	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.

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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.

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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.

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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.

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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.

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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.

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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.

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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,

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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.