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

REIYN KEOHANE,	)	
	)	
***Plaintiff*,**	)	
	)	
v.	)	**Case No. 4:24-cv-00434-AW-MAF**
	)	
RICKY D. DIXON, *et al.*,	)	
	)	
***Defendants*.**	)	

DECLARATION OF DR. DANNY MARTINEZ, MD, MPH

I, Danny Martinez, M.D., pursuant to 28 U.S.C. § 1746, hereby makes the following Declaration under penalty of perjury, declare that the statements made below are true, and state as follows:

1. I am over the age of eighteen (18) years and make this Declaration based on personal knowledge.

2. I currently serve as the Chief of Medical Services for the Florida Department of Corrections ("FDC" or the "Department"). In my role as Chief of Medical Services, I bear responsibility for overseeing the medical treatment provided to all inmates in FDC custody, including those inmates diagnosed with gender dysphoria and other similar conditions.

3. I began working for FDC in August 2020. Beginning with my first weeks working for FDC the medical and mental health leadership regularly

discussed difficulties related to the provision of hormone therapy treatment to inmates diagnosed with gender dysphoria.

4. At the time, FDC operated under FDC procedure 403.012 "Identification and Management of Inmates Diagnosed with Gender Dysphoria." (Attached hereto as **Exhibit A**). Pursuant to procedure 403.012 the "Gender Dysphoria Review Team ("GDRT")," consisted of the Chief of Medical Services, Chief of Mental Health Services, Chief of Security Operations, Chief of Classification Management, and the Prison Rape Elimination Act ("PREA") Coordinator. (Exhibit A at 3). The GDRT possessed authority and responsibility to "review recommendations for the treatment and management of inmates diagnosed with gender dysphoria to ensure individualization in the decision-making process." (Id.). The GDRT met quarterly to address any issues in the treatment and management of inmates diagnosed with gender dysphoria. (Id.). Pursuant to procedure 403.012 mental health staff possessed the responsibility for diagnosing inmates with gender dysphoria following a comprehensive assessment completed by a psychologist credentialed to diagnose and treat gender dysphoria.

5. Procedure 403.012 provided that each inmate diagnosed with gender dysphoria receive access to necessary mental health treatment to include, clinical group therapy once per week, psychoeducational group interventions twice weekly, and individual psychotherapy at least every thirty (30) days. (Exhibit A at 4).

Additionally, procedure 403.012 provided that "Gender-affirming hormonal medication will be prescribed as *clinically* indicated." (Id. at 5). Moreover, the procedure provided that an inmate may begin receiving hormonal medication if the "GDRT determines that the hormones are *medically necessary* and not contraindicated for any reason." (Id.). Procedure 403.012 also provided that inmates diagnosed with gender dysphoria may receive alternate canteen items, alternate grooming standards, and alternate uniform and under garment requirements. (Id. at 6).

6. From the time I began working with FDC the medical and mental health leadership determined that procedure 403.012 needed revision for several reasons. I also served as a member of the GDRT team beginning in 2020. I along with the medical and mental health team engaged in a review of treatment outcomes for inmates receiving hormone therapy and identified several key areas of concern. From my review, I noted that many inmates receiving hormone therapy failed to comply with the other aspects of their treatment plan i.e., individual and group therapy. Approximately, one-third of the population of inmates receiving hormone therapy were non-compliant with their treatment plan. Additionally, I observed no decrease, and in fact an increase in grievances to the medical and mental health staff from inmates receiving hormone therapy, indicating to me that the treatment solely based on hormone therapy without additional mental health treatment produced

limited success. I along with the medical and mental health leadership determined that to provide individualized, holistic treatment, and assess the efficacy of that treatment on an individual basis the procedures for gender dysphoria treatment required revision.

7. First, the previous procedure provided no mechanism for removing an inmate from hormone treatment either voluntarily upon request by the inmate, or where the GDRT determined hormone therapy no longer medically necessary or contraindicated for treatment purposes. Second, Procedure 403.012 provided no mechanism to ensure that inmates receiving hormone therapy complied with the additional requirements of their treatment plans. Lastly, Procedure 403.12 provided no points of assessment or re-evaluation to determine whether the individual's treatment effectively addressed and reduced negative symptoms or produced negative side effects. As such, in December 2020, I began researching medical and mental health treatment for gender dysphoria as it relates to Procedure 403.012.

8. The medical and mental health leadership of FDC review all Office of Health Services ("OHS") HSBs on an annual basis. Beginning in March 2023, the medical and mental health teams began working to update the procedures related to inmates diagnosed with gender dysphoria. In May 2023, the medical and mental health teams received approval to begin drafting revised procedures. The process for updating the gender dysphoria treatments took approximately seven-months and

included hundreds of hours of research and development. I personally completed the World Professional Association for Transgender Health's ("WPATH") Foundations of Gender Dysphoria course offered through WPATH's Global Education Institute. I also reviewed WPATH's published standards of treatment and completed an independent assessment of the medical literature related to treatment of gender dysphoria, including contributions by Dr. Steven Levine and Dr. James Cantor, both clinical psychiatrists with experience treating adults diagnosed with gender dysphoria, and recognized experts in treating individuals diagnosed with gender dysphoria.

9. In 2022 the Florida Agency for Health Care Administration ("AHCA") requested the Division of Florida Medicaid review current research in the treatment of gender dysphoria and "sex reassignment treatment" which is defined as "medical services used to obtain the primary and/or secondary physical sexual characteristics of a male or female." (*Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria*, Florida Agency for Healthcare Administration (June 2022) attached hereto as **Exhibit B**). The AHCA report examined the current medical literature regarding treatment of gender dysphoria and the efficacy of sex reassignment through medical intervention. The AHCA report concluded that:

> medical literature provides insufficient evidence that sex reassignment through medical intervention is a safe and effective treatment for gender dysphoria. Studies presenting the benefits to mental health, including those

> claiming that the services prevent suicide, are either low or very low quality and rely on unreliable methods such as surveys and retrospective analyses, both of which are cross-sectional and highly biased. Rather, the available evidence demonstrates that these treatments cause irreversible physical changes and side effects that can affect long-term health.

(Id. at 2). The AHCA report identifies contradictions within the WPATH recommendations to clinicians in the treatment of gender dysphoria. For example, the AHCA report provides that "WPATH does assert that clinicians do need to treat any other underlying mental health issues secondary or co-occurring with gender dysphoria," yet also advises practitioners "to prescribe cross-sex hormones on demand." (Id. at 7).

10. According to studies cited in the AHCA report, a majority of individuals receiving hormone therapy reported experiencing other mental health issues prior to beginning hormone therapy, such as depression and even suicidal ideations. (Id. at 19). However, the efficacy of hormone therapy to alleviate these symptoms remains low.

11. WPATH provides guidance on administering cross-sex hormones to individuals diagnosed with gender dysphoria and acknowledges that hormone treatment should only be administered with a confirmed diagnosis of gender dysphoria and following a full psychosocial assessment. (Id. at 17). The AHCA report also notes that WPATH asserts itself as a professional organization, however,

in practice WPATH functions like an advocacy group allowing open membership to non-clinicians. This is consistent with my personal knowledge and review of WPATH.

12. The AHCA report explains that "arguments favoring cross-sex hormones assert that the desired physical changes can alleviate mental health issues in individuals with gender dysphoria." (Id.). But, "evidence of psychological benefit from cross-sex hormones is low-quality and relies heavily on self-assessments taken from small sample groups." (Id. at 19). Moreover, the AHCA report identifies long-term health risks associated with cross-sex hormone treatment including, reduction in life expectancy, increased risk of cardio-vascular disease, increased risk of blood clots, increased levels of hypertension, high cholesterol, obesity, and heart attacks. (Id. at 21). The AHCA report concludes that "the literature reveals that the evidence for cross-sex hormones as treatment for gender dysphoria is weak and insufficient." (Id.).

13. After the medical and mental health leadership conducted updated research into gender dysphoria diagnosis and treatment we incorporated our research into the revised procedures, and developed a policy designed to provide individualized, comprehensive care and treatment to inmates diagnosed with gender dysphoria in December 2023.

14. Ultimately, the medical and mental health leadership of FDC developed Health Services Bulletin ("HSB") 15.05.23, a true and correct copy of which is attached hereto as **Exhibit C**, in September 2024, and finalized HSB 15.05.23 on September 30, 2024. HSB 15.05.23 establishes guidelines for the mental health evaluation and treatment of inmates meeting the diagnostic criteria for gender dysphoria. (Exhibit C at 1, § I). HSB 15.05.23 describes the purpose of the policy remains "[t]o ensure inmates diagnosed with gender dysphoria receive timely, appropriate mental health services and individualized treatment programming as clinically indicated."

15. HSB 15.05.23 provides that a mental health clinician completes a clinical assessment within fourteen (14) days of an inmate's intake to the reception center or transfer to another institution. (Exhibit C at 3 § V.A.). If the inmate reports or presents a documented history of gender dysphoria prior to incarceration, the inmate will complete form DC4-711B "Consent and Authorization for Use and Disclosure, Inspection, and Release of Confidential Information" to allow FDC to obtain the inmate's prior mental health records. (Exhibit C at 3, § V.B.). HSB 15.05.23 provides that a psychologist makes all diagnoses of gender dysphoria. (Exhibit C at 3, § V.C.). Once a psychologist diagnoses an inmate with gender dysphoria the Multidisciplinary Services Team ("MDST") consisting of leadership from the medical, mental health, and security teams, reviews the inmate's medical

and mental health records. (Id.). To receive approval of a gender dysphoria diagnosis and treatment, the MDST must unanimously approve of the diagnosis. (Id.).

16. Gender dysphoria describes an array of differing conditions which require individualized assessment and treatment. Pursuant to HSB 15.05.23, "[a]ll inmates diagnosed with gender dysphoria will be individually evaluated [, and] a complete psychodiagnostics and psychiatric assessment should be performed." (Ex. C. at 3, § VI.A.).

17. Additionally, for inmates currently receiving hormone therapy, like Keohane, HSB 15.05.23 provides for the continuation of hormone therapy after review and unanimous approval "by a team consisting of the Chief of Medical Services, the Chief of Mental Health Services, and the Chief Clinical Advisor." Such continuation "shall only be sought (1) after satisfying all preceding provisions of this policy and (2) if necessary to comply with the U.S. Constitution or a court decision." (Id. at 7, § IX.C.).

18. The FDC diagnosed Reiyn Keohane, the Plaintiff in this case, with gender dysphoria. Keohane currently receives hormone therapy for treatment of gender dysphoria.

19. For inmates currently receiving hormone therapy, like Keohane, those inmates "will be evaluated by" FDC's MDST "to determine if the diagnosis is still

warranted. For those inmates, whose diagnosis is no longer warranted, titration and discontinuation of cross-sex hormone therapy should be initiated over a period of nine weeks." (Id. at 8, § IX.D.).

20. Thus, neither Keohane, nor any other inmate in FDC custody currently undergoing hormone therapy for treatment of gender dysphoria, immediately or imminently risks losing access to hormone therapy. First, the MDST may determine that the diagnosis of gender dysphoria remains warranted (Id.), in which case the inmate's case will proceed under the treatment process established by Section IX.C. of HSB 15.05.23. (Id. at 7, § IX.C.). The team consisting of the Chief of Medical Services, the Chief of Mental Health Services, and the Chief Clinical Advisor will then determine whether to grant the inmate a variance to allow continued treatment of the inmate's gender dysphoria with cross-sex hormones. Importantly, the inmate will **remain** on hormone therapy while moving through the reevaluation processes.

21. As indicated by HSB 15.05.23, the process of discontinuation (if warranted) of hormone therapy for inmates currently receiving it for treatment for gender dysphoria will require, at minimum: (i) an initial review by the MDST to determine whether the inmate's gender dysphoria diagnosis remains warranted; (ii) a review by the team consisting of the Chief of Medical Services, the Chief of Mental Health Services, and the Chief Clinical Advisor to determine whether to grant the inmate a variance; and, if the team denies the variance, (iii) titration off hormones

over a nine (9) week period. (Id. at 8, § IX.D.; 7, § IX.C.). The Chief of Medical Services, Chief Clinical Advisor and Chief of Mental Health services meet and review treatment planning when the MDST recommends initiation of hormone therapy. (Id. at 7, § IX.C.). Additionally, each inmate already receiving hormone therapy will receive an individualized assessment and evaluation by a psychologist to determine whether continued hormone therapy remains appropriate for the inmate's care and treatment.

22. The initial review by the MDST and the review by the variance team will take place over a matter of weeks. Then, if medically determined, the titration off hormones will take place over a period of ninety (90) days. Thus, the total discontinuation of hormone therapy for any inmates, currently receiving it for treatment of gender dysphoria will not take place for at least three (3) months from October 31, 2024.

23. In fact, pursuant to HSB 15.05.23 Reiyn Keohane received an individual assessment and evaluation by the MDST on November 7, 2024. The MDST relied upon a clinical interview with Keohane, a mental status examination of Keohane, a review of Keohane's medical and mental health records, a review of Keohane's classification records, and discussion with staff at the Wakulla Correctional Institution ("Wakulla"). The MDST preliminarily determined that,

following Keohane's evaluation and a full review of all information available, that Keohane continue to receive hormone therapy as prescribed.

24. Following the final recommendation of the MDST to continue Keohane's hormone therapy, the variance team will review the recommendation for a final determination of continuation of hormone therapy. If the variance team approves the recommendation of the MDST, Keohane will continue receiving hormone therapy.

I declare under penalty of perjury that the foregoing is true and correct. I understand that a false statement in this Declaration will subject me to penalties for perjury.

Date: November 13, 2024

Danny Martinez, MD, MPH

EXHIBIT A

MARK S. INCH
SECRETARY

PROCEDURE NUMBER: 403.012

PROCEDURE TITLE: IDENTIFICATION AND MANAGEMENT OF INMATES DIAGNOSED WITH GENDER DYSPHORIA

RESPONSIBLE AUTHORITY: OFFICE OF HEALTH SERVICES

EFFECTIVE DATE: NOVEMBER 13, 2019

INITIAL ISSUE DATE: JULY 13, 2017

SUPERSEDES: NONE

RELEVANT DC FORMS: DC4-643A, DC4-643E, DC4-643F, DC4-643G, DC4-711L, DC4-711M, AND DC6-1009

ACA/CAC STANDARDS: 4-4281-5 AND 4-4371

STATE/FEDERAL STATUTES: 28 C.F.R §115.5-501; 42 U.S.C. §15601-15609

FLORIDA ADMINISTRATIVE CODE: CHAPTER 33-603.101

PURPOSE: To provide guidelines for a medical appraisal, mental health screening, evaluation and treatment of inmates meeting criteria for a diagnosis of Gender Dysphoria.

DEFINITIONS:

(1) **Clinical Group Therapy**, where used herein, refers to a cognitive behavioral or psychodynamic process by which a group of individuals is led by a Psychologist or Behavioral Health Specialist to guide interpersonal and intrapersonal growth through an examination of the patients' thoughts, feelings, experiences, and skills.

(2) **Gender Dysphoria**, where used herein, previously known as Gender Identify Disorder, refers to discomfort or distress experienced by an individual because of a perceived discrepancy between the individual's gender identity and the inmate's gender assigned at birth.

(3) **Gender Dysphoria Review Team (GDRT)**, where used herein, refers to a team composed of the Chief of Medical Services, Chief of Mental Health Services, Chief of Security Operations, Chief of Classification Management, and the Prison Rape Elimination Act (PREA) Coordinator. The team members may designate or send a representative when circumstances exist, which, prevents their attendance.

(4) **Gender-Affirming Hormonal Therapy**, where used herein, refers to prescribed medication to facilitate biological change(s) during transitioning

(5) **Individual Psychotherapy,** where used herein, refers to a collaborative treatment based on the therapeutic relationship between the patient and Mental Health Clinician, including, but not limited to, cognitive behavioral, dialectical behavioral, psychodynamic, and interpersonal modalities.

(6) **Intersex**, where used herein, refers to a person whose sexual/reproductive anatomy or chromosomal pattern does not seem to fit the typical biological definition of male or female.

(7) **Multidisciplinary Services Team (MDST)**, where used herein, refers to staff representing different professions and disciplines, which has the responsibility for ensuring access to necessary assessment, treatment, continuity of care and services to inmates in accordance with their identified mental health needs, and which collaboratively develops, implements, reviews, and revises an individualized service plan, as needed.

(8) **Psychoeducational Group Intervention,** where used herein, refers to a didactic form of group therapeutic services designed to teach patients about their disorder and help them learn how to manage the related symptoms, behaviors and consequences. This may include workbook and/or homework activity.

(9) **Transgender**, where used herein, refers to a general term used for inmate whose gender identity does not conform to the typical expectations associated with the gender they were assigned at birth. A male-to-female transgender inmate refers to a biological male who identifies as, or desires to be, a member of the female gender; a female-to-male transgender inmate refers to a biological female who identifies as, or desires to be, a member of the male gender. A transgender

inmate may or may not qualify for a diagnosis of Gender Dysphoria depending on her/his level of distress or impairment.

(10) **Transitioning**, where used herein, refers to the process during which transgender inmates may change their physical, social, and legal characteristics to the gender with which they identify. Transition may also be regarded as an ongoing process of physical change and psychological adaptation.

GENERAL GUIDELINES:

These standards and responsibilities apply to both Department staff and Comprehensive Health Care Contractor (CHCC) staff.

(1) **GENDER DYSPHORIA REVIEW TEAM ROLE AND RESPONSIBILITY:**

(a) The GDRT has the authority and responsibility to review recommendations for the treatment and management of inmates diagnosed with Gender Dysphoria to ensure individualization in the decision-making process.

(b) The GDRT will convene at least quarterly to address issues in the treatment and management of inmates diagnosed with Gender Dysphoria. The GDRT may request any information it determines necessary to assist in its decision-making process.

(c) The GDRT may consult with the warden and any other staff at the facility where an inmate diagnosed with Gender Dysphoria resides when making decisions regarding their management and plans of care.

(d) The GDRT may access an outside consultant to evaluate known or potential Gender Dysphoria inmates and provide recommendations for treatment and transitioning. Recommendations from an outside consultant may be considered, but are not binding on the GDRT.

(e) Specific facilities will be identified by the Department to provide ongoing treatment and accommodations for Gender Dysphoria.

SPECIFIC PROCEDURES:

(1) **SCREENING AND IDENTIFICATION**:

(a) Mental health staff is responsible for the diagnosis of Gender Dysphoria. All initial diagnoses of Gender Dysphoria will be provisional until a comprehensive assessment can be completed by a psychologist credentialed to diagnose and treat Gender Dysphoria and the results are reviewed by the GDRT. The provisional diagnosis must be a consensus of the MDST or, if not available, a clinician credentialed to diagnose and treat Gender Dysphoria.

(b) The MDST or, if not available, a clinician credentialed to diagnose and treat Gender Dysphoria will enter the provisional diagnosis into the Offender Based Information System (OBIS) within three business days and will notify the Regional Mental Health Director by e-mail of the provisional diagnosis, while initiating the transfer process as outlined in "Mental Health Transfers," Procedure 404.003.

(c) Within three business days of receipt of the request for the Gender Dysphoria evaluation, the Central Office Mental Health Transfer Coordinator will review and log the request into an excel spreadsheet for tracking purposes. The request will be forwarded by e-mail to Population Management and Reception/Youthful Offender Services, which will notify the Central Office Mental Health Transfer Coordinator of its approval for transfer.

(d) The inmate, along with the current medical and mental health record, will be transferred to an institution designated by the GDRT for completion of the "Psychological Evaluation for Gender Dysphoria," DC4-643E.

(2) **ASSESSMENT OF GENDER DYSPHORIA**:

(a) Upon the inmate's arrival at an institution designated by the GDRT, the Psychological Services Director will place a mental health hold on the inmate pending completion of the evaluation and further disposition by the GDRT.

(b) An appointment for the inmate will be scheduled by the evaluating psychologist, who must be credentialed in the diagnosis and treatment of Gender Dysphoria. The psychologist will:

1. explain the limits of confidentiality and the potential consequences of a Gender Dysphoria diagnosis;
2. explain the potential treatment and permissible accommodations; and
3. obtain a new "Consent to Mental Health Evaluation or Treatment," DC4-663.

(c) The DC4-643E will be completed within 90 calendar days of an inmate's arrival to the designated site.

(d) Upon Completion, form DC4-643E will be sent to the CHCC Regional Mental Health Director for review. Within seven business days, the CHCC Regional Mental Health Director will forward the completed evaluation to the GDRT for review and final disposition.

(3) **TREATMENT FOR GENDER DYSPHORIA**:

(a) Inmates diagnosed with gender dysphoria shall have access to necessary mental health treatment at each of the designated Gender Dysphoria facilities. Treatment will include, but not be limited to, clinical group therapy once weekly, psychoeducational group interventions twice weekly, and individual psychotherapy at least every 30 days.

(b) Inmates with a provisional diagnosis of Gender Dysphoria who refuse the evaluation for Gender Dysphoria will be assigned to a facility designated by the GDRT and will be offered treatment that will include, but not be limited to, individual psychotherapy at least weekly.

(c) While receiving any treatments for Gender Dysphoria inmates must remain at a mental health designation of S-2 or higher.

(d) Treatment interventions will focus on the ambivalence and/or dysphoria regarding gender identity, social transitioning, assisting with adjustment to incarceration, and community re-entry. Gender-affirming hormonal medication will be prescribed as clinically indicated.

(4) **GENDER AFFIRMING HORMONAL THERAPY**:

(a) All gender-affirming hormonal therapy will be provided on a single dosage basis.

(b) An inmate who is receiving hormonal medication at the time of intake will be continued on hormonal medications provided the following conditions are met:
1. the hormones represent an established treatment that has been prescribed under the supervision of a qualified clinician;
2. the inmate cooperates with health care staff in obtaining written records or other necessary confirmation of her/his previous treatment; and
3. health care staff determine the hormones are medically necessary and not contraindicated for any reason.

(c) An inmate who is not receiving hormonal medication at the time of intake may be started on hormonal medications while incarcerated provided the following conditions are met:
1. the inmate cooperates with health care staff in efforts to obtain written records or other necessary confirmation of previous treatment, if present; and
2. the GDRT determines that the hormones are medically necessary and not contraindicated for any reason.

(d) Gender-affirming hormonal therapy shall not be implemented unless the appropriate consent form, either "Transgender Hormone Therapy – Testosterone Informed Consent," DC4-711M, or "Transgender Hormone Therapy – Estrogen and Antiandrogens Informed Consent," DC4-711L, is signed by the inmate, the psychologist, and the medical practitioner. The medical practitioner and psychologist shall allow the inmate to read the appropriate consent form, as well as discuss the content of the form with the inmate to ensure that she/he understands this content thoroughly. A signed copy of the informed consent shall be given to the inmate. The original shall be placed in the health record on the left side under the sub-divider entitled Consents/Refusals.

(e) Gender-affirming hormonal treatment shall be managed by a CHCC Physician and/or outside consultant. Any Transgender or Gender Dysphoric inmates on hormone therapy will be placed in the Miscellaneous – Chronic Illness Clinic (HSB 15.03.05 Appendix 3) for treatment and monitoring by the institutional CHO/Medical Director

(f) The CHO/Medical Director shall write and submit a consult for a follow-up appointment as requested by the consultant, but no longer than 180 days from the last consult until the hormonal levels are within normal range for a transgendered individual.

(g) If an inmate chooses to discontinue hormonal medications while incarcerated and then wishes to restart hormonal medications, the GDRT shall evaluate the request and consider the medical necessity of the treatment option.

(5) **ACCOMMODATIONS FOR INMATES WITH A DIAGNOSIS OF GENDER DYSPHORIA**:

(a) To assist in transitioning, facilities designated by the Department will:
1. provide alternate canteen and quarterly order menus in addition to the menus available to other inmates at the facility;
2. allow inmates to wear make-up inside the housing unit. Make-up will be removed prior to departing the housing unit;
3. allow inmates to grow and style their hair in accordance with the female hair standards as stated in Rule 33-602.101, F.A.C.; and
4. issue opposite gender inmate uniform and under garments. Inmates will be issued the approved type, but may purchase other types of under garments independently from either the alternate canteen or quarterly menu. These items can be worn outside of the housing unit.

(b) The name of the inmate as it appears on the on the indictment page of the commitment package shall be used, unless there is a subsequent court order for a name change. If so, a new indictment page of the commitment package must be issued or the court order must specifically state "change all records."

(c) Inmates may use preferred titles of Ms., Miss, Mrs., or Mr. in correspondence; however, the name at the time of commitment and DC number must be used.

(d) Facilities shall encourage staff to use gender-neutral forms of address (e.g., Inmate Smith or Smith) for gender dysphoria inmates who request it.

(e) All other requested accommodations must be presented to the GDRT for review and final determination.

(6) **GENDER DYSPHORIA REVIEW TEAM DISPOSITIONS:**

(a) Following review of the completed DC4-643E, the GDRT will document its disposition on the "Gender Dysphoria Review Team Dispositions," DC4-643F and the "Accommodation(s) Pass," DC4-643G. Property and apparel shall be consistent with the inmate's DC4-643F as approved by the GDRT. These forms will be routed and filed as follows:

1. the Mental Health Quality Assurance Manager in Central Office will e-mail the completed DC4-643F and DC4-643G to the CHCC State Mental Health Director, CHCC Regional Mental Health Director, Psychological Services Director, and the Health Services Administrator (HSA);
2. the original forms will be mailed to the HSA at the institution who will be responsible for reviewing with treating mental health and medical staff;

3. the HSA will ensure these forms are filed in the Mental Health Evaluation Reports section of the health record next to the DC4-643E; and
4. a copy of the DC4-643G will be provided to the inmate by the Health Services Administrator at the institution. A replacement DC4-643G will be provided to an inmate upon request due to loss or excessive damage. Inmates found to have altered their DC4-643G may be subject to discipline in accordance with Rules 33-601.301-.314, F.A.C.

(b) The PREA coordinator will notify the Warden at the facility currently housing the inmate through e-mail advising her/him of the final disposition(s). The notice will include the DC4-643F and the "Transgender/Intersex Housing Determination," DC6-1009. The Warden will be responsible for notifying the appropriate staff/departments within the facility regarding any applicable dispositions for accommodations or actions to be taken.

(c) For inmates requiring transfer subsequent to the completion of the DC4-643F, an automated e-mail notification will be generated to the sending and receiving facilities to notify the Warden(s) of the upcoming transfer. The sending facility will be responsible for ensuring all applicable forms/dispositions are included in the inmate's records. The receiving facility will be responsible for ensuring any accommodations/dispositions are met upon the inmate's arrival.

(d) For those inmates receiving a formal diagnosis of Gender Dysphoria, further facility and housing assignments shall be made on a case by case basis with inmates being placed at one of the designated treatment facilities for Gender Dysphoria. The health and safety of the inmate, as well as all treatment, management, and security concerns will be examined. The inmate's own views regarding safety shall be given careful consideration.

(e) Issues relating to an inmate's Gender Dysphoria diagnosis that emerge after completion of the DC4-643F will be addressed through the institutional MDST. At institutions where there is no available MDST, issues will be addressed by a mental health clinician credentialed to provide a Gender Dysphoria evaluation. If it is determined additional review by the GDRT is required, the MDST or the credentialed mental health clinician may refer the issue(s) to the GDRT for further consideration.

(6) **RELEASE PLANNING**: Pre-release continuity of care planning for necessary medical and mental health treatment and services shall be provided in accordance with "Pre-release Planning for Continuity of Health Care," HSB 15.03.29; and "Mental Health Re-Entry Aftercare Planning Services," HSB 15.05.21, respectively.

Chief of Staff

EXHIBIT B

Florida Medicaid

Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria

June 2022

Ron DeSantis, Governor
Simone Marstiller, Secretary

Contents

Introductory Remarks and Abstract

Generally Accepted Professional Medical Standards

The Secretary of the Florida Agency for Health Care Administration requested that the Division of Florida Medicaid review the treatment of gender dysphoria for a coverage determination pursuant to Rule 59G-1.035, Florida Administrative Code (F.A.C.) (See Attachment A for the Secretary's Letter to Deputy Secretary Tom Wallace). The treatment reviewed within this report included "sex reassignment treatment," which refers to medical services used to obtain the primary and/or secondary physical sexual characteristics of a male or female. As a condition of coverage, sex reassignment treatment must be "consistent with generally accepted professional medical standards (GAPMS) and not experimental or investigational" (Rule 59G-1.035, F.A.C., see Attachment B for the complete rule text).

The determination process requires that "the Deputy Secretary for Medicaid will make the final determination as to whether the health service is consistent with GAPMS and not experimental or investigational" (Rule 59G-1.035, F.A.C.). In making that determination, Rule 59G-1.035, F.A.C., identifies several factors for consideration. Among other things, the rule contemplates the consideration of "recommendations or assessments by clinical or technical experts on the subject or field" (Rule 59G-1.035(4)(f), F.A.C.). Accordingly, this report attaches five assessments from subject-matter experts:

- **Attachment C:** Romina Brignardello-Petersen, DDS, MSc, PhD and Wojtek Wiercioch, MSc, PhD: *Effects of Gender Affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence*. 16 May 2022.
- **Attachment D:** James Cantor, PhD: *Science of Gender Dysphoria and Transsexualism*. 17 May 2022.
- **Attachment E:** Quentin Van Meter, MD: *Concerns about Affirmation of an Incongruent Gender in a Child or Adolescent*. 17 May 2022.
- **Attachment F:** Patrick Lappert, MD: *Surgical Procedures and Gender Dysphoria*. 17 May 2022.
- **Attachment G:** G. Kevin Donovan, MD: *Medical Experimentation without Informed Consent: An Ethicist's View of Transgender Treatment for Children*. 16 May 2022.

Abstract

Available medical literature provides insufficient evidence that sex reassignment through medical intervention is a safe and effective treatment for gender dysphoria. Studies presenting the benefits to mental health, including those claiming that the services prevent suicide, are either low or very low quality and rely on unreliable methods such as surveys and retrospective analyses, both of which are cross-sectional and highly biased. Rather, the available evidence demonstrates that these treatments cause irreversible physical changes and side effects that can affect long-term health.

Five clinical and technical expert assessments attached to this report recommend against the use of such interventions to treat what is categorized as a mental health disorder (See attachments):

- **Health Care Research:** Brignardello-Petersen and Wiercioch performed a systematic review that graded a multitude of studies. They conclude

that evidence supporting sex reassignment treatments is low or very low quality.

- **Clinical Psychology:** Cantor provided a review of literature on all aspects of the subject, covering therapies, lack of research on suicidality, practice guidelines, and Western European coverage requirements.
- **Plastic Surgery:** Lappert provided an evaluation explaining how surgical interventions are cosmetic with little to no supporting evidence to improve mental health, particularly those altering the chest.
- **Pediatric Endocrinology:** Van Meter explains how children and adolescent brains are in continuous phases of development and how puberty suppression and cross-sex hormones can potentially affect appropriate neural maturation.
- **Bioethics:** Donovan provides additional insight on the bioethics of administering these treatments, asserting that children and adolescents cannot provide truly informed consent.

Following a review of available literature, clinical guidelines, and coverage by other insurers and nations, Florida Medicaid has determined that the research supporting sex reassignment treatment is insufficient to demonstrate efficacy and safety. In addition, numerous studies, including the reports provided by the clinical and technical experts listed above, identify poor methods and the certainty of irreversible physical changes. Considering the weak evidence supporting the use of puberty suppression, cross-sex hormones, and surgical procedures when compared to the stronger research demonstrating the permanent effects they cause, these treatments do not conform to GAPMS and are experimental and investigational.

Health Service Summary

Gender Dysphoria

Frequently used to describe individuals whose gender identity conflicts with their natural-born sex, the term gender dysphoria has a history of evolving definitions during the past decades (Note: This report uses the term "gender" in reference to the construct of male and female identities and the term "sex" when regarding biological characteristics). Prior to the publication of the *Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders* (DSM-V), the American Psychiatric Association (APA) used the diagnosis of gender identity disorder (GID) to describe individuals who sought to transition to the opposite gender. However, behavioral health clinicians sought a revision after determining that using GID created stigma for those who received the diagnosis. This is despite the APA having adopted GID to replace the previous diagnosis of transsexualism for the exact same reason (APA, 2017).[1]

When crafting its new definition and terminology, the APA sought to remove the stigma of classifying as a disorder the questioning of one's gender identity by focusing instead on the psychological distress that such questioning can evoke. This approach argues that individuals seeking behavioral health and transition services are doing so due to experiencing distress and that gender non-conformity by itself is not a mental health issue. This led to the adoption of gender dysphoria in 2013 when the APA released the DSM-V. In addition to using a new term, the APA also differentiated the diagnosis between children and adolescents and adults, listing different characteristics for the two age groups (APA, 2017).

According to the DSM-V, gender dysphoria is defined as "the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender." As for the criteria to receive the diagnosis, the APA issued stricter criteria for children than adolescents and adults. For the former, the APA states that a child must meet six out of eight behavioral characteristics such as having "a strong desire to be of the other gender or an insistence that one is the other gender" or "a strong preference for cross-gender roles in make-believe or fantasy play." The criteria for adults and adolescents are less stringent with individuals only having to meet two out of six characteristics that include "a strong desire to be the other gender" or "a strong desire to be rid of one's primary and/or secondary sexual characteristics." The APA further notes that these criteria can also apply to young adolescents (DSM-V, 2013).

In 2021, the Merck Manual released a slightly different definition for gender dysphoria, citing that the condition "is characterized by a strong, persistent cross-gender identification associated with anxiety, depression, irritability, and often a wish to live as a gender different from the one associated with the

[1] The concept of gender being part of identity and disconnected from biological sex originated during the mid-twentieth century and was publicized by psychologist John W. Money. His research asserted that gender was a complete social construct and separate from biology, meaning that parents and/or caregivers could imprint on a young child (under three years) the identity of a boy or girl. In 1967, Money's theories led to a failed experiment on twin boys where physicians surgically transitioned one to appear as a girl. The twin that underwent sex reassignment never fully identified as a female. However, Money never publicly acknowledged this and reported the experiment as a success. Furthermore, he promoted his conclusions across the scientific community, concealing what actually unfolded. As a result, Money's ideas on gender fluidity served as a basis for performing procedures on children with hermaphroditic features or genital abnormalities. The case reveals how the understanding of a concept (e.g., gender) at any given time can lead to incorrect medical decisions with irreversible consequences (Gaetano, 2015).

sex assigned at birth." Additionally, the Merck Manual further states that "gender dysphoria is a diagnosis requiring specific criteria but is sometimes used more loosely for people in whom symptoms do not reach a clinical threshold" (Merck Manual, 2021). This definition is largely consistent with the DSM-V but does not emphasize the distress component to the same extent.[2]

Like other behavioral health diagnoses classified in the DSM-V, gender dysphoria has the following subtypes:

- **Early-Onset Gender Dysphoria:** This subtype begins during childhood and persists through adolescence into adulthood. It can be interrupted by periods where the individual does not experience gender dysphoria signs and may classify as homosexual (DSM-V, 2013).
- **Late-Onset Gender Dysphoria:** Occurring after puberty or during adulthood, this subtype does not begin until late adolescence and can emerge following no previous signs of gender dysphoria. The APA attributes this partially to individuals who did not want to verbalize their desires to transition (DSM-V, 2013).

Further studies have identified additional subtypes of gender dysphoria. In 2018, Lisa Littman introduced the concept of a rapid-onset subtype. Classified as rapid-onset gender dysphoria (ROGD), it features characteristics such as sudden beginnings during or following puberty. However, it differs from the DSM-V definitions because ROGD is associated with other causes such as social influences (e.g., peer groups, authority figures, and media). In other words, adolescents who had no history of displaying typical gender dysphoria characteristics go through a sudden change in identity following intense exposure to peers and/or media that heavily promotes transgender lifestyles (Littman, 2018). While more long-term studies are needed to confirm whether ROGD is a temporary or long-term condition, Littman's study has initiated discussions regarding potential causes of gender dysphoria as well as introduced a potential subtype.

Additionally, the frequent use of gender dysphoria in clinical and lay discourse has led to a fracturing of the definition. Studies on the topic frequently do not apply the DSM-V's criteria for the diagnosis and overlook certain key features such as distress. In a 2018 review by Zowie Davy and Michael Toze, the authors evaluated 387 articles that examine gender dysphoria and noted stark departures from the APA's definition. They further asserted that the APA intended to "reduce pathologization" by establishing a new definition for gender dysphoria in the DSM-V. This in turn would reduce diagnoses, although as Davy and Toze note, the tendency for the literature to diverge from the APA's definition may result in increased numbers of individuals classified as having gender dysphoria when they do not meet the DSM-V's criteria (Davy and Toze, 2018). This further raises the question of whether individuals are receiving potentially irreversible treatments for the condition when they might not actually have it.

The current usage of gender dysphoria is the result of discussions spanning across decades as demonstrated in the past editions of the DSM. Until 2013, the APA considered having gender identity issues a mental disorder by itself regardless of the presence of psychological distress. That perspective has since shifted to only consider the adverse psychological effects of questioning one's gender as a disorder. In addition, the APA considers gender as part of one's identity, which is not subject to a diagnosis. Whether the APA has shifted its terminology and criteria for gender identity issues due to

[2] Following the release of the Florida Department of Health's guidelines for treating gender dysphoria, Merck removed its definition for "gender dysphoria" from the Merck Manual (Fox News, 2022).

emerging clinical data or cultural changes is another question. In 1994, the APA replaced transsexualism with gender identity disorder as part of the "effort to reduce stigma" (APA, 2017). This raises questions about what influences decisions to revise definitions and criteria; is it social trends or medical evidence?

Behavioral Health Issues Co-Occurring with Gender Dysphoria

Because gender dysphoria pertains directly to the distress experienced by an individual who desires to change gender identities, secondary behavioral health issues can co-occur such as depression and anxiety. If left untreated, these conditions can lead to the inability to function in daily activities, social isolation, and even suicidal ideation. Studies do confirm that adolescents and adults with gender dysphoria report higher levels of anxiety, depression, and poor peer relationships than the general population (Kuper et al, 2019). Other associated conditions include substance abuse, eating disorders, and compulsivity. A significant proportion of individuals with gender dysphoria also have autism spectrum disorder (ASD) (Saleem and Rizvi, 2017). Although the number reporting secondary issues is increased, individuals diagnosed with gender dysphoria do not necessarily constitute the entire population that is gender non-conforming (i.e., does not identify with natal sex), and no information is available breaking down the percentage of those who are non-conforming with gender dysphoria and those who are non-conforming with no distress. Additionally, available research raises questions as to whether the distress is secondary to pre-existing behavioral health disorders and not gender dysphoria. This is evident in the number of adolescents who reported anxiety and depression diagnoses prior to transitioning (Saleem and Rizvi, 2017).

Furthermore, conventional treatments for secondary behavioral health issues are available. These include cognitive behavioral therapy, medication, and inpatient services. The APA reports that treatments for these are highly effective with 80% to 90% of individuals diagnosed with depression responding positively (APA, 2020). In addition, a high percentage of adolescents diagnosed with gender dysphoria had received psychiatric treatment for a prior or co-occurring mental health issue. A 2015 study from Finland by Kaltiala-Heino et al noted that 75% of children seeking sex reassignment services had been treated by a behavioral health professional (Kaltiala-Heino et al, 2015).

Diagnosing Gender Dysphoria

Prior to the publication of the DSM-V, diagnosing individuals experiencing gender identity issues followed a different process. Behavioral health clinicians could assign the diagnosis based on gender non-conformance alone. That has changed since 2013. Today, non-conforming to one's gender is part of personal identity and not a disorder requiring treatment. This change has led professional associations to shift the diagnostic criteria for gender dysphoria to focus on the distress caused by shifting identities (DSM-V, 2013).

For adolescents, the APA identifies "a marked incongruence between one's experienced/expressed gender and natal sex, of at least 6 months' duration" as the core component of gender dysphoria (DSM-V, 2013). What the APA does not elucidate is the threshold for "marked." This raises questions as to whether practitioners exercise uniformity when applying the diagnostic criteria or if they do so subjectively. For example, the WPATH's *Standards of Care for the Health of Transsexual, Transgender, and Gender Non-Conforming People* provides guidance on the processes mental health practitioners should use when assessing for gender dysphoria but offers no benchmarks for meeting diagnostic criteria (WPATH, 2012).

Such processes include evaluating for gender non-conforming behaviors and other co-existing mental disorders like anxiety or depression. This involves not only interviewing the adolescent but also the family in addition to reviewing medical histories. WPATH also asserts that gender dysphoria assessments need to account for peer relationships, academic performance, and provide information of potential treatments. This last component is necessary because it might affect an individual's choices regarding transitioning, particularly if the information does not correspond to the desired outcome (WPATH, 2012).

The diagnosis of gender dysphoria is a relatively recent concept in mental health, being the product of decades of discussion and building upon previous definitions. Instead of treating gender non-conformity as a disorder, behavioral health professionals acknowledge it as part of one's identity and focus on addressing the associated distress. Considering the new criteria, this changes the dynamics of the population who would have qualified for a diagnosis before 2013 and those who would today. Given that desiring to transition into a gender different from natal sex no longer qualifies as a disorder, behavioral health professionals are treating distress and referring adolescents and adults to therapies that are used off-label and pose irreversible effects.

Current Available Treatments for Gender Dysphoria

At present, proposed treatment for gender dysphoria occurs in four stages, beginning with psychological services and ending with sex reassignment surgery. As an individual progresses through each stage, the treatments gradually become more irreversible with surgical changes being permanent. Because of the increasing effects, individuals must have attempted treatment at the previous stage before pursuing the next one (Note: late adolescents and adults have already completed puberty and do not require puberty blockers). Listed in order, the four stages are as follows:

- **Behavioral Health Services:** Psychologists and other mental health professionals are likely the first practitioners individuals with gender dysphoria will encounter. In accordance with clinical guidelines established by the World Professional Association for Transgender Health (WPATH)[3], behavioral health professionals are supposed to "find ways to maximize a person's overall psychological well-being, quality of life, and self-fulfillment." WPATH further discourages services for attempting to change someone's gender identity. Instead, it instructs practitioners to assess for the condition and readiness for puberty blockers or cross-sex hormones while offering guidance to function in a chosen gender. WPATH does assert that the clinicians do need to treat any other underlying mental health issues secondary or co-occurring with gender dysphoria (WPATH, 2012). However, the organization provides conflicting guidance because it also advises practitioners to prescribe cross-sex hormones on demand (Levine, 2018).
- **Puberty Suppression:** Used only on individuals in the earliest stages of puberty (Tanner stage 2), preventing pubertal onset provides additional time to explore gender identities before the physical characteristics of biological sex develop. This treatment is intended to reduce distress and anxiety related to the appearance of adult sexual physical features. To suppress puberty, pediatric endocrinologists inject gonadotropin releasing hormone (Gn-RH) at specific intervals (e.g., 4 weeks or 12 weeks). The Gn-RH suppresses gonadotropin receptors that allow for the

[3] The World Professional Association for Transgender Health asserts that it is a professional organization. However, it functions like an advocacy group by allowing open membership to non-clinicians (WPATH, 2022).

development of primary and secondary adult sexual characteristics. Prior to receiving puberty suppression therapy, individuals must have received a diagnosis of gender dysphoria and have undergone a mental health evaluation (Kyriakou et al, 2020).

- **Cross-Sex Hormones:** For adults and late adolescents (16 years or older), the next treatment phase recommended is taking cross-sex hormones (e.g., testosterone or estrogen) to create secondary sex characteristics. In men transitioning into women, these include breast development and widening around the pelvis. Women who transition into men experience deeper voices, redistribution of fat deposits, and growing facial hair. According to the Endocrine Society, late adolescents who qualify for cross-sex hormones must have a confirmed diagnosis of gender dysphoria from a mental health practitioner with experience treating that population. Some physical changes induced by these hormones are irreversible (Endocrine Society, 2017).
- **Sex Reassignment Surgery:** Sometimes referred to as "gender affirming" surgery, this treatment does not consist of just one procedure but several, depending on the desires of the transitioning individual. Primarily, sex reassignment procedures alter the primary and secondary sexual characteristics. Men transitioning into women (trans-females) undergo a penectomy (removal of the penis), orchiectomy (removal of the testes), and vulvoplasty (creation of female genitals). Other procedures trans-females may undergo include breast augmentation and facial feminization. For women that transition into men (trans-males), procedures include mastectomy (removal of the breasts), hysterectomy (removal of the uterus), oophorectomy (removal of the ovaries), and phalloplasty (creation of male genitals). Because of the complexities involved in phalloplasty, many trans-males do not opt for this procedure and limit themselves to mastectomies. Additionally, the effects of sex reassignment surgery, such as infertility, are permanent (WPATH, 2012).

While some clinical organizations assert that they are the standard of care for gender dysphoria, the U.S. Food and Drug Administration (FDA) currently has not approved any medication as clinically indicated for this condition (Unger, 2018). Although puberty blockers and cross-sex hormones are FDA approved, the FDA did not approve them for treating gender dysphoria, meaning that their use for anything other than the clinical indications listed is off-label (American Academy of Pediatrics, 2014). As for surgical procedures, the FDA does not evaluate or approve them, but it does review all surgical devices (FDA, 2021). In addition, the Endocrine Society concedes that its practice guidelines for sex reassignment treatment does *not* constitute a "standard of care" and that its grades for available services are low or very low (Endocrine Society, 2017).[4]

[4] Disagreement over how to treat gender dysphoria, gender identity disorder, and transsexualism has persisted since sex reassignment surgery first became available in the 1960s. In a 2006 counterargument, Paul McHugh highlights how individuals seeking surgery had other reasons that extended beyond gender identity, including sexual arousal and guilt over homosexuality. In addition, he asserts that undergoing sex reassignment procedures did not improve a patient's overall behavioral health and that providing a "surgical alteration to the body of these unfortunate people was to collaborate with a mental disorder rather than to treat it" (McHugh, 2006).

Literature Review: Introduction

Currently, an abundance of literature and studies on gender dysphoria is available through academic journals, clinical guidelines, and news articles. Similar to other mental health issues, the material addresses a broad range of topics consisting of available treatments, etiology (i.e., causes), risks, benefits, and side effects. Although most stories reported by the media indicate that treatments such as cross-sex hormones and sex reassignment surgery are the most effective, research reveals that numerous questions still exist. These include what are the long-term health effects of taking cross-sex hormones, what are the real causes of gender dysphoria, and how many individuals that transition will eventually want to revert to their natal sex. Additionally, much of the available research is inconclusive regarding the effectiveness of sex reassignment treatments with multiple studies lacking adequate sample sizes and relying on subjective questionnaires. While much of the scientific literature leans in favor of cross-sex hormones and surgery as options for improving the mental health of individuals with gender dysphoria, it does not conclusively demonstrate that the benefits outweigh the risks involved, either short or long-term. What studies do reveal with certainty is that sex reassignment surgery and cross-sex hormones pose permanent effects that can result in infertility, cardiovascular disease, and disfigurement. All of this indicates that further research is necessary to validate available treatments for gender dysphoria. Thus, physicians, who recommend sex reassignment treatment, are not adhering to an evidence-based medicine approach and are following an eminence-based model.

The following literature review addresses the multiple facets of this condition and presents areas of ongoing debate and persisting questions. Beginning with the condition's etiology and continuing with evaluations of puberty blockers, cross-sex hormones, and surgery, the review explains each area separately and in context of gender dysphoria at large. Additionally, the review provides an analysis on available research on mental health outcomes as well as the condition's persistence into adulthood. Taken as a whole, the available studies demonstrate that existing gender dysphoria research is inconclusive and that current treatments are used to achieve cosmetic benefits while posing risky side effects as well as irreversible changes.

Literature Review: Etiology of Gender Dysphoria

What causes gender dysphoria is an ongoing debate among experts in the scientific and behavioral health fields. Currently, the research indicates that diagnosed individuals have higher proportions of autism spectrum disorder (ASD), history of trauma or abuse, fetal hormone imbalances, and co-existing mental illnesses. Also, experts acknowledge that genetics may factor into gender dysphoria. Another potential cause is social factors such as peer and online media influence. At the moment, none of the studies provides a definite cause and offer only correlations and weakly supported hypotheses. In addition, evidence favoring a biological explanation is highly speculative. However, the research does raise questions about whether treatments with permanent effects are warranted in a population with disproportionately high percentages of ASD, behavioral health problems, and trauma.

In a 2017 literature review by Fatima Saleem and Syed Rizvi, the authors examine gender dysphoria's numerous potential causes and the remaining questions requiring further research. In conclusion, the pair indicate that associations exist between the condition and ASD, schizophrenia, childhood abuse, genetics, and endocrine disruption chemicals but that more research is needed to improve understanding of how these underlying issues factor into a diagnosis. Throughout the review, Saleem and Rizvi identify the following as potential contributing elements to the etiology of gender dysphoria:

- **Neuroanatomical Etiology:** During fetal development, the genitals and brain develop during different periods of a pregnancy, the first and second trimesters respectively. Because the processes are separate, misaligned development is possible where the brain may have features belonging to the opposite sex. The authors identify one study where trans-females presented with a "female-like putamen" (structure at the base of the brain) when undergoing magnetic resonance imaging (MRI) scans.[5]
- **Psychiatric Associations:** Saleem and Rizvi identify multiple studies reporting that individuals with gender dysphoria have high rates of anxiety and depressive disorders with results ranging as high as 70% having a mental health diagnosis. In addition, the pair note that schizophrenia may also influence desires to transition. However, the review does not assess whether the mental health conditions are secondary to gender dysphoria.
- **Autism Spectrum Disorder:** Evidence suggests a significant percentage of individuals diagnosed with gender dysphoria also have ASD. The authors note that the available studies only establish a correlation and do not identify mechanisms for causation.
- **Childhood Abuse:** Like the above causes, Saleem and Rizvi note that those with gender dysphoria tended to experience higher rates of child abuse across all categories, including neglect, emotional, physical, and sexual.
- **Endocrine Disruptors:** Although this cause still requires substantial research, it is a valid hypothesis regarding how phthalates found in plastics can create an imbalance of testosterone in fetuses during gestation, which can potentially lead to gender dysphoria. The authors point to one study that makes this suggestion.

[5] Research on neuroanatomical etiology for gender dysphoria remains highly speculative due to limitations of brain imaging (Mayer and McHugh, 2016). In addition, neuroscience demonstrates that exposures to certain environments and stimuli as well as behaviors can affect brain changes (Gu, 2014). Furthermore, available research indicates that male and female brains have different physical characteristics but cannot be placed in separate categories due to extensive overlap of white/grey matter and neural connections (Joel et al, 2015).

Saleem and Rizvi's review reveal that gender dysphoria's etiology can have multiple factors, most of which require treatments and therapies not consisting of cross-sex hormones or surgery. (Saleem and Rizvi, 2017).

Out of the research on the condition's etiology, a large portion focuses on the correlation with ASD. One of the more substantial studies by Van der Miesen et al published in 2018 evaluates 573 adolescents and 807 adults diagnosed with ASD and compares them to 1016 adolescents and 846 adults from the general population. The authors' findings note that adolescents and adults with ASD were approximately 2.5 times more likely to indicate a desire of becoming the opposite sex. Although the methodology used to reach this conclusion consisted of surveys where respondents had a choice of answering "never," "sometimes," or "often," the results correspond with those of similar studies. Van der Miesen et al also indicate that most responses favoring a change in gender responded with "sometimes." Additionally, the authors do not state how many in their sample group actually had a gender dysphoria diagnosis. (Van der Miesen et al, 2018).

Another study by Shumer et al from 2016 utilizes a smaller sample size (39 adolescents) referred to an American hospital's gender clinic. Unlike Van der Miesen et al's research, Shumer et al evaluate subjects with a diagnosis of gender dysphoria for possible signs of ASD or Asperger's syndrome. Their findings revealed that 23% of patients presenting at the clinic would likely have one of the two conditions. Possible explanations for the high percentage are the methods used to gather the data. Shumer et al requested a clinical psychologist to administer the Asperger Syndrome Diagnostic Scale to the parents of the sample patients, four of whom already had an ASD diagnosis. The authors conclude that the evidence to support high incidence of gender dysphoria in individuals with ASD is growing and that further research is needed to determine the specific cause (Shumer et al, 2016).

Research indicating a strong correlation between ASD and gender dysphoria is not the only area where new studies are emerging. Discussions about the effects of prenatal testosterone levels are also becoming more prevalent. One such example is Sadr et al's 2020 study that looks at the lengths of the index and ring fingers (2D:4D) of both left and right hands of 203 individuals diagnosed with gender dysphoria. The authors used this method because prenatal testosterone levels can affect the length ratios of 2D:4D. By comparing the ratios of a group with gender dysphoria to a cohort from the general population, Sadr et al could assess for any significant difference. Their results indicated a difference in trans-females who presented with more feminized hands. For trans-males, the difference was less pronounced. The results for both groups were slight, and the meta-analysis that accompanies the study notes no statistically significant differences in multiple groups from across cultures. However, Sadr et al further assert that the evidence strongly suggests elevated prenatal testosterone levels in girls and reduced amounts in boys may contribute to gender dysphoria, requiring additional research (Sadr et al, 2020).

In addition to biological factors and correlations with ASD, researchers are exploring psychological and social factors to assess their role in gender dysphoria etiology. This literature examines a range of potential causative agents, including child abuse, trauma, and peer group influences. One such study by Kozlowska et al from 2021 explores patterns in children with high-risk attachment issues who also had gender dysphoria. The authors wanted to assess whether past incidents of abuse, loss, or trauma are associated with higher rates of persons desiring to transition. As a basis, Kozlowska et al cite John Bowlby's research on childhood brain development, noting that the process is not linear and depends

heavily on lived experiences. The study further acknowledges that biological factors combined with life events serve as the foundation for the next developmental phase and that early poor-quality attachment issues increase the risk for psychological disorders in adolescence and adulthood. Such disorders include mood and affective disorders, suicidal ideations, and self-harm. Kozlowska et al also cite other studies that indicate a high correlation between gender dysphoria and "adverse childhood events" and further assert that the condition "needs to be conceptualized in the context of the child's lived experience, and the many different ways in which lived experience is biologically embedded to shape the developing brain and to steer each child along their developmental pathway" (Kozlowska et al, 2021).

For their study, Kozlowska et al recruited 70 children diagnosed with gender dysphoria and completed family assessments going back three generations. This in-depth level was necessary to ascertain any and all events that could affect a child's developmental phases. Additionally, the researchers individually assessed the diagnosed children. To establish comparisons, Kozlowska et al performed assessments on a non-clinical group and a mixed-psychiatric group. Their results demonstrate that children with gender dysphoria have significantly higher rates of attachment issues as well as increased reports of "adverse childhood events" such as trauma (e.g., domestic violence and physical abuse). Furthermore, the authors indicate that a high proportion of families reported "instability, conflict, parental psychiatric disorder, financial stress, maltreatment events, and relational ruptures." These results led Kozlowska et al to conclude that gender dysphoria can be "associated with developmental pathways – reflected in at-risk patterns of attachment and high rates of unresolved loss and trauma – that are shaped by disruptions to family stability and cohesion." The study also cites that treatment requires "a comprehensive biopsychosocial assessment with the child and family, followed by therapeutic interventions that address, insofar as possible, the breadth of factors that are interconnected with each particular child's presentation" (Kozlowska et al, 2021).

This recent study raises questions regarding the medical necessity of gender dysphoria treatments such as puberty blockers and cross-sex hormones for adolescents. If high percentages of children diagnosed with gender dysphoria also have histories of trauma and attachment issues, should conventional behavioral health services be utilized without proposing treatments that pose irreversible effects? Would that approach not provide additional time to address underlying issues before introducing therapies that pose permanent effects (i.e., the watchful waiting approach)?

Aside from the notion that childhood abuse and adversity can potentially cause gender dysphoria, other possible explanations such as social factors (e.g., peer influences and media) may be contributing factors. Research on rapid onset gender dysphoria (ROGD) links this phenomenon to peer and social elements. In an analysis utilizing parent surveys, Lisa Littman asserts that the rapid rise of ROGD is not associated with the traditional patterns of gender dysphoria onset (i.e., evidence of an individual's gravitation to the opposite sex documented over multiple years) but rather exposure to "social and peer contagion." Littman uses this term in the context of definitions cited in academic literature, stating that "social contagion is the spread of affect or behaviors through a population" and that "peer contagion is the process where an individual and peer mutually influence each other in a way that promotes emotions and behaviors that can potentially undermine their own development or harm others." Examples of the latter's negative effects include depression, eating disorders, and substance abuse. What prompted this study is a sudden increase of parents reporting their daughters declaring themselves to be transgender without any previous signs of gender dysphoria. Littman also indicates

that these parents cite that their daughters became immersed in peer groups and social media that emphasized transgender lifestyles (Littman, 2018).

In addition to identifying characteristics of ROGD, the study examines social media content that provides information to adolescents regarding how to obtain cross-sex hormones through deception of physicians, parents, and behavioral health professionals. Such guidance includes coaching on how to fit a description to correspond to the DSM-V and pressures to implement treatment during youth to avoid a potential lifetime of unhappiness in an undesirable body. Littman further states that "online content may encourage vulnerable individuals to believe that non-specific symptoms and vague feelings should be interpreted as gender dysphoria." The study also notes that none of the individuals assessed using the parental surveys qualified for a formal diagnosis using the DSM-V criteria (Littman, 2018).

The survey responses revealed similar data to Kozlowska et al's study with 62.5% of the adolescents having a mental health or neurodevelopmental disorder. Furthermore, the responses indicate a rapid desire to bypass behavioral health options and pursue cross-sex hormones. 28.1% of parents surveyed stated that their adolescents did not want psychiatric treatments. One parent even reported that their daughter stopped taking prescribed anti-depressants and sought advice only from a gender therapist. Littman's research further reveals that 21.2% of parents responded that their adolescent received a prescription for puberty blockers or cross-sex hormones at their first visit (Littman, 2018). These responses indicate that practitioners do not uniformly follow clinical guidelines when making diagnoses or prescribing treatment.

In the discussion, Littman proposes two hypotheses for the appearance of ROGD. The first states that social and peer contagion is one of the primary causes, and the second asserts that ROGD is a "maladaptive coping mechanism" for adolescents dealing with emotional and social issues. While the surveyed parents did not report early signs of gender dysphoria, a majority noted that their daughters had difficulty in handling negative emotions. Littman concludes that ROGD is distinct from gender dysphoria as described in the DSM-V and that further research is needed to assess whether the condition is short or long-term (Littman, 2018). What the study does not explore, but raises the question, is what proportion of those being treated for gender dysphoria are adolescents with ROGD.

Littman's study along with the others reveal that the causes of gender dysphoria are still a mystery and could have multiple biological and social elements. Because of this ongoing uncertainty, treatments that pose irreversible effects should not be utilized to address what is still categorized as a mental health issue. That allows adequate opportunity for individuals to receive treatment for co-existing mental disorders, establish their gender dysphoria diagnoses, and understand how cross-sex hormones and surgery will alter the appearance of their bodies as well as long-term health.

Literature Review: Desistance of Gender Dysphoria and Puberty Suppression

The World Professional Association for Transgender Health (WPATH) and the Endocrine Society both endorse the use of gonadotropin releasing hormones (Gn-RH) to suppress puberty in young adolescents who have gender dysphoria. Both organizations state that the treatment is safe and fully reversible. In addition, they state that delaying pubertal onset can provide extra time for adolescents to explore the gender in which they choose to live. The associations further state that puberty suppression is necessary to prevent the development of primary and secondary sexual characteristics that can inhibit successful transitions into adulthood (WPATH, 2012; Endocrine Society, 2017). Of the two groups, WPATH offers clinical criteria an individual should meet to qualify for puberty suppression such as addressing psychological co-morbidities and assessing whether gender dysphoria has intensified (WPATH, 2012).

Neither organization explains that the majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex and that the puberty suppression can have side effects. Both organizations neglect to mention that using Gn-RH for gender dysphoria by altering the appearance is not an FDA-approved clinical indication. Furthermore, the research used to justify puberty suppression is low or very-low quality and little information is available on long-term effects (Hruz, 2019). Additionally, in his assessment, Quentin Van Meter explained that physical differences between central precocious puberty and natural onset puberty demonstrate that Gn-RH does not have permanent adverse effects for those treated for the former but can for the latter such as insufficient bone-mineral density and neural development (Van Meter, 2022). Also, as recently as May 17, 2022, during a U.S. Senate Committee on Appropriations hearing, Lawrence Tabak, acting director of the National Institutes of Health, responded to Senator Marco Rubio, acknowledging that no long-term studies are available evaluating the effects of puberty blockers when used for gender dysphoria (U.S. Senate Committee on Appropriations, 2022).

Currently, some studies provide weak support for this treatment but leave too many questions as to its effectiveness and medical necessity, especially considering how many children decide against transitioning. In addition, puberty blockers halt development of primary and secondary sexual characteristics and deny opportunities for adolescents to adapt and become comfortable with their natal sex. Instead, puberty blockers can serve as a potential “gateway drug” for cross-sex hormones by denying them the experience of physically maturing (Laidlaw et al, 2018).

A 2013 study by Steensma et al offers data on the percentage of children who opt not to transition after experiencing gender dysphoria. The authors follow 127 adolescents (mean age of 15 during the evaluation period) for four years who had been referred to a Dutch gender dysphoria clinic. Out of this cohort, 47 (37%; 23 boys and 24 girls) continued experiencing the condition and applied for sex reassignment treatment. The other 80 adolescents never returned to the clinic. Because this clinic was the only one that treated gender dysphoria in the Netherlands, Steensma et al assumed that those who did not return no longer desired transitioning. The study indicates one of the key predictors for persisting gender dysphoria was the age of first presentation. Older adolescents that started going to the clinic were more likely to persist, while younger adolescents tended not to follow through. Steensma et al provide further insight into other predicting factors, particularly on how each individual views his or her gender identity. The authors note that adolescents who “wished they were the other sex” were more likely to become desisters and that those who “believed that they were the other sex” persisted

and later sought sex reassignment treatment (Steensma et al, 2013). While the study focuses on factors that contribute to the condition's persistence or desistance, it raises the question as to whether puberty suppression is necessary when age plays such an important role regarding the decision to transition.

WPATH and the Endocrine Society state that the primary reason for initiating pubertal suppression is not to treat a physical condition but to improve the mental health of adolescents with gender dysphoria. However, available research does not yield definitive results that this method is effective at addressing a mental health issue. The "gold standard" for medical studies is the randomized-controlled trial (RCT). Because RCTs utilize large sample sizes, have blind testing groups (i.e, placebos), and use objective controls, they can offer concrete conclusions and shape the array of established treatments. In addition, RCTs require comparisons between cohort outcomes and ensure that participants are randomly assigned to each group. These measures further reduce the potential for bias and subjectivity (Hariton and Locascio, 2018).

Presently, no RCTs that evaluate puberty suppression as a method to treat gender dysphoria are available. Instead, the limited number of published studies on the topic utilize small sample sizes and subjective methods (Hruz, 2019). A 2015 article by Costa et al is one such example. The study asserts that "psychological support and puberty suppression were both associated with an improved global psychological functioning in gender dysphoric adolescents." To reach this conclusion, the authors selected 201 children diagnosed with the condition and divided them into two groups, one to receive psychological support only and the other to get puberty blockers in addition to psychological support. Costa et al did not create a third group that lacked a gender dysphoria diagnosis to serve as a control. To assess whether puberty suppression is an effective treatment, the authors administered two self-assessments (Utrect Gender Dysphoria Scale and Children's Global Assessment Scale)[6] to the groups at 6-month intervals during a 12-month period. Because the study relies heavily on self-assessments, the conclusions are likely biased and invalid. Another problem that is also present and common throughout articles supporting puberty suppression is the short-term period of the study. Costa et al's conclusions may not be the same if additional follow-ups occurred three or five years later (Costa et al, 2015). This further raises the question whether low-quality studies like Costa et al's should serve as the basis for clinical guidelines advising clinicians to prescribe drugs for off-label purposes.

Aside from questionable research, information regarding the full physical effects of puberty suppression is incomplete. In a 2020 consensus parameter prepared by Chen et al, 44 experts in neurodevelopment, gender development, and puberty/adolescence reached a conclusion stating that "the effects of pubertal suppression warrant further study." The basis for this was that the "full consequences (both beneficial and adverse) of suppressing endogenous puberty are not yet understood." The participating experts emphasized that the treatment's impact on neurodevelopment in adolescents remains unknown. Chen et al explain that puberty-related hormones play a role in brain development as documented in animal studies and that stopping these hormones also prevents neurodevelopment in addition to sexual maturation. The authors further raise the question whether normal brain development resumes as if it had not been interrupted when puberty suppression ceases. Because this

[6] Behavioral health practitioners use the Children's Global Assessment Scale (CGAS) to measure child functioning during the evaluation process to determine diagnoses. Available evidence indicates that the CGAS is not effective for evaluating children who experienced trauma and presented with mental health symptoms (Blake et al, 2006).

question remains unanswered, it casts doubt on the veracity of organizations' assertions that puberty suppression is "fully reversible" (Chen et al, 2020).

In addition to the unanswered questions and low-quality research, puberty suppression causes side effects, some of which have the potential to be permanent. According to a 2019 literature review by De Sanctis et al, most side effects associated with Gn-RH are mild, consisting mostly of irritation around injection sites. However, clinicians have linked the drug to long-term conditions such as polycystic ovarian syndrome, obesity, hypertension, and reduced bone mineral density. While reports of these events are low and the authors indicate that Gn-RH is safe for treating central precocious puberty (Note: De Sanctis et al do not consider gender dysphoria in their analysis), the review raises questions about whether off-label use to treat a psychological condition is worth the risks (De Sanctis et al, 2019).

Furthermore, De Sanctis et al cite studies noting increased obesity rates in girls who take Gn-RH but that more research is needed to gauge the consistency. Additionally, the authors note that evidence is strong regarding reduced bone mineral density during puberty suppression but indicate that the literature suggests it is reversible following treatment (De Sanctis et al, 2019). While research leans toward the reversibility of effects on bone mineral density, the quantity of studies available on this subject are limited. Also, no long-term research has been completed on how puberty suppression affects bone growth. This is significant because puberty is when bone mass accumulates the most (Kyriakou et al, 2020). One example of a complication involving bone growth and Gn-RH is slipped capital femoral epiphysis. This condition occurs when the head of the femur (i.e., thighbone) can slip out of the pelvis, which can eventually lead to osteonecrosis (i.e., bone death) of the femoral head. Although the complication is rare, its link to puberty suppression indicates that the "lack of adequate sex hormone exposure" could be a cause (De Sanctis et al, 2019).

The current literature on puberty suppression indicates that using it to treat gender dysphoria is off-label, poses potentially permanent side effects, and has questionable mental health benefits. The limited research and lack of FDA approval for that clinical indication prompt questions about whether medications with physically altering effects should be used to treat a problem that most adolescents who experience it will later overcome by conforming to their natal sex. Additional evidence is required to establish puberty suppression as a standard treatment for gender dysphoria.

Literature Review: Cross-Sex Hormones as a Treatment for Gender Dysphoria

Currently, the debate surrounding the use of cross-sex hormones to treat gender dysphoria revolves around their ability to improve mental health without causing irreversible effects. It is not about whether taking cross-sex hormones can alter someone's appearance. The evidence demonstrating the effectiveness of cross-sex hormones in achieving the secondary sexual characteristics of the opposite sex is abundant. Also, the overall scientific consensus concludes that individuals who take cross-sex hormones will reduce the primary sexual function of his or her natal sex organs. What researchers continue evaluating are the short and long-term effects on mental health, impacts on overall physical health, and how the changes affect the ability to detransition. Of these, benefits to mental health overshadow the other discussions. Prescribers of cross-sex hormones focus so heavily on behavioral health outcomes that they de-emphasize that these drugs cause permanent physical changes and side effects that can lead to premature death (Hruz, 2020). Some clinical guidelines such as WPATH's do not even indicate that some of the changes are irreversible.

Like puberty suppression, the Endocrine Society and WPATH provide guidance on administering cross-sex hormones to individuals with gender dysphoria. Both organizations state that this treatment should not be administered without a confirmed diagnosis of gender dysphoria and only after a full psychosocial assessment. In addition, behavioral health practitioners must ensure that any mental comorbidities are not affecting the individual's desire to transition. WPATH and the Endocrine Society further state that clinicians should administer hormone replacements such as testosterone and Estradiol (estrogen) in gradual phases, where the dose increases over several months. For trans-females, the organizations state that progesterone (anti-androgen) is also necessary to block the effects of naturally produced testosterone (WPATH, 2012; Endocrine Society, 2017). When taking cross-sex hormones, trans-males need increased doses for the first six months. After that, the testosterone's effects are the same on lower doses. Once started, individuals cannot stop taking hormones unless they desire to detransition (Unger, 2016).

Although the two groups provide similar guidance, they vary on statements that can have significant impact on long-term outcomes, particularly regarding age. According to WPATH's standards, 16 years is the general age for initiating cross-sex hormones, but the organization acknowledges that the treatment can occur for younger individuals depending on circumstances (WPATH, 2012). This differs from the Endocrine Society, which states no specific age for appropriateness and explains the disagreements in assigning a number. The group highlights that most adolescents have attained sufficient competence by age 16 but may not have developed adequate abilities to assess risk (Endocrine Society, 2017). This raises the question whether adolescents can make sound decisions regarding their long-term health. Additionally, the varying guidance raises an issue with WPATH not only using age 16 as a standard but also indicating that younger adolescents are capable of making that choice.

WPATH's guidance also does not stress the irreversible nature of cross-sex hormones, citing the treatment as "partially reversible" and not indicating which changes are permanent. Furthermore, parts of WPATH's information are misleading and directly conflict with guidance issued by clinics and other sources. One such example consists of WPATH stating that "hormone therapy *may* (emphasis added) lead to irreversible changes." This statement is misleading in light of existing research, which indicates that multiple physical changes are permanent. In addition, WPATH claims that certain effects of cross-

sex hormones such as clitoral enlargement can last one to two years when it is actually irreversible (UCSF, 2020). WPATH also does not explain the risks to male fertility, noting that lowered sperm count or sterility is "variable." The University of California at San Francisco (UCSF) provides starkly different information by stating that trans-females should expect to become sterile within a few months of starting cross-sex hormones. UCSF also advises trans-females to consult a sperm bank if they may want to father children after transitioning (WPATH, 2012; UCSF, 2020). Below is a chart that outlines the effects of cross-sex hormones and identifies which ones are reversible or permanent.

Physical Changes Effectuated by Cross-Sex Hormones	
Physical Changes in Trans-Males (Female-to-Male Transitions)	
Physical Change	**Reversible or Irreversible**
Oily Skin or Acne	Reversible
Facial and Body Hair Growth	Irreversible
Male-Pattern Baldness	Irreversible
Increased Muscle Mass	Reversible
Body Fat Redistribution	Reversible
Ceasing of Menstruation	Reversible
Enlarged Clitoris	Irreversible
Vaginal Atrophy	Reversible
Deepening of Voice	Irreversible
Physical Changes in Trans-Females (Male-to-Female Transitions)	
Body Fat Redistribution	Reversible
Decreased Muscle Mass	Reversible
Skin Softening or Decrease in Oiliness	Reversible
Lower Libido	Reversible
Fewer Spontaneous Erections	Reversible
Male Sexual Dysfunction	Possibly Irreversible
Breast Growth	Irreversible
Decrease in Testicular Size	Reversible
Decrease in Sperm Production or Infertility	Likely Irreversible
Slower Facial and Body Hair Growth	Reversible

Sources: UCSF, 2020; WPATH, 2012; Endocrine Society, 2017[7]

The above chart demonstrates that trans-males and trans-females experience different effects from cross-sex hormones that can cause myriad issues in later life. For example, trans-males who opt to detransition may face challenges related to permanent disfigurement (e.g., facial hair and deepened voices). Trans-females, on the other hand, may not endure the same issues pertaining to visible physical changes but might become despondent over being unable to reproduce. This can occur regardless of whether the transitioning individual is satisfied with sex reassignment. Given that the clinical guidelines do not provide uniform information on the permanent effects of cross-sex hormones, clinicians are unable to make sound recommendations to patients. This treatment can supposedly alleviate symptoms

[7] This chart consists of conclusions regarding physical changes made by three different clinical organizations. If one organization determined that a physical change was irreversible, that was sufficient to meet the criteria to be listed as "irreversible" in the chart.

of distress. However, cross-sex hormones' permanent effects also have the potential to cause psychological issues.

Arguments favoring cross-sex hormones assert that the desired physical changes can alleviate mental health issues in individuals with gender dysphoria but do not consider that hormones used in this manner, like puberty blockers, are off-label. While the FDA has approved estrogen and testosterone for specific clinical indications (e.g., hypogonadism), it has not cleared these drugs for treating gender dysphoria. Additionally, these arguments do not acknowledge that the U.S. Drug Enforcement Administration (DEA) lists testosterone as a Schedule III controlled substance, meaning that it has a high probability of abuse (DEA, 2022). Furthermore, evidence of psychological benefit from cross-sex hormones is low-quality and relies heavily on self-assessments taken from small sample groups (Hruz, 2020).

A 2019 study by Kuper et al seeks to demonstrate that adolescents desiring cross-sex hormones have elevated rates of depression, anxiety, and challenges with peer relationships. To make their findings, the authors provided questionnaires to 149 adolescents who presented at a gender clinic in Dallas, Texas and concluded that half of the sample group experienced increased psychological issues. One problem with the study is that it relies on parent or self-assessments such as the Youth-Self Report, Body-Image Scale, and the Child Behavior Checklist. While these assessments have strong reliability, the sample is cross-sectional, consisting of gender dysphoric individuals who presented for an initial visit at the clinic. Also, Kuper et al do not directly link these psychological symptoms to gender dysphoria but rather insinuate a strong connection. Without an analysis of the longitudinal histories of the participants, the study cannot demonstrate whether gender dysphoria was a direct cause of the psychological issues, which could possibly result from trauma, abuse, or family dysfunction. Kuper et al's study only presents weak correlation between adolescents who report symptoms of distress and gender dysphoria. While the authors do not claim that the participants' psychological problems caused the condition, they fail to explicitly state that no demonstrable relationship exists and explain that their findings are "broadly consistent with the previous literature" (Kuper et al, 2019).

Additionally, a more comprehensive literature review from 2019 by Nguyen et al evaluates the effect of cross-sex hormones on mental health outcomes. Although the authors argue that the evidence supports the treatment, they do note that available studies use "uncontrolled observational methods" and "rely on self-report." The review also asserts that "future research should focus on applying more robust study designs with large sample sizes, such as controlled prospective cohort studies using clinician-administered ratings and longitudinal designs with appropriately matched control groups." All of these are characteristics of RCTs. While Nguyen et al highlight flaws in the studies in their conclusion, they do not emphasize them in their analysis, opting to focus primarily on results. Another problem with the studies selected for the review is the short-term periods for evaluation. Out of 11 studies Nguyen et al discuss, only one tracks its participants for 24 months. The others only follow their cohorts for 6 or 12 months (Nguyen et al, 2019). Without long-term data to support assertions that cross-sex hormones substantially improve the mental health of individuals with gender dysphoria, the review cannot make definitive conclusions on the treatment's benefits.

Basing their stances on this low-quality evidence, clinical associations such as the American Academy of Pediatrics (AAP) and the American Psychology Association endorse the use of cross-sex hormones as treatments for gender dysphoria. In particular, the AAP discourages use of the term "transition" and

asserts that medical treatments used to obtain secondary characteristics of the opposite sex are "gender affirming." This decision mirrors the DSM-V's interpretation of gender being part of identity. The AAP further states that taking cross-sex hormones is an "affirmation and acceptance of who they (i.e., patient) have always been" (AAP, 2018). The American Psychological Association also takes a similar stance in its *Resolution on Gender Identity Change Efforts* by asserting that medical treatments such as puberty suppression, cross-sex hormones, and surgery improve mental health and quality of life and reinforce the notion that transitioning and seeking sex reassignment therapies do not constitute a psychological disorder (American Psychological Association, 2021). Stances like these can substantially influence practitioners and their treatment recommendations. Given that low-quality evidence serves as the basis for supportive positions, this raises questions about whether clinicians can make informed decisions for their patients that will promote the best outcomes.

James Cantor published a critique in 2020 of the AAP's endorsement of "gender affirming" treatments, arguing that the organization did not base its recommendations on established medical evidence. He asserts that the AAP's position is based on research that does not support intervention but rather supports "watchful waiting" because most transgender youths desist and identify as their natal sex during puberty. Cantor further argues that the AAP not only disregards evidence but also cites "gender affirming" interventions as the only effective method. To conclude, he states the organization is "advocating for something far in excess of mainstream practice and medical consensus" (Cantor, 2020).

Given those evidentiary problems, those who rely on the AAP's endorsement as a basis for "gender affirming" treatments are practicing eminence-based medicine as opposed to evidence-based medicine. Eminence-based medicine refers to clinical decisions made by relying on the opinions of prominent health organizations rather than relying on critical appraisals of scientific evidence (Nhi Le, 2016). While it is true that the AAP has more knowledge than a lay person and a degree of credibility in the medical community, the opinions of such organizations are not valid unless they are based on quality evidence.

Research on sex reassignment also does not adequately address the reasons for and prevalence of detransitioning. Although no definite numbers are available regarding the percentage of transgender people who decide to detransition, research indicates that roughly 8% decide to return to their natal sex. The reasons range from treatment side effects to more self-exploration that provided insight on individuals' gender dysphoria. In a 2020 study by Lisa Littman, 101 people who had detransitioned provided their basis for doing so. Out of the sample group, 96% had taken cross-sex hormones and 33% had sex reassignment surgery. The average age for transitioning was 22 years, and the mean duration for the transition was 4 years. This indicates that even allowing additional time beyond the recommended age of 16 years can still lead to regrets. The study also raises the question as to whether individuals who transitioned at 16 or younger wanted to detransition in greater numbers. The author further offers reasons why these individuals sought cross-sex hormones and surgery, which include having endured trauma (mental or sexual), homophobia (challenged to accept oneself as a homosexual), peer and media influences, and misogyny (applicable only to trans-males). To obtain the results, the participants responded to a survey that asked about their backgrounds (e.g., reasons for transitioning, mental health comorbidities), and motivations for detransitioning. Littman noted that half of the women (former trans-males) had a mental health disorder and/or had experienced trauma within a year of deciding to transition. Men (former trans-females) reported much lower numbers of behavioral health issues and trauma after de-transitioning. Additionally, 77% of men surveyed identified as the opposite gender prior to transition, whereas just 58% of women had (Littman, 2020).

Of the reasons cited for detransitioning, the majority (60%) noted that they became more comfortable with their natal sex. Other reasons included concerns over complications from the treatments, primarily cross-sex hormones, and lack of improved mental health. Other less-cited explanations include concerns about workplace discrimination and worsening physical health. The study also notes that approximately 36% of participants experienced worse mental health symptoms. Based on the findings, Littman concludes that more research is needed in tracking the transgender population to obtain accurate percentages of those who decide to detransition and that men and women reported varying reasons for deciding to transition and later return to their natal sex. The author notes that higher rates of trauma and peer group influences might have contributed to women's decisions, which Littman attributes partially to rapid onset gender dysphoria (Littman, 2020). What the study also indicates is that cross-sex hormones are not a validated treatment for gender dysphoria. Nearly all of the participants had taken them and decided against maintaining the physical changes. Given that the majority of surveyed detransitioners cited that they were comfortable with their biological sex, the study indicates that gender dysphoria is not necessarily a lifelong issue. This necessarily raises doubts about whether cross-hormones, which cause permanent physical damage, is justified.

In addition to the psychological factors, cross-sex hormones pose significant long-term health risks to transitioning individuals. Currently, little information is available given that researchers have not had adequate time to study the effects in this population. However, use of hormones for other conditions has yielded data on how these drugs can affect the body and the cardiovascular system in particular. Because of the high dosages required to achieve physical change and the need to continuously take the drugs, cross-sex hormones can potentially harm quality of life and reduce life expectancy for transitioning individuals. According to Dutra et al, trans-females are three times more likely to die from a cardiovascular event than the general population. In their 2019 literature review, Dutra et al examined the results of over 50 studies evaluating the effects of cross-sex hormones on not only transgender individuals but those with menopause and other endocrine disorders, all of which indicate that use of estrogen or testosterone can increase risks for cardiovascular disease. Throughout their review, Dutra et al cite examples of trans-females having higher triglyceride levels after 24 months of cross-sex hormones and how researchers halted a study on estrogen due to an increase in heart attacks among participants. Another article the authors reference indicates a higher risk for thromboembolisms (i.e., blood clots) in trans-females. For trans-males, Dutra et al explain that research shows significant increased risk for hypertension, high cholesterol, obesity, and heart attacks. One study noted that trans-males have a four times greater risk of heart attack compared to women identifying as their natal sex. Dutra et al conclude that most transgender individuals are younger than 50 and that more studies are needed as this population ages. They do note that available studies indicate that cross-sex hormones pose dangers to long-term cardiovascular health (Dutra et al, 2019).

In sum, the literature reveals that the evidence for cross-sex hormones as a treatment for gender dysphoria is weak and insufficient. Between the permanent effects, off-label use, and consequences to long-term health, cross-sex hormones are a risky option that does not promise a cure but does guarantee irreversible changes to both male and female bodies. Additionally, the inadequate studies serving as the basis for recommendations by clinical associations can lead to providers making poorly informed decisions for their patients. Research asserting that taking cross-sex hormones improves mental health is subjective and short-term. More studies that utilize large sample sizes and appropriate

methods is required before the medical profession should consider cross-sex hormones as one of gender dysphoria's standard treatments.

Literature Review: Sex Reassignment Surgery

The final phase of treatment for gender dysphoria is sex reassignment surgery. This method consists of multiple procedures to alter the appearance of the body to resemble an individual's desired gender. Some procedures apply to the genitals (genital procedures) while others affect facial features and vocal cords (non-genital procedures). While the surgery creates aesthetical aspects, it does not fully transform someone into the opposite biological sex. Transgender persons who undergo the procedures must continue taking cross-sex hormones to maintain secondary sexual characteristics. Additionally, all physical changes are irreversible, and the success rate of a surgery varies depending on the procedure and the population. For example, surgeries for trans-females have much better results than those for trans-males. Complications such as post-operative infections can also arise with the urinary tract system. However, sex reassignment surgery supposedly can provide drastic, if not complete, relief from gender dysphoria (Endocrine Society, 2017). The following is a list of procedures (both genital and non-genital) for trans-females and trans-males that create physical features of the desired sex.

Procedures for Trans-Females

- **Genital Surgeries:** These consist of penectomy (removal of the penis), orchiectomy (removal of the testicles), vaginoplasty (construction of a neo-vagina), clitoroplasty (construction of a clitoris), and vulvoplasty (construction of a vulva and labia). To perform, a surgeon begins by deconstructing the penis and removing the testicles. The penile shaft and glans are repurposed to serve as a neo-vagina and artificial clitoris (Note: These are not actual female genitalia but tissue constructed to resemble female anatomy). If the shaft tissue is insufficient, the surgeon may opt to use a portion of intestine to build a neo-vagina. The scrotum serves as material for fashioning a vulva and labia. In addition to constructing female genitalia, the surgeon reroutes the urethra to align with the neo-vagina. Genital surgeries for trans-females result in permanent sterility (Bizic et al, 2014).
- **Chest Surgery:** To attain full breasts, trans-females can undergo enlargement. The procedure is similar to breast augmentation for women where a surgeon places implants underneath breast tissue. Prior to surgery, trans-females need to take cross-sex hormones for roughly 24 months to increase breast size to get maximum benefit from the procedure (Endocrine Society, 2017).
- **Cosmetic and Voice Surgeries:** Designed to create feminine facial features, fat deposits, and vocal sounds, these procedures are secondary to genital procedures and intended to alter trans-females' appearances to better integrate into society as a member of the desired gender (WPATH, 2012).

Procedures for Trans-Males

- **Mastectomy:** This is the most performed sex reassignment surgery on trans-males because cross-sex hormones and chest-binding garments are often insufficient at diminishing breasts. To remove this secondary sexual characteristic, trans-males can undergo a mastectomy where a surgeon removes breast tissue subcutaneously (i.e., under the skin) and reconstructs the nipples to appear masculine. The procedure can result in significant scarring (Monstrey et al, 2011).
- **Genital Surgeries:** Unlike the procedures for trans-females, genital surgeries for trans-males are more complex and have lower success rates. Consisting of hysterectomy, oophorectomy

(removal of the ovaries), vaginectomy (removal of the vagina), phalloplasty (construction of a penis), and scrotoplasty (construction of prosthetic testicles), a team of surgeons must manufacture a penis using skin from the patient (taken from an appendage) while removing the vagina and creating an extended urethra. The functionality of the artificial penis can vary based on how extensive the construction was. Attaining erections requires additional surgery to implant a prosthesis, and the ability to urinate while standing is often not achieved. Genital procedures for trans-males result in irreversible sterility (Monstrey et al, 2011).

- **Cosmetic Surgeries:** Similar to trans-females, these procedures create masculine facial features, fat deposits, and artificial pectoral muscles. They aid trans-males with socially integrating as their desired gender. Surgery to deepen voices is also available but rarely performed (WPATH, 2012).

Because sex reassignment surgery is irreversible, the criteria for receiving these procedures is the strictest of all gender dysphoria treatments. WPATH and the Endocrine Society suggest rigorous reviews of patient history and prior use of other therapies before approving. Furthermore, the two organizations recommend that only adults (18 years old) undergo sex reassignment surgery.[8] WPATH and the Endocrine Society also recommend ensuring a strongly documented diagnosis of gender dysphoria, addressing all medical and mental health issues, and at least 12 months of cross-sex hormones for genital surgeries. Although the organizations agree on most criteria, they differ on whether hormones should be taken prior to mastectomies. WPATH asserts that hormones should not be a requirement, whereas the Endocrine Society advises up to 2 years of cross-sex hormones before undergoing the procedure (WPATH, 2012; Endocrine Society, 2017). What this indicates is that trans-males might undergo breast removal without having first pursued all options if their clinician adheres to WPATH's guidelines, which can lead to possible regret over irreversible effects.

As with cross-sex hormones, sex reassignment surgery's irreversible physical changes can potentially show marked mental health improvements and prevent suicidality in people diagnosed with gender dysphoria. In April 2022, the chair of the University of Florida's pediatric endocrinology department, Dr. Michael Haller, advocated for the benefits of "gender affirming" treatments (WUSF, 2020). However, the available evidence calls such statements into question. Recent research assessing both cross-sex hormones and sex reassignment surgery indicate that the effects on "long-term mental health are largely unknown." In studies regarding the benefits of surgery, the results have the same weaknesses as the research for the effectiveness of cross-sex hormones. These include small sample sizes, self-report surveys, and short evaluation periods, all of which are insufficient to justify recommendations for irreversible treatments (Bränström et al, 2020).

Two studies conducted in Sweden provide insight on the effectiveness of sex reassignment surgery in improving the behavioral health of transgender persons. Because Sweden has a nationalized health system that collects data on all residents, this country can serve as a resource to assess service utilization and inpatient admissions. Both studies, one by Dhejne et al from 2011 and another by Bränström et al published in 2020, assessed individuals who had received sex reassignment surgery and examined outcomes over several decades. Dhejne et al's findings indicate that sex reassignment

[8] Although practice guidelines indicate the minimum age to undergo sex reassignment surgery is 18, available evidence demonstrates that mastectomies have been performed on adolescent girls as young as 13 who experience "chest dysphoria" (Olson-Kennedy et al, 2018).

procedures do not reduce suicidality. The authors explained that individuals who underwent sex reassignment surgery were still more likely to attempt or commit suicide than those in the general population. This study is unique because it monitored the subjects over a long period of time. Dhejne et al note that the transgender persons tracked for the study did not show an elevated suicide risk until ten years after surgery (Dhejne et al, 2011). Given that a high proportion of research follows sex reassignment patients for much shorter timeframes, this evidence indicates that surgery might have little to no effect in preventing suicides in gender dysphoric individuals over the long run.

In addition to having an increased suicide risk, Dhejne et al discuss how individuals who underwent sex reassignment procedures also had higher mortality due to cardiovascular disease. The authors do not list the specific causes but establish the correlation. Given that cross-sex hormones can damage the heart, the increased risk could be related to the drugs and not the surgery. Furthermore, the study explains that the tracked population had higher rates of psychiatric inpatient admissions following sex reassignment. Dhejne et al established this by examining the rates of psychiatric hospitalizations in these individuals prior to surgery and noted higher utilization in the years following the procedures. These results are in comparison to the Swedish population at large. While the study contradicts other research emphasizing improvements in mental health issues, it has its limitations. For example, the sample size is small. Dhejne et al identified only 324 individuals who had undergone sex reassignment surgery between 1973 and 2003. In addition, the authors noted that while the tracked population had increased suicide risks when compared to individuals identifying as their natal sex, the rates could have been much higher if the procedures were not available (Dhejne et al 2011). What this study postulates is that sex reassignment surgery does not necessarily serve as a "cure" to the distress resulting from gender dysphoria and that ongoing behavioral health care may still be required even after a complete transition.

Bränström et al's study evaluating the Swedish population used a larger sample (1,018 individuals who had received sex reassignment surgery) but tracked them for just a ten-year period (2005 to 2015).[9] Unlike Dhejne et al, the authors did not track suicides and focused primarily on mood or anxiety disorder treatment utilization. Their results indicate that transgender persons who had undergone surgery utilized psychiatric outpatient services at lower rates and were prescribed medications for behavioral health issues at an annual decrease rate of 8%. Bränström et al also did not limit comparisons to Sweden's overall population and factored in transgender persons who take cross-sex hormones but have not elected to have surgery. Those results still presented a decrease in outpatient mental health services. However, Bränström et al note that individuals only on cross-sex hormones showed no significant reduction in that category, which calls into question claims regarding effectiveness of cross-sex hormones in ameliorating behavioral issues.

The Bränström et al study prompted numerous responses questioning its methodology. The study lacked a prospective cohort or RCT design, and it did not track all participants for a full ten-year period (Van Mol et al, 2020). These criticisms resulted in a retraction, asserting that Bränström et al's conclusions were "too strong" and that further analysis by the authors revealed that the new "results demonstrated no advantage of surgery in relation to subsequent mood or anxiety disorder-related

[9] Although Bränström et al claim to follow individuals for a ten-year period, peer reviews of the research revealed that this was not the case, noting the authors had varying periods of tracking, ranging from one to ten years (Van Mol et al, 2020).

health care visits or prescriptions or hospitalizations following suicide attempts in that comparison" (Kalin, 2020).

There are multiple explanations for why the Bränström et al study reached different results than the Dhejne et al study. For starters, Bränström et al tracked a larger sample group over a later period (2005 to 2015 as opposed to 1973 to 2003) during which gender dysphoria underwent a dramatic shift in definition. Also, Dhejne et al did not see elevated suicides until after ten years, raising the question as to whether sex reassignment surgery has temporary benefits on mental health rather than long-term or permanent benefits. Like the other Swedish study, Bränström et al's findings are a correlation and do not specifically state that the procedures cause reduced psychiatric service utilization (Bränström et al, 2020).

A 2014 study by Hess et al in Germany evaluated satisfaction with sex reassignment procedures by attempting to survey 254 trans-females on their quality of life, appearance, and functionality as women. Out of the participants selected, only 119 (47%) returned completed questionnaires, which Hess et al indicate is problematic because dissatisfied trans-females might not have wanted to provide input. The results from the collected responses noted that 65.7% of participants reported satisfaction with their lives following surgery and that 90.2% indicated that the procedures fulfilled their expectations for life as women. While these results led Hess et al to conclude that sex reassignment surgery generally benefits individuals with gender dysphoria, the information is limited and raises questions (Hess et al, 2014). Such questions include whether the participants had mental health issues before or after surgery and did their satisfaction wane over time. Hess et al only sent out one questionnaire and not several to ascertain consistency over multiple years. Questions like these raise doubts about the validity of the study. Although Hess et al's research is just one study, numerous others utilize the same subjective methods to reach their conclusions (Hruz, 2018).

In his assessment, Patrick Lappert contributes additional insight on the appropriate clinical indications for mastectomies, noting that removal of breast tissue is necessary following the diagnosis of breast cancer or as a prophylactic against that disease. He cites that this basis is verifiable through definitive laboratory testing and imaging, making it an objective diagnosis, whereas gender dysphoria has no such empirical methods to assess and depends heavily on the patient's perspective. Also, Lappert notes that trans-males who make such decisions are doing so on the idea that the procedure will reduce their dysphoria and suicide risk. However, they are making an irreversible choice based on anticipated outcomes supported only by weak evidence, and thus cannot provide informed consent (Lappert, 2022).

The literature is inconclusive on whether sex reassignment surgery can improve mental health for gender dysphoric individuals. Higher quality research is needed to validate this method as an effective treatment. This includes studies that obtain detailed participant histories (e.g., behavioral diagnoses) and track participants for longer periods of time. These are necessary to evaluate the full effects of treatments that cause irreversible physical changes. In addition, sex reassignment procedures can result in severe complications such as infections in trans-females and urethral blockage in trans-males. Health issues related to natal sex can also persist. For example, trans-males who undergo mastectomy can still develop breast cancer and should receive the same recommended screenings (Trum et al, 2015). Until more definitive evidence becomes available, sex reassignment surgery should not qualify as a standard treatment for gender dysphoria.

Literature Review: Quality of Available Evidence and Bioethical Questions

Quality of Available Evidence

Clinical organizations that have endorsed puberty suppression, cross-sex hormones, and sex reassignment surgery frequently state that these treatments have the potential to save lives by preventing suicide and suicidal ideation. The evidence, however, does not support these conclusions. James Cantor notes that actual suicides (defined as killing oneself) are low, occur at higher rates for men, and that interpretations of available research indicate a blurring of numbers between those with gender dysphoria and homosexuals (Cantor, 2022). Although information exists that contradicts certain arguments, media outlets continue to report stories emphasizing the "lifesaving" potential of sex reassignment treatment. A May 2022 story by NBC announced survey results under the headline "Almost half of LGBTQ youths 'seriously considered suicide in the past year'" (NBC, 2022). This is a significant claim that can have a sensational effect on patients and providers alike, but how strong is the evidence supporting it? Almost all of the data backing this assertion are based on surveys and cross-studies, which tend to yield low-quality results (Hruz, 2018). In addition, how many gender dysphoric individuals are seeing stories in the media and not questioning the narrative? Because research on the effectiveness of treatments is ongoing, a debate persists regarding their use in the adolescent and young-adult populations, and much of it is due to the low-quality studies serving as evidence.

In their assessment, Romina Brignardello-Petersen and Wojtek Wiercioch examined the quality of 61 articles published between 2020 and 2022 (Note: See Attachment A for the full study). They identified research on the effectiveness of puberty blockers, cross-sex hormones, and sex reassignment surgery and assigned a grade (high, moderate, low, or very low) in accordance with the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. Out of the articles reviewed, all with a few exceptions received grades of low or very low quality when demonstrating outcomes regarding improvements in mental health and overall satisfaction with transitioning. For puberty blockers, Brignardello-Petersen and Wiercioch identified low quality evidence for alleviating gender dysphoria and very low quality for reducing suicidal ideation. The authors also had nearly identical findings for cross-sex hormones. However, they noted moderate quality evidence for the likelihood of cardiovascular side effects. Regarding surgery, Brignardello-Petersen and Wiercioch graded articles that examined overall satisfaction and complication rates. None of the studies received grades higher than low quality. These findings led the authors to conclude that "there is great uncertainty about the effects" of sex reassignment treatments and that the "evidence alone is not sufficient to support" using such treatments. Among the studies graded was one the U.S. Department of Health and Human Services cited in its information on "gender affirming" treatments. The authors noted this research had a "critical risk of bias" and was of low quality (Brignardello-Petersen and Wiercioch, 2022).

For his part, James Cantor provided a review of available literature, which addresses studies on etiology, desistance, effectiveness of puberty blockers and cross-sex hormones, suicidal behaviors, and clinical association and international guidelines. Throughout his analysis, Cantor cites weak evidence, poor methodologies (e.g., retrospective versus prospective studies), and lack of professional endorsements in research that indicates the benefits of sex reassignment treatment. Additionally, he notes that improvements in the behavioral health of adolescents who take cross-sex hormones can be attributed to the counseling they receive concurrently and that suicidality is not likely to result from gender

dysphoria but from co-occurring mental disorders. The reasoning behind the third point is based on the blending of suicide and suicidality, which are two distinct concepts. The former refers specifically to killing oneself, and the second regards ideation and threats in attempts to receive help. Cantor specifically notes that actual suicides are highly unlikely among gender dysphoric individuals, particularly trans-males. His other conclusions indicate that young children who experience gender identity issues will most likely desist by puberty, that multiple phenomena can cause the condition, and that Western European health services are not recommending medical intervention for minors. The basis for these statements is the paucity of high to moderate quality evidence on the effectiveness of sex reassignment treatments and numerous studies demonstrating desistance (Cantor, 2022).

Despite the need for stronger studies that provide definitive conclusions, many practitioners stand by the recommendations of the AAP, Endocrine Society, and WPATH. This is evident in a letter submitted to the *Tampa Bay Times*, which was a rebuttal to the Florida Department of Health's (DOH) guidance on treatment for gender dysphoria (Note: The guidance recommends against using puberty blockers, cross-sex hormones, or surgery for minors) (DOH, 2022). The authors, led by six professors at the University of Florida's College of Medicine, state that recommendations by clinical organizations are based on "careful deliberation and examination of the evidence by experts." However, evaluations of these studies show otherwise. Not only does the available research use cross-sectional methods such as surveys, but it provides insufficient evidence based on momentary snapshots regarding mental health benefits. These weak studies are the foundation for the clinical organizations' guidelines that the University of Florida professors tout as a gold standard. In addition, the letter's authors state that DOH's guidance is based on a "non-representative sample of small studies and reviews, editorials, opinion pieces, and commentary" (Tampa Bay Times, 2022). That statement misses the point when it comes to evidence demonstrating whether treatments with irreversible effects are beneficial because the burden of proof is on those advocating for this treatment, not on those acknowledging the need for further research. This raises the question concerning how much academic rigor these professors are applying to practice guidelines released by clinical organizations and whether they also apply the same level of rigor to novel treatments for other conditions (e.g., drugs, medical devices).

Another example of a lack of rigor is a 2019 article by Herman et al from the University of California at Los Angeles (UCLA) that evaluated responses to a 2015 national survey on transgender individuals and suicide. Unlike other studies, this one utilized a large cohort with 28,000 participants from across the U.S. responding. However, the researchers used no screening criteria and did not randomly select individuals. In addition, responses consisted entirely of self-reports with no supporting evidence to even prove a diagnosis of gender dysphoria. Although Herman et al conclude that the U.S. transgender population is at higher risk for suicidal behaviors, the authors' supporting evidence is subjective and serves as a weak basis. Additionally, the survey results do not establish gender dysphoria as a direct cause of suicide or suicidal ideation. The questions required participants to respond about their overall physical and mental health. Out of those that indicated "poor" health, 77.7% reported suicidal thoughts or attempts during the previous year, whereas just 29.1% of participants in "excellent" health had. These percentages indicate that causes beyond gender dysphoria could be affecting suicidal behaviors. Other reasons cited include rejection by family or religious organizations and discrimination. The authors also acknowledge that their findings are broad, not nationally representative, and should serve as a basis for pursuing future research (Herman et al, 2019).

Yet another example is a study published in 2022 by Olson et al tracks 300 young children that identify as transgender over a 5-year period, and asserts low probabilities for detransitioning, while supporting interventions such as puberty blockers. The authors found that children (median age of 8 years) who identified as a gender that differed from their natal sex were unlikely to desist at a rate of 94% and conclude that "transgender youth who socially transitioned at early ages" will continue "to identify that way." While this appears to contradict earlier studies that demonstrate most young adolescents who change gender identities return to their "assigned gender at birth," the authors note differences and limitations with the results. For example, Olson et al notes that they did not verify whether the participants met the DSM-V's diagnostic criteria for gender dysphoria and that the children's families supported the decisions to transition. Instead, the authors relied on a child's chosen pronouns to classify as transgender. Also, Olson et al acknowledged that roughly 66% of the sample was biologically male. This is particularly significant considering that the majority of transitioning adolescents in recent years were natal females. Another issue with the study includes the median age at the end of follow-up (13 years), which is when boys begin puberty. Furthermore, the authors cite that the participants received strong parental support regarding the transitions, which constitutes positive reinforcement (Olson et al, 2022). Other research demonstrates that such feedback on social transitioning from parents and peers can prevent desistance following pubertal onset (Zucker, 2019). Despite these limitations, the New York Times announced the study's publication under the headline "Few Transgender Children Change Their Minds After 5 Years" (New York Times, 2022). Such a title can add to the public's perception that gender dysphoria requires early medical intervention to address.

Bioethical Questions

The irreversible physical changes and potential side effects of sex reassignment treatment raise significant ethical questions. These questions concern multiple bioethical principles including patient autonomy, informed consent, and beneficence. In a 2019 article, Michael Laidlaw, Michelle Cretella, and Kevin Donovan argue that prescribing puberty blockers or cross-sex hormones on the basis that they will alleviate psychological symptoms should not be the standard of care for children with gender dysphoria. Additionally, the three authors assert that such treatments "constitute an unmonitored, experimental intervention in children without sufficient evidence of efficacy or safety." The primary ethical question Laidlaw, Cretella, and Donovan pose is whether pushing physical transitioning, particularly without parental consent, violates fully informed consent (Laidlaw et al, 2019).

In accordance with principles of bioethics, several factors must be present to obtain informed consent from a patient. These consist of being able to understand and comprehend the service and potential risks, receiving complete disclosure from the physician, and voluntarily providing consent. Bioethicists generally do not afford the ability of giving informed consent to children who lack the competence to make decisions that pose permanent consequences (Varkey, 2021). Laidlaw, Cretella, and Donovan reinforce this point regarding sex reassignment treatment when they state that "children and adolescents have neither the cognitive nor the emotional maturity to comprehend the consequences of receiving a treatment for which the end result is sterility and organs devoid of sexual function" (Laidlaw et al, 2019). This further raises the question whether clinicians who make such treatment recommendations are providing full disclosure about the irreversible effects and truly obtaining informed consent.

Another issue is the conflict between consumerism and the practitioner's ability to provide appropriate care. Consumerism refers to patients learning about treatments through media/marketing and requesting their health care provider to prescribe it, regardless of medical necessity. Considering that social media is rife with individuals promoting "gender affirmative" drugs and surgeries, children are making self-assessments based on feelings they may not understand and that can lead to deep regret in the future (Littman, 2018). This can contribute to patients applying pressure on their doctors to prescribe medications not proven safe or effective for the condition. Consumerism can also affect bioethical compliance because it constrains clinicians from using their full "knowledge and skills to benefit the patient," which is "tantamount to a form of patient abandonment and therefore is ethically indefensible" (Varkey, 2021).

In his assessment, G. Kevin Donovan explains the bioethical challenges related to sex reassignment treatment, emphasizing the lack of informed consent when administering these services. He asserts that gender dysphoria is largely a self-diagnosis practitioners cannot verify with empirical tests (e.g., labs and imaging) and that providing such treatments is experimental. Because of the lack of consent and off-label use of puberty blockers and cross-sex hormones, Donovan raises the question as to how "experienced and ethical physicians so mislead others or be so misled themselves?" He further attributes this phenomenon to societal and peer pressures that influence self-diagnosis and confirm decisions to transition. As a result, these pressures lead to individuals wanting puberty blockers, cross-sex hormones, and surgery. Donovan goes on to identify several news stories where embracing sex reassignment treatment is a "cult-like" behavior. To conclude, he links these factors back to the failure to obtain informed consent from transgender patients and how that violates basic bioethical principles (Donovan, 2022).

Coverage Policies of the U.S. and Western Europe

U.S. Federal Level Coverage Policies

Medicare: In 2016, the Centers for Medicare and Medicaid Services (CMS) published a decision memo announcing that Medicare Administrative Contractors (MACs) can evaluate sex reassignment surgery coverage on a "case-by-case" basis.[10] CMS specifically noted that the decision memo is not a National Coverage Determination and that "no national policy will be put in place for the Medicare program" (CMS, 2016). This memo was the result of CMS reviewing over 500 studies, reports, and articles to the validity of the procedures. Following its evaluation, CMS determined that "the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding . . . small sample sizes, lack of validated assessment tools, and considerable (number of participants in the studies) lost to follow up." In 2017, CMS reinforced this position with a policy transmittal that repeated the 2016 memo's criteria (CMS, 2017).

The basis for Medicare's decision is that the "clinical evidence is inconclusive" and that "robust" studies are "needed to ensure that patients achieve improved health outcomes." In its review of available literature, CMS sought to answer whether there is "sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria." After evaluating 33 studies that met inclusion criteria, CMS's review concludes that "not enough high-quality evidence" is available "to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively." Additionally, out of the 33 studies, just 6 provided "useful information" on the procedures' effectiveness, revealing that their authors "assessed quality of life before and after surgery using validated (albeit non-specific) psychometric studies" that "did not demonstrate clinically significant changes or differences in psychometric test results" following sex reassignment surgery (CMS, 2016).

U.S. Department of Defense – Tricare: Tricare does not cover sex reassignment surgery, but it will cover psychological services such as counseling for individuals diagnosed with gender dysphoria and cross-sex hormones when medically necessary (Tricare, 2022).[11]

U.S. Department of Veterans Affairs: The U.S. Department of Veterans Affairs (VA) does not cover sex reassignment surgery, although it will reimburse for cross-sex hormones and pre- and post-operative care related to transitioning. Because the VA only provides services to veterans of the U.S. armed forces, it cannot offer sex reassignment treatment to children (VA, 2020).[12]

[10] The Centers for Medicare and Medicaid Services is part of the U.S. Department of Health and Human Services. Its primary functions are to administer the entire Medicare system and oversee federal compliance of state Medicaid programs. In addition, CMS sets reimbursement rates and coverage criteria for the Medicare program.
[11] Tricare is the insurance program that covers members of the U.S. armed forces and their families. This includes children of all ages.
[12] The U.S. Department of Veterans Affairs oversees the Veterans Health Administration (VHA), which consists of over 1,000 hospitals, clinics, and long-term care facilities. As the largest health care network in the U.S., the VHA provides services to veterans of the U.S. armed forces.

State-Level Coverage Policies

Florida: In April 2022, DOH issued guidance for the treatment of gender dysphoria, recommending that minors not receive puberty blockers, cross-sex hormones, or sex reassignment surgery. [13] The justification offered for recommending against these treatments is that available evidence is low-quality and that European countries also have similar guidelines. Accordingly, DOH provided the following guidelines:

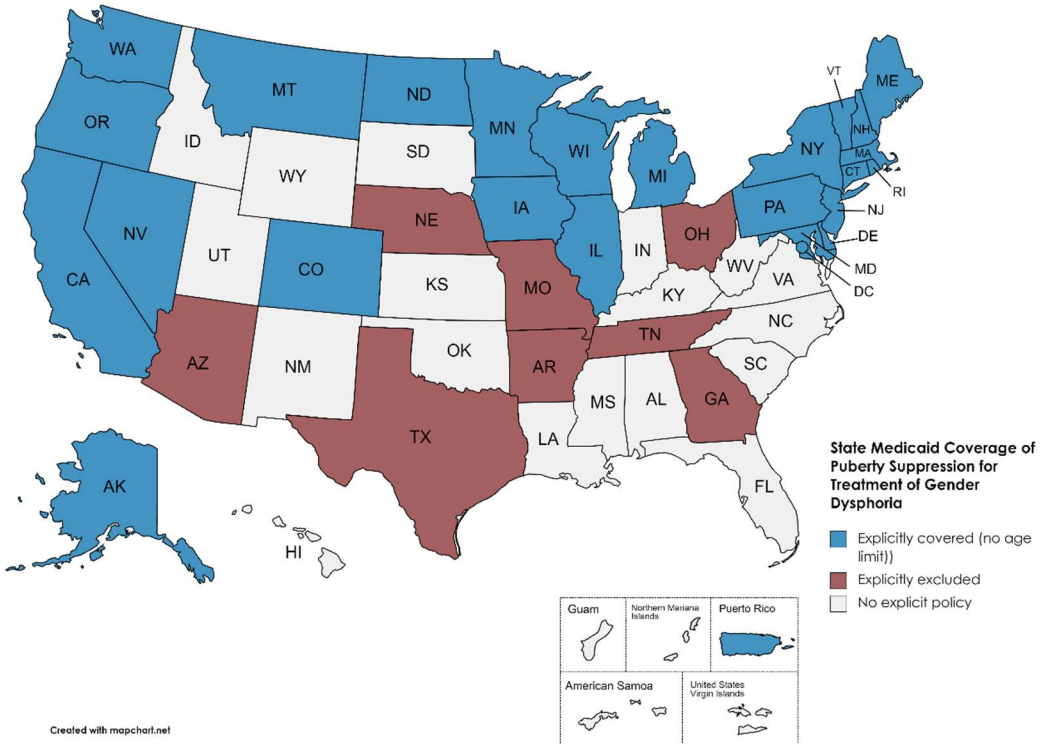
- "Social gender transition should not be a treatment option for children or adolescents."
- "Anyone under 18 should not be prescribed puberty blockers or hormone therapy."
- "Gender reassignment surgery should not be a treatment option for children or adolescents."
- "Children and adolescents should be provided social support by peers and family and seek counseling from a licensed provider."

In a separate fact sheet released simultaneously with the guidance, DOH further asserts that the evidence cited by the federal government cannot establish sex reassignment treatment's ability to improve mental health (DOH, 2022).

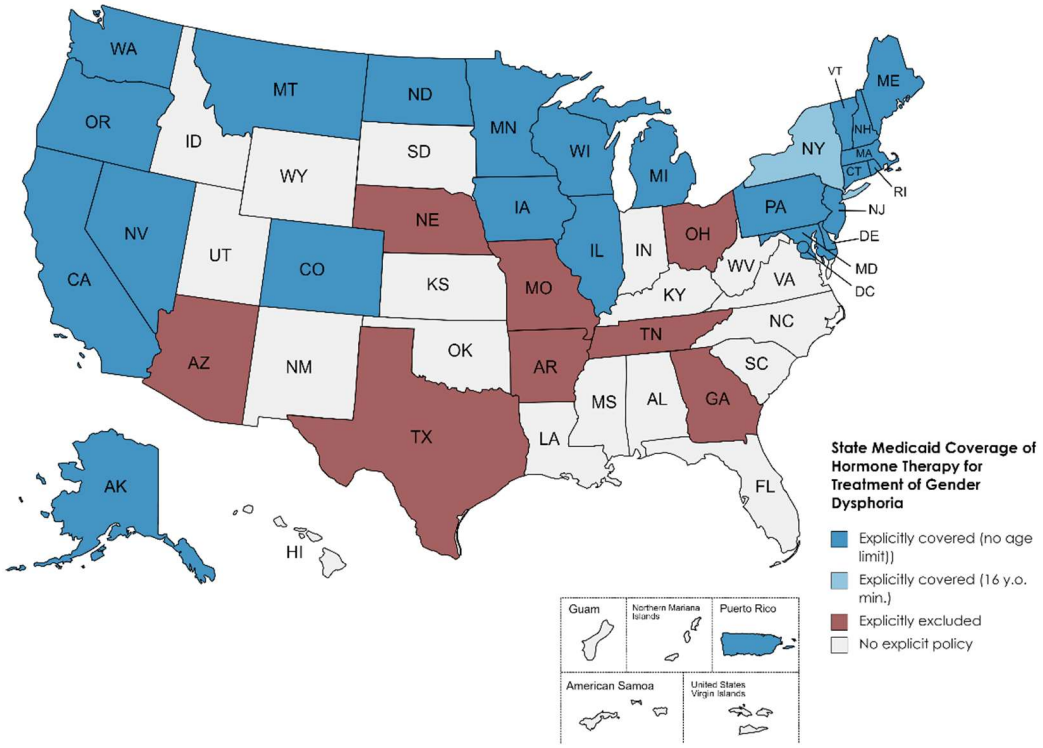
State Medicaid Programs: Because individual states differ in health services offered, Medicaid programs vary in their coverage of sex reassignment treatments. The following maps identify states that cover sex reassignment treatments, states that have no policy, and states that do not cover such treatments.

[13] Unlike the federal government, the State of Florida delegates responsibilities for Medicaid and health care services to five separate agencies (Agency for Health Care Administration, Department of Health, Department of Children and Families, Department of Elder Affairs, and Agency for Persons with Disabilities). Each agency has its own separate head (secretary or surgeon general), which reports directly to the Executive Office of the Governor. As Florida's public health agency, DOH oversees all county health departments, medical professional boards, and numerous health and welfare programs (e.g., Early Steps and Women, Infants, and Children). Because it oversees the boards, DOH has authority to release practice guidelines.

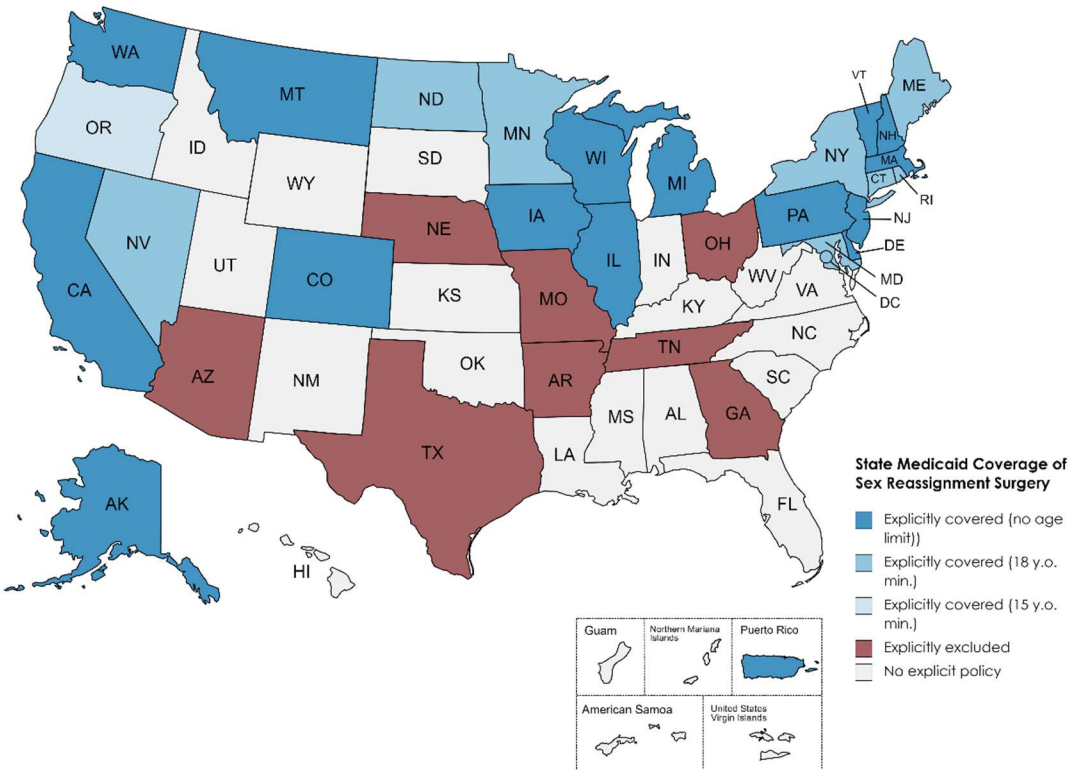
State Medicaid programs with coverage decisions regarding puberty blockers:



State Medicaid programs with coverage decisions regarding cross-sex hormones:



State Medicaid programs with coverage decisions regarding sex reassignment surgery:



Western Europe

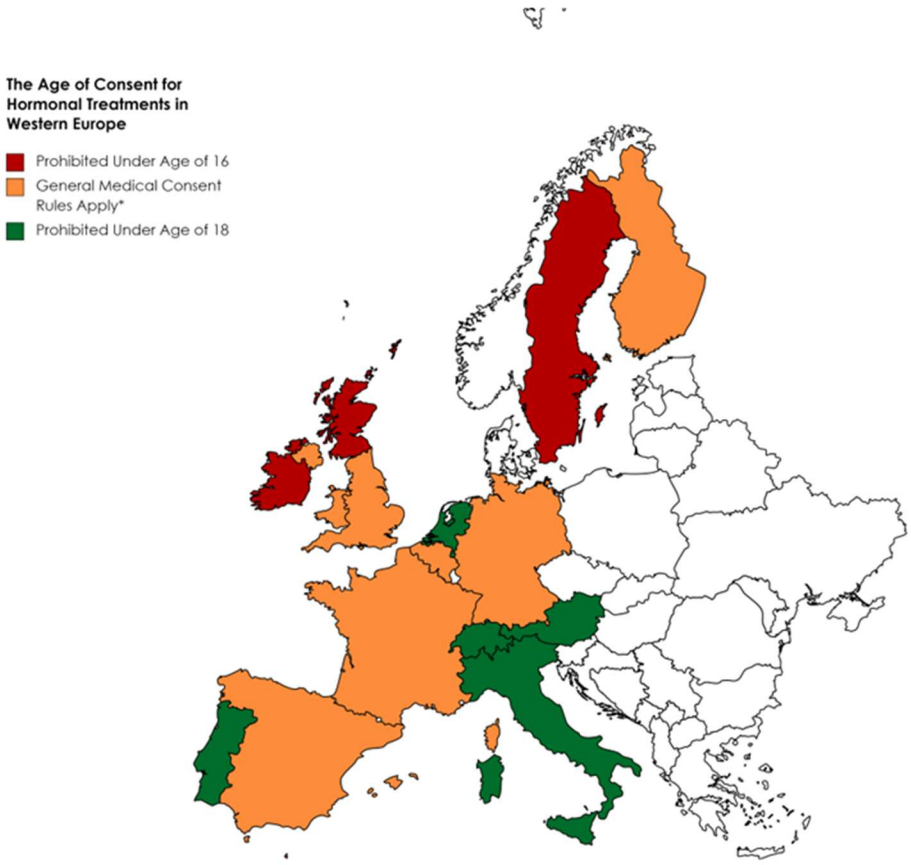
Scandinavian countries such as Sweden and Finland have released new guidelines on sex reassignment treatment for children. In 2022, the Swedish National Board of Health stated that "the risks of hormonal interventions for gender dysphoric youth outweigh the potential benefits." With the exception of youths who exhibited "classic" signs of gender identity issues, adolescents who present with the condition will receive behavioral health services and gender-exploratory therapy (Society for Evidence Based Gender Medicine, 2022).

In Finland, the Palveluvalikoima issued guidelines in 2020 stating that sex reassignment in minors "is an experimental practice" and that "no irreversible treatment should be initiated." The guidelines further assert that youths diagnosed with gender dysphoria often have co-occurring psychiatric disorders that must be stabilized prior to prescribing any cross-sex hormones or undergoing sex reassignment surgery (Palveluvalikoima, 2020).

The United Kingdom (U.K.) is also reassessing the use of irreversible treatments for gender dysphoria due the long-term effects on mental and physical health. In 2022, an independent interim report commissioned by the U.K.'s National Health Service (NHS) indicates that additional research and systematic changes are necessary to ensure the safe treatment of gender dysphoric youths. These include reinforcing the diagnosis process to assess all areas of physical and behavioral health, additional training for pediatric endocrinologists, and informing parents about the uncertainties regarding puberty blockers. The interim report is serving as a benchmark until the research is completed for final guidelines (The Cass Report, 2022).

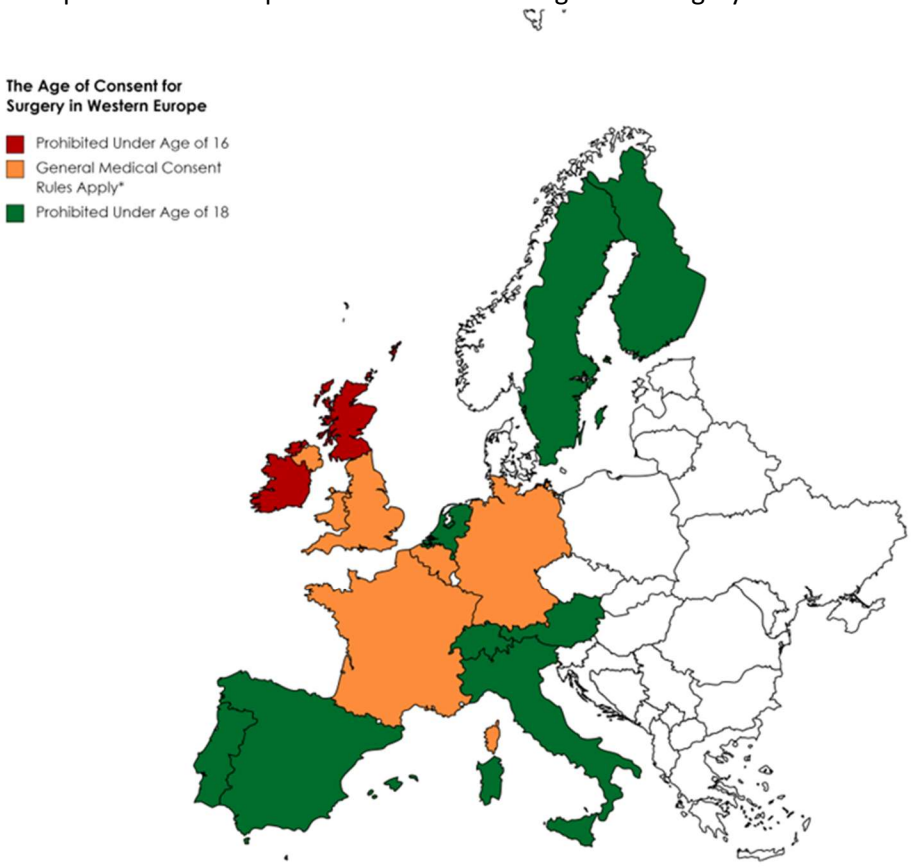
Like state Medicaid programs, health systems across Western Europe also vary in their coverage of sex reassignment treatment.

Western European nations' requirements for cross-sex hormones:



In this context, the age requirement for access to any medical treatment without consent of parents or of a public authority. This age may range from 16 to 18 years depending on each country's laws.

Western European nations' requirements for sex reassignment surgery:



In this context, the age requirement for access to any medical treatment without consent of parents or of a public authority. This age may range from 16 to 18 years depending on each country's laws.

Generally Accepted Professional Medical Standards Recommendation

This report does not recommend sex reassignment treatment as a health service that is consistent with generally accepted professional medical standards. Available evidence indicates that the services are not proven safe or effective treatments for gender dysphoria.

Rationale

The available medical literature provides insufficient evidence that sex reassignment through medical intervention is a safe and effective treatment for gender dysphoria. As this report demonstrates, the evidence favoring "gender affirming" treatments, including evidence regarding suicidality, is either low or very low quality:

- **Puberty Blockers:** Evidence does not prove that puberty blockers are safe for treatment of gender dysphoria. Evidence that they improve mental health and reduce suicidality is low or very low quality.
- **Cross-Sex Hormones:** Evidence suggesting that cross-sex hormones provide benefits to mental health and prevents suicidality is low or very low quality. Rather, evidence shows that cross-sex hormones cause multiple irreversible physical consequences as well as infertility.
- **Sex Reassignment Surgery:** Evidence of improvement in mental health and reduction in suicidality is low or very low quality. Sex reassignment surgery results in irreversible physical changes, including sterility.

While clinical organizations like the AAP endorse the above treatments, none of those organizations relies on high quality evidence. Their eminence in the medical community alone does not validate their views in the absence of quality, supporting evidence. To the contrary, the evidence shows that the above treatments pose irreversible consequences, exacerbate or fail to alleviate existing mental health conditions, and cause infertility or sterility. Given the current state of the evidence, the above treatments do not conform to GAPMS and are experimental and investigational.

__✓__**Concur** ____**Do not Concur**

Comments:

_____

_____

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_____ 6/2/22

Deputy Secretary for Medicaid (or designee) *Date*

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Attachments

Attachment A: Secretary for the Florida Agency for Health Care Administration's Letter to Deputy Secretary Thomas Wallace. 20 April 2022.

Attachment B: Complete text of Rule 59G-1.035, F.A.C.

Attachment C: Romina Brignardello-Petersen, DDS, MSc, PhD and Wojtek Wiercioch, MSc, PhD: *Effects of Gender Affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence*. 16 May 2022.

Attachment D: James Cantor, PhD: *Science of Gender Dysphoria and Transsexualism*. 17 May 2022.

Attachment E: Quentin Van Meter, MD: *Concerns about Affirmation of an Incongruent Gender in a Child or Adolescent*. 17 May 2022.

Attachment F: Patrick Lappert, MD: *Surgical Procedures and Gender Dysphoria*. 17 May 2022.

Attachment G: G. Kevin Donovan, MD: *Medical Experimentation without Informed Consent: An Ethicist's View of Transgender Treatment for Children*. 16 May 2022.

EXHIBIT C

FLORIDA DEPARTMENT OF CORRECTIONS
OFFICE OF HEALTH SERVICES

HEALTH SERVICES BULLETIN NO: **15.05.23** Page **1** of **8**

SUBJECT: MENTAL HEALTH TREATMENT OF INMATES WITH GENDER DYSPHORIA

EFFECTIVE DATE: 09/30/2024

I. PURPOSE:

To establish professional guidelines for the mental health evaluation and treatment of inmates meeting the diagnostic criteria[1] for Gender Dysphoria.[2]

II. POLICY:

To ensure inmates diagnosed with Gender Dysphoria receive timely, appropriate mental health services and individualized treatment programming as clinically indicated. Treatment interventions shall target psychological distress/dysphoria, as well as any co-occurring mental health disorders, and be tailored to the unique needs of the inmate.

III. DEFINITIONS:

A. **Clinical Group Psychotherapy:** a cognitive behavioral or psychodynamic process by which a group of persons is led by a psychologist or behavioral health specialist to guide interpersonal and intrapersonal growth through an examination of the persons' thoughts, feelings, experiences, and skills.

B. **Gender Dysphoria:** a psychological disorder caused by clinically significant distress or impairment due to the perceived discrepancy between a person's expressed/experienced gender identity and his or her biological sex.

C. **Gender Identity:** a person's internal sense of being male or female.

D. **Individual Psychotherapy:** a collaborative treatment based on the therapeutic relationship between the patient and Mental Health Clinician, including, but not limited to, cognitive behavioral, dialectical behavioral, psychodynamic, and interpersonal modalities.

E. **Multidisciplinary Services Team (MDST):** a group of staff representing different professions or disciplines, which has the responsibility for ensuring access to necessary assessment, treatment, continuity of care, and services to inmates in accordance with their identified mental health needs, and which collaboratively

[1] As defined by the *Diagnostic and Statistical Manual of Mental Disorders* – 5th Edition, Text Revision (DSM-5-TR; American Psychiatric Association, 2022), https://doi.org/10.1176/appi.books.9780890425787.

[2] *Id.* at 511-520.

develops, implements, reviews, and revises the DC4-643A, *Individualized Service Plan* (ISP) as needed.

F. **Psychoeducational Group Intervention:** a didactic form of group therapeutic services designed to teach patients about their disorder and help them learn how to manage the related symptoms, behaviors, and consequences. These services may include workbook or homework activities, medication management, stress/anger management, prosocial skills training, coping skills exercises, and managing activities of daily living in a carceral setting.

IV. TARGET POPULATION AND GOALS FOR GENDER DYSPHORIA CARE:

A. **Mental health** staff will offer assessment, consultation, and treatment services to inmates with Gender Dysphoria to facilitate their ability to function adequately in a prison environment. The inmate will be made aware of the limitations and potential risks associated with treatment for Gender Dysphoria in a carceral setting. Therapy will focus on alleviating the distress associated with Gender Dysphoria. Mental health professionals will inform inmates suffering from Gender Dysphoria that no psychotherapeutic, medical, or surgical therapy can permanently eradicate all psychological and physical vestiges of one's biological sex.[3] Mental health care will be provided in the context of a collaborative therapeutic relationship with the inmate.

B. **Crisis intervention** services are offered to inmates who may be experiencing acute distress or acute symptoms of mental illness to prevent suicide and self-injury (in accordance with Procedure 404.001, *Suicide and Self-Injury Prevention*) or to provide relief from symptoms of mental illness and prevent further decompensation.

C. **Assessment and consultation** services are provided in response to referrals by staff, inmate requests, or situational factors (such as the placement of the inmate in special housing). In providing these services, mental health staff should assess an inmate's mental health needs and provide guidance or recommendations regarding treatment or precautions.

D. **Ongoing mental health care** will be provided on an outpatient basis to alleviate symptoms of mental illness that result in the impairment of an inmate's ability to adapt and function in the prison environment. A DC4-643A, *Individualized Service Plan* (ISP) must be developed in accordance with HSB 15.05.11, *Planning and*

[3] *Standards of Care for Gender Identity Disorders* 12 (6th ed. 2001).

Implementation of Individualized Mental Health Services, for those inmates participating in ongoing mental health care.

V. SCREENING:

A. The mental health clinician will complete a clinical interview within 14 days of an inmate's arrival to the reception center or transfer institution and will document the interview on the DC4-642B, *Mental Health Screening Evaluation*.

B. If an inmate presents with a reported or documented history of Gender Dysphoria prior to incarceration, the inmate will complete a DC4-711B, *Consent and Authorization for Use and Disclosure, Inspection, and Release of Confidential Information* to authorize the Department to obtain the inmate's prior mental health records from community providers who diagnosed or treated the inmate.

C. As appropriate, a diagnosis of Gender Dysphoria will be made by a psychologist with the consensus of the MDST. The diagnosis and Problem #124, Gender Dysphoria, will be added to the ISP. At a minimum, the inmate will be classified and maintained as an S-3.

D. If referral to medical or psychiatric staff is needed, mental health staff will complete the DC4-529, *Staff Request/Referral*, and route it to the appropriate medical staff member within the electronic medical record (EMR).

VI. EVALUATION:

A. A diagnosis of Gender Dysphoria can encompass a diverse array of conditions, with widely differing pathways and characteristics depending on the patient's age of onset, mental health, intelligence, environment, and motivation for identifying as the opposite sex. Like many DSM-V psychiatric conditions, Gender Dysphoria is complex and often accompanied by other psychiatric comorbidities.[4]

B. All inmates diagnosed with gender dysphoria will be individually evaluated. A complete psychodiagnostic and psychiatric assessment should be performed. All

[4] In the scientific research literature, there has been a gradual shift from definitive "gender-affirmative care," which prioritizes access to medical interventions, to a more conservative approach that addresses psychiatric comorbidities and psychotherapeutically explores the developmental etiology of the gender dysphoria. *See* Levine, S.B., Abbruzzese, E. Current Concerns About Gender-Affirming Therapy in Adolescents. *Curr Sex Health Rep* 15, 113-123 (2023). *See also Standards of Care: The Hormonal and Surgical Sex Reassignment of Gender Dysphoric Persons* (4th ed. 1990).

medical and psychiatric comorbidities must be identified as these comorbidities can complicate the treatment of Gender Dysphoria.[5]

C. The following complement of assessment instruments (with any additional instruments if they become available in the future) should be used as applicable to evaluate the inmate:

1. Clinical interview
2. *Sex Offender Screening and Selection* as per HSB 15.05.03
3. Adaptive Behavioral Checklist (ABC)
4. Wechsler Adult Intelligence Scale Revised (WAIS-R)
5. Montreal Cognitive Assessment (MoCA)
6. Millon Clinical Multiaxial Inventory-III (MCMI-III)
7. Columbia Suicide Severity-Rating Scale Lifetime Recent (C-SSRS)
8. Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5)
9. Miller Forensic Assessment of Symptoms Test (M-FAST)
   - If the inmate's score is high enough, then further evaluation for malingering or response style may be warranted (*e.g.*, Structured Interview of Reported Symptoms-2nd edition [SIRS-2]; Minnesota Multiphasic Personality Inventory-2 [MMPI-2])
10. If diagnosed with an Autism Spectrum Disorder (ASD), the inmate may be additionally assessed with the Adaptive Behavior Assessment System 3rd edition (ABAS-3)
    - If the inmate's ASD diagnosis qualifies for an SY-D designator, then refer to 15.05.17, *Intake Mental Health Screening at Reception Centers*
11. If the inmate is diagnosed with Self Injury Behavior (SIB), he or she will be tracked using the Self-Injury Prevention System (SIPS)
12. The evaluation and testing results will be documented on the DC4-643E, *Psychological Evaluation for Gender Dysphoria*

VII. TREATMENT:

A. If treatment for Gender Dysphoria is likely to be necessary based on the results of the foregoing evaluation, the following treatment protocol should be followed:

1. All identified medical and psychiatric comorbidities must first be addressed. As appropriate, psychiatric comorbidities should be addressed through psychotherapy, psychotropic medication, or other appropriate medically

[5] Experts have opined that unaddressed psychiatric issues and unaddressed childhood trauma could lead to misdiagnosis of gender dysphoria. *See* Littman, L., Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned; A Survey of 100 Detransitioners, Arch Sex Behav, 50, 3353-3369, 3364 (2021).

accepted interventions.[6] Once these medical and psychiatric comorbidities are resolved and ruled out as the potential cause of the Gender Dysphoria, further treatment for Gender Dysphoria may proceed.

2. Psychotherapy should be prioritized. Treatment should include, at a minimum, individual or group clinical psychotherapy weekly and case management at least every 60 days or more frequently as clinically indicated. Additionally, other treatments, such as psychoeducational group interventions, may be added as clinically indicated. Treatment interventions will focus on managing the psychological distress/dysphoria, assisting with adjustment to incarceration, community re-entry, and strengthening resilience. Follow-up mental health care should target any associated emotional or behavioral problems and should emphasize supportive treatment modalities.

3. Psychotropic medication should be considered to determine if its use may alleviate the symptoms of Gender Dysphoria.

4. Diagnosis and treatment of Gender Dysphoria will be discontinued if the MDST decides that the inmate no longer meets the criteria for the diagnosis based on clinical outcomes. The ISP will be updated to reflect discontinuation of diagnosis, and Problem #124 will be removed from the ISP and EMR.

5. The inmate must actively participate in psychotherapy for at least one year to ameliorate the symptoms of Gender Dysphoria, to acclimate the inmate to the prison environment, and to develop an understanding of the limitations of the prison environment. An established pattern of attendance and participation in mental health treatment for at least one year is required prior to the consideration of any variances.

VIII. DOCUMENTATION:

A. All progress notes concerning outpatient mental health care shall be made on the pertinent DC4-642 series form in the EMR in accordance with 15.05.18, *Outpatient Mental Health Services*. All documentation must be completed in its entirety, signed, and dated by the clinician.

B. Each individual clinical encounter must be documented in SOAP (Subjective, Objective, Assessment, and Plan) format in the EMR on a DC4-642 series form on the date of the encounter.

[6] *See Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria*, Agency for Healthcare Administration (June 2022).

C. Group psychotherapy contacts shall be documented with an incidental note on DC4-642U, *Clinical Group Therapy Note,* at least monthly and upon group enrollment and termination. The monthly group psychotherapy note shall include the proportion of scheduled sessions attended, the inmate's relative level of participation, and the inmate's observed progress toward treatment goals as referenced by ISP problem number.

D. Relevant statutes, rules, and procedures:

1. Section 456.52, Florida Statutes (2023)
2. Emergency Rules 64B8ER23-11 and 64B15ER23-12, Florida Administrative Code
3. DC4-529 Staff Request/Referral
4. DC4-642B, Mental Health Screening Evaluation
5. DC4-642U, Clinical Group Therapy Note
6. DC4-643A, Individualized Service Plan
7. DC4-643E Psychological Evaluation for Gender Dysphoria
8. DC4-647 Sex Offender Screening and Selection
9. DC4-711B Consent and Authorization for Use and Disclosure, Inspection, and Release of Confidential Information
10. HSB 15.05.11, Planning and Implementation of Individualized Mental Health Services
11. HSB 15.05.17, Intake Mental Health Screening at Reception Centers
12. HSB 15.05.18, Outpatient Mental Health Services
13. Procedure 404.001, Suicide and Self-Injury Prevention
14. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
15. Department of Health Forms DH5082, Feminizing Medications for Patients with Gender Dysphoria and DH5083, Masculinizing Medications for Patients with Gender Dysphoria

IX. VARIANCES:

A. The use of cross-sex hormones as a treatment for gender dysphoria is extensive in its effects, is invasive to the integrity of the human body, has effects and consequences which are not readily known or reversible, and may be requested by persons experiencing short-termed delusions or beliefs which may later be changed and reversed. Published and unpublished case histories indicate that, in some situations, the decision to undergo hormone therapy was, after the fact, regretted and the final result of such therapy proved to be psychologically and physically debilitating to the patients.[7] The use of cross-sex hormones may result in infertility,

[7] *See Standards of Care: The Hormonal and Surgical Sex Reassignment of Gender Dysphoric Persons* §§ 4.1.1, 4.1.2, 4.1.3, 4.1.4 (4th ed. 1990).

neurological issues, cardiovascular disease, disfigurement, and other permanent effects.[8] Studies presenting the benefits to mental health, including those claiming that the services prevent suicide, are either low or very low quality and rely on unreliable methods.[9]

B. State law prohibits the Department from expending any state funds to purchase cross-sex hormones for the treatment of Gender Dysphoria. Section 286.311, Florida Statutes. The Department shall comply with this statutory requirement unless compliance with the U.S. Constitution or a court decision requires otherwise.

C. In rare instances deemed medically necessary, a variance may be approved to permit the use of cross-sex hormones to treat an inmate's Gender Dysphoria. Variances must be unanimously approved after review by a team consisting of the Chief of Medical Services, the Chief of Mental Health Services, and the Chief Clinical Advisor, and shall only be sought (1) after satisfying all preceding provisions of this policy and (2) if necessary to comply with the U.S. Constitution or a court decision.

1. Variances should only be considered after completion of the treatment protocol in Section VII. An inmate may be assessed for cross-sex hormone therapy if the treating physician can demonstrate with documented evidence that such treatment may improve clinical outcomes by treating the etiological basis of the pathology. Such evidence must be based on sound scientific methods and research that were subject to the formal peer review process. Any recommendation for cross-sex hormone therapy must be supported by a consensus of the MDST. The need for continued cross-sex hormone therapy will be re-evaluated every 90 days during the first year of use and every 180 days thereafter, or as determined by the MDST. This will be documented in the ISP.

2. Prior to initiating cross-sex hormone therapy treatment, the physician providing the prescription must fully inform the inmate of the nature of the proposed prescription, the benefits and risks of the prescription, including the potential irreversible effects of such treatment (infertility, hair growth, voice deepening, clitoral enlargement in the female-to-male inmate, and infertility and breast growth in the male-to-female inmate),[10] the possible and likely consequences

[8] *See Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria*, Agency for Healthcare Administration (June 2022).

[9] *See id.*

[10] *Standards of Care: The Hormonal and Surgical Sex Reassignment of Gender Dysphoric Persons* § 4.4.2 (4th ed. 1990).

of cross-sex hormone therapy in the prison environment, and the potential alternative treatments.

3. Before cross-sex hormone therapy commences, the inmate must sign the informed consent form adopted by the Board of Medicine and the Board of Osteopathic Medicine (Forms DH5082 and DH 5083). Consent must be voluntary, and the inmate must be able to understand and appreciate the risks and potential side effects of the prescription, the long-term consequences and complications of cross-sex hormone intervention, and the alternative treatment options available. If the required documented evidence is insufficient, or if the inmate fails to sign the consent form, the clinician shall not prescribe hormones for the inmate's Gender Dysphoria.

D. Every inmate who receives cross-sex hormones specifically for Gender Dysphoria will be evaluated by the MDST to determine if the diagnosis is still warranted. For those inmates whose diagnosis is no longer warranted, titration and discontinuation of cross-sex hormone therapy should be initiated over a period of nine weeks. During and following the titration process, the inmate should continue to receive ongoing mental health services and work collaboratively with his or her treatment team in customizing a mental health service plan that best meets the inmate's needs (*e.g.*, individual psychotherapy, group counseling, psychiatric services, psychotropic medications, *etc.*).

Clayton Weiss

Health Services Director