IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

ALISHEA KINGDOM, et al.,

Case No. 1:25-cv-00691

Plaintiffs,

DECLARATION OF DR. CATHY THOMPSON

v.

DONALD J. TRUMP, et al.,

Defendants.

I, Cathy Thompson, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

INTRODUCTION AND SCOPE OF WORK

1. I am a licensed clinical psychologist and recently retired Federal law enforcement officer with more than 20 years' experience working in correctional settings. My experience includes providing direct mental health services to incarcerated individuals inside prison and jail facilities. I later served as a national administrator for the Department of Justice's Federal Bureau of Prisons (BOP) and therefore have extensive experience in developing programs and services and drafting and implementing policies specific to the safety and treatment of individuals in BOP custody. I was involved in the development and implementation of BOP's procedures for managing transgender inmates. I retired from federal service effective September 23, 2023, and I now work as a consultant.

- 2. I have been retained by counsel for Plaintiffs in the class action complaint for declaratory and injunctive relief in *Kingdom v. Trump* (Trump Administration and BOP's categorical ban on gender-affirming health care for people with gender dysphoria in the custody of the Federal Bureau of Prisons), Case No.: 1:25-cv-00691. I have been asked to provide expert testimony about BOP policies and practices for transgender people prior to the executive order, and my expert opinion on the current and future impact of BOP's recent policy changes pertaining to treatment and management of transgender individuals in BOP custody.
- 3. My opinion, which is explained in further detail below, addresses the history of BOP's approach to managing and treating transgender people and the ways in which the recent guidance and policy issued by the BOP 1) cause harm to both those individuals and the staff who work with them, and 2) are not consistent with standards and accepted practices applicable to BOP.
- 4. It is my understanding that since January 2025, the BOP has rescinded its policy about transgender individuals, issued guidance prohibiting accommodations for transgender people, and directed medical staff to cease provision of gender affirming care, including hormones for all persons in custody.
- 5. It is my opinion that (1) a blanket ban on treating individuals who are transgender or have gender dysphoria is neither safe nor consistent with accepted practices, and (2) providing gender affirming care promotes security efforts.

PROFESSIONAL BACKGROUND

6. In 2000, I obtained my doctorate in Clinical Psychology from Texas Tech

University. As part of this degree, I completed an internship with the BOP during 1999-2000. After graduating, I continued my career with the BOP which spanned over 23 years until my retirement in 2023.

- 7. During more than two decades with BOP, I held positions of increasing responsibility in both prisons and administrative offices across the United States wherein I not only practiced psychology, but worked collaboratively and closely with other disciplines to meet the agency's mission of operating facilities that were safe while also delivering quality, evidence-based services.
- 8. For approximately the first decade, I promoted through positions located inside prisons. I provided treatment to men and women with a wide range of presenting issues. I provided supportive counseling to individuals struggling with issues of gender identity and more intensive psychological interventions for comorbid gender dysphoria and depressive disorders, posttraumatic stress disorder (PTSD), or anxiety disorders. Consistent with the standards mandated by the Prison Rape Elimination Act (PREA), I conducted assessments and provided treatment to incarcerated victims of sexual abuse.
- 9. In 2009, I was chosen for my first administrative oversight position within the BOP. In this capacity, I began to not only provide safe treatment and management directly, but to start giving guidance to others on how to create and maintain proper correctional environments through reliance on policy and accepted practices.
- 10. Five years later, I was promoted to a national level mental health position. My primary responsibility was the oversight, development, and implementation of substance use and mental health treatment programs. My work included ensuring these

services were relevant and beneficial to all individuals in BOP custody and addressing the care of transgender individuals was a large part of that work.

- 11. I had primary responsibility for ensuring BOPs residential treatment programs operated as modified therapeutic communities (MTCs). This is an evidencebased approach to residential substance use treatment designed to maximize the positive benefits of a supportive community that welcomes all members.¹
- 12. While serving in this role, I was asked to be the acting national administrator for psychology services. During this time, BOP's policies regarding transgender inmates advanced significantly, and I was part of those efforts. I advised both my supervisors and institution staff on the accepted practices in caring for this population. I also provided input on policy development, and as it was implemented, I provided consultation and expertise to BOP's Transgender Executive Committee (TEC) regarding placement for transgender people that maximized opportunities for access to mental health treatment, reentry programming, and personal safety. I collaborated with other subject matter experts to develop lesson plans for annual training provided to all BOP staff on a wide range of psychological issues, including the accepted practices in the management of transgender people in secure settings. Most importantly, I was in a national leadership role advising on the importance of providing individualized and affirming services to transgender people, and I saw the benefits of this approach firsthand.

¹ De Leon, George. (2000). *The Therapeutic Community*. Springer Publishing Company.

- 13. Throughout the course of my BOP career, I remained engaged in scientific research which I published and presented outside the agency. I also taught courses at the college level. I retired in 2023 and do part-time consulting and treatment work. My resume is attached as Exhibit A.
- 14. I am being compensated at the rate of \$500 per hour for my time completing this declaration.

BASES FOR OPINIONS

- 15. In preparing this report, I have relied on my training; my years of experience working in correctional settings and my specific experience within the BOP making care decisions about individuals who are transgender; my knowledge of the policies and practices surrounding these issues in both BOP and other correctional systems; and my knowledge of the relevant literature and standards.
- 16. In addition, in preparing this report, I have reviewed the following information to inform my opinion: the class action complaint filed March 10, 2025 and the two associated exhibits. I also reviewed publicly available materials as cited in this document.

BRIEF HISTORY OF BOP'S TRANSGENDER PRACTICES AND STANDARDS

17. As part of operating safe facilities, over the last several decades correctional systems have begun to have a better understanding of how to provide care to transgender inmates, just as they have provided care to individuals with any other

medical, mental health, learning, or other need. These efforts are supported by data demonstrating transgender individuals are both more likely to become involved in the justice system, and also more likely to experience sexual assault while incarcerated.² Thus, in service to operating a safe facility and meeting the agency mission, sound correctional practices have long included provision of individualized health care and accommodations to transgender or intersex persons.

- 18. In 2003, the Prison Rape Elimination Act (PREA) was signed into law, and in 2012, the Department of Justice published the PREA Final Rule, which included standards for implementing the statute.⁴⁵ PREA drew national attention to the needs of the incarcerated transgender population, and was the first federal law identifying best care practices. Five standards specify requirements addressing transgender persons in carceral settings.
- 19. One of those standards, PREA standard 115.42(c) establishes the necessity of individualized assessments, stating, "the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems." The Department of Justice

² Grant, Jaime M.; Mottet, Lisa A.; Tanis, Justin; Harrison, Jack; Herman, Jody L.; Keisling, Mara (2011). Injustice at Every Turn: A Report of the National Transgender Discrimination Survey (PDF) (Report). Washington: National Center for Transgender Equality and National Gay and Lesbian Task Force.

³ Beck, A. J., & Shandler, S. (2013). Sexual Victimization in Prisons and Jails Reported by Inmates, 2011-2012. U.S. Department of Justice, Bureau of Justice Statistics.

⁴ 28 CFR Part 115 National Standards To Prevent, Detect, and Respond to Prison Rape; Final Rule.

⁵ Prison Rape Elimination Act (PREA) of 2003 (P.L. 108-79).

also determined assigning housing to a transgender person based solely on genitalia is a violation of PREA.⁶

- 20. Mental health and medical treatment of transgender individuals was improving through the establishment of standards or accepted practices while PREA standards were being developed and issued. Research indicates, for example, that transgender individuals are at higher risk for suicide than non-transgender persons. ⁷ In 2015, the American Psychological Association issued guidance on working with transgender and non-binary individuals, including a key principle that "Psychologists strive to recognize the influence of institutional barriers on the lives of [transgender] people and to assist in developing [transgender]-affirmative environments." ⁸ Similarly, the American Medical Association has made a number of public statements supporting the importance of and right to access gender affirming interventions. 10
- 21. Meanwhile, BOP along with correctional systems across the country and world were developing procedures to ensure appropriate care for transgender inmates.

BOP POLICY AND PROCEDURES IMPACT

⁶ National PREA Resource Center. (2016). FAO: Does a policy that houses transgender or intersex inmates based exclusively on external genital anatomy violate Standard 115.42(c) & (e).

⁷ Marshall E, Claes L, Bouman WP, et al. (2016). Non-suicidal self-injury and suicidality in trans people: A systematic review of the literature. Int Rev Psychiatry. 28, 58–69.

⁸ American Psychological Association. (2015). *Guidelines for Psychological Practice* with Transgender and Gender Nonconforming People. American Psychologist, 70 (9), 832-864. Retrieved from https://www.apa.org/practice/guidelines/transgender.pdf ⁹ *Id.*, at 840.

¹⁰ See https://transhealthproject.org/resources/medical-organization-statements/americanmedical-association-statements/

- 22. The BOP is the largest correctional system in the United States and operates 122 prison facilities across the country. Facilities are classified into four security-level categories, and men and women are housed in separate units or facilities. Over 35,000 employees work for BOP.
- 23. BOP, like most correctional systems, utilizes policy and training as dual methods to ensure staff are complying with the law and using the most accepted and safest practices available. Any policy is developed in response to a need for guidance and grounded in science, law, and safety.
- 24. Going back to the beginning of my BOP career in 1999, BOP has recognized that individuals who are transgender or intersex may not easily fit into BOP's housing structure. Thus, senior officials at the agency have made decisions about the most appropriate housing for these persons, based on the safety of both the individual and others. Yet, BOP did not have a policy, and while transgender people did receive treatment and in some cases were housed in accordance with their gender identity, , the lack of agency directive raised questions as to how to best make such decisions.
- 25. Following the passage of PREA in 2003, BOP updated its policy on sexual abuse to ensure it was compliant with the statute and standards. ¹¹ In particular, the policy included language from the PREA standards and explained to staff in clear language the importance of individualized decision-making about the safety of transgender inmates.
 - 26. While staff became familiar with these standards and recognized the

¹¹ DOJ-BOP. (2015). Program Statement 5324.12, Sexually Abusive Behavior Prevention and Intervention.

benefits of the individualized approaches, questions also arose as to how to make the best, fairest, and safest decisions with regard to housing and health care treatment. Many staff, particularly in remote locations, were not well acquainted with transgender terminology, for example, or were not familiar with external guidance documents, such as the standards from the World Professional Association for Transgender Health (WPATH). 12 Further, BOP data demonstrated a significant over-representation of transgender persons in restrictive housing settings, often for safety instead of disciplinary reasons.

- 27. Individuals with gender dysphoria experience significant clinical distress and, as noted previously, are at increased risk for suicide. Before BOP implemented national policy that was consistent with the accepted practices in the care and management of transgender people in prison settings, it was my experience that transgender individuals in BOP custody were more likely to require services to manage mental health crises than incarcerated individuals who are not transgender. In cases of severe gender dysphoria, risks included attempts at self-surgery and suicide.
- 28. Thus, in 2016, BOP began to develop national policy and guidance on the management and treatment of transgender persons in custody. This meant that, consistent with BOP labor relationships agreements, agency leadership began meeting with union representatives to develop what would be published in January 2017 as the Transgender

¹² World Professional Association for Transgender Health. Standards of care. Retrieved from https://wpath.org/publications/soc8/

Offender Manual (TOM). 13 14

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- 29. Until recently, all policies issued by BOP underwent significant negotiation and review by both management and bargaining unit staff. Following several months of this review, the first TOM provided a great deal of information and direction to BOP staff. In addition to providing definitions, the policy set requirements for training, accommodations, pronoun usage, medical treatment, and housing placement.
- 30. I worked alongside the person leading TOM policy development, providing input specific to treatment and later helping her ensure implementation. Speaking about policy development, she described it as, "just a safe practice that comported with the law." The key components of the policy were identifying how to implement accepted practices and ensuring any gender affirming services were provided based on individual need.
- 31. The TOM also established clear parameters around a decision-making body, known as the Transgender Executive Council (TEC). Membership on this body included senior leaders from the Women and Special Populations Branch as well as the senior psychologist, psychiatrist, security expert, and medical administrator in the

¹³ DOJ-BOP. (2017, 2018, 2020). Program Statement 5200.08, Transgender Offender Manual.

¹⁴ The TOM was updated two times. The first update clarified factors in placement and the second elucidated surgery processes. The BOP has since deleted all versions of the TOM from its website as a result of President Trump's Executive Order. The most recent version, dated Jan. 13, 2022, is preserved and available at https://perma.cc/4BP6-YWRP and **is attached as Exhibit B**.

¹⁵ Schwartzapfel, B. (January 23, 2025). *Trump's Order Takes Aim at Transgender People in Prison*. The Marshall Project.

agency.

- 32. Although BOP had provided mental health and medical care before the TOM was issued, once the policy was in place, national administrators began to roll out training and supports for staff to ensure implementation was done with fidelity. Training was delivered to all employees, and advanced continuing education sessions were delivered to clinicians who delivered therapy or prescribe hormones.
- 33. In keeping with these efforts to ensure treatment was tied to evidence and that guidance was available, the BOP's Health Services Division also created a Transgender Clinical Care Team (TCCT) made of experienced medical professionals who could offer guidance to prescribers working in the prisons who may not have expertise in endocrinology or the prescription of hormones. Importantly, clinical assessments for hormone medication or other medical treatments included assessments by both psychologists and medical providers for the presence of gender dysphoria. In other words, to receive medical treatment, a person must actually have a condition warranting such an approach. Hormones or surgeries were provided only based on individual clinical need. Attached as Exhibit C are the most recent version of the clinical guidelines for health care staff, dated June 2023. Again, these guidelines were taken down from the BOP website after President Trump's Executive Order, but are also preserved at https://perma.cc/U5UT-S9PN. These clinical guidelines were an update of the previous guidelines from health care staff that had been operative since December 2016.
- 34. At the same, mental health procedures were developed to guide psychologists in the best ways to treat transgender people. While psychologists do not

prescribe medication in BOP, they were taught the benefit of gender affirming care, including hormones, in improving safety and wellbeing. This same information was conveyed to all staff because gender affirming care can reduce distress.

- 35. Support groups and other types of mental health treatment were also developed, eventually becoming part of BOP's list of approved programs under the First Step Act.
- 36. Accommodations were also described in policy, again as ways to better care for and manage the inmate population. Accommodations included allowing for the use of preferred pronouns and the provision of undergarments to match gender identity. Individuals were also given the option to purchase gender affirming items other than medication and undergarments that were allowed inside prison but required the use of personal funds (such as make-up). As noted, these items were intended to improve individual functioning, decrease crises, and therefore not only improve individuals' health but also make prisons safer.
- 37. Finally, the TOM created clear processes and benchmarks for a transgender individual to potentially be housed at a facility that aligns with their gender identity. The TOM took an approach grounded in safety where decisions were made by the TEC based on a number of factors and requirements.
- 38. Within a few years of the TOM's issuance in January 2017, BOP staff had fully implemented the policy. Gender affirming care was consistently available when indicated, and transgender people were afforded greater opportunities for engagement and positive programming that reduced psychological distress, reduced sexual

victimization, increased personal and institutional safety, and improved reentry outcomes.

Agency policies direct consistent practice across all components and are reinforced by positive outcomes, and the TOM was no different.

DISCUSSION AND ANALYSIS OF RECENT BOP POLICY CHANGES

- 39. In early 2025, BOP abruptly rescinded a number of policies, including the TOM, following a Presidential Executive Order. BOP staff were suddenly operating without a policy but no guidance about what services or practices were supposed to replace the policy.
- 40. On February 21, 2025, Dana DiGiacomo, Acting Assistant Director of the BOP Reentry Services Division, and Shane Salem, Assistant Director of the BOP Correctional Programs Division, two individuals with whom I worked at BOP, issued a memo clarifying that BOP had been temporarily blocked by legal action from removing medical and mental health care from transgender persons in custody, but was proceeding with other restrictions. (This memo is filed with the Court at Docket 1-1.) Specifically, the aforementioned accommodations of gender affirming pronouns, undergarments, and purchased personal items were to cease. Additionally, programs for transgender persons and training on accepted practices with them stopped. Finally, the TEC itself was renamed and repurposed. Despite being authored by two individuals with no professional expertise on transgender care and no clinical degrees, the memo also indicated the TEC would no longer refer people for surgery.
- 41. A week later, Chris Bina, a pharmacist who leads BOP's Health Services Division, issued a memo stating no BOP funds could be used to treat any transgender

person in a way that validates their gender identity. It specifically states that "no Bureau of Prisons funds are to be expended for any medical procedure, treatment, or drug for the purpose of conforming an inmate's appearance to that of the opposite sex." (This memo is filed with the Court at Docket 1-2.)

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- 42. The blanket ban on gender affirming care, is not only inconsistent with PREA and professional association guidance, it is also unsafe.
- 43. First, BOP's TOM was consistent with the law and medical standards. It served not only as a guide for BOP, but for other systems because it was effective. ¹⁶ The TOM was tied to PREA, whereas the new BOP approach is inconsistent with the individualized approach to housing required under PREA. Similarly, the new BOP approach is not consistent with psychological or medical association positions on the importance of delivering individualized gender affirming care and treatment to transgender persons who have a clinical need for that care.
- 44. Not only are these new BOP directives incompatible with accepted practices and law, they can cause significant harm and danger. Denying gender-affirming hormones to patients with a clinical need for such treatment has negative consequences, including causing or exacerbating distress and depression. Additionally, denying hormone therapy and access to other accommodations and treatments for gender dysphoria will bring about the return of the dysphoric symptoms, potentially causing

¹⁶Murphy, M., Et. al. (2023). *Implementing Gender-Affirming Care in Correctional Settings: A Review of Key Barriers and Action Steps for Change*. Journal of Correctional Health, 29(1).

attempts to self-castrate, self-harm, suicide, and aggression. All of these create safety concerns not only for people who are transgender, but for everyone who works or is incarcerated in the entire system. And with BOP's staffing crisis, there simply are not enough clinicians to manage the increased suicide watches and crisis, which could be deadly.¹⁷

45. Instead, BOP's former approach of providing gender affirming health care when indicated, as well as accommodations that support social transition under the TOM, was effective in maintaining transgender individuals' health and promoting institutional safety. Providing this care improves the agency goals of security and rehabilitation. Prohibiting such care undermines these goals.

CONCLUSION

- 46. BOP has the responsibility of managing and treating everyone in its custody, which means individuals with all sorts of health issues and conditions, including people who have gender dysphoria.
 - 47. Treatment and care in BOP involves evidence-based approaches, and has

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¹⁷ Separate from the changes specific to transgender policies, BOP for years has experienced a crisis of custody and health care staffing shortages. Staffing shortages are evident across every job type, from psychologists to correctional officers. Moreover, under the new Administration, BOP announced that it will "greatly reduce, and in some cases eliminate, retention incentives across the agency, effective March 23, 2025." *See* Testimony of Kathleen Toomey, BOP Associate Deputy Director, before the U.S. House Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies during a hearing on Oversight of the Federal Bureau of Prisons, Feb. 26, 2025, at https://docs.house.gov/meetings/AP/AP19/20250226/117920/HHRG-119-AP19-Wstate-ToomeyK-20250226.pdf. This cut in salaries is likely to worsen staffing problems. As a result of these staffing shortages, all incarcerated individuals – not only those who are transgender - are likely to receive less medical and mental health care than they need.

always been individualized. Not only does it comport with the law, but it is also an accepted practice to provide treatment and accommodations based on individual factors. Prisons that support individual needs are safer and have fewer crises. I have grave concerns about the well-being of transgender individuals in BOP custody and the continued safe operations within BOP, should its ban on providing individualized care to transgender persons continue.

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

Executed on this 17th day of March, 2025.

Dr. Cathy Thompson

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EXHIBIT A

EXHIBIT A – RESUME OF CATHY THOMPSON

EDUCATION

Ph.D. in Clinical Psychology – Texas Tech University (APA Accredited), 2000 Dissertation: Gender Effects, Consistency, and Assessment in Coping Licensed Clinical Psychologist – Texas State Board of Examiners of Psychologists (Since 2002)

M.A. in Clinical Psychology – Texas Tech University (APA Accredited), 1996

B.A. in Psychology (Summa Cum Laude) – Texas Tech University, 1992
 Minor: Family Studies
 Member of Psi Chi & National Golden Key Honor Society

PROFESSIONAL EXPERIENCE

2025 - Present Consultant AMM Solutions Washington D.C.

Provide consultation, training and subject matter expertise to include investigative support, litigation support and expert witness testimony on a wide range of correctional and mental health topics. Analyze complaints to develop mitigation reports or strategy guidance. Deliver workshops and design curricula and interventions.

2024 - Present Clinical Psychologist, Owner Thompson & Associates Psychological Services, PLLC North Richland Hills, TX

Provide comprehensive psychological services to a diverse client population. Administer psychological assessments to inform diagnosis and individualized treatment planning. Conduct individual therapy sessions for clients dealing with anxiety, depression, trauma, and relationship issues using evidence-based interventions. Offer expert guidance on substance use treatment, stress management, and behavioral interventions.

2024 - Present Trainer and Consultant The Change Companies Carson City, NV Develop and deliver training on evidence-based interventions, program fidelity, and best practices in behavioral health treatment. Consult with organizations and professionals to enhance the implementation of evidence-based practices in behavioral health and substance use treatment. Facilitate workshops and provide expert guidance on treatment effectiveness, compliance, and program development strategies.

2018 - 2023

National Chief of Drug Treatment Programs/Acting National Psychology Services Administrator Federal Bureau of Prisons (Department of Justice) Washington, D.C.

Responsible for coordinating and evaluating all services and activities of the agency's substance use treatment programs (both residential and non-residential) for federal offenders incarcerated in over 120 correctional facilities. Coordinated a system of technical assistance and training to ensure compliance with policy and best standards of clinical practice as related to all facets of correctional psychology. Analyzed information and provided recommendations for the formulation, establishment, or modification of program objectives, plans, and policies. Managed a \$15M+ budget and supervised a diverse team of psychologists, clinicians, and administrative staff. Responded to high-level inquiries from various oversight bodies, including the Government Accountability Office (GAO) and the Office of the Inspector General (OIG). Served as senior agency psychologist on Transgender Executive Committee.

2015 - 2018 Supervisory Psychology Treatment Program Coordinator Federal Bureau of Prisons (Department of Justice) Washington, D.C.

Led teams of subject matter experts who provided on-site technical assistance and training to ensure compliance with policy and best standards of clinical practice as related to all facets of correctional psychology. Supervised a multidisciplinary team, including psychologists, clinicians, and administrative personnel. Spearheaded a major update of the agency's data analysis system to enhance tracking and ensure program utilization targets were met.

2013 - 2015 Psychology Treatment Program Coordinator Federal Bureau of Prisons (Department of Justice) Annapolis Junction, MD

Provided on-site technical assistance and training to ensure compliance with policy and best standards of clinical practice as related to all facets of correctional psychology. Served as the Employee Assistance Program Coordinator for Regional Office staff,

providing support and resources to enhance employee well-being. Engaged in staff recruitment efforts to attract and retain top talent within the agency.

2009 - 2013 Transitional Drug Abuse Program Coordinator Federal Bureau of Prisons (Department of Justice) Annapolis Junction, MD

Responsible for the procurement and administration of over 45 contracts for community-based substance use, mental health, and sex offender treatment, ensuring compliance with regulations, performance standards, and fiscal accountability. Managed a \$15M+ budget and supervised a diverse team of clinicians and administrative staff.

1999 - 2009 Additional Roles

Federal Bureau of Prisons (Department of Justice)

Internship Program Coordinator – Developed and implemented a pre-doctoral psychology internship program, gaining agency approval. Coordinated site registration, designed training rotations, and authored the Internship Brochure and Training Manual. Managed application reviews, interview processes, and applicant ranking. Provided clinical and administrative supervision of interns and psychologists.

Challenge Program Coordinator – Managed a large residential treatment program for high- security male offenders, addressing substance use and mental health needs. Provided therapy, crisis intervention, psychological evaluations, and suicide risk assessments for all incarcerated individuals, including women, transgender people, and veterans. Provided clinical and administrative supervision of subordinate staff.

Step-Down Program Coordinator – Managed a large residential treatment program for severely mentally ill male offenders. Provided therapy, crisis intervention, psychological evaluations, and suicide risk assessments for all incarcerated individuals, including special populations such as transgender people and veterans. Provided clinical and administrative supervision of subordinate staff.

Drug Abuse Program Coordinator – Managed a non-residential drug abuse program at a medium-security federal prison. Provided individual and group therapy, crisis intervention, and suicide risk assessments. Served as a Mental Health Consultant for the Hostage Negotiation Team. Provided clinical and administrative supervision of subordinate staff.

Post-Doctoral Psychologist – Conducted individual and group psychotherapy for male offenders. Completed forensic evaluations to determine competency and responsibility.

Managed the Suicide Prevention Program, conducted extensive audits of departmental operations, delivered staff training, and consulted with Human Resources regarding hiring of qualified personnel.

TEACHING EXPERIENCE

Contributing Faculty – Adtalem Global Education (2004–Present)

Responsible for instructing graduate foundational and advanced graduate psychology courses, serving as dissertation committee member, and overseeing practicum/internship field experiences.

Adjunct Instructor – South Plains Junior College (1995–1999)

Responsible for all phases of teaching undergraduate General Psychology and Human Growth and Development courses, including the preparation and administration of lectures, construction and administration of examinations, and the computation and assignment of course grades. Lecture format with approximately 25 undergraduate students per semester. Fourteen sections taught.

Adjunct Instructor – Texas Tech University (1995–1997)

Responsible for all phases of teaching a senior-level undergraduate Abnormal Psychology course, including the preparation and administration of lectures, construction and administration of examinations, and the computation and assignment of course grades. Lecture format with approximately 50 undergraduate students per semester. Five sections taught.

PROFESSIONAL AFFILIATIONS

Member, American Psychological Association (APA) (Since 1995) Member, APA Division 18: Psychologists in Public Service (Since 2000)

PUBLICATIONS & PRESENTATIONS

Publications:

Cook, S. W., Thompson, C. L., & Coca-Lyle, V. A. (2000). The psychology of stress and coping. In Management of Stress and Eating Disorders for Women and Children (2nd ed.), CRC Press.

Selected Presentations:

Thompson, C. L. (2023, August). Substance use disorders and treatment options for justice-involved populations. Presentation given at the 2023 National Pretrial Services Leadership Conference.

Thompson, C. L. (2022, August). Meeting the needs of incarcerated women: Best

- practices. Presentation given at the American Psychological Association National Convention, Minneapolis, MN.
- Thompson, C. L. (2021, November). Treatment of substance use and associated mental illness in the federal prison system in the United States. Presentation given at the United Nations Office on Drugs and Crime technical consultation.
- Thompson, C. L. (2019, August). Federal Bureau of Prisons: Drug abuse programs.

 Presentation given at the American Psychological Association National
 Convention,
 Chicago, IL.
- Thompson, C. L. (2012, May). Evolving perspectives on reentry. Presentation given at the 2012 Mid-Atlantic Regional Contractors Conference, Nashville, Tennessee.
- Thompson, C. L., & Cook, S. W. (2000, August). Dispositional versus situational assessment, consistency, and gender effects in coping. Poster presentation given at the American Psychological Association National Convention, Washington, DC.

KEY SKILLS & EXPERTISE

Clinical Psychology & Mental Health

Licensed clinical psychologist with over 20 years of experience Expertise in psychological assessments, therapy, and crisis intervention Expertise in special populations, including women, veterans, and transgender people

Specialized in substance use treatment, trauma, and evaluations

Corrections & Criminal Justice

Extensive career in the Federal Bureau of Prisons, holding leadership roles Developed and managed residential and non-residential treatment programs for incarcerated individuals

Expertise in correctional policy, reentry programs, and offender rehabilitation Program Development & Administration

Designed and implemented large-scale treatment programs for diverse correctional populations and settings

Managed budgets exceeding \$15M and supervised multidisciplinary teams Developed training curricula for behavioral health professionals Ensured policy compliance and program effectiveness through auditing and technical assistance

Leadership & Executive Management

Served as National Chief of Drug Treatment Programs for the Federal Bureau of Prisons

Led national teams of psychologists, clinicians, and administrative staff

Provided expert consultation and support in correctional psychology Experienced in soliciting, awarding, and managing federal contracts

Teaching & Academic Contributions

Contributing faculty member for graduate psychology programs since 2004 Extensive experience in curriculum development and dissertation advisement Taught undergraduate and graduate courses in psychology for multiple institutions

Public Speaking & Expert Testimony

Speaker at national and international conferences on substance use, reentry, and correctional psychology

Presented at the American Psychological Association National Convention and United Nations Office on Drugs and Crime

Provided expert witness testimony and consultation on legal cases involving mental health and corrections

Publications & Research

Published works in psychology and behavioral health, focusing on stress, coping, and substance use disorders

Conducted research on gender effects in coping and correctional psychology

Dr. Thompson's expertise spans clinical psychology, correctional mental health, program administration, and policy development, making her a leader in the field of correctional psychology and behavioral health treatment.

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EXHIBIT B



PROGRAM STATEMENT

OPI: RSD/WASPB

NUMBER: 5200.08

DATE: January 13, 2022

Transgender Offender Manual

/s/

Approved: M.D. Carvajal

Director, Federal Bureau of Prisons

1. PURPOSE AND SCOPE

To ensure the Bureau of Prisons (Bureau) properly identifies, tracks, and provides services to the transgender population.

- **a. Program Objectives**. Expected results of this program are:
- This policy provides guidance to staff in dealing with the unique issues that arise when working with transgender inmates.
- Institutions ensure transgender inmates can access programs and services that meet their needs as appropriate, and prepare them to return to the community.
- Sufficient resources will be allocated to deliver appropriate services to transgender inmates.
- Staff will complete training, enabling them to work effectively with transgender inmates.
- To enhance staff's understanding of the increased risk of suicide, mental health issues and victimization of transgender inmates.

b. Summary of Changes

Rescinded P5200.04 CN-1 Transgender Offender Manual (5/11/2018)

This reissuance incorporates the following modifications:

- Clarified duties and responsibilities of various staff.
- Added an institution requirement for maintaining a copy of the Case Management Activity (CMA) Assignment form BP-A1110, Consent Form for Transgender Inmates. Inmates can no longer request to have a CMA assignment removed, and then re-added at a later date.
- Clarified transfer, consultation, and program requirements.

■ Updated guidance regarding initial designation and redesignation procedures for transgender offenders.

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- Added information about gender affirming surgery.
- c. **Institution Supplement**. None required. Should local facilities make any changes outside changes required in national policy or establish any additional local procedures to implement national policy, the local Union may invoke to negotiate procedures or appropriate arrangements.

2. **DEFINITIONS**

Gender – a construct used to classify a person as male, female, both, or neither. Gender encompasses aspects of social identity, psychological identity, and human behavior.

Gender identity – a person's sense of their own gender, which is communicated to others by their gender expression.

Gender expression – includes mannerisms, clothing, hairstyle, and choice of activities.

Gender nonconforming – a person whose appearance or manner does not conform to traditional societal gender expectations.

Transgender – the state of one's gender identity not matching one's sex assigned at birth. For the purposes of this policy, a transgender inmate is one who has met with a Bureau Psychologist and signed the form indicating consent to be identified within the agency as transgender. This step allows accommodations to be considered.

Cisgender – the state of one's gender identity matching one's sex assigned at birth.

Sexual orientation – the direction of one's sexual interest towards members of the same, opposite, or both genders (e.g., heterosexual, homosexual, bisexual, asexual). Sexual orientation and gender identity are not related.

Gender Dysphoria (GD) – a mental health diagnosis currently defined by DSM-5 as, "A strong and persistent cross-gender identification. It is manifested by a stated desire to be the opposite sex and persistent discomfort with his or her biologically assigned sex." Not all transgender inmates will have a diagnosis of GD, and a diagnosis of GD is not required for an individual to be provided services.

Intersex – a person whose sexual or reproductive anatomy or chromosomal pattern does not seem to fit typical physiological definitions of male or female. Not all intersex people identify as

transgender; unless otherwise specified, this policy does not apply to intersex people who do not identify as transgender.

Transition – measures that change one's gender expression or body to better reflect a person's gender identity.

Gender Affirming – describes behaviors or interventions that support the gender identity of a person.

3. STAFF RESPONSIBILITIES

The following Bureau components are responsible for ensuring consistent establishment of the programs, services, and resource allocations necessary for transgender offenders.

a. Central Office

- (1) The **Women and Special Populations Branch (WASPB)** is the agency's primary source and point of contact on accommodation/transition, classification, management, and intervention/treatment programs and practices for transgender inmates in Bureau custody. The Branch is responsible for the following functions as they relate to transgender inmates:
- Engaging stakeholders, including serving as the primary point of contact on issues affecting transgender inmates with external entities including judges, congress, and advocacy groups.
- Ensuring the Bureau offers appropriate services to transgender inmates.
- Preparing budget requests to deliver national and pilot programs or services affecting transgender inmates.
- Providing guidance and direction to staff and institution, region, and agency leadership on transgender issues.
- Developing and implementing staff training on transgender issues.
- Building a research-based foundation for the Bureau's work with transgender inmates, including implementation support and intervention services.
- Presenting at internal and external conferences/events regarding the agency's transgender inmates' practices.
- Developing and monitoring monthly reports on the transgender population and institutional programs.
- Conducting an annual survey of transgender inmates in the Bureau and sharing results with internal and external stakeholders.
- Providing national oversight of pilot programs and initiatives serving transgender offenders.
- Overseeing the Transgender Executive Council (TEC).
- Ensure that a National Program and Policy Coordinator is assigned to each Region who will meet quarterly to discuss staffing and programming needs of transgender inmates.

(2) The **Health Services Division** oversees all medical and psychiatric guidance and treatment as it applies to transgender inmates. Clinical guidance on the most current research-driven clinical medical and psychiatric care of transgender inmates will be provided at the direction of the Medical Director. The Medical Director only receives referrals from the TEC and determines whether gender affirming surgery requests will be referred to a surgeon.

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- (3) The **Psychology Services Branch** oversees all mental health programs and services as they apply to transgender inmates, to include providing advice and guidance on identification and evaluation of transgender inmates, and making recommendations for treatment needs of transgender inmates and/or inmates with GD.
- (4) **Central Office Branches** of Correctional Services, Psychology Services, Education, Correctional Programs, Reentry Affairs, Residential Reentry Management, Health Programs, Litigation, Chaplaincy Services, Intelligence and Counter Terrorism Branch, and Trust Fund meet annually with the Women and Special Populations Branch to discuss transgender population needs and evaluate current gender-responsive services. The National Union and the Central Office LGBT Special Emphasis Program Manager will be invited to attend these meetings.
- (5) The **Transgender Executive Council** (**TEC**) will consist of senior level staff members (GS-14 and above) from the Women and Special Populations Branch, the Psychology Services Branch, Health Services Division, and the Designation and Sentence Computation Center (DSCC). The team is led by the Senior Deputy Assistant Director, Reentry Services and also includes the Senior Deputy Assistant Director, Correctional Programs Division (DSCC), and the Senior Deputy Assistant Director, Health Services. The TEC is the agency's official decision-making body on all issues affecting the transgender population. It will meet a minimum of monthly to offer advice and guidance on unique measures related to treatment and management needs of transgender inmates and/or inmates with GD, including training, designation issues, and reviewing all transfers for approval. Staff or inmates may raise issues on specific inmates to the TEC through the Women and Special Populations Branch. The Office of General Counsel is consulted as needed.

b. Regional Offices

 Provide oversight to institutions regarding services and other relevant trends managing transgender inmates.

c. Institutions

The Warden will establish a multi-disciplinary approach to the management of transgender inmates. The Associate Warden of Programs is the primary point of contact in the institution for transgender issues and will consult as needed with the Chief Psychologist, Captain, Clinical

Director, Unit Manager, or other individuals as appropriate; and specifically to:

- Ensure transgender inmates have access to services.
- Enter tracking information for self-identified transgender inmates by updating SENTRY CMA assignments and other databases (e.g., PDS).
- Maintain a copy of the Case Management Activity (CMA) SENTRY Assignment Consent Form for Transgender Inmates (BP-A1110) in the Central File and Psychology Data System (PDS).
- Provide appropriate reentry resources that may be specific to the population.
- Advise the Local Union of transgender inmate management issues.
- Consult and refer transgender inmates to the TEC.
- Provide programming developed by the Reentry Services Division for transgender inmates.

4. STAFF TRAINING

Staff are provided specialized training in working with unique issues when managing transgender inmates as part of annual training. Institutions housing transgender inmates should provide additional training.

The Women and Special Populations Branch is responsible for developing training materials and current information on the management of transgender inmates. This information will be made available to staff via the Bureau's intranet.

In addition, the Prison Rape Elimination Act (PREA) regulations incorporated into the BOP Program Statement, **Sexually Abusive Behavior Prevention and Intervention Program** have training requirements concerning pat searches and communication skills for transgender inmates. See 28 C.F.R. § 115.15(f) and 115.31 (a) (9). Please refer to this Program Statement regarding implementation of those training requirements.

Staff will be provided adequate time to complete these trainings during duty hours. Staff will be provided proper relief to complete the training.

5. INITIAL DESIGNATIONS

The PREA regulations (section 28 C.F.R. § 115.42 (c)), incorporated into the Program Statement **Sexually Abusive Behavior Prevention and Intervention Program**, state:

"In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates...the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems."

Upon receipt of information from a Pre-Sentence Report, court order, U.S. Attorney's Office, defense counsel, the offender, or other source that an individual entering BOP custody is

transgender or intersex, designations staff will refer the matter to the TEC.

Institution staff managing pretrial or holdover offenders must also refer cases to the TEC for review. Any TEC recommendations concerning pretrial inmates will be coordinated with the appropriate United States Marshals Service District Office.

The TEC will consider factors including, but not limited to, an inmate's security level, criminal and behavioral/disciplinary history, current gender expression, programming, medical, and mental health needs/information, vulnerability to sexual victimization, and likelihood of perpetrating abuse. The TEC may also consider facility-specific factors, including inmate populations, staffing patterns, and physical layouts (e.g., types of showers available). The TEC will consider the wellbeing of all inmates while exploring appropriate options available to assist with mitigating risk to the inmate, to include but not limited to cell and/or unit assignments, application of management variables, programming missions of the facility, and security of the institution.

It will be documented on all SENTRY designation notes for transgender inmates that the TEC reviewed the inmate for appropriate institution designation.

6. HOUSING AND PROGRAMMING ASSIGNMENTS

During Initial Classification and subsequent Program Reviews, unit management staff will review the inmate's current housing unit status and programming available for transgender inmates. This review will be documented by Unit Management staff in the inmate central file and for holdovers in the holdover file, with institution oversight by the Associate Warden.

The reviews will consider on a case-by-case basis that the inmate placement does not jeopardize the inmate's wellbeing and does not present management or security concerns.

In making housing unit and programming assignments, a transgender or intersex inmate's own views with respect to his/her own safety must be given serious consideration.

Transgender inmates shall be given the opportunity to shower separate from other inmates when individual shower stalls are unavailable.

The agency shall not place transgender or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status. The only exception is if such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

Wardens will consult with WASPB prior to submitting a designation request to the DSCC for the redesignation of transgender inmates when the designation is related to the individual's

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transition. The DSCC and Office of Medical Designations will consult with WASPB prior to the designation or redesignation of all transgender inmates.

In situations where the transfer request is related to progressing the individual inmate's transition (i.e., transfer to a different sex facility) the TEC will consider the case. Prior to considering the case, the Warden will submit documentation to the TEC showing the inmate has met the minimum standards of compliance with programs, medications and mental health treatment, and meeting hormone goal levels. Ordinarily, inmates will not be submitted to the TEC for consideration until they have maintained one year clear conduct for 100 and 200 series incident report sanctions, though they may be considered for submission on a case-by-case basis by the Warden, as appropriate.

It will be noted in all SENTRY designation notes that the TEC reviewed the inmate for appropriate institution designation.

7. DOCUMENTATION AND SENTRY ASSIGNMENTS

The PREA regulations in 28 C.F.R. part 115, Subpart A, incorporated into the Program Statement Sexually Abusive Behavior Prevention and Intervention Program and the Program Statement Intake Screening, address intake screening. Screening of transgender inmates will be conducted in accordance with these policies and all other applicable policies and procedures.

- a. Medical and Mental Health Information. Medical and mental health information for transgender inmates will be maintained in the current electronic recordkeeping system or health record system in accordance with the Program Statements Health Information Management and Psychology Services Manual. Medical and mental health information is considered confidential, and may only be released in accordance with appropriate laws, rules, and regulations.
- **b. Initial Screening**. For initial designations, staff will assign Case Management Activity (CMA) SENTRY assignments if information in the PSR or other documentation indicates a likely transgender identity. The screening codes are:

SCRN M2F – inmate should be screened for male to female transgender identification. SCRN F2M – inmate should be screened for female to male transgender identification.

Any inmate arriving at the designated institution with a screening code is to be referred to the Chief Psychologist or designee for review within 14 days. If the code was assigned in error, the screening code will be removed by the Psychologist. If the inmate identifies as transgender, the psychologist will replace the screening code with an identifying code, as indicated below. Holdover facilities are exempt from this initial screening requirement, as limited available

records and brevity of stay do not typically allow for a comprehensive screening.

Any inmate who arrives without a screening code but identifies as transgender during intake, or at any time during the incarceration period, is referred to the Chief Psychologist or designee and interviewed within 14 days of the inmate notification. Inmates in pretrial status at Bureau facilities may also receive a transgender screening CMA SENTRY assignment.

c. Notification to Staff and Tracking. After consultation with Psychology Services, and if the inmate affirms his/her transgender identity, the screening code will be updated to a permanent assignment by a Psychologist:

TRN M2F – inmate identifies as male to female transgender (transgender female). TRN F2M – inmate identifies as female to male transgender (transgender male).

The inmate must request to Psychology Services staff that the Case Management Activity (CMA) assignment be entered, and the inmate consents that all staff will therefore be notified that the individual is transgender. The inmate's request will be documented on a Case Management Activity (CMA) SENTRY Assignment Consent Form for Transgender Inmates (BP-A1110). Psychology Services shall maintain the form in the electronic mental health record.

Staff should consult the transgender CMA assignment when interacting with the inmate; e.g., use of pronouns and access to accommodations. All inmates have access to transgender treatment, regardless of assignment.

If there are questions about the need to continue a CMA assignment, the Warden will contact the WASPB. Inmates may request in writing to have CMA assignments removed. If this occurs, ordinarily the assignment will not be re-added at a later date.

8. HORMONE THERAPY AND MEDICAL TREATMENT

Hormone therapy or other medical treatment may be provided after an individualized assessment of the requested inmate by institution medical staff. Medical staff will request consultation from Psychology Services regarding the mental health benefits of hormone or other medical treatment. If appropriate for the inmate, hormone treatment will be provided in accordance with the Program Statement Patient Care and relevant Clinical Guidance. Questions concerning hormone treatment may be referred to the WASPB or the Health Services Division.

In the event this treatment changes the inmate's appearance to the extent a new identification card is needed, the inmate will not be charged for the identification card as is standard practice.

9. SURGERY

While not all inmates who identify as transgender may be interested in seeking surgical intervention, such a decision does not preclude them from obtaining other accommodations as described in this Program Statement. For transgender inmates in Bureau custody, surgery may be the final stage in the transition process and is generally considered only after one year of clear conduct and compliance with mental health, medical, and programming services at the gender affirming facility. Once that period elapses, an inmate may submit a request to his or her Warden requesting surgical consideration. The Warden will forward the request to the TEC. The TEC is the sole body who may determine that all milestones and individual goals for surgical consideration have been met. When this occurs, the case is referred to the agency's Medical Director for medical consideration. He or she may review existing records and/or interview the inmate, institution staff, and members of the TEC. After this individualized assessment, the Medical Director will determine if the surgery is medically appropriate for referral to a gender affirming surgeon.

10. OTHER MENTAL HEALTH SERVICES

Bureau Psychologists provide assessment and treatment services for transgender inmates, as appropriate. Guidance on assessment procedures is available on the Psychology Services intranet page.

If an inmate identifies as transgender, the Psychologist will provide the inmate with information regarding the range of treatment options available in the Bureau and their implications. In addition, based upon the Psychologist's preliminary assessment and the inmate's expressed interest, a referral to the Clinical Director and/or Chief Psychiatrist may be generated. While the initial interview must be scheduled within 14 days, an assessment may take longer in some instances.

In addition to a referral for medical services, a transgender inmate may be offered individual psychotherapy. Individual psychotherapy goals might include: (1) helping the inmate to live more comfortably within a gender identity and deal effectively with non-gender issues; (2) emphasizing the need to set realistic life goals related to daily living, work, and relationships, including family of origin; (3) seeking to define and address issues that may have undermined a stable lifestyle, such as substance abuse and/or criminality; and (4) addressing any co-occurring mental health issues. Mood disorders, anxiety disorders, substance use disorders, and personality disorders, etc., may also be present; any effective treatment plan will fully address these symptoms. Group treatment may also be recommended.

Common concerns of transgender inmates, which can be addressed effectively in a group setting, include self-esteem issues and relationship issues.

Psychologists who provide mental health treatment for transgender inmates address all mental health needs, including suicide risk, if present. If an inmate who identifies as a transgender harms, attempts to remove, or removes his or her genitalia or other gender-specific anatomy, a suicide risk assessment is conducted consistent with the Program Statement, Suicide Prevention Program. In addition, the treating psychologist notifies the Chief Psychologist who in turn notifies the Regional Psychology Services Administrator and the Psychology Services Branch.

Psychologists working with transgender inmates are encouraged to consult the Reentry Services Division in Central Office for additional resources.

11. SPECIAL POPULATIONS SERVICES

Some facilities have Special Populations Coordinators on staff. These individuals are responsible for delivering First Step Act and other programs, which includes programs developed specifically for inmates who identify as transgender. In the absence of such staff, the Warden will seek consultation from WASPB regarding the delivery of group interventions and services.

12. PRONOUNS AND NAMES

Staff interacting with inmates who have a CMA assignment of transgender, shall either use the authorized gender-neutral communication with inmates (e.g., by the legal last name or "Inmate" last name) or the pronouns associated with the inmate's identified gender. Deliberately and repeatedly mis-gendering an inmate is not permitted.

The name entered on the inmate's Judgment and Commitment Order is the official committed name for all Bureau records (incident reports, progress reviews, sentence calculations, etc.). An official committed name change while in BOP custody must be done consistent with the Program Statement Correctional Systems Manual. Any additional names or aliases should be entered into SENTRY, as appropriate.

13. PAT SEARCH ACCOMMODATIONS

Pat searches of transgender inmates will be conducted in accordance with the Program Statement Searches of Housing Units, Inmates, and Inmate Work Areas.

Pat search information refers only to individuals at male facilities who identify as female. The Bureau does not offer "male only" pat searches.

Unless there is a history of inappropriate sexual behavior suggesting approval poses risks to staff, requests are ordinarily approved by the Warden's Office. Inmates may request denials be reviewed by the TEC through the Administrative Remedy Program. Inmates who are granted this exception under policy may have it reversed by the Warden if found to have violated

institution rules concerning contraband.

In exigent circumstances, any staff member may conduct a pat search of any inmate consistent with the Program Statement Searches of Housing Units, Inmates, and Inmate Work Areas.

14. VISUAL SEARCHES

For purposes of a visual search, inmates will be searched in accordance with the gender of the institution, or housing assignment, to which they are assigned. The visual search shall be made in a manner designed to ensure as much privacy to the inmate as practicable. Staff should consider the physical layout of the institution, and the characteristics of an inmate with a transgender CMA assignment, to adjust conditions of the visual search as needed for the inmate's privacy.

Transgender inmates may also request an exception to be visually searched by a staff member of the inmate's identified gender. The exception must be pre-authorized by the Warden, after consultation with staff from Health Services, Psychology Services, Unit Management, and Correctional Services. Exceptions must be specifically described (e.g., "visual search only by female staff"), clearly communicated to relevant staff through a memorandum, and reflected in SENTRY (or other Bureau database). Inmates should be provided a personal identifier (e.g., notation on identification, etc.) that indicates their individual exception, to be carried at all times and presented to staff prior to visual searches.

Inmates request an exception by submitting an Inmate Request to Staff (BP-A0148) to the Warden. The Warden will consult with the departments listed above, and the memo approving or denying the request will be generated by the Warden's Office. Inmates may request denials be reviewed by the TEC through the Administrative Remedy Program. Inmates who are granted this exception may have it reversed by the Warden if found to have violated institution rules concerning contraband.

Transgender inmates placed at an institution or in a housing unit that does not correspond with their identified gender, and who are granted an exemption as indicated above, will be searched by staff of the inmate's identified gender who consent to participate in the search, or Health Services clinical staff.

Transgender inmates placed at an institution or in a housing unit of their identified gender will be searched by staff of the inmate's identified gender who consent to participate in the search or medical staff.

Institutions should consider using available body scanning technology in lieu of visual searches of transgender inmates.

In exigent circumstances, any staff member may conduct a visual search of any inmate consistent with the Program Statement Searches of Housing Units, Inmates, and Inmate Work Areas.

15. CLOTHING, COMMISSARY ITEMS, AND OTHER ACCOMMODATIONS

Consistent with safety and security concerns, inmates with the CMA assignment of transgender will have the opportunity to have undergarments of their identified gender even if they are not housed with inmates of the identified gender. Institutional laundry will have available institutional undergarments that fulfill the needs of transgender inmates. Undergarments will not have metal components.

Standardized lists of Commissary items for transgender inmates are available in accordance with the Program Statement Trust Fund/Deposit Manual and the information on the RSD intranet page.

Additional items based on an individualized assessment of the transgender inmate population may be approved by the Warden. Additional items may be provided by the institution or purchased by the inmate, as appropriate. Any concerns regarding such items are directed to the WASPB.

Inmates who purchase and/or are provided items under this section will be subject to disciplinary sanctions, including the removal of these items, if they are found to have violated institution rules relating to the possession of these items.

Any other accommodation requests are discussed with the TEC through the WASPB.

16. REENTRY NEEDS

In accordance with the Program Statement Release Preparation Program, institution staff assist transgender inmates in addressing reentry issues prior to release or placement in a Residential Reentry Center/Home Confinement.

During Initial Classification and Program Reviews, unit management formulates a pre-release plan that assists transgender inmates in obtaining identification, finding housing and employment, and providing community resources to assist with reintegration into the community.

The Reentry Affairs Coordinator will assist staff with identifying these resources. Community Treatment Services staff or Institution and/or Regional Social Workers may be contacted concerning the continuity of medical care.

The WASPB can be contacted to provide guidance and resources for any additional reentry

needs of transgender inmates. All accommodation and treatment decisions for inmates in community custody are made by the Residential Reentry Management Branch in consultation with the TEC.

17. ADMINISTRATIVE REMEDIES

Inmates who wish to seek formal review of any issue relating to this policy may use the procedures in the Program Statement **Administrative Remedy Program**.

REFERENCES

| Program Statements | | |
|--------------------|--|--|
| P1330.18 | Administrative Remedy Program (1/6/14) | |
| P4500.12 | Trust Fund/Deposit Fund Manual (3/15/18) | |
| P5100.08 | Security Designation and Custody Classification Manual (9/4/19) | |
| P5290.15 | Intake Screening (3/30/09) | |
| P5310.17 | Psychology Services Manual (08/25/16) | |
| P5310.16 | Treatment and Care of Inmates with Mental Illness (5/1/14) | |
| P5322.13 | Inmate Classification and Program Review (5/16/14) | |
| P5324.08 | Suicide Prevention (4/5/07) | |
| P5324.12 | Sexually Abusive Behavior Prevention and Intervention Program (6/4/15) | |
| P5325.07 | Release Preparation Program (8/15/19) | |
| P5521.06 | Searches of Housing Units, Inmates, and Inmate Work Areas (6/4/15) | |
| P5800.15 | Correctional Systems Manual (9/23/16) | |
| P6031.04 | Patient Care (6/3/14) | |
| P6090.04 | Health Information Management (3/2/15) | |

Federal Regulations

28 CFR part 115

Additional Resources For Clinicians

Diagnostic and Statistical Manual of Mental Disorders (DSM), most current version. World Professional Association for Transgender Health (WPATH) standards.

ACA Standards

- American Correctional Association Standards for Adult Correctional Institutions, 5th Edition: 5-ACI-1C-09, 5-ACI-1D-12, 5-ACI-1D-13, 5-ACI-2C-02, 5-ACI-1D-08, 5-ACI-3D-05, 5-ACI-3D-08(M), 5-ACI-3D-09, 5-ACI-3D-10, 5-ACI-3D-11, 5-ACI-3D-12, 5-ACI-3D-13, 5-ACI-3D-14, 5-ACI-3D-15, 5-ACI-3D-16, 5-ACI-6A-21(M), 5-ACI-6A-32(M), 5-ACI-6C-14(M)
- American Correctional Association Performance Based Standards for Adult Local Detention Facilities, 4th Edition: 4-ALDF-2A-29, 4-ALDF-2A-32, 4-ALDF-2A-34, 4-ALDF-6B-03, 4-ALDF-2C-03, 4-ALDF-4C-22M, 4-ALDF-4C-30M, 4-ALDF-4D-22, 4-ALDF-4D-22-1, 4-

ALDF-4D-22-2, 4-ALDF-4D-22-3, 4-ALDF-4D-22-4, 4-ALDF-4D-22-5, 4-ALDF-4D-22-6M, 4-ALDF-4D-22-7, 4-ALDF-4D-22-8, 4-ALDF-7B-08, 4-ALDF-7B-10, 4-ALDF-7B-10-1.

- American Correctional Association Standards for Administration of Correctional Agencies, 2nd Edition: None.
- American Correctional Association Standards for Correctional Training Academies: None.

Records Retention

Requirements and retention guidance for records and information applicable to this program are available in the Records and Information Disposition Schedule (RIDS) on Sallyport.

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EXHIBIT C

GENDER-AFFIRMING CARE OF TRANSGENDER AND GENDER NONBINARY PERSONS

Federal Bureau of Prisons
Clinical Guidance

June 2023

Federal Bureau of Prisons (BOP) Clinical Guidance is made available to the public for informational purposes only. The BOP does not warrant this guidance for any other purpose and assumes no responsibility for any injury or damage resulting from the reliance thereof. Proper medical practice necessitates that all cases are evaluated on an individual basis and that treatment decisions are patient-specific. Consult the BOP Health Management Resources Web page to determine the date of the most recent update to this document: http://www.bop.gov/resources/health_care_mngmt.jsp.

Gender-Affirming Care of Transgender and Gender Nonbinary Persons

June 2023

WHAT'S NEW IN THIS DOCUMENT

This guidance on *Gender-Affirming Care of Transgender and Gender Nonbinary Persons* is an update to the BOP Clinical Guidance on *Medical Management of Transgender Inmates*, issued in December 2016. Significant changes were made throughout this document to more closely align with community standards and the World Professional Association for Transgender Health (WPATH) *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8* published in 2022. While WPATH Standards of Care were referenced when updating this guidance, deviations due to the unique correctional environment were made when necessary. The key revisions include:

- Addition of *Transition Pathway for Transgender Inmate Patients* for guidance in patient care decisions found in *Section 4* and *Appendix 1*.
- Added language in <u>Section 5</u> to describe the process for requesting designation to a cross/gender reaffirming institution according to BOP policy.
- New sections created with emphasis on care in correctional environment:
 - Preventative Health Screening (<u>Section 13</u>)
 - ▶ Minimally or Non-Invasive (<u>Section 14</u>) and Invasive [Surgical] Procedures (<u>Section 15</u>)
 - Information regarding facial hair removal expounded (Facial Hair Removal)
 - Including description of the use of Transgender Utilization Review Advisory Group
 - ► Transitions of Care (Section 16)

DOCUMENT ORGANIZATION

- The **ABBREVIATIONS** are now listed in a new section, <u>Key to Abbreviations</u>, preceding the appendices. (This list does not replace the list of <u>Definitions</u> in <u>Section 2</u>.)
- The appendices summarizing HORMONE TREATMENT have been renumbered, as follows:
 - ▶ Appendix 2. Summary Charts for Feminizing Hormone Therapy
 - ► Appendix 3. Summary Chart for MASCULINIZING Hormone Therapy
- The main body of the **MEDICATION MONITORING** guidance is now in two new appendices:
 - ► Appendix 4. Monitoring During FEMINIZING Hormone Therapy
 - Appendix 5. Monitoring During MASCULINIZING Hormone Therapy
- The items in the *References* section are now listed alphabetically by author or source.

Gender-Affirming Care of Transgender and Gender Nonbinary Persons
June 2023

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Gender-Affirming Care of Transgender and Gender Nonbinary Persons

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1. PURPOSE

The Federal Bureau of Prisons (BOP) Clinical Guidance for *Gender Affirming Care of Transgender and Gender Nonbinary Persons* provides recommendations for the medical management and treatment of transgender and gender nonbinary federal inmates, referred to in this guidance as *transgender* and/or *gender nonbinary* and *individual(s)*, *patient(s)*, or *person(s)*.

2. DEFINITIONS

BISEXUAL: Refers to a person attracted to both sexes.

BIGENDER: Refers to those who identify with two genders or multigender.

BOP TRANSGENDER CLINICAL CARE TEAM: A group of physicians (primary care and psychiatrists), pharmacists, and social workers devoted to advocating and advancing the treatment options for this population. The team provides education and the tools to institutional staff to develop clinical treatment plans for the TG and gender nonbinary population. This team has no authority to review, approve or disapprove gender affirming surgery referrals.

BOP TRANSGENDER EXECUTIVE COUNCIL (TEC): A group of BOP management personnel who mitigate executive level administrative gender affirming issues.

BOP TRANSGENDER UTILIZATION REVIEW ADVISORY GROUP: A group of BOP physicians, psychiatrists, pharmacists, and social workers assigned by the Medical Director to provide clinical review of gender-confirming surgical requests.

CISGENDER: denoting or relating to a person whose sense of personal identity and gender corresponds with their sex assigned at birth.

COMPLEX AND INVASIVE GENDER CONFIRMING PROCEDURES: complex and invasive medical procedures will almost always require general anesthesia, and a surgeon with advanced skills. Most of these procedures carry the inherent risk for blood loss, infection, pain, multi-day hospitalization, and post-operative complications; in this guidance, these terms refer to all procedures listed in <u>Table 5</u>, which require the approval of the Medical Director.

FEMALE-TO-MALE (FTM): Refers to a biological female who identifies as, or desires to be, a member of the male gender. The term **transgender male**, or **trans male** for short, is used to refer to the **GENDER IDENTITY** of a person who is **FTM**. (See the definition of **TRANSGENDER** below.)

GAY: Refers to a person who is romantically or sexually attracted to persons of the same gender. The term is mostly used to describe males. (See the definition of **LESBIAN** below.)

GENDER-AFFIRMING HORMONES: Hormonal therapy utilized to facilitate physiological change(s) during **TRANSITION** (see definition below). The term **CROSS-SEX HORMONES** is often utilized in the medical literature, but it is falling out of use.

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GENDER-AFFIRMING SURGERY/GENDER-CONFIRMING SURGERY: The surgical component of an individual's **TRANSITION** (see definition below); these terms have replaced the outdated terminology of **SEX REASSIGNMENT SURGERY**.

GENDER BINARY: A system of viewing gender as consisting solely of two, opposite categories of gender, termed "male and female"

GENDER CONFORMITY: Behavior and appearance that adheres to the social expectations of a particular **GENDER**. (See the definition of **GENDER NONCONFORMITY** below.)

GENDER DYSPHORIA (GD): The condition of feeling that one's emotional and psychological identity as male or female is different from one's biological sex assigned at birth. **GD implies that there is a state of distress or anxiety directly related to this conflict.** In the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)*, released in May 2013, people whose assigned sex at birth is contrary to the one they identify with *and* who are experiencing a state of distress should be diagnosed with **GD**.

- → This diagnosis of **GD** is a revision of the criteria in the DSM-IV for **GENDER IDENTITY DISORDER (GID)** and is intended to better characterize the experiences of affected individuals. The DSM-5 no longer uses the term **GID**.
- → A Gender Dysphoria diagnosis may be necessary in some regions to access transition-related care.

GENDER EXPRESSION: Includes mannerisms, clothing, hair style, and choice of activities that individuals use to express their **GENDER IDENTITY**.

GENDER FLUID: A changing or "fluid" gender identity.

GENDER IDENTITY: How one identifies oneself: female, male, both, or neither. **GENDER** encompasses aspects of social identity, psychological identity, and human behavior.

GENDER NONBINARY: someone who does not identify as exclusively male or female

GENDER NONCONFORMITY (ALSO KNOWN AS GENDER NONBINARY): Behavior or appearance that does not adhere to the social expectations of a particular **GENDER**.

GENDER QUEER: Denoting or relating to a person who does not subscribe to conventional gender distinctions but identifies with neither, both or a combination of male and female genders.

INFORMED CONSENT: A patient's ability to understand the risks, benefits, alternatives, unknowns, limitations, and risks of treatment pertaining to a specific healthcare intervention.

INTERSEX: Refers to a person whose sexual/reproductive anatomy or chromosomal pattern does not seem to fit the typical biological definition of male or female.

LESBIAN: Refers to a female who is romantically or sexually attracted to other females.

MALE-TO-FEMALE (MTF): Refers to a biological male who identifies as, or desires to be, a member of the female gender. The term **transgender female**, or **trans female** for short, is used to refer to the **GENDER IDENTITY** of a person who is **MTF**. (See the definition of **TRANSGENDER** below.)

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MINIMALLY INVASIVE GENDER AFFIRMING PROCEDURES: minimally invasive medical procedures are usually same day office or hospital-based procedures that may require anesthesia and break skin or enter an organ; in this guidance, this term refers to professional facial hair removal services, and other procedures typically labeled as aesthetic in a non-trans population.

Non-invasive gender affirming treatment modalities: non-invasive medical modalities typically do not break skin or enter a body part; in this guidance, this term refers to treatment modalities such as voice and communication training.

PATIENT-CENTERED CARE: Care in which patients are partners with their health care providers and health care decisions are driven by the patient's specific health needs and desired health outcomes.

SEX: A biological classification based on chromosomal composition, reproductive anatomy (primary sex characteristics), and the phenotypic characteristics that develop during pubertal maturation (secondary sex characteristics).

SEXUAL ORIENTATION: The direction of one's sexual interest. It is not defined by the person's gender identity. People of the same gender identity may have different sexual orientations.

TRANSGENDER (TG) (ALSO KNOWN AS TRANSSEXUAL) OR TRANS SPECTRUM: An umbrella term used for individuals whose **GENDER IDENTITY** does not conform to the typical expectations associated with the gender they were assigned at birth. It is important to note that terminology changes often and the latter term is falling out of use.

TRANSPHOBIA: Dislike of or strong prejudice against transgender people with attitudes such as fear, discomfort, distrust, or disdain.

TRANSITION: The period during which **TG** individuals 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. Individuals may want to proceed to different stages of transition.

3. INTRODUCTION & GENERAL CONSIDERATIONS

TRANSGENDER (**TG**) people are those whose gender identity is different from the sex which they were assigned at birth. **GENDER DYSPHORIA** (**GD**)—previously known as **GENDER IDENTITY DISORDER** (**GID**)—is the *discomfort or distress* caused by a discrepancy between a person's gender identity and that person's gender assigned at birth.

- TG people have many of the same health needs as the general population. They may also have other special healthcare needs.
- Not all TG person(s) will be diagnosed with GD, and a diagnosis of GD is not required for access for all TG services. According to the American Psychological Association's guidelines (see <u>References</u> section), an individual's identification as **TG or GENDER NONBINARY** can be healthy and self-affirming and is not considered pathological.
- However, some TG or GENDER NONBINARY individuals experience distress associated with their gender identity, their body, or their sex assigned at birth. There is also distress associated with

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- societal stigma and discrimination. A systematic review of studies by Valentine, et al (2018) indicates significantly higher rates of mental health morbidity compared with the general population—particularly anxiety, depression, and suicidality.
- Gender-affirming health care involves supporting individuals through social, psychological, behavioral, or medical (including hormonal treatment or surgery) treatments—to support and affirm an individual's experienced gender identity.

The **BOP Transgender Clinical Care Team**. The team provides education and the tools to institutional staff to develop clinical treatment plans for the TG and gender nonbinary population. This team has no authority to review, approve or disapprove gender affirming surgery referrals. This team is composed of physicians (primary care physicians and psychiatrists), pharmacists, and social workers who are available to help institution providers. For example, when patients have medical contraindications (relative or absolute) to hormone treatments, consultation with the TCCT may be helpful. Institution staff may refer to their Regional Medical Director for a list of current team members and their contact information.

STIGMA

Stigma and prior negative experiences in institutions can contribute to healthcare disparities. Stigma commonly leads to prejudice and discrimination, which may also exacerbate mental health concerns in transgender and gender-nonconforming individuals.

Respect and trust are essential to the provider-patient relationship. Respectful language and terms should always be used, affirming the patient's experienced gender identity. Once an individual has identified as TG, use of pronouns or salutations preferred by the TG individual is appropriate, especially for those patients with a Case Management Activity (CMA) Sentry assignment of TRANSGENDER (either TRN M2F or TRN F2M; see <u>TABLE 1</u> below). This practice is more likely to facilitate a cooperative relationship between the TG individual and others, and generally reduces the stress of gender transition.

→ Using this informal approach is distinct from a legal name change while in BOP custody; a legal name change must conform to the policy requirements in the **Program Statement 5800.15 Correctional**Systems Manual (or the most recent version).

MENTAL HEALTH CONCERNS AND SUICIDALITY

As reported by Valentine, et al (2018), a higher prevalence of depression, anxiety, and suicidality is seen among TG adults compared to the general population. It has been suggested these elevated rates are linked to complex trauma, stigma, violence, and discrimination. A recent study by Baker, et al (2021) suggests that appropriate gender-affirming care, including medical and surgical care, can lessen psychiatric symptoms. Transgender adults with **GD** are at an increased risk of suicidal ideation and suicide prior to initiation of their gender transition, regardless of the clinical endpoint of their transition - whether that endpoint is living as the psychologically identified gender, hormone therapy, cosmetic treatments, breast augmentation/removal, and/or gender-affirming surgery (Wolford-Clevenger et al 2018). For many individuals, the risk of suicide may decrease after receiving the appropriate, individualized treatment (Turban et al 2022).

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COMORBID CONDITIONS

- Anxiety and Depression: The most common mental health conditions seen in **TG** adults are anxiety and depression. A significant interdisciplinary approach between Psychology and Health Services is always required for **TG** patient care.
 - → See BOP Program Statement 5310.16, Treatment and Care of Inmates with Mental Illness, available at https://www.bop.gov/policy/progstat/5310_16.pdf.
- HIV Infection: Epidemiologic studies indicate a higher prevalence of HIV in the TG populations, specifically among transgender male persons. HIV services for TG people should address the specific biological, pathological, and social needs of this population (i.e., antiretroviral therapy, HIV prevention and care programs). Effective risk assessment requires obtaining an accurate sexual risk history, including anatomy-specific sexual behavior.
 - → See CDC's website on HIV and Transgender People, listed in the References section.

PATIENT-CENTERED MULTIDISCIPLINARY TREATMENT APPROACH

A patient-centered multidisciplinary team approach is recommended for managing issues associated with the incarceration of TG individuals. Incarcerated individuals may present to an institution with a well-established gender identity or begin their transgender or gender nonbinary journey while incarcerated. It is important to have a system in place to allow for individualized treatment. Individuals requesting care for gender dysphoria should have access to a diverse range of treatment services. Patient-centered care explores individualized therapeutic options, which may differ from person to person.

The BOP offers **Trauma-Informed Correctional Care (TICC)**, which incorporates an understanding that patient attitudes, behaviors, and concerns are likely to be affected by prior traumatic experiences. **TICC** includes both training and treatment programs, emphasizes the recognition of trauma in all forms, and incorporates the principle that all staff may have a role in reducing its impact.

HOUSING ASSIGNMENTS, PROGRAM ASSIGNMENTS, AND PAT SEARCHES

- → Refer to the current version of BOP **Program Statement 5324.12, Sexually Abusive Behavior Prevention and Intervention Program**, available at

 https://www.bop.gov/policy/progstat/5324 012.pdf
- → Refer also to the BOP **Program Statement 5200.08 Transgender Offender Manual**, available at https://www.bop.gov/policy/progstat/5200-08-cn-1.pdf

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PRISON RAPE ELIMINATION ACT (PREA)

Per the national Prison Rape Elimination Act (PREA) Resource Center, being transgender is a known risk factor for being sexually victimized in confinement settings. Consequently, PREA regulations and BOP Program Statements provide ways to protect the transgender population through the following:

- PREA regulations, incorporated into Program Statement 5324.12, Sexually Abusive Behavior Prevention and Intervention Program (available at https://www.bop.gov/policy/progstat/5324_012.pdf), state that the intake screening shall assess the individual's risk of sexual victimization by considering, at a minimum, whether the individual is known or perceived to be gay, lesbian, bisexual, TG, intersex, or gender nonconforming.
- According to the PREA (<u>28 C.F.R. § 115.41 (h)</u>), individuals may not be disciplined for refusing to answer, or for not disclosing complete information in response to, [questions about being gay, lesbian, bisexual, **TG**, intersex, or gender nonconforming].
- According to the PREA (<u>28 C.F.R. § 115.15 (e)</u>), staff shall not search or physically examine a
 transgender or intersex inmate for the sole purpose of determining the inmate's genital status. If
 the inmate's genital status is unknown, it may be determined as appropriate during
 conversations with the inmate, by reviewing medical records, or, if necessary, learning that
 information as part of a broader medical examination conducted in private by a medical
 provider.

4. TRANSITION PATHWAY FOR TRANSGENDER PATIENTS

<u>Appendix 1</u> summarizes a pathway for TG patients to access gender-affirming mental health and medical care in the BOP. The order depicted in this table is not as important as the provision of individualized treatment, e.g., individuals may approach a medical professional before they approach a mental health professional and this should not preclude them or delay appropriate treatment if the medical provider is qualified in this area.

A gender dysphoria (GD) diagnosis is not necessary for hormone treatment, and TG patients may not be interested in following up with a mental health professional. However, the reverse might also occur: TG patients may seek out a mental health professional for months before they are ready to be referred for a medical evaluation. Not all gender non-binary patients will require gender-affirming hormone treatment and treatment is individualized to the patient's needs.

5. DESIGNATION TO A CROSS/GENDER-AFFIRMING INSTITUTION

In accordance with <u>Program Statement 5200.08 Transgender Offender Manual</u>, transgender individuals may ask their respective warden to be considered for designation to a gender-affirming institution. All requests for designation are reviewed by the Transgender Executive Council (TEC). The memo is submitted from the Warden to the TEC indicating the patient is requesting re-designation to an institution able to provide full-time gender affirming life experiences in identified gender.

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6. PRESENTATION OF GENDER NON-CONFORMITY

Gender non-conformity status is based on an individual's experienced gender identity, role, or expression differing from societal norms assigned to a particular sex. When an individual self-identifies as TG and requests referral or evaluation for treatment, an evaluation is conducted according to PS5200.08, and further referrals may be made, as clinically appropriate, to fully evaluate the individual's treatment needs.

Discussion of the following areas may be useful in helping a person describe their gender identity:

- Persistent and marked differences between experienced gender and their biologic or natal sex.
- Strong feelings about primary or secondary sex characteristics.
- Strong feelings about being treated as or becoming another gender.
- Belief that one's actions, feelings, or mannerisms are more characteristic of another gender.

Gender non-conformity often (but not always) presents with gender dysphoria, which denotes the discomfort or distress that is caused by the nonconformity of a person's gender identity, and that person's sex assigned at birth. Gender nonconformity may present in a spectrum of expressed or desired gender affirmation needs. Patients may experience:

- Strong desires to be treated as the identified gender
- Strong convictions that one has feelings and reactions typical of the identified gender
- Strong inclinations to look in a way that affirms the identified gender

Clinicians must accurately assess and document the patient's individual presentation. Attention should be given as to whether the level of distress meets criteria for a formal diagnosis of gender dysphoria, and/or if there are other coexisting mental or medical health disorders.

7. GENDER-AFFIRMING MENTAL HEALTH ASSESSMENT

When TG individuals present to mental health professionals it is important to conduct a thorough mental health evaluation. The mental health professional is encouraged to affirm the individual's experienced gender and whether there is gender dysphoria. The mental health professional should conduct a thorough evaluation including assessing for any mental health diagnosis. The clinician will develop an individualized treatment plan for the TG patient and collaborate with the medical provider.

A mental health assessment for TG individuals typically includes:

- Obtaining a gender identity history and screening for GD
- Screening for other mental health disorders related to mood, anxiety, autism, eating, personality, psychosis, and substance use
- Identifying a history of abuse or neglect
- Assessing any current or past self-harm ideations or attempts
- Performing an assessment of affective, cognitive, and psychosocial functioning
- Psychosocial treatment recommendations; and/or
- Medical referral, if indicated.
- → Please also refer to the APA's Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, listed in the <u>References</u> section.

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MENTAL HEALTH TREATMENT CONSIDERATIONS

The mental health team plays an important role in gender-affirming care. This can include screening for mental health disorders and assisting with treatment planning. Prior to engaging in treatment, conversations regarding the individual's realistic expectations of outcome are encouraged to identify realistic goals for treatment.

→ A collaborative approach with both mental health and medical services staff is highly recommended.

Patients can also be referred to psychiatry services for mental health concerns or medication management of mental illness.

- **PSYCHOTHERAPY:** This is a general term for treating mental health problems; it includes a broad variety of techniques to help individuals with emotional difficulties or coexisting mental illnesses. Psychotherapy can be used to learn about and treat an individual's moods, thoughts, and behaviors. It can also be supportive to individuals experiencing distressing thoughts, feelings and/or behavior.
- PSYCHIATRY SERVICES: Individuals can also be referred to psychiatry services for mental health
 concerns or medication management of other mental illness in conjunction with GD.
 Appropriate pharmacotherapy is considered when indicated to optimally manage co-existing
 mental health concerns prior to, or concurrently with, treatment of GD.

GENDER DYSPHORIA (GD) CRITERIA

Individuals identifying as TG or gender nonbinary do not necessarily have GD. Although data regarding the prevalence rates of GD in the transgender population is limited, many clinicians anecdotally report that most TG individuals experience some degree of dysphoria in the absence of treatment.

Because untreated or under-treated **GD** is associated with increased morbidity and mortality (Jackson et al 2023), screening for **GD** in **TG** individuals is essential. Without treatment, this population may experience higher rates of depression, anxiety, self-harm, and suicidality. Gender-affirming treatment supports TG people throughout their lifespan. Treatment modalities are designed to meet the individual's unique goals and may include social supports, mental health treatment, and medical treatment (including hormone therapy and surgery). These interventions may improve medical and psychological health, increase social support, decrease **GD**, treat mental health comorbidities, and improve TG individuals' overall quality of life. The DSM-5 criteria may be used to make the diagnosis of GD.

→ Refer to The American Psychiatric Association <u>A Guide for Working With Transgender and Gender Nonconforming Patients</u> for guidance on diagnosis of GD.

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8. GENDER-AFFIRMING MEDICAL ASSESSMENT

A MEDICAL EVALUATION should include:

- Thorough review of all co-occurring medical conditions and whether they are reasonably controlled.
 - → Comorbidities are not necessarily a contraindication to therapy and must be assessed for each patient. See more about drug risks in Table 2 (Feminizing Therapy) and Table 3 (Masculinizing Therapy).
- Review of any mental health evaluations and coordination with mental health care providers.
- Physical Examination: Healthcare providers should utilize a gender-affirming approach, including using the individual's preferred name and pronouns during each clinical encounter. This also includes using non-gender specific terminology (ex. genital instead of penis/vagina or chest instead of breast) for anatomical body parts or asking if the patient has a preferred term to be used. The physical exam should only be performed on parts of the body indicated for the medical reason for the specific visit.
- **Documentation of Previous Treatment:** Hormonal therapy, surgery, etc.
- Informed Consent: Individuals must be counseled on the risks and long-term effects of hormonal therapy. Use of gender-affirming hormones in the management of **TG** individuals is considered an off-label use and does not currently have FDA approval but is considered a community standard. Due to the irreversibility of some of the treatment options and the side effects, the individual's informed consent is required before initiating treatment and must be documented within the medical record.
 - → See <u>Section 9. Patient Education & Informed Consent.</u>
- Contraindications and Precautions to Hormone Therapy:
 - → See also the Summary Charts for Hormonal Therapy in <u>Appendix 2. Feminizing Hormone Therapy</u> and <u>Appendix 3. Masculinizing Hormone Therapy</u> for medication-specific contraindications.

FEMINIZING THERAPY

- CONTRAINDICATIONS: Current diagnosis of estrogen-sensitive cancer (e.g., breast cancer); current diagnosis of thromboembolic disease (may consider after subspecialty consultation)
- PRECAUTIONS: History of estrogen-sensitive cancer or history of thromboembolic disease should prompt referral to expert specialist prior to initiation of therapy. Presence of liver, kidney, or heart disease/stroke (or risk factors for heart disease such as high cholesterol, diabetes, obesity, smoking); retinal vascular thrombosis, history of macroprolactinoma, strong family history of breast cancer or thromboembolic disease; gallbladder disease.

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MASCULINIZING THERAPY

- CONTRAINDICATIONS: Pregnancy; breast feeding; trans men with current carcinoma of the breast
- PRECAUTIONS: Erythrocytosis (hematocrit >50%) History of breast or uterine cancer (testosterone may have anti-proliferative effects on most, but not all cancers-referral to expert specialist recommended prior to initiation of therapy). Androgen-sensitive epilepsy; migraines; sleep apnea; depression; cardiac failure; renal failure or severe hypertension susceptible to salt retention and fluid overload; significant liver disease; coronary artery disease (CAD) or risk factors for CAD; bleeding disorders (for injected testosterone); significant history of violent behavior.

ASSESSMENT & DOCUMENTATION OF ACCURATE EHR CODES

Appropriately diagnosing individuals as to their gender identity is imperative for accurate individual record keeping and continuity of care ensuring all individuals are receiving appropriate preventive and gender affirming care and management both as incarcerated individuals and upon release to their community. All BOP individuals who identify as **TG or gender nonbinary** or are identified by history or current presentation as **TG or gender nonbinary**, should be referred to appropriate mental health professionals and/or health service providers. Utilization of inclusionary diagnoses in the EHR helps clinicians provide patient-centered care and medical interventions specific to organs present and transgender care (e.g., a transgender male who has residual breast tissue or an intact cervix getting a mammogram or pap smear).

For purposes of providing appropriate medical treatment and management, all individuals who identify as **TG**—whether or not they are receiving hormone treatment—need to have an accurate diagnostic code entered into the EHR health problem list, as listed in <u>Table 1</u>.

TABLE 1. ICD-10 EHR DIAGNOSTIC CODES FOR TRANSGENDER AND GENDER NONBINARY INDIVIDUALS

| BOP Transgender Determination | ICD-10 EHR Codes | Corresponding Sentry CMA Codes |
|---|---------------------|-----------------------------------|
| Transgender/Gender Identity DO/Gender Dysphoria - male to female | F64.0F ¹ | TRN M2F |
| Transgender/Gender Identity DO/ Gender Dysphoria - female to male | F64.0M ¹ | TRN F2M |
| Transgender/Gender Identity DO-Other- questioning/queer | F64.8Q ² | |
| Personal History of Sex Reassignment | Z87890 ³ | |

¹ Document the degree of distress or impairment in social, occupational, or other important areas of functioning.

² This respective code is to be applied to patients who may not have consolidated their gender identity (questioning), or who identified as gender fluid/queer.

³ If an individual has undergone gender-affirming surgery, use code Z87890 (Personal History of Sex Reassignment) along with the appropriate F64 code above. Document the type of surgery in detail.

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9. PATIENT EDUCATION AND INFORMED CONSENT

Patient education and informed consent are crucial to the treatment process.

- Consent forms for gender affirming hormone therapy are designed to guide counseling and can
 be found in <u>Appendix 6</u> and <u>Appendix 7</u>. The information in these appendices is not all-inclusive
 and providers may add information to this document as clinically appropriate. Individuals
 should be provided with ample time to review this information and have all questions addressed
 prior to signing the document. Informed consent must be documented within the EMR.
- Securing consent for gender affirming surgery is the responsibility of the surgeon. Once the
 individual is approved by the Medical Director for surgical intervention for the treatment of GD,
 surgeons are responsible for discussing different surgical techniques, advantages and
 disadvantages of each, limitations of the different procedures, and a frank discussion of all the
 inherent risks and complications to include their own complication rates with each procedure.

10. HORMONE THERAPY: ELIGIBILITY, GOALS, OVERVIEW

Hormone therapy is an important part of gender affirming care. Studies demonstrate improved satisfaction (in the range of 70–80%) as it relates to mental health, quality of life, and sexual function for **TG** individuals who are receiving gender affirming hormone therapy (Siira et al 2023).

After a thorough and individualized evaluation, the medical provider may initiate hormone therapy after the risks and benefits have been discussed with the individual.

→ Refer to the <u>Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline</u> for more detailed information.

ELIGIBILITY AND READINESS FOR GENDER-AFFIRMING HORMONE THERAPY

Patients do not need to meet the DSM criteria for **GD** to initiate gender-affirming hormone therapy. The eligibility for gender-affirming hormone treatment can be achieved by confirming gender incongruence, verifying transition is clinically appropriate, and patient understands the risks, and benefits of treatment through completion of the <u>Mental Health Assessment</u> and/or the <u>Medical Assessment</u>.

- → Gender-nonconformity is based on the individual's self-report. Therefore, the history or subjective component of the evaluation serves as the primary source for identifying a person as TG.
- → An important aspect of eligibility and readiness for gender-affirming hormone therapy while incarcerated is the understanding that fertility may be affected permanently. According to BOP Program Statement 6031 Patient Care: Inmates are not authorized for fertility preservation services (sperm or egg/banking), even when infertility is an expected side effect of medically necessary treatment e.g., chemotherapy, pelvic radiation, or gender affirming treatment. Inmates are not authorized to donate sperm or eggs.

GENERAL GOALS OF HORMONE THERAPY

The goal of hormone therapy is to reduce characteristics of the natal sex and induce those of the identified gender, allowing individuals to project their **GENDER IDENTITY**. Hormone therapy is focused on

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affirming a person's gender identity, which is not always binary. Patient-centered therapy is focused on meeting the patient's needs.

11. FEMINIZING HORMONE THERAPY

The goal of feminizing hormone therapy is generally to suppress male secondary sex characteristics and the development of female secondary sex characteristics. Most clinical studies and guidelines recommend combined therapy with an anti-androgen, estrogen, and sometimes a progestin adjunct.

EXPECTATIONS OF FEMINIZING HORMONE THERAPY

Prior to beginning treatment, patients should be educated on realistic expectations of results, as well as the timeline of when to expect them. Every case is different, and slow change can lead to frustration.

- → It is important to discuss realistic expectations with the patient to avoid any attempts to self-increase the dosage in hopes of speeding up results.
 - Within the first six months of treatment, changes may be seen in body fat redistribution, loss of muscle mass, breast growth (usually to Tanner stage 2 or 3), testicular atrophy, decreased erections, decreased sperm production, and a slowing of body/facial hair growth.
 - The maximum effect of treatment may not be seen for more than two years.
 - Treatment does not provide voice alteration.
 - Feminizing hormone therapy may also bring about changes in emotional and social functioning.
 - Most treatment results are reversible upon cessation of treatment, but breast growth is permanent, and infertility may be irreversible.
 - Refer to <u>Figure 1</u> on for a general timeline of listed effects.

FIGURE 1. FEMINIZING EFFECTS IN TRANSGENDER FEMALES

| Effect | Onset | Maximum |
|--------------------------------------|----------|----------|
| Redistribution of body fat | 3-6 mo | 2-3 y |
| Decrease in muscle mass and strength | 3-6 mo | 1-2 y |
| Softening of skin/decreased oiliness | 3-6 mo | Unknown |
| Decreased sexual desire | 1-3 mo | 3-6 mo |
| Decreased spontaneous erections | 1-3 mo | 3-6 mo |
| Male sexual dysfunction | Variable | Variable |
| Breast growth | 3-6 mo | 2-3 y |
| Decreased testicular volume | 3-6 mo | 2-3 y |
| Decreased sperm production | Unknown | >3 y |
| Decreased terminal hair growth | 6-12 mo | >3 ya |
| Scalp hair | Variable | Б |
| Voice changes | None | c |

Estimates represent clinical observations: Toorians et al. (149), Asscheman et al. (156), Gooren et al. (157).

Note: Adapted from Table 13. Feminizing Effects in Transgender Females reprinted from Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline by W.C. Hembree, P.T. Cohen-Kettenis, L Gooren, S. E. Hannema, W. J. Meyer, M. H. Muran, S. M. Rosenthal, J.D. Safer, V. Tangpricha, G. G. T'Sjoen, 2017, The Journal of Clinical Endocrinology & Metabolism 102(11):1-35.

^aComplete removal of male sexual hair requires electrolysis or laser treatment or both.

^bFamilial scalp hair loss may occur if estrogens are stopped.

^cTreatment by speech pathologists for voice training is most effective.

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SERUM HORMONE LEVELS FOR FEMINIZING HORMONE THERAPY

GOAL LEVELS FOR MTF: Serum Estradiol 100-200 pg/ml and Serum Total Testosterone <50 ng/dl

- While the goal of gender affirming hormone therapy is to suppress male secondary sex characteristics, serum estradiol levels should not exceed those of a premenopausal cis female (200 pg/ml); doses used to achieve an adequate level may be significantly higher than those used in hormone replacement therapy in menopausal women.
- It is important to note there are individuals who do not require estradiol as part of their hormonal therapy regimen and do well on an anti-androgen therapy alone. Bone density considerations should be fully disclosed to the patient who is considering this approach.
- There are individuals who require very little estrogen to obtain desired body characteristics and adequately treat any presenting dysphoria/incongruence (in these cases, a specific hormone level is NOT the patient's goal. Hormone levels are monitored to assure the level does not exceed 200 pg/ml).
- Patients should be treated with the lowest effective hormone doses.
 - ► As stated above, estradiol levels should not routinely exceed a premenopausal level of 200 pg/ml.
 - ► The same holds true for total testosterone levels. While the goal is <50 ng/dl, there is a subset of individuals who do poorly with levels below 35 ng/dl. The ideal levels for these individuals may be between 35–50 ng/dl.
- → Titration of dose is based on the individual's goals within the context of clinical response, hormone levels, and safety monitoring (e.g., risk factors such as smoking or renal function may warrant dose adjustments).

The Endocrine Society recommends monitoring of hormone levels every 3 months, during the first year of therapy and/or when titrating treatment regimens or altering therapy before stabilization of dosages has been achieved. After the first year of therapy, hormone levels can be monitored every 6-12 months as clinically indicated.

→ The laboratory monitoring quide for feminizing hormone therapy is included in Appendix 4.

DOSE TITRATION

The science and interpretation of serum hormone levels for TG individuals is evolving. Titration of hormone therapy doses should be driven by patient goals and clinical response per individual. Monitoring for potential medication sided effects and hormone levels are critical components of adjusting treatment.

- The recommended titration approach for patients includes increasing both estrogen and antiandrogen medication dosing to achieve desired physiological changes, but not to exceed the premenopausal cis female physiologic ranges (100–200 pg/mL).
- Another approach includes maintaining current physiologic estrogen dosing, titration of antiandrogen therapy, and the addition of a progestin, if appropriate.
- Regardless of initial dosing regimen utilized, dosages may be titrated upwards over 3–6 months.

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FEMINIZING MEDICATIONS

→ See the Summary Tables for TRANSGENDER FEMALE Hormone Therapy in <u>Appendix 2</u> for information on each of the medication groups below.

ANTI-ANDROGENS

Anti-androgens reduce testosterone levels and allow estrogen therapy to be used in lower doses while still reaching a maximum effect. Medications with anti-androgen effects include spironolactone, finasteride, GnRH agonists, and progestins.

- **SPIRONOLACTONE** is a potassium-sparing diuretic that directly inhibits testosterone secretion and androgen binding to the androgen receptor. It is the most commonly prescribed anti-androgen for gender nonconforming individuals in the United States.
 - ► Spironolactone can suppress facial and body hair growth, male pattern baldness, libido, and sexually stimulated erections. It decreases symptoms of benign prostate hypertrophy (BPH) and can lead to modest breast growth.
 - Due to its diuretic effects, patients may also experience self-limited polyuria, polydipsia, or orthostatic hypotension.
 - → The use of spironolactone must be carefully monitored in renal insufficiency and is contraindicated in patients with a potassium value greater than 5.5 mEq/L. Spironolactone can cause severe hyperkalemia and hypotension. Caution should be used when prescribed in conjunction with angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs). It is important to monitor potassium levels and blood pressure of individuals taking spironolactone.
- **5α-REDUCTASE INHIBITORS** (finasteride and dutasteride) inhibit 5-alpha reductase, the enzyme responsible for converting testosterone to its potent form, dihydrotestosterone.
 - ▶ Per WPATH SOC 8, data on the use of these medications in trans feminine populations is very limited: It is unclear whether this class of medication could have any clinical benefit in trans feminine individuals whose testosterone and dihydrotestosterone levels have already been lowered with estrogen and an antiandrogen. We [WPATH] therefore do not recommend their routine use in trans feminine populations. Rare use may be indicated in specific clinical circumstances such as for patients unable to tolerate spironolactone and which GnRH antagonists are not indicated or available.
- GNRH AGONISTS (goserelin, nafarelin, and leuprolide) suppress pituitary gonadotropin levels and gonadal steroids. They are most often used in adolescents for suppression of puberty but can be used to decrease testosterone levels and the amount of estrogen needed to achieve targeted physical effects.
 - ► Primary utilization in adult patients is for those who are unable to tolerate spironolactone due to hyperkalemia, increased frequency of urination, and/or a reduction in blood pressure or those who have some other contraindication to spironolactone use.
 - ► GnRH agonists do not carry a risk of thromboembolic disease, but use can result in osteoporosis if doses of estrogen given concurrently are insufficient.

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- ► The high cost to the patient upon release should be considered in those with proximal release dates.
- ► In cases of persistent elevations of testosterone despite maximized spironolactone dosing, adherence must be thoroughly evaluated prior to consideration of a GnRH antagonist. Directly observed therapy should be considered. If complete adherence is determined to exist and levels are still elevated beyond reason, autonomous endogenous production (i.e., tumor) should be considered and appropriate evaluation should be conducted.
- PROGESTINS are a group of hormones that include medroxyprogesterone. Use of
 medroxyprogesterone is controversial and not routinely recommended. It is purported to aid in
 breast development at a cellular level as well as mood management, but its effect is mainly on
 the uterus. Evidence as an effective agent in gender-affirming hormone therapy is lacking. Per
 WPATH: there is currently insufficient evidence the potential benefits of progesterone
 administration outweigh the potential risks. Additionally, an association between progesterone
 use in transgender woman and VTE has also been identified.
 - Medroxyprogesterone treatment comes with risk of developing mood disorders (depression/ irritability), lipid abnormalities, weight gain, and edema. There is also a concern of increased cardiovascular risk.

ESTROGENS

Estrogens are used to provide feminization in the form of physical appearance and sexual

characteristics. Effects include development of breasts, redistribution of body fat, softening of the skin, shrinkage of the testes, and testicular atrophy. Many formulations of estrogen are available, including parenteral, transdermal, sublingual, and oral. Estrogen may have positive health effects more generally, including increased high-density lipoprotein, decreased low-density lipoprotein, and preservation of bone mineral density. <u>Table 2</u> below lists conditions that can be exacerbated by gender-affirming estrogen therapy.

TABLE 2. MEDICAL CONDITIONS REQUIRING INCREASED MONITORING WITH ESTROGEN THERAPY

Contraindications • Current thromboembolic disease (may consider after • Unstable ischemic cardiovascular disease subspecialty consultation) Current diagnosis of estrogen-sensitive cancer **Precautions (Consider Subspecialist Consult)** · History of prolactinoma Coronary artery disease • Breast cancer (non-estrogen dependent) · Cerebrovascular disease Severe liver dysfunction • Severe migraine headaches (transaminases >3x upper limit of normal) · Retinal vascular thrombosis **Precautions (Recommend Increased Monitoring)** Obesity · High cholesterol · History of cigarettes, tobacco, other nicotine use · High blood pressure Migraines or epilepsy Heart, liver, kidney, or clotting disease Diabetes Hypoparathyroidism · History of thromboembolic disease Porpyria

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- All estrogens come with a risk of thromboembolism, but lower doses and transdermal formulations are considered safer and should be used in populations at higher risk of thromboembolism (>40 years old, smoker, obese, etc.). Aspirin therapy may be considered for those at higher risk of thromboembolic disease.
- Intramuscular (IM) injections can cause greater peaks and troughs in estrogen levels, causing more mood disturbances than oral and transdermal preparations, making oral and transdermal preparations preferable for some patients. Reductions in peak and troughs can be partially mitigated by more frequent dosing of the injections.
- Use of estrogen should be individualized and adjusted regularly, based on serum estradiol levels
 and individual-specific goals or concerns. Estrogen should be started at low doses and titrated
 up as needed, based on hormone levels as well as individual tolerance and goals. If
 discontinuation is necessary, consider tapering therapy to alleviate mood disturbances.
- In patients scheduled for surgery or an immobilizing event, the treatment team (i.e., assigned surgeon) should be made aware of current hormone therapy. Limited evidence suggests low risk for thrombotic events whether therapy is continued or temporarily held (Totaro et al 2021). An individualized risk assessment should be performed in determining the appropriate treatment plan.
- Estrogens are partially metabolized by CYP3A4 and interactions may occur with agents that inhibit or induce CYP3A4. Refer to current drug interaction references and/or a pharmacist for additional information.
- → Conjugated and synthetic estrogen formulations cannot be measured through serum estradiol concentrations and are no longer recommended for gender-affirming hormone therapy.
- → Synthetic estrogens, especially ethinyl estradiol, have been shown to have a higher risk of thromboembolism and should be avoided. Patients entering the BOP on synthetic estrogens should be transitioned to a more appropriate formulation.

MONITORING

Gender-affirming hormone therapy may have risks up to and equivalent of those associated with hormone replacement therapy in biological females. Appropriate monitoring is crucial.

- Weight, blood pressure, physical exams, risk factors, medications, complete blood counts, renal and liver function, and lipid and glucose metabolism should be monitored for all TG individuals receiving gender-affirming hormone therapy.
- In addition, individuals undergoing feminizing hormone treatment should be monitored for development of feminine characteristics, target blood levels, and any adverse effects of the medication.
- Refer to <u>Appendix 4. Monitoring During Feminizing Hormone Therapy</u> for additional guidance regarding monitoring.

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12. MASCULINIZING HORMONE THERAPY

The goal of masculinizing hormone therapy is the development of male secondary sex characteristics and suppression/minimization of female sex characteristics; this is usually done by the administration of a testosterone formulation.

EXPECTATIONS OF MASCULINIZING HORMONE THERAPY

Prior to beginning treatment, patients should receive education on realistic expectations of the treatment results, as well as the timeline of when to expect them. Every case is different, and slow change can lead to frustration.

- Effects developing within the first 6 months of treatment (onset within the first 3 months) include body fat redistribution, an increase in libido, an increase in skin oiliness and acne, clitoral enlargement, vaginal atrophy, cessation of menses, and infertility. Maximum effect usually occurs in 1–2 years but may take up to 5 years in some cases.
- Effects developing in the 6–12 month time frame include increased facial and body hair, scalp hair loss, increased muscle mass and strength, and deepening of the voice. Maximum effect often occurring in 1–2 years.
- Uterine bleeding should cease within a few months of high-dose testosterone therapy, but treatments such as GnRH agonists, medroxyprogesterone, and endometrial ablation may be used to stop menses prior to starting testosterone therapy or to decrease estrogen levels, if not responding to standard treatment.
- Most effects are reversible upon cessation of treatment, but changes in hair, voice depth, and infertility may be irreversible.
- Refer to Figure 2 below for a general timeline of listed effects.

FIGURE 2. MASCULINIZING EFFECTS IN TRANSGENDER MALES

| Effect | Onset | Maximum |
|--------------------------------|---------|---------|
| Skin oiliness/acne | 1-6 mo | 1–2 y |
| Facial/body hair growth | 6-12 mo | 4–5 y |
| Scalp hair loss | 6-12 mo | _a´ |
| Increased muscle mass/strength | 6-12 mo | 2-5 y |
| Fat redistribution | 1-6 mo | 2–5 y |
| Cessation of menses | 1-6 mo | B |
| Clitoral enlargement | 1-6 mo | 1–2 y |
| Vaginal atrophy | 1-6 mo | 1–2 y |
| Deepening of voice | 6-12 mo | 1–2 y |

Estimates represent clinical observations: Toorians et al. (149), Asscheman et al. (156), Gooren et al. (157), Wierckx et al. (158).

Note: Adapted from Table 12. Masculinizing Effects in Transgender Males reprinted from Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline by W.C. Hembree, P.T. Cohen-Kettenis, L Gooren, S. E. Hannema, W. J. Meyer, M. H. Muran, S. M. Rosenthal, J.D. Safer, V. Tangpricha, G. G. T'Sjoen, 2017, The Journal of Clinical Endocrinology & Metabolism 102(11):1-35.

^aPrevention and treatment as recommended for biological men.

Menorrhagia requires diagnosis and treatment by a gynecologist.

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SERUM HORMONE LEVELS FOR MASCULINIZING HORMONE THERAPY

GOAL LEVELS FOR MASCULINIZING HORMONE THERAPY: Serum Estradiol <50 pg/ml and Serum Total Testosterone 320–1000 ng/dl

Goal treatment levels are serum estradiol <50 pg/ml and serum total testosterone 320–1000 ng/dl (male physiologic range; some sources quote a normal reference range of 400–800 ng/dl). If a peak total testosterone level is drawn for injectable testosterone, the level should not exceed 1,000 ng/ml. If total testosterone levels exceed this range, refer to a transgender clinical care team physician or pharmacist for guidance in adjusting therapy.

→ Free testosterone level monitoring is rarely required during gender affirming treatment. Dose adjustments are based on Serum Total Testosterone levels.

MASCULINIZING HORMONE THERAPY DURING PREGNANCY

- Gender-affirming hormone therapy is contraindicated during pregnancy.
 - While therapy may lead to potentially irreversible infertility, it does not function as contraception, and pregnancy is still possible during treatment. Precautions should be taken to avoid pregnancy during treatment.
 - A pregnancy test is obtained prior to starting treatment for all individuals with childbearing potential.

TITRATION OF MASCULINIZING HORMONE THERAPY

Titration of hormone therapy doses should be driven by patient goals and clinical response per individual, including hormone level and safety monitoring.

- Clinical response is measured objectively by the presence of amenorrhea by month 6 of therapy.
- Lab references for testosterone levels vary (e.g., 320–1000 ng/dl). However, TG men with levels on the lower end of the range may express concerns about slow progress in gender affirmation or may experience low energy, libido, or mood—and thus warrant increased doses.
- Titration of testosterone should be done slowly with close monitoring for adverse events. Evidence remains unclear on whether increased doses will have positive effects once testosterone levels are greater than the midpoint of the reference range.
- Daily testosterone levels in TG men do not fluctuate as they do in natal males; however, they may vary over the laboratory monitoring intervals.

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MASCULINIZING MEDICATIONS

- → See the Summary Charts for MASCULINIZING Hormone Therapy in <u>Appendix 3</u> for a full list of the different formulations of testosterone—including summarized information on dosing, adverse effects, contraindications, and interactions.
- → Monitoring is covered in Appendix 5. Monitoring During Masculinizing Hormone Therapy

TESTOSTERONE

Androgen supplementation is used to induce male sex characteristics, including cessation of menses, voice changes, increased facial/body hair growth, increased muscle mass, hairline recession/baldness, changes in sweat and odor patterns, and clitoral enlargement. Other effects include increased libido and energy. Vaginal dryness will also likely occur. Higher doses of testosterone may be needed for TG men than for natal males who are being treated for low testosterone.

- Several formulations are available, ranging from IM injections to transdermal patches and gels. Due to the classification of all testosterone preparations as DEA-controlled substances and their associated risk of potential abuse and/or diversion, in the correctional environment, injectable formulations are the preferred method of administration.
- The IM injections release slowly from the muscle but may induce cyclical adverse effects that coincide with varying plasma concentrations. This can be mitigated by using a lower dose of IM testosterone given one to twice weekly (rather than every two or more weeks).
- While oral formulations are available, they are not used, due to extensive liver metabolism and the associated potential for hepatic complications.
- Androgen use should be individualized and adjusted based on serum total testosterone levels, tolerance, efficacy, and patient goals. Dosing should start low and be titrated up to an appropriate level while keeping the dose as low as possible to minimize adverse reactions.
- Ovulation may still be possible even when undergoing long-term testosterone therapy. Therefore, it is possible for a transgender man to become pregnant.

PROGESTINS AND GNRH AGONISTS

Medroxyprogesterone and GnRH agonists are not routinely used but may be treatment options in individuals wishing to cease menstruation and decrease estrogen levels prior to testosterone treatment. These medications may also have a use in individuals receiving high-dose testosterone therapy who still experience uterine bleeding after the first few months of treatment.

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DRUG RISKS

TABLE 3 lists conditions that can be exacerbated by gender-affirming testosterone therapy.

TABLE 3. MEDICAL CONDITIONS REQUIRING INCREASED MONITORING WITH TESTOSTERONE THERAPY

Contraindications Pregnancy Breastfeeding • Trans Men with carcinoma of the breast **Precautions** • Severe liver dysfunction (transaminases >3x upper Epilepsy limit of normal) Renal failure · Breast or uterine cancer • Severe hypertension susceptible to salt retention • Erythrocytosis (hematocrit >50%) and fluid overload • Androgen-sensitive epilepsy Coronary artery disease (CAD) or risk factors for CAD Migraines • Bleeding disorders (for injected testosterone) • Sleep apnea • Depression or significant history of violent behavior

MONITORING

Masculinizing hormone therapy has the same risks associated with hormone replacement therapy in biological males. Appropriate monitoring is crucial.

The Endocrine Society recommends monitoring of hormone levels every 3 months, especially when titrating treatment regimens or altering therapy before stabilization of dosages has been achieved. Once stabilization of dosages has been achieved, hormone levels are typically done every 6-12 months or as clinically indicated.

- Weight, blood pressure, physical exams, risk factors, medications, complete blood counts, renal
 and liver function, and lipid and glucose metabolism should be monitored for all TG individuals
 receiving gender-affirming hormone therapy.
- In addition, individuals undergoing masculinizing hormone treatment should be monitored for development of masculine characteristics, target blood levels, and any adverse effects of the medication. Some of the adverse effects experienced with chronic testosterone therapy are erythrocytosis, liver dysfunction, hypertension, excessive weight gain, salt retention, lipid changes, excessive or cystic acne, and adverse psychological changes.
- → Refer to <u>Appendix 5. Monitoring During Masculinizing Hormone Therapy</u> for additional guidance.

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13. PREVENTIVE HEALTH SCREENINGS

Regardless of the patient's identified gender or gender-confirming procedures, if the patient has a particular body part or organ, they must continue to have preventative health screening of that organ per recommended guidelines. Additionally, TG patients who are currently on or have previously been on gender affirming hormone treatment are at increased risk for some medical conditions which may require more frequent preventative health screenings. It is important to obtain a thorough medication and surgical history to fully ascertain the individual's screening needs. Table 4 provides and overview of preventive screening needs of TG patients.

TABLE 4. PREVENTATIVE HEALTH SCREENING FOR TG PATIENTS

| Health Screening | Transgender Women | Transgender Men | |
|---------------------------|--|--|--|
| Breast cancer | Screen patients age >50 years based on established clinical guidance. | Intact breasts: Routine screening as for natal females. Postmastectomy: Yearly chest wall and axillary exams. | |
| Cardiovascular Disease | Recommended periodically in accordance with established guidance. Parameters should include weight, BMI, blood pressure, lipids, and blood sugar/A1C. | | |
| Cervical cancer | Vaginoplasty: no screening. | Cervix intact: Routine screening as for natal females. Absent cervix: No screening | |
| Colon cancer | Recommended in accordance with established guidance. | | |
| Diabetes Mellitus | Recommended periodically in accordance with established guidance. If on estrogen: increased risk and frequency of screening may be increased. | Recommended periodically in accordance with established guidance. | |
| Hyperlipidemia | Recommended periodically in accordance with established guidance. If on estrogen: annual lipid screening. | Recommended periodically in accordance with established guidance If on testosterone: annual lipid screening | |
| Osteoporosis | Testes intact: Routine screening as for natal males. Postorchiectomy: Screen all patients > 65 years. Screen all patients age 50-65 years if off hormones for >5 years | Screen all patients age >65 years Screen patients age 50-65 if off hormones for >5 years | |
| Prostate cancer | Routine screening as for natal males. | Not applicable | |
| Testicular cancer | Pre-orchiectomy with intact testes: Recommended periodically in accordance with established guidance. | Not applicable | |
| Refer to UpToDate | Primary Care of Transgender Individuals and BC | OP Clinical Guidance for Preventive Health | |

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14. MINIMALY INVASIVE AND NON-INVASIVE GENDER AFFIRMING TREATMENT MODALITIES

There are several minimally invasive and non-invasive gender-affirming treatment modalities available to TG patients such as voice and communication training, professional laser facial hair removal, and chondrolaryngoplasty (tracheal shaving). Lesser invasive or minor surgical procedures may be deemed medically necessary and considered on a case-by-case basis.

The purpose of these gender-affirming treatment modalities is to decrease or stabilize the gender dysphoria/incongruence experienced by the TG patient and improve the psychosocial functioning of the TG individual. The primary care treatment provider should use sub-specialty consultation requests in the electronic health record (EHR) to order these modalities. It is the responsibility of the medical provider to document the medical necessity, using accepted medical standards for gender-affirming treatment, for each of the requested lesser invasive and non-invasive interventions.

Requests for these treatment modalities (other than hormone treatment) such as voice and communication training, professional laser facial hair removal/electrolysis, will be reviewed in accordance with Program Statement 6031 Patient Care, section on Utilization Review; a subspecialty consult will be placed in BEMR and referred to the local Utilization Review committee for review. All procedures approved at the local URC meeting will require referral to the Regional Medical Director (RMD) for review and approval per PS 6031.

Appendix 1. Transition Pathway for Transgender Patients lists the transition pathway for the affirmation treatment of the incarcerated TG individual from diagnosis to referral for major gender affirming surgery. These steps are not required to be fulfilled in chronological order before progressing to more invasive and non-reversible gender affirming treatment modalities but are an example of treatment modalities from least to most invasive.

VOICE AND COMMUNICATION TRAINING

Providers are encouraged to reach out to Regional Physical and Occupational Therapists, who can assist in finding appropriate resources. The American Speech-Language-Hearing Association (ASHA) has a provider directory for speech language pathologists who specialize in voice and communication therapy for transgender and gender diverse people.

FACIAL HAIR REMOVAL

Facial hair is often a source of distress and suffering for patients who identify as trans-female. Several noninvasive options are available to our incarcerated population. Patients can access the commissary to purchase extra razors, hygiene items such as hair removal creams and lotions, as well as foundation/coverage cremes/liquids to match the color of their skin; some of these products require special order purchases. Hair removal through waxing is a custody concern and is avoided in an incarcerated environment.

When commissary items fail to achieve desired results, and there is continued Gender Dysphoria, Health Services may provide over-the-counter laser hair removal devices as medically necessary. These are secured/maintained in Health Services and used by the patient under monitoring of staff.

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Most laser hair removal devices marketed for at-home use are IPL (Intense Pulsed Light) devices. These devices cause a reduction in hair by emitting multiple wavelengths of light to the skin targeting melanin in the hair follicle, which then heats up the hair follicle causing it to weaken or be destroyed. IPL devices only work on hair that is in the growth phase and attached to the follicle therefore multiple treatments are often required. These devices work best on brown and black hair and typically do not provide results on white, grey, light blonde, or red hair. IPL devices work best on Fitzpatrick skin types I-IV which includes all skin tones except dark brown or black skin.

Another laser hair removal device marketed for at-home use is the diode laser. The diode laser works like the IPL devices, except instead of emitting multiple various wavelengths of light it emits a single wavelength of concentrated light. The diode devices are considered safer for all skin types as the IPL cannot be used on darker skin due to lower effectiveness and increased risk of skin burning. It is important to check what skin types the device can treat prior to obtaining the device.

Patients need to be educated on realistic expectations of these devices including: understanding that treatment often is not permanent; will require multiple treatments, often to the same areas; and different devices have varied effectiveness depending on skin and hair color, among other factors. Additionally, they are not without adverse reactions, sometimes causing skin irritation, pain, blistering or scarring. They should not be used on skin with large moles, birthmarks, or tattoos. All visible hair should be shaved in the area prior to use. Sun exposure, before and after treatments, should be avoided.

Prior to obtaining a laser hair removal device, institutions must check to see if the device is FDA cleared using the link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Search by device name and look for the designation of "Substantially Equivalent (SESE)" to determine if FDA cleared. In addition, institutions will need to consider the options for cleaning between patient use with each product.

If these measures fail to remove the facial hair or are contraindicated (e.g., documented allergy or repeated infections) and patient has persistent unresolved Gender Dysphoria/incongruence, a referral consultation for professional laser facial hair removal or electrolysis may be submitted to the local Utilization Review Committee for consideration.

15. INVASIVE AND COMPLEX GENDER-CONFIRMING SURGERIES

→ Gender-Confirming surgery has also been referred to as sex reassignment surgery. It is important to note terminology changes often and the latter term is falling out of use.

TG patients who have been compliant with all aspects of gender affirming care may desire further gender affirming treatment by requesting consideration for invasive and complex gender-confirmation surgery.

Gender confirming surgery may be medically necessary and is considered on a case-by-case basis. The BOP strives to provide community standard medical and surgical care within the confines its systems.

Surgical confirmation for trans individuals in BOP custody may be the final stage in their transition process. While many individuals may not require any surgery, for some it is medically necessary to complete more than a single procedure to alleviate their gender dysphoria/incongruence. See <u>Table 5</u> for different examples of surgical procedures.

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TABLE 5. GENDER CONFIRMING PROCEDURES

| Feminizing Surgical Procedures | |
|-----------------------------------|---|
| Breast Augmentation | Enlarging the breasts using breast implants |
| Clitoroplasty | Surgical creation of a clitoris |
| Labiaplasty | Creation or reshaping of the labia around the vagina |
| Penectomy | Removal of all or part of the penis |
| Orchiectomy | Removal of one or both testicles |
| Masculinizing Surgical Procedures | |
| Bilateral Mastectomy | Removal of both breasts |
| Male Chest Contouring | Contouring the chest into a masculine shape |
| Hysterectomy | Removal of the uterus |
| Ovariectomy/Salpingo-oophorectomy | Removal of ovaries/removal of ovaries and fallopian tubes |
| Penile Prosthesis | An erectile prosthetic device is placed to allow for an erection |
| Phalloplasty | Construction of a penis which may involve multiple surgeries |
| Scrotoplasty | Creation of a scrotum |
| Metoidioplasty | A surgical procedure that works with existing genital tissue to form a phallus, or new penis. |
| Permanent Hair Removal | When clinically required in preparation for bottom surgery |

In accordance with <u>Program Statement 5200.08 Transgender Offender Manual</u>, the TEC reviews all general administrative criteria for major gender affirming surgery and reviews additional correctional/custody considerations. The request for invasive and complex gender confirming surgery requires executive level administrative approval (by TEC), and approval from the Medical Director.

The **Clinical Director's (or designee's) role** at the referral institution is to support and treat the trans patient according to this guidance and document it accordingly. In general, clinical criteria for gender confirming consideration in the Bureau include the following:

- The patient has received ongoing gender affirming treatment by assigned medical and mental health providers, and there is persistent well-documented GD.
- There is clinical documentation of patient-centered discussions and documented ongoing follow-up regarding the specific therapeutic and surgical needs.
- The patient has been deemed capable to make fully informed decisions.
- Any significant medical and mental health conditions are reasonably well controlled.
- There have been 12 continuous months of hormone therapy as appropriate to the patient's individual goals (unless medically contraindicated).
 - ► Hormone therapy in trans-males is NOT a prerequisite for mastectomy and male chest contouring.
 - ► Hormone therapy in trans-females will maximize breast growth when continued for at least 2-3 years. Some surgeons will only perform the breast augmentation surgery after this period of time has elapsed. While this may be ideal, there will be times when Gender Dysphoria symptoms may warrant breast augmentation surgery after a minimum of one year of gender-affirming hormone treatment.
 - ► Patients should undergo masculinizing hormone therapy for at least 12-24 months prior to clitoral enlargement.

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- There have been 12 continuous months of living in a gender role that is congruent with their gender identity. This experience provides ample opportunity for patients to experience and socially adjust to their desired gender role before undergoing irreversible surgery.
- Per <u>Program Statement 5200.08 Transgender Offender Manual</u>, the Warden submits a referral request to the TEC who will complete an administrative readiness review for gender-confirming surgery.
- When the TEC administratively approves a patient for surgical consideration, a referral is made
 to the Medical Director who remains the final authority in approving or disapproving a patient
 for gender confirming procedures. At the direction of the Medical Director, all pertinent clinical
 information will be reviewed by the Transgender Utilization Review Advisory Group to establish
 medical appropriateness for the procedure according to community standards.

TRANSGENDER UTILIZATION REVIEW ADVISORY GROUP REVIEW

The Transgender Utilization Review Advisory Group is made up of members of the Transgender Clinical Care Team. Each utilization medical review meeting will require one pharmacist, one psychiatrist, a primary care physician and one social worker from the Transgender Clinical Care Team.

All clinical information in the surgical referral packet submitted by the patient's treatment providers is reviewed. The Transgender Utilization Review Advisory Group may need to interview the patient and/or contact members of the treatment team at the referring institution for additional clinical information (EKG, Pulmonary Function Testing, etc). A targeted utilization review is conducted to assure the proposed procedure(s) are medically needed and appropriate according to community standard prior to making their recommendation to the Medical Director. The Medical Director has the final clinical authority, according to BOP Policy, for approving/disapproving patients for referral for Gender Confirming Surgery.

CLINICAL CONTENTS OF THE GENDER CONFIRMING SURGICAL REFERRAL PACKET

The **SURGICAL REFERRAL PACKET** should include the following items:

MENTAL HEALTH EVALUATION: the mental health professional (typically a Psychologist familiar with the patient) will document the patient's personal mental health and gender non-conformity history, progress, and suitability for surgery based on the stability of co-existing mental illness, and consolidation of one's identity. Recommended content of the mental health provider's referral for surgery include:

- The presenting general identifying characteristics.
- A list of all active mental health diagnoses.
- A review of history of suicidality, homicidality, history of violence, any psychiatric hospitalizations, and residential treatment for mental health or substance use.
- Any current and past substance use including nicotine.
- The duration of the mental health professional's relationship with the client, including the type of evaluation(s) and therapy or counseling to date.
- If and how long the patient has been living in the identified gender.
- An explanation that the criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery.

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- Formal evaluation and documentation of capacity to give consent.
- Any issues regarding communication (e.g., English fluency, hearing impairments, an autism spectrum disorder, literacy level, learning differences, etc.)

MEDICAL EVALUATION: the objective of the medical evaluation of a pre-surgical candidate for gender-confirmation surgery is to establish medical suitability for the upcoming procedure. The medical evaluation will address both gender non-binary consolidation medical needs according to <u>WPATH</u>, as well as a general pre-surgical evaluation according to community standard. Recommended content for the medical evaluation for referral for surgery should include documentation on:

- Presence of persistent gender dysphoria/incongruence.
- Type of surgery patient is requesting.
- General statement about patient's ability to understand the irreversible aspects of the procedure.
- General patient discussion regarding risks for surgery which will be dependent on what type of surgery is being done. Some general risks to discuss with the patient include but are not limited to:
 - Significant pain.
 - Suboptimal appearance.
 - ▶ Risk related to general anesthesia to include death.
 - Excessive blood loss and need for transfusion.
 - Blood clots.
 - ▶ Damage to surrounding structures.
 - Nerve damage and loss of sensation.
 - ▶ Hematomas.
 - ▶ Infection or abscess potentially resulting in necrosis.
 - Excessive scarring.
 - Patient should also be informed that any detailed surgical technique information, risks of the procedure, and complication rates will be discussed with the surgeon, who is responsible for obtaining surgical consent.
- Documentation that the patient understands expected aftercare plan, what is to be expected
 during the healing process, and how the plan may change based on surgical results and
 recommendations from the surgeon.
- Patient History
 - History of present illness
 - Current medical and mental health status.
 - Medical and mental health conditions are reasonably well controlled.
 - Past medical history
 - Allergies

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- Medications
 - All active medications.
 - Dose and frequency.
 - Duration of hormone therapy (if applicable).
- Review of systems
- Family history
- Social history
- Surgical history
- Sexual reproductive history and wishes
- Physical Exam (complete)
 - ▶ Including HEENT, cardiac, pulmonary, abdominal, extremities and neurologic
 - Special attention to signs of conditions that would be absolute/relative contraindications to surgery
- Laboratory Studies
 - Complete blood count with differential, comprehensive metabolic panel with liver function tests
 - Applicable hormone levels
- Pre-Surgical Work-Up- this may be at the preference of the surgeon and may include:
 - Recent EKG/Chest x-ray
 - Stress test
 - Nutritional assessment

PSYCHOSOCIAL EVALUATION: The social work psychosocial assessment for gender affirming surgery is utilized to gain a comprehensive understanding of the patient within their environment, both while incarcerated and upon release. It is completed by the social worker in the EHR. The assessment addresses the following areas:

- Family relationships, past and current
- Education, work/vocation, military history
- Religious/spiritual and/or cultural needs
- Financial resources
- Mental health, substance use, and medical history
- Sexual orientation and gender identity history
- Expectations or concerns regarding surgery
- Psychosocial functioning, support, and aftercare

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16. TRANSITIONS OF CARE

Quality care and treatment includes planning for what will happen when a patient leaves the institution and BOP custody. Consultation with Transitional Care Team (TCT) should be pursued to assist with release planning efforts for transgender individuals, especially as it pertains to medical needs and gender affirming hormone therapy. The TCT can coordinate with relevant stakeholders and connect patients transitioning into the community with appropriate services and resources to ensure continuity of care. Aftercare planning for transgender individuals should include the following considerations:

NOTE: If the institution is without a staff social worker, regional social workers are available to assist with aftercare planning.

- A Consent for Release of Medical Information should be obtained from the inmate patient, in accordance with BOP policy, so that the inmate patient's treatment plan can be discussed with the community health care provider.
- An adequate supply of medications should be provided to the inmate prior to release or during community placement, in accordance with BOP policy.
- Patients transferring to Residential Re-entry Centers (RRC) or Home Confinement (HC) will be referred to BOP Health Systems Specialists (HSS) and Community Treatment Specialists (CTS) for continuity of care while in the RRC or on HC.
- If a patient is receiving gender affirming hormone therapy and is not transferring to RRC or HC, an aftercare plan should be established to ensure continuity of care.

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KEY TO ABBREVIATIONS

Below is a list of abbreviations used throughout this guidance.

→ See <u>Section 2. Definitions</u> for explanation of the terms marked with an asterisk (*).

| AEs | Adverse events |
|-------|--|
| ARB | Angiotensin II receptor blocker |
| BMD | Bone mineral density |
| ВМР | Basic metabolic panel, including glucose, calcium, sodium, potassium, CO2, chloride, blood urea nitrogen, and serum creatinine |
| CAD | Coronary artery disease |
| СВС | Complete blood count |
| CCARE | BOP Care Coordination and Reentry Team |
| СМА | Case Management Activity (codes) |
| CV | Cardiovascular |
| DM | Diabetes mellitus |
| FSH | Follicle-stimulating hormone |
| GD* | Gender dysphoria |
| GnRH | Gonadotropin-releasing hormone |
| hCG | Human chorionic gonadotropin |
| IM | Intramuscular |
| LFT | Liver function test |
| LH | Luteinizing hormone |
| N/V | Nausea and vomiting |
| PCOS | Polycystic ovarian syndrome |
| PREA | Prison Rape Elimination Act (see <u>Section 3</u>) |
| q | "Every" (example: q2wk = every 2 weeks) |
| SHBG | Sex hormone-binding globulin |
| SQ | Subcutaneous |
| TCCT* | BOP Transgender Clinical Care Team |
| TEC* | BOP Transgender Executive Council |
| TICC | Trauma-Informed Correctional Care in the BOP |
| TG* | Transgender |
| VTE | Venous thromboembolism |
| | |

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APPENDIX 1. TRANSITION PATHWAY FOR TRANSGENDER PATIENTS

| 1 | Patient self-identifies as TG or gender nonbinary to BOP staff member. Referral is made to a mental health professional or medical provider. | | | | |
|---|---|--|--|--|--|
| 2 | The mental health professional completes an assessment and documents gender non-conformity and/or gender dysphoria as indicated. (<u>Section 7</u>) Initiate gender-affirming live experiences within the prison system. | | | | |
| 3 | Referral to medical provider for evaluation if pati affirming hormone treatment (<u>Section 8</u>). Hormone treatment can be initiated prior to men medical provider first and meets treatment criter | tal health evaluation, when/if patient presents to | | | |
| 4 | Initiation of gender affirming hormone treatment after appropriate counseling completed on expected risks, outcomes, and complications. If needed, case can be discussed with BOP TCCT prior to initiation, though not required. Obtain informed consent (Section 9). | | | | |
| | FEMINIZING THERAPY | MASCULINIZING THERAPY | | | |
| 5 | Begin hormonal therapy with anti-androgen (spironolactone first, unless contraindicated) and estradiol Start low and titrate (no more than every few weeks) to appropriate level while using lowest effective dose. See Section 11. Feminizing Hormone Therapy | Begin hormonal therapy with testosterone Start low and titrate (no more than every few weeks) to appropriate level while using lowest effective dose. → See Section 12. Masculinizing Hormone Therapy | | | |
| | If treatment has reached maximum estradiol dose without desired effects after appropriate amount of time, consider adding another antiandrogen such as finasteride, a GnRH agonist, or medroxyprogesterone. Consult BOP TCCT if needed. If still experiencing uterine bleeding after 6 months of high-dose testosterone therapy, consider adding medroxyprogesterone or a GnRH agonist to suppress menstruation. Consult BOP TCCT if needed. | | | | |
| 6 | After initiation and compliance with continuous gender affirming hormone treatment, a patient may request further gender affirmation by living in agender affirming institution. e.g., transfemale desires to live in a female institution/ trans-male desires to live in a male institution. The warden at the respective institution will request an administrative review by the TEC | | | | |
| 7 | If approved by the TEC, the patient will be designated to the gender affirming institution (aka institution of the identified gender) | | | | |
| 8 | Institutions that house transgender or gender non-conforming patients should develop a multidisciplinary team ¹ who meet and discuss the patient's needs and progress | | | | |
| | (table continues on | next page) | | | |

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| Tran | nsition Pathway for Transgender Patients (Cont.) |
|------|--|
| | After 12 months of living in the identified gender at the gender-affirming institution or original institution if the TG patient does not request transfer, compliance with continuous gender affirming hormone treatment and with documentation of persistent gender incongruence, the patient may benefit from lesser/non-invasive gender affirming treatment modalities or invasive/complex gender confirmation surgery ² |
| 9 | For all lesser/non-invasive gender affirming treatment modalities (ex. voice and communication training, professional laser facial hair removal) the individual provider will place the appropriate consult in the EHR and refer to the local Utilization Review Committee for review. Referral to the RMD will be required. |
| | For invasive/complex gender confirmation surgery- the warden at the respective institution will first request an administrative review by the TEC. |
| | The TEC determines whether general administrative criteria for gender confirming surgery is met and refers the case to the Medical Director for a medical review. |
| 10 | The Medical Director will request review by the Transgender Utilization Review Advisory Group who will clinically review the surgical referral packet submitted by the Clinical Director. If the patient meets the clinical criteria for surgery, a memo, with all accompanying clinical supporting materials will be sent to the Medical Director, who is the final authority in approving a patient for referral to the gender confirming surgeon. |
| 11 | Gender confirming surgical evaluation will be completed by the contracted community surgeon who is responsible to meet with the patient to confirm readiness and medical suitability for complex surgery. Informed consent surrounding all aspects of the surgery to include risks, complication rates, and expected outcomes is the responsibility of the surgeon. |
| APP, | tment team should consist of the Clinical Director (or designee), psychiatrist (as needed), Primary Care osychologist, social worker, and pharmacist. Other representative members may include unit team, captain, ain (or patient representative), and associate warden. The patient may be invited to attend to clearly |

articulate and establish his/her clinical needs.

² Individuals will desire to progress to different stages of the stepwise approach. Only a subset of all gender nonconforming patients will pursue a surgical intervention.

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APPENDIX 2. SUMMARY TABLES FOR FEMINIZING HORMONE THERAPY

- → See <u>Section 11</u> for more discussion on the medications used in Feminizing Hormone Therapy.
- → These charts are not all-inclusive and are meant to summarize major considerations for medications. Refer to current drug interaction references, manufacturer information, and/or a pharmacist for additional information regarding drug dosing (to include renal and hepatic dosing), interactions, adverse effects, and contraindications.

Table 1A: Anti-Androgen Drugs for Feminizing Hormone Therapy

| SPIRONOLACTONE Starting: 2: Typical: 10 in 2 divided Max: 200 m FINASTERIDE Low: 1 mg used to trea alopecia if r desired afte individualize of androger achieved) High: 5 mg | | CHANISM OF ACTION | RISK CONSIDERATION | Notes |
|---|--|---|---|---|
| Typical: 10 in 2 divided Max: 200 m Low: 1 mg used to treat alopecia if redesired after individualize of androger achieved) High: 5 mg | | | /Contraindications | NOTES |
| used to treat alopecia if redesired after individualized of androger achieved) High: 5 mg | 00-300mg/day antih d doses directing mg BID testo andr | assium-sparing hypertensive that ctly inhibits osterone secretion and rogen binding to the rogen receptor | Renal insufficiency Potassium >5.5 mmol/L (use with caution if patient has comorbid condition or medications known to increase potassium) | |
| who cannot spironolacto | Low: 1 mg daily (generally used to treat androgenetic alopecia if needed and desired after individualized target level of androgen blockade is androgen receptor 5α reductase inhibitor that blocks the conversion of testosterone to the more active 5α dihydrotestosterone (DHT) | | None pertinent | Predicted to have little utility if the testosterone levels are suppressed and there is no substrate to generate DHT. WPATH recommends against routine use in patients where testosterone and dihydrotestosterone levels have already been lowered with estrogen and an antiandrogen. Note, this includes for the use of androgenetic alopecia. Use in combo with spironolactone for rare individuals not achieving desired effects. May be used after orchiectomy if hirsutism or male pattern baldness are present. When compared to placebo, 5-alpha-reductase inhibitors have been associated with an increase in the incidence of high-grade prostate cancers. |

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| ★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL 100-200 PG/ML AND SERUM TESTOSTERONE <50 NG/DL ★ | | | | | | | |
|---|---|--|--|--|--|--|--|
| Drug | Dose | MECHANISM OF ACTION | RISK CONSIDERATION/ CONTRAINDICATIONS | Notes | | | |
| GNRH AGONISTS: GOSERELIN LEUPROLIDE | Goserelin: 3.6 mg SQ implant q4 weeks Leuprolide: 3.75–7.5 mg SQ/IM monthly or 11.25mg SQ/IM q3 months Lupron Depot® is administered IM Eligard® is administered SQ | receptor, thus degreasing levels of FSH & LH resulting in highly effective gonadal blockade receptor, thus degreasing levels of FSH & LH resulting in highly effective gonadal blockade In cases of persistent elevations of despite maximized antiandrogen do must be thoroughly evaluated prior GnRH Antagonist use. Directly obsessionable to exist, autonomous er production (i.e., tumor) should be compropriate evaluation should be comprovated in proximal release dates. Intolerable hyperkalemia, increased urination, and/or a reduction in bloos spironolactone. In cases of persistent elevations of despite maximized antiandrogen do must be thoroughly evaluated prior GnRH Antagonist use. Directly obsessionable to exist, autonomous er production (i.e., tumor) should be compropriate evaluation should be comprovated in proximal release dates. In cases of persistent elevations of despite maximized antiandrogen do must be thoroughly evaluated prior GnRH Antagonist use. Directly obsessionable determined to exist, autonomous er production (i.e., tumor) should be comprovated in proximal release dates. | | In cases of persistent elevations of testosterone despite maximized antiandrogen dosing, adherence must be thoroughly evaluated prior to consideration of GnRH Antagonist use. Directly observed therapy should be considered. If complete adherence is determined to exist, autonomous endogenous production (i.e., tumor) should be considered and appropriate evaluation should be conducted. High cost should be considered in patients with | | | |
| PROGESTIGENS: MEDROXYPROGESTER ONE | Starting: 2.5 mg daily Typical: 5–10 mg daily Max: 10 mg daily | Inhibits secretions of pituitary gonadotropins (1, Table 1a, Page 2 of 2 (see Key)) | Similar to estrogen. See CHART 1B below. | No well-designed studies documenting efficacy. Use in standard care generally lack formal recommendation for use. If a patient is to be placed on a progestin, goals of use should be clearly documented and periodically evaluated. If goals are not achieved, medication should be discontinued. Antidotal reports improved breast development, mood, and libido. However, evidence of benefit is unlikely to outweigh risk, which includes VTE | | | |

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TABLE 1B: ESTROGEN FOR FEMINIZATION

| | ★ Goal levels for MtF: Serum Estradiol <200 pg/ml and Serum Testosterone <50 ng/dl ★ | | | | | | | |
|--|---|---|---|----------------|--|--|--|--|
| Drug | Dose | MECHANISM OF ACTION | RISK CONSIDERATION/ CONTRAINDICATIONS | Notes | | | | |
| ESTRADIOL ESTRADIOL VALERATE IM (DELESTROGEN) | Typical: 2-6 mg daily Occasionally higher doses are used as clinically indicated (literature recommends maximum does of 6-8mg depending on source) If greater than 2 mg/day, recommend divided twicedaily dosing. Typical: 5-30 mg IM q2wk May divide dose into weekly injections for cyclical symptoms. | Estrogens modulate the pituitary secretion of gonadotropins, LH, and FSH through a negative feedback system | Transdermal formulations are preferred for persons > 40 years old or those with risk factors for thromboembolic disease Inform treatment team prior to surgery of hormone therapy. Individual risk assessment to determine adjustments to therapy perioperatively. Individuals who enter the BOP on conjugated estrogen should be switched to a different form of estrogen due to inability to monitor estrogen levels with this preparation IM injections cause greater peaks and troughs in estrogen levels making oral and transdermal preparations preferable | | | | | |
| ESTRADIOL CYPIONATE IM (DEPO-ESTRADIOL) | • Typical: 2–10 mg IM q1wk | | PorpyriaDiseases exacerbated by fluid retention | | | | | |
| ESTRADIOL PATCH (CLIMARA, ESTRADERM, ALORA, VIVELLE-DOT) | Typical: 0.025 mg – 0.2 mg/day Max single patch dose available is 0.1 mg per 24 hours. More than one patch can be applied at a time Frequency of patch change is brand/product dependent. | Same as above. | | | | | | |
| | APPENDIX | (1, TABLE 1B, PAGE 1 OF 1 (see <u>Ke</u> | y to Abbreviations in section precedir | ng Appendices) | | | | |

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APPENDIX 3. SUMMARY TABLE FOR MASCULINIZING HORMONE THERAPY

- → See <u>Section 12</u> for more discussion on the medications used in Masculinizing Hormone Therapy.
- → These charts are not all-inclusive and are meant to summarize major considerations for medications. Refer to current drug interaction references, manufacturer information, and/or a pharmacist for additional information regarding drug dosing (to include renal and hepatic dosing), interactions, adverse effects, and contraindications.

| | ★ Goal Levels for FtM: Serum Estradiol <50 pg/ml and Serum Testosterone 320-1000 ng/dl ★ | | | | | | |
|---|---|---|--|--|--|--|--|
| Drug | DRUG DOSE I MECHANISM OF ACTION I | | RISK CONSIDERATION/ CONTRAINDICATIONS | Notes | | | |
| TESTOSTERONE CYPIONA (in cottonseed oil) TESTOSTERONE ENANTHATE (in sesame oil) | • Typical: 50-100mg IM/SQ once weekly or 100-200mg IM every 2 weeks • Max: 200 mg q2wk or 100 mg/wk | Maintains secondary sex characteristics in androgen-deficient patients | Absolute: • Pregnancy • Breast cancer (testosterone may have anti-proliferative effects on most, but not all, breast cancers) | transdermal Transdermal reaches same levels as IM, but in longer timeframe. | | | |
| TESTOSTERONE PATCH Available strengths: 2 mg 2.5 mg, 4 mg, 5 mg | • Typical : 2.5-7.5 mg/day q PM • Max : 8 mg/day q PM | | Precautions: may persist when usi • Erythrocytosis • Testosterone is a DE | Menses typically stop in early months of treatment but may persist when using transdermals. Testosterone is a DEA controlled substance. For the first 2 to 2 months of treatment total. | | | |
| TESTOSTERONE GEL (TESTIM 1%, ANDROGEL 1%) | • Typical:50-100mg/day | | Cardiac, hepatic, renal, or vascular disease with edema or risk of edema | For the first 3 to 9 months of treatment, total testosterone levels may be elevated with free testosterone levels remaining in the biological female | | | |
| TESTOSTERONE GEL (ANDROGEL 1.62%) | 31.0 | | Sleep apnea or high risk of sleep apnea due to obesity or chronic lung disease | range due to high sex hormone binding globulin levels in some biological women. 15% of patients on testosterone will experience | | | |
| TESTOSTERONE SOLUTIO (AXIRON axillary solution) | ч · | | Dyslipidemia Migraines Epilepsy Depression, significant history of violent behavior | transient elevations in liver enzymes. If increase > 3x D/C and seek consultation. Cypionate and enanthate formulations cannot be used interchangeably due to differences in duration of action. | | | |
| MEDROXYPROGESTERONI AND GNRH AGONISTS | Not routinely used. Refer to current and contraindications/precaution | _ | osing, mechanism of action, | Use is recommended in patients who desire but have not yet begun testosterone therapy, or in conjunction with testosterone therapy for breakthrough bleeding | | | |
| | APPENDIX | 2 , PAGE 1 OF 1 (see <u>Key to Ab</u> | obreviations in section preceding App | pendices) | | | |

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APPENDIX 4. MONITORING DURING FEMINIZING HORMONE THERAPY

Appropriate monitoring during gender-affirming hormone therapy is crucial to (1) ascertaining that target blood levels of hormones are being met and (2) assessing and maintaining the individual's health overall.

- **Clinical and laboratory monitoring** is appropriate every three months during the first year, and then as clinically indicated (typically once or twice yearly).
 - ► Monitor for development of feminine characteristics, for target blood levels, and for adverse effects of medication and other treatment.
- **Cardiovascular risk assessment** is recommended periodically for all patients treated with hormones in accordance with established guidelines and BOP guidance when available.
 - ► Specific parameters that should be monitored include weight and body mass index, blood pressure, lipids, and blood sugar and/or hemoglobin A1C levels, in accordance with established guidelines.
- **Serum ESTRADIOL and TESTOSTERONE levels** are obtained before starting those respective medications, and then every three months while on treatment.
 - ► Target levels are <200 pg/ml for estradiol and <50 ng/dl for testosterone. Higher levels of testosterone indicate inadequate suppression; higher levels of estradiol are associated with increased risks for thromboembolic disease, liver dysfunction, and development of hypertension.
- **Serum electrolytes, most importantly potassium, and renal function** are obtained prior to starting **SPIRONOLACTONE**, every three months during the first year of treatment, periodically thereafter, or more frequently with increases in dosage or as clinically indicated.
 - ► Dose adjustment or discontinuation of spironolactone is recommended for elevated potassium levels or serum creatinine >4 mg/dL.
- **Screening for colon and prostate cancer** is recommended in accordance with established guidelines and BOP guidance when available.
- **Breast cancer screening** guidelines for women are followed for transgender women treated with hormone therapy.
- Screening for osteoporosis with a DEXA scan may be appropriate in some cases. In addition,
 monitoring of hormone levels to ensure suppressed gonadotropin levels may serve as a
 surrogate marker to indicate adequate sex hormone levels in maintaining bone density in these
 patients.
 - ▶ In the absence of sufficient data to formulate evidence-based guidelines, it is considered appropriate to screen those who are at least five years post-gonadectomy, those who are 50 to 65 years old and have risk factors for osteoporosis, and all those who are 65 years or older.
 - ▶ Bone density measurements for transgender women are compared with standards for biological females.

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• Baseline and periodic monitoring of liver enzymes and prolactin levels may be appropriate in those treated with ESTRADIOL, but there is insufficient data available to make a specific recommendation.

The following table below summarizes the monitoring schedule for individuals undergoing FEMINIZING hormone therapy.

→ See Key to Abbreviations in section preceding Appendices.

LABORATORY MONITORING DURING FEMINIZING HORMONE THERAPY

| Lab Test | Comments | Baseline | 3 Mos ¹ | 6 Mos ¹ | 12 Mos ¹ | Yearly | PRN |
|------------------------------------|---|----------|--------------------|--------------------|---------------------|--------|-----|
| ВМР | For individuals on spironolactone | Х | Х | Х | Х | Х | |
| Lipids | As clinically indicated | Х | | | | | Х |
| A1C/Glucose | As clinically indicated | Х | | | | | Х |
| Estradiol | Range: generally, 100–200 pg/mL, but should not exceed 200 pg/ml | Х | Х | Х | Х | Х | |
| Total Testosterone ² | Range: < 50 ng/dL | | Х | Х | Х | Х | |
| Prolactin | Only if symptoms of prolactinemia | | | | | | Х |
| LFTs | After baseline, optional if on estrogen, progesterone, or medroxyprogesterone | Х | | | | Х | |

¹ In the first year of therapy only

² Every 3 months in the first year then 1-2 times per year thereafter.

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APPENDIX 5. MONITORING DURING MASCULINIZING HORMONE THERAPY

Appropriate monitoring during gender-affirming hormone therapy is crucial to (1) ascertaining that target blood levels of hormones are being met and (2) assessing and maintaining the individual's health overall.

- → A pregnancy test is obtained prior to starting treatment for all persons assigned as female at birth and have child-bearing potential.
 - **Clinical and laboratory monitoring** is appropriate every three months during the first year, and then as clinically indicated (typically once or twice yearly).
 - → Monitor for development of masculine characteristics, for target blood levels, and for adverse of effects of medication and other treatments.
 - Cardiovascular risk assessment is recommended periodically for all patients treated with hormones, in accordance with established guidelines and BOP guidance when available.
 - ► Specific parameters that should be monitored include weight and body mass index, blood pressure, lipids, and blood sugar and/or hemoglobin A1c levels.
 - Serum testosterone levels are obtained before starting treatment with testosterone, and then every three months while on treatment.
 - ▶ Timing of the testosterone level is determined by the route of administration.
 - Testosterone enanthate/cypionate injections, testosterone levels should be obtained midway between injections. The target testosterone level is 400-700ng/dL.
 - Transdermal testosterone levels can be done any time after one week of therapy.
 - Serum estradiol levels are obtained before starting hormone therapy, and then every three
 months while on treatment until estradiol levels are < 50 pg/ml and cessation of menses has
 been six months.
 - A complete blood count (CBC) and liver panel are obtained prior to starting hormone therapy, every three months during the first year of treatment, once or twice yearly thereafter, or more frequently as clinically indicated.
 - ▶ Dose adjustment or discontinuation of testosterone is indicated if the hematocrit is > 54%.
 - Screening for colon cancer is recommended in accordance with established guidelines and BOP guidance when available.
 - Breast cancer screening guidelines for women are followed for **TG** individuals treated with hormone therapy and who have not had mastectomies.
 - Cervical cancer screening is performed annually in those who are treated with hormone therapy and have cervical tissue (i.e., no hysterectomy).
 - Screening for osteoporosis with a DEXA scan may be appropriate in some cases.
 - ▶ In the absence of sufficient data to formulate evidence-based guidelines, it is considered appropriate to assess bone mineral density prior to starting treatment in those with risk factors for osteoporosis, those who are at least five years status post-gonadectomy, and all those who are 60 to 65 years or older.

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► Bone density measurements for transgender men are compared with standards for biological males.

The following table below summarizes the monitoring schedule for individuals undergoing hormone masculinizing therapy.

→ See Key to Abbreviations in section preceding Appendices.

LABORATORY MONITORING OF MASCULINIZING HORMONE THERAPY

| Lab Test | Comments | Baseline | 3 Mos ¹ | 6 Mos ¹ | 12 Mos ¹ | Yearly | PRN |
|---|-------------------------|----------|--------------------|--------------------|---------------------|--------|-----|
| CBC (Hgb & Hct) | | Х | Х | Х | Х | Х | |
| hCG (if child- bearing potential) | | Х | | | | | |
| Lipids | As clinically indicated | Х | | | | | Х |
| A1C/Glucose | As clinically indicated | Х | | | | | Х |
| LFTs | | Х | | Х | Х | Х | |
| Estradiol | Range: <50pg/mL | | Х | | | | Х |
| Total Testosterone ² | | Х | Х | Х | Х | Х | Х |

¹ In the first year of therapy only

² If IM/SQ – check midway between injections (target level is 400-700ng/dL). Alternatively measure peak and trough levels to ensure levels remain in the normal male range. If patch – check after 1 week. Monitor levels every 3 months until levels are at goal.

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APPENDIX 6. FEMINIZING GENDER-AFFIRMING HORMONE THERAPY – CONSENT AND COUNSELING FORM

FEMINIZING GENDER-AFFIRMING HORMONE THERAPY FOR TRANSGENDER PATIENTS CONSENT AND COUNSELING FORM

| INSTITUTION NAME: | |
|-------------------|-------|
| PATIENT NAME: | ID #: |

You want to take estrogen and other medications to feminize your body. Once you start these medications, some of them will need to be taken for the rest of your life to maintain their effects. Before using these medications, you need to know more about how they might affect you, including possible benefits, side effects, risks, and warning signs. We have listed them here for you. It's important that you understand all this information before you start. Please notify your health care provider should you have any questions.

WHAT ARE THE DIFFERENT MEDICATIONS THAT CAN HELP TO FEMINIZE YOU?

ESTROGEN is the female gender-affirming hormone. There are also medications—called **ANDROGEN ANTAGONISTS** (or **ANTI-ANDROGENS** or **ANDROGEN BLOCKERS**)—that stop the production of male hormones and can help you appear less like a man.

WARNING — WHO SHOULD NOT TAKE ESTROGEN?

It should NOT be used by anyone who has a current diagnosis of:

- An estrogen-dependent cancer
- Blood clots that could or did travel to the lungs

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

- Has a personal or strong family history of breast cancer or other cancers that grow faster when estrogens are present
- · History of previous clots and currently not on blood thinners
- Has diabetes
- Has eye problems such as retinopathy
- Has heart disease, heart valve problems, or a tendency to have easily clotted blood
- Has hepatitis
- · Has high cholesterol
- Has kidney or liver disease
- Has migraines or seizures
- Is obese
- Smokes cigarettes

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Please review and <u>initial each statement</u> to show you understand the benefits, risks, and changes that may occur from taking these medications. At the end of the document, <u>indicate your preference</u> regarding hormone therapy, then sign and date it.

FEMINIZING EFFECTS OF ESTROGEN AND ANTI-ANDROGENS: I know that estrogen or anti-androgens—or both—may be prescribed to help me appear less like a man and more like a woman. I know that it can take several months to years for the effects to become noticeable. I know that no one can predict how fast—or how much—change will happen. _ I know that if I am taking estrogen, I will probably develop breasts. • I know it can take several years for breasts to get to their full size. • I know the breasts will remain, even if I stop taking estrogen. • I know I should examine my breasts for irregularities as soon as they start growing. I should also have a clinician examine them every year. • I know I might have a milky discharge from my nipples (galactorrhea). If I do, I know I should have it evaluated by my clinician because it could be caused by the estrogen or by other medications or medical conditions. I know that no one knows if taking estrogen increases the risk of breast cancer. I know that the following changes are usually not permanent—they are likely to go away if I stop taking the medicines: I know my body hair will become less noticeable and will grow more slowly, but it won't stop completely, even if I take the medicines for years. • I know I will probably have less fat on my abdomen and more on my buttocks, hips, and thighs. It will be redistributed to a more female shape, changing from an "apple" shape to more of a "pear" shape. • I know that if I already have male pattern baldness, it may slow down, but will probably not stop completely. It is also unlikely that hair that has been lost will grow back. • I know I may lose muscle and strength in my upper body. I know my skin may become softer. I know that my body will make less testosterone. Upon release, this may affect my sex life in different ways and my future ability to cause a pregnancy:

- I know this treatment may (but is not assured to) make me permanently unable to make a woman pregnant.
- I know my sperm may no longer reach maturity. This could make me less able to cause a pregnancy. I also know I might never produce mature sperm again, but I know that it's also possible that my sperm could still mature. So, I know that I might get someone pregnant if we have vaginal intercourse, and we don't use birth control.
- I know this treatment may cause permanent infertility, and I will not be able to preserve or donate my sperm while incarcerated.

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- I know my testicles may shrink down to half their size. Even so, I know that I will need regular checkups for them.
- I know it is likely that my penis won't be hard in the morning as often as it has been before. It is also likely that I will have fewer spontaneous erections.
- I know I may lose the ability to obtain an erection for intercourse.
- I know I may have less sex drive.
- I know that sex between inmates, or between inmates and staff, is not permitted within the BOP.

_____ I know that some parts of my body will not change much by using these medicines.

- I know the hair of my beard and moustache may grow more slowly than before. It may become less noticeable, but it will not go away.
- I know the pitch of my voice will not rise, and my speech patterns will not become more like a woman's.
- I know my Adam's apple will not shrink.
- Although these medicines can't make these changes happen, there are other treatments that may be helpful.

RISKS OF TAKING FEMINIZING MEDICATIONS (ESTROGEN AND ANTI-ANDROGENS):

| be long-term risks that are not yet known. |
|---|
| I know that I should not take more medicine than I am prescribed. I know it increases health risks. I know that taking more than I am prescribed won't make changes happen more quickly or more significantly. I know my body can convert extra estrogen into testosterone which can slow down or stop my appearing more womanly. |
| I know these medicines may damage the liver and may lead to liver disease. I know I should be checked for possible liver damage as long as I take them. |
| I know these medicines cause changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know I can reach out to psychology services to help me find support resources. I also know that the BOP does not tolerate harassment, discrimination, and violence in any circumstances. If I feel I am the recipient of any of these actions, I will notify a BOP staff member. |

RISKS OF TAKING ESTROGEN:

I know that taking estrogen increases the risk of blood clots that can result in:

- Chronic problems with veins in the legs
- Heart attack
- Pulmonary embolism (blood clot to the lungs), which may cause permanent lung damage or death
- Stroke, which may cause permanent brain damage or death

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|--|--|
| I know the danger is | of blood clots is much worse if I smoke cigarettes, especially if I am over 40. so high that I should stop smoking completely if I start taking estrogen and rt to smoke again when I am released from a BOP institution. |
| | strogen can increase the deposits of fat around my internal organs. This can diabetes and heart disease. |
| | strogen can raise my blood pressure. I know that if my blood pressure goes work with me to try to control it with diet, lifestyle changes, and/or |
| | strogen increases my risk of getting gallstones. I know that I should talk with evere or long-lasting pain in my abdomen. |
| I know that estroger I have long-lasting n | n can cause nausea and vomiting. I know that I should talk with my clinician if ausea or vomiting. |
| | n can cause headaches or migraines. I know I should talk with my clinician if I migraines often, or if the pain is unusually severe. |
| non-cancerous tumo they can damage vis | yet known if taking estrogen increases the risk of prolactinomas. These are ors of the pituitary gland. I know they are not usually life-threatening, but ion and cause headaches. I know this possibility needs to be checked ician for at least three years after I start taking estrogen. |
| I know that I am mo | re likely to have dangerous side effects if: |
| • I smoke. | , |
| I am overweight. | |
| I am over 40 yea | |
| I have a history of | |
| • | of high blood pressure. |
| My family has a | history of breast cancer. |
| RISKS OF TAKING ANDROGEN A | NTAGONISTS: |
| I know that spironol | actone affects the balance of water and salts in the kidneys, which may: |
| • | ount of urine I produce, making it necessary to urinate more frequently. |
| Increase thirst. | |
| Reduce blood pre | essure. |
| Cause (although) | rarely) high levels of potassium in the blood, possibly leading to changes in at may be life-threatening. |
| | drogen antagonists make it more difficult to evaluate test results for cancer ow that if I am over 50, I should have my prostate evaluated every year with a |

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prostate-specific antigen test, as applicable.

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| PREVENTION OF MEDICAL COMPLICATIONS: |
|--|
| I agree to take feminizing medications as prescribed, and I agree to tell my clinician if I have any problems or if I am unhappy with the treatment. |
| I know that the dose and type of medication that is prescribed for me may not be the same as fo someone else. |
| I know that I need periodic physical exams and blood tests to check for any side effects. |
| I know that feminization medications can interact with other drugs and medicines—including alcohol, diet supplements, herbs, other hormones, and street drugs—causing complications. I know that I need to prevent complications because they can be life-threatening. That's why I need to be honest with my clinician about whatever else I take or use. I also know that this will not interfere with my getting medical care; I will continue to get medical care here no matter what information I share about what I take. |
| I know that it can be risky for anyone with certain conditions to take feminizing medicines. I agree to be evaluated if my clinician thinks I may have such a condition. Then, we will decide if it's a good idea for me to start or continue using these medications. |
| I know that there may be a risk for blood clots after surgery, especially if I will not be mobile for an extended period. I will need to talk with the surgeon and my doctor to decide if I need to stop taking estrogen before and/or after the surgery or immobilizing event. |
| I know that using these medicines to appear more womanly is an "off-label" use. I know that this means that using these medicines for this purpose is not approved by the Food and Drug Administration (FDA). I know that the medicine and dose that is recommended for me is based on the judgment and experience of the clinician. |
| I know that I can choose to stop taking these medicines at any time. I know that if I decide to do that, I should do it with the help of my clinician. This will help me make sure there are no negative reactions. I also know that my clinician may suggest that I cut the dose or stop taking it altogether if certain conditions develop. This may happen if the side effects are severe or if there are health risks that cannot be controlled. |
| My signature below confirms that: |
| My clinician has talked with me about: The benefits and risks of taking feminizing medication. The possible or likely consequences of hormone therapy. Potential alternative treatments. |
| |

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- I understand the risks that may be involved.
- I know that the information in this form includes the known effects and risks. I also know that there may be unknown long-term effects or risks.
- I have had enough opportunity to discuss treatment options with my clinician.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to take, refuse, or postpone therapy with feminizing medications.
- I am 18 years old or older.

| ı | RASED | ON ALI | THIC | INICOR | MATION: |
|---|-------|--------|-------|--------|----------|
| | DASEL | ON AL | LIDIS | INFUR | VIATIUN. |

| I understand the risks, and decided I do | not consent to taking androgen antagonists (|
|---|--|
| I understand the risk | not consent to taking and |
| I understand the risks, and decided I do spironolactone). | not consent to taking androgen antagonists (|
| spironoiactorie). | |
| | · |
| Patient's Signature | Date |

Your health is important to us. If you have any questions or concerns, please come to sick call and an appointment with your provider will be made.

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APPENDIX 7. MASCULINIZING GENDER-AFFIRMING HORMONE THERAPY – CONSENT AND COUNSELING FORM

MASCULINIZING GENDER-AFFIRMING HORMONE THERAPY FOR TRANSGENDER PATIENTS CONSENT AND COUNSELING FORM

| INSTITUTION NAME: | | |
|-------------------|----------|--|
| PATIENT NAME: | ID#: | |

You have expressed a desire to take testosterone to masculinize your body. Before beginning treatment, there are several details about treatment that you need to be familiar with, including the possible advantages, disadvantages, risks, warnings, and alternatives. These topics are covered below. It is important that you understand all this information before initiating treatment. Please notify your health care provider should you have any questions.

WHAT IS TESTOSTERONE?

Testosterone is the hormone responsible for male features. It builds muscle, causes the development of facial hair, and is responsible for the deepening of a person's voice during puberty. Testosterone also may increase sex-drive.

HOW IS TESTOSTERONE TAKEN?

Testosterone is usually injected every one to four weeks. It is not used as a pill because the body may not absorb it properly, and it can cause liver problems. Some people use skin creams and patches, but these are not used in the correctional environment.

The doses used for injections differ from product to product, and from patient to patient. Doses may range from 100 mg to 400 mg. The injections are administered into a large muscle to slow the release of the hormone. There can be unwanted swings in hormone levels. This can be controlled by changing how often the dose is given, how much of a dose is given, or by changing formulations.

WARNING — WHO SHOULD NOT TAKE TESTOSTERONE?

Testosterone should *not* be used by anyone who is pregnant or has uncontrolled coronary artery disease.

It should be used with caution and only after a full discussion of risks by anyone who has: acne, family history of heart disease or breast cancer, blood clot history, high levels of cholesterol, liver disease, or high red-blood-cell count. Caution should also be used in obese patients and persons who smoke.

MONITORING:

Periodic blood tests to check on the effects of the hormone will be required for treatment. Routine breast exams and pelvic exams with pap tests should be continued, when applicable.

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BENEFITS AND RISKS OF TESTOSTERONE TREATMENT:

| Benefits | Risks |
|--|---|
| Appearing more like a man: Larger clitoris* Coarser skin Deeper voice* Increased body hair* Increased facial hair* Increased muscle mass Increased strength Elimination of menstrual periods Increased physical energy Protection against bone thinning (osteoporosis) *These are permanent changes. | Acne (may permanently scar) Blood clots (thrombophlebitis) Emotional changes Headache High blood pressure (hypertension) Increased red-blood-cell count Infertility Inflamed liver Interaction with drugs for diabetes and blood thinning, e.g., Coumadin and Warfarin Male pattern baldness Increased abdominal fat Increased risk of heart disease Swelling of hands, feet, and legs Weight gain |

Please review and <u>initial each statement</u> to show that you understand the benefits, risks, and changes that may occur from taking these medications. At the end of the document, <u>indicate your preference</u> <u>regarding hormone therapy, then sign and date it</u>.

| N | 1 v c C I I | HINITING | FEEECTS | OF TEST | OSTERONE: |
|----|-------------|----------|----------|-----------|------------|
| IV | | | FFFF(IN | ()F F \ | UNIERCHAE: |

| I know that testosterone may be prescribed to make me appear less like a woman and more like a man. |
|--|
| I know that it can take several months or longer for the effects to become noticeable. |
| I know that no one can predict how fast or how much change will take place. |
| I know that the changes may not be complete for two to five years after starting testosterone. |
| I know the following changes are likely to be permanent, even if I stop taking testosterone: |
| Bigger clitoris — typically about half an inch to a little more than an inch Deeper voice |
| Growth of facial hair (moustache and beard) |
| Hair loss at the temples and crown of the head and the possibility of becoming completely bald |
| More, thicker, and coarser hairs on abdomen, arms, back, chest, and legs |

- _____ I know that the following changes are usually ΝΟΤ permanent and will likely go away if I stop taking testosterone:
 - Acne (however, acne scars will be permanent)
 - Elimination of menstrual periods (typically stop one to six months after starting testosterone)
 - Increased abdominal fat (redistribution of fat to a more masculine shape)
 - Decreased fat on buttocks, hips, and thighs
 - More muscle mass and strength

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| | Vaginal dryness |
|------|--|
| | I know that the effects of testosterone on fertility are unknown and may cause permanent infertility. I have been told that I may or may not be able to get pregnant even if I stop taking testosterone. I know I might still get pregnant even after testosterone stops my menstrual periods. I know I cannot take testosterone if I am pregnant. By continuing treatment, I accept that I may never be able to biologically parent a child. I know this treatment may cause permanent infertility, and I will not be able to preserve or donate my eggs while incarcerated |
| | I know that some aspects of my body will not be changed: |
| | Losing some fat may make my breasts appear slightly smaller, but they will not shrink very much. |
| | Although my voice may deepen, other aspects of the way I speak will not change. |
| | I know that there are other treatments that may be helpful to make my breasts smaller or my speech manlier. If I have concerns, I can discuss treatment options with my clinician. |
| Risk | S OF TESTOSTERONE: |
| | I know that the medical effects and safety of testosterone are not completely known. There may be long-term risks that are not yet known. |
| | I know not to take more testosterone than prescribed. I know this would be a risk to my health. I know that taking more testosterone than I am prescribed will not make changes happen more quickly or more significantly. I know that my body can convert extra testosterone into estrogen, which can slow down or reverse the progress of my transition. |
| | I know that testosterone can cause changes that increase my risk of heart disease. I know these changes include: |
| | Less good cholesterol (HDL), which is needed to protect against heart disease, and more bad cholesterol (LDL), which may increase the risk of heart disease Higher blood pressure |
| | Increased deposits of fat around my internal organs |
| | I know that my risk of heart disease is higher if people in my family have had heart disease, if I am overweight, or if I smoke. |
| | I know that I should have periodic heart-health checkups for as long as I take testosterone. I know I must watch my weight and cholesterol levels and have them checked by my clinician. |
| | I know that testosterone can damage the liver and possibly lead to liver disease. I know I should be checked periodically for possible liver damage for as long as I take testosterone. |
| | I know that testosterone can increase my red blood cell count and hemoglobin. I know the increase is usually only to the level that is normal for a man. I know normal levels would have no health risks; however, higher increases can cause problems that can be life-threatening. These problems include stroke and heart attack. As such, I know I need to have periodic blood checks for as long as I take testosterone. |

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|--------------------------------------|---|----------------|
| respor | that taking testosterone can increase my risk for diabetes. It may decrease my body's se to insulin, cause weight gain, and increase deposits of fat around my internal organ should have periodic checks of my blood glucose for as long as I take testosterone. | |
| | that my body can turn testosterone into estrogen. I know that no one knows if this coethe the risk of cancers of the breast, ovaries, or uterus. | uld |
| can lea is a wo | that taking testosterone can thin the tissue of my cervix and the walls of my vagina. The to tears or abrasions during vaginal intercourse. I know it does not matter if my part man or a man. This raises my risk of getting a sexually transmitted infection, including should speak frankly with my provider regarding the best ways to prevent and check ns. | tner HIV. |
| I am a | are that sex between inmates, or between inmates and staff, is not permitted. | |
| | that testosterone can give me headaches or migraines. I know it is best to talk with m if I get them frequently or if the pain is unusually severe. | У |
| irritab | that testosterone can cause emotional changes. For example, I could become more of the frustrated, or angry. I know my provider can help me find resources to explore and case changes. | cope |
| have e suppo resour tolerat | that testosterone causes changes that other people will notice. Some transgender people perienced harassment, discrimination, and violence because of this. Others have lost of loved ones. I know I can reach out to psychology services to help me find support es. I also know that in the BOP, harassment, discrimination, and violence are not ed under any circumstances. If I feel I am the recipient of any of these actions, I will not taff member. | the |
| PREVENTION O | MEDICAL COMPLICATIONS: | |
| | to take testosterone as prescribed, and I agree to tell my clinician if I have any problem nhappy with the treatment. | ms |
| | that the dose and type of medication prescribed for me may not be the same as it is for the else. | or |
| I know | that I need periodic physical exams and blood tests to check for any side effects. | |
| supple compl need t interfe | that testosterone can interact with other drugs and medicines, including alcohol, diet nents, herbs, other hormones, and street drugs. This kind of interaction can cause ations. I know that I need to prevent complications because they can be life-threaten be honest with my clinician about other items I am taking. I also know that this will ne with my getting medical care; I will continue to get medical care here no matter what it is a share about what I take. | ning. I not |
| evalua | that it can be risky for anyone with certain conditions to take testosterone. I agree to ed if my clinician thinks I may have one of these conditions. Then, we will decide if it is ea to start or continue using testosterone. | |

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|---|---|------------------|
| it is not approved by th | terone to appear more masculine is an "off-label" use. I know this me Food and Drug Administration (FDA) for this purpose. I know the mmended for me is based on the judgment and experience of the | neans |
| should discontinue wit my clinician may sugge | to stop taking testosterone at any time. I know if I decide to stop, I the help of my clinician to ensure there are no negative reactions. I t I cut the dose or stop taking it altogether if certain medical condition if the side effects are severe or if there are health risks that cann | l know ions |
| MY SIGNATURE BELOW CONFIRMS | HAT: | |
| My clinician has talked with The benefits and risks of the possible or likely of the possible or likely of the potential alternative tree. | f taking testosterone. nsequences of hormone therapy. | |
| | | |
| I understand the risks that I know that the information may be unknown long-term | in this form includes the known effects and risks. I also know that the | here |
| | nity to discuss treatment options with my clinician. | |
| · · | en answered to my satisfaction. ake, refuse, or postpone testosterone therapy. | |
| BASED ON ALL THIS INFORMATION | | |
| I understand the risks, | nd consent to taking testosterone. | |
| I understand the risks, | nd decided I do not consent to taking testosterone at this time. | |
| Patient's Signature | | |
| Prescribing Physician's Signati | re Date | |

Your health is important to us. If you have any questions or concerns, please come to sick call and an appointment with your provider will be made.

 ${\it Masculinizing Gender-Affirming Hormone Treatment for TG \ Patients-Consent \ and \ Counseling \ Form, \ page 5 \ of 5}$