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Risks of Masculinizing Hormone Therapy (FtM)

Likely increased risk:

Polycythemia

- Masculinizing hormone therapy involving testosterone or other androgenic steroids increases the risk of polycythemia (hematocrit > 50%), particularly in patients with other risk factors.
- Transdermal administration and adaptation of dosage may reduce this risk

Weight gain/visceral fat

- Masculinizing hormone therapy can result in modest weight gain, with an increase in visceral fat.

Possible increased risk:

Lipids

- Testosterone therapy decreases HDL, but variably affects LDL and triglycerides.
- Supraphysiologic (beyond normal male range) serum levels of testosterone, often found with extended intramuscular dosing, may worsen lipid profiles, whereas transdermal administration appears to be more lipid neutral.
- Patients with underlying polycystic ovarian syndrome or dyslipidemia may be at increased risk of worsening dyslipidemia with testosterone therapy.

Liver

- Transient elevations in liver enzymes may occur with testosterone therapy.
- Hepatic dysfunction and malignancies have been noted with oral methyltestosterone. However, methyltestosterone is no longer available in most countries and should no longer be used.

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Psychiatric

Masculinizing therapy involving testosterone or other androgenic steroids may increase the risk of hypomanic, manic, or psychotic symptoms in patients with underlying psychiatric disorders that include such symptoms. This adverse event appears to be associated with higher doses or supraphysiologic blood levels of testosterone

Inconclusive or no increased risk: Items in this category include those that may present risk, but for which the evidence is so minimal that no clear conclusion can be reached.

Osteoporosis

- Testosterone therapy maintains or increases bone mineral density among FtM patients prior to oophorectomy, at least in the first three years of treatment.
- There is an increased risk of bone density loss after oophorectomy, particularly if testosterone therapy is interrupted or insufficient. This includes patients utilizing solely oral testosterone.

Cardiovascular

- Masculinizing hormone therapy at normal physiologic doses does not appear to increase the risk of cardiovascular events among healthy patients.
- Masculinizing hormone therapy may increase the risk of cardiovascular disease in patients with underlying risks factors.

Hypertension

- Masculinizing hormone therapy at normal physiologic doses may increase blood pressure but does not appear to increase the risk of hypertension.
- Patients with risk factors for hypertension, such as weight gain, family history, or polycystic ovarian syndrome, may be at increased risk.

Type 2 diabetes mellitus

- Testosterone therapy does not appear to increase the risk of type 2 diabetes among FtM patients overall.

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- Testosterone therapy may further increase the risk of type 2 diabetes in patients with other risk factors, such as significant weight gain, family history, and polycystic ovarian syndrome. There are no data that suggest or show an increase in risk in those with risk factors for dyslipidemia.

Breast cancer

- Testosterone therapy in FtM patients does not increase the risk of breast cancer.

Cervical cancer

- Testosterone therapy in FtM patients does not increase the risk of cervical cancer, although it may increase the risk of minimally abnormal Pap smears due to atrophic changes.

Ovarian cancer

- Analogous to persons born with female genitalia with elevated androgen levels, testosterone therapy in FtM patients may increase the risk of ovarian cancer, although evidence is limited.

Endometrial (uterine) cancer

- Testosterone therapy in FtM patients may increase the risk of endometrial cancer, although evidence is limited.

Other side effects of masculinizing therapy:

The following effects may be considered minor or even desired, depending on the patient, but are clearly associated with masculinization.

Fertility and sexual function

- Testosterone therapy in FtM patients reduces fertility, although the degree and reversibility are unknown.
- Testosterone therapy can induce permanent anatomic changes in the developing embryo or fetus.
- Testosterone therapy induces clitoral enlargement and increases libido.

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Acne, androgenic alopecia

Acne and varying degrees of male pattern hair loss (androgenic alopecia) are common side effects of masculinizing hormone therapy.

APPENDIX C
SUMMARY OF CRITERIA FOR HORMONE THERAPY AND SURGERIES

As for all previous versions of the *SOC*, the criteria put forth in the *SOC* for hormone therapy and surgical treatments for gender dysphoria are clinical guidelines; individual health professionals and programs may modify them. Clinical departures from the *SOC* may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm reduction strategies. These departures should be recognized as such, explained to the patient, and documented through informed consent for quality patient care and legal protection. This documentation is also valuable to accumulate new data, which can be retrospectively examined to allow for health care – and the *SOC* – to evolve.

Criteria for Feminizing/Masculinizing Hormone Therapy (one referral or chart documentation of psychosocial assessment)

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country (if younger, follow the *SOC* for children and adolescents);
4. If significant medical or mental concerns are present, they must be reasonably well-controlled.

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Criteria for Breast/Chest Surgery (one referral)

Mastectomy and creation of a male chest in FtM patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country (if younger, follow the *SOC* for children and adolescents);
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Hormone therapy is not a pre-requisite.

Breast augmentation (implants/lipofilling) in MtF patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country (if younger, follow the *SOC* for children and adolescents);
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Although not an explicit criterion, it is recommended that MtF patients undergo feminizing hormone therapy (minimum 12 months) prior to breast augmentation surgery. The purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results.

Criteria for genital surgery (two referrals)

Hysterectomy and ovariectomy in FtM patients and orchiectomy in MtF patients:

1. Persistent, well documented gender dysphoria;

2. Capacity to make a fully informed decision and to consent for treatment;

3. Age of majority in a given country;

4. If significant medical or mental health concerns are present, they must be well controlled;

5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones).

The aim of hormone therapy prior to gonadectomy is primarily to introduce a period of reversible estrogen or testosterone suppression, before a patient undergoes irreversible surgical intervention.

These criteria do not apply to patients who are having these surgical procedures for medical indications other than gender dysphoria.

Metoidioplasty or phalloplasty in FtM patients and vaginoplasty in MtF patients:

1. Persistent, well documented gender dysphoria;

2. Capacity to make a fully informed decision and to consent for treatment;

3. Age of majority in a given country;

4. If significant medical or mental health concerns are present, they must be well controlled;

5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones);

6. 12 continuous months of living in a gender role that is congruent with their gender identity.

Although not an explicit criterion, it is recommended that these patients also have regular visits with a mental health or other medical professional.

The criterion noted above for some types of genital surgeries – i.e., that patients engage in 12 continuous months of living in a gender role that is congruent with their gender identity – is based on expert clinical consensus that this experience provides ample opportunity for patients to experience and socially adjust in their desired gender role, before undergoing irreversible surgery.

APPENDIX D
EVIDENCE FOR CLINICAL OUTCOMES OF THERAPEUTIC APPROACHES

One of the real supports for any new therapy is an outcome analysis. Because of the controversial nature of sex reassignment surgery, this type of analysis has been very important. Almost all of the outcome studies in this area have been retrospective.

One of the first studies to examine the post-treatment psychosocial outcomes of transsexual patients was done in 1979 at Johns Hopkins University School of Medicine and Hospital (USA) (J. K. Meyer & Reter, 1979). This study focused on patients' occupational, educational, marital, and domiciliary stability. The results revealed several significant changes with treatment. These changes were not seen as positive; rather, they showed that many individuals who had entered the treatment program were no better off or were worse off in many measures after participation in the program. These findings resulted in closure of the treatment program at that hospital/medical school (Abramowitz, 1986).

Subsequently, a significant number of health professionals called for a standard for eligibility for sex reassignment surgery. This led to the formulation of the original *Standards of Care* of the Harry Benjamin International Gender Dysphoria Association (now WPATH) in 1979.

In 1981, Pauly published results from a large retrospective study of people who underwent sex reassignment surgery. Participants in that study had much better outcomes: Among 83 FtM patients, 80.7% had a satisfactory outcome (i.e., patient self report of "improved social and emotional adjustment"), 6.0% unsatisfactory. Among 283 MtF patients, 71.4% had a satisfactory outcome, 8.1% unsatisfactory. This study included patients who were treated before the publication and use of the *Standards of Care*.

Since the *Standards of Care* have been in place, there has been a steady increase in patient satisfaction and decrease in dissatisfaction with the outcome of sex reassignment surgery. Studies conducted after 1996 focused on patients who were treated according to the *Standards of Care*. The findings of Rehman and colleagues (1999) and Krege and colleagues (2001) are typical of this body of work; none of the patients in these studies regretted having had surgery, and most reported being satisfied with the cosmetic and functional results of the surgery. Even patients who develop severe surgical complications seldom regret having undergone surgery. Quality of surgical results is one of the best predictors of the overall outcome of sex reassignment (Lawrence, 2003). The vast majority of follow-up studies have shown an undeniable beneficial effect of sex reassignment surgery on postoperative outcomes such as subjective well being, cosmesis, and sexual function (De Cuypere et al., 2005; Garaffa, Christopher, & Ralph, 2010; Klein & Gorzalka, 2009), although the specific magnitude of benefit is uncertain from

the currently available evidence. One study (Emory, Cole, Avery, Meyer, & Meyer III, 2003) even showed improvement in patient income.

One troubling report (Newfield et al., 2006) documented lower scores on quality of life (measured with the SF-36) for FtM patients than for the general population. A weakness of that study is that it recruited its 384 participants by a general email rather than a systematic approach, and the degree and type of treatment was not recorded. Study participants who were taking testosterone had typically being doing so for less than 5 years. Reported quality of life was higher for patients who had undergone breast/chest surgery than for those who had not ($p<.001$). (A similar analysis was not done for genital surgery). In other work, Kuhn and colleagues (2009) used the King's Health Questionnaire to assess the quality of life of 55 transsexual patients at 15 years after surgery. Scores were compared to those of 20 healthy female control patients who had undergone abdominal/pelvic surgery in the past. Quality of life scores for transsexual patients were the same or better than those of control patients for some subscales (emotions, sleep, incontinence, symptom severity, and role limitation), but worse in other domains (general health, physical limitation, and personal limitation).

It is difficult to determine the effectiveness of hormones alone in the relief of gender dysphoria. Most studies evaluating the effectiveness of masculinizing/feminizing hormone therapy on gender dysphoria have been conducted with patients who have also undergone sex reassignment surgery. Favorable effects of therapies that included both hormones and surgery were reported in a comprehensive review of over 2000 patients in 79 studies (mostly observational) conducted between 1961 and 1991 (Eldh, Berg, & Gustafsson, 1997; Gijs & Brewaeys, 2007; Murad et al., 2010; Pfäfflin & Junge, 1998). Patients operated on after 1986 did better than those before 1986; this reflects significant improvement in surgical complications (Eldh et al., 1997). Most patients have reported improved psychosocial outcomes, ranging between 87% for MtF patients and 97% for FtM patients (Green & Fleming, 1990). Similar improvements were found in a Swedish study in which "almost all patients were satisfied with sex reassignment at 5 years, and 86% were assessed by clinicians at follow-up as stable or improved in global functioning" (Johansson, Sundbom, Höjerback, & Bodlund, 2010). Weaknesses of these earlier studies are their retrospective design and use of different criteria to evaluate outcomes.

A prospective study conducted in the Netherlands evaluated 325 consecutive adult and adolescent subjects seeking sex reassignment (Smith, Van Goozen, Kuiper, & Cohen-Kettenis, 2005). Patients who underwent sex reassignment therapy (both hormonal and surgical intervention) showed improvements in their mean gender dysphoria scores, measured by the Utrecht Gender Dysphoria Scale. Scores for body dissatisfaction and psychological function also improved in most categories. Fewer than 2% of patients expressed regret after therapy. This is the largest prospective study to affirm the results from retrospective studies that a combination of hormone therapy and surgery improves gender dysphoria and other areas of psychosocial functioning. There is a need for further research on the effects of hormone therapy without surgery, and without the goal of maximum physical feminization or masculinization.

Overall, studies have been reporting a steady improvement in outcomes as the field becomes more advanced. Outcome research has mainly focused on the outcome of sex reassignment surgery. In current practice there is a range of identity, role, and physical adaptations that could use additional follow-up or outcome research (Institute of Medicine, 2011).

APPENDIX E
DEVELOPMENT PROCESS FOR THE STANDARDS OF CARE, VERSION 7

The process of developing *Standards of Care, Version 7* began when an initial *SOC* "work group" was established in 2006. Members were invited to examine specific sections of *SOC, Version 6.* For each section, they were asked to review the relevant literature, identify where research was lacking and needed, and recommend potential revisions to the *SOC* as warranted by new evidence. Invited papers were submitted by the following authors: Aaron Devor, Walter Bockting, George Brown, Michael Brownstein, Peggy Cohen-Kettenis, Griet DeCuypere, Petra DeSutter, Jamie Feldman, Lin Fraser, Arlene Istar Lev, Stephen Levine, Walter Meyer, Heino Meyer-Bahlburg, Stan Monstrey, Loren Schechter, Mick van Trotsenburg, Sam Winter, and Ken Zucker. Some of these authors chose to add co-authors to assist them in their task.

Initial drafts of these papers were due June 1, 2007. Most were completed by September 2007, with the rest completed by the end of 2007. These manuscripts were then submitted to the *International Journal of Transgenderism (IJT)*. Each underwent the regular *IJT* peer review process. The final papers were published in Volume 11 (1-4) in 2009, making them available for discussion and debate.

After these articles were published, a *Standards of Care* Revision Committee was established by the WPATH Board of Directors in 2010. The Revision Committee was first charged with debating and discussing the *IJT* background papers through a Google website. A subgroup of the Revision Committee was appointed by the Board of Directors to serve as the Writing Group. This group was charged with preparing the first draft of *SOC, Version 7* and continuing to work on revisions for consideration by the broader Revision Committee. The Board also appointed an International Advisory Group of transsexual, transgender, and gender nonconforming individuals to give input on the revision.

A technical writer was hired to (1) review all of the recommendations for revision – both the original recommendations as outlined in the *IJT* articles and additional recommendations that emanated from the online discussion – and (2) create a survey to solicit further input on these potential revisions. From the survey results, the Writing Group was able to discern where these experts stood in terms of areas of agreement and areas in need of more discussion and debate. The technical writer then (3) created a very rough first draft of *SOC, Version 7* for the Writing Group to consider and build on.

The Writing Group met on March 4 and 5, 2011 in a face-to-face expert consultation meeting. They reviewed all recommended changes and debated and came to consensus on various controversial areas. Decisions were made based on the best available science and expert consensus. These decisions were incorporated into the draft, and additional sections were written by the Writing Group with the assistance of the technical writer.

The draft that emerged from the consultation meeting was then circulated among the Writing Group and finalized with the help of the technical writer. Once this initial draft was finalized it was circulated among the broader *SOC* Revision Committee and the International Advisory Group. Discussion was opened up on the Google website and a conference call was held to resolve issues. Feedback from these groups was considered by the Writing Group, who then made further revision. Two additional drafts were created and posted on the Google website for consideration by the broader *SOC* Revision Committee and the International Advisory Group. Upon completion of these three iteratations of review and revision, the final document was presented to the WPATH Board of Directors for approval. The Board of Directors approved this version on September 14, 2011.

The plans are to disseminate this version of the *SOC* and invite feedback for further revisions. The WPATH Board of Directors decides the timing of any revision of the *SOC*.

Funding

The *Standards of Care* revision process was made possible through a generous grant from the Tawani Foundation and a gift from an anonymous donor. These funds supported the following:

1. Costs of a professional technical writer;
2. Process of soliciting international input on proposed changes from gender identity professionals and the transgender community;
3. Working meeting of the Writing Group;
4. Process of gathering additional feedback and arriving at final expert consensus from the professional and transgender communities, the *Standards of Care, Version 7* Revision Committee, and WPATH Board of Directors;
5. Costs of printing and distributing *Standards of Care, Version 7* and posting a free downloadable copy on the WPATH website;

6. Plenary session to launch the *Standards of Care, Version 7* at the 2011 WPATH Biennial Symposium in Atlanta, Georgia, USA.

Members of the Standards of Care Revision Committee[1]

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Walter Bockting, PhD (USA)*
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1 * Writing Group member
All members of the *Standards of Care, Version 7 Revision Committee* donated their time to work on this revision.

International Advisory Group

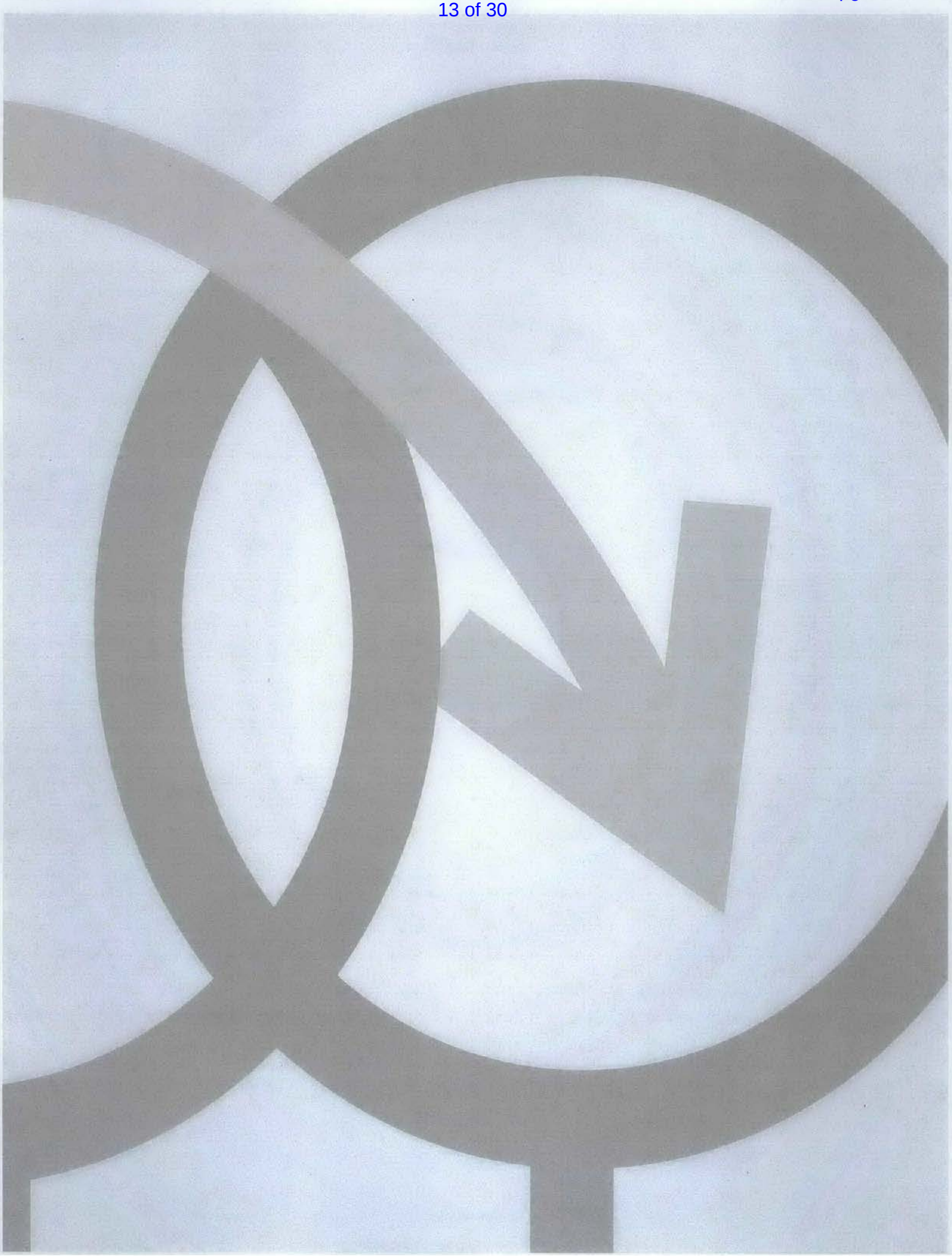
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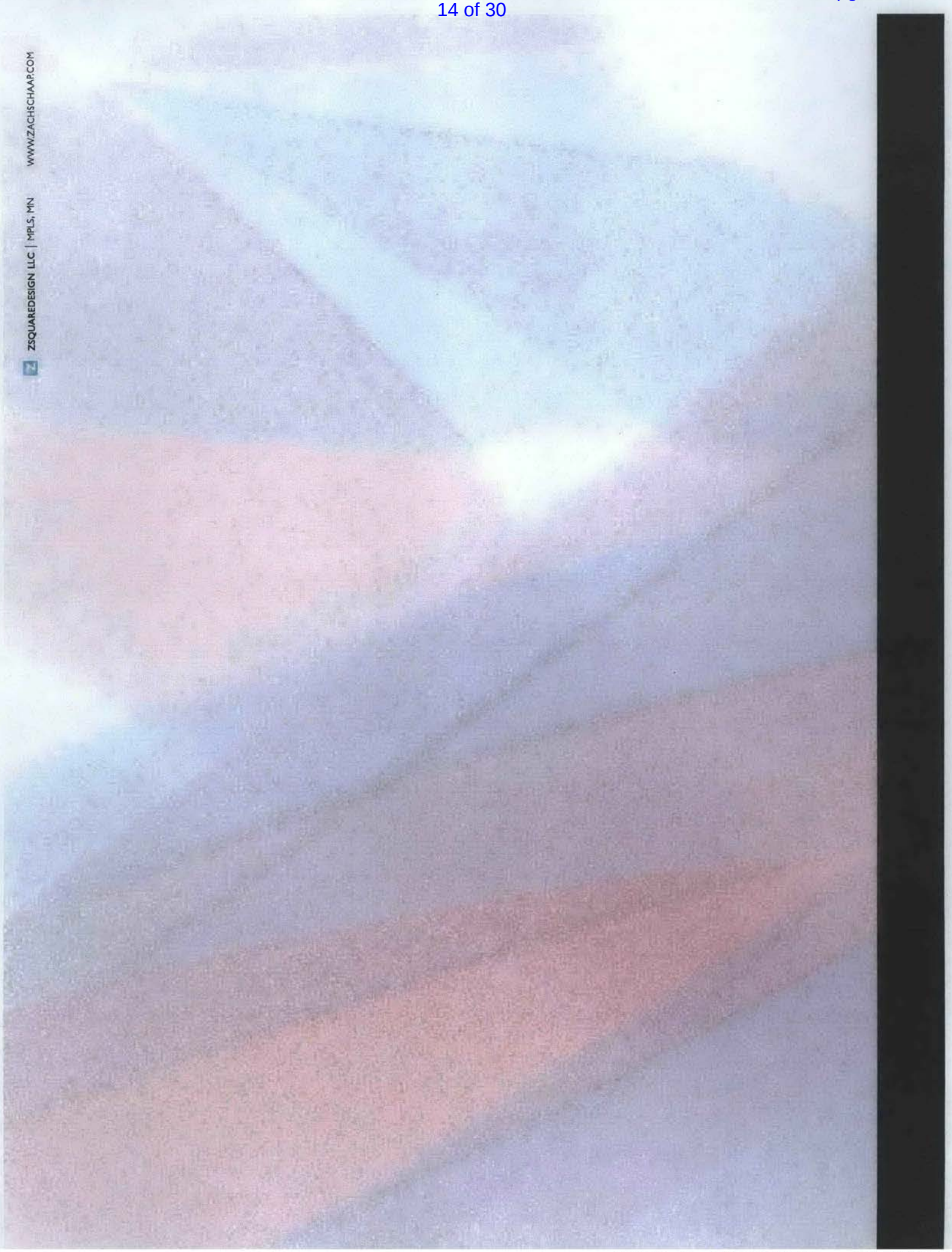
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VHA DIRECTIVE 2013-003

February 8, 2013

PROVIDING HEALTH CARE FOR TRANSGENDER AND INTERSEX VETERANS

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy regarding the respectful delivery of health care to transgender and intersex Veterans who are enrolled in the Department of Veterans Affairs (VA) health care system or are otherwise eligible for VA care.

2. BACKGROUND: In accordance with the medical benefits package (title 38 Code of Federal Regulations (CFR) section 17.38), VA provides care and treatment to Veterans that is compatible with generally accepted standards of medical practice and determined by appropriate health care professionals to promote, preserve, or restore the health of the individual.

a. VA provides health care for transgender patients, including those who present at various points on their transition from one gender to the next. This applies to all Veterans who are enrolled in VA's health care system or are otherwise eligible for VA care, including those who have had sex reassignment surgery outside of VHA, those who might be considering such surgical intervention, and those who do not wish to undergo sex reassignment surgery but self-identify as transgender. Intersex individuals may or may not have interest in changing gender or in acting in ways that are discordant with their assigned gender.

b. VA does not provide sex reassignment surgery or plastic reconstructive surgery for strictly cosmetic purposes.

c. **Definitions**

(1) **Sex.** Sex refers to the classification of individuals as female or male on the basis of their reproductive organs and functions.

(2) **Gender.** Gender refers to the behavioral, cultural, or psychological traits that a society associates with male and female sex.

(3) **Transgender.** Transgender is a term used to describe people whose gender identity (sense of themselves as male or female) or gender expression differs from that usually associated with their sex assigned at birth.

(a) Transsexual (Male-to-Female). Male-to-female (MtF) transsexuals are a subset of transgender individuals who are male sex at birth but self-identify as female and often take steps to socially or medically transition to female, including feminizing hormone therapy, electrolysis, and surgeries (e.g., vaginoplasty, breast augmentation).

THIS VHA DIRECTIVE EXPIRES FEBRUARY 28, 2018

(b) Transsexual (Female-to-Male). Female-to-male (FtM) transsexuals are a subset of transgender individuals who are female sex at birth but self-identify as male and often take steps to socially or medically transition to male, including masculinizing hormone therapy and surgeries (e.g., phalloplasty, mastectomy).

(4) **Sex reassignment surgery.** Sex reassignment surgery includes any of a variety of surgical procedures (including vaginoplasty and breast augmentation in MtF transsexuals and mastectomy and phalloplasty in FtM transsexuals) done simultaneously or sequentially with the explicit goal of transitioning from one sex to another. This term includes surgical revision of a previous sex reassignment surgery for cosmetic purposes. ***NOTE:*** *This term does not apply to non-surgical therapy (e.g., hormone therapy, mental health care, etc.) or intersex Veterans in need of surgery to correct inborn conditions related to reproductive or sexual anatomy or to correct a functional defect.*

(5) **Gender Identity Disorder (GID).** GID is a conflict between a person's physical sex and the gender with which the person identifies.

(6) **Intersex.** Intersex individuals are born with reproductive or sexual anatomy and/or chromosome pattern that do not seem to fit typical definitions of male or female. People with intersex conditions are often assigned male or female gender by others at birth (e.g., parents), although the individual may or may not later identify with the assigned gender.

3. POLICY: It is VHA policy that medically necessary care is provided to enrolled or otherwise eligible intersex and transgender Veterans, including hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following sex reassignment surgery. Sex reassignment surgery cannot be performed or funded by VA.

4. ACTION

a. **Veterans Integrated Service Network (VISN) Director.** Each VISN Director must ensure that necessary and appropriate health care is provided to all enrolled or otherwise eligible Veterans based on the Veteran's self-identified gender, regardless of sex or sex reassignment status.

b. **Medical Facility Director, Chief of Staff, and Associate Director for Patient Care Services or Nurse Executive.** The medical facility Director, Chief of Staff, and Associate Director for Patient Care Services or Nurse Executive are responsible for ensuring:

(1) Transgender patients and intersex individuals are provided all care included in VA's medical benefits package including but not limited to: hormonal therapy, mental health care, preoperative evaluation, and medically necessary post-operative and long-term care following sex reassignment surgery to the extent that the appropriate health care professional determines that the care is needed to promote, preserve or restore the health of the individual and is in accord with generally-accepted standards of medical practice.

(a) Patients will be addressed and referred to based on their self-identified gender. Room assignments and access to any facilities for which gender is normally a consideration (e.g., restrooms) will give preference to the self-identified gender, irrespective of appearance and/or surgical history, in a manner that respects the privacy needs of transgender and non-transgender patients alike. Where there are questions or concerns related to room assignments, an ethics consultation may be requested.

(b) The documented sex in the Computerized Patient Record System (CPRS) needs to be consistent with the patient's self-identified gender. In order to modify administrative data (e.g., name and sex) in CPRS, patients must provide official documentation as per VHA guidance and policy on Identity Authentication for Health Care Services and Data Quality Requirements for Identity Management and Master Patient Index Functions.

(c) Sex reassignment surgery as defined in subparagraph 2c(4), will not be provided or funded.

(d) Non-surgical, supportive care for complications of sex-reassignment surgery must be provided. For example, a MtF patient over the age of 50 may be offered breast cancer screening and may wish to discuss the benefits and harms of prostate cancer screening with her provider. A FtM transsexual patient may be offered screening for breast and cervical cancer.

(e) A diagnosis of GID, or other gender dysphoria diagnoses, is not a pre-condition for receiving care consistent with the Veteran's self-identified gender.

(2) All other health services are provided to transgender Veterans without discrimination in a manner consistent with care and management of all Veteran patients.

(3) All staff, including medical and administrative staff, are required to treat as confidential any information about a patient's transgender status or any treatment related to a patient's gender transition, unless the patient has given permission to share this information.

(4) VA Mandates diversity awareness and maintains a zero-tolerance standard for harassment of any kind.

5. REFERENCES

Title 38 CFR § 17.38 (c).

6. FOLLOW-UP RESPONSIBILITY: The Office of Patient Care Services (10P4) is responsible for the contents of this Directive. Questions related to medical care may be referred to Specialty Care Services (10P4E) at (202) 461-7120. Questions related to mental health care may be referred to the Office of Mental Health Services (10P4M) at (202) 461-7310.

7. RESCISSIONS: VHA Directive 2011-024, Providing Health Care for Transgender and Intersex Veterans, is rescinded. This VHA Directive expires February 28, 2018.

Robert A. Petzel, M.D.
Under Secretary for Health

Attachment

DISTRIBUTION: E-mailed to the VHA Publications Distribution List 2/11/2013

Attachment A

FREQUENTLY ASKED QUESTIONS (FAQ) REGARDING THE PROVISION OF HEALTH CARE FOR TRANSGENDER AND INTERSEX VETERANS

1. What is the prevalence of transgender individuals? Is there a difference between transgender and transsexual individuals?

a. The prevalence of transgender individuals is not known in general or in the Veteran population. This is because of challenges in defining gender identity, the reluctance of individuals to identify themselves to others as transgender, and measures that are narrowly focused on subsets of individuals who either have been diagnosed with gender identity disorder (GID) or have had sex reassignment surgery. It is for these reasons that the Institute of Medicine issued their report "The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding" (March 31, 2011) and called on Health and Human Services (HHS) and other Federal agencies to "implement a research agenda designed to advance knowledge and understanding of Lesbian, Gay, Bisexual, and Transgender (LGBT) health. This agenda includes appropriate data gathering on sexual orientation and gender identity in public health research tools and electronic health records.

b. Current estimates of the prevalence of transsexual individuals with GID are approximately 1:11,000 natal males and 1:30,000 natal females. The prevalence of all transgender individuals is much higher since "transgender" is an umbrella term that includes individuals who do not have GID.

c. Based on these data, the estimated prevalence of Male-to-Female (MtF) to Female-to-Male (FtM) transsexual individuals is approximately 3:1 in the general population. This prevalence ratio is likely to be higher in the predominantly male Veteran population. It is important to note that FtM transsexual individuals are also part of the Veteran population.

d. Intersex Veterans, that is, individuals who are born with reproductive or sexual anatomy and/or chromosome pattern that do not seem to fit typical definitions of male or female, may or may not identify as transgender.

2. Is transgender the same as being "gay" or "lesbian?"

No. The term "transgender" refers to gender identity or the sense of oneself as male, female, or other, (e.g., androgynous, eunuch, etc.). The terms "gay" (in the case of men) and "lesbian" (in the case of women) refer to sexual orientation. The sexual orientation of gay and lesbian persons is attraction to the same gender whereas heterosexual persons are attracted to the opposite gender. A transgender Veteran may identify as heterosexual ("straight"), gay, lesbian, bisexual (i.e., attracted to both genders), queer, pansexual, asexual, etc. Knowing someone's gender identity gives you no information about their sexual orientation.

3. What is intersex?

Intersex individuals are born with reproductive or sexual anatomy and/or chromosome pattern that do not seem to fit typical definitions of male or female. People with intersex conditions are often assigned male or female gender by others at birth (e.g., parents), although the individual may or may not later identify with the assigned gender.

4. Do all intersex individuals identify as transgender?

No. For example, an individual may be assigned the physical status of "female" at birth and identify as female throughout her lifetime, with or without knowledge of an intersex condition. Some intersex persons with male chromosomes who have been assigned female become gender dysphoric even without knowing that they were "reassigned" at, or near, birth. Knowing someone has an intersex condition gives you no information about their gender identity or sexual orientation.

5. What is sex reassignment surgery?

Sex reassignment surgery includes any of a variety of surgical procedures done simultaneously or sequentially with the explicit goal of transitioning from one gender to another. This term includes surgical revision of a previous sex reassignment surgery for cosmetic purposes. This term does not apply to non-surgical therapy (e.g., hormone therapy, mental health care, etc.) or to intersex Veterans in need of surgery to correct inborn conditions related to reproductive or sexual anatomy or to correct a functional defect.

6. Will VA provide sex reassignment surgery and plastic reconstructive surgery if needed?

VA does not provide sex reassignment surgery in VA facilities or through non-VA care. In addition, VA does not provide plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care. However, patients with GID or other gender dysphoria conditions may elect to have one or more medical or surgical procedures over their lifetime to bring their bodies into a closer alignment with their perceived gender. ***NOTE:*** *Only a minority of transgender Veterans will undergo sex reassignment surgery, as their symptoms may often be adequately treated with other therapeutic interventions.* Some Veterans receiving care at the VA may have had sex reassignment surgery somewhere else. The VA does provide health care to pre- and post-operative transsexual Veterans, including treatment of surgical complications.

7. Will the VA provide for electrolysis through non-VA care for male-to-female transsexual (MtF) Veterans?

No. VA will not provide electrolysis as this is considered by VHA to be cosmetic rather than medically necessary to promote, preserve, or restore health of the Veteran.

8. What are the guidelines for clinical care and the informed consent process?

a. Effective clinical care for transgender and intersex patients ideally involves an interdisciplinary, coordinated treatment approach with special attention to the needs of the individual patient and collaboration among multiple specialties, notably: gynecology, mental health, primary and specialty care, women's health, pharmacy, and urology. For all treatments and procedures, informed consent and shared decision-making needs to be the basis for individualized care that weighs the possible benefits and harms, with an emphasis on the lowest (safest) dose to achieve benefits. ***NOTE:*** *Procedures regarding informed consent can be found in VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures at: http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2055.*

b. For treatment plans that include cross-sex hormone therapy, VA clinicians must, consistent with requirements of informed consent (VHA Handbook 1004.01), discuss the risks, benefits, and limitations of cross-sex hormone therapy with the patient. Signature consent is not required for cross-sex hormone therapy. Ongoing monitoring of treatment is required.

9. Will VA provide feminizing or masculinizing hormone therapy?

Yes, if it is consistent with the patient's wishes, the treatment team's clinical recommendations, and VA treatment guidance.

10. What guidance is available to clinicians regarding hormone therapy?

VA Pharmacy Benefits Management Services has developed guidance for the use of hormone therapy in transgender and intersex patients in VA. This guidance is located at: http://vaww.national.cmop.va.gov/PBM/default.aspx. ***NOTE:*** *This is an internal Web site and is not available to the public.*

11. What are the goals of cross-sex hormonal treatment? What effects and risks are associated with hormonal treatment?

a. Cross-sex hormonal treatment is used to reduce or eliminate gender dysphoria and other symptoms related to the discordance between a transgender or intersex individual's gender identity and their biological sex at birth or the gender they were assigned at birth. The treatment produces changes in hormonally-sensitive sex characteristics (i.e., reducing characteristics of the original sex and inducing those of the opposite sex). VA clinicians need to provide transgender and intersex patients with a careful evaluation prior to providing a prescription for cross-sex hormonal therapy.

b. The goal of cross-sex hormone therapy in treatment of MtF transgender patients is to suppress testosterone levels and introduce estrogen to achieve a pre-menopausal female hormonal range. The effects are decreased facial and body hair, redistribution of fat, breast development and prostate and testicular atrophy. Risks include venous thromboembolism, liver dysfunction, hypertension, and cardiovascular disease. As with any medical therapy, benefits

and harms of treatment need individualization using principles of shared decision-making, with an emphasis upon the lowest (safest) dose to achieve benefits.

c. The goal of cross-sex hormone therapy in treatment of FtM transgender patients is to maintain testosterone and estrogen levels in the normal male range, generally through testosterone supplementation and sometimes in combination with a Gonadotropin Releasing Hormone (GnRH) agonist or progestins to suppress menses. The effects are increased facial and body hair and muscle, acne, permanent deepening of the voice, cessation of menses, redistribution of fat mass, and clitoral enlargement. Risks include hypertension, erythrocytosis, liver dysfunction, lipid changes, weight gain, and sodium retention.

12. Are there specific diagnostic criteria to consider in prescribing cross-sex hormone therapy?

a. A diagnosis of GID or other dysphoria condition should be the basis for prescription for cross-sex hormonal therapy for transgender patients. There may be clinical exceptions to the diagnosis for prescribing cross-sex hormone therapy (e.g., transgender individuals with "GID not otherwise specified").

b. Intersex patients are excluded from the GID diagnosis by DSM IV criteria. Transgender patients with intersex conditions who are seeking hormonal treatment need to fulfill DSM IV criteria for "GID not otherwise specified." Intersex and transgender individuals may have different mental health considerations.

13. Transgender and intersex Veterans are presenting to VA providers with prescriptions for hormones from outside sources, such as from another provider, the internet, or illicit sources. Should we stop these medications while we do a full evaluation or should a VA provider rewrite the prescriptions so they can be filled in a VA pharmacy and continued?

Under current VHA National Dual Care Policy, VA providers are not permitted to simply re-write prescriptions from an outside provider, unless the VA provider has first made a professional assessment that the prescribed medication is medically appropriate. However, cross sex hormones cannot generally be stopped abruptly without negative physical and psychiatric consequences. If the patient has records that support a thorough evaluation and psychotherapy prior to initiation of hormones, then it may be appropriate for a VA provider to rewrite the prescriptions so they can be filled in a VA pharmacy and continued while the evaluation is in progress and to monitor hormone levels. A mental health exam in this situation is not required and is based on the clinical situation. Very high doses of cross-sex hormones are associated with a greater likelihood of side effects, and a reduction in dose may be required. Additionally, the benefits and harms of hormonal therapy differ based upon the presence or absence of risk factors for, or occurrence of, serious complications (cardiovascular, thrombotic-embolic) and thus dosage needs to be individualized.

14. What if a transgender or intersex Veteran presents to VA and self-reports that they have been taking cross sex hormones that they would like to continue but can provide no supportive documentation from a physician?

Consistent with the VHA National Dual Care Policy, VA clinicians need to provide transgender patients with a careful medical and mental health evaluation prior to providing a prescription for cross-sex hormonal therapy.

15. Is a mental health evaluation necessary or required?

A thorough and careful mental health evaluation needs to be completed prior to provision of hormone therapy and needs to include evaluation and treatment for psychiatric comorbidities that may have overlapping presentations, such as depression, anxiety, Post Traumatic Stress Disorder (PTSD) or substance use disorders. The presence of other psychiatric and physical conditions is not necessarily a barrier to initiating treatment. For patients who enter VA with well-documented cross-sex hormone therapy from outside clinicians, mental health evaluations are optional based on the clinical presentation.

16. I understand that VA does not provide sex reassignment surgery, but are there any special considerations regarding a mental health evaluation prior to sex reassignment surgery?

Mental health evaluation prior to surgery includes specialized exams by knowledgeable doctoral level clinicians. Some professional associations with expertise on transgender issues (see resources in paragraph 28 of this Attachment) recommend that individuals contemplating genital surgery need to participate in a minimum of a 1-year "real life experience" i.e., living full time in the preferred gender role, prior to any genital surgical intervention.

17. In what ways would a pre-operative medical evaluation differ for these Veterans?

Medical evaluation prior to surgery includes pre-operative cardiac risk assessment and careful evaluation of current medications including hormone dosing.

18. What types of surgeries might transgender Veterans consider?

a. As part of their transition, FtM patients might consider undergoing several types of surgery including mastectomy, hysterectomy or oopherectomy, and neophallus construction. The common complications of neophallus construction include flap or graft necrosis, fistulae, urinary tract infection, donor site scarring, and infections. Mastectomy and hysterectomy have far fewer complications. Clinicians need to be aware that VA does not provide sex reassignment surgery or plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care.

b. As part of their transition, MtF patients might consider undergoing several types of surgery including orchiectomy, penectomy, vaginoplasty, breast implants, laryngeal shave, and facial feminization procedures. Common complications of genital surgeries include strictures,

infections, fistulae, urinary tract complications and loss of genital sensation. Clinicians need to be aware that VA does not provide sex reassignment surgery or plastic reconstructive surgery for strictly cosmetic purposes in VA facilities or through non-VA care. MtF patients may consider undergoing electrolysis for hair removal. Clinicians need to be aware that VA does not provide electrolysis as this is considered a cosmetic rather than a medically necessary procedure.

19. If a patient has had sex reassignment surgery, how do we handle preventive screening requirements?

In addition to treatments related to their new gender identity, transgender patients need appropriate medical screening and/or treatment specific to their birth sex. This includes prostate exams and mammograms for MtF patients and vaginal exams and mammograms for FtM patients, as indicated.

20. Can a transgender Veteran request a change of gender or sex in Computerized Patient Record System (CPRS) before having sex reassignment surgery?

Amending the gender or sex of the Veteran in CPRS is based on the Veteran making a request to the facility Privacy Officer and providing the official documentation as required by VHA policies. Sex reassignment surgery is not a prerequisite for amendment of gender or sex in the Veteran's record.

21. What constitutes "official documentation" in order for gender or sex to be changed in CPRS?

A Veteran's request for amendment to gender or sex in the record is considered a Privacy Act "amendment request."

a. One of the following is required as supporting documentation: Legal documentation (i.e., amended birth certificate or court order), passport or a signed original statement on office letterhead, from a licensed physician. Sex reassignment surgery is not a prerequisite for amendment of gender/sex in the Veteran's record.

b. The licensed physician's statement must include all of the following information:

(1) Physician's full name;

(2) Medical license or certificate number;

(3) Issuing state of medical license or certificate;

(4) Drug Enforcement Administration (DEA) registration number assigned to the physician or comparable foreign designation, if applicable;

(5) Address and telephone number of the physician;

(6) Language stating that the physician has treated the patient or reviewed and evaluated the medical history of the applicant. The physician also has a doctor patient relationship with the applicant, which is evident in having one or more clinical encounters between doctor and patient;

(7) Language stating that the patient has had appropriate clinical treatment for gender transition to the new gender (specifying male or female); and

(8) Language stating, "I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct."

22. Do I need to become an expert in treating transgender Veterans?

a. All clinicians and staff who provide clinical services to transgender Veterans need to become more knowledgeable about transgender health issues. Everyone needs to be aware that transgender Veterans deserve to receive health care at VA and need to be treated with dignity and respect. Primary Care and Mental Health providers need to be encouraged to consult with specialty physicians on any aspect of management for which they need advice or for ongoing management, as they would for any other complex patient. The initial VA prescription for cross-sex hormone therapy need to be restricted to facility-designated providers experienced with the use of cross-sex hormone therapy (e.g., women's health specialist, endocrinologist, psychiatrist, or other local designee).

b. The potential lack of clinical expertise in specialties such as endocrinology, mental health, and surgery regarding clinical care of transgender and intersex Veterans, may necessitate establishing a mechanism for timely expert consultation on complicated cases within Veterans Integrated Service Networks (VISN) or facilities.

23. What education will be provided to VA staff?

Cultural awareness and sensitivity education for field staff was developed and implemented in fiscal year 2012. The VA standard of zero tolerance for discrimination, harassment, or abuse of Veterans applies to VHA treatment of transgender and intersex Veterans.

24. What is the correct pronoun to use when speaking with a transgender Veteran and in documentation of the clinical encounter in a progress note?

Transgender Veterans should always be addressed and referred to based on their self-identified gender, in conversation and in documentation in the patient record, irrespective of the Veteran's appearance. Neither sex reassignment surgery nor official documentation of change in sex is required for Veterans to be identified by their preferred gender or for documentation of preferred gender in the patient record.

25. Are transgender Veterans allowed to use the bathroom of their choice?

Transgender Veterans who presently self-identify as female are allowed to use bathrooms for women. Likewise, those who presently self-identify as males are allowed to use bathrooms for

men. This is irrespective of the Veteran's appearance or whether the Veteran has had sex reassignment surgery. The privacy needs of other patients must also be considered; availability of "unisex" bathrooms (for men and women) throughout facilities is a practical approach to this issue and is common practice in some facilities.

26. What about room assignments?

Patient room assignments are made in accordance with the patient's self-identified gender irrespective of the Veteran's appearance or whether the Veteran has had sex reassignment surgery, and in consideration of the needs of other patients. ***NOTE:*** *Ethics consultations are encouraged when concerns arise related to the provision of respectful care for transgender and intersex Veterans and other patients.*

27. In situations where shared inpatient rooms are common, might assignments be made such that a MtF transsexual patient and a biologic female would be assigned to share a room or a FtM transsexual patient and a biologic male would be assigned to share a room?

Yes. According to current VHA policy, "*room assignments will give preference to the self-identified gender, irrespective of appearance and/or surgical history, in a manner that respects the privacy needs of transgender and non-transgender patients alike.*" Privacy and confidentiality dictate that staff may not share any information about one patient with another without express permission. If a room assignment leads to distress for either patient, then efforts need to be made to assign one of them to a private room. When this cannot be accommodated or when there are questions or concerns related to room assignments, an ethics consultation needs to be requested.

28. Are there any recommended resources for further information?

VA does not currently have clinical practice guidelines for the care of transgender and intersex Veterans. While VA does not endorse the following private sector guidelines, they may serve to provide information and education about the complexities of caring for this patient population.

a. World Professional Association for Transgender Health's Standards of Care for Gender Identity Disorders, Version 7, 2011. Available from www.WPATH.org

b. Endocrine Society Guidelines http://www.endo-society.org/guidelines/final/upload/Endocrine-Treatment-of-Transsexual-Persons.pdf

c. Clinical Protocol Guidelines for Transgender Care http://www.vch.ca/transhealth or http://transhealth.vch.ca/resources/careguidelines.html

d. The Joint Commission: *Advancing Effective Communication, Cultural Competence and Patient-and-Family Centered Care for the Lesbian, Gay, Bisexual and Transgender (LGBT) Community: A Field Guide*. Oak Brook, IL, Oct. 2011. http://www.jointcommission.org/lgbt/

29. REFERENCES

a. Brown, G. R. (2010). Autocastration and autopenectomy as surgical self-treatment in incarcerated persons with gender identity disorder. *International Journal of Transgenderism, 12*(1), 31-39 doi:10.1080/15532731003688970.

b. Institute of Medicine. (2011). *The health of lesbian, gay, bisexual, and transgender people: Building a foundation for better understanding.* Washington, DC: The National Academies Press: http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx.

c. Murad, M. H., Elamin, M. B., Garcia, M. Z., Mullan, R. J., Murad, A., Erwin, P. J., &Montori, V. M. (2010). Hormonal therapy and sex reassignment: A systematic review and meta-analysis of quality of life and psychosocial outcomes. *Clinical Endocrinology, 72*(2), 214-231. doi:10.1111/j.1365-2265.2009.03625.x.

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

JOAQUÍN CARCAÑO ET AL., *Plaintiffs*, v. PATRICK MCCRORY ET AL., *Defendants*.	No. 1:16-cv-00236-TDS-JEP

EXPERT DECLARATION OF DEANNA ADKINS, M.D.

PRELIMINARY STATEMENT

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation. I have actual knowledge of the matters stated in this declaration. My professional background, experience, and publications are detailed in my curriculum vitae, a true and accurate copy which is attached as Exhibit A to this declaration. I received my medical degree from the Medical College of Georgia in 1997. I am currently the Fellowship Program Director of Pediatric Endocrinology at Duke University School of Medicine and the Director of the Duke Center for Child and Adolescent Gender Care.

2. I have been licensed to practice medicine in the state of North Carolina since 2001.

3. I have extensive experience working with children with endocrine disorders and I am an expert in the treatment of children with differences or disorders of sex development and gender dysphoria.

4. I am a member of the American Academy of Pediatrics, the North Carolina Pediatric Society, the Pediatric Endocrine Society, and The Endocrine Society. I am also a member of the World Professional Association for Transgender Health ("WPATH"), the leading association of medical and mental health professionals in the treatment of transgender individuals.

5. I am the founder of the Duke Center for Child and Adolescent Gender Care ("Gender Care Clinic"), which opened in 2015. I currently serve as the Director of the clinic. The Gender Care Clinic treats children, adolescents, and young adults between the ages of 7 and 22 who have gender dysphoria and/or differences or disorders of sex development. I have been caring for these individuals in my routine practice for many years prior to opening the clinic

6. I currently treat approximately 90 transgender and intersex young people from North Carolina and across the southeast at the Gender Care Clinic. I have treated approximately 150 transgender and intersex young people in my career.

7. As part of my practice, I stay familiar with the latest medical science and treatment protocols related to differences or disorders of sex development and gender dysphoria.

8. I am regularly called upon by colleagues to assist with the sex assignment of infants who cannot be classified as male or female at birth due to a range of variables in which sex-related characteristics are not completely aligned as male or female.

9. In preparing this declaration, I reviewed the materials listed in the attached Bibliography (Exhibit B). I may rely on those documents as additional support for my opinions. I have also relied on my years of experience in this field, as set out in my curriculum vitae (Exhibit A), and on the materials listed therein. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject.

10. In the past four years, I have testified as an expert at trial or deposition in the following matter: *United States v. Oversby, Brandon R.*, SPC, U.S. Army, B Company (Second Judicial Circuit, Fort Bragg Oct. 15, 2014).

11. I am being compensated at an hourly rate for actual time devoted, at the rate of $275 per hour. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

WHAT DOES IT MEAN TO BE TRANSGENDER OR INTERSEX?

12. A transgender individual is an individual who has a gender identity that differs from the person's birth-assigned sex.

13. Individuals who are intersex (also known as having "differences of sex development") have sex characteristics that are a mixture of those typically associated with both "male" and "female" sex designations.

14. At birth, infants are generally classified as male or female based on observation of their external genitalia. This classification becomes the person's birth-assigned sex but may not be the same as the person's gender identity.