender incongruent or with gender dysphoria grow up to be homosexual.

Also, that the largest cohort of adolescents referred to GIDS were homosexual. From the statements of both Mrs Sonia Appleby and Dr David Bell, we know that homophobia from within the GIDS services and from patients’ families, as well as within the patient themselves, was a driving force in propelling many patients to and through The Service. As a group who advocate for homosexual males, we are

dismayed and confused as to why the ISS fails to cite homophobia as a safeguarding risk for young people presenting with gender incongruence.

We suggest that specific mention of homophobia as a safeguarding risk be made in the following sections:

7.1 Service aims

- We suggest an additional bullet point highlighting "Safeguarding against internalised and external homophobia as a reason for seeking referral to The Service"

8.1 Future Service Model

- We suggest adding a bullet point indicating that The Service will take appropriate action with regard to safeguarding concerns, particularly in the case of overrepresented groups within the patient cohort such as homosexuals.
- We would further suggest that the research programmes to be developed to better understand gender incongruence and clinical outcomes of treatment make specific reference to the sexuality of patients as a data point to be recorded, in appropriate circumstances.

8.2 Current Pathways

Support to Local Professional Networks

- We suggest adding text to the bullet point "… identifying co-existing mental health, neuro-developmental or other conditions" such that it reads "…Identify co-existing mental health, neuro-developmental or other conditions or safeguarding risks acting as drivers for referrals/service use such as internalised or external source homophobia"

Screening, triage and professional consultation & advice

- We suggest augmenting the text "Identify additional mental health needs/neurodevelopmental needs/safeguarding risks that require local professional care planning and support" such that the screening process includes assessment of the patient's experiences of homophobia, both internalised and external.

Standardised Assessment

- We suggest that the bullet point "With adolescents – psychosexual development and any sexual experiences" be modified to include sexual orientation.
- We suggest adding a bullet point to this list which deals with the initial MDT assessment to the effect of "The presence of internalised or external sources of homophobia where it appears they are driving referral to or use of The Service."

Psychoeducation

- The recommended psychoeducation resources in the ISS should be clear that not conforming to sex stereotypes is not a pathology. Practitioners should be alive to the fact that many young people who present as gender non-conforming will grow up to be homosexual adults.

Direct work with prepubertal children, and their families

- We suggest that therapeutic approaches for younger and prepubertal children also take into consideration the potential for homophobia or "avoiding having a homosexual child" when assessing familial/social circumstances and recommend the appropriate safeguarding measures where it is felt homophobia could be a contributing factor for referral to The Service.

Direct work with adolescents, and their families

- We suggest this section include direct reference to sexuality/sexual orientation as a source of distress for young people and their families. Furthermore, we suggest that The Service should treat with extreme caution, the use of or recommendation of social transition. Many homosexual people do not conform to sex stereotypes and were singled out and targeted as children for gender non-conforming behaviours. Clinicians need to be clear that not conforming to sex stereotypes is not a pathology and should not itself be a driver for referral to The Service, either by the patient themselves or by their family and certainly not by unqualified lobby groups.

Where a young person is mature enough to safely express a settled position about their sexual orientation, it should be recorded in the SPC charts and general data collection considered in section 7.2 of the proposed ISS. Robust data is necessary to understand the demographics of Service users in order to protect those young people who would otherwise grow up to be homosexual from unnecessary medicalisation and physical interventions.

In 2012, Dr Az Hakeem published his work on specialist psychotherapeutic intervention with adults experiencing gender dysphoria3. He describes a group therapy model bringing together patients experiencing gender dysphoria and those who have desisted or detransitioned. Hakeem found that, through the group therapeutic process, most patients resolved their gender dysphoria, did not go on to pursue physical interventions and were able, subsequently, to address any co-existing mental health difficulties that may have been contributing to their gender dysphoria. Such group therapeutic approaches could be applied to children and adolescents and should be part of any reformed treatment model.

In addition to his work on group therapeutic approaches to treating gender dysphoria, Hakeem, along with colleagues, devised a questionnaire, the Gender Preoccupation and Stability Questionnaire4 (GPSQ). The GPSQ which can be used both as a diagnostic tool for gender dysphoria but also track progress through any treatment – physical, social or psychological – in terms of the stability of the patient's sense of their gender and how troubled the person is by their gender. While the GPSQ was devised for adults, a version adapted for children, GPSQ25, has also been developed. We believe that the ISS should support the use of these tools as a means of gathering clinical data on patients moving through treatment for gender incongruence or dysphoria.

We note with some concern the proposal in the ISS for a research programme into the outcomes of treating gender incongruence/dysphoria with GnRHa hormone analogues and other masculinising/feminising drugs. We feel that this proposal should be subject to public consultation as to how such an exercise could possibly be ethical. It is our view that it cannot be.

We are further concerned about the inclusion of "voluntary community services" in the list of independent service components in Section 8.5 of the ISS. If The Service is to avoid a repeat of the scandal that unfolded at the Tavistock GIDS and Dr Cass's judgment that it was "not safe", the involvement of any volunteer community service must be closely regulated. We recommend that the ISS explicitly limit the role of such groups to make clear they have no role in or influence over best clinical practice for children and young people. This needs a strict and narrow definition as to what is meant and what, if any, services should even have a role to play.

We note the proposed ISS makes no provision for detransitioners. While we appreciate the objective of the proposed ISS is to allocate children and young people to appropriate clinical pathways reducing the number of detransitioners, it would be over-ambitious to imagine that this group will never be represented in the under-18 age range. Detransitioners presently face serious and significant challenges in accessing appropriate therapeutic and endocrine care and many are now speaking publicly on the subject. Given that fact, we consider the complete absence of detransitioners from the proposed ISS to be an omission which ought to be remedied by dedicated guidance on how the clinical needs of this cohort can be best met.

Question 7: To what extent do you agree that the Equality and Health Inequalities Impact Assessment reflects the potential impact on health inequalities which might arise as a result of the proposed changes?

We are surprised by the Equality and Health Inequalities Impact Assessment, in particular, the way it deals with homosexuals. In relation to the protected characteristic of sexual orientation we note the summary explanation of the main potential positive or adverse impacts of your proposal where you state "NHS England does not hold relevant data." This cannot be right.

All the available evidence suggests that homosexuals are one key group seriously impacted by a failure of safeguarding due to malpractice at the Tavistock GIDS. We therefore consider the Equality and Health Inequalities Impact Assessment to be wholly inadequate in two respects:

- First, the fact that sexual orientation data is not available suggests that homophobia has not been taken seriously up to this point. We have recommended recording this data so a reliable understanding of its influence on referrals can be obtained. Beyond this, we would suggest that the apparent overrepresentation of homosexuals in the patient cohort is itself a sign that homophobia is a concern.
- Second, we agree that the proposed ISS will do much to mitigate the concern that homophobia, both internalised and external, has been a significant problem at GIDS. However, the equality assessment makes no mention of historic homophobia at The Service, how the reformed Service intends to address homophobia as a safeguarding risk or how it will

be managed in the future. Indeed, the proposed ISS does not mention the word "homophobia" at all. We consider this to be a serious omission given the evidence. Homophobia has long been a concern in gender medicine and this fact ought to be reflected in both the proposed ISS and the Equality and Health Inequalities Impact Assessment if it is to be avoided in the future.

While we welcome much of the approach of the proposed ISS, in the context of this question we do emphasise and remind NHS England of its public sector equality duty under section 149 of the Equality Act 2010. Particularly as it relates to discrimination and harassment pertaining to sexual orientation. In addition, we note NHS England's various responses to its equality duties as follows (taken from NHS England's latest response/policy):

"The public sector Equality Duty that is set out in the Equality Act 2010 requires public authorities, in the exercise of their functions, to have due regard to the need to: Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act."

We trust that NHS England will have due regard to its own policies. The lack of safeguarding and the risk of homophobia we have referenced throughout this response does also give rise to a significant risk to the NHS of civil claims and Regulatory sanctions. We note you acknowledge in the impact assessment (and in the proposed ISS) prior intervention by the Care Quality Commission (CQC) at GIDS and its report and findings published in 2021 in terms of implementing recommendations. Here are two extracts from the CQC's report in relation to GIDS which are instructive:

"Staff did not always work well with other agencies to safeguard young people. Most records did not include plans, agreed with other agencies, on sharing information and protecting young people."

and

"Staff did not always feel able to raise concerns without fear of retribution. Some staff, particularly those in non-clinical roles, said there was a fear of blame within the service. This meant they were reluctant to raise concerns. Staff knew how to use the whistle-blowing process and about the role of the Speak Up Guardian. The Speak Up Guardian presented an annual report to the trust board. In their report in May 2019, the Speak Up Guardian stated that staff at GIDS had raised concerns and that many of these staff felt worried about speaking in open groups."

Accordingly, for the reasons we have given, we do not think that the impact assessment of risks in relation to sexual orientation are adequate. Over and above NHS England's public sector equality duty we remind you of your statutory duty to provide safe care and to safeguard users from improper treatment and abuse as per Regulations 12 and 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Section 13 also stipulates that care or treatment for service users must not be provided in a way that includes discrimination against a service user on grounds of any protected characteristic per the Equality Act 2010. Such duties should be clear legal requirements, be embedded into the assessment of risk, as well as the proposed ISS more generally.

TONIC

Interim service specification:

Interim specialist service for children and young people with gender incongruence

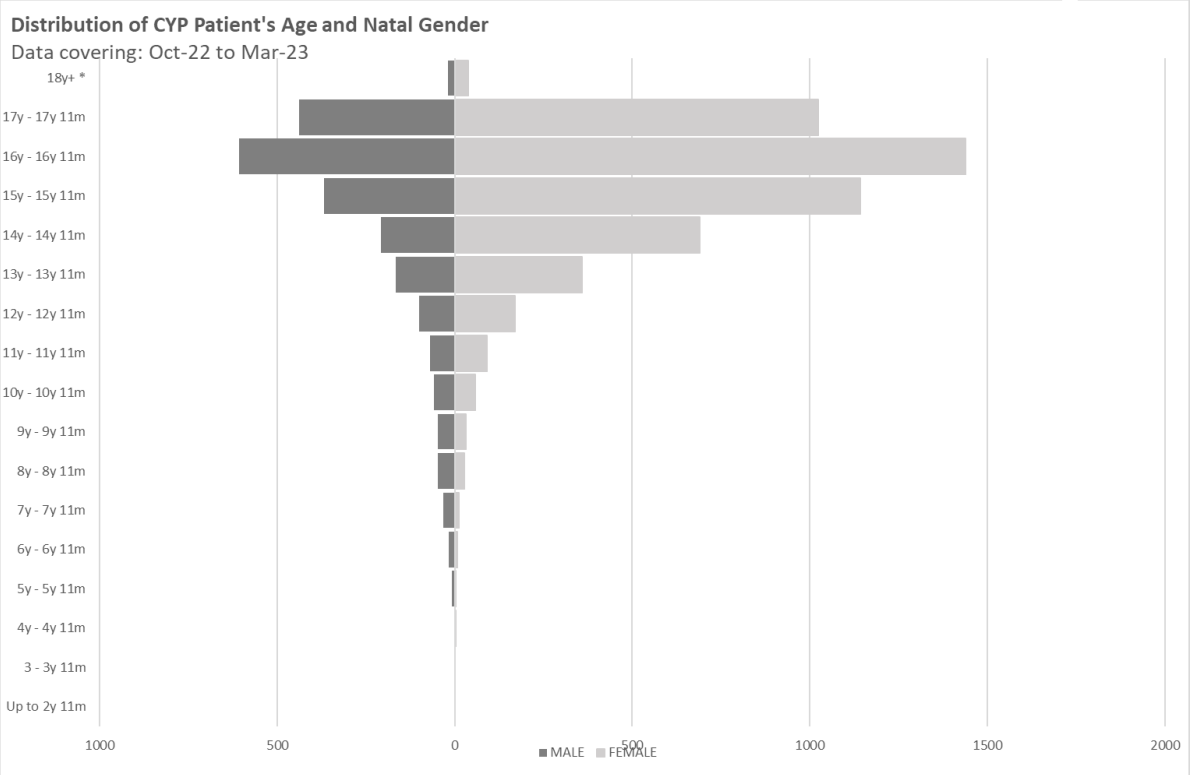
9 June 2023

1. Service name	INTERIM SERVICE SPECIFICATION Interim Specialist Service for Children and Young People with Gender Incongruence
2. Service specification number	
3. Date published	8 June 2023
4. Accountable Commissioner	NHS England

5.	**Summary**
	The Service will provide care to children and young people, and their families, who express gender incongruence and who are likely to benefit from clinical support. The Service will adopt a holistic, multi-disciplinary integrated approach to assessing and responding to an individual's needs in view of the range of co-presentations that may typically present in this patient cohort, and the range of complexities relating to gender identity development. The most appropriate clinical pathway in the best interests of the child or young person will be determined through an integrated multidisciplinary team (MDT) approach, fully involving the child or young person and their family. Providers delivering The Service must be an established specialist tertiary paediatric unit with a strong partnership with mental health services; be an established academic centre with a strong track record of research in children and young people; and have robust safeguarding frameworks in place.

	The clinical management approach should be open to exploring all developmentally and psychosocially appropriate options for children and young people who are experiencing gender incongruence. The clinical approach should be mindful that this may be a transient phase, particularly for pre-pubertal children, and that there will be a range of pathways to support these children and young people and a range of outcomes. Not all children and young people who present with issues of gender incongruence will require direct interaction with The Service; in many cases the most appropriate care can be provided locally including with additional support and consultation by The Service. A significant proportion of children and young people who are concerned about, or distressed by, issues of gender incongruence experience co-existing mental health, neuro-developmental and/or personal, family or social complexities in their lives. The relationship between these presentations and gender incongruence may not be readily apparent and will often require careful exploration. Where children and young people present with co-existing conditions or presentations, these will normally be addressed by the appropriate local service alongside this Service. The primary intervention for children and young people who are assessed as suitable for The Service is psychosocial (including psychoeducation) and psychological support and intervention; the main objective is to alleviate distress associated with gender incongruence and promote the individual's global functioning and wellbeing. The approach for onward referrals to endocrinology clinics are described in separate NHS England clinical commissioning policies for puberty suppressing hormone treatment and gender affirming hormone treatment.
6.	**Population and/or geography to be served**
6.1	**Population Covered** The defined patient cohort is children and young people up to their 18th birthday who are: • Registered with a General Practitioner in England or who are otherwise the commissioning responsibility of NHS England; AND • Who were under the care of the Gender Identity Development Service at the Tavistock and Portman NHS Foundation Trust; OR • Who were on the NHS waiting list for the Gender Identity Development Service managed by the Tavistock and Portman NHS Foundation Trust; OR

	• Who are referred to The Service because gender incongruence concerns may be present and which exceed the scope and expertise of local services. **Terminology** Gender incongruence of childhood (ICD11 HA61) *"Gender incongruence of childhood is characterised by a marked incongruence between an individual's experienced/expressed gender and the assigned sex in pre-pubertal children. It includes a strong desire to be a different gender than the assigned sex; a strong dislike on the child's part of his or her sexual anatomy or anticipated secondary sex characteristics and/or a strong desire for the primary and/or anticipated secondary sex characteristics that match the experienced gender; and make-believe or fantasy play, toys, games, or activities and playmates that are typical of the experienced gender rather than the assigned sex. The incongruence must have persisted for about two years. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis".* Gender Incongruence of Adolescence and Adulthood (ICD11 HA60) *"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".*
6.2	**Minimum population size** Estimates for the proportion of adults or children with gender incongruence vary considerably. This reflects a number of factors such as: variable data reporting by providers; differences in diagnostic thresholds applied and inconsistent terminology; the methodology and diagnostic classification used – population surveys give a much higher estimate than numbers based on service use; and the year and country in which the studies took place. Few studies have taken place in the United Kingdom, and there are no published studies in young children. Published estimates for the proportion of people who are gender diverse range from 0.3% to 0.5% of adults, and around 1.2% of people aged 14-18 years. The number

	of referrals is currently likely to be around 1 per 2000 population per year. The current referral profile suggests that the majority of referrals will be of adolescents following the onset of puberty.  **Eligible Patient Cohort** The Service will assume a share of the responsibility for: the existing open caseload; and existing national waiting list of children and young people who are waiting to access a specialist gender incongruence service. New referrals will continue to be made to NHS Arden & GEM Commissioning Support Unit (The CSU) who will hold the national waiting list on behalf of NHS England until referrals may be passed to a new provider in chronological order. Young people aged 17 years and who are unlikely to be seen by The Service by the time of their 18th birthday may be transferred to the waiting list of an NHS-commissioned Gender Dysphoria Clinic for adults. In such cases, the Gender Dysphoria Clinic will honour the original referral date to the children and young person's service for the purpose of access into the adult service.
7.	**Service aims and outcomes**
7.1	**Service aims**

	Pending the establishment of a new national service specification that will describe all elements of the new regional service, this interim service specification describes a model for delivery that will: • Tailor an individual care plan following a standardised approach to assessment, formulation and care planning • Provide psychosocial land clinical interventions for children and young people with gender incongruence, including support for the family • Provide advice in respect of and, onward referral to endocrine intervention services • Support local services in meeting the gender incongruence needs of children and young people where appropriate through professional liaison and collaboration • Through professional liaison and collaboration support local services to meet the wider needs of children and young people (including mental health, neuro-developmental and safeguarding) and in risk mitigation • Build research capabilities to conduct high quality studies across the clinical pathway • Build and document the history and nature of gender incongruence to establish evidence-based practice
7.2	**Outcomes** **NHS Outcomes Framework Domains & Indicators**

Domain 1	Preventing people from dying prematurely
Domain 2	Enhancing quality of life for people with long-term conditions
Domain 3	Helping people to recover from episodes of ill-health or following injury
Domain 4	Ensuring people have a positive experience of care
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm

	Service defined outcomes/outputs • To deliver a plan that maximises capacity, delivers assessments and delivers the full pathway of care. • To provide continuing high-quality data: – Workforce plan including vacancy status reported monthly – A monthly SPC Chart on first consultations by region, age, biological sex and aggregated – A monthly SPC Chart on work in progress (WIP) by region, age, biological sex and aggregated – A monthly SPC Chart on discharges by region, and aggregated • Evidence of engagement with children, young people and families in design and review of service delivery • Collection and reporting of children and young people's experience of the service • Build Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs) for routine deployment no later than one year following service initiation
7.3	**Audit and evaluation** The Service will take part in continuous data collection, reporting and audit to support the NHS in developing a better understanding of the relevant patient cohorts; and for the purpose of evaluating and enhancing the benefits and value of the service model; and for the purpose of building research capabilities to conduct high quality studies across the clinical pathway. NHS England will commission a third party to support a Learning Healthcare System working with designated providers to build standardised workflows, apply continuous improvement and to create a standard data set for service evaluation through audit and research.
8.	**Service description**
8.1	**Future Service model** The future service model will be developed while this interim service specification is used to initiate the service development. Providers are encouraged to adopt a

range of service provision strategies within a structured framework to determine which approaches should be standardised into the workflow.

As a developing area of clinical practice, commissioned providers must actively participate in an ongoing programme of quality improvement to enable continued refinement of models of patient access, assessment, treatment delivery and follow up. This will include:

- Proactive and visible clinical leadership within each service
- Strong links with primary and community care services
- Enhanced data collection, reporting and audit
- Sharing of data and learning between commissioned providers and with national commissioners
- Identification, sharing and rapid adoption of good practice
- Contributing to the prioritisation and focus of national service and quality improvement programmes and initiatives
- Active participation in and delivery of quality improvement initiatives, both at provider level and through a co-ordinated national network approach
- Regular review of service level data at each stage of the pathway and service user feedback, with prompt delivery of any resulting actions for improvement, including where inequalities in access or outcomes are identified

It is important that the opportunity is taken to gather further evidence on the safety, potential benefits and harms of medical interventions.

In addition, well-structured research programmes will be developed through a National Children and Young People's Gender Incongruence Research Oversight Board to include for example: epidemiology; prediction; the course of gender querying; and outcomes of psychological treatments to reduce distress.

Commissioned centres must:

- Contribute to the identification of study and treatment evaluation priorities through participation in the National Children and Young People's Gender Incongruence Research Oversight Board
- Deliver research and evaluation programmes within the service and in partnership with other commissioned service providers

	• Ensure an enhanced data set is collected from assessment through to follow up to facilitate research and evaluation, including for those whom, following assessment, it is determined would not benefit from intervention by the Service Providers will build clear relationships with the range of services and skills across all Integrated Care Systems within the regional catchment.
8.2	**Current Pathways** Referrals into the service will be through a National Referral Support Service [DN Insert Link to Specification once approved]. The provider will deliver The Service through an integrated MDT. An individualised pathway will be determined in the child or young person's best interests by, among other things, the clarity, persistence and consistency of gender incongruence, the presence and impact of other clinical needs, and family and social context. An individual care plan will be tailored to the specific needs of the individual following careful therapeutic exploration; this plan may require a focus on supporting other clinical needs and risks with networked local services. The care plan will be regularly updated at least every six months while the child or young person remains in the service. **Standardised Assessment** All children and young people who are seen by The Service will receive a standardised comprehensive assessment that will identify and develop a shared formulation of a child or young person's needs based on a comprehensive, holistic assessment including developmental history, history of gender incongruence and associated needs and risks. Assessments should be respectful of the experience of the child or young person and be developmentally informed. Clinicians will meet families with diverse needs and at different stages in thinking about their gender. This could include where: long-standing social transition has already been made; or no social transition has been made, but the child/young person expresses certainty around a different gender identity; or the child/young person expresses uncertainty and confusion around feelings about gender and distress. Families may have unity around the use of names and pronouns, whereas in others, this may be causing conflict and concern. The objectives of the process of assessment will be:

- Establish a positive clinical relationship, clinician approach and stance e.g., modelling curiosity, holding balance and neutrality; including sensitivity and flexibility to issues around pronouns, names and language
- Set the context, explain the rationale for a holistic needs assessment and manage expectations
- Seek agreement to understand different areas of the child/young person's life, including wider family/networks
- Identify or confirm significant co-existing conditions or challenges
- Establish next steps in relation to the young person's gender querying / gender incongruence – including the respective contributions from local healthcare (and other multi-agency) services and the nationally commissioned Service
- Identify and signpost to supportive resources for psychoeducation and/or transition pathway options
- Develop an initial, 'working' formulation to guide care planning and next steps

The Service will adopt a holistic, multi-disciplinary integrated approach to assessing and responding to an individual's needs. The most appropriate clinical pathway in the best interests of the child or young person will be determined through an integrated MDT approach, fully involving the child or young person and their family.

There is an increased prevalence of mental health needs in children and young people who present to gender identity services (such as depression; anxiety; risk-taking behaviours) and these children and young people will have spent many years on the waiting list. There is also thought to be an increased prevalence of neurodevelopmental disorders in children and young people on the waiting list. In view of the range of co-presentations that may typically present in this patient cohort the MDT will include expertise for the direct assessment of autism, attention deficit hyperactivity disorder and other forms of neurodiversity.

Initially there will be a focus on understanding the expression of gender incongruence and identifying associated physical and mental health and neurodevelopmental needs; and on identifying and responding to clinical risk, including mental health and safeguarding needs. The Service will identify and initiate action on immediate health and support needs, including in relation to co-existing conditions and, in some cases, safeguarding concerns.

Assessment should seek to understand the holistic needs of the child or young person and their family. This process should determine whether there are any co-occurring and/or contributory elements of the individual's presentation that are affecting their psychosocial wellbeing or functioning and require support as the basis of an individual care plan.

Clinicians should remain open and explore the child or young person's experience and the range of support or treatment options and their implications that may best address their needs, including any specific needs of neurodiverse children and young people.

Assessments will focus on:

- Subjective sense of the child / young person's identity over time
- Their expression of gender identity across different contexts over time and different settings
- Their hopes and expectations and that of their family members/carers and their stance towards the child / young person's gender identification
- Any steps that have been taken along a gender transition
- Developmental needs including cognitive functioning and capacity of the child / young person, and their understanding of gender
- Associated physical mental health and neurodevelopmental needs and their relationship with gender incongruence
- Risk including mental health, safeguarding including risk of vulnerability and exploitation and impact of any unregulated medication
- Psychosocial functioning and impact of the gender incongruence (eg on educational attendance and progress, or experience of bullying or harassment)
- With adolescents – sexual orientation; psychosexual development and any sexual experiences
- Assessment of family functioning and quality of relationships within the family, including children and young people in care (or kinship care or who have been adopted) and the wider community
- Exploration of parent/carer and family views on the child or young person's gender identity journey and family support
- Peer relationships and wider social support
- Family's spiritual, cultural, or religious beliefs

- Protective factors – strengths and resources that the young person and family are able to build on

Outcomes of the process of assessment

- Presentations, pathways and outcomes for this cohort will be individualised in the best interests of the child or young person, who is introduced to the service team and service offer, with a focus on promoting or maintaining the child or young person's overall wellbeing and global functioning.
- A child or young person with mental health or neurodevelopmental needs and / or risk-taking behaviours that require immediate intervention will be supported to access this through professional liaison and care navigation with local services including health, social care and education. The Service should confirm collaborative care arrangements for further assessment and treatment with local services through professional liaison. A significant number of children and young people with very complex needs may also be *Looked After* or may not live with their birth family and may require the active involvement from children's social care and/or expert social work advice.
- Identification of co-existing conditions or needs will lead to an exploration of the relationship between the presentation and gender incongruence through an integrated approach by MDT members.

Support to Local Professionals Following Assessment

The service model will reflect that not all children and young people with gender incongruence will need to be seen directly by The Service or, may only need to be seen for an initial or brief assessment by the Service. The process of assessment will seek to identify children and young people for whom consultation and active support through local professionals is appropriate, including support in formulation of needs and risks and individualised care planning. The level and type of consultation offered to the professional network will be determined according to the individual needs of each case, the resources available locally, and through a process of clinical prioritisation.

The Role of Formulation

Formulation is a process used by a range of professionals to summarise and integrate a broad range of information gathered in an assessment. A formulation is a set of hypotheses about an individual's difficulties, which links theory and

evidence with practice. It is developed collaboratively with the young person and their family, and should inform and guide subsequent support and intervention.

The process of assessment and formulation should conclude with a set of recommendations in relation to a care plan. This will include potential pathways of psychosocial support, recommendations on therapeutic interventions, parent/carer support options as well as wider recommendations for further support that might be accessed from the local professional networks. It should also include clear pathways around discharge where appropriate.

The Service will make a recommendation on the need for further support and information, incorporating the views and wishes of the child, young person and parents/carers and referring professionals, and make recommendations for a specialist explorative assessment in relation to the medical pathway if appropriate.

The outcome of the process of assessment including formulation of needs and risks will be confirmed in writing with the GP and referrer and shared with the family.

Psychoeducation

Psychoeducation material for children and young people, parents/carers and local professionals alike will include information on gender identity development including research evidence and how to support an exploratory approach that allows their child or young person time and opportunity to consider different options in a flexible and non-judgemental context.

Children and young people who are seen by The Service, and their parents/carers, will receive psychoeducational information that is appropriate to their needs. Parents, carers and families, (including siblings) will have the opportunity to access additional resources including facilitated group discussions with peers on a similar pathway.

Social transition as a part of a clinical intervention

Social transition is something that should be led by the young person with family input.

For the purpose of this interim service specification the reference to 'social transition' is intended to refer to the support offered by NHS clinicians to children, young people and their families who have decided that the child or young person will present in public fully with a gender identity different to that of their natal sex in all forms and aspects of their daily lives – rather than less profound forms of gender

diverse expressions, behaviours or interests such as engaging in activities or presentations socially defined and typically associated with another gender presentation.

The ability to express individuality – and autonomy to change and adapt that expression over time – can be important to a child or young person's development of the self and to their overall wellbeing. However, due to the social and psychological implications that social transition may have, advice about social transition should be seen as informing a significant decision when it forms part of an individual's care.

While there are different views on the benefits versus the harms of early social transition, it is important to acknowledge that it is not a neutral act - and that information is needed about long-term outcomes to support decision making. Information and discussion about this with the MDT is an important part of supporting a child or young person in The Service.

At the point of presentation to The Service some children and young people will have already socially transitioned or be in the process of effecting a social transition, while others may be considering this. The Service will support a shared decision-making process - it is important that the risks and benefits of social transition are discussed with the child or young person and family, referencing best available evidence. Decisions will be individual, and the agency to make the decision rests with the young person, along with their family.

The Service's MDT will engage children and young people and their families in an in-depth process of discussion and thinking around the decision of social transition. The MDT will support a consideration of: how this will fit within the broader holistic approach to addressing the child or young person's needs; how the process might proceed; how they will be supported; and how they will be given opportunities to reflect on their lived experience including autonomy to change or cease social transition if the gender incongruence changes or abates. This interim service specification recognises that pre-pubertal children have different needs to older adolescents and that the detail of the different clinical approaches across the age ranges will develop as the services evolve and the evidence becomes available.

Direct work with pre-pubertal children, and their families

The clinical approach in regard to pre-pubertal children will reflect opinion that exploration of gender diversity in childhood is an expected aspect of general human

development, and that diverse gender expressions in children cannot be assumed to reflect gender incongruence.

Some children will remain stable in a gender identity they articulate in early life that is discrepant from natal sex and for others it will be a transient phase. While intensity of early gender incongruence in children may be an important predictor of persistence of gender incongruence, gender trajectories in prepubescent children in particular cannot be reliably predicted and may evolve over time.

Generally, the clinical approach will focus on a careful observation of how gender incongruence develops as puberty approaches and is reached. The therapeutic approach for younger and pre-pubertal children is not directed at gender incongruence itself but instead focused on other clinical presentations and needs, or familial/social circumstances that may impact on the child's psychological health and gender incongruence.

The level and timing of intervention will be commensurate to the individual's needs and may range from advice by The Service to the family and professional network where there are no concomitant issues, to more intensive clinical interventions that seek to address other clinical diagnoses delivered by local secondary services with support, advice and consultation by The Service.

Psychological support and interventions provided directly by The Service will focus on children whose presentations are persistent and who have impaired functioning, with the aims of alleviating or preventing the onset of emotional problems, behavioural problems and social relationship problems, improving psychosocial health and global functioning. For younger pre-pubertal children, local services will often be the most appropriate source of continuing direct psychological support and intervention, with or without consultation support from the Specialist Service.

Support will be offered as part of the collaborative care agreement with local services and may be provided by the local and/or specialist service and, could be offered through individual / family work or group work.

In cases where a pre-pubertal child has effected, or is effecting, a social transition (or expresses a wish to effect a social transition) the clinical approach has to be mindful of the risks of an inappropriate gender transition and the difficulties that the child may experience in returning to the original gender role upon entering puberty if the gender incongruence does not persist into adolescence.

However, some children state that they want to make a social transition to their preferred gender role long before puberty, which means that increasing numbers of children may have made a partial or full social transition prior to the first attendance with The Service.

In summary, for pre-pubertal children the clinical approach and advice applied by The Service will be supportive and non-judgemental, balancing on a case-by-case basis a watchful approach overall with a more individualised approach in cases where the child's level of global functioning may be maintained or improved through a carefully observed process of exploration of social transition. Where social transition is occurring or is being considered by the family, The Service will support the family in weighing the potential benefits, challenges and risks.

Direct work with adolescents and their families

Psychological support and interventions provided directly by The Service, including family therapy/work, will focus on alleviating or preventing the onset of emotional problems, behavioural problems and social relationship problems, improving psychosocial health and global functioning, while responding to co-existing needs and conditions.

Clinicians should remain open and explore the young person's experience and the range of support or treatment options and their implications that may best address their needs, including any specific needs of neurodiverse children and young people. The overall aim is to reduce distress in the individual; support the development of positive self-image and self-esteem; promote the individual's global functioning; facilitate understanding and acceptance within the family unit.

Interventions with adolescents should be at a level commensurate with the needs of the individual. More intensive clinical interventions may be needed that seek to address other clinical diagnoses and will be delivered by local secondary services with support, advice and consultation by The Service.

Factors that could influence the complexity and length of the intervention include:

- Unstable or escalating mental health problems
- Ongoing risk issues, and safeguarding issues
- Levels of emotional and cognitive maturity
- Concerns with regard to competency or capacity to understand and consent
- Family conflict about how to proceed

Not all adolescents will want or benefit from social transition. Where social transition is occurring or is being considered by the young person and their family, The Service will support the young person and family in weighing the potential benefits, challenges and risks.

In view of the potentially profound impact of social transition on the young person's life the provision of approaches to support social transition will be considered in cases where expressions of gender incongruence or gender diversity have been persistent; and the young person expresses a clear wish to affirm their gender transition and fully understands the implications of affirming a social transition (informed consent); and where the proposed approach is considered by The Service as necessary for the promotion or maintenance of the young person's overall health, wellbeing and social functioning. In these cases the clinical approach will involve a focus on exploring or supporting (as appropriate to the individual) social transition through psychological support and interventions, family work/therapy and guidance for the local professional network. Young people and their families will be supported in making difficult decisions regarding the expression of a gender role that is consistent with their gender identity, including the timing of changes to gender role and possible social transition.

The Service will aim to maintain a therapeutic relationship with young people and their families throughout any subsequent social changes or physical interventions. This ensures that decisions about gender expression and the treatment of gender incongruence are thoughtfully and recurrently considered. The same reasoning applies if a young person has already socially changed gender role prior to being seen by The Service.

Referrals for assessment for endocrine interventions

Separate but linked NHS England clinical commissioning policies will define the use as part of the NHS commissioned service of i) puberty suppressing hormone treatment; and, ii) masculinising / feminising hormones from around the age of 16 years.

Prescribing from unregulated sources and unregulated providers

Children, young people and their families are strongly discouraged from sourcing puberty suppressing or gender affirming hormones from unregulated sources or from on-line providers that are not regulated by UK regulatory bodies.

If a child or young person has already been started on **puberty suppressing hormones** outside of NHS protocols by the time that they are seen by the NHS, The Service may consider assuming clinical responsibility for prescribing through NHS protocols if The Service's MDT jointly concludes with the related endocrine clinic that this is an appropriate harm reduction measure. In such cases administration of puberty suppressing hormones would need to be stopped for a brief period of time to allow baseline investigations to be undertaken by The Service. If the patient is felt to be appropriate to be restarted on treatment after assessment by The Service treatment may be resumed in accordance with NHS protocols, including the requirement for the patient to be enrolled in the formal research protocol.

If a young person has already been started on **masculinising / feminising hormones** outside of NHS protocols, The Service will consider (jointly with the related endocrine clinic) a continuation of prescribing through NHS protocols as a harm reduction measure where ALL of the following criteria are met:

- Evidence of a comprehensive documented assessment by a multi-disciplinary team that includes a medical practitioner with specialist expertise in gender incongruence in children and adolescents; and
- Evidence of continued psychological support through engagement with the MDT; and
- Administration of puberty suppressing hormones was commenced not before Tanner stage 2; and
- Masculinising / feminising hormones commenced after at least twelve months on puberty suppressing hormones; and
- Masculinising / feminising hormones were commenced not before approximately 16 years of age; and
- Evidence that impact to fertility was discussed with the young person before initiation of the hormones.

Where the Service is not able to accept responsibility for prescribing puberty suppressing hormones or masculinising / feminising hormones the Service will not offer clinical supervision for the management of the endocrine intervention and will not enter into shared care arrangements with a health professional who is making recommendations for prescribing / is prescribing to the child or young person. In such cases The Service will make the child or young person and their family aware of the risks, contraindications and any irreversible or partially reversible effects of the interventions; and will make the GP or local health professional (as appropriate)

	aware and suggest that the GP or local health professional considers what safeguarding protocols may be appropriate for the individual child or young person's wider circumstances including the extent to which the parents / carers are able to protect or safeguard the child or young person. Safeguarding procedures may be necessary regardless of the endeavours and best intentions of the parents / carers in reducing risk of harm. Safeguarding protocols should be initiated immediately where the child or young person is at risk of immediate, serious harm. It would also be important for the GP or local health professional to explore what regulatory bodies may need to be informed if healthcare professionals registered with a UK professional body are prescribing medication contrary to NHS protocols. **Transition to adult services and discharge** The Service may provide support to young people up to their 18th birthday. The Service will review the needs and progress of the young person in relation to their gender incongruence and the goals of treatment and will step down or discharge their care to local primary care or secondary care services as appropriate. For young people who have been seen by The Service and who are approaching their 18th birthday The Service will co-ordinate a transition and support plan with the professional network specific to the young person's needs. A transfer may be made to an NHS-commissioned Gender Dysphoria Clinic from 17 years of age where the young person meets the access criteria. A co-ordinated transfer to appropriate local adult services will be needed where complex presentations continue.
8.3	**Essential Staff Groups** The key clinical leadership role will be through a medical consultant with significant experience in the developmental needs of children and adolescents. The MDT will have (or have access to) the following competencies and experience (see also Appendix A). Practitioners will need access to clinical supervision across a range of clinical areas (e.g., psychological, mental and physical health, safeguarding and gender identity development) to support their roles.

	• Multi-agency working including provision of consultation, liaison and advice for complex cases, and care navigation • Expertise in child safeguarding and assessment and management of risk-taking behaviours • Childhood and adolescent development, including cognitive, social and sexual development; gender identity development and gender expression • Paediatric medicine, including psychological health • Child and adolescent mental health, including expertise in assessment and formulation, delivery of evidence based therapeutic interventions, trauma informed approaches; and family work/family therapy • Cognitive Behavioural Therapy • Neurodevelopment disorders including learning disability and autism spectrum conditions • Gender incongruence • Expertise in sex development, and endocrine intervention • Expertise to support children and young people who may be Looked After or in Special Guardianship or who may be adopted.
8.4	**Essential equipment and/or facilities** The provider must have in place premises that are appropriate to ensure effective delivery of the services described in this service specification; and in an age-appropriate environment that children and young people regard as safe and welcoming. Providers will be mindful that the majority of individuals are likely to be of an age following the onset of puberty.
8.5	**Interdependent Service Components – Links with other NHS services** The Service must be expert in working with a wide variety of agencies. It is expected that close working will be needed in particular with Children and Young People's Mental Health Services, child health and neurodevelopment services, voluntary community services, education professionals, children's social care and with general practitioners. The Service should also be competent in their understanding of and close working with children and young people with social care needs – including adopted children and young people, and children in care, and in working with schools and colleges to facilitate wellbeing and full access for their education.

	Collaborative care arrangements Referrers, together with local healthcare services, will agree with The Service collaborative care arrangements particularly in relation to the young person's mental health, neurodevelopmental needs and / or risk-taking behaviours. Local services including children and young people's mental health services, paediatric healthcare services and local authorities will continue to provide the care that they would routinely offer young people and families as part of local or national commissioning arrangements across relevant care pathways. It is not the expectation that The Service will address these broader needs. Collaborative care arrangements should be clarified through professional liaison and confirmed in writing with all stakeholders including the young person and parents/carers.
8.6	**Additional requirements** The provider must have in place: • A robust system of clinical governance that ensures, *inter alia*, all clinical staff are trained in assessing and meeting the health needs of children and young people including those on the waiting list, have access to clinical supervision, and are deemed competent to deliver the interventions as per their role; this will include a documented approach to safeguarding that is consistent with NICE guideline NG76. • A robust system of corporate governance, including a nominated senior manager, that demonstrates effective management, guidance, oversight and accountability by the host organisation; and supported by experienced communications and engagement teams. • Arrangements in place to ensure that the service delivers culturally appropriate and trauma informed care and support; individuals must be able to access services in a way that ensures their cultural, language and communication needs do not prevent them receiving the same quality of healthcare as others. • Sufficient administrative and managerial support needed for efficient and timely delivery of services.

	• Arrangements in place (including ongoing training) to ensure that all staff in public-facing roles have cultural sensitivity towards children and young people who may be gender diverse. • Arrangements in place to ensure that service design and improvement is co-produced with experts by experience and promotes equality, diversity and inclusion., This should include routine outcomes and experience monitoring and be able to demonstrate how improvement is achieved via means that are accessible, transparent and inclusive. • Arrangements in place to ensure that feedback, comments and complaints by individuals and their families are acknowledged investigated and responded to promptly; and that the means to complain are publicised and accessible.
8.7	**Commissioned providers** Providers delivering The Service must be an established specialist tertiary paediatric unit with strong links to mental health services and have established academic partnerships. NHS England will establish a framework for a co-ordinated and collegiate approach across all of the new regional services - focusing initially on development of the model and then moving to issues of operational delivery, service development, improvement and audit. This approach will help to ensure continuity of provision for children and young people if they move across sub / regional boundaries. Providers will co-operate as part of a clinical network with other designated providers to support sharing of best practice, quality improvement and research processes and consistency against the service specification and model of care.
8.9	**Links to other key documents** This interim service specification supersedes service specification E13/S(HSS)/e Gender Identity Development Service for Children and Adolescents (2016) Other key documents: NHS England Service Specification: Gender Identity Services for Adults (Non-Surgical Interventions); 2019 as amended; 1719

	The Cass Review Interim Report, February 2022 NHS England Statement: "Implementing the Recommendations of the Cass Review", July 2022

Appendix A MULTIDISCIPLINARY TEAM COMPETENCIES AND EXPERIENCE

Gender Incongruence in Children and Young People under 18 years of age	• Understanding of the wider social context in which specialist health services for gender incongruence operate; and specifically, understanding of the operation of specialist NHS services for gender incongruence in the context of recent judicial, regulatory and commissioning decisions • Understanding of the contested debate around different management approaches for responding to children and adolescents who have gender incongruence; and the limited evidence base to inform clinical approaches and service delivery; and limited data on outcomes • Understanding of the various reasons why professionals may make a referral to specialist gender incongruence services • Understanding of the current NHS pathway for children and young people up to 17 years • Understanding of diagnostic formulation currently DSM-V moving to ICD-11) on the NHS pathway of care • Understanding of how gender incongruence presents in children and young people, and the resulting mental health and psychosocial needs of children and young people on the NHS pathway of care including while they are on the waiting list • Understanding of approaches to care that are delivered by NHS specialist gender services, and support needs and support options for children and young people who have degrees of gender incongruence • Understanding of the intended outcomes for children and young people who are seen by NHS specialist gender incongruence services • Understanding of the relationship / interface between: - The Service and Adult Gender Dysphoria Clinics - Specialist NHS gender incongruence / dysphoria services and primary care - Specialist NHS gender incongruence / dysphoria services and other statutory services
Multi-Disciplinary Clinical Leadership team	In addition to specific expertise in gender identity development and incongruence, the clinical leadership team of The Service should include strong, consultant level expertise in: • Paediatric healthcare including child development and endocrinology • Psychological healthcare including child cognitive and emotional development, psychological interventions and therapy, including consultation and liaison approaches to healthcare delivery • Mental health diagnoses and intervention, including pharmacological interventions and in-patient mental healthcare • The psychological and mental health aspects of healthcare for children & young people with physical healthcare need • Neuro-developmental conditions, including autism and attention deficit with hyperactivity disorder (ADHD) • Consent and mental capacity in a child development context where there may be a complex and contentious aspects.

	• Designing, monitoring and redesigning or improving effective, efficient and responsive care pathways in collaboration with experts by experience
Knowledge and Experience of Specific Presentations and Interventions	Awareness of a range of mental and physical disorders; and knowledge of models of intervention and their application in practice. Including knowledge and experience of: • Neurodevelopment disorders including autistic spectrum conditions • Mental health disorders including depressive conditions; anxiety and trauma; eating disorders • Endocrine conditions including Disorders of Sex Development • Pharmacology, particularly in the context of gender incongruence • Range of risks that may present in the child or young person including deliberate self-harm; exploitation; high risk behaviours; substance abuse • Family contexts for children and young people that include being a child in care, or kinship care (including special guardianship) or being adopted
Child and Young Person Development	• Knowledge of development in children and young people; including normative development; social and behavioural development; sexual development; gender identity development and gender expression • Understanding of the differences in sexual identity and gender identity, and expression • Knowledge and understanding of mental health problems in children and young people • Knowledge and understanding of neurodevelopment disorders in children and young people • Knowledge of the physical development of children and young people • Knowledge of the needs of young people who are moving from paediatric to adult services • Understanding of mental and physical health problems in children and young people in the context of impact to: - Educational attainment - Social development including formation of peer relationships
Family Development and Relationships	• Understanding of normative family development • Understanding of mental and physical health problems in children and young people in the context of impact to family relationships • Understanding of parents with additional needs and impact of their mental and physical health needs to children and young people
Assessment, Formulation and Diagnosis	• Ability to contribute to assessment, formulation and diagnosis while acting in a consultation role to the professional network (including specialist mental health assessment) • Ability to contribute to risk assessment and management while acting in a consultation role to the professional network
Cultural Competence	• Cultural competence and understanding of equality and diversity principles • Understanding of the wide diversity of children and young people who are referred to specialist gender incongruence services • Understanding of the social, emotional and mental health needs of relevant groups in the local communities who share protected characteristics

Multi-Agency Working	• Ability to work within and across different agencies (health; education; social services; youth justice; other) and an understanding of how these agencies operate including the local voluntary sector • Understanding of the role of education services in supporting children and young people with gender incongruence (supporting full access to the curriculum and pastoral support including, vulnerable children policies; toilet and changing room policies; pupils with special education needs and, addressing, exclusion, bullying and harassment) • Ability to act in a coordinating and consultation role in case work, working with professionals across different services and agencies
Safeguarding / Professional	• Recognise and respond to concerns about child protection and safeguarding • Knowledge of legal frameworks relating to children and young people • Knowledge of and ability to work within relevant professional and ethical guidelines • Knowledge of, and ability to work with, issues of confidentiality, consent and capacity

06.06.2023

Ranking Member Cassidy, Tuberville Attempt to Uncover Details of Tragic Deaths During NIH-Funded Transgender Youth Study

WASHINGTON – U.S. Senators Bill Cassidy, M.D. (R-LA), ranking member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, and Tommy Tuberville (R-AL) are seeking answers from the National Institutes of Health (NIH) following the suicide deaths of two youth participants who were involved in a NIH-funded study that observed the effects of hormone treatments on transgender youths as young as 12 years old.

On January 19, 2023, the New England Journal of Medicine published the results of a project funded by the National Institutes of Health (NIH) which studied the physical and psychosocial outcomes of 315 transgender youths who were receiving hormone treatments over a two-year period. The authors reported that two of the youths died by suicide while they were participating in the study. Additionally, 11 participants reported experiencing suicidal thoughts, and six participants withdrew from the study prior to its conclusion. According to the article, the researchers intend to continue "following this cohort" in the future to further their observations on the effects of youth hormone treatments.

The participants were recruited from gender clinics at children's hospitals in Chicago, San Francisco, Boston, and Los Angeles, and ranged from 12 to 20 years old.

"We are shocked and deeply troubled that two young people died by suicide and eleven youth experienced suicidal ideation while participating in a study funded with taxpayer dollars," **wrote the senators**. "The article does not identify the age of the participants who died or contemplated suicide, nor does it explain what measures, if any, the researchers took to prevent these tragic deaths."

"Given that the researchers are continuing to follow this cohort, we are extremely concerned that there are insufficient safeguards in place to ensure that no further tragedies occur in the course of this study—or any other study funded by NIH," **continued the senators**. "In order to understand NIH's decision to fund this study and the steps NIH has taken to prevent any future tragedies, we request you answer the following questions, on a question-by-question basis, by **close of business on June 20, 2023**."

Read the full letter here or below.

Acting Director Tabak:

On January 19, 2023, the New England Journal of Medicine published the results of a study funded by the National Institutes of Health (NIH) entitled "Psychosocial Functioning in Transgender Youth After 2 Years of Hormones."[1] The study consisted of a cohort of 315 youth who identified as transgender or non-binary and were receiving hormone treatment, over 75 percent of whom were under the age of 18.[2] According to the article, hormone treatment resulted in "increases in positive affect and life satisfaction and decreases in depression and anxiety symptoms."[3] Tragically, however, two participants died by suicide during the study, and eleven participants reported experiencing suicidal ideation.[4]

We are shocked and deeply troubled that two young people died by suicide and eleven youth experienced suicidal ideation while participating in a study funded with taxpayer dollars. The article does not identify the age of the participants who died or contemplated suicide, nor does it explain what measures, if any, the researchers took to prevent these tragic deaths. According to the article, the researchers intend to continue "following this cohort to see whether gains in functioning are sustained over a longer follow-up period."[5]

*NIH should take all available steps to ensure the safety and wellbeing of research participants in any study it funds, especially minors such as those included in this cohort, who may already experience significant mental health challenges.[6] Given that the researchers are continuing to follow this cohort, we are extremely concerned that there are insufficient safeguards in place to ensure that no further tragedies occur in the course of this study—or any other study funded by NIH. In order to understand NIH's decision to fund this study and the steps NIH has taken to prevent any future tragedies, we request you answer the following questions, on a question-by-question basis, by **close of business on June 20, 2023**.*

- *Please explain in detail NIH's process for approving this study and the number of NIH employees who were involved in the decision to approve it. With respect to NIH funding, please also provide the specific dollar amount spent on this study as of the date of this letter. Please also provide an estimate for the amount of money NIH anticipates spending on this study moving forward, if any. Finally, please provide an itemized list of expenditures of NIH funds for each of the four study sites.*

2. *With respect to NIH's decision to fund studies involving mental health issues and the terms and conditions NIH applies to such funding, please explain in detail the steps NIH takes to work with the investigators and Institutional Review Boards to ensure that there are appropriate protocols in place to identify potential mental health risks of study participants and provide research participants with appropriate treatment upon enrollment and during the study.*

3. *Has NIH funded any additional studies on the effects of medical intervention intended to facilitate the transition of transgender and non-binary minors? If so, please provide (1) the specific dollar amount spent on each study as of the*

date of this letter, (2) the specific dollar amount spent on any future studies that have been approved to receive NIH funds, (3) a brief description of every such study, and (4) the names of all investigators and institutions affiliated with each study.

4. *Please provide the age of both participants in the study who died by suicide. Was NIH made aware of the two deaths described in the study? If so, please describe when and how NIH first learned of the deaths and any action the agency took in response, in coordination with the investigators and the Institutional Review Board.*

5. *Please provide the age of the participants in the study who experienced suicidal ideation. Was NIH made aware of these experiences? If so, please describe when and how NIH first learned that the participants experienced suicidal ideation and any action the agency took in response, in coordination with the investigators and the Institutional Review Board.*

6. *With respect to NIH-funded studies of transgender youth, please describe in detail what safeguards, if any, NIH requires of investigators in order to prevent deaths by suicide, suicide attempts, or suicidal ideation by study participants.*

7. *Please explain what processes and procedures, if any, were in place for the investigators to communicate and share information with the clinics where the participants were enrolled in the study. Were the investigators required to share with the clinics any potential concerns regarding the safety and wellbeing of the participants? If not, why not?*

8. *For participants experiencing serious mental health issues, did the investigators or clinics provide any supportive services for the participants? If not, why not?*

Thank you for your prompt attention to this matter.

###

For all news and updates from HELP Republicans, visit our website or Twitter at @GOPHELP.

From: elizablairbacon=gmail.com@mg.gospringboard.io on behalf of Blair Bacon
To: BOM Public Comment
Subject: Reject rules to restrict access to gender affirming care
Date: Saturday, June 10, 2023 10:59:44 AM

Dear

I am writing to you today to urge the Florida State Board of Medicine to reject rule 64B8-9.019 and the Florida State Board of Osteopathic Medicine to reject rule 64B15-14.014. Both proposed rules cover Standards of Practice for the Treatment of Gender Dysphoria in Minors, to restrict access to gender-affirming healthcare.

Care providers, doctors, and leading medical associations have been clear that gender-affirming care is safe, effective, evidence-based, and lifesaving.

The nation's leading health organizations support gender-affirming care for transgender and gender non-conforming people, including the American Academy of Pediatrics; the American Medical Association; The American College of Obstetricians and Gynecologists; The American College of Physicians; The American Psychiatric Association; The American Psychological Association; The American Academy of Family Physicians; The Endocrine Society; The Pediatric Endocrine Society; American Nurses Association; American Public Health Association; American Heart Association; National Association of Social Workers; World Medical Association; and The World Professional Association for Transgender Health, among others.

There is overwhelming evidence to support the positive mental health impacts of gender-affirming medical care for transgender adolescents - including in some of the very studies cited by the DOH and Board of Medicine. Prohibiting social transition is clear government intrusion on personal and parental decision-making. Numerous studies have found that after social transition, transgender youth report similar mental health levels to the general youth population, eliminating mental health disparities typically seen. When transgender youth are affirmed by people around them, reported rates of depression and suicidality drop significantly. This rule will deny them this life-saving treatment.

The Florida State Board of Medicine and the Florida Board of Osteopathic Medicine must reject proposed policies like these that are not grounded in science and research and are clearly based on prejudice and political agendas. The evidence is clear: denying transgender youth the ability to access critical healthcare is dangerous and life-threatening.

I urge you to reject these rules.

Sincerely,

Blair Bacon

From: lavender_star=comcast.net@mg.gospringboard.io on behalf of Candice Golden
To: BOM Public Comment
Subject: Reject rules to restrict access to gender affirming care
Date: Tuesday, June 13, 2023 7:06:03 PM

Dear

I am writing to you today to urge the Florida State Board of Medicine to reject rule 64B8-9.019 and the Florida State Board of Osteopathic Medicine to reject rule 64B15-14.014. Both proposed rules cover Standards of Practice for the Treatment of Gender Dysphoria in Minors, to restrict access to gender-affirming healthcare.

Care providers, doctors, and leading medical associations have been clear that gender-affirming care is safe, effective, evidence-based, and lifesaving.

The nation's leading health organizations support gender-affirming care for transgender and gender non-conforming people, including the American Academy of Pediatrics; the American Medical Association; The American College of Obstetricians and Gynecologists; The American College of Physicians; The American Psychiatric Association; The American Psychological Association; The American Academy of Family Physicians; The Endocrine Society; The Pediatric Endocrine Society; American Nurses Association; American Public Health Association; American Heart Association; National Association of Social Workers; World Medical Association; and The World Professional Association for Transgender Health, among others.

There is overwhelming evidence to support the positive mental health impacts of gender-affirming medical care for transgender adolescents - including in some of the very studies cited by the DOH and Board of Medicine. Prohibiting social transition is clear government intrusion on personal and parental decision-making. Numerous studies have found that after social transition, transgender youth report similar mental health levels to the general youth population, eliminating mental health disparities typically seen. When transgender youth are affirmed by people around them, reported rates of depression and suicidality drop significantly. This rule will deny them this life-saving treatment.

The Florida State Board of Medicine and the Florida Board of Osteopathic Medicine must reject proposed policies like these that are not grounded in science and research and are clearly based on prejudice and political agendas. The evidence is clear: denying transgender youth the ability to access critical healthcare is dangerous and life-threatening.

I urge you to reject these rules.

Sincerely,

Candice Golden

From: amy.green31101=gmail.com@mg.gospringboard.io on behalf of Tate Green
To: BOM Public Comment
Subject: Reject rules to restrict access to gender affirming care
Date: Saturday, June 10, 2023 10:59:10 AM

Dear

I am writing to you today to urge the Florida State Board of Medicine to reject rule 64B8-9.019 and the Florida State Board of Osteopathic Medicine to reject rule 64B15-14.014. Both proposed rules cover Standards of Practice for the Treatment of Gender Dysphoria in Minors, to restrict access to gender-affirming healthcare.

Care providers, doctors, and leading medical associations have been clear that gender-affirming care is safe, effective, evidence-based, and lifesaving.

The nation's leading health organizations support gender-affirming care for transgender and gender non-conforming people, including the American Academy of Pediatrics; the American Medical Association; The American College of Obstetricians and Gynecologists; The American College of Physicians; The American Psychiatric Association; The American Psychological Association; The American Academy of Family Physicians; The Endocrine Society; The Pediatric Endocrine Society; American Nurses Association; American Public Health Association; American Heart Association; National Association of Social Workers; World Medical Association; and The World Professional Association for Transgender Health, among others.

There is overwhelming evidence to support the positive mental health impacts of gender-affirming medical care for transgender adolescents - including in some of the very studies cited by the DOH and Board of Medicine. Prohibiting social transition is clear government intrusion on personal and parental decision-making. Numerous studies have found that after social transition, transgender youth report similar mental health levels to the general youth population, eliminating mental health disparities typically seen. When transgender youth are affirmed by people around them, reported rates of depression and suicidality drop significantly. This rule will deny them this life-saving treatment.

The Florida State Board of Medicine and the Florida Board of Osteopathic Medicine must reject proposed policies like these that are not grounded in science and research and are clearly based on prejudice and political agendas. The evidence is clear: denying transgender youth the ability to access critical healthcare is dangerous and life-threatening.

I urge you to reject these rules.

Sincerely,

Tate Green

From: lost.floating.dreamer=gmail.com@mg.gospringboard.io on behalf of Hannah Kocsmiersky
To: BOM Public Comment
Subject: Please REJECT rules to restrict access to gender affirming care!
Date: Monday, June 5, 2023 5:26:34 PM

Dear

I am writing to you today to urge the Florida State Board of Medicine to reject rule 64B8-9.019 and the Florida State Board of Osteopathic Medicine to reject rule 64B15-14.014. Both proposed rules cover Standards of Practice for the Treatment of Gender Dysphoria in Minors, to restrict access to gender-affirming healthcare.

Care providers, doctors, and leading medical associations have been clear that gender-affirming care is safe, effective, evidence-based, and lifesaving.

The nation's leading health organizations support gender-affirming care for transgender and gender non-conforming people, including the American Academy of Pediatrics; the American Medical Association; The American College of Obstetricians and Gynecologists; The American College of Physicians; The American Psychiatric Association; The American Psychological Association; The American Academy of Family Physicians; The Endocrine Society; The Pediatric Endocrine Society; American Nurses Association; American Public Health Association; American Heart Association; National Association of Social Workers; World Medical Association; and The World Professional Association for Transgender Health, among others.

There is overwhelming evidence to support the positive mental health impacts of gender-affirming medical care for transgender adolescents - including in some of the very studies cited by the DOH and Board of Medicine. Prohibiting social transition is clear government intrusion on personal and parental decision-making. Numerous studies have found that after social transition, transgender youth report similar mental health levels to the general youth population, eliminating mental health disparities typically seen. When transgender youth are affirmed by people around them, reported rates of depression and suicidality drop significantly. This rule will deny them this life-saving treatment.

The Florida State Board of Medicine and the Florida Board of Osteopathic Medicine must reject proposed policies like these that are not grounded in science and research and are clearly based on prejudice and political agendas. The evidence is clear: denying transgender youth the ability to access critical healthcare is dangerous and life-threatening.

I urge you to reject these rules.

Sincerely,

Hannah Kocsmiersky

From: mike morse
To: BOM Public Comment
Subject: Informed Consent Meeting for SB254
Date: Tuesday, June 6, 2023 2:50:06 PM

To the Florida Board of Medicine,

My name is Mike, I am a non-binary transgender person from Brevard County, FL, and I was in attendance of the Joint Rules and Legislative Committee Meeting of Florida's Boards of Medicine and Osteopathic Medicine on June 1 to discuss the informed consent forms for gender affirming care for both minors and adults. Overall, to say I was disappointed with how the meeting was handled would be an understatement. From the start, the Board members did not give me any confidence that they had any knowledge of the task at hand. Additionally, the Board did not publicly discuss all the agenda points; instead, the floor was opened for public comment after the Board briefly spoke about care for minors and did not once discuss care for adults in front of the public. The standard I am aware of for public comment is that it should occur *after* all agenda points are finished, and before the meeting is adjourned.

I did not have a chance to speak yesterday, but I do have a recommendation for BOTH the minor and adult informed consent forms. Gender affirming care is simply a medical process and should not be treated differently than any other procedure or treatment. There is no need to create a brand-new informed consent form, as that will just take more time and further stigmatizes the trans community. This process should be simple; a pre-existing informed consent form should be adapted to include language relevant to gender affirming care and hormone replacement therapy, NOT "sex reassignment treatment."

I also ask that the Board please do not include the amendment that during this interim period, doctors are not able to change dosage for their clients. This could be considered borderline malpractice as it should be up to the doctor's expertise to decide what dosage of medication their client needs. Trans people need to adjust their meds all the time for a multitude of reasons, often to lower them, not just raising them. If trans folks are not able to lower or adjust and balance their medication, this is more likely to cause harm to the person in the long run. Hormone levels can be unbalanced in trans people just like in cisgender people, which is why doctors regularly monitor these levels and adjust as needed.

Finally, I ask that the Board expedite this process as quickly as possible. Delaying this process is preventing thousands of individuals from being able to receive their medication or proper healthcare. This in itself should be considered malpractice, as this limbo is keeping people from receiving life-saving treatment. Although, as the Board stated, there have been few studies to show physical harm for stopping or reversing hormone replacement therapy, I can tell you from firsthand experience (as can many of my peers) that the mental effects of reversing this treatment can be life threatening. I urge the Board to understand the importance and repercussions of delaying access to healthcare.

After listening to the dozens of outraged trans folks and their allies, I also ask that the Board please do not completely disregard or hold in contempt the emotional responses they heard throughout the day. While speakers were consistently met with remarks that their comments were "out of the scope" of the discussion, I ask that you, the Board, please take into context that for the most part, these (mostly young) people are speaking out in reaction to threats to their health and wellbeing. What you, the Board, experienced firsthand yesterday is merely a population living in fear as they watch their rights to bodily autonomy and access to life-saving health care be stripped away right in front of them through the creation of these laws and emergency orders. While the Board has no ability to change the laws that have been signed, it is and should be the Board's top priority to ensure that ALL people have access to health care with as few barriers as possible.

Thank you for your time,

Mike Morse (they/them)

Brevard County, FL

From: shawnoakley11=gmail.com@mg.gospringboard.io on behalf of Nickolai Oakley
To: BOM Public Comment
Subject: Reject rules to restrict access to gender affirming care
Date: Monday, June 5, 2023 5:29:20 PM

Dear

I am writing to you today to urge the Florida State Board of Medicine to reject rule 64B8-9.019 and the Florida State Board of Osteopathic Medicine to reject rule 64B15-14.014. Both proposed rules cover Standards of Practice for the Treatment of Gender Dysphoria in Minors, to restrict access to gender-affirming healthcare.

Care providers, doctors, and leading medical associations have been clear that gender-affirming care is safe, effective, evidence-based, and lifesaving.

The nation's leading health organizations support gender-affirming care for transgender and gender non-conforming people, including the American Academy of Pediatrics; the American Medical Association; The American College of Obstetricians and Gynecologists; The American College of Physicians; The American Psychiatric Association; The American Psychological Association; The American Academy of Family Physicians; The Endocrine Society; The Pediatric Endocrine Society; American Nurses Association; American Public Health Association; American Heart Association; National Association of Social Workers; World Medical Association; and The World Professional Association for Transgender Health, among others.

There is overwhelming evidence to support the positive mental health impacts of gender-affirming medical care for transgender adolescents - including in some of the very studies cited by the DOH and Board of Medicine. Prohibiting social transition is clear government intrusion on personal and parental decision-making. Numerous studies have found that after social transition, transgender youth report similar mental health levels to the general youth population, eliminating mental health disparities typically seen. When transgender youth are affirmed by people around them, reported rates of depression and suicidality drop significantly. This rule will deny them this life-saving treatment.

The Florida State Board of Medicine and the Florida Board of Osteopathic Medicine must reject proposed policies like these that are not grounded in science and research and are clearly based on prejudice and political agendas. The evidence is clear: denying transgender youth the ability to access critical healthcare is dangerous and life-threatening.

I urge you to reject these rules.

Sincerely,

Nickolai Oakley

From: draggedyannetrash=gmail.com@mg.gospringboard.io on behalf of Spencer Robertson
To: BOM Public Comment
Subject: Reject rules to restrict access to gender affirming care
Date: Monday, June 5, 2023 5:24:45 PM

Dear

I am writing to you today to urge the Florida State Board of Medicine to reject rule 64B8-9.019 and the Florida State Board of Osteopathic Medicine to reject rule 64B15-14.014. Both proposed rules cover Standards of Practice for the Treatment of Gender Dysphoria in Minors, to restrict access to gender-affirming healthcare.

Care providers, doctors, and leading medical associations have been clear that gender-affirming care is safe, effective, evidence-based, and lifesaving.

The nation's leading health organizations support gender-affirming care for transgender and gender non-conforming people, including the American Academy of Pediatrics; the American Medical Association; The American College of Obstetricians and Gynecologists; The American College of Physicians; The American Psychiatric Association; The American Psychological Association; The American Academy of Family Physicians; The Endocrine Society; The Pediatric Endocrine Society; American Nurses Association; American Public Health Association; American Heart Association; National Association of Social Workers; World Medical Association; and The World Professional Association for Transgender Health, among others.

There is overwhelming evidence to support the positive mental health impacts of gender-affirming medical care for transgender adolescents - including in some of the very studies cited by the DOH and Board of Medicine. Prohibiting social transition is clear government intrusion on personal and parental decision-making. Numerous studies have found that after social transition, transgender youth report similar mental health levels to the general youth population, eliminating mental health disparities typically seen. When transgender youth are affirmed by people around them, reported rates of depression and suicidality drop significantly. This rule will deny them this life-saving treatment.

The Florida State Board of Medicine and the Florida Board of Osteopathic Medicine must reject proposed policies like these that are not grounded in science and research and are clearly based on prejudice and political agendas. The evidence is clear: denying transgender youth the ability to access critical healthcare is dangerous and life-threatening.

I urge you to reject these rules.

Sincerely,

Spencer Robertson

From: sherri.a.silver=gmail.com@mg.gospringboard.io on behalf of Sherri Silver
To: BOM Public Comment
Subject: Reject rules to restrict access to gender affirming care
Date: Monday, June 5, 2023 5:17:39 PM

Dear

I am writing to you today to urge the Florida State Board of Medicine to reject rule 64B8-9.019 and the Florida State Board of Osteopathic Medicine to reject rule 64B15-14.014. Both proposed rules cover Standards of Practice for the Treatment of Gender Dysphoria in Minors, to restrict access to gender-affirming healthcare.

Care providers, doctors, and leading medical associations have been clear that gender-affirming care is safe, effective, evidence-based, and lifesaving.

The nation's leading health organizations support gender-affirming care for transgender and gender non-conforming people, including the American Academy of Pediatrics; the American Medical Association; The American College of Obstetricians and Gynecologists; The American College of Physicians; The American Psychiatric Association; The American Psychological Association; The American Academy of Family Physicians; The Endocrine Society; The Pediatric Endocrine Society; American Nurses Association; American Public Health Association; American Heart Association; National Association of Social Workers; World Medical Association; and The World Professional Association for Transgender Health, among others.

There is overwhelming evidence to support the positive mental health impacts of gender-affirming medical care for transgender adolescents - including in some of the very studies cited by the DOH and Board of Medicine. Prohibiting social transition is clear government intrusion on personal and parental decision-making. Numerous studies have found that after social transition, transgender youth report similar mental health levels to the general youth population, eliminating mental health disparities typically seen. When transgender youth are affirmed by people around them, reported rates of depression and suicidality drop significantly. This rule will deny them this life-saving treatment.

The Florida State Board of Medicine and the Florida Board of Osteopathic Medicine must reject proposed policies like these that are not grounded in science and research and are clearly based on prejudice and political agendas. The evidence is clear: denying transgender youth the ability to access critical healthcare is dangerous and life-threatening.

I urge you to reject these rules.

Sincerely,

Sherri Silver

From: BOM Public Comment
To: Strickland, Bettye C
Subject: FW: Boards should pass rule which terminate children"s current taking of puberty blocker drugs and cross sex hormones
Date: Wednesday, June 14, 2023 7:10:24 PM
Attachments: Outlook-irls2fd0.png

Dear Board of Medicine and Board of Osteopathic Medicine:

In response to Chapter 2023-90, Laws of Florida (CS/SB 254), the Board of Medicine (BOM) and Board of Osteopathic Medicine (BOOM) should promulgate rules which prevent medical doctors (MD's) and doctors of osteopathic medicine (DO's) from prescribing puberty blocker drugs and cross-sex hormones to children who were grandfathered-in to continue taking these drugs by previous rules of the BOM and BOOM. The boards should reject the argument that continuation of these drugs by children should be left to the treatment decision of the medical professionals who have children as their patients. MD's and DO's who prescribe puberty blocker drugs and cross-sex hormones to children are biased transgender idealogues who are very unlikely to even consider counseling their patients to cease taking these very harmful drugs. A study published in JAMA Network Open proves this bias and opposition to ceasing treatment by these medical professionals. The study is: " Health Care Experiences of Patients Discontinuing or Reversing Prior Gender-Affirming Treatments." See JAMA Open. 2022.5(7):e2224717.doi:101001/jamanetworkopen.2022.24717. This study found that people who wanted to cease taking puberty blockers and cross-sex hormones encountered doctors who avoided them and stigmatized them and their desire to detransition. The study found that the doctors lacked detransition-related clinical knowledge. The findings of this study are not surprising considering the extremely small number of doctors who have decided to prescribe puberty blocker drugs and cross-sex hormones to children. The findings of the study are consistent with common-sense: the doctors who have prescribed children these irreversibly harmful, powerful, drugs are committed to transgender ideology and are repulsed by a patient who wishes to even discuss the cessation of taking these harmful drugs.

If the BOM and BOOM do not promulgate rules which terminate doctors from prescribing these drugs, then an untold number of children will become sterilized by the drugs and suffer serious health effects such as tumor-like masses in the brain, retardation of cognitive development, visual disturbances, headache, vomiting, papilledema (swelling of optive nerve), increased blood pressure, and abducens neuropathy (eye paralysis). See" FDA Slaps Warning on Puberty Blockers," by Joshua Arnold, July 28, 2022; https://www.dailysignal.com/2022/08/05/fda-slaps-warning-on-puberty-blockers/?utm_source=TDS_Email&utm_medium=email&utm_campaign=top5. It would be sad and disappointing for the BOM and BOOM to not prevent this inevitable medical sterilization of children and not prevent the serious injury of children who have, so far, been grandfathered in by the Boards to continue to be harmed by puberty blocker drugs and cross-sex hormones.

The Boards should reject the argument that forcing doctors to cease prescribing these drugs to children will lead to increased suicidal ideation and even suicide by their child patients. The opposite is true: allowing children to continue to take these harmful drugs will increase suicide rate. This was the finding of the study, "Puberty Blockers, Cross-Sex Hormones, and Youth Suicide," The Heritage Foundation, June 13, 2022, by Jay P. Greene, PhD. See http:.//.report.heritage.org/bg3712. The takeaways from this study were: 1) Studies finding that "gender-affirming" interventions prevent suicide fail to show a causal relationship and have been poorly executed; 2) A superior research design shows that easing access to puberty blockers and cross-sex hormones by minors increases suicide rate.

Based on the above authorities and argument, I respectfully submit that the BOM and BOOM should promulgate rules which prohibit MD's and DO's from prescribing puberty blocker drugs and cross-sex hormones to children who were grandfathered in to continue taking these harmful drugs by prior rules of the BOM and BOOM.

Sincerely,

FLORIDA PUBLIC DEFENDER

Blaise Trettis
Public Defender, 18th Judicial Circuit, Brevard & Seminole Counties
2725 Judge Fran Jamieson Way, Bldg. E
Viera, Florida 32940
Phone: (321) 617-7373, option 7
wait for voice prompt, ext. 4
Fax (321) 633-2122
http://www.18thjudicialcircuitpublicdefender.com

Puberty Suppression Treatment for Patients with Gender Dysphoria

Patient Information and Informed Parental Consent and Assent for Minors

Before a minor continues treatment to suppress puberty with puberty blockers, you and the minor need to be aware of the effects and possible risks associated with the use of these medications. After your questions or concerns are addressed and you have decided to have the minor continue treatment with puberty blockers, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

What are other options if I do not wish to have the minor continue treatment with puberty blockers?

One option available is psychological therapy with a mental health provider that has experience in treating minors with gender dysphoria. This is recommended regardless of whether the minor undergoes suppression of puberty or not, due to the high risk of anxiety, depression, self-harm, and suicide. Another option is _____.

What are different medications that are used to suppress puberty?

The main mechanism by which physical changes of puberty can be put on hold is by using medication to block the signal from the brain to the organs that make hormones. These hormones are estrogen and testosterone. Estrogen is made by the ovaries. Testosterone is made by the testicles.

Pediatric endocrinologists (children's doctors who specialize in hormones and puberty) use these medications frequently to suppress puberty in children with precocious (early) puberty, which is the U.S. Food and Drug Administration (FDA) approved use. None of the medications have been approved by the FDA to be used in minors with gender dysphoria. In other words, using these medications for gender dysphoria is considered "off label" use because they are not being used for their intended purpose.

Lupron and Histrelin are called GnRH analogs and are the most effective forms of treatment for puberty suppression. When used for precocious puberty, Lupron is given as a monthly or every 3-month intramuscular injection. When used for precocious puberty, Histrelin (brand name Supprelin) is an implant that is surgically placed under the skin and needs to be replaced every 1 to 2 years.

Provera is a pill that needs to be taken twice a day and is approved to be used in female adolescents with abnormal uterine bleeding. Provera is less effective than Lupron and Histrelin. Depo-Provera injections are approved for the use in females with abnormal bleeding and as birth control.

What are the requirements to receive puberty suppression for gender dysphoria?

To receive treatment with puberty blockers, there are specific requirements that must be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, treatment with puberty blockers may be discontinued by the prescribing physician.

The specific requirements for a minor to receive and continue treatment include the following:

1. Meets the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has adequate psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (this is the first stage of puberty and refers to breast or testicle growth), which must be confirmed by a physician; and
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery.
7. Undergoes an evaluation by the prescribing physician at least every 3 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing at least every 4 months;
10. X-ray of the hand (bone age) no less than once a year;
11. Bone (DEXA) scan, which will allow monitoring of the minor's bone density (bone strength) during treatment, as puberty blockers may decrease bone density if given for long periods of time;
12. Annual mental health assessment by a Board-certified Florida-licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with providing puberty suppression treatment to the minor.

Effects of Treatment of Suppression of Puberty

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			Puberty blockers are used to temporarily suspend or block the physical changes of puberty for minors

			If a minor stops treatment with puberty blockers, in a few months their body may restart the changes of puberty at the developmental stage they were before starting medication. However, the effects of these medications could be permanent.
			It can take several months for the medications to be effective. It cannot be predicted how quickly or slowly or even if a minor's body will respond to the medication.
			Taking these medications, will cause a minor's body to stop producing testosterone or estrogen.
			These medications will not change a minor's sex (chromosomes), and it will not change a minor's internal or external reproductive structures.
			Puberty blockers can interfere with fertility.
			Puberty blockers do not affect the minor's ability to contract a sexually transmitted infection.
			The use of puberty blockers in minors for the treatment of gender dysphoria is an off-label use. This means these medications are not approved by the FDA to treat this specific diagnosis.

Risks of Treatment of Suppression of Puberty

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			The adverse effects and safety of puberty blockers used for the treatment of gender dysphoria in minors is not well known.
			Treatment with puberty blockers will not prevent serious psychiatric events such as a suicide.
			Treatment with puberty blockers may cause new or worsened psychiatric problems, including: • Crying • Irritability • Restlessness (impatience) • Anger • Acting aggressive
			It is the responsibility of the parent/guardian to notify the prescribing physician if the minor has any new or worsening physical or psychiatric problems while taking this medication.
			During the first 4 weeks of treatment, puberty blockers can cause an increase in some hormones. During this time, a minor may notice more signs of puberty, including vaginal bleeding.
			Seizures are a risk associated with taking puberty blockers.

			The risk of seizures may be higher in people who: • Have a history of seizures • Have a history of epilepsy • Have a history of brain or brain vessel (cerebrovascular) problems or tumors • Are taking a medicine that has been connected to seizures, such as bupropion or selective serotonin reuptake inhibitors (SSRIs).
			It is the responsibility of the parent/guardian to immediately notify the appropriate health care providers including the minor's prescribing physician if the minor has a seizure while taking puberty blockers.
			Increased pressure in the fluid around the brain is a risk associated with taking puberty blockers. It is the responsibility of the parent/guardian to notify the minor's prescribing physician if the minor has any of the following symptoms while taking puberty blockers: • Headache • Eye problems including blurred vision, double vision, and decreased eyesight • Eye pain • Ringing in the ears • Dizziness • Nausea
			Puberty blockers should not be used if a minor is: • Allergic to GnRH, GnRH agonist medicines, or Progesterones. • Pregnant or becomes pregnant because puberty blockers can cause birth defects or loss of the baby. It is the responsibility of the parent/guardian to notify the prescribing physician if a minor becomes pregnant while taking puberty blockers.
			The most common side effects of puberty blockers include: • Injection site reactions such as pain, swelling, and abscess which may result in surgery • Weight gain • Pain throughout body • Headache • Acne or red, itchy rash and white scales (seborrhea) • Serious skin rash (erythema multiforme) • Mood changes • Swelling of vagina (vaginitis), vaginal bleeding, and vaginal discharge • Upper stomach pain • Diarrhea

			• Bleeding • Nausea and vomiting • Fever • Itching • Pain in extremities • Rash • Back pain • Ligament sprain • Weight gain • Fracture • Breast tenderness • Difficulty sleeping • Chest pain • Excessive sweating
			Puberty blockers may decrease bone density.
			Minors may grow less than their peers while taking puberty blockers.
			Puberty blockers may cause stalling of typical cognitive or brain development in minors.

Requirements of Treatment of Suppression of Puberty

I understand the following:

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			Compliance with the requirements explained above is a prerequisite to receive treatment for puberty suppression.
			The prescribing physician may stop prescribing puberty blockers if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
			The parent/guardian or the minor can change their mind and stop treatment at any time.

PARENTAL CONSENT:
The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
    a. The benefits and risks of treatment with puberty blockers;
    b. The possible or likely consequences of treatment with puberty blockers and puberty suppression; and
    c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with puberty blockers. I know that there may be other unknown short-term and long-term effects or risks.

3. I have had sufficient time and opportunity to discuss relevant treatment options with my minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for my minor to take, refuse, or postpone using puberty blocking medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for my minor to begin treatment for suppression of puberty.

_____
Parent/legal guardian's name (required)

_____ _____
Parent/legal guardian's signature (required) Date

Parent/legal guardian's name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

Prescribing physician's name (required)

Prescribing physician's signature (required) Date

ASSENT OF MINOR:

I have discussed the benefits and risks of treatment to suppress puberty with my prescribing physician and my parent(s) or legal guardian(s), and I wish to receive it.

Minor's name (required)

Minor's signature (required) Date

WITNESS:

_____
Witness printed name

_____ _____
Witness signature Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluid in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

_____
Interpreter's printed name

_____ _____
Interpreter's Signature Date

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent and Assent for Minors

Before a minor starts or continues treatment with hormones or hormone antagonists, you and the minor need to be aware of the effects and possible risks associated with use of these medications.

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

What are the medications that can feminize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications by minors even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered "off label" because they are not being used for their intended purpose.

Different forms of estrogen are used to feminize one's appearance. Estrogen can be given as an injection either weekly or every other week, as a pill that is taken daily or twice a day, or as a patch that is changed weekly or every three or four days.

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone is the androgen blocker that is most commonly used in the United States. In some cases, Bicalutamide, an antiandrogen, is used to block the effects of testosterone, though it will not reduce testosterone levels. Bicalutamide (brand name Casodex) is a cancer drug approved for the treatment of prostate cancer. Fulminant hepatotoxicity, a severe liver injury often resulting in death, has been noted with bicalutamide use.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the minor's prescribing physician to make sure that there are no negative medical or mental health effects.

HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect a minor's mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

What are my other options if I do not wish to start or continue my minor's treatment with hormones, hormone antagonists, or antiandrogens?

One option available is psychological therapy with a mental health provider that has experience in treating minors with gender dysphoria. This is recommended regardless of whether or not the minor undergoes treatment with hormones, hormone antagonists, or antiandrogens due to the high risk of anxiety, depression, self-harm, and suicide. Another option is _____.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Before beginning or continuing HRT, a minor must undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for a minor to receive and continue HRT treatment include the following:

1. Meets the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Has pubertal changes resulting in an increase in gender dysphoria;
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has adequate psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
7. Undergoes an evaluation by the prescribing physician at least every 3 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Bone (DEXA) scan once a year to allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT;
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with treating a minor with feminizing medications.

Effects of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make a minor appear less like a male and more like a female.
			It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
			This treatment will not change the minor's sex chromosomes.
			If a minor takes estrogen, the following changes in a minor's breasts will occur: • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported the minor's prescribing physician • The minor's risk of breast cancer may significantly increase
			If a minor takes feminizing medications, the minor's body will make less testosterone, which may affect the minor's sex life in different ways, including: • The minor's testicles may shrink • The minor's penis may never fully develop, particularly if the minor has previously taken puberty blockers • The minor will have fewer spontaneous erections • The minor's sperm may no longer mature causing infertility which may be permanent

			even if treatment is discontinued, the risk of which is increased if the minor took puberty blockers prior to starting feminizing medications • Conversely, it is possible that a minor's sperm could still mature while taking feminizing medications and the minor may cause someone to get pregnant
			To improve the possibility that the minor may have biological children in the future, the options for sperm banking by the minor have been explained.
			If a minor takes feminizing medications, some parts of the minor's body will not change much, including: • If present, the minor's facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, the minor's body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If the minor went through puberty and has a deep voice, the pitch of the minor's voice will not rise and the minor's speech patterns will not become more like a woman's • If present, the minor's Adam's apple will not shrink
			Even if a minor stops taking feminizing medications, the following changes may occur: • The minor's body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • The minor may have decreased muscle mass and strength in the upper body • The minor's skin may become softer
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to feminize a minor is an off-label use of the medications. This means these medications are not approved by the FDA for this

			purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the minor's prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications for minors.

Risks of Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			The medical effects and the safety of minors taking femininizing medications are not completely known and there may be unknown long-term risks.
			Taking feminizing medications causes changes that other people will notice.
			Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
			The minor must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
			Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Estrogen **SHOULD NOT** be used by anyone who has a history of:

- Any estrogen-dependent cancer
- Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist

Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who:

- Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present
- Has a family history of heart disease
- Has diabetes

- Has chronic hepatitis or other liver disease
- Has high levels of cholesterol
- Has migraines or seizures
- Is obese
- Smokes cigarettes or uses tobacco products

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death
			The risk of blood clots while take estrogen is much greater if the minor smokes cigarettes. The danger is so high that the minor should stop smoking completely while taking estrogen.
			Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke.
			Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
			Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain experience by the minor while taking estrogen must be reported to the minor's prescribing physician.
			Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage the minor's vision and cause headaches if not treated properly. Any changes in the minor's vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the

			nipples must be reported to the minor's prescribing physician.
			Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to the minor's prescribing physician.
			Taking estrogen can cause migraines or can make them worse if the minor already has them.
			Taking estrogen can cause hot flashes.
			Taking estrogen can cause the minor to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by the minor's kidneys, making it necessary to urinate more frequently • Increase the minor's thirst • Increase the minor's risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness

			Taking Spironolactone affects the balance of potassium in the kidneys, which may result in the minor experience high potassium levels resulting in:
			• Changes in heart rhythms that may be life threatening
			• Low blood pressure, which can cause:
			  ○ Fatigue
			  ○ Lightheadedness
			  ○ Tingling feelings
			  ○ Muscle weakness
			  ○ Shortness of breath
			• The minor's need for regular blood tests to monitor risks while on the medication

			Taking Bicalutamide may cause numerous side effects which should be reported to the minor's prescribing physician, including: • Hot flashes or flushing • Bone, back, or pelvic pain • Muscle weakness • Muscle or joint pain • Headaches • Shortness of breath • Chest pain • Elevated blood pressure • Swelling of the hands, feet, ankles, or lower legs • Cough • Constipation • Nausea • Vomiting • Abdominal pain • Diarrhea • Gas • Changes in weight (loss or gain) • Loss of appetite • Dizziness • Pain, burning, or tingling in the hands or feet • Difficulty sleeping • Feeling of uneasiness or dread • Rash • Sweating • Need to urinate frequently during the night • Bloody urine • Painful or difficult urination • Frequent and urgent need to urinate • Difficulty emptying bladder • Painful or swollen breasts • Yellowing of the skin or eyes • Pain in the upper right part of the abdomen • Extreme tiredness • Unusual bleeding or bruising • Lack of energy • Upset stomach • Loss of appetite

			• Flu-like symptoms • Dull or sharp side pain

Requirements of Treatment with Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			Compliance with the requirements explained above is a prerequisite for a minor to receive treatment with feminizing medications.
			The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with Feminizing Medications

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned parent(s)/legal guardian(s) agree(s) to take the minor to physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of taking feminizing medications;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for the minor to take, refuse, or postpone taking feminizing medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for the minor to begin treatment with feminizing medications.

_____
Parent/legal guardian's printed name (required)

_____ _____
Parent/legal guardian's signature (required) Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required) Date

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with feminizing medications with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive them.

Minor's printed name (required)

Minor's signature (required) Date

WITNESS:

_____
Witness' printed name (required)

_____ _____
Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluid in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

_____
Interpreter's printed name

_____ _____
Interpreter's Signature Date

Masculinizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent and Assent for Minors

Before a minor starts or continues treatment with hormones or hormone antagonists, you and the minor need to be aware of the effects and possible risks associated with use of these medications.

After your questions or concerns are addressed and you have decided to have the minor start or continue treatment with hormones or hormone antagonists, a parent/legal guardian and the minor must initial the statements below and sign this form. Both the parent/legal guardian and the minor must sign in person.

What are the medications that can masculinize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice. Testosterone when used by minors, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval to be used by minors and its use in this population is considered "off label" because they are not being used for their intended purpose.

What are my other options if I do not wish to start or continue my minor's treatment with hormones or hormone antagonists?

One option available is psychological therapy with a mental health care provider that has experience in treating minors with gender dysphoria. This is recommended regardless of whether or not the minor undergoes treatment with hormones or hormone antagonists due to the high risk of anxiety, depression, self-harm, and suicide. Another option is _____.

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not given in pill form because the body may not absorb it properly which may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). A minor taking testosterone may experience unwanted swings in hormone levels based on the amount and how often doses are given.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the minor's prescribing physician to make sure that there are no negative medical or mental health effects.

Both testosterone and the treatment process can affect a minor's mood. Therefore, minors must be under the care of a licensed mental health care professional while undergoing treatment. This professional can work with the minor, your family and friends, and your school staff.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor the minor's medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Before beginning or continuing HRT, a minor needs to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for a minor to receive and continue HRT treatment include the following:

1. Meets the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. meets the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD)
3. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. Has adequate psychological and social support during treatment;
5. Has experienced puberty to at least Tanner Stage 2 (first stage of puberty), which must be confirmed by a physician;
6. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
7. Undergoes an evaluation by the prescribing physician at least every 3 months;
8. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
9. Undergoes relevant laboratory testing, at least every 4 months;
10. X-ray of the hand (bone age) at least once a year if the minor is still growing;
11. Bone (DEXA) scan once a year to allow monitoring of the minor's bone density (bone strength) during treatment, which can be altered by HRT;
12. Annual mental health assessments by a Board-certified Florida licensed psychiatrist or psychologist; and
13. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Who should not take testosterone?

Testosterone **SHOULD NOT** be used by anyone who:

- Is pregnant
- Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack

Testosterone should be used **WITH CAUTION** and only after a full discussion of risks by anyone who:

- Has acne
- Has a family history of heart disease or breast cancer
- Has had a blood clot
- Has high levels of cholesterol
- Has liver disease
- Has a high red blood cell count
- Is obese
- Smokes cigarettes or uses tobacco products

Summary of Testosterone Benefits and Risks

BENEFITS	RISKS
• Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive	• Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning such as Coumadin and Warfarin • Male pattern baldness • More abdominal fat – redistributed to a male shape • Risk of heart disease • Swelling of hands, feet, and legs • Weight gain

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with a minor taking testosterone.

Masculinizing Effects

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			Testosterone may be prescribed to make a minor appear less like a female and more like a male.
			It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
			Changes from testosterone may not be complete for 2 to 5 years after treatment is started.
			The following changes are likely to be permanent even if testosterone is discontinued: • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald • More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
			The following changes could be permanent, but may improve if I stop taking testosterone: • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from "pear shape" to "apple shape" • More muscle mass and strength • More sexual interest • Vaginal dryness
			This treatment will not change the minor's sex chromosomes.

			Testosterone may reduce the minor's ability to become pregnant, but it will not eliminate the risk of pregnancy. A person can become pregnant while on testosterone. I agree to inform the minor's prescribing physician if the minor becomes pregnant.
			Some aspects of the minor's body will not change: • Fat loss may make breasts appear slightly smaller (if present) • The voice will deepen, but other aspects of the way the minor speaks may not sound more masculine
			Mood changes may be caused by these medicines, and the minor will continue therapy with a licensed mental health care professional during treatment.
			Using these medicines to masculinize a minor is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the minor's prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT for minors.

Risks of Testosterone

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			The medical effects and the safety of minors taking testosterone are not completely known and there may be unknown long-term risks.
			Taking testosterone causes changes that other people will notice.
			Treatment with testosterone will not prevent serious psychiatric events, including suicide.

			The minor must not take more testosterone than prescribed. Taking too much testosterone: • Will increase health risks; • Will not make changes happen more quickly or more significantly; and • May cause the body to convert extra testosterone into estrogen that can slow down or stop the minor appearing more masculine
			Taking testosterone can cause changes that increase the risk of heart disease into adulthood. These changes include: • Less good cholesterol (HDL) that may protect against heart disease and more bad cholesterol (LDL) that may increase the risk of heart disease; • Higher blood pressure; and • More deposits of fat around the internal organs
			Taking testosterone can damage the liver and possibly lead to liver disease.
			Taking testosterone can increase red blood cells and hemoglobin, which may increase my risk of life-threatening problems such as stroke or heart attack.
			Taking testosterone can increase the risk for diabetes (high blood sugars), which decrease the body's response to insulin, cause weight gain, and increase deposits of fat around internal organs increasing the risk of heart disease and stroke.
			Treatment with testosterone can cause ovaries to not release eggs and may cause infertility.
			Treatment with testosterone increases the risk of cancer to the uterus, ovaries, or breasts. It is unclear if taking testosterone plays any role in HPV infection or cervical cancer.
			Taking testosterone causes or worsen migraines.
			Taking testosterone can cause emotional changes, such as irritability, frustration, aggression, and anger.

Requirements of Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			Compliance with the requirements explained above is a prerequisite for a minor to receive treatment with testosterone.
			The prescribing physician may stop prescribing testosterone if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
			The parent/guardian or the minor can change their mind and stop treatment at any time although some effects of HRT may be permanent.

Prevention of Complications while under Treatment with HRT

Parent/legal guardian (required)	Parent/legal guardian (optional)	Minor	Statement
			The undersigned parent(s)/legal guardian(s) agree(s) to notify the minor's prescribing physician if the minor suffers from any side effects during treatment or is unhappy with the treatment in any way, particularly if the parent(s)/legal guardian(s) has/have any concerns that the minor has worsening signs of depression or anxiety or expresses a desire harm themselves or attempt suicide.
			The prescribing physician is required to monitor the minor for any side effects during treatment and may refer the minor to another physician or specialist for treatment. The undersigned parent(s)/legal guardian(s) agree(s) to take the minor physicians and specialists as recommended by the prescribing physician.

PARENTAL CONSENT:

The signature(s) below confirm(s) the following:

1. The minor's prescribing physician has fully informed me about:
   a. the benefits and risks of taking testosterone;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with testosterone. I know that there may be other unknown short-term and long-term effects or risks.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the minor's prescribing physician.

4. All my questions have been answered to my satisfaction by the minor's prescribing physician.

5. I know enough to give informed consent for the minor to take, refuse, or postpone taking testosterone.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent for the minor to begin treatment with testosterone.

_____

Parent/legal guardian's printed name (required)

_____ _____

Parent/legal guardian's signature (required) Date

Parent/legal guardian's printed name (optional)

Parent/legal guardian's signature (optional) Date

PRESCRIBING PHYSICIAN:

My signature below attests to my compliance with 456.52, Florida Statutes.

Prescribing physician's printed name (required)

Prescribing physician's signature (required) Date

ASSENT OF A MINOR:

I have discussed the benefits and risks of treatment with masculinizing medication with my prescribing physician, parent(s) or legal guardian(s), and I wish to receive it.

Minor's printed name (required)

Minor's signature (required) Date

WITNESS:

Witness' printed name (required)

Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluid in English and in the native language of the person indicating consent and/or assent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient and/or adult(s) legally responsible for the minor child has indicated understanding of the contents of this form.

Interpreter's printed name

Interpreter's Signature Date

DRAFT FOR JUNE 23, 2023 - JOINT COMMITTEE MEETING

64B8ER-XX/64B15ER-XX - Sex-reassignment Standards of Practice in Minors

The standards of practice in this rule do not supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.

(1) Pursuant to Section 456.52, Florida Statutes, sex-reassignment prescriptions and procedures are prohibited for patients younger than 18 years of age, except that a physician may continue to treat such patient with a prescription if such treatment for sex-reassignment was commenced before, and is still active on, May 17, 2023. The physician is required to obtain voluntary, informed consent while physically present in the same room as the patient. Consent is not required for renewal of such prescriptions if a physician and his or her patient have met the requirements for consent for the initial prescription or renewal; however, a separate consent is required for any new prescription for a pharmaceutical product not previously prescribed to the patient.

(2) Informed Consent. The Board has approved the following mandatory informed consent forms for the continued treatment of minors with sex-reassignment prescriptions:

(a) For patients prescribed puberty blocking medications, form DOH-MQA-XXXX, (06/23), entitled "NAME," which is hereby incorporated by reference and available from http://www.flrules.org/Gateway/reference.asp?No=Ref- and from the Board's website at [DOH LINK].

(b) For patients prescribed sex-reassignment feminizing medications, form DOH-MQA-XXXX, (06/23), entitled "NAME," which is hereby incorporated by reference and available from http://www.flrules.org/Gateway/reference.asp?No=Ref- and from the Board's website at [DOH LINK].

(c) For patients prescribed sex-reassignment masculinizing medications, form DOH-MQA-XXXX, (06/23), entitled "NAME," which is hereby incorporated by reference and available from http://www.flrules.org/Gateway/reference.asp?No=Ref- and from the Board's website at [DOH LINK].

(3) A Board-approved informed consent form is not executed until:

(a) The physician issuing the prescription, while physically present in the same room as the patient, has informed the patient and the patient's parent or legal guardian of the nature and risks of the prescription, and has provided and received the written acknowledgement of the patient and the patient's legal guardian before the prescription is prescribed or administered. The physician is prohibited from delegating this responsibility to another person. The physician is also required to sign the informed consent form.

(b) The patient's parent or legal guardian is required to sign the informed consent form.

(c) The patient is required to assent to the informed consent form.

(d) A competent witness is also required to sign the informed consent form.

(4) Standards of Practice. The nature and extent of the requirements set forth below will vary depending on the practice setting and circumstances presented to the prescribing physician. A prescribing physician who continues to treat a minor patient with sex-reassignment prescriptions pursuant to section 456.52(1)(a), Florida Statutes, shall comply with the following:

Clinical determinations.

(a) Patient Evaluation. An in-person thorough medical history and physical examination of the patient conducted by the prescribing physician must be documented in the patient's medical record prior to prescribing any new sex-reassignment prescription.

(b) Clinical determinations. Based on the patient evaluation, the following must be confirmed:

1. The patient meets the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. The patient has pubertal changes resulting in an increase in gender dysphoria;
3. The patient does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
4. The patient will have adequate psychological and social support during treatment;
5. The patient has experienced puberty to at least Tanner Stage 2; and
6. The patient demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of puberty suppression, future cross-sex hormone treatment, as well as the medical and social risks and benefits of sex reassignment surgery based on the patient's current treatment status;

(c) Patient Visit. The physician must meet with the patient every three (3) months for the purpose of monitoring the patient and must document each visit in the patient's medical records.

(d) Suicide Risk Assessment. A suicide risk assessment by a licensed mental health care professional must be performed every three (3) months.

(e) Laboratory Testing. Relevant laboratory testing must be performed every four (4) months.

(f) X-rays. X-rays of the hand must be performed each year to monitor and document the patient's bone age progression.

(g) Bone (DEXA) Scan. A bone (DEXA) scan must be performed each year to monitor the patient's bone density during treatment.

(h) Mental Health Assessment. The physician must have the patient undergo a annual mental health assessment to be performed by a board-certified Florida licensed psychiatrist or psychologist.

(i) Counseling. The physician must refer the patient for counseling with a licensed mental health care professional during the treatment period, with a frequency as recommended by the licensed mental health care professional.

(j) Additional Consultations. The physician must refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.

Rulemaking Authority 456.52 FS. Law Implemented 456.52 FS. History – New____.

Feminizing Medications for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with use of these medications.

Your prescribing physician will make a medical decision in consultation with you about the medications that are best for you, keeping in mind your overall health during the treatment process. Your prescribing physician will discuss with you all of the available information relating to hormone therapy. You are asked to read and understand the following information and to discuss any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue treatment with hormones or hormone antagonists, you must initial the statements below and sign this form in person with your prescribing physician.

What are the different medications that can feminize one's appearance?

Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking estrogen, as well as medicines to block the body from producing or utilizing testosterone. Use of these medications, even when the criteria listed below are followed, does not have U.S. Food and Drug Administration (FDA) approval and its use to treat gender dysphoria is considered "off label" because they are not being used for their intended purpose

Different forms of estrogen are used to feminize a person's appearance. Estrogen can be given as an injection either weekly or every other week, as a pill that is taken daily or twice a day, or as a patch that is changed weekly or every three or four days.

Medications that block the production or effects of testosterone are called androgen blockers. Spironolactone is the androgen blocker that is most commonly used in the United States. In some cases, Bicalutamide, an antiandrogen, is used to block the effects of testosterone, though it will not reduce testosterone levels. Bicalutamide (brand name Casodex) is a cancer drug approved for the treatment of prostate cancer. Fulminant hepatotoxicity, a severe liver injury often resulting in death, has been noted with bicalutamide use.

Cyproterone acetate, a synthetic progestogen with strong antiandrogen activity, is commonly used in many countries. When paired with estrogen, cyproterone acetate is associated with elevated prolactin, decreased HDL cholesterol, and rare meningiomas (tumors). Cyproterone acetate has also been associated with uncommon episodes of fulminant hepatitis.

The administration of finasteride blocks the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved uses of finasteride include the treatment

benign prostatic hypertrophy and androgenic alopecia. Finasteride is not recommended for routine use in treating populations with gender dysphoria.

Various forms of progestins may also be used. This class includes micronized bioidentical progesterone (Prometrium) as well as oral medroxyprogesterone acetate (Provera). Although there are anecdotal reports of progesterone use for breast development and mood management, there is currently insufficient evidence that the potential benefits of progesterone administration outweigh the potential risks. There is also a theoretical risk of breast cancer associated with long-term exogenous progesterone.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to your prescribing physician to make sure that there are no negative medical or mental health effects.

HRT, the use of androgen blockers and antiandrogens, and the treatment process can affect your mood. Therefore, you must be under the care of a licensed mental health care professional while undergoing treatment.

What are my other options if I do not wish to start or continue treatment with hormones, hormone antagonists, or antiandrogens?

One option available is psychological therapy with a mental health provider that has experience in treating people with gender dysphoria. This is recommended regardless of whether or not the person undergoes treatment with hormones, hormone antagonists, or antiandrogens due to the high risk of anxiety, depression, self-harm, and suicide. Another option is _____.

What are the requirements to receive hormone replacement therapy (HRT)?

To receive HRT, there are specific requirements that need to be met before and during treatment. These requirements will allow the prescribing physician to monitor your medical and mental health status during treatment. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Before beginning or continuing HRT, you must undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for you to receive and continue HRT treatment include the following:

1. Meets the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders or International Classification of Diseases;
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Gender dysphoria is marked and sustained;
4. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
5. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
6. Has adequate psychological and social support during treatment;
7. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
8. Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options;
9. Undergoes an evaluation by the prescribing physician at least every 3 months
10. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;
11. Undergoes relevant laboratory testing at least every 6 months;
12. Bone (DEXA) scan once a year to allow monitoring of your bone density (bone strength) during treatment, which can be altered by HRT;
13. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
14. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Please initial each statement on this form to show that you understand the benefits, risks, and changes associated with taking feminizing medications.

Effects of Feminizing Medications

Patient	Statement
	Feminizing medications, including estrogen, androgen blockers, or antiandrogens, given singularly or in combination, may be prescribed to make me appear less like a male and more like a female.
	It can take several months or longer for the effects of feminizing medications to become noticeable and no one can predict how fast or how much change will occur.
	This treatment will not change my sex chromosomes.

	If I take estrogen, the following changes in my breasts will occur: • Breasts will develop but will not reach their full size for several years • Breasts will remain even if estrogen treatment is discontinued • A milky discharge from the nipples may appear, which should be reported to my prescribing physician • My risk of breast cancer may significantly increase
	If I take feminizing medications, my body will make less testosterone, which may affect my sex life in different ways, including: • My testicles may shrink • My penis may never fully develop, particularly if I previously took puberty blockers • I will have fewer spontaneous erections • My sperm may no longer mature causing infertility which may be permanent even if treatment is discontinued, the risk of which is increased if I took puberty blockers prior to starting feminizing medications • Conversely, it is possible that my sperm could still mature while taking feminizing medications and I may cause someone to get pregnant
	The options for sperm banking have been explained.
	If I take feminizing medications, some parts of my body will not change much, including: • If present, my facial hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If present, my body hair may grow more slowly, but it will not go away completely even after taking feminizing medications for many years • If I went through puberty and have a deep voice, the pitch of my voice will not rise and my speech patterns will not become more like a woman's • If present, my Adam's apple will not shrink
	Even if I stop taking feminizing medications, the following changes may occur: • My body fat may be redistributed with less fat on the abdomen and more on the buttocks, hips, and thighs creating a more female shape • I may have decreased muscle mass and strength in the upper body • My skin may become softer
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to feminize my body is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of my prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of feminizing medications.

Risks of Feminizing Medications

Patient	Statement
	The medical effects and the safety of taking femininizing medications are not completely known and there may be unknown long-term risks.
	Taking femininizing medications causes changes that other people will notice.
	Treatment with femininizing medications will not prevent serious psychiatric events, including suicide.
	I must not take more feminizing medication than prescribed. Taking too much medication: • Will increase health risks • Will not make changes happen more quickly or more significantly
	Taking feminizing medication can damage the liver and possibly lead to liver disease.

Risks of Estrogen

Estrogen **SHOULD NOT** be used by anyone who has:

- Any estrogen-dependent cancer
- Any disorder that makes them more likely to get blood clots that could travel to the lungs unless they are also taking blood thinners and are being followed by a specialist

Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who:

- Has a family history of breast cancer or other cancers that grow more quickly when estrogens are present
- Has a family history of heart disease
- Has diabetes
- Has chronic hepatitis or other liver disease
- Has high levels of cholesterol
- Has migraines or seizures
- Is obese
- Smokes cigarettes or uses tobacco products

Patient	Statement
	Taking estrogen increases the risk of blood clots and problems with blood vessels that can result in: • Chronic problems with veins in the legs, which may require surgery • Heart attack which may cause permanent heart damage or death • Pulmonary embolism (blood clot in the lungs), which may cause permanent lung damage or death • Stroke, which may cause permanent brain damage or death

	The risk of blood clots while take estrogen is much greater if you smoke cigarettes. The danger is so high that you should stop smoking completely while taking estrogen.
	Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke.
	Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke.
	Taking estrogen increases the risk of gallstones (stones in the gallbladder). Any long-term abdominal pain you experience while taking estrogen must be reported to your prescribing physician.
	Taking estrogen increases the risk of elevated prolactin levels and prolactinomas, which are non-cancerous tumors of the pituitary gland. While not typically life threatening, prolactinomas can damage your vision and cause headaches if not treated properly. Any changes in your vision, the occurrence of headaches that are worse when waking up in the morning, or any milky discharge from the nipples must be reported to your prescribing physician.
	Taking estrogen can cause nausea and vomiting. Any long-term nausea or vomiting must be reported to your prescribing physician.
	Taking estrogen can cause migraines or can make them worse if you already have them.
	Taking estrogen can cause hot flashes.
	Taking estrogen can cause you to feel tired and have difficulty focusing.

Risks of Androgen Blockers and Antiandrogens (Spironolactone and Bicalutamide)

Patient	Statement
	Taking Spironolactone affects the balance of water and salt in the kidneys, which may: • Increase the amount of urine produced by your kidneys, making it necessary to urinate more frequently • Increase your thirst • Increase your risk of dehydration, which can be evidenced by less frequent urination than usual, dark and strong-smelling urine, thirst, and light-headedness

	Taking Spironolactone affects the balance of potassium in the kidneys, which may result in you experiencing high potassium levels resulting in:
	• Changes in heart rhythms that may be life threatening
	• Low blood pressure, which can cause:
	  ○ Fatigue
	  ○ Lightheadedness
	  ○ Tingling feelings
	  ○ Muscle weakness
	  ○ Shortness of breath

	• Your need for regular blood tests to monitor risks while on the medication
	Taking Bicalutamide may cause numerous side effects which should be reported to your prescribing physician, including: • Hot flashes or flushing • Bone, back, or pelvic pain • Muscle weakness • Muscle or joint pain • Headaches • Shortness of breath • Chest pain • Elevated blood pressure • Swelling of the hands, feet, ankles, or lower legs • Cough • Constipation • Nausea • Vomiting • Abdominal pain • Diarrhea • Gas • Changes in weight (loss or gain) • Loss of appetite • Dizziness • Pain, burning, or tingling in the hands or feet • Difficulty sleeping • Feeling of uneasiness or dread • Rash • Sweating • Need to urinate frequently during the night • Bloody urine • Painful or difficult urination • Frequent and urgent need to urinate • Difficulty emptying bladder • Painful or swollen breasts • Yellowing of the skin or eyes • Pain in the upper right part of the abdomen • Extreme tiredness • Unusual bleeding or bruising • Lack of energy • Upset stomach • Loss of appetite • Flu-like symptoms

	• Dull or sharp side pain

Requirements of Treatment with Feminizing Medications

Patient	Statement
	Compliance with the requirements explained above is a prerequisite for you to receive treatment with feminizing medications.
	The prescribing physician may stop prescribing feminizing medications if the prescribing physician or mental health care professionals providing treatment pursuant to this consent determine the benefit of treatment no longer outweighs the risks, there is insufficient social or psychological support, or the requirements in this consent are not met.
	I can change my mind and stop treatment at any time.

Prevention of Complications while under Treatment with Feminizing Medications

Patient	Statement
	I agree to notify the prescribing physician if I suffer from any side effects during treatment or are unhappy with the treatment in any way, particularly if I have any concerns about worsening signs of depression or anxiety or if I desire to harm myself or attempt suicide.
	I acknowledge that taking feminizing medications is only a part of my overall health, and that a range of preventative health activities are necessary so that remain healthy. These include, but are not limited to: • Monthly breast self-examination (report any new lumps to the prescribing physician) • Regular age-appropriate breast mammograms • Regular age-appropriate prostate examinations • Appropriate immunizations • Regular STI screening depending on my level of risk • HIV prevention depending on my level of risk • Regular physical activity, including resistance exercise for bone health • Healthy eating • Quitting smoking
	The prescribing physician is required to monitor me for any side effects during treatment and may refer me to another physician or specialist for treatment. I agree to go to any physicians and specialists recommended by the prescribing physician.

CONSENT:

The signature below confirms the following:

1. The prescribing physician has fully informed me about:
   a. the benefits and risks of taking feminizing medications;
   b. the possible or likely consequences of hormone therapy; and
   c. potential alternative treatments.

2. The information provided to me in this form and by the prescribing physician includes the known effects and risks of treatment with feminizing medications. I know that there may be other unknown short-term and long-term effects or risks.

3. I have had sufficient time and opportunity to discuss relevant treatment options with the prescribing physician.

4. All my questions have been answered to my satisfaction by the prescribing physician.

5. I know enough to give informed consent for me to take, refuse, or postpone taking feminizing medications.

6. The Florida Board of Medicine or the Florida Board of Osteopathic Medicine requires that your prescribing physician provide this form in accordance with section 456.52, F.S. This form contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician.

7. My signature below attests to my consent to begin treatment with feminizing medications.

_____
Patient's printed name (required)

_____ _____
Patient's signature (required) Date

PRESCRIBING PHYSICIAN SIGNATURE:

My signature below attests to my compliance with section 456.52, Florida Statutes.

_____
Prescribing physician's printed name (required)

_____ _____
Prescribing physician's signature (required) Date

WITNESS:

_____
Witness' printed name (required)

_____ _____
Witness' signature (required) Date

FOR PATIENTS WHOSE PRIMARY LANGUAGE IS NOT ENGLISH:

I certify that I am fluid in English and in the native language of the person indicating consent on the above form. I certify that I have accurately and completely interpreted the contents of this form, and that the patient has indicated understanding of the contents of this form.

_____
Interpreter's printed name

_____ _____
Interpreter's Signature Date

Testosterone Treatment for Patients with Gender Dysphoria

Patient Information and Informed Consent

Before starting or continuing treatment with hormones or hormone antagonists, you need to be aware of the effects and possible risks associated with the use of these medications.

The prescribing physician will make a medical decision, in consultation with you, about the medications that are best for you, keeping in mind your overall health during your gender transition process. The effects and possible risks associated with the use of these medications will be discussed with you. It your responsibility to read and understand the following information and raise any questions you have with your prescribing physician.

After your questions or concerns are addressed and you have decided to start or continue hormones or hormone antagonists, you will need to initial the statements below and sign this form.

What are the medications that can masculinize one's appearance?
Treatment with hormones is called hormone replacement therapy or HRT. HRT will require taking testosterone, which increases muscle mass and causes the development of facial hair and a deeper voice**.** Testosterone when used by biological women, even when the criteria listed below are followed, does not have the U.S. Food and Drug Administration (FDA) approval to be used in the treatment of gender dysphoria and is considered "off label" use because they are not being used for their intended purpose.

How is testosterone taken?

Testosterone is usually injected every one to four weeks. Typically, it is not used as a pill because the body may not absorb it properly and may cause potentially fatal liver problems. The doses used for injection differ from product to product and from patient to patient. The injections are given in the muscle (intramuscular) or can be given with a smaller needle under the skin (subcutaneous). Taking testosterone may cause unwanted swings in hormone levels based on the amount and how often doses are given. Skin creams and patches may also be used. Both testosterone and the treatment process can affect mood. Therefore, individuals must be under the care of a licensed mental health care professional while undergoing treatment.

Finasteride is a treatment option for individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. The administration of 5α-reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The FDA approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. The use of 5α-reductase inhibitors may impair clitoral growth and the development of facial and body hair. Future studies are needed to assess the efficacy and safety of 5α-reductase inhibitors in in treatment for gender dysphoria.

Every medication has risks, benefits, and side effects that are important to understand before taking. The effects and side effects of medicines used to treat gender dysphoria must be monitored with laboratory studies and regular visits to the prescribing physician to make sure that there are no negative medical or mental health effects.

What are my other options if I do not wish to start or continue medical treatments?

One option available is psychological therapy with a mental health care provider that has experience in treating people with gender dysphoria. This is recommended regardless of whether the individual undergoes treatment with hormones or hormone antagonists or not, due to the high risk of anxiety, depression, self-harm, and suicide. Another option is _____.

What are the requirements to receive hormone replacement therapy?

To receive hormone replacement therapy, there are specific requirements that need to be met before and during the treatment. These requirements will allow the prescribing physician to monitor medical as well as mental health wellbeing during HRT. If these requirements are not met, HRT may be discontinued by the prescribing physician.

Before beginning or continuing HRT, the individual needs to undergo a thorough psychological and social evaluation performed by a Florida licensed board-certified psychiatrist or a Florida licensed psychologist. The psychiatrist or psychologist must submit a letter to the prescribing physician confirming this.

The specific requirements for an individual to receive and continue HRT treatment include the following:

1. Meets the criteria for gender dysphoria in the current Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD);
2. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
3. Gender dysphoria is marked and sustained;
4. Demonstrates capacity to consent for the specific gender dysphoria hormone treatment;
5. Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
6. Has adequate psychological and social support during treatment;
7. Demonstrates knowledge and understanding of the risks, benefits, and expected outcomes of HRT as well as the medical and social risks and benefits of sex reassignment surgery;
8. Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options;
9. Undergoes an evaluation by the prescribing physician at least every 3 months
10. Undergoes a suicide risk assessment by a licensed mental health care professional at least every 3 months;

11. Undergoes relevant laboratory testing, at least every 6 months;
12. Bone (DEXA) scan once a year to allow monitoring of bone density (bone strength) during treatment, which can be altered by HRT;
13. Annual mental health assessments by a board-certified Florida licensed psychiatrist or psychologist; and
14. Continued counseling with a licensed mental health care professional during the treatment period, with the frequency recommended by the licensed mental health care professional.

Who should not take testosterone?

Testosterone **SHOULD NOT** be used by anyone who:

- Is pregnant
- Has uncontrolled coronary artery disease as it could increase your risk for a fatal heart attack

It should be used **WITH CAUTION** and only after a full discussion of risks by anyone who:

- Has acne
- Has a family history of heart disease or breast cancer
- Has had a blood clot
- Has high levels of cholesterol
- Has liver disease
- Has a high red blood cell count
- Is obese
- Smokes cigarettes

Summary of Testosterone Benefits and Risk

BENEFITS	RISKS
• Appear more like a man • Bigger clitoris • Coarser skin • Lower voice • More body hair • More facial hair • More muscle mass • More strength • No or minimal menstrual periods • More physical energy • More sex drive	• Acne (may permanently scar) • Blood clots (thrombophlebitis), risk significantly increased by smoking • Emotional changes, for example, more aggression • Headache • High blood pressure (hypertension) • Increased red-blood-cell count • Infertility • Inflamed liver • Interaction with drugs for diabetes and blood thinning — for example Coumadin and Warfarin • Male pattern baldness • More abdominal fat — redistributed to a male shape • risk of heart disease • Swelling of hands, feet, and legs • Weight gain

Please initial each statement on this form to show that you understand the benefits, risks, and changes that may occur from taking testosterone.

Masculinizing Effects

Patient	Statement
	Testosterone may be prescribed to make me appear less like a female and more like a male.
	It can take several months or longer for the effects of testosterone to become noticeable and no one can predict how fast or how much change will occur.
	The following changes are likely to be permanent even if testosterone is discontinued: • Bigger clitoris - typically about half an inch to a little more than an inch • Deeper voice • Gradual growth of moustache and beard • Hair loss at the temples and crown of the head and the possibility of being completely bald

	• More, thicker, and coarser hair on abdomen, arms, back, chest, and legs
	The following changes could be permanent, but may improve if I stop taking testosterone: • Acne (although there may be permanent scars) • Menstrual periods (if present), typically stop one to six months after starting • More abdominal fat – redistributed to a male shape: decreased on buttocks, hips, and thighs; increased in abdomen – changing from "pear shape" to "apple shape" • More muscle mass and strength • More sexual interest • Vaginal dryness
	This treatment will not change the individual' s sex chromosomes.
	Testosterone may reduce the ability to become pregnant, but it will not eliminate the risk of pregnancy. A person become pregnant while on testosterone. I agree to inform the prescribing physician if I become pregnant.
	Some aspects of my body will not change: • Fat loss may make breasts appear slightly smaller • The voice will deepen, but other aspects of the way I speak may not sound more masculine
	Mood changes may be caused by these medicines, and I will continue therapy with a licensed mental health care professional during treatment.
	Using these medicines to masculinize is an off-label use of the medications. This means these medications are not approved by the FDA for this purpose. I know that the medicine and dose that is recommended is based solely on the judgment and experience of the prescribing physician and there is no data in the medical literature or controlled research studies that support the timing, dosing, and type of administration of HRT.

Risks of Testosterone

Patient	Statement
	The medical effects and the safety of testosterone are not completely known and there may be unknown long-term risks.
	Taking testosterone causes changes that other people will notice.
	Treatment with testosterone will not prevent serious psychiatric events, including suicide.
	Taking more testosterone than prescribed could may: • Will increase health risks; • Will not make changes happen more quickly or more significantly; and