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May 9, 2016

Robert A. McDonald, Secretary
U.S. Department of Veterans Affairs
810 Vermont Ave, NW
Washington, DC 20420

Re: Petition for Rulemaking to Promulgate Regulations

Dear Secretary McDonald:

Dee Fulcher, Giuliano Silva, and the Transgender American Veterans Association hereby petition the Secretary of Veterans Affairs to amend or repeal the rules and regulations, including 38 C.F.R. § 17.38(c)(4) and any implementing directives, that exclude medically necessary sex reassignment surgery for transgender veterans from the medical benefits package provided to veterans under the health care system of the Department of Veterans Affairs, and to promulgate regulations expressly including medically necessary sex reassignment surgery for transgender veterans in that medical benefits package. The petition is enclosed.

Thank you for your consideration.

Sincerely,

Alan E. Schoenfeld /APV

Alan E. Schoenfeld

cc: Leigh A. Bradley, General Counsel, VA
Danny Pummill, Acting Under Secretary for Benefits, VA
M. Dru Levasseur, Lambda Legal Defense and Education Fund, Inc.
Ilona Turner, Transgender Law Center

PETITION FOR RULEMAKING TO

PROMULGATE REGULATIONS GOVERNING PROVISION OF SEX REASSIGNMENT

SURGERY TO TRANSGENDER VETERANS

SUBMITTED TO

THE UNITED STATES DEPARTMENT OF VETERANS AFFAIRS

MAY 9, 2016

Dee Fulcher, Giuliano Silva, and Transgender American Veterans Association

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Dee Fulcher, Giuliano Silva, and the Transgender American Veterans Association ("TAVA") (together, "Petitioners") hereby petition the Secretary of Veterans Affairs (the "Secretary") to amend or repeal the rules and regulations, including 38 C.F.R. § 17.38(c)(4) and any implementing directives, that exclude medically necessary sex reassignment surgery for transgender veterans from the medical benefits package provided to veterans under the health care system of the Department of Veterans Affairs ("Department" or "VA"), and to promulgate regulations expressly including medically necessary sex reassignment surgery for transgender veterans in that medical benefits package.

I. INTRODUCTION

When Congress enacted the Veterans Health Care Eligibility Reform Act of 1996 (Pub. L. 104-262), establishing the current framework for veteran eligibility for medical benefits under the VA health care system, the United States sought to ensure that the medical needs of all American veterans would be met through the provision of quality health care. To implement that directive, the Department has promulgated a series of regulations establishing robust coverage for the panoply of medical needs that veterans of our armed services might confront. But in contravention of that directive, the Department also has promulgated a discriminatory regulation that singles out transgender veterans and bars the provision of medically necessary sex reassignment surgery to treat gender dysphoria. *See* 38 C.F.R. § 17.38(c)(4) (prohibiting coverage for "gender alterations") (the "Regulation").

That bar has remained in place notwithstanding the existence of a broad medical consensus about the need for sex reassignment surgery for many transgender people, and notwithstanding the United States' own evolving policies on the ability of transgender people to serve openly in the military. The Department's exclusion for sex reassignment surgery was not supported by medical evidence when it was implemented in 1999, and it is even more

indefensible today. The Department should eliminate the categorical exclusion of sex reassignment surgery as a treatment for gender dysphoria, and expressly include sex reassignment surgery in the medical benefits package available to veterans, either as an exercise of the Secretary's discretion or in recognition of the fact that the exclusion is both arbitrary and capricious and unconstitutional.

Providing sex reassignment surgery to transgender veterans for whom it is medically indicated is required by the Department's stated policy of providing medically necessary care to all veterans. That sex reassignment surgery is a medically necessary treatment for gender dysphoria is not in dispute within the medical community; all major medical associations recognize this treatment as such. Providing sex reassignment surgery to transgender veterans is essential to relieving the serious distress caused by gender dysphoria. Our Nation owes transgender veterans this treatment in the same way it owes all other veterans medically necessary care for their serious medical conditions. Finally, although the Department has never justified the exclusion for sex reassignment surgery on cost grounds, it bears emphasis here that any marginal increase in the Department's total expenditures on medical care—which should be negligible—should be offset in whole or in part by the reduced costs of long-term health care that would otherwise be necessary for some transgender veterans denied surgical treatment.

Including sex reassignment surgery in the medical benefits package is legally required, and the refusal to do so would constitute arbitrary and capricious agency action, subject to reversal by the federal courts. The established medical consensus plainly requires the inclusion of sex reassignment surgery in the medical benefits package, on equal footing with medical treatments that address other similarly serious and treatable medical conditions. Indeed, the Department recognizes the seriousness of gender dysphoria as a medical condition: It offers

other treatments that may be necessary (but not sufficient) to ameliorate that condition, such as hormone therapy, and it offers ancillary treatments supporting sex reassignment surgery, such as pre- and post-surgical care, for the few who can pay for the surgery on their own. Nor does the Department appear to have any rational objection to the forms of surgery involved in sex reassignment surgery: The Department's regulations and directives offer surgeries identical or substantially similar to those constituting sex reassignment surgery to veterans with other medical conditions. And, finally, the VA excluded sex reassignment surgery without examining any relevant data and without giving any public explanation for the exclusion. All of this lays bare the arbitrariness of the exclusion at issue here.

The Fifth Amendment to the Constitution likewise bars the exclusion. To offer certain medically necessary surgeries to veterans for some conditions, yet to deny the same or substantially similar surgeries to transgender veterans to treat gender dysphoria, constitutes unconstitutional discrimination on the basis of sex and transgender status, and the regulations implementing this discrimination fail to survive any level of scrutiny that may be applied. These regulations—lacking any connection to medical consensus or any other rational justification—are also unconstitutional under a long line of Supreme Court cases forbidding discriminatory treatment that appears to be based on "'a bare … desire to harm a politically unpopular group'[.]" *United States v. Windsor*, 133 S. Ct. 2675, 2693 (2013) (quoting *Department of Agriculture v. Moreno*, 413 U.S. 528, 534-35 (1973)).

The amendments this petition seeks are not only good policy and legally required—they also are urgent. The suicide rate for individuals with untreated gender dysphoria is significantly higher than that of the general population, as is the prevalence of depression, self-harm, and drug and alcohol addiction. Appropriate treatment is necessary to prevent such suffering and long-

term harm. Petitioners respectfully request that the Secretary attend to the urgency of the need of some transgender veterans for sex reassignment surgery in his consideration of this petition.

II. LEGAL AUTHORITY

Congress granted the Secretary of Veterans Affairs the "authority to prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department," which include laws governing veterans' benefits. 38 U.S.C. § 501(a). The Secretary thus has the authority to amend or repeal the rules and regulations that are the focus of this petition, including 38 C.F.R. § 17.38(c)(4), and to issue appropriate rules and regulations in their place.

III. PETITIONERS

Petitioners each have the statutory right to petition the Department for rulemaking pursuant to 5 U.S.C. § 553(e), which requires "[e]ach agency [to] give an interested person the right to petition for the issuance, amendment, or repeal of a rule." Petitioners also satisfy the standing requirements of Article III of the United States Constitution.

TAVA is a 501(c)(3) organization dedicated to ensuring that transgender veterans receive appropriate and necessary medical care. TAVA was founded in 2003 to advocate on behalf of transgender veterans within the VA health care system. Its mission is to work with the VA, Congress, veterans, active-duty military personnel, and LGBT groups to influence the VA and military policy, regulations, and procedures regarding the provision of medical and psychological care to veterans with gender dysphoria. While TAVA primarily focuses on ensuring the fair and equal treatment of transgender individuals, it is committed to improving the health care of all American veterans.

TAVA is a membership organization, and many of its members are transgender veterans currently enrolled in the VA health care system. Affidavit of Evan Young ("Young Aff.") ¶ 11.

Some of those individuals have been diagnosed with gender dysphoria by the VA and have been provided some medical care related to their diagnosis. *Id*. However, members who have sought sex reassignment surgery through the VA, or coverage of such surgery by the VA, have been denied such surgery or coverage because of the existing regulatory exclusion of "gender alterations" from covered benefits. *Id*. Many of those veterans rely on the VA for provision of their mental and physical health care, and they satisfy all the medical prerequisites for sex reassignment surgery: They have been diagnosed with gender dysphoria (often by VA clinicians), they have spent multiple years living in a gender role consistent with their gender identity and are currently undergoing hormone therapy to assist in their transition, and they have been prescribed sex reassignment surgery by qualified mental health providers as medically necessary treatment for their condition. *Id*. Nevertheless, these veterans have been unable to obtain medically necessary sex reassignment surgery due to the VA's categorical bar on "gender alterations." *Id*. These veterans are currently, concretely, and directly harmed by the VA's bar on sex reassignment surgery; granting the petition and repealing or amending the Regulation as requested herein would provide them with redress.

TAVA's purpose in submitting this petition is to advocate on behalf of its members who have been denied medically necessary treatment as a result of the VA's regulations. Young Aff. ¶ 12. This petition directly advances one of TAVA's central organizational goals—to achieve reform of the VA's policies regarding coverage of sex reassignment surgery and other medical procedures related to gender dysphoria. *Id*. If the VA were to amend its regulations to include coverage of sex reassignment surgery, such an amendment would significantly improve the physical and mental health of TAVA members and of other transgender veterans with gender dysphoria. *Id*.

Although the relief requested by TAVA in this petition does not require the participation of TAVA's individual members, *see, e.g.*, *Biotechnology Industry Organization v. District of Columbia*, 496 F.3d 1362, 1369 (Fed. Cir. 2007), TAVA is joined in this petition by Dee Fulcher and Giuliano Silva, individual transgender veterans whose interests are directly affected by the VA's exclusion of sex reassignment surgery.

Dee Fulcher is a veteran of the U.S. Marine Corps and a member of TAVA. Affidavit of Dee Fulcher ("Fulcher Aff.") ¶ 2. Dee is a transgender woman. *Id*. She was first diagnosed with gender dysphoria by a physician outside of the VA health care system. *Id*. ¶ 6. Ms. Fulcher's diagnosis of gender dysphoria has been confirmed by a clinical mental health social worker and a board certified physician in internal medicine, both at the Southeast Louisiana Veterans Healthcare System (part of the VA health care network). *Id*. ¶¶ 6-7. Ms. Fulcher's VA clinicians have both recommended that she receive sex reassignment surgery as the next step in her treatment for gender dysphoria. *Id*. If that were covered by the VA, Ms. Fulcher would pursue such surgery, including penectomy, vaginoplasty, facial feminization, breast augmentation, and electrolysis. *Id*. ¶ 8. Yet due to the VA's exclusion of sex reassignment surgery, Ms. Fulcher cannot receive this medically necessary treatment that her physician and mental health provider have prescribed for her.

Giuliano Silva is a veteran of the U.S. Army and a member of TAVA. Affidavit of Giuliano Silva ("Silva Aff.") ¶ 2. Mr. Silva is a transgender man and has been diagnosed with gender dysphoria by medical providers at the Miami VA Healthcare System. *Id*. ¶ 10. While Mr. Silva would seek sex reassignment surgery (in particular, a mastectomy) if that surgery were covered, Mr. Silva also has suffered, and continues to suffer, from additional effects of the VA's exclusion of sex reassignment surgery on the medical practices of VA healthcare providers.

Id. ¶ 15. The VA's exclusion of sex reassignment surgery has had the effect of preventing Mr. Silva from receiving a mastectomy, which a VA physician has recommended to Mr. Silva to treat his severe back pain and related problems. *Id*. ¶ 11. The surgeon to whom this physician referred Mr. Silva appears to have determined that Mr. Silva is seeking the mastectomy primarily as transition-related surgery, rather than as a surgery to address his severe back problems, and has consequently determined that the surgery is not covered. *Id*. In Mr. Silva's experience, the VA's exclusion of sex reassignment surgery has left VA doctors skeptical of the medical needs of transgender veterans and outwardly hostile to treating them. *Id*. ¶ 12.

IV. BACKGROUND: THE CURRENT REGULATORY FRAMEWORK, GENDER DYSPHORIA, AND SEX REASSIGNMENT SURGERY

A. The VA's Provision of Medical Care

Under 38 U.S.C. § 1710, the Secretary "shall furnish" "medical services" that the Secretary determines to be "needed" by several classes of veterans, including those with a service-connected disability, former prisoners of war, veterans of World War I, and all veterans who are unable "to defray the expenses of necessary care," which include all veterans who qualify for Medicaid, receive a qualifying pension, or meet specified income thresholds. 38 U.S.C. §§ 1710(a)(1)-(2), 1722 (a)(1)-(3). In addition, under § 1710, the Secretary is authorized to provide "needed" "medical services" to all veterans "to the extent resources and facilities are available." 38 U.S.C. § 1710(a)(3). Thus, all veterans are eligible to receive medically necessary health care, as determined by the Secretary, as long as the VA has the resources to provide or pay for such care. As President Clinton explained in signing the current enabling statute into law, it "authorizes the Department of Veterans Affairs to furnish comprehensive medical services to all veterans." Presidential Statement on Signing Veterans Legislation, 32 Weekly Comp. Pres. Doc. 2018 (Oct. 9, 1996).

Veterans who enroll in the VA health care system (as well as certain other veterans meeting other criteria[1]) are entitled to a "medical benefits package" as defined by regulation (the "Medical Benefits Package"). 38 C.F.R. § 17.36. The regulation sets forth a broad and overarching directive for the provision of veterans' health care: Veterans are meant to receive a given medical treatment "if it is determined by appropriate healthcare professionals 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." 38 C.F.R. § 17.38(b). Care is deemed "to promote health" if "the care will enhance the quality of life or daily functional level of the veteran." *Id*. at 17.38(b)(1). To that end, the regulation broadly covers inpatient and outpatient medical, surgical, and mental health care. *See* 38 C.F.R. § 17.38(a).

B. Gender Dysphoria and Sex Reassignment Surgery

At issue in this petition is the VA's coverage of medically necessary health care for veterans with gender dysphoria. By way of background, "gender identity" is an established medical concept, referring to one's intrinsic understanding of oneself as being a particular gender. Declaration of Dr. Randi C. Ettner ("Ettner Decl.") ¶ 11. Gender identity is an innate aspect of personality that is firmly established, generally by the age of four, although individuals vary in the age at which they come to understand and express that identity. *Id.* Typically, people who are designated female at birth based on the appearance of their genitalia identify as girls or women, and people who are designated male at birth identify as boys or men. *Id*. ¶ 12. For transgender individuals, however, the person's gender identity differs from the sex assigned to

[1] Under 38 C.F.R. § 17.37, even veterans who are not enrolled in the VA health care system may receive the care in the Medical Benefits Package, or some subset thereof, if they fall within one of certain specified classes. For example, veterans with service-connected disabilities that meet specified severity criteria are entitled to all the care in the Medical Benefits Package (§ 17.37(a)), and a veteran with a compelling medical need to complete a course of VA treatment started when the veteran was enrolled in the VA health care system may continue to receive that treatment regardless of the veteran's continuing enrollment status (§ 17.37(d)).

that person at birth.[2] The medical diagnosis for that feeling of incongruence is gender dysphoria, which can cause severe distress if untreated. *Id*. ¶ 13.

The major medical associations and diagnostic manuals uniformly recognize gender dysphoria as a serious medical condition. For example, the *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition—on which the VA regulations governing ratings for disability relating to mental disorder rely, *see* 38 C.F.R. § 4.130—dedicates an entire chapter to the diagnosis of gender dysphoria.[3] Other manuals too, such as the *International Classification of Diseases*, provide for a diagnosis of gender dysphoria (albeit using different terminology).[4] Major medical organizations—including the American Psychiatric Association, the American Medical Association, the Endocrine Society, and the American Psychological Association—likewise recognize gender dysphoria, and provide for its diagnosis and full treatment, including through sex reassignment surgery where necessary. Declaration of Dr. Marci L. Bowers ("Bowers Decl.") ¶ 36; Ettner Decl. ¶¶ 11, 13-14, 18, 24, 35.

In May 2012, the American Psychiatric Association ("APA") issued an official Position Statement on Access to Care for Transgender and Gender Variant Individuals, which: (1) recognizes that appropriately evaluated transgender and gender variant individuals can benefit greatly from medical and surgical gender transition treatments; (2) advocates for removal

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2 A transgender man is a person who was assigned the sex of female at birth but whose gender identity is male. A transgender woman is a person who was assigned the sex of male at birth but whose gender identity is female.

3 The *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition ("DSM" or "DSM-5"), is used throughout the world as the authoritative guide to the diagnosis of mental disorders and includes gender dysphoria. The DSM "provides a common language for clinicians to communicate about their patients and establishes consistent and reliable diagnoses that can be used in the research of mental disorders." American Psychiatric Association, DSM Development, *available at* http://www.dsm5.org/about/Pages/faq.aspx.

4 World Health Organization, "Gender Identity Disorders," International Statistical Classification of Diseases and Related Health Problems, 10th Revision (2016), at F64, *available at* http://apps.who.int/classifications/icd10/browse/2016/en#/F64.0.

of barriers to care and supports both public and private health insurance coverage for gender transition treatment; and (3) opposes categorical exclusions of coverage for such medically necessary treatment when prescribed by a physician.[5]

The protocol for diagnosing and treating gender dysphoria is well established and generally accepted by the medical community. The Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People promulgated by the World Professional Association for Transgender Health ("WPATH Standards" or "Standards of Care") set forth the accepted protocol for the diagnosis and treatment of gender dysphoria, and are recognized as authoritative standards of care by the American Psychiatric Association, the Endocrine Society, and the American Psychological Association. Ettner Decl. ¶ 18.

The Standards of Care identify the following treatment protocols for treating individuals with gender dysphoria:

- Changes in gender expression and role (which may involve living part-time or full-time in another gender role, consistent with one's gender identity);
- Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support; improving body image; or promoting resilience;
- Hormone therapy to feminize or masculinize the body; and

[5] American Psychiatric Association, Position Statement on Access to Care for Transgender and Gender Variant Individuals (2012), *available at* http://www.psychiatry.org/File%20Library/Learn/Archives/Position-2012-Transgender-Gender-Variant-Access-Care.pdf.

- Surgery to change primary and/or secondary sex characteristics (*e.g.*, breasts/chest, external and/or internal genitalia, facial features, body contouring).

Sex reassignment surgery is a well-established, effective, and often critical treatment for gender dysphoria. Bowers Decl. ¶¶ 31-38; Ettner Decl. ¶¶ 15, 19-34. While not all individuals with gender dysphoria require sex reassignment surgery, the WPATH Standards recognize that hormone therapy and psychotherapy may be inadequate to treat severe cases of gender dysphoria, and in those cases, failure fully to treat gender dysphoria through sex reassignment surgery may cause serious mental and physical health issues for the patient. Bowers Decl. ¶¶ 34, 37; Ettner Decl. ¶¶ 19-20. Without treatment, individuals with severe gender dysphoria experience anxiety, depression, suicidality, and other attendant mental health issues. Bowers Decl. ¶ 37; Ettner Decl. ¶ 15. Many such individuals carry a burden of shame and low self-esteem, attributable to a feeling of being inherently "defective," and as a result become socially isolated. Ettner Decl. ¶ 15. This isolation in turn leads to the stigmatization of such individuals, which over time proves ravaging to healthy personality development and interpersonal relationships. *Id*. As a result, without treatment, many such individuals are unable to function effectively in occupational, social, or other important areas of daily living. *Id*. A recent survey shows a 41% rate of suicide attempts among transgender people, far above the baseline rates for North America. *Id*. As with the diagnosis of gender dysphoria, there is a consensus within the medical community that sex reassignment surgery may be the only adequate treatment for some cases of gender dysphoria. *Id*. ¶¶ 21, 23; Bowers Decl. ¶ 34.

Courts too have recognized that gender dysphoria is a serious medical condition and that sex reassignment surgery may be medically necessary to treat certain individuals with gender

dysphoria. In *Soneeya v. Spencer*, for example, the court held that a prisoner's gender dysphoria constituted a "serious medical need" that the Massachusetts Department of Correction ("MDOC") was required under the Eighth Amendment to address adequately.[6] Moreover, although the MDOC had provided the prisoner with psychotherapy and hormone treatment, offering such treatment alone was inadequate, as the MDOC also was required to "consider whether sex reassignment surgery … [was] medically indicated."[7] Likewise, in *Fields v. Smith*, the court found that gender dysphoria was a "serious medical need" within the meaning of the Eighth Amendment, and held that a statutory prohibition on hormone therapy and sex reassignment surgery for inmates was unconstitutional on its face because it deprived inmates of access to "medically necessary" treatment.[8]

In a recent Tax Court case, *O'Donnabhain v. Commissioner*, the court conducted a trial and an in-depth review of the medical evidence regarding treatment of gender dysphoria.[9] The court noted the broad acceptance of the WPATH Standards throughout the psychiatric profession, as evidenced by multiple psychiatric and medical reference texts and court opinions, all concluding that sex reassignment surgery is medically necessary to ensure the health of some patients suffering from gender dysphoria.[10] Other courts to consider the necessity of surgery to treat gender dysphoria have reached similar conclusions.[11]

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6 851 F. Supp. 2d 228, 231-232, 252 (D. Mass. 2012).

7 *Id.* at 252.

8 712 F. Supp. 2d 830, 844 (E.D. Wis. 2010).

9 *See O'Donnabhain v. Commissioner*, 134 T.C. 34, 65-70 (2010).

10 *Id.*

11 *See, e.g.*, *De'lonta v. Johnson*, 708 F.3d 520, 526 (4th Cir. 2013) (noting that sex reassignment surgery is an "accepted, effective, medically indicated treatment for GID").

Sex reassignment surgery often may be the only adequate treatment for gender dysphoria. In certain cases, sex reassignment surgery—which can include, depending upon the circumstances, removal or construction of the breasts, penectomy, vaginoplasty, phalloplasty, and penile and testicular implants—is medically necessary to treat the symptoms of gender dysphoria, and indeed may be the only medically adequate treatment.[12]

The VA's categorical ban on sex reassignment surgery in all instances, no matter how necessary it may be for an individual, flies in the face of the medical consensus on this subject. This categorical exclusion is all the more irrational because the VA recognizes that gender dysphoria is a serious medical condition that requires treatment. For example, the VA will provide, where medically necessary, hormone treatment to address gender dysphoria. The VA also will provide pre- and post-operative care for veterans who have undergone sex reassignment surgery outside the VA system. Thus, the VA appears to have no *medical* objection to sex reassignment surgery. Yet the VA irrationally continues to exclude coverage for sex reassignment surgery—no matter how medically necessary.

C. The VA's Current Provision of Surgeries Constituting Sex Reassignment Surgery To Treat Other Conditions

The VA already provides each of the surgeries that constitute sex reassignment surgery. The VA provides these surgeries for a variety of reasons, including to address certain intersex conditions, to repair traumatic injuries, and to treat cancer, but the VA denies those same procedures to transgender veterans for the treatment of gender dysphoria. For example, VA policy covers surgery for intersex veterans "in need of surgery to correct inborn conditions related to reproductive or sexual anatomy." VHA Directive 2013-003 (Feb. 8, 2013) ("VHA

[12] *See id.* (noting, in the Eighth Amendment context, that providing some treatment consistent with the WPATH Standards does not mean that constitutionally adequate treatment has been provided); *see also Norsworthy v. Beard*, 87 F. Supp. 3d 1164, 1188 (N.D. Cal. 2015) (granting preliminary injunction where plaintiff was likely to succeed in establishing that surgery was "the only way to treat her persistent symptoms of gender dysphoria").

Directive 2013-003" or "Directive 2013-003"), at 2. Under 38 C.F.R. § 17.38(a)(1)(x), the VA offers veterans "[r]econstructive (plastic) surgery required as a result of disease or trauma," which under VHA Directive 1091 (Feb. 21, 2014) ("Directive 1091") includes "those surgical procedures performed for the revision of external bodily structures which deviate from normal either from congenital or acquired causes."

Under 38 C.F.R. § 17.38(a)(1)(x) and Directive 1091, the VA offers breast reconstruction to cisgender[13] women who have had a mastectomy, and penile and testicular implants to cisgender males whose penises or testes have been damaged.[14] Hysterectomy and mastectomy are offered to cisgender females for, among other reasons, reduction of cancer risk.[15] The VA also offers cisgender males orchiectomies, scrotectomies, and penectomies for various medical reasons.[16] Moreover, under the clear language of Directive 2013-003, the VA offers various procedures, including vaginoplasty and phalloplasty, for certain intersex individuals born with ambiguous genitalia.

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[13] "Cisgender" is a term used to describe a person whose self-identity conforms to the sex he or she was assigned at birth—*i.e.*, someone who is not transgender. *See Norsworthy v. Beard*, 87 F. Supp. 3d 1104, 1120 n.9 (N.D. Cal. 2015).

[14] *See* Leong *et al*., *Effective Breast Reconstruction in Female Veterans*, 198(5) Am. J. Surg. 658-63 (Nov. 2009) (addressing outcomes of breast reconstruction performed at VA hospitals); *Shimansky v. West*, 17 Vet. App. 90, 90 (1999) (patient received a penile prosthesis at the Wilmington, Delaware VA Medical Center); *Brewer v. Nicholson*, 21 Vet. App. 420, 420 (2006) (patient received a penile prosthesis at the Jackson, Mississippi VA Medical Center); Board of Veteran's Appeals, Docket No. 96-07-121 (Sept. 26, 1997) (stating patient received a "testicular prosthetic implantation" at a VA hospital).

[15] *See* Gardella *et al.*, *Prevalence of Hysterectomy and Associated Factors in Women Veterans Affairs Patients*, 50(3) J. Reprod. Med. 166, 166-72 (Mar. 2005) (estimating the prevalence of hysterectomies provided by the VA Puget Sound Health Care System); Hynes *et al*., *Breast Cancer Surgery Trends and Outcomes: Results from a National Department of Veterans Affairs Study*, 198(5) J. of the Am. College of Surgeons 707-16 (Mar. 2004) (examining trends in breast cancer surgery performed at VA hospitals).

[16] *See Norvell v. Peake*, 22 Vet. App. 194, 195 (2008) (noting that the patient underwent a bilateral orchiectomy at Lexington, Kentucky, VA Medical Center), *aff'd sub nom. Norvell v. Shinseki*, 333 F. App'x 571 (Fed. Cir. 2009); Corman *et al*., *Fournier's Gangrene in a Modern Surgical Setting: Improved Survival with Aggressive Management*, BJU International, 84: 85-88 (July 1999) (noting that all patients covered in the survey had received scrotectomies for Fournier's Gangrene and that some of the patients had been treated at West Los Angeles Veterans Administration Hospital); Board of Veterans Appeals, Docket No. 05-31 519 (Oct. 25, 2007) (noting that the patient had undergone a total penectomy at a VA hospital due to cancer).

These procedures are excluded from coverage, however, if they are necessary to treat a transgender veteran's gender dysphoria. The regulation at issue here, *i.e.*, 38 C.F.R. § 17.38(c)(4), expressly excludes "[g]ender alterations" from the Medical Benefits Package. VHA Directive 2013-003 clarifies that this exclusion constitutes an absolute bar to coverage for "sex reassignment surgery," which the Directive defines to include "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." VHA Directive 2013-003 at 2. Heedless of the current medical consensus regarding the medical necessity of sex reassignment surgery for some individuals suffering from gender dysphoria, the Directive puts such surgery on equal footing with "plastic reconstructive surgery for strictly cosmetic purposes." It does this even though, as noted above, substantively identical procedures are available to intersex veterans under the clear language of the Directive, and to other veterans for various reasons, including to repair traumatic injuries and to treat cancer.

The illogic of the exclusion on sex reassignment surgery is underscored not only by the fact that the VA provides its constituent procedures to other veterans to treat other conditions, but also by the fact that the VA covers *other* aspects of transgender health, including hormone therapy and post-sex-reassignment-surgery health care. Specifically, the VA provides mental health care, hormone therapy, and preoperative evaluation for transgender veterans, as well as continuing hormone replacement therapy and post-operative care to veterans who have received sex reassignment surgery outside the VA health care system. VHA Directive 2013-003 at 2. The VA clearly views those treatments as medically necessary, but irrationally excludes only surgical treatments needed to treat gender dysphoria.

D. The Critical Need for Sex Reassignment Surgery in the Transgender Veteran Population

Recent empirical studies show that the estimated prevalence of transgender individuals in the Nation's military is five times greater than the estimated prevalence in the civilian population.[17] As of May 2014, there are an estimated 129,700 transgender veterans of the U.S. Military, as well as 4,600 retired transgender members of the U.S. Reserves and National Guard. Approximately 15,500 transgender individuals currently serve as members of the U.S. Armed Forces, Reserves, and Guard.[18] The population of transgender veterans is so significant that since 2015, clinics have opened in Cleveland, Ohio and Tucson, Arizona to specialize in providing medical care to these veterans.[19] Similarly, the VA Boston Healthcare System has formed the Interdisciplinary Transgender Treatment Team, which provides medical care tailored to the needs of transgender veterans.[20]

Moreover, recent progress in policies affecting transgender military personnel suggests that the population of transgender active-duty military and veterans is likely only to increase. In July 2015, United States Secretary of Defense Ashton B. Carter issued a directive to devise new rules to allow transgender individuals to serve openly in the military.[21] These rules are expected to reverse the military's longstanding policy of preventing transgender individuals from serving

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[17] Blosnich *et al.*, *Prevalence of Gender Identity Disorder and Suicide Risk Among Transgender Veterans Utilizing Veterans Health Administration Care*, 103(10) Am. J. of Public Health e27 (2001).

[18] Gates & Herman, *Transgender Military Service*, Williams Institute (May 2014).

[19] Albrecht, *VA's First Transgender Clinic Opens in Cleveland*, Cleveland.com (Nov. 2015); Jenkins, *New VA Clinic Opens for Transgender Vets*, National Public Radio (Dec. 29, 2015).

[20] Dep't of Veterans Affairs, VA Boston Healthcare Sys. (Mar. 3, 2016).

[21] Somashekhar & Whitlock, *Military To Allow Transgender Members To Serve Openly*, Wash. Post, July 13, 2015.

and reflect a growing recognition on the part of the federal government as a whole that transgender individuals deserve fair and equal treatment under the law.[22]

While the percentage of veterans who are transgender is very significant compared to the percentage of transgender individuals in the general population, the transgender veteran population nevertheless constitutes only a small percentage of the total veteran population. Based on the best available data, only 0.6% of the national population of veterans and retirees of the U.S. Armed Forces, Army Reserves, and National Guard is transgender.[23]

E. Developments in Health Care Coverage for Transgender Individuals

The VA's categorical exclusion of sex reassignment surgery from the package of medical benefits available to transgender veterans has become increasingly divorced from the practices of other federal agencies and States, which have recognized that sex reassignment surgery may be a medical necessity to treat gender dysphoria. Several federal agencies and state governments have adopted laws and policies to prohibit discrimination against transgender individuals in access to health care. In particular, these agencies and governments have prohibited categorical bars on sex reassignment surgery in coverage determinations made by insurers and health care programs receiving federal and state financial assistance.

At the federal level, the Department of Health and Human Services ("HHS") recently issued a proposed rule under Section 1557 of the Affordable Care Act ("ACA") that would prohibit sex discrimination (including on the basis of gender identity) in any health program or activity receiving federal financial assistance. 42 U.S.C. § 18116; *see* Nondiscrimination in

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[22] On January 14, 2016, Matthew Allen, a Pentagon spokesperson, stated that he anticipates that the Secretary's final approval of the rules will be issued in spring 2016. Johnson, *Pentagon Expects Decision on Trans Military Ban in Spring*, Wash. Blade, January 14, 2016, *available at* http://www.washingtonblade.com/2016/01/14/pentagon-expects-determination-on-trans-military-ban-in-spring.

[23] Gates & Herman, *supra* note 18 at 4.

Health Programs and Activities, 80 Fed. Reg. 54,172 (Sept. 8, 2015). That prohibition applies to all covered entities under the ACA that provide or administer health-related insurance or other health-related coverage. Although the prohibition does not apply to the VA, it is nonetheless instructive for the VA as it formulates its own nondiscriminatory practices. The proposed rule clarifies that the statutory bar on sex discrimination includes discrimination on the basis of gender identity, and voids any explicit categorical exclusion for coverage of health services related to gender transition, such as the one at issue here. The rule also would prohibit denial of any specific health services related to gender transition "where such a denial or limitation results in discrimination against a transgender individual." 80 Fed. Reg. at 54,190. For example, a health care plan may be discriminatory if it generally provides coverage of hysterectomies but denies coverage of a hysterectomy needed to treat gender dysphoria. *See id*.

Additionally, the HHS Departmental Appeals Board recently overturned a thirty-year-old National Coverage Determination ("NCD") denying Medicare coverage of all sex reassignment surgery as a treatment for gender dysphoria.[24] An NCD is "a determination by the Secretary [of Health and Human Services] with respect to whether or not a particular item or service is covered nationally under [title XVIII (Medicare)]." Social Security Act §§ 1862(l)(6)(A), 1869(f)(1)(B); *see also* 42 C.F.R. § 400.202 (NCD "means a decision that [the Centers for Medicare & Medicaid Services] makes regarding whether to cover a particular service nationally under title XVIII of the Social Security Act."). NCDs "describe the clinical circumstances and settings under which particular [Medicare items and] services are reasonable and necessary (or are not reasonable and necessary)." 67 Fed. Reg. 54,534, 54,535 (Aug. 22, 2002). The Appeals Board found that the exclusion of coverage of sex reassignment surgery was unreasonable in

[24] *See* Decision No. 2576, Department of Health and Human Services, Departmental Appeals Board (May 30, 2014), *available at* http://www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf.

light of significant and unchallenged empirical evidence supporting the safety, effectiveness, and necessity of that treatment for certain individuals with severe gender dysphoria.[25]

Other federal agencies and multiple States have acknowledged the need to establish clear policies that recognize the medical consensus that sex reassignment surgery may be medically necessary for a number of transgender individuals. For example, the Office of Personnel Management ("OPM") recently issued a letter to health insurance carriers participating in the Federal Employees Health Benefits Program stating that no carrier "may have a general exclusion of services, drugs or supplies related to gender transition or 'sex transformations.'"[26] The guidance from OPM recognizes "the evolving professional consensus that treatment may be medically necessary to address a diagnosis of gender dysphoria."[27] And an increasing number of States, including California, Colorado, Connecticut, Illinois, Maryland, Massachusetts, Minnesota, Nevada, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington, as well as the District of Columbia, have adopted laws and policies that recognize the discriminatory nature of health care programs that deny necessary coverage for the treatment of gender dysphoria.[28] These recent policy revisions and clarifications focus on the inappropriateness of blanket exclusions of sex reassignment surgery and other treatments for

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[25] *Id.*

[26] U.S. Office of Personnel Management, FEHB Program Carrier Letter, Letter No. 2015-12 (June 23, 2015), *available at* https://www.opm.gov/healthcare-insurance/healthcare/carriers/2015/2015-12.pdf.

[27] *Id.*

[28] *See* Pennsylvania Ins. Dep't, Notice Regarding Nondiscrimination, Pa.B. Doc. No. 16-762, 46 Pa.B. 2251 (Apr. 30, 2016), *available at* http://www.pabulletin.com/secure/data/vol46/46-18/762.html; 80 Fed. Reg. at 54,189; Rhode Island Office of the Health Ins. Comm'r, Bulletin No. 2015-3 (Nov. 23, 2015), *available at* http://www.ohic.ri.gov/documents/Bulletin-2015-3-Guidance-Regarding-Prohibited-Discrimination.pdf; Minnesota Dep't of Commerce, Administrative Bulletin 2015-5 (Nov. 24, 2015), *available at* http://mn.gov/commerce-stat/pdfs/bulletin-insurance-2015-5.pdf; Maryland Ins. Admin., Bulletin 14-02 (Jan. 27, 2014), *available at* http://insurance.maryland.gov/Insurer/Documents/bulletins/bulletin-1402-transgender.pdf.

gender dysphoria while still preserving providers' ability to make medical necessity determinations on an individual basis.

The VA is quickly becoming an outlier among health care providers in its failure to provide full coverage of the treatment necessary for patients with gender dysphoria.

V. THE VA SHOULD AMEND THE REGULATION TO COVER SEX REASSIGNMENT SURGERY

The VA should offer sex reassignment surgery to transgender veterans, first and foremost, because doing so is good policy. The VA may adopt a new policy if it "is permissible under the statute, [] there are good reasons for it, and [] the agency *believes* it to be better, which the conscious change adequately indicates." *F.C.C. v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009). Offering sex reassignment surgery is clearly permissible under 38 U.S.C. § 1710, which broadly authorizes the Secretary to provide "needed" medical care to veterans, and there are good reasons for this policy change: providing this surgery is consistent with, and mandated by, the VA's mission, would impose at most only a relatively minor burden on the VA health care system, and would provide medically necessary care to alleviate the physical suffering, depression, and suicidal ideation of transgender veterans who, in the absence of such care, are likely to be gravely afflicted with such conditions.

Providing sex reassignment surgery is required by the VA's mission to promote the health of veterans through coverage of medically accepted treatments that enhance the quality of life or daily functional level of veterans. The Secretary is charged with providing hospital care and medical services to veterans. *See* 38 U.S.C. § 1710. The VA has determined that this mandate includes care that is "needed to promote, preserve, or restore the health of the individual and is consistent with generally accepted standards of medical practice." 38 C.F.R. § 17.38(b). Care is deemed "to promote health" if "the care will enhance the quality of life or daily

functional level of the veteran," *id*. § 17.38(b)(1), and care is deemed to "preserve health" if the care will maintain the current quality of life or daily functional level of the veteran," including by "extend[ing] lifespan," *id*. § 17.38(b)(2). Notwithstanding its categorical exclusion for some of the most essential medical care for transgender veterans, VHA Directive 2013-003 states that "[i]t is the VHA policy that medically necessary care is provided to enrolled or otherwise eligible intersex and transgender veterans." VHA Directive 2013-003 at 2.[29]

As discussed above, there is no genuine dispute within the medical community that sex reassignment surgery is a medically necessary component of treatment for some individuals with gender dysphoria. Indeed, the VA implicitly acknowledges the necessity of sex reassignment surgery by providing preoperative assessment and post-operative care to veterans who may undergo, or who have already undergone, such surgery. Not all individuals suffering from gender dysphoria require surgery, yet those who do may be some of the most vulnerable to related complications from lack of access to care—namely, depression and suicide. Transgender individuals who need but do not receive sex reassignment surgery are significantly more susceptible than the general population to depression and suicide.[30]

Relative to the extraordinarily salubrious effect of providing medically necessary sex reassignment surgery to those in need of it, a change in VA policy would impose an immaterial cost burden on the VA health care system. Only a small absolute number of veterans are

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[29] Notably, in addition to preventing transgender veterans from receiving medically necessary care, the VA's exclusion of sex reassignment surgery from coverage appears to be having other unfortunate effects, evidently causing some providers to be skeptical of the medical needs of transgender veterans that are unrelated to gender transition, and outwardly hostile to treating them. *See* Silva Aff. ¶¶ 11-12.

[30] *See* Ettner Decl. ¶ 15 ("A recent survey shows a 41% rate of suicide attempts among transgender people, far above the baseline rates for North America. (Haas et al., 2014)."); Blosnich *et al*., Prevalence of Gender Identity Disorder and Suicide Risk Among Transgender Veterans Utilizing Veterans Health Administration Care," 103 Am. J. Pub. Health e27 (Oct. 2013), *available at* http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2013.301507 (the "rate of suicide-related events among GID-diagnosed VHA veterans was more than 20 times higher than were rates for the general VHA population.").

transgender, and likely only a fraction of them will require sex reassignment surgery.[31] And sex reassignment surgery is no more expensive than substantially identical surgeries included in the Medical Benefits Package for cisgender veterans. *See, e.g.*, Bowers Decl. ¶ 20. Moreover, the VA's failure to treat gender dysphoria fully in a given patient leads to collateral consequences, both for the individual veteran who experiences continued mental and physical impairment from his or her partially treated condition, and for the VA health care system itself, which must continue to pay for such veterans' mental health care, sometimes indefinitely. In fact, a recent study shows that the upfront costs of sex reassignment surgery are negligible when compared with the ongoing costs associated with treatment of long-term depression in individuals with cases of gender dysphoria for which surgery is appropriate.[32]

The California Department of Insurance likewise recently conducted an assessment of the economic impact of covering transition-related health care and determined that "transgender insureds who have access to treatment see rates of depression drop and anxiety decrease," and that "[t]his overall improvement in mental health and reduction in utilization of mental health

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[31] *See supra* note 18 and accompanying text. The WPATH Standards of Care reference available studies of individuals who "present for gender-transition-related care at specialist gender clinics," and notes that these studies estimate the prevalence of such individuals in the general population at between "1:11,900 to 1:45,000 for male-to-female individuals … and 1:30,400 to 1:200,000 for female-to-male … individuals." Some researchers have suggested that, given the sources of the study participants, the figures in these studies approximate the prevalence of individuals who undergo sex reassignment surgery. *See* Olyslager & Conway, "On the Calculation of the Prevalence of Transsexualism" (Sept. 2007), at 1 (paper presented at the WPATH 20th International Symposium), *available at* http://www.changelingaspects.com/ PDF/2007-09-06-Prevalence of Transsexualism.pdf.

The New York Times has reported that a recent yet currently unreleased study commissioned by the Department of Defense and conducted by the RAND Corporation predicted that between only 29 and 129 active service members would seek transition-related medical care annually. The study also found that given these low numbers, the cost of providing transition-related care to active duty service members would be negligible. Editorial Board, *The Military's Transgender Policy, Stalled*, N.Y. Times, Apr. 6, 2016.

[32] Padula *et al.*, *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis*, J. of General Internal Medicine (Oct. 19, 2015).

services could be a source of cost savings for employers, insurers, and insureds."[33] Citing the California assessment, HHS agreed in its proposed rule on Section 1557 of the Affordable Care Act that "providing transgender individuals non-discriminatory insurance coverage and treatment … will have minimal impact on the overall cost of care and on health insurance premiums."[34]

Finally, offering sex reassignment surgery to transgender veterans is the right thing to do. Offering sex reassignment surgery to transgender veterans can be a life-saving treatment to treat the serious distress associated with gender dysphoria. Bowers Decl. ¶¶ 34-35, 37; Ettner Decl. ¶¶ 15-16, 21. The VA implicitly acknowledges what the broader medical community does not question—that sex reassignment surgery is medically necessary for some patients—yet the VA refuses to provide this medically necessary care to those patients. Our Nation owes transgender veterans this life-changing treatment in the same way it owes all other veterans medically necessary care for their most significant medical conditions. It is time for the VA to take the next step and provide complete treatment to transgender veterans.

VI. THE EXISTING REGULATION IS ARBITRARY AND CAPRICIOUS

Under the Administrative Procedure Act, a court may hold unlawful and set aside final agency action, such as a regulation or a denial of a petition for rulemaking or to amend existing rules, that it finds to be, *inter alia*, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706. To comply with the requirements of the Act, the agency "must examine the relevant data and articulate a satisfactory explanation for its action." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 552, (2009) (quoting *Motor Vehicles Mfrs.*

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[33] California Department of Insurance, "Economic Impact Assessment of Gender Nondiscrimination in Health Insurance," Reg. File No. REG-2011-00023 (Apr. 13, 2012), *available at* http://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.

[34] Notice of Proposed Rulemaking Nondiscrimination in Health Programs and Activities, Medicare & Medicaid Guide 220954, 80 Fed. Reg. 54,171, 54,206 (Sept. 8, 2015).

Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42-43 (1983)). That explanation must "includ[e] a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 42-43. "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise[.]" *Fox Television*, 556 U.S. at 552 (quoting *State Farm*, 463 U.S. at 42-43). Moreover, "it is well-established that 'an agency action is arbitrary when the agency offer[s] insufficient reasons for treating similar situations differently.'" *SKF USA Inc. v. United States*, 263 F.3d 1369, 1382 (Fed. Cir. 2001) (quoting *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996)).

A denial of this petition would be arbitrary and capricious for three reasons: (1) the VA already recognizes that gender dysphoria is a treatable medical condition and currently provides some treatments for it, yet arbitrarily excludes sex reassignment surgery from the covered treatments; (2) the VA covers certain treatments for cisgender and intersex veterans yet arbitrarily denies the same or analogous treatments for transgender veterans; and (3) the VA excluded sex reassignment surgery without examining any relevant data and without giving any public explanation for the exclusion, while the overwhelming medical consensus supports the inclusion of sex reassignment surgery.

It is the height of arbitrary and capricious action to recognize gender dysphoria as a treatable medical condition and provide some treatments for it, while denying other equally necessary medical treatments. The VA's current policy with respect to the provision of medical care to transgender veterans states:

> VHA policy [requires] that medically necessary care [be] 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.

VHA Directive 2013-003 at 2.[35] Thus, VA policy clearly recognizes that medically necessary care must be provided to transgender veterans, and also recognizes that some level of care related to sex reassignment surgery is medically necessary. For example, the VA currently provides mental health care coverage and hormonal therapy—which, like surgery, is specifically designed to assist transgender individuals in treating their dysphoria by making their bodies congruent with their gender. VA policy likewise provides transgender individuals with therapies, namely "preoperative evaluation, and medically necessary post-operative and long-term care following sex-reassignment surgery," that are specifically tailored to assist individuals seeking sex reassignment surgery with the pre- and post-surgical aspects of such surgery. And VA policy recognizes as medically necessary evaluations of transgender individuals performed prior to their obtaining sex reassignment surgery (namely, preoperative evaluation). Thus, the VA recognizes the medical necessity of *every aspect of care* for transgender veterans undergoing sex reassignment surgery, except surgery itself. That policy is incoherent because it is internally inconsistent, and therefore arbitrary and capricious.

The arbitrary and capricious nature of the VA's policy is underscored by the fact that the VA offers the same or substantially similar surgeries to cisgender and intersex veterans for other medically necessary conditions. As explained above, sex reassignment surgery is an umbrella term referring to a compliment of surgeries that may include, penectomy, vaginoplasty, chest reconstruction, phalloplasty, hysterectomy, and/or mastectomy.

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[35] *See also*, Dep't of Veterans Affairs, Patient Care Services, (Mar. 3, 2016), *available at* http://www.patientcare.va.gov/Lesbian_Gay_Bisexual_and_Transgender_LGBT_Veteran_Care.asp.

Under the clear language of the VA regulations and directives, each of these surgeries is provided as a matter of VA policy to cisgender and intersex veterans for other conditions that the VA recognizes to be medically necessary. VA policy grants surgery to intersex individuals "to correct inborn conditions related to reproductive or sexual anatomy," and so provides penectomy and vaginoplasty to certain intersex individuals born with ambiguous genitalia. VHA Directive 2013-003 at 2. Hysterectomy and mastectomy are offered to cisgender females for, among other reasons, reduction of cancer risk, but the same surgeries are denied to transgender males. *See supra*, note 15. The VA offers, and so deems medically necessary, breast reconstruction to cisgender women who have had a mastectomy, but denies a substantially identical surgery, breast augmentation, to transgender women. *See supra*, note 14. The VA offers penile and testicular implants to cisgender males whose penises or testes have been damaged, but refuses very similar treatment to transgender men. *See id*.

In each of these comparisons, the VA offers certain surgeries to cisgender or intersex individuals for their conditions, but refuses to cover the same or substantially similar surgeries to transgender individuals for their conditions. The VA cannot justify this inconsistent treatment by claiming that these surgeries are medically necessary for treatment of some conditions, but not medically necessary for the treatment of gender dysphoria—as explained above, *see supra* Section IV.B, there is no genuine dispute within the medical community that sex reassignment surgery is medically necessary for certain patients. Accordingly, the VA's current policy amounts to offering certain surgeries when they are medically necessary, only not when those surgeries are medically necessary to treat gender dysphoria. This policy is incoherent and unjustifiable, and the VA's action in continuing it would be arbitrary and capricious. *See SKF USA Inc.*, 263 F.3d at 1382.

Finally, the VA has given no public explanation for excluding from coverage sex reassignment surgery for transgender veterans. Neither the proposed nor the final Regulation explained the exclusion or offered any evidence that the VA had "examine[d] the relevant data" in arriving at its decision to exclude this surgery from coverage. *State Farm*, 463 U.S. at 42-43; *see* 63 Fed. Reg. 37,299 (July 10, 1998) (proposed rule); 64 Fed. Reg. 54,207 (Oct. 6, 1999) (final regulation). The subsequent VHA directives that implemented the exclusion of sex reassignment surgery from the Medical Benefits Package likewise contained no explanation. *See* VHA Directive 2011-024 (June 9, 2011); VHA Directive 2013-003 (Feb. 8, 2013). The VA has therefore failed thus far even to attempt to "articulate a satisfactory explanation for its action" in excluding sex reassignment surgery from the Medical Benefits Package, or to offer a "rational connection between [] facts found and the choice made." *State Farm*, 463 U.S. at 42-43; *see also Michigan v. E.P.A.*, 135 S. Ct. 2699, 2706 (2015) ("Federal administrative agencies are required to engage in 'reasoned decisionmaking.'") (citation omitted).

As explained above, if the VA were to examine data relevant to its policy of excluding sex reassignment surgery from the Medical Benefits Package, the VA would find that such data clearly support reversing this exclusion. The medical community has reached consensus that sex reassignment surgery is a medically necessary treatment for a significant number of individuals with gender dysphoria—medically necessary in the same way as any other medical treatment that is required "to promote, preserve, or restore" the well-being of the patient. VHA Directive 1091 (Feb. 21, 2014), at 1; *see also* Bowers Decl. ¶¶ 34-37; Ettner Decl. ¶¶ 21, 23. No major medical association considers sex reassignment surgery to be a form of cosmetic surgery. Bowers Decl. ¶ 35; Ettner Decl. ¶ 23. As discussed above, the costs of providing sex reassignment surgery are negligible in context. *See supra* Section V at 21-22.

For these reasons, a denial of this petition to amend the Regulation to include sex reassignment surgery in the Medical Benefits Package would constitute unlawful, arbitrary and capricious agency action.

VII. THE EXISTING REGULATION VIOLATES THE EQUAL PROTECTION COMPONENT OF THE FIFTH AMENDMENT

A denial of this petition to amend the Regulation to include sex reassignment surgery in the Medical Benefits Package would also violate the Equal Protection component of the Fifth Amendment. The Federal Circuit is required to "hold unlawful and set aside" any VA regulation "contrary to constitutional right, power, privilege, or immunity." 38 U.S.C. § 7292(d)(1)(B). The Regulation violates those guarantees by discriminating against transgender veterans on the basis of their sex and their transgender status, without any compelling, or even arguably permissible, government interest.

A. Discrimination Against Transgender People Receives Heightened Scrutiny

1. Discrimination Against Transgender People Is Sex Discrimination

It is "firmly established" that laws or policies that discriminate based on sex are evaluated under close scrutiny. *Mississippi Univ. for Women v. Hogan*, 458 U.S. 718, 723 (1982). Discrimination against transgender people receives the same scrutiny. In fact, since *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989), every court of appeals to consider the question has concluded that prohibitions against sex discrimination protect transgender people.

In *Price Waterhouse*, the Supreme Court held that discrimination on the basis of gender stereotypes is sex-based discrimination. In that case, a female employee with the Price Waterhouse firm had been denied partnership in the firm because she was considered too "macho" and was told she needed to "walk more femininely, talk more femininely, dress more femininely, wear make-up, have her hair styled, and wear jewelry." 490 U.S. at 235. Six

members of the Supreme Court agreed that that kind of discrimination due to failure to conform to sex stereotypes constituted sex discrimination. *Id*. at 250-251 (plurality opinion); *id*. at 258-261 (White, J., concurring); *id*. at 272-273 (O'Connor, J., concurring).

Since that decision, federal courts have been nearly unanimous in holding that discrimination against transgender people is also a form of sex discrimination under *Price Waterhouse*. *See, e.g., G.G. ex rel. Grimm v. Gloucester Cnty. Sch. Bd.*, No. 15-2056, __ F.3d __, 2016 WL 1567467, at *4-8 (4th Cir. Apr. 19, 2016); *Glenn v. Brumby*, 663 F.3d 1312, 1316-1320 (11th Cir. 2011); *Smith v. City of Salem*, 378 F.3d 566, 571-575 (6th Cir. 2004); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213, 215-216 (1st Cir. 2000); *Schwenk v. Hartford*, 204 F.3d 1187, 1201-1202 (9th Cir. 2000); *see also Schroer v. Billington*, 577 F. Supp. 2d 293, 303-306 (D.D.C. 2008).

As the Eleventh Circuit observed in *Glenn*, "[a] person is defined as transgender precisely because of the perception that his or her behavior transgresses gender stereotypes" and there is therefore "a congruence between discriminating against transgender and transsexual individuals and discrimination on the basis of gender-based behavioral norms." 663 F.3d at 1316.

Schroer offered another formulation of why discrimination against transgender people must be understood as sex discrimination, posing a helpful analogy:

> Imagine that an employee is fired because she converts from Christianity to Judaism. Imagine too that her employer testifies that he harbors no bias toward either Christians or Jews but only "converts." That would be a clear case of discrimination "because of religion." No court would take seriously the notion that "converts" are not covered by the statute. Discrimination "because of religion" easily encompasses discrimination because of a *change* of religion.

577 F. Supp. 2d at 306. Applying that logic, the court held that the discrimination against a transgender job applicant because she disclosed her intent to transition from male to female "was *literally* discrimination 'because of … sex.'" *Id.* at 308; *see also Fabian v. Hosp. of Cent.*

Conn., No. 3:12-cv-1154, 2016 WL 1089178, at *28 (D. Conn. Mar. 18, 2016) ("[D]iscrimination on the basis of gender stereotypes, or on the basis of being transgender, or intersex, or sexually indeterminate … is literally discrimination 'because of sex.'").

Recognizing that no responsible argument to the contrary remains, the federal government has adopted the position that discrimination against transgender people is sex discrimination. In *Macy v. Holder*, the Equal Employment Opportunity Commission ("EEOC") held unanimously that discrimination against a transgender person is, "by definition," a form of sex discrimination.[36] E.E.O.C. Appeal No. 0120120821, 2012 WL 1435995, at *11 (Feb. 24, 2012); *see also* Memorandum from the Attorney General, Treatment of Transgender Employment Discrimination Claims Under Title VII of the Civil Rights Act of 1964 (Dec. 15, 2014) (announcing that the Department of Justice will take the position that discrimination against transgender people violates Title VII); U.S. Department of Labor, Office of Federal Contract Compliance Programs, Directive 2014-02 (Aug. 19, 2014) (clarifying that sex discrimination "under Executive Order 11246 … includes discrimination on the bas[is] of … transgender status").[37]

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[36] *Macy* was decided under Title VII, but "the showing a plaintiff must make to recover on a disparate treatment claim under Title VII mirrors that which must be made to recover on an equal protection claim." *Smith*, 378 F.3d at 577; *see also Glenn*, 663 F.3d at 1316-1318 (reviewing Title VII precedent to conclude that the Fourteenth Amendment prohibits discrimination against transgender employees).

[37] The U.S. Department of Education also has made clear that "Title IX's sex discrimination prohibition extends to claims of discrimination based on gender identity or failure to conform to stereotypical notions of masculinity or femininity." Dep't of Educ., Office of Civil Rights, *Questions and Answers on Title IX and Sexual Violence* (Apr. 29, 2014), at 5, *available at* http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf. Numerous federal courts have agreed. *See, e.g.*, *G.G.*, 2016 WL 1567467, at *7; *Pratt v. Indian River Cent. Sch. Dist.*, 803 F. Supp. 2d 135, 151-152 (N.D.N.Y. 2011); *Doe v. Brimfield Grade Sch.*, 552 F. Supp. 2d 816, 823 (C.D. Ill. 2008); *Montgomery v. Independent Sch. Dist. No. 709*, 109 F. Supp. 2d 1081, 1090 (D. Minn. 2000); *see also Rumble v. Fairview Health Servs.*, No. 14-cv-2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (holding that Section 1557 of the Affordable Care Act, which incorporates Title IX's prohibition on sex-based discrimination, "protects plaintiffs … who allege discrimination based on 'gender identity'").

2. Discrimination Based on Transgender Status Also Receives Heightened Scrutiny

Even aside from its inextricable connection to sex discrimination, discrimination based on transgender status is separately entitled to heightened scrutiny. If a classification disadvantages certain groups, it may be considered "suspect" or "quasi-suspect," and therefore scrutinized with extra care. The Supreme Court consistently has applied heightened scrutiny where the classified group has suffered a history of discrimination, and the classification has no bearing on a person's ability to perform in society. *See, e.g.*, *Massachusetts Bd. of Ret. v. Murgia*, 427 U.S. 307, 313 (1976) (heightened scrutiny is warranted where a classified group has "experienced a 'history of purposeful unequal treatment' or been subjected to unique disabilities on the basis of stereotyped characteristics not truly indicative of their abilities"). In addition, the Supreme Court has sometimes considered whether the group is a minority or relatively politically powerless, and whether the characteristic is defining or "immutable" in the sense of being beyond the group member's control or not one the government has a right to insist an individual try to change. *See, e.g.*, *Lyng v. Castillo*, 477 U.S. 635, 638 (1986); *see also Kerrigan v. Comm'r of Pub. Health*, 957 A.2d 407, 425-28 (Conn. 2008) (analyzing federal equal protection law to conclude that history of discrimination and ability to contribute to society are the two central considerations, and collecting authorities). While not all considerations need point toward heightened scrutiny, *Plyler v. Doe*, 457 U.S. 202, 216 n.14, (1982); *Golinski v. Office of Pers. Mgmt.*, 824 F. Supp. 2d 968, 983 (N.D. Cal. 2012), here all demonstrate that laws that discriminate based on transgender status should be subjected to heightened review.

Under any faithful application of that standard, discrimination against transgender people must receive heightened review. In recent decisions, federal courts have recognized that discrimination against transgender people—beyond its connection to discrimination based on

sex—must be evaluated under heightened scrutiny. *See, e.g.*, *Adkins v. City of New York*, __ F. Supp. 3d __, No. 14 Civ. 7519, 2015 WL 7076956, at *3-4 (S.D.N.Y. Nov. 16, 2015); *Norsworthy v. Beard*, 87 F. Supp. 3d 1104, 1119 (N.D. Cal. 2015). In *Adkins*, the court found that all four of the hallmarks of heightened scrutiny were present with respect to the transgender community. It found that "transgender people have [inarguably] suffered a history of persecution and discrimination," 2015 WL 7076956, at *3;[38] that "transgender status bears no relation to ability to contribute to society," *id.*; that "transgender status is a sufficiently discernible characteristic to define a discrete minority class," *id.*; and that "transgender people are a politically powerless minority," noting that "there have [n]ever been any transgender members of the United States Congress or the federal judiciary," *id.*at *4. The court therefore concluded that transgender people constituted a "quasi-suspect class" entitled to intermediate scrutiny. *Id.* at *4.

Another federal court examined the same question in a case challenging a health care policy—like the VA's here—that denied transgender people access to sex reassignment surgery. *Norsworthy*, 87 F. Supp. 3d at 1119. That court noted the recent federal decisions indicating that discrimination based on sexual orientation must be evaluated with heightened scrutiny, holding that such conclusion "applies with at least equal force to discrimination against transgender people, whose identity is equally immutable and irrelevant to their ability to contribute to society, and who have experienced even greater levels of societal discrimination and marginalization." *Id.* at 1119 n.8. As a result, the court held squarely that "discrimination based

[38] *See also* Sears *et al.*, *Documenting Discrimination on the Basis of Sexual Orientation and Gender Identity in State Employment*, Williams Institute (2009), *available at* http://williamsinstitute.law.ucla.edu/research/workplace/documenting-discrimination-on-the-basis-of-sexual-orientation-and-gender-identity-in-state-employment; Grant *et al.*, *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey* (2011), *available at* http://www.thetaskforce.org/downloads/reports/reports/ntds_full.pdf.

on transgender status … qualifies as a suspect classification under the Equal Protection Clause." *Id*. at 1119.

B. The Regulation Cannot Survive Any Level of Review

The Regulation is plainly discriminatory: It denies transgender veterans treatments critical for their health, while providing the same treatments for other veterans. To state the obvious, an exclusion of coverage for surgeries related to "gender alteration," which the VA applies *only* to transgender veterans, targets transgender veterans for differential treatment. 38 C.F.R. § 17.38(c)(4); VHA Directive 2013-003 at 2 (defining the prohibited surgery to apply to transgender, but not intersex, veterans). That is facial discrimination based on sex and transgender status. Because there is no permissible justification for that exclusion, the Regulation is unconstitutional.

Under the heightened scrutiny standard applicable to claims of discrimination based on sex or transgender status, the challenged action must "serve important governmental objectives" and be "substantially related to the achievement of those objectives." *Craig v. Boren*, 429 U.S. 190, 197 (1976); *see also United States v. Virginia*, 518 U.S. 515, 531, 533 (1996) (under intermediate scrutiny, government "must demonstrate an exceedingly persuasive justification for that action," the burden for which "is demanding and … rests entirely on the state") (internal quotation marks and citations omitted).

No such "important" objective can be advanced by denying transgender veterans the same medically necessary treatments that are provided to other veterans. For example, the facts of this case are nearly identical to those in *Norsworthy*. That case challenged the policy of a state prison that sex reassignment surgery could never be provided to transgender people in prison, although the prison did provide the same treatments for non-transgender individuals, and it did provide mental health and hormone treatments to transgender individuals. The state was

unable to identify any "important governmental interest, much less describe how their gender classification—which makes it more difficult for a transgender person to receive vaginoplasty than it is for a cisgender woman—[could be] substantially related to that interest." 87 F. Supp. 3d at 1120. The court therefore concluded that a state policy of "treat[ing a transgender woman] differently from a similarly situated non-transgender woman in need of [the same] medically necessary surgery" would violate her right to equal protection. *Id*.

Even under the most deferential standard of review, however, the policy cannot stand. Governmental action that "neither burdens a fundamental right nor targets a suspect class" will be upheld only "so long as it bears a rational relation to some legitimate end." *Romer v. Evans*, 517 U.S. 620, 631 (1996). That test is not "toothless." *Mathews v. Lucas*, 427 U.S. 495, 510 (1976). In particular, the review must be meaningful when the policy at issue targets a vulnerable group. *See Romer*, 517 U.S. at 634-635 (invalidating law that burdened the "politically unpopular group" of lesbian, gay, and bisexual people); *Lawrence v. Texas*, 539 U.S. 558, 580 (2003) (O'Connor, J., concurring) ("When a law exhibits such a desire to harm a politically unpopular group, we have applied a more searching form of rational basis review to strike down such laws under the Equal Protection Clause."); *Kelo v. City of New London*, 545 U.S. 469, 490-491 (2005) (Kennedy, J., concurring) (distinguishing between the rational basis test applied to "economic regulation" versus classifications discriminating against a particular group of people).

As discussed above, because the VA already provides the same or similar treatments to non-transgender and intersex veterans, there is no conceivable non-discriminatory basis for excluding coverage for transgender veterans alone. The Regulation and its implementing directives do not deny transgender veterans surgical treatments for gender dysphoria because of

concerns about medical necessity, or because it is expensive (which it is not),[39] or because it is impractical or difficult to provide—if any of those were the case, the VA would bar provision of those treatments for *any* veteran, not just transgender veterans. And the reason cannot be that the VA disagrees with the necessity of medical treatments for gender dysphoria generally—because if that were the case, the VA would not provide the many other medical treatments it *does* provide for transgender veterans, such as hormone therapy and pre- and post-operative care.

Accordingly, the only conceivable explanation for the transgender-specific surgery exclusion appears to be the fear of potential political controversy that could result from extending care to this vulnerable minority, which is not a permissible consideration under any standard of review. *See U.S. Dep't of Ag. v. Moreno*, 413 U.S. 528, 534 (1973) (intention to exclude a "politically unpopular group" from receiving benefits "cannot constitute a legitimate governmental interest"); *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 448 (1985) ("mere negative attitudes, or fear, unsubstantiated by factors which are properly cognizable … are not permissible bases" for differential treatment of a vulnerable group).

VIII. CONCLUSION

For the foregoing reasons, Petitioners respectfully request that the Secretary of Veterans Affairs amend or repeal the rules and regulations, including 38 C.F.R. § 17.38(c)(4), that exclude sex reassignment surgery for transgender veterans from the Medical Benefits Package provided to veterans under the Veterans Affairs health system, and promulgate regulations expressly

[39] Because the population of transgender veterans affected by the Regulation is small compared to the overall population, cost concerns have no basis in reality. But regardless, the Fifth Amendment does not safeguard equality only when it is costless. Seeking to justify the Regulation as a budgetary matter would do what the Supreme Court has condemned: attempt to "protect the public fisc by drawing an invidious distinction between classes of its citizens." *Memorial Hosp. v. Maricopa Cnty.*, 415 U.S. 250, 263 (1974); *see also Graham v. Richardson*, 403 U.S. 365, 374-375 (1971).

including sex reassignment surgery for transgender veterans within that Medical Benefits Package.

Dated: May 9, 2016

Respectfully submitted,

By: Alan Schoenfeld /APV

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Attorneys for Petitioners

AFFIDAVIT OF EVAN YOUNG

I, Evan Young, declare as follows:

1. I am the National President and a current board member of the Transgender American Veterans Association ("TAVA"). I am 45 years old and I reside in Dover, Arkansas. I have personal knowledge of the matters stated in this declaration and could and would so testify if called as a witness.

2. I have over fourteen years of active service in the U.S. military. I retired as a Major. I received a Bachelor of Arts from Northwestern State University of Louisiana, where I majored in English, and a Master of Science in Management Information Systems from Nova Southeastern University.

3. During my enlisted service, I was stationed in Illesheim, Germany, Fort Story, Virginia, and Fort Polk, Louisiana. Following my commission, I was selected to serve as a recruiter and held positions at the 369th Adjutant General Battalion as a company executive officer and at the Adjutant General School as a special project officer. I served in the Hawaii Army National Guard as Communications-Electronics Officer for the 29th Support Battalion, Information Officer for the 29th Separate Infantry Brigade, Public Affairs Officer for the State Area Command, and Commander of the 117th Mobile Public Affairs Detachment. After transferring to the United States Army Reserves, I served as Broadcast Officer for the 209th Broadcast Public Affairs Detachment in Rome, Georgia. I was a public affairs officer for NORAD and USNORTHCOM from 2008-2011, as well as the recruiting officer for the University of Michigan Reserve Officers' Training Corps department from 2011-2013.

4. I have received numerous awards and medals including two National Defense Service Medals, the Joint Service Commendation Medal, the Army Commendation Medal, three Army Achievement Medals, and the Alaska Community Service Medal.

5. I have been involved with TAVA since 2013, when I joined as a Board Member at Large. That same year, the board of directors elected me Secretary. In July 2014, I was elected Vice-President, and in December 2014, I was elected President. My duties include building coalitions and developing relationships with organizations and individuals that align with our mission; recruiting, growing, and mentoring our board of directors; influencing policy with the U.S. Department of Veterans Affairs ("VA"); setting public policy goals to assist transgender veterans; and providing support and outreach to transgender veterans on a range of issues, including, but not limited to, health care and identity documents.

6. TAVA is a 501(c)(3) organization that was founded in 2003 to advocate on behalf of transgender veterans within the VA health care system. As the only national organization focused exclusively on advocating and conducting educational outreach on behalf of transgender veterans, TAVA is a leading voice and source of information for the transgender veteran population. Its mission is to work with the VA, Congress, veterans, active-duty military personnel, and LGBT groups to influence the VA and military policy, regulations, and procedures regarding the provision of medical and psychological care to veterans with gender dysphoria to ensure that transgender veterans receive necessary and appropriate care. While TAVA primarily focuses on ensuring the fair and equal treatment of transgender individuals, it is committed to improving the health care of all American veterans.

7. TAVA's advocacy goals include: open transgender military service; continued improvement in the quality and breadth of health care and other services provided to transgender

service members through the VA system and Tricare; access to name and gender changes, particularly for low-income veterans; and transgender veteran employment, among other goals. TAVA also works with individual transgender service members to assist them in securing benefits for themselves and their spouses and family. TAVA works towards these goals through educating the VA and the Department of Defense and through serving as a liaison between transgender veterans and VA staff to raise members' issues with the staff and to connect members to appropriate resources.

8. TAVA has spent considerable time and resources on educating veterans, policymakers and others about the exclusion of medically necessary transition-related surgeries from the VA's medical benefits package, and on advocating the removal of that exclusion and addressing the needs of transgender veterans affected by it. For example, we have produced "know your rights" materials for transgender veterans to educate them about the VA's exclusion of coverage for transition-related surgery,[1] prepared educational reports that include discussion of the harms caused by the surgery exclusion,[2] and sponsored community gatherings to discuss strategies to end this exclusion.[3] In my capacity as TAVA's President, I have spent considerable time speaking with veterans across the country by phone to educate them about the VA's exclusion of transition-related surgeries and how it affects them. Additionally, several of our

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1 *See, e.g.*, http://transveteran.org/for-veterans/know-your-rights/.

2 *See, e.g.*, The American Military Partner Association and the Transgender American Veterans Association, "How the Department of Defense Transgender Ban Harms Our Military Families" (March 30, 2015), *available at* http://militarypartners.org/wp-content/uploads/2015/03/AMPA-Report-on-Transgender-Military-Ban-1.pdf.

3 *See, e.g.*, https://sacvalleyvets.wordpress.com/2011/12/11/aver-tava-sponsors-transgender-service-summit/.

board members have spent time talking with news outlets across the country in an effort to educate the public about the VA's exclusion of transition-related surgeries and to call for reform.

9. TAVA has approximately 2,268 members throughout the country who have joined our efforts through social media, and even though a significant percentage of such members have low incomes, numerous social-media members have contributed time and resources to help the organization achieve its goals. Other members have joined TAVA outside of social media, through contributing financially to our organization in amounts determined by the individual donors; roughly 80 individuals have become members through this method.

10. According to recent estimates, TAVA represents the interests an estimated 129,700 transgender veterans of the U.S. Military, as well as 4,600 retired transgender members of the U.S. Reserves and National Guard. *See* Gary J. Gates and Jody L. Herman, Transgender Military Service in the United States (May 2014), *available at* http://williamsinstitute.law.ucla.edu/wp-content/uploads/Transgender-Military-Service-May-2014.pdf.

11. Many of TAVA's members are transgender veterans currently enrolled in the VA health care system. Some of those individuals have been diagnosed with gender dysphoria by the VA and have been provided some medical care related to their diagnosis. However, some members who have sought sex reassignment surgery through the VA, or coverage of such surgery by the VA, have been denied such surgery or coverage because of the existing regulatory exclusion of "gender alterations" from covered benefits. Many of those veterans rely on the VA for the provision of their physical and mental health care, and many satisfy all the medical prerequisites for sex reassignment surgery: They have been diagnosed with gender dysphoria (often by VA clinicians), they have spent multiple years living in a gender role consistent with

their gender identity and are currently undergoing hormone therapy to assist in their transition, and they have been prescribed sex reassignment surgery by qualified medical providers as medically necessary treatment for their condition. Nevertheless, these veterans have been unable to obtain medically necessary sex reassignment surgery due to the VA's categorical exclusion of this surgery from its medical benefits package.

12. TAVA's purpose in submitting this petition is to advocate on behalf of its members who have been denied medically necessary treatment as a result of the VA's regulations. This petition directly advances TAVA's central organizational goal—to achieve reform of the VA's policies regarding coverage of sex reassignment surgery and other medical procedures related to gender dysphoria. If the VA were to amend its regulations to include coverage of sex reassignment surgery, such an amendment would significantly improve the physical and mental health of TAVA members and of other transgender veterans with gender dysphoria.

13. Many TAVA members have been prescribed, and desire to receive, medically necessary transition-related surgeries, but the VA's exclusion of these surgeries from coverage has prevented them from receiving this care. Many members of TAVA have experienced and continue to experience extreme and sometimes life-threatening hardships because they cannot obtain coverage for these health care services that their doctors deem to be medically necessary.

14. These hardships, and the extreme toll they exact, are not hypothetical. For example, in June 2015, a transgender veteran, who was a retired Sergeant, took her own life. In her suicide note, she referenced her inability to have her medical procedures covered as a reason for her desperation and hopelessness.

***

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

Dated: May 5th, 2016

Evan Young

AFFIDAVIT OF DEE FULCHER

I, Dee Fulcher,[1] declare as follows:

1. I make this declaration based on personal knowledge, and, if called as a witness, I could and would testify competently to the matters stated herein.

2. I am a veteran of the United States Marine Corps. I have four children, ranging in age from nine to 34 years old, and I am a grandmother to twin grandchildren. I am 54years old, and live in Slidell, Louisiana. I am female, and I am also transgender. I am a member of Transgender American Veterans Association ("TAVA").

3. After graduating from high school in 1981, I joined the Marine Corps because I knew that I wanted to serve my country. I served until 1992, with posts in North Carolina and Tennessee. My first post was Radio Operator, from which I was promoted to Maintenance Management, then Radio Chief, and finally, Communications Chief in 1986. I subsequently transferred laterally to Marine Corps Aviation. After attending aviation school, I specialized in hydraulic systems for helicopters and was transferred to New River Air Station in North Carolina, where I worked on helicopters and attained the rank of Platoon Sergeant. During my service, I received a Navy Achievement Medal with a star, two Meritorious Mast awards, a Good Conduct Medal with two stars, a National Defense Service Medal, a Sea Service Deployment Ribbon with a star, and a Rifle Marksman Badge.

4. I was honorably discharged from the Marine Corps for medical reasons in 1992. While stationed at Marine Corps Base Camp Lejeune, North Carolina, I was exposed to drinking water contaminated with industrial solvents, including benzene, and other chemicals. I was later

[1] My legal name is David Lynn Fulcher, Junior, but until I can afford the fees required to change my name legally, I use the preferred name Dee Dee ("Dee") Fulcher.

diagnosed with Behcet's Syndrome, and while I felt deep pride in serving my country and did not want to leave the military, the medication I was prescribed for this condition lowered my immune system functioning to the point where I was non-deployable, leading to my discharge. In my early forties, I was diagnosed with colon cancer, a diagnosis that I fear was also related to my exposure to contaminated water at Camp Lejeune.

5. After my discharge from the Marine Corps, I worked for eight years as a truck driver in Pennsylvania. I moved to Louisiana in 2000, where I worked as a crane mechanic until I was laid off in October 2015. My earnings have always been modest, and I have never made enough to pay for the care I need as a transgender woman. I began my gender transition while working as a crane mechanic, but after being laid off, I have been unable to find work. I am now exploring my options for returning to school.

6. I was first diagnosed with gender dysphoria by a physician outside the Veterans Health Administration ("VHA"), and began hormone replacement therapy in December 2013. In July 2014, I began seeing Danielle Rosenfeld for weekly psychotherapy appointments through the Southeast Louisiana Veterans Health Care System, which is part of the VHA network. Ms. Rosenfeld is a clinical mental health social worker who holds a master's degree in social work and is licensed to practice psychotherapy by the Louisiana State Board of Social Work Examiners. The primary purpose of this therapy has been to address issues relating to my gender identity and transition. During the course of that treatment, Ms. Rosenfeld confirmed my diagnosis of gender dysphoria. She also confirmed in a letter that I have undergone "appropriate clinical treatment for gender transition," and that I should receive sex reassignment surgery. A true and correct copy of Ms. Rosenfeld's letter is attached as Exhibit A.

7. In August 2014, I began seeing Dr. Jamie Buth, a board certified physician in internal medicine, through the Southeast Louisiana Veterans Health Care System. Dr. Buth oversees the hormone therapy that I receive through the VHA. Dr. Buth also has confirmed my gender dysphoria diagnosis, in a letter dated October 28, 2015. As Dr. Buth's letter reflects, she "recommend[s] proceeding to surgical gender reassignment" as the next step in my treatment for gender dysphoria. A true and correct copy of that letter is attached as Exhibit B.

8. If I had access to care, I would pursue sex reassignment surgery, including a penectomy, vaginoplasty, facial feminization, breast augmentation, and electrolysis. I have been informed by my doctor, however, that no transition-related procedures would be covered by the VHA. For that reason—and despite receiving two recommendations for surgical care from medical and mental health professionals within the VHA—I have not formally requested these procedures.

9. It is hard to put into words how profoundly I am affected by the VHA's policy of denying transition-related surgical care to people like me. This denial touches every aspect of my life, from my physical and mental health, to my ability to sustain family relationships. For example, because the VHA will not provide me with an orchiectomy, I continue to have testes, which produce testosterone. By my understanding, that requires me to take additional medication to help block the effects of the testosterone, and to take higher doses of estrogen than otherwise would be required. I worry about the long-term side effects of all the extra medication that I am required to take.

10. Additionally, my inability to receive the transition-related care I need has contributed to serious depression, which makes it difficult to function in my daily life. The VHA currently provides me with anti-depressants to help manage the depression. But I am trapped in

the frustrating position of receiving treatment only for a symptom of my gender dysphoria (*i.e.*, the depression) rather than the underlying cause of that condition (*i.e.*, the need for transition-related surgery). The depression also is exacerbated by my isolation. Forming an intimate relationship with another person is unimaginable to me until my body is aligned with my gender identity, and the loneliness that accompanies this wait contributes to my feelings of suffering. Without access to feminizing surgery, my children also have had trouble fully accepting that I am a woman, rather than a "man in women's clothes," and that lack of full acceptance has been a source of stress and anxiety.

11. Of course, I am glad to be receiving hormone therapy. Every day that I have taken feminizing hormones, I felt like a light was going on. But simultaneously, it is excruciating to be trapped at an incomplete stage of gender transition. The experience is like having a gaping wound treated with a band-aid. I am desperate to be released from what feels like an unending gender-transition purgatory.

12. Because of my unemployment, modest average earnings even when I am working, and financial obligations to my youngest daughter, my only hope for this release is coverage through the VHA.

***

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

Dated: May 5TH, 2016

David L. Fulcher Jr.

Dee Fulcher (David Lynn Fulcher)

EXHIBIT A

DEPARTMENT OF VETERANS AFFAIRS
Southeast Louisiana Veterans Health Care System
1601 Perdido Street
New Orleans LA 70112-1262
504-571-8324

November 9, 2015

To Whom It May Concern:

I, Danielle Rosenfeld, LCSW-BACS, license #5650, Louisiana Board of Social Work Examiners, am the treating mental health provider of David Lynn Fulcher, (aka: Dee Dee Lynn Fulcher), social security number , with whom I have a psychotherapist/patient relationship.

Ms. Fulcher has been under my care since July 2014. I am actively treating her, and I have reviewed her past psychosocial history. Ms. Fulcher is diagnosed as a Male to Female Transsexual, and I have been seeing her for individual psychotherapy weekly for gender identity issues, always with the goal of Sexual Reassignment Surgery (SRS). She has had appropriate clinical treatment for gender transition to the new female gender. Ms. Fulcher has been on hormone therapy for the past two and a half years, and during the past year she has been living full time as her target gender of female. She has come out as a transsexual female to her family and to her co-workers.

I recommend proceeding to surgical gender reassignment, in accordance with patient's wishes. If I can be of any further assistance, please do not hesitate to contact me. Thank you in advance for treating my patient with dignity and respect.

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

Sincerely,

Danielle Rosenfeld, LCSW-BACS

Danielle Rosenfeld, LCSW-BACS
Family Mental Health Social Worker
Southeast Louisiana Veteran's Healthcare System
504-571-8324

EXHIBIT B

DEPARTMENT OF VETERANS AFFAIRS
Southeast Louisiana Veterans Health Care System
P.O. Box 61011
New Orleans LA 70161

October 28, 2015

To Whom It May Concern

Ms. Dee Dee Lynn Fulcher (aka David Lynn Fulcher Jr), social security number , has been a patient of mine since August, 2014. I am actively treating this patient and have reviewed her past medical history. She is diagnosed as a Male to Female Transsexual and has been on cross gender hormones for two and a half years. These cross gender hormones consist of estradiol, spironolactone, and finasteride. These constitute successful hormonal gender change/reassignment to the female gender. I recommend proceeding to surgical gender reassignment, in accordance with patient's wishes.

My full name is Jamie Buth MD
Louisiana License: MD.011979R
Drug Enforcement Administration (DEA): FB3488384

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

Respectfully,

Jamie Buth MD
Associate Chief of Staff for Clinics
Southeast Louisiana Veterans Health Care System
504-558-3637

AFFIDAVIT OF GIULIANO SILVA

I, Giuliano Silva,[1] declare as follows:

1. I make this declaration based on personal knowledge, and, if called as a witness, I could and would testify competently to the matters stated herein.

2. I am a veteran of the United States Army. I am 26 years old, and live in Denver, Colorado. I am male, and I am also transgender. I am a member of the Transgender American Veterans Association ("TAVA").

3. I graduated from high school in 2006. I attended the University of Miami briefly and pursued a bachelor's degree in biology with a minor in world history.

4. I joined the Army in April 2008 and served until September 2012. I completed Boot Camp in Fort Jackson, South Carolina. Thereafter, I was stationed at: Fort Riley, Kansas; Fort Sam Houston, San Antonio, Texas; Fort Sill, Oklahoma; and Fort Bragg, North Carolina. For my first six months, I was assigned to Military Police. Following that, I was reclassified as an Ammunition Specialist and remained in that capacity until I retired.

5. I medically retired from the Army in 2012 due to post-traumatic stress disorder ("PTSD"). The Army initially assigned me a 30% disability rating, but later reevaluated me and assigned me my current 75% disability rating. I also qualify as 100% disabled with the Veterans Health Administration ("VA").

6. Since my medical retirement began, I have been unable to find employment due to my PTSD and anxiety related to my gender dysphoria.

[1] My legal name is Vanessa Silva, but I am in the process of changing my name to Giuliano "Gio" Silva.

7. I have struggled with my gender identity since I was a child, largely because my family is Roman Catholic, and in my experience, being transgender is not acceptable in our particular faith community.

8. When I was young, I told my mom several times that I felt like a boy, and she would slap me across the face. I argued with my mother about my gender identity from a young age, and I struggled to be what she wanted me to be. By the time I was about fifteen years old, I decided I could not dress like a girl anymore. I wanted to kill myself, because I was stuck in a body in which I did not feel comfortable. I asked my mother many times for me to see a doctor, but she refused. Eventually I snapped, left the house, and came out as a lesbian. I figured my community might be more accepting of a cisgender lesbian than of a straight transgender man.

9. In 2014, I hit a breaking point and decided that I needed to come out as transgender. My partner at the time was not supportive of my decision, and she ended our relationship. My coming out as transgender also precipitated a huge fallout within my family. My mother and I no longer speak because of it. I have some family in both Brazil and Italy, including half-siblings through my dad. I do not speak with any of them. No one in my family accepts me because of their religious beliefs. However, I have found some support among my friends and the wider transgender community.

10. In February 2015, I was diagnosed with gender dysphoria at the Miami VA Healthcare System.

11. In June 2015, I moved to Cayuga, Indiana where I sought care at the VA Illiana Health Care System in Danville, Illinois for gender dysphoria and related medical issues. In July 2015, Joyce Brunt, M.D. of the VA Illiana Health Care System recommended a mastectomy for me to treat my severe back pain/problems as a result of having abnormally large breasts for my

build. Dr. Brunt referred me to the Richard L. Roudebush VA Medical Center in Indianapolis, Indiana. On September 22, 2015, I informed my doctor at this facility, Dr. Adam Cohen, that I am transgender. Dr. Cohen then informed me that the VA would not cover the procedure.

12. It makes no sense to refuse to provide veterans with medically necessary care because that care is also used to treat gender dysphoria. But my experience in the VA is that providers can be skeptical of the medical needs of transgender veterans and outwardly hostile to treating them. My providers have refused to call me by male pronouns or by my preferred name even though I am in the VA system as a transgender male. Dr. Cohen accused me of "using [being transgender] to my advantage" in seeking a mastectomy. On several occasions, I have complained to the director of the VA in Miami about what I feel are unnecessary obstacles the VA has place in the way of my receiving medically necessary care, though nothing changed as a result of those complaints. I believe that VA policy treating transgender veterans' medical needs comparably to other medical needs is critical to my health and survival, and that of other transgender veterans.

13. I moved back to Miami in December 2015.

14. I have tried to get a second opinion and to obtain a mastectomy at multiple VA clinics, but I have been unsuccessful.

15. I seek a mastectomy not only to alleviate my back pain, but also to make my body more consistent with my gender identity. Unfortunately, I have been informed by my doctor at the VA in Miami that no transition-related surgical procedures are covered by the VA. If the VA were to offer mastectomy as part of treatment for gender dysphoria, I would seek and obtain this surgery.

16. It is hard to put into words how profoundly I am affected by the VA's policy of denying transition-related surgical care to people like me. This denial touches every aspect of my life, from my physical and mental health, to my ability to sustain family relationships. Because the VA will not provide me with a mastectomy, I continue to have breasts, which make me mentally and emotionally uncomfortable and are physically painful.

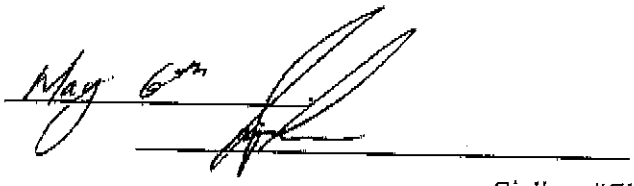
17. On a personal and emotional level, I can't have a romantic relationship because of my body image. It is so hard to be the man I want to be when I have this body. I have difficulty wearing men's clothing—clothing that is consistent with, and critical in expressing, my male gender identity—because I have large breasts. My body affects my social life. There are days when I cannot leave the house due to the physical pain. I have attempted suicide many times because of my inability to access the medical care I need.

18. Because of my unemployment, my only hope for relief from this pain is coverage through the VA. I also believe that I will no longer be as anxious and depressed after my transition and will be able to find employment.

***

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

Dated: May 6th, 2016



Giuliano "Gio" Silva (Vanessa Silva)

EXPERT DECLARATION OF DR. MARCI L. BOWERS

1. I, Marci L. Bowers, MD have been asked to provide my expert medical opinion regarding the efficacy and appropriateness of sex reassignment surgery ("SRS") as a medically necessary treatment for gender dysphoria. I have actual knowledge of the matters stated herein and could and would so testify if called as a witness.

QUALIFICATIONS AND BACKGROUND

2. I am a pelvic and gynecologic surgeon with over 25 years' experience. I was the former Department Chairperson at Swedish Medical Center (Providence) in Seattle, where I practiced as an Obstetrician/Gynecologist for 20 years, delivering more than 2,200 babies. I currently practice general gynecology and surgery and am the first North American gynecologic surgeon trained to functionally reverse female genital cutting.

3. I am board certified by the American Board of Obstetrics & Gynecology.

4. I am licensed to practice medicine in the states of Washington and California.

5. I have completed over 3,000 sex reassignment surgeries and perform approximately 220 other surgeries related to gender transition annually. Around 90% of the surgeries have been for people transitioning from male to female.

6. I received my bachelor's degree in Medical Microbiology (1980) from the University of Wisconsin, Madison, WI, and my medical degree (1986) from the University of Minnesota, Minneapolis, MN. I completed my residency (1986-1990) in Obstetrics/Gynecology at the University of Washington, Seattle, WA.

7. I am a current member of the European Academy of Sciences. I was honored as one of the Best Doctors in America (2002-2004), awarded the Chief Resident Award for Teaching Excellence (1986-1990), and was President of the University of Minnesota Medical Student Council (1985-1986).

8. I frequently speak at medical schools across the United States and with media on the subject of SRS. I have demonstrated SRS surgical techniques for plastic surgeons and urologists in Australia, Belgium, Brazil, China, Israel, Mexico, Serbia and other countries.

9. I have published three chapters in books related to sex reassignment surgery:

- "Complications of Male-to-Female Vaginoplasty" in MANAGEMENT OF GENDER DYSPHORIA: A MULTIDISCIPLINARY APPROACH. Trombetta et al. (Eds.), 2015.
- "Transgender Surgery" in TRANS BODIES, TRANS SELVES: A RESOURCE FOR THE TRANSGENDER COMMUNITY. Erickson-Schroth (Ed.), 2014.
- "Male-to-female Vaginoplasty" in AESTHETIC GYNECOLOGY. Goodman, Alsinrod, et al. (Eds.), 2016.

10. I have not provided deposition or trial testimony as an expert witness in the past four years.

11. I am providing my expert consulting services in this case pro bono.

12. A copy of my curriculum vitae is attached as Exhibit A.

OPINIONS

13. In forming my opinions, I have relied on my scientific education and training, my knowledge of the scientific literature in the pertinent fields, and my extensive clinical experience in treating patients with sex reassignment surgery. Based on my review of the foregoing, and for reasons set forth in more detail below, my opinions are the following:

I. Sex Reassignment Surgery

14. For transgender female patients, sex reassignment surgery commonly includes orchiectomy (removal of the testes) and vaginoplasty, and may also include breast augmentation, tracheal shaving (chondrolaryngoplasty), and facial feminization surgery.

15. Vaginoplasty is often seen as the definitive male-to-female sex reassignment surgery. It involves a variety of procedures including an orchiectomy, removal of the penis, creation of a vaginal cavity, a procedure to line the cavity, the shortening of the urethra, and the construction of the labia and a clitoris. The vagina should have a hairless epithelium (the tissue lining the inside of the vagina) and should have an adequate depth and diameter in order to function properly.

16. The procedure was first developed in 1933, and has evolved in the years since. In the 1950s, Dr. Georges Burou, a gynecologist, pioneered the modern vaginoplasty technique known as "penile inversion." Other leading surgeons performing the procedure included Dr. Stanley Biber, who provided over 4,000 sex reassignment surgeries from 1969 until the mid-2000s, and Drs. Yvan Menard and Pierre Brassard.

17. I worked closely with Drs. Biber and Brassard during 2003-2005. Under their tutelage, I developed a "one-stage procedure" for vaginoplasty with the basic principles of embryology in mind. As everyone has female genitalia early in gestation, the goal of the procedure is to reverse the current anatomy to its earlier configuration and to create a vagina as feminine in function and appearance as possible. The procedure is a version of the original "penile inversion technique," modified to include the use of scrotal skin grafting to line the vagina, and other advances. The two-stage procedure included one stage for function and a second stage designed to improve appearance and define the labia and clitoral hood. Utilizing the mucosa of the urethra, the one-stage procedure utilizes tissue that is sensory and secretory, pink and non-hair bearing to line the inner labia. The procedure is the most compatible with the normal developmental process the patient would have undergone had the patient been born with female genitals.

18. I typically see patients twice after a surgery: first to instruct them on dilation, and then again shortly before they return home. I also see patients at any other time, if needed. Patients usually return home within two weeks of surgery and are shifted to the care of a primary care physician. All patients are given detailed instructions on what to expect and a guide to

possible complications. I encourage patients to see their primary care physician one month following the surgery or sooner if needed. I also urge patients to implement a long-term follow up plan that will include a Pap smear at a frequency similar to that of a natal woman who has had a hysterectomy and a speculum examination once yearly at minimum.

19. For transgender male patients, sex reassignment surgeries may include chest reconstruction (mastectomy and reconstruction), metoidioplasty, phalloplasty, scrotoplasty, hysterectomy, and vaginectomy, among other surgical treatments. Of those, I regularly provide hysterectomies, vaginectomies, metoidioplasties, and scrotoplasties. I have performed over 2000 hysterectomies and over 350 metoidioplasties.

20. A hysterectomy usually includes removal of both ovaries and fallopian tubes (salingo-oophrectomy). The procedure can be performed from below (vaginal) or through the abdomen. The hysterectomy procedures I have performed on transgender men do not differ significantly from the hysterectomy procedures I have performed on women. When I have performed hysterectomy procedures on transgender men, the primary diagnosis is to treat gender dysphoria, rather than a gynecological diagnosis. When I have performed hysterectomy procedures on women, the medical necessity arises from pathology. Although many transgender men do not have a gynecological diagnosis, I have found in my practice that 15-20% will find incidental pathology at the time of the hysterectomy, meaning the post-surgical pathology report indicates pathology that was undetected prior to surgery, such as endometriosis, fibroids, pre-cancerous conditions of the uterus or cervix such as dysplasia or ovarian cysts, tumors, or adhesive disease. The procedure for transgender men does not differ in price from hysterectomies performed on women. In fact, it may be cheaper since there is generally less pathology and therefore, the procedure is generally less complicated and less time-consuming.

21. The simple metoidioplasty ("SM") is a release of the testosterone-enlarged clitoris/phallus from the labia minora. The released hood is sewn along the midline undersurface to fashion a male penis. The penis is bulked by use of the labial subcutaneous tissue and levator musculature. A final length of 3-8 centimeters in length for the penis can be expected although without the ability to urinate through the phallus. The procedure is reasonably free of complications and inexpensive. It is performed as an outpatient procedure and can be combined with scrotoplasty in the same surgery.

22. Vaginectomy is the removal or obliteration of the vaginal walls, which allows full surgical closure of the vagina. It may be provided either alone or in combination with hysterectomy or metoidioplasty. One advantage of vaginal closure is to allow positioning of the testicles to a more masculine scrotal shape.

23. Scrotoplasty is the construction of a testicle implant laden scrotal sac, also known as testicle implants. The procedure can be combined with SM or done as a separate procedure. If done in combination with SM, the original incisions allow the implants to be placed through a single incision hidden in the midline between the testicles.

24. Most of the procedures that constitute SRS also are performed to treat conditions other than gender dysphoria, and most of these procedures are substantially similar when

performed as part of SRS and when performed for other medical reasons. For example, a vaginoplasty performed as part of SRS does not differ substantially from a vaginoplasty performed to address certain intersex conditions. Penectomies, orchiectomies, mastectomies, vaginectomies and hysterectomies performed as part of SRS do not differ substantially when these procedures are performed to address tissue pathology. Likewise, scrotoplasties and breast enlargement procedures performed as part of SRS are similar when performed for reconstructive purposes.

II. Requirements for Genital Sex Reassignment Surgery

25. Before performing SRS, I conduct an extensive consultation to review all of the inclusion criteria and to make certain that patients are aware of each aspect of the procedure. In making this assessment, I adhere to the guidelines established by the internationally recognized standards of care for transgender health care promulgated by the World Professional Association of Transgender Health ("WPATH").

26. For genital SRS, in accordance with the WPATH standards of care, I require that the patient have two referrals from qualified mental health professionals who have independently assessed the patient.

27. Certain medical concerns may delay surgery, such as serious cardiac issues, significant obesity, or a smoking habit. The risk of surgical complications for smokers is much higher, and tissue healing following surgery is much slower. I treat patients who have been diagnosed as HIV-positive or with Hepatitis C unless they are not receiving the appropriate treatment protocol for those co-existing conditions.

28. Psychiatric diagnoses generally do not preclude treatment and, in fact, those conditions generally improve after SRS.

29. The age of the patient by itself is not a determining factor, although the patient must be the legal age of majority in the jurisdiction.

30. Other requirements include that the patient demonstrate an understanding of the surgery, its potential complications and post-surgical complications and the required length of stay in the hospital.

III. Efficacy of Sex Reassignment Surgery

31. The vast majority of studies have shown that sex reassignment surgery is clinically effective. In my professional experience, the success rate of SRS is extremely high. A useful measure of the success rate of SRS is the rate of regret expressed by patients after receiving SRS. It is exceedingly rare for a patient to express regret following the treatment, and when they do it generally relates to issues of societal discrimination and relationship difficulties. Indeed, in my professional experience, patients who have had sex reassignment surgery have less regret than any other surgery of which I am aware.

32. Sex reassignment surgery has a very low rate of complications, and the complications that may result from sex reassignment surgery are mainly minor in nature.

33. My clinic contacts patients one year after their surgery to determine the impact on their life, and an overwhelming majority of patients report less self-loathing and significantly more confidence and well-being. Many patients report a dramatic improvement in mental health following surgery, and patients have been able to become productive members of society, no longer disabled with severe depression and gender dysphoria.

VI. Sex Reassignment Surgery Is Medically Necessary Treatment

34. Although some transgender people are able to treat their gender dysphoria effectively through other treatments, sex reassignment surgery for many is medically necessary to treat the individual's gender dysphoria and establish congruence between the individual's physical features and gender identity.

35. Sex reassignment surgery is not an "experimental" or "cosmetic" procedure. Many thousands of gender corrective surgeries have been performed worldwide for decades, and the treatment is in no way "experimental." Rather, sex reassignment surgery has been shown to be a life-saving procedure and is unequivocally medically necessary.

36. The American Medical Association ("AMA"), the preeminent health care organization in the United States, and the American Psychiatric Association and other health care organizations have issued resolutions supporting coverage of sex reassignment surgery as a medically necessary treatment for gender dysphoria.

37. It is vital that patients with severe gender dysphoria have access to sex-reassignment surgery in a timely manner. Gender dysphoria, if left untreated, can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death. As stated in the AMA resolution, "delays in access to appropriate medical care for gender identity disorder can result in significant psychological distress including debilitating depression, suicidality and death."

38. MediCal is California's version of the federal Medicaid program, which provides health coverage for low-income people and people with disabilities. MediCal covers sex reassignment surgery as a medically necessary treatment. I have a contract with the San Francisco Health Plan and also contract with other county MediCal administrators in California to provide SRS and other transition-related surgeries. We have performed operations on approximately two dozen MediCal contracted patients to date, all with relatively positive outcomes.

***

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

Dated: May 7, 2016

Marci L. Bowers, MD

EXHIBIT A

Marci L. Bowers, MD
345 Lorton Avenue, Suite 101
Burlingame, CA 94010
Phone: 650-570-2270
Fax: 650-570-2283
marcibdoc@gmail.com

EDUCATION

1980
Bachelor of Sciences in Medical Microbiology
University of Wisconsin
Madison, WI

1986
Medical Degree
University of Minnesota, Minneapolis, MN

RESIDENCY

1986 – 1990
Obstetrics/Gynecology Residency
University of Washington
Seattle, WA

BOARD CERTIFICATION

Board Certified, American Board of Obstetrics & Gynecology 1992, 2004-present

LICENSURE

Washington, California

PROFESSIONAL EXPERIENCE

1990 – 2002
The Polyclinic
Obstetrics and Gynecology
1145 Broadway
Seattle, WA 98122-4299

2002 – Present
Seattle Reproductive Healthcare
Obstetrics and Gynecology
1229 Madison Street Suite #840
Seattle, WA 98104

2003 – 2010
Trinidad Reproductive Healthcare
328 Bonaventure Street, Suite #2
Trinidad, CO 81082

2010 – present
Bay Area Reproductive Healthcare and Surgery
345 Lorton Ave Suite #101, Burlingame, CA 94010

HOSPITAL AFFILIATIONS

1990 – 2003
Swedish Hospital Medical Center/Seattle, WA

2003 – 2011
Mount San Rafael Hospital, Trinidad, CO

2010 – present
Mills-Peninsula Medical Center (Sutter Health),
Burlingame, CA

PROFESSIONAL MEMBERSHIPS

Fellow,
American College of Obstetrics & Gynecology

Member,
San Mateo Medical Association

Member,
World Professional Association for Transgender Health

COMMITTEES

1983 – 1984
Representative, Medical School Educational Policy Committee
University of Minnesota, MN

1993 – 1995
Chairperson, Quality Assurance Committee (CQI)
Department of Obstetrics/Gynecology
Swedish Medical Center (Providence), Seattle, WA

1996-1998
Chairperson, Department of OB/GYN
Swedish (Providence) Medical Center

2002 – 2008
Advisory Board
Midwives' Association of Washington State

2007 – 2009
Chief of Surgery
Mt. San Rafael Hospital

2011 – present
National Board of Directors
GLAAD

2011 – present
National Board of Directors
Transgender Law Center (TLC)

HONORS AND AWARDS

1984 – 1985
President
University of Minnesota Medical School
Minneapolis, MN

1985 – 1986
President, Medical Student Council
University of Minnesota
Minneapolis, MN

1986 – 1990
Chief Resident Award for Teaching Excellence
University of Washington, Obstetrics & Gynecology
Seattle, WA

1990 – 1998
Family Practice Teaching Awards
Providence Medical Center, Seattle, WA
Swedish Medical Center, Seattle, WA

2002 – 2004
Best Doctors in America
American Research Council

2003 – present
Member-Elect
European Academy of Sciences

PUBLICATIONS

Management of Gender Dysphoria: A Multidisciplinary Approach; “Complications of Male-to-Female Vaginoplasty”, 2014.

Trans Bodies Trans Selves; “Transgender Surgery”, 2014.

MEDIA APPEARANCES

2004 CSI: Las Vegas 100th episode

2007 The Oprah Winfrey Show

2008 CBS Sunday Morning

2009 CNN

2008-2011 The Tyra Banks Show (5 appearances)

2012 The Doctors Show

2014 BBC

EXPERT DECLARATION OF DR. RANDI C. ETTNER

1. I, Randi C. Ettner, have been retained by counsel for the Transgender American Veterans Association ("TAVA") in connection with its petition to the Secretary of the Department of Veterans Affairs for rulemaking to promulgate regulations governing provision of sex reassignment surgery to transgender veterans. TAVA's counsel have asked me to provide my expert opinion regarding whether there is any basis in medicine or science for the Veterans Health Administration's policy of excluding sex reassignment surgery from the medical benefits package offered to veterans. This exclusion is embodied in regulation 38 C.F.R. § 17.38(c) ("Section 17.38") and in the current implementing directive for that regulation, VHA Directive 2013-003 (Feb. 8, 2013).[1] My conclusion is that this exclusion for sex reassignment surgery has no medical or scientific basis. I base this conclusion on: (i) scientific research on gender dysphoria and its impact on the health and well-being of individuals with that diagnosis; and (ii) information regarding best practices and the generally accepted standards of care for individuals with gender dysphoria, including the efficacy of sex reassignment surgery as a treatment for gender dysphoria. I have actual knowledge of the matters stated herein, except where otherwise stated, and could and would so testify if called as a witness.

I. QUALIFICATIONS

2. I received my doctorate in psychology from Northwestern University in 1979. I have been the chief psychologist at the Chicago Gender Center since 2005, which specializes in the treatment of individuals with gender dysphoria. I have been involved in treating patients

[1] Section 17.38 reads, in relevant part, "In addition to the care specifically excluded from the "medical benefits package" under paragraphs (a) and (b) of this section, the "medical benefits package" does not include the following: … (4) Gender alterations."

with gender dysphoria[2] since 1977, when I was an intern at the Cook County Hospital in Chicago, Illinois.

3. During the course of my career, I have evaluated and/or treated between 2,500 and 3,000 individuals with gender dysphoria and mental health issues related to gender variance.

4. I have published four books related to the treatment of individuals with gender dysphoria, including the medical text entitled *Principles of Transgender Medicine and Surgery*. (Ettner, Monstrey & Eyler, 2007) and the second edition (Ettner, Monstrey & Coleman, 2016). In addition, I have authored numerous articles in peer-reviewed journals regarding the provision of health care to this population. I have served as a member of the University of Chicago Gender Board, and am a member of the editorial boards for the *International Journal of Transgenderism* and *Transgender Health*.

5. I am a member of the Board of Directors of the World Professional Association for Transgender Health (WPATH) (formerly the Harry Benjamin International Gender Dysphoria Association) and an author of the WPATH Standards of Care for the Health of Transsexual, Transgender and Gender-nonconforming People, 7th version, published in 2012. The WPATH-promulgated Standards of Care ("Standards of Care") are the internationally recognized guidelines for the treatment of persons with gender dysphoria and serve to inform medical treatment in the United States and throughout the world.

6. I have lectured throughout North America, Europe and Asia on topics related to gender dysphoria. On numerous occasions, I have given grand rounds presentations on gender dysphoria at medical hospitals.

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[2] The American Psychiatric Association published a revised version of its Diagnostic and Statistical Manual of Mental Disorders in 2013, which replaced the "gender identity disorder" diagnosis with "gender dysphoria." For consistency, I will refer to the condition as "gender dysphoria" throughout my report, even when making reference to the condition prior to 2013.

7. I have been retained as an expert regarding gender dysphoria and the treatment of gender dysphoria in multiple court cases and administrative proceedings. I was deposed as an expert in three cases over the past ten years: *Fields v. Smith*, No. 06-C-112 (E.D. Wis. 2006), *Doe v. Clenchy*, No. CV-09-2011 (Me. Super. Ct. Nov. 20, 2012), and *Kothmann v. Rosario*, 558 F. App'x 907 (11th Cir. 2014).

8. My fees in this case are as follows: $265 USD per hour for consulting; $395 USD per hour for deposition and trial testimony; and $900 USD per day for travel time spent out of the office. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

9. A true and correct copy of my Curriculum Vitae, which provides a complete overview of my education, training, and work experience, and a full list of my publications, is attached hereto as Exhibit A.

II. MATERIALS CONSIDERED

10. I have considered information from various sources in forming my opinions expressed herein, in addition to drawing on my extensive experience and review of the literature related to gender dysphoria over the past three decades. A complete bibliography of the materials referenced in this report is attached hereto as Exhibit B. 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.

III. BACKGROUND INFORMATION ON GENDER DYSPHORIA

11. Scientific and clinical evidence of gender dysphoria and current medical standards of care for the treatment of gender dysphoria make clear that Section 17.38(c) and its 2013 implementing directive lack any basis in medicine or science. The concept of "gender identity"

is well-established in medicine and refers to every person's deeply held understanding of the person's own gender. Gender identity is an innate aspect of personality that is firmly established, generally by the age of four, although individuals vary in the age at which they come to understand and express that identity.

12. Typically, people who are designated female at birth based on the appearance of their genitalia identify as girls or women, and people who are designated male at birth identify as boys or men. For transgender individuals, however, the person's gender identity differs from the sex assigned to that person at birth, and this incongruence gives rise to a sense of being "wrongly embodied."

13. The medical diagnosis for this feeling of incongruence is Gender Dysphoria, formerly known as Gender Identity Disorder. Gender dysphoria is a serious medical condition codified in the International Classification of Diseases, 10th revision (World Health Organization, 2010) and the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, 5th edition (American Psychiatric Association, 2013) ("DSM-5"). The condition is manifested by symptoms such as preoccupation with ridding oneself of primary and secondary sex characteristics. Untreated gender dysphoria can result in significant clinical distress, debilitating depression, and often suicidality. Gender dysphoria is also the psychiatric term used to describe the severe and unremitting emotional pain associated with the condition.

14. The diagnostic criteria for establishing a diagnosis of Gender Dysphoria in adults are set forth in the DSM-V (302.85):

> A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:

1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics.

2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender.

3. A strong desire for the primary and/or secondary sex characteristics of the other gender.

4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).

5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).

6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational or other important areas of functioning.

15. Adults who manifest a severe degree of such dysphoria are commonly referred to as "transsexual individuals" or "transgender individuals." Without treatment, individuals with gender dysphoria experience anxiety, depression, suicidality and other attendant mental health issues. (*See, e.g.*, Fraser, 2009; Schaefer & Wheeler, 2004; Ettner, 1999; Brown, 2000, DSM-5 (2013).) Many such individuals carry a burden of shame and low self-esteem, attributable to a feeling of being inherently "defective," and as a result become socially isolated. This isolation in turn leads to the stigmatization of such individuals, which over time proves ravaging to healthy personality development and interpersonal relationships. As a result, without treatment, many such individuals are unable to function effectively in occupational, social, or other important

areas of daily living. A recent survey shows a 41% rate of suicide attempts among transgender people, far above the baseline rates for North America. (Haas *et al*., 2014.)

16. Transsexuals without access to appropriate care are often desperate for relief, and in some instances resort to self-surgery, such as life-threatening attempts at auto-castration (*i.e.*, the removal of one's testicles). (Brown, 2010; Brown & McDuffie, 2009.)

17. Gender dysphoria intensifies with age. Middle-aged and elderly gender dysphoric adults experience an exacerbation of symptoms. (Ettner, 2013; Ettner & Wiley, 2013.)

IV. TREATMENT OF GENDER DYSPHORIA

A. WPATH Standards of Care

18. The World Professional Association for Transgender Health ("WPATH") has established internationally accepted Standards of Care for treating gender dysphoria. The WPATH Standards of Care are recognized as authoritative by the American Medical Association, the Endocrine Society, and the American Psychological Association. (*See* Br. of Amici Curiae Medical and Mental Health Professionals at 6, Nos. 10-2339 and 10-2446 (7th Cir. Nov. 29, 2010), *available at* www.lambdalegal.org/sites/default/files/fields_v__smith_-_brief_of_amici_curiae_medical_and_mental_health_professionals.pdf; American Psychological Association Policy Statement on Transgender, Gender Identity, and Gender Expression Non-discrimination (2009).)[3]

19. The Standards of Care identify the following treatment protocols for treating individuals with gender dysphoria:

[3] *See also* Wylie C. Hembree, *Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline*, J. of Clinical Endocrinology & Metabolism, 94:9, 3132-3154 (2009), *available at* http://press.endocrine.org/doi/full/10.1210/jc.2009-0345#sthash.ffOiZnIN.dpuf.

- Changes in gender expression and role (which may involve living part-time or full-time in another gender role, consistent with one's gender identity);
- Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support; improving body image; or promoting resilience;
- Hormone therapy to feminize or masculinize the body; and
- Surgery to change primary and/or secondary sex characteristics (*e.g.*, breasts/chest, external and/or internal genitalia, facial features, body contouring).

20. Once a diagnosis of gender dysphoria is made, a treatment plan should be developed based on an individualized assessment of the medical needs of the particular patient. Treatment short of sex reassignment surgery, such as psychotherapy or counseling, and hormone therapy, can provide support and help with many of the issues that arise in tandem with gender dysphoria. Counseling and hormone therapy alone are not substitutes for surgical intervention where surgical intervention is needed. By analogy, for breast cancer, counseling might provide psychoeducation about treatment and prognosis, and information about nutrition, but it does not obviate the need for medically necessary surgical treatment.

B. Sex Reassignment Surgery

21. For many individuals with severe gender dysphoria, relief from their dysphoria cannot be achieved without surgical intervention to modify primary and/or secondary sex characteristics.

22. Genital reconstructive surgery, for example, has two therapeutic purposes. *First*, removal of the gonads (*i.e.*, testes or ovaries, which are hormone-producing organs) eliminates

the major source of hormone production in the body. *Second*, the patient attains body congruence by gaining normal appearing and functioning uro-genital structures that conform to the patient's gender. Achieving both purposes is critical to alleviating or eliminating gender dysphoria in many patients.

23. Contrary to some outdated speculation, sex reassignment surgery is neither experimental nor cosmetic—no major medical association considers sex reassignment surgery to be either. Decades of careful and methodologically sound scientific research have demonstrated that sex reassignment surgery is a safe and effective treatment for severe gender dysphoria, and indeed, for many people, it is the only effective treatment. (*See, e.g.*, Pfafflin & Junge, 1998; Smith *et al.*, 2005; Jarolim *et al.*, 2009.)

24. WPATH, the American Medical Association, the Endocrine Society, the American Psychiatric Association, and the American Psychological Association all support surgery in accordance with the WPATH Standards of Care as medically necessary treatment for individuals with severe gender dysphoria. *See* American Medical Association (2008), Resolution 122 (A-08) ("public and private health insurance coverage for treatment of gender identity disorder as recommended by the patient's physician"); Endocrine Society (Hembree, W. *et al*., 2009), Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline ("For many transsexual adults, genital sex reassignment surgery may be the necessary step towards achieving their ultimate goal of living successfully in their desired gender role."); American Psychiatric Association (2012), Position Statement on Access to Care for Transgender and Gender Variant Individuals (the American Psychiatric Association "[r]ecognizes that appropriately evaluated transgender and gender variant individuals can benefit greatly from medical and surgical gender transition treatments"); American Psychological

Association (2009), Policy Statement on Transgender, Gender Identity and Gender Expression Nondiscrimination (recognizing "the efficacy, benefit and medical necessity of gender transition treatments" and referencing studies demonstrating the effectiveness of sex-reassignment surgeries).

25. Surgeries are considered "effective" from a medical perspective if they "have a therapeutic effect." (Monstrey *et al*., 2007.)

26. More than three decades of research confirms that sex reassignment surgery is therapeutic and therefore an effective treatment for gender dysphoria. In a 1998 meta-analysis, Pfafflin and Junge reviewed data from 80 studies, spanning 30 years, from 12 countries. They concluded that "reassignment procedures were effective in relieving gender dysphoria. There were few negative consequences and all aspects of the reassignment process contributed to overwhelmingly positive outcomes." *Id*.

27. Numerous subsequent studies confirm this conclusion. Researchers reporting on a large-scale prospective study of 325 individuals in the Netherlands concluded that after surgery there was "a virtual absence of gender dysphoria" in the cohort and "results substantiate previous conclusions that sex reassignment is effective." (Smith *et al.*, 2005.) Indeed, the authors of the study concluded that the surgery "appeared therapeutic and beneficial" across a wide spectrum of factors, and "[t]he main symptom for which the patients had requested treatment, gender dysphoria, had decreased to such a degree that it had disappeared." (*Id*.)

28. In 2007, Gijs and Brewayes analyzed 18 studies published between 1990 and 2007, encompassing 807 patients. The researchers concluded: "Summarizing the results from the 18 outcome studies of the last two decades, the conclusion that [sex reassignment surgery] is the most appropriate treatment to alleviate the suffering of extremely gender dysphoric

individuals still stands: Ninety-six percent of the persons who underwent [surgery] were satisfied and regret was rare." (*Id*.)

29. Studies conducted in countries throughout the world conclude that surgery is an extremely effective treatment for gender dysphoria. For example, a 2001 study published in Sweden states: "The vast majority of studies addressing outcome have provided convincing evidence for the benefit of sex reassignment surgery in carefully selected cases." (Landen, 2001.) Similarly, urologists at the University Hospital in Prague, Czech Republic, in a Journal of Sexual Medicine article concluded, "Surgical conversion of the genitalia is a safe and important phase of the treatment of male-to-female transsexuals." (Jarolim, 2009.)

30. Patient satisfaction is an important measure of effective treatment. Achieving functional and normal physical appearance consistent with gender identity alleviates the suffering of gender dysphoria and enables the patient to function in everyday life. Studies have shown that by alleviating the suffering and dysfunction caused by severe gender dysphoria, sex reassignment surgery improves virtually every facet of a patient's life. This includes satisfaction with interpersonal relationships and improved social functioning (Rehman *et al.*, 1999; Johansson *et al*., 2010; Hepp *et al.*, 2002; Ainsworth & Spiegel, 2010; Smith *et al.*, 2005); improvement in self-image and satisfaction with body and physical appearance (Lawrence, 2003; Smith *et al.*, 2005; Weyers *et al.*, 2009); and greater acceptance and integration into the family (Lobato *et al.*, 2006).

31. Studies have also shown that surgery improves patients' abilities to initiate and maintain intimate relationships (Lobato *et al.*, 2006; Lawrence, 2005; Lawrence, 2006; Imbimbo *et al.*, 2009; Klein & Gorzalka, 2009; Jarolim *et al.*, 2009; Smith *et al.*, 2005; Rehman *et al.*, 1999; DeCuypere *et al.*, 2005).

32. Multiple long-term studies have confirmed these results. *See, e.g.*, "Transsexualism in Serbia: A Twenty-Year Follow-up Study" (Vujovic *et al.*, 2009); "Long-term Assessment of the Physical, Mental, and Sexual Health Among Transsexual Women" (Weyers, 2009); "Treatment Follow-up of Transsexual Patients" (Hepp *et al.*, 2002); "A Five-year Follow-up Study of Swedish Adults with Gender Identity Disorder" (Johansson *et al.*, 2010); "A Report from a Single Institute's 14-Year Experience in Treatment of Male-to-Female Transsexuals" (Imbimbo *et al.*, 2009); 'Followup of Sex Reassignment Surgery in Transsexuals: A Brazilian Cohort" (Lobato *et al.*, 2006).

33. Recognizing this consensus in the literature, in 2008, WPATH issued a "Medical Necessity Statement" stating: "These medical procedures and treatment protocols are not experimental: decades of both clinical and medical research show they are essential to achieving well-being for the transsexual patient." (World Professional Association for Transgender Health, 2008).

34. On May 30, 2014, the Appellate Division of the Departmental Appeals Board of the United States Department of Health and Human Services issued decision number 2576, in which the Board determined that a Medicare regulation denying coverage of "all transsexual surgery as a treatment for transsexualism" was not valid under the "reasonableness standard." (U.S. Dept. of Health and Human Services, 2014). The Board specifically concluded that "transsexual surgery is an effective treatment option for transsexualism in appropriate cases." *Id*.

35. Because of the overwhelming scientific evidence that transition-related care, including sex reassignment surgery, is medically necessary for the treatment of gender dysphoria in some patients, many of the leading medical and professional organizations have stated their opposition to exclusions of insurance coverage for that care, including the American Medical

Association, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, the American Psychiatric Association, and WPATH.[4]

36. Moreover, I understand that the Department of Veterans Affairs provides non-surgical medical care in connection with gender transition, including hormone therapy, and pre- and post-surgical care. In light of that, the surgical exclusion is particularly arbitrary. As described above, hormone therapy and other forms of non-surgical treatments are not substitutes for surgical intervention where such intervention is needed. I am aware of no support in the medical or scientific literature for policies that provide access to non-surgical care, while simultaneously maintaining a blanket exclusion of surgical care regardless of an individual's medical needs.

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[4] *See* (a) The American Medical Association, Resolution 122 (2008), attached as Exhibit C at 489 ("RESOLVED, That our American Medical Association support public and private health insurance coverage for treatment of gender identity disorder as recommended by the patient's physician."); (b) The American Academy of Family Physicians ("AAFP"), Summary of Actions: 2012 National Conference of Special Constituencies, Action on Resolution No. 1004, attached hereto in excerpted form as Exhibit D ("RESOLVED, [AAFP] supports efforts to require insurers to provide coverage for comprehensive care of transgendered individuals including … when medically necessary, gender reassignment surgery."); (c) The American College of Obstetricians and Gynecologists, Committee Opinion of the Committee on Healthcare for Underserved Women, No. 512 (Dec. 2011), attached hereto as Exhibit E at 1 ("The American College of Obstetricians and Gynecologists opposes discrimination on the basis of gender identity and urges public and private health insurance plans to cover the treatment of gender identity disorder."); (d) The American Psychiatric Association, "Position Statement on Access to Care for Transgender and Gender Variant Individuals" (2012), attached hereto as Exhibit F (stating that the American Psychiatric Association "[a]dvocates for removal of barriers to care and supports both public and private health insurance coverage for gender transition treatment" and "[o]pposes categorical exclusions of coverage for such medically necessary treatment when prescribed by a physician"); (e) The American Psychological Association, "Transgender, Gender Identity & Gender Expression Non-Discrimination" Policy Statement (Aug. 2008), attached hereto as Exhibit G at 26 ("BE IT FURTHER RESOLVED that APA recognizes the efficacy, benefit, and necessity of gender transition treatments for appropriately evaluated individuals and calls upon public and private insurers to cover these medically necessary treatments"); and (f) WPATH SOC, attached hereto as Exhibit H at 186 ("WPATH urges health insurance companies and other third-party payers to cover the medically necessary treatments to alleviate gender dysphoria").

V. CONCLUSION

37. Given the extensive scientific research, spanning decades, that supports the efficacy and necessity of sex reassignment surgery, it is clear that sex reassignment surgery is neither experimental nor cosmetic, but rather is a medically necessary treatment for gender dysphoria in patients prescribed this treatment. Accordingly, I am aware of no medical or scientific basis for the Department of Veterans Affairs' policy of excluding sex reassignment surgery from the medical benefits package offered to veterans. The exclusion embodied in Section 17.38 and its 2013 implementing directive has no basis in the scientific literature and is contrary to the medical consensus recognizing the efficacy and necessity of access to sex reassignment surgery.

***

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

Dated: 5.5.16, 2016

Randi C. Ettner, Ph.D.

Randi C. Ettner, Ph.D.

EXHIBIT A

RANDI ETTNER, PHD

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POSITIONS HELD

Clinical Psychologist
Forensic Psychologist
Fellow and Diplomate in Clinical Evaluation, American Board of Psychological Specialties
Fellow and Diplomate in Trauma/PTSD
President, New Health Foundation Worldwide
Board of Directors, World Professional Association of Transgender Health (WPATH)
Chair, Committee for Incarcerated Persons, WPATH
University of Minnesota Medical Foundation: Leadership Council
Psychologist, Chicago Gender Center
Adjunct Faculty, Prescott College
Editorial Board, *International Journal of Transgenderism*
Editorial Board, *Transgender Health*
Television and radio guest (more than 100 national and international appearances)
Internationally syndicated columnist
Private practitioner
Medical staff privileges attending psychologist; Advocate Lutheran General Hospital

EDUCATION

PhD, 1979	Northwestern University (with honors) Evanston, Illinois
MA, 1976	Roosevelt University (with honors) Chicago, Illinois Major: Clinical Psychology
BA, 1969-72	Indiana University (cum laude) Bloomington, Indiana Major: psychology, Minor: sociology
1972	Moray College of Education Edinburgh, Scotland

International Education Program

1970 Harvard University
Cambridge, Massachusetts
Social relation undergraduate summer program in group dynamics and processes

CLINICAL AND PROFESSIONAL EXPERIENCE

2016 Psychologist: Chicago Gender Center
Consultant: Walgreens; Tawani Enterprises
Private practitioner

2011 Instructor, Prescott College: Gender - A multidimensional approach

2000 Instructor, Illinois Professional School of Psychology

1995-present Supervision of clinicians in counseling gender non-conforming clients

1993 Post-doctoral continuing education with Dr. James Butcher in MMPI-2 interpretation University of Minnesota

1992 Continuing advanced tutorial with Dr. Leah Schaefer in psychotherapy

1983-1984 Staff psychologist, Women's Health Center, St. Francis Hospital, Evanston, Illinois

1981-1984 Instructor, Roosevelt University, Department of Psychology: Psychology of Women, Tests and Measurements, Clinical Psychology, Personal Growth, Personality Theories, Abnormal Psychology

1976-1978 Research Associate, Cook County Hospital, Chicago, Illinois Department of Psychiatry

1975-1977 Clinical Internship, Cook County Hospital, Chicago, Illinois, Department of Psychiatry

1971 Research Associate, Department of Psychology, Indiana University

1970-1972 Teaching Assistant in Experimental and Introductory Psychology Department of Psychology, Indiana University

1969-1971 Experimental Psychology Laboratory Assistant, Department of

LECTURES AND HOSPITAL GRAND ROUNDS PRESENTATIONS

Foundations in mental health; role of the mental health professional in legal and policy issues, WPATH global education initiative, Chicago, 2015; Atlanta, 2016; *The transitioning client*, Springfield, MO, 2016

Pre-operative evaluation in gender-affirming surgery-American Society of Plastic Surgeons, 2015

Gender affirming psychotherapy; Assessment and referrals for surgery- Standards of Care- Fenway Health Clinic, Boston, 2015

Gender reassignment surgery- Midwestern Association of Plastic Surgeons, 2015

Adult development and quality of life in transgender healthcare- Eunice Kennedy Shriver National Institute of Child Health and Human Development, 2015

Healthcare for transgender inmates- American Academy of Psychiatry and the Law, 2014

Supporting transgender students: best school practices for success- American Civil Liberties Union of Illinois and Illinois Safe School Alliance, 2014

Addressing the needs of transgender students on campus- Prescott College, 2014

The role of the behavioral psychologist in transgender healthcare – Gay and Lesbian Medical Association, 2013

Understanding transgender- Nielsen Corporation, Chicago, Illinois, 2013;

Role of the forensic psychologist in transgender care; *Care of the aging transgender patient*- University of California San Francisco, Center for Excellence, 2013

Evidence-based care of transgendered patients- North Shore University Health Systems, University of Chicago, Illinois, 2011; Roosevelt-St. Vincent Hospital, New York; Columbia Presbyterian Hospital, Columbia University, New York, 2011

Children of Transsexuals-International Association of Sex Researchers, Ottawa, Canada, 2005; Chicago School of Professional Psychology, 2005

Gender and the Law- DePaul University College of Law, Chicago, Illinois, 2003; American Bar Association annual meeting, New York, 2000

Gender Identity and Clinical Issues –WPATH Symposium, Bangkok, Thailand, 2014; Argosy College, Chicago, Illinois, 2010; Cultural Impact Conference, Chicago, Illinois, 2005; Weiss Hospital, Department of Surgery, Chicago, Illinois, 2005; Resurrection Hospital Ethics Committee, Evanston, Illinois, 2005; Wisconsin Public Schools, Sheboygan, Wisconsin, 2004, 2006, 2009; Rush North Shore Hospital, Skokie, Illinois, 2004; Nine Circles Community Health Centre, University of Winnipeg, Winnipeg, Canada, 2003; James H. Quillen VA Medical Center, East Tennessee State University, Johnson City, Tennessee, 2002; Sixth European Federation of Sexology, Cyprus, 2002; Fifteenth World Congress of Sexology, Paris, France, 2001; Illinois School of Professional Psychology, Chicago, Illinois 2001; Lesbian Community Cancer Project, Chicago, Illinois 2000; Emory University Student Residence Hall, Atlanta, Georgia, 1999; Parents, Families and Friends of Lesbians and Gays National Convention, Chicago, Illinois, 1998; In the Family Psychotherapy Network National Convention, San Francisco, California, 1998; Evanston City Council, Evanston, Illinois 1997; Howard Brown Community Center, Chicago, Illinois, 1995; YWCA Women's Shelter, Evanston, Illinois, 1995; Center for Addictive Problems, Chicago, 1994

Psychosocial Assessment of Risk and Intervention Strategies in Prenatal Patients- St. Francis Hospital, Center for Women's Health, Evanston, Illinois, 1984; Purdue University School of Nursing, West Layette, Indiana, 1980

Psychonueroimmunology and Cancer Treatment- St. Francis Hospital, Evanston, Illinois, 1984

Psychosexual Factors in Women's Health- St. Francis Hospital, Center for Women's Health, Evanston, Illinois, 1984

Sexual Dysfunction in Medical Practice- St. Francis Hospital, Dept. of OB/GYN, Evanston, Illinois, 1980

Sleep Apnea - St. Francis Hospital, Evanston, Illinois, 1996; Lincolnwood Public Library, Lincolnwood, Illinois, 1996

The Role of Denial in Dialysis Patients - Cook County Hospital, Department of Psychiatry, Chicago, Illinois, 1977

PUBLICATIONS

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"Social and Psychological Issues of Aging in Transsexuals," proceedings, Harry Benjamin International Gender Dysphoria Association, Bologna, Italy, 2005.

"The Role of Psychological Tests in Forensic Settings," *Chicago Daily Law Bulletin,* 1997.

Confessions of a Gender Defender: A Psychologist's Reflections on Life amongst the Transgendered. Chicago Spectrum Press. 1996.

"Post-traumatic Stress Disorder," *Chicago Daily Law Bulletin*, 1995.

"Compensation for Mental Injury," *Chicago Daily Law Bulletin*, 1994.

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"Transsexualism- The Phenotypic Variable," Proceedings of the XV Harry Benjamin International Gender Dysphoria Association Symposium; Vancouver, Canada, 1997.

"The Work of Worrying: Emotional Preparation for Labor," Pregnancy as Healing. A Holistic Philosophy for Prenatal Care, Peterson, G. and Mehl, L. Vol. II. Chapter 13, Mindbody Press, 1985.

PROFESSIONAL AFFILIATIONS

University of Minnesota Medical School –Leadership Council
American College of Forensic Psychologists
World Professional Association for Transgender Health
World Health Organization (WHO) Global Access Practice Network
TransNet national network for transgender research
American Psychological Association
American College of Forensic Examiners
Society for the Scientific Study of Sexuality
Screenwriters and Actors Guild
Phi Beta Kappa

AWARDS AND HONORS

The Randi and Fred Ettner Transgender Health Fellowship-Program in Human Sexuality, University of Minnesota, 2016

Phi Beta Kappa, 1971
Indiana University Women's Honor Society, 1969-1972
Indiana University Honors Program, 9-1972
Merit Scholarship Recipient, 1970-1972
Indiana University Department of Psychology Outstanding Undergraduate Award Recipient, 1970-1972
Representative, Student Governing Commission, Indiana University, 1970

LICENSE

Clinical Psychologist, State of Illinois, 1980

EXHIBIT B

Bibliography of Sources Cited

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Smith, Y.L.S., Van Goozen, S. H. M., Kuiper, A.J., & Cohen-Kettenis, P.T. (2005). Sex reassignment: Outcomes and predictors of treatment for adolescent and adult transsexuals. *Psychological Medicine*, 35(1):89-99.

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Weyers, S., et al. (2009). Long-term assessments of the physical, mental and sexual health among transsexual women. *Journal of Sexual Medicine*, 6(3):752-60.

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World Professional Association for Transgender Health (2008). WPATH Clairification on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A. Retrieved from http://www.wpath.org/uploaded_files/140/files/Med%20Nec%20on%202008%20Letterhead.pdf

World Professional Association for Transgender Health (2012). *Standards of Care for the Health of Transsexual, Transgender and Gender-nonconforming People* (7th version). Retrieved from http://www.wpath.org/uploaded_files/140/files/IJT%20SOC,%20V7.pdf.

EXHIBIT C

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 122
(A-08)

Introduced by:	Resident and Fellow Section, Massachusettes Medical Society, California Medical Association, Medical Society of the State of New York
Subject:	Removing Financial Barriers to Care for Transgender Patients
Referred to:	Reference Committee A

Whereas, The American Medical Association opposes discrimination on the basis of gender identity[1] and

Whereas, Gender Identity Disorder (GID) is a serious medical condition recognized as such in both the Diagnostic and Statistical Manual of Mental Disorders (4th Ed., Text Revision) (DSM-IV-TR) and the International Classification of Diseases (10th Revision),[2] and is characterized in the DSM-IV-TR as a persistent discomfort with one's assigned sex and with one's primary and secondary sex characteristics, which causes intense emotional pain and suffering;[3] and

Whereas, GID, if left untreated, can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death;[4] and

Whereas, The World Professional Association For Transgender Health, Inc. ("WPATH") is the leading international, interdisciplinary professional organization devoted to the understanding and treatment of gender identity disorders,[5] and has established internationally accepted Standards of Care [6] for providing medical treatment for people with GID, including mental health care, hormone therapy and sex reassignment surgery, which are designed to promote the health and welfare of persons with GID and are recognized within the medical community to be the standard of care for treating people with GID; and

Whereas, An established body of medical research demonstrates the effectiveness and medical necessity of mental health care, hormone therapy and sex reassignment surgery as forms of therapeutic treatment for many people diagnosed with GID; [7] and

Whereas, Health experts in GID, including WPATH, have rejected the myth that such treatments are "cosmetic" or "experimental" and have recognized that these treatments can provide safe and effective treatment for a serious health condition;[7] and

Whereas, Physicians treating persons with GID must be able to provide the correct treatment necessary for a patient in order to achieve genuine and lasting comfort with his or her gender, based on the person's individual needs and medical history;[8] and

Whereas, The AMA opposes limitations placed on patient care by third-party payers when such care is based upon sound scientific evidence and sound medical opinion;[9, 10] and

Whereas, Many health insurance plans categorically exclude coverage of mental health, medical, and surgical treatments for GID, even though many of these same treatments, such as psychotherapy, hormone therapy, breast augmentation and removal, hysterectomy, oophorectomy, orchiectomy, and salpingectomy, are often covered for other medical conditions; and

Whereas, The denial of these otherwise covered benefits for patients suffering from GID represents discrimination based solely on a patient's gender identity; and

Whereas, Delaying treatment for GID can cause and/or aggravate additional serious and expensive health problems, such as stress-related physical illnesses, depression, and substance abuse problems, which further endanger patients' health and strain the health care system; therefore be it

RESOLVED, That the AMA support public and private health insurance coverage for treatment of gender identity disorder (Directive to Take Action); and be it further

RESOLVED, That the AMA oppose categorical exclusions of coverage for treatment of gender identity disorder when prescribed by a physician (Directive to Take Action).

Fiscal Note: No significant fiscal impact.

References

1. AMA Policy H-65.983, H-65.992, and H-180.980
2. Diagnostic and Statistical Manual of Mental Disorders (4th ed.. Text revision) (2000) ("DSM-IV-TR"), 576-82, American Psychiatric Association; International Classification of Diseases (10th Revision) ("ICD-10"), F64, World Health Organization. The ICD further defines transsexualism as "[a] desire to live and be accepted as a member of the opposite sex, usually accompanied by a sense of discomfort with, or inappropriateness of, one's anatomic sex, and a wish to have surgery and hormonal treatment to make one's body as congruent as possible with one's preferred sex." ICD-10, F64.0.
3. DSM-IV-TR, 575-79
4. Id. at 578-79.
5. World Professional Association for Transgender Health: http://www.wpath.org. Formerly known as The Harry Benjamin International Gender Dysphoria Association.
6. The Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders, Sixth Version (February, 2001). Available at http://wpath.org/Documents2/socv6.pdf.
7. Brown G R: A review of clinical approaches to gender dysphoria. J Clin Psychiatry. 51(2):57-64, 1990. Newfield E, Hart S, Dibble S, Kohler L. Female-to-male transgender quality of life. Qual Life Res. 15(9):1447-57, 2006. Best L, and Stein K. (1998) "Surgical gender reassignment for male to female transsexual people." Wessex Institute DEC report 88; Blanchard R, et al. "Gender dysphoria, gender reorientation, and the clinical management of transsexualism."J Consulting and Clinical Psychology. 53(3):295-304. 1985; Cole C, et al. "Treatment of gender

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8. The Harry Benjamin International Gender Dysphoria Association’s Standards of Care for Gender Identity Disorders, at 18.
9. Id.
10. AMA Policy H-120.988

Relevant AMA policy

H-65.983 Nondiscrimination Policy

The AMA opposes the use of the practice of medicine to suppress political dissent wherever it may occur. (Res. 127, A-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CEJA Rep. 2, A-05)

H-65.992 Continued Support of Human Rights and Freedom

Our AMA continues (1) to support the dignity of the individual, human rights and the sanctity of human life, and (2) to oppose any discrimination based on an individual's sex, sexual orientation, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies. (Sub. Res. 107, A-85; Modified by CLRPD Rep. 2, I-95; Reaffirmation A-00; Reaffirmation A-05)

H-180.980 Sexual Orientation as Health Insurance Criteria

The AMA opposes the denial of health insurance on the basis of sexual orientation. (Res. 178, A-88; Reaffirmed: Sub. Res. 101, I-97)

H-120.988 Patient Access to Treatments Prescribed by Their Physicians

The AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an unlabeled indication when such use is based upon

sound scientific evidence and sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as reasonable and necessary medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate "off-label" uses of drugs on their formulary. (Res. 30, A-88; Reaffirmed: BOT Rep. 53, A-94; Reaffirmed and Modified by CSA Rep. 3, A-97; Reaffirmed and Modified by Res. 528, A-99; Reaffirmed: CMS Rep. 8, A-02; Reaffirmed: CMS Rep. 6, A-03; Modified: Res. 517, A-04)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 314
(A-08)

Introduced by: Resident and Fellow Section

Subject: Physician Scientist Benefit Equity

Referred to: Reference Committee C

Whereas, The importance of physician-scientists to modern medicine is well known as "Virtually everything now used in clinical medicine can trace its roots to investigations performed in a clinical or basic science department…;"[1] and

Whereas, The number of physician-scientists has been steadily declining and "There are nearly 25% fewer physician-scientists on medical school faculties today than two decades ago;"[2] and

Whereas, The reasons for the decline in the number of physician-scientists are numerous, they are known to include "the heavy accumulation of debt through many years of research training…" and "questions about earning a living from academic life:"[2] and

Whereas, A significant loss of benefits can occur when house staff work as physician-scientists and receive salary support from research training grants, such as provided by the National Institutes of Health (NIH) and other programs, including loss of health insurance, medical liability insurance, life insurance, disability insurance, and retirement benefits; and

Whereas, This loss of benefits can present a disincentive to resident physicians pursuing a research career and furthering medical knowledge to improve patient care; and

Whereas, This loss of benefits produces inequities between resident physicians serving in research versus clinical roles within the same institution; therefore be it

RESOLVED, That our AMA support the concept that all resident and fellow physicians who function in a role as physician scientists are provided with benefits packages comparable to those provided to their peers in clinical residencies or fellowships, to include disability insurance, life insurance, HIV indemnity, malpractice insurance including tail coverage, retirement benefits, health, sick leave and wages commensurate with their education and experience, and if a given benefit or salary is provided to some residents within a given program at the same postgraduate level, then that benefit must be provided to all residents.

Fiscal Note: No significant fiscal impact

References

1. Neilson EG, Ausiello D, and Demer LL. J. Invest. Med. 1995, 43(6), 534-542
2. Neilson EG. J. Clin. Invest. 2003, 111(6),765-7.

Relevant AMA-RFS Policy

310.799R Benefit Packages for Resident Physicians
Resolved 1) that the AMA-RFS seek to assure that all institutions be required to provide their resident physicians with disability insurance, life insurance, HIV indemnity, malpractice insurance including tail coverage, retirement benefits, health, sick leave and wages commensurate with their education and experience; and 2) if a given benefit or salary is provided to some residents within a given program at the same postgraduate level, then that benefit must be provided to all residents. However, this provision cannot be used to eliminate the benefit in question. (RFS Substitute Resolution 13, I-92: Reaffirmed: RFS Report C, I-02)

310.992R Minimum Resident Benefits
Asked that the AMA-RFS continue to monitor the revision of the "General Requirements" of the Essentials of Accredited Residencies in Graduate Medical Education for significant changes in benefits language, and act on them as appropriate within current AMA-RFS actions and AMA policies. (RFS Report I, I-89; Reaffirmed, RFS Report C, I-99)

Relevant AMA Policy

H-460.971 Support for Training of Biomedical Scientists and Health Care Researchers

Our AMA: (1) continues its strong support for the Medical Scientists Training Program's stated mission goals;

(2) supports taking immediate steps to enhance the continuation and adequate funding for stipends in federal research training programs in the biomedical sciences and health care research, including training of combined MD and PhD, biomedical PhD, and post-doctoral (post MD and post PhD) research trainees;

(3) supports monitoring federal funding levels in this area and being prepared to provide testimony in support of these and other programs to enhance the training of biomedical scientists and health care research;

(4) supports a comprehensive strategy to increase the number of physician-scientists by: (a) emphasizing the importance of biomedical research for the health of our population; (b) supporting the need for career opportunities in biomedical research early during medical school and in residency training; (c) advocating National Institutes of Health support for the career development of physician-scientists; and (d) encouraging academic medical institutions to develop faculty paths supportive of successful careers in medical research; and

(5) supports strategies for federal government-sponsored programs, including reduction of education-acquired debt, to encourage training of physician-scientists for biomedical research. (Res. 93, I-88; Reaffirmed: Sunset Report, I-98; Amended: Sub. Res. 302, I-99; Appended: Res. 515 and Reaffirmation A-00)

H-310.999 Guidelines for Housestaff Contracts or Agreements
The "Essentials of Approved Residencies, " approved by the House of Delegates in 1970, includes a section on relationships of housestaff and institutions. The following outline is intended to promote additional guidance to all parties in establishing the conditions under which house officers learn and provide services to patients.
Training programs have been central to the process of graduate medical education which has produced a high level of medical competence in the United States. The American Medical

Association recognizes that the integrity of these programs is a primary objective in achieving the best possible care of the patient. It is, therefore, incumbent upon members of the housestaff and the institutions in which they are being trained to be aware of the parameters and responsibilities applicable to their training programs. In the absence of such awareness, unreasonable expectations may arise to threaten the harmony between hospital and housestaff in the performance of their joint mission.

It should be emphasized that these guidelines are not intended as a fixed formula. Guidelines that seek to cover public, voluntary and proprietary hospitals necessarily entail so many variables from training institution to training institution that no single form of contract or agreement would be universally applicable. This set of guidelines has, therefore, been developed to cover the more significant substantive provisions of a housestaff contract or agreement.

The subjects included in the Guidelines are not intended to be the only subjects important or appropriate for a contract or agreement. Moreover, the definition of the respective responsibilities, rights and obligations of the parties involved can assume various forms: individual contracts or agreements, group contracts or agreements, or as a part of the rules of government of the institution.

II. Proposed Terms and Conditions A. *Parties to the Contract or Agreement* (1) Contracts or agreements may be formed between individuals or groups, and institutions. Such a group might be a housestaff organization. (2) The two parties to an agreement or contract may be a single institution or a group of institutions, and an individual member of the housestaff, an informal group of the housestaff, or a formally constituted group or association of the housestaff, as determined by the housestaff organization.

B. *General Principles* (1) Contracts or agreements are legal documents and must conform to the laws, rules, and regulation to which the institutions are subject. Position, salary and all other benefits should remain in effect insofar as possible without regard to rotational assignments even when the member of the housestaff is away from the parent institution. Exceptions required by law or regulations should be clearly delineated to the house officer at the time of the appointment. Changes in the number of positions in each year of a training program should be made so as not to affect adversely persons already in, or accepted in, that program. The agreement should provide fair and equitable conditions of employment for all those performing the duties of interns, residents and fellows. When a general contract or agreement is in effect between an association and an institution, individual contracts or agreements should be consistent. (2) Adequate prior notification of either party's intent not to review the contract or agreement should be required, and the date of such notification should be included in the contract or agreement. (3) The institution and the individual members of the housestaff must accept and recognize the right of the housestaff to determine the means by which the housestaff may organize its affairs, and both parties should abide by that determination; provided that the inherent right of a member of the housestaff to contract and negotiate freely with the institution, individually or collectively, for terms and conditions of employment and training should not be denied or infringed. No contract should require or prescribe that members of the housestaff shall or shall not be members of an association or union.

C. *Obligation of the Housestaff* (1) Members of the housestaff agree to fulfill the educational requirements of the graduate training programs, and accept the obligation to use their efforts to provide safe, effective and compassionate patient care as assigned or required under the circumstances as delineated in the ACGME "Essentials of Approved Residencies" and previously approved standards of the AMA Council on Medical Education. (2) Members of the housestaff should comply with the laws, regulations, and policies to which the institution is subject.

D. *Obligation of the Institution* (1) The institution agrees to provide an educational program that meets the standards of the ACGME "Essentials of Approved Residencies." (2) The institution agrees to maintain continuously its staff and its facilities in compliance with all of the standards in the ACGME "Essentials of Approved Residencies."
E. *Salary for Housestaff* (1) The salary to be paid and the frequency of payment should be specified. The salary schedule should be published. The basis for increments and the time of the increments should be specified. (2) In determining the salary level of a member of the housestaff, prior educational experience should be considered, and a determination made as to whether credit should be given. (3) The responsibilities of senior residents should be recognized in salary differentials.
F. *Hours of Work* There should be recognition of the fact that long duty hours extending over an unreasonably long period of time or onerous on-call schedules are not consistent with the primary objective of education or the efficient delivery of optimal patient care. The institution should commit itself to fair scheduling of duty time for all members of the housestaff, including the provision of adequate off-duty hours.
G. *Off-Duty Activities* The contract or agreement should provide that a member of the housestaff is free to use his off-duty hours as he sees fit, including engaging in outside employment if permitted by the terms of the original contract or agreement, so long as such activity does not interfere with his obligations to the institution or to the effectiveness of the educational program to which he has been appointed.
H. *Vacation and Leave* The AMA encourages residency programs across the country to permit and schedule off-duty time separate from personal vacation time to enable residents to attend educational and/or organized medicine conferences. The amount of vacation, sick leave, and educational leave to which each member of the housestaff is entitled should be specified. Vacations should be expressed in terms of customary working days as defined by the institution. If vacations may be taken only at certain times of the year, this restriction should be stated. Any requirements for scheduling vacation time should also be stated. Provisions may also cover leaves for maternity, paternity, bereavement, military duty, examinations and preparations therefore, and educational conferences. Reimbursement for tuition and expenses incurred at educational conferences should be considered. The agreement should set forth any progressive increases in the amount of time allowed for vacation, sick leave, and educational leave. Educational leave should not be deducted from vacation time.
I. *Insurance Benefits* Insurance benefits should be set forth with particularity and should be tailored to the specific needs of the housestaff. Some of the more common insurance benefit provisions are (1) hospitalization and basic medical coverage for the member of the housestaff, spouse, and minor children; (2) major medical coverage for the member of the housestaff, spouse, and minor children; and (3) group life insurance, and dismemberment and disability insurance for the member of the housestaff only. It should also be specified whether the institution will pay the full amount of premiums or only a portion of the premiums, the balance to be paid by the member of the housestaff. Co-paid benefits should be established, separately from other hospital employee benefits, as a means of maximizing benefits. In some instances, free care for the housestaff and their families at the training institutions may be provided. In lieu of insurance benefits, the contract or agreement may provide for fixed annual payments to a housestaff association for each member of the housestaff so that the housestaff association may determine and provide for insurance or other benefits for the housestaff.
J. *Professional Liability Insurance* The contract or agreement should specify the amount of professional liability insurance that the institution will provide for each member of the housestaff together with the limits of liability applicable to such coverage. It might also be appropriate to provide in the contract or agreement that the housestaff and the institution will cooperate fully with the insurance company in the handling of any professional liability claim.

K. *Committee Participation* Insofar as possible, the institution should agree to provide for appropriate participation by the housestaff on the various committees within the institution. This participation should be on committees concerning institutional, professional and administrative matters including grievance and disciplinary proceedings. Members should have full voting rights. Representatives of the housestaff should be selected by the members of the housestaff.
L. *Grievance Procedures* The contract or agreement should require and publish a grievance procedure. A grievance procedure typically involves the following: (1) A definition of the term "grievance" (e.g., any dispute or controversy about the interpretation or application of the contract, any rule or regulation, or any policy or practice). (2) The timing, sequence, and end point of the grievance procedure. (3) The right to legal or other representation. (4) The right of an individual member of the housestaff or a housestaff association to initiate a grievance procedure and the obligation of the housestaff to maintain patient care during the grievance procedure. (5) A statement of the bases and procedures for the final decision on grievances (end point), and agreement of both parties to abide by the decision. (6) Should costs arise in the grievance procedure, a prior agreement as to how these costs will be apportioned between the parties.
M. *Disciplinary Hearings and Procedure* With respect to disciplinary procedures, the provisions of Article VIII - Hearing and Appellate Review Procedure of the JCAHO Guidelines for the Formulation of Medical Staff Bylaws, Rules, and Regulations shall be applicable to the housestaff in the same manner as they are to all other members of the medical staff with the proviso that the Hearing and Appeals Committees shall contain appropriate representation of the housestaff.
N. *Description of the Educational Program* The specific details of the operation of the educational experience should be made available to each prospective candidate. These data should include specific descriptions of training programs, including numbers of resident positions at each level of training, copies of existing housestaff contracts or agreements, approval status of programs to which candidate is applying, methods of evaluation, procedures for grievances and disciplinary action, and commitments for further training.
O. *Patient-Care Issues* The quality of patient-care services and facilities may be specified in the contract, and could include such matters as adequate equipment, bedspace, clinical staffing, and clinical staff structuring.
P. *Other Provisions* The agreement should provide for adequate, comfortable, safe, and sanitary facilities.
The foregoing provisions are not all-inclusive. Depending upon the institution's size, resources, location, and affiliations, if any, and also depending upon the relationship between the institution and the housestaff association, other provisions may be included, such as: (1) Maintenance of existing benefits and practices not otherwise expressly covered; (2) Housing, meals, laundry, uniforms, living-out and telephone allowances; (3) Adequate office space, facilities, and supporting services for housestaff affairs; (4) Housestaff association seminars and meetings. (BOT Rep. H, I-74; Reaffirmed: CLRPD Rep. C, A-89; Appended: Res.323, I-97; Reaffirmation A-00)

H-310.929 Principles for Graduate Medical Education
Our AMA urges the Accreditation Council for Graduate Medical Education to incorporate these principles in the revised "Institutional Requirements" of the Essentials of Accredited Residencies of Graduate Medical Education, if they are not already present.
(1) PURPOSE OF GRADUATE MEDICAL EDUCATION. There must be objectives for residency education in each specialty that promote the development of the knowledge, skills, attitudes, and behavior necessary to become a competent practitioner in a recognized medical specialty.

(2) RELATION OF ACCREDITATION TO THE PURPOSE OF RESIDENCY TRAINING. Accreditation requirements should relate to the stated purpose of a residency program and to the knowledge, skills, attitudes, and behaviors that a resident physician should have on completing residency education.
(3) EDUATION IN THE BROAD FIELD OF MEDICINE. GME should provide a resident physician with broad clinical experiences that address the general competencies and professionalism expected of all physicians, adding depth as well as breadth to the competencies introduced in medical school.
(4) SCHOLARLY ACTIVITIES FOR RESIDENTS. Graduate medical education should always occur in a milieu that includes scholarship. Resident physicians should learn to appreciate the importance of scholarly activities and should be knowledgeable about scientific method. However, the accreditation requirements, the structure, and the content of graduate medical education should be directed toward preparing physicians to practice in a medical specialty. Individual educational opportunities beyond the residency program should be provided for resident physicians who have an interest in, and show an aptitude for, academic and research pursuits. The continued development of evidence-based medicine in the graduate medical education curriculum reinforces the integrity of the scientific method in the everyday practice of clinical medicine.
(5) FACULTY SCHOLARSHIP. All residency faculty members must engage in scholarly activities and/or scientific inquiry. Suitable examples of this work must not be limited to basic biomedical research. Faculty can comply with this principle through participation in scholarly meetings, journal club, lectures, and similar academic pursuits.
(6) INSTITUTIONAL RESPONSIBILITY FOR PROGRAMS. Specialty-specific GME must operate under a system of institutional governance responsible for the development and implementation of policies regarding the following; the initial authorization of programs, the appointment of program directors, compliance with the Essentials for Accredited Residencies in Graduate Medical Education, the advancement of resident physicians, the disciplining of resident physicians when this is appropriate, the maintenance of permanent records, and the credentialing of resident physicians who successfully complete the program. If an institution closes or has to reduce the size of a residency program, the institution must inform the residents as soon as possible. Institutions must make every effort to allow residents already in the program to complete their education in the affected program. When this is not possible, institutions must assist residents to enroll in another program in which they can continue their education. Programs must also make arrangements, when necessary, for the disposition of program files so that future confirmation of the completion of residency education is possible. Institutions should allow residents to form housestaff organizations, or similar organizations, to address patient care and resident work environment concerns. Institutional committees should include resident members.
(7) COMPENSATION OF RESIDENT PHYSICIANS. All residents should be compensated. Residents should receive fringe benefits, including, but not limited to, health, disability, and professional liability insurance and parental leave and should have access to other benefits offered by the institution. Residents must be informed of employment policies and fringe benefits, and their access to them. Restrictive covenants must not be required of residents or applicants for residency education.
(8) LENGTH OF TRAINING. The usual duration of an accredited residency in a specialty should be defined in the "Program Requirements." The required minimum duration should be the same for all programs in a specialty and should be sufficient to meet the stated objectives of residency education for the specialty and to cover the course content specified in the Program Requirements. The time required for an individual resident physician’s education might be

modified depending on the aptitude of the resident physician and the availability of required clinical experiences.
(9) PROVISION OF FORMAL EDUCATIONAL EXPERIENCES. Graduate medical education must include a formal educational component in addition to supervised clinical experience. This component should assist resident physicians in acquiring the knowledge and skill base required for practice in the specialty. The assignment of clinical responsibility to resident physicians must permit time for study of the basic sciences and clinical pathophysiology related to the specialty.
(10) INNOVATION OF GRADUATE MEDICAL EDUCATION. The requirements for accreditation of residency training should encourage educational innovation and continual improvement. New topic areas such as continuous quality improvement (CQI), outcome management, informatics and information systems, and population-based medicine should be included as appropriate to the specialty.
(11) THE ENVIRONMENT OF GRADUATE MEDICAL EDUCATION. Sponsoring organizations and other GME programs must create an environment that is conducive to learning. There must be an appropriate balance between education and service. Resident physicians must be treated as colleagues.
(12) SUPERVISION OF RESIDENT PHYSICIANS. Program directors must supervise the clinical performance of resident physicians. The policies of the sponsoring institution, as enforced by the program director, must ensure that the clinical activities of each resident physician are supervised to a degree that reflects the ability of the resident physician. Integral to resident supervision is the necessity for frequent evaluation of residents by faculty, with discussion between faculty and resident. It is a cardinal principle that responsibility for the treatment of each patient and the education of resident and fellow physicians lies with the physician/faculty to whom the patient is assigned and who supervises all care rendered to the patient by residents and fellows.
(13) EVALUATION OF RESIDENTS AND SPECIALTY BOARD CERTIFICATION. Residency program directors and faculty are responsible for evaluating and documenting the continuing development and competency of residents, as well as the readiness of residents to enter independent clinical practice upon completion of training. Program directors should also document any deficiency or concern that could interfere with the practice of medicine and which requires remediation, treatment, or removal from training. Inherent within the concept of specialty board certification is the necessity for the residency program to attest and affirm to the competence of the residents completing their training program and being recommended to the specialty board as candidates for examination. This attestation of competency should be accepted by specialty boards as fulfilling the educational and training requirements allowing candidates to sit for the certifying examination of each member board of the ABMS.
(14) GRADUATE MEDICAL EDUCATION IN THE AMBULATORY SETTING. Graduate medical education programs must provide educational experiences to residents in the broadest possible range of educational sites, so that residents are trained in the same types of sites in which they may practice after completing GME. It should include experiences in a variety of ambulatory settings, in addition to the traditional inpatient experience. The amount and types of ambulatory training is a function of the given specialty.
(15) VERIFICATION OF RESIDENT PHYSICIAN EXPERIENCE. The program director must document a resident physician’s specific experiences and demonstrated knowledge, skills, attitudes, and behavior, and a record must be maintained within the institution. (CME Rep. 9, A-99)

H-295.942 Providing Dental and Vision Insurance to Medical Students and Resident Physicians

The AMA urges (1) all medical schools to pay for or offer affordable policy options and, assuming the rates are appropriate, require enrollment in disability insurance plans by all medical students; (2) all residency programs to pay for or offer affordable policy options for disability insurance, and strongly encourage the enrollment of all residents in such plans; (3) medical schools and residency training programs to pay for or offer comprehensive and affordable health insurance coverage, including but not limited to medical, dental, and vision care, to medical students and residents which provides no less than the minimum benefits currently recommended by the AMA for employer-provided health insurance and to require enrollment in such insurance; (4) carriers offering disability insurance to: (a) offer a range of disability policies for medical students and residents that provide sufficient monthly disability benefits to defray any educational loan repayments, other living expenses, and an amount sufficient to continue payment for health insurance providing the minimum benefits recommended by the AMA for employer-provided health insurance; and (b) include in all such policies a rollover provision allowing continuation of student disability coverage into the residency period without medical underwriting. (5) Our AMA: (a) actively encourages medical schools, residency programs, and fellowship programs to provide access to portable group health and disability insurance, including human immunodeficiency virus positive indemnity insurance, for all medical students and resident and fellow physicians; (b) will work with the ACGME and the LCME, and other interested state medical societies or specialty organizations, to develop strategies and policies to ensure access to the provision of portable health and disability insurance coverage, including human immunodeficiency virus positive indemnity insurance, for all medical students, resident and fellow physicians; and (c) will prepare informational material designed to inform medical students and residents concerning the need for both disability and health insurance and describing the available coverage and characteristics of such insurance. (BOT Rep. W, I-91; Reaffirmed: BOT Rep. 1, I-934; Appended: Res. 311, I-98; Modified: Res. 306, A-04)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 315
(A-08)

Introduced by: Resident and Fellow Section

Subject: Evaluation of Increasing Resident Review Committee (RRC) Requirements

Referred to: Reference Committee C

Whereas, The creation of the Outcome Project and the development of the six core competencies from the Accreditation Council for Graduate Medical Education has lead to a novel and valuable shift in the focus of graduate medical education toward competency-based learning; and

Whereas, The shift in focus to competency-based learning has created a need for new assessment tools, structured curricula, and extensive documentation of resident performance data in an attempt to quantify a largely qualitative experience; and

Whereas, Excessive documentation requirements could detract from time available for residents and fellows to learn directly from patients during clinical encounters and less time for staff to teach residents, therefore be it

RESOLVED, That the AMA study residency/fellowship documentation requirements for program accreditation and the impact of these documentation requirements on program directors and residents with recommendations for improvement.

Fiscal Note: Estimated cost of $38,602 to visit between 10 to 20 GME sponsoring institutions and analyze work effort involved by a representative sample of program directors and Designated Institutional Officers to respond to ACGME accreditation requirements.

Relevant AMA Policy

H-315.982 CMS Documentation Guidelines for Teaching Physicians
The AMA will work with the CMS to: (1) reduce the redundant and burdensome documentation for teaching physicians; (2) accept documentation by the physician team under the supervision of a teaching physician if it collectively meets all CMS documentation requirements: and (3) accept a statement of the teaching physician's level of participation in patient care as sufficient or adequate documentation. (Res. 861, A-98)

D-300.995 Reducing Burdens of CME Accreditation and Documentation
Our AMA will work with the Accreditation Council for Continuing Medical Education to simplify the requirements for documentation and administration of accredited CME programs. (Res. 304, I-01)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 316
(A-08)

Introduced by: Resident and Fellow Section

Subject: Loss of Status Following Family Medical Leave Act (FMLA) Qualified Leave During Residency Training

Referred to: Reference Committee C

Whereas, Current AMA policy (H-420.967) states "Physicians should be able to return to their practices or training programs after taking maternity leave without the loss of status"; and

Whereas, The Family Medical Leave Act (FMLA) guarantees that eligible employees be given "a minimum of twelve weeks of unpaid leave per year" for certain medical and family reasons (including pregnancy/childbirth) and be restored "to the same or an equivalent position" upon their return to work[1]; and

Whereas, Certain residency training programs require residents taking family medical leave (including maternity leave) for periods protected under the FMLA (up to 12 weeks) to repeat the entire year, citing this requirement as necessary to maintain board eligibility[2]; and

Whereas, Specialty board policies regarding board eligibility do not seem to explicitly require a resident taking family medical leave to repeat the entire year (rather than simply extend training) in the event of a resident taking a period of leave protected under the FMLA[3, 4]; and

Whereas, Residents who must repeat an entire year of training as a direct result of taking an FMLA-protected maternity leave suffer a "loss of status", as well as lost potential income, as a result of taking maternity leave; and

Whereas, Perpetuation of policies that result in this kind of "loss of status" due to residents taking maternity leave lowers morale for many residents and may discourage women from entering the specialty of their choice [5, 6]; and

Whereas, Residency programs imposing such a requirement as a result of actual or falsely construed specialty board policy may unknowingly be committing a tort against those residents who suffered a "loss of status" and those who did not take desired leave as a result of the threat of "loss of status"; and

Whereas, The policies of the specialty boards regarding family medical leave and board eligibility requirements are extremely variable between specialties and confusing to residents and faculty alike; therefore be it

RESOLVED, That our AMA oppose requiring residents to repeat a year of training when returning to work following a leave that qualifies under the federal Family Medical Leave Act (New HOD Policy); and be it further

RESOLVED, That our AMA urge the American Board of Medical Specialties and its member boards to be in compliance with the Family Medical Leave Act and to retract any policies that do not comply (Directive to Take Action).

Fiscal Note: Less than $1000

References

1. U.S. Department of Labor: Compliance Assistance - Family and Medical Leave Act. http://www.dol.gov/esa/whd/fmla/
2. Jagsi R, Tarbell, NJ, and DF Weinstein. Supplement to "Becoming a Doctor, Starting a Family — Leaves of Absence from Graduate Medical Education." *New England Journal of Medicine*, 2007; 357(19): 1889-1891.
3. American Board of Orthopedic Surgery, Inc. 2008 Rules and Procedures for Residency Education. https://www.abos.org/documents/2008RP.doc
4. Rose, SH, Burkle CM, Elliott BA, et al. "The Impact of Parental Leave on Extending Training and Entering the Board Certification Examination Process." *Mayo Clinic Proceedings.* 2006; 81(11):1449-53.
5. Jagsi R, Tarbell, NJ, and DF Weinstein. "Becoming a Doctor, Starting a Family — Leaves of Absence from Graduate Medical Education." *New England Journal of Medicine*, 2007; 357(19): 1889-1891.

Relevant AMA Policy:

H-420.967 Maternity Leave Policies
Over the past decade, the medical community has made significant progress in responding to the unique needs of women medical students and physicians, including the issue of maternity leave. The continuation and enhancement of these efforts should be encouraged. Therefore, (1) The AMA urges medical schools, residency training programs, medical specialty boards, the Accreditation Council for Graduate Medical Education, and medical group practices to incorporate and/or encourage development of written maternity leave policies as part of the physician's standard benefit agreement.
(2) AMA policy regarding recommended components of maternity leave policies for physicians, as specified in Policy 420.987 is expanded to include physicians in practice, reading as follows: (a) Residency program directors and group practice administrators should review federal law concerning maternity leave for guidance in developing policies to assure that pregnant physicians are allowed the same sick leave or disability benefits as those physicians who are ill or disabled; (b) Staffing levels and scheduling are encouraged to be flexible enough to allow for coverage without creating intolerable increases in other physicians' work loads, particularly in residency programs; and (c) Physicians should be able to return to their practices or training programs after taking maternity leave without the loss of status.
(3) Our AMA encourages residency programs, specialty boards, and medical group practices to incorporate into their maternity leave policies a six-week minimum leave allowance, with the understanding that no woman should be required to take a minimum leave. (BOT Rep. HH, I-90; Modified: Sunset Report, I-00)

H-420.961 Education -- Policies for Maternity, Family and Medical Necessity Leave for Residents and Employed Physicians
AMA adopts as policy the following guidelines for, and encourage the implementation of, Maternity and Family Leave for Residency Programs and Employed Medical Staffs: (1) The AMA urges medical schools, residency training programs, medical specialty boards, and the

Accreditation Council for Graduate Medical Education to incorporate and/or encourage development of written leave policies, including parental leave, family leave, and medical leave; (2) Residency program directors should review federal and state law for guidance in developing policies for parental, family, and medical leave; (3) Physicians who are unable to work because of pregnancy, childbirth, and other related medical conditions should be entitled to such leave and other benefits on the same basis as other physicians who are temporarily unable to work for other medical reasons; (4) Residency programs should develop written policies on parental leave, family leave, and medical leave for physicians. Such written policies should include the following elements: (a) leave policy for birth or adoption; (b) duration of leave allowed before and after delivery; (c) category of leave credited (e.g., sick, vacation, parental, unpaid leave, short term disability); (d) whether leave is paid or unpaid; (e) whether provision is made for continuation of insurance benefits during leave and who pays for premiums; (f) whether sick leave and vacation time may be accrued from year to year or used in advance; (g) extended leave for resident physicians with extraordinary and long-term personal or family medical tragedies for periods of up to one year, without loss of previously accepted residency positions, for devastating conditions such as terminal illness, permanent disability, or complications of pregnancy that threaten maternal or fetal life; (h) how time can be made up in order for a resident physician to be considered board eligible; (i) what period of leave would result in a resident physician being required to complete an extra or delayed year of training; (j) whether time spent in making up a leave will be paid; and (k) whether schedule accommodations are allowed, such as reduced hours, no night call, modified rotation schedules, and permanent part-time scheduling; (5) Staffing levels and scheduling are encouraged to be flexible enough to allow for coverage without creating intolerable increases in the workloads of other physicians, particularly those in residency programs; (6) Physicians should be able to return to their practices or training programs after taking parental leave, family leave, or medical leave without the loss of status; and (7) Residency program directors must assist residents in identifying their specific requirements (for example, the number of months to be made up); because of leave for eligibility for board certification. Residency program directors must notify residents on leave if they are in danger of falling below minimal requirements for board eligibility. Program directors must give these residents a complete list of requirements to be completed in order to retain board eligibility. (CME Rep. 6, A-98; Reaffirmation I-03)

H-420.979 AMA Statement on Family and Medical Leave
Our AMA supports policies that provide employees with reasonable job security and continued availability of health plan benefits in the event leave by an employee becomes necessary due to documented medical conditions. Such policies should provide for reasonable periods of paid or unpaid: (1) medical leave for the employee, including pregnancy; (2) maternity leave for the employee-mother; (3) leave if medically appropriate to care for a member of the employee's immediate family, i.e., a spouse or children; and (4) leave for adoption or for foster care leading to adoption. Such periods of leave may differ with respect to each of the foregoing classifications, and may vary with reasonable categories of employers. Such policies should encourage voluntary programs by employers and may provide for appropriate legislation (with or without financial assistance from government). Any legislative proposals will be reviewed through the Association's normal legislative process for appropriateness, taking into consideration all elements therein, including classifications of employees and employers, reasons for the leave, periods of leave recognized (whether paid or unpaid), obligations on return from leave, and other factors involved in order to achieve reasonable objectives recognizing the legitimate needs of employees and employers. (BOT Rep. A, A-88; Reaffirmed: Sunset Report, I-98)

H-420.987 Maternity Leave for Residents
The AMA believes that: (1) Residency program directors should review federal law concerning maternity leave and note that for policies to be in compliance, pregnant residents must be allowed the same sick leave or disability benefits as other residents who are ill or disabled. (2) The duration of disability leave should be determined by the pregnant resident's physicians, based on the individual's condition and needs. (3) All residency programs should develop a written policy on maternity and paternity leave for residents that addresses: (a) duration of leave allowed before and after delivery; (b) category of leave credited; (c) whether leave is paid or unpaid; (d) whether provision is made for continuation of insurance benefits during leave, and who pays the premium; (e) whether sick leave and vacation time may be accrued from year to year or used in advance; (f) how much time must be made up in order to be considered board eligible; (g) whether make-up time will be paid; (h) whether schedule accommodations are allowed; (i) leave policy for adoption; and (j) leave policy for paternity. (4) Resident numbers and scheduling are encouraged to be flexible enough to allow for coverage without creating intolerable increases in other residents' work loads. (5) Residents should be able to return to their training program after disability leave without loss of training status. (BOT Rep. Z, A-84; Reaffirmed by CLRPD Rep. 3 - I-94; Reaffirmed and Modified: CME Rep. 2, A-04)

H-420.996 Maternity Leave for Housestaff
Our AMA encourages flexibility in residency training programs, incorporating maternity leave and alternative schedules for pregnant housestaff. (Sub. Res. 89, I-79; Reaffirmed: CLRPD Rep. B, I-89; Reaffirmed: Sunset Report, A-00)

D-310.970 Improving Parental Leave Policies for Residents
Our AMA will study and encourage the Accreditation Council for Graduate Medical Education's participation in such study of (1) the feasibility of considering guaranteed paid maternity leave for residents of no less than six weeks duration, with the possibility of unpaid maternity leave of an additional six weeks; (2) written leave policies for residents for paternity and adoption; and (3) the effect of such maternity, paternity, and adoption leave policies on residency programs, with report back to the House of Delegates at the 2008 Annual Meeting. (Res. 303, A-07)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 317
(A-08)

Introduced by: Resident and Fellow Section

Subject: Telemedicine and Medical Licensure

Referred to: Reference Committee C

Whereas, The advancement of telemedicine will allow patients both in the United States of America and worldwide to obtain excellence in healthcare; and

Whereas, Telemedicine promotes increased access to healthcare by eliminating travel expenses, aiding those with impediments to mobility, and connecting patients directly with the most highly trained physicians in the world; and

Whereas, Physicians who wish to obtain a U.S. state medical license must first successfully pass all three Steps of the United States Medical Licensing Examination, an examination sponsored by the National Board of Medical Examiners, not a state board medical examination; and

Whereas, Physicians wishing to be board certified in the U.S. must successfully pass their respective specialty board examination(s), usually a national board examination for each specialty, not a state specific specialty board exam; and

Whereas, Physicians nationwide should, to the best of their ability, practice medicine according to evidence-based medicine, regardless of where the physician was trained, the state in which the physician treats patients, or the state in which the patient is a permanent resident; and

Whereas, Currently each state has its own medical license which must be successfully applied for and maintained if a physician wishes to treat patients in that state (with limited consultative exceptions), and the application for and acquisition of a state medical license is typically a long process; and

Whereas, For physicians engaging in repetitive telemedicine activities, the maintenance of multiple active medical licenses is economically prohibitive as annual or semi-annual renewal fees accrue; and

Whereas, Physicians with a valid state license who practice in a Veterans Health Administration (VHA) Hospital are permitted to work in VHA hospitals beyond the state in which they are licensed, without being required to hold multiple licenses; and

Whereas, Our patients should be free to seek healthcare they deem most appropriate and the AMA should lead the charge for constant medical innovation by supporting increased access to excellent medical care; therefore be it

RESOLVED, That the AMA study how guidelines regulating medical licenses are affected by telemedicine and medical technological innovations that allow for physicians to practice outside their states of licensure (Directive to Take Action).

Fiscal Note: Estimated cost of $135,128 to develop instrument and conduct survey and follow up.

Relevant AMA Policy:

H-160.937 The Promotion of Quality Telemedicine
(1) The AMA adopts the following principles for the supervision of nonphysician providers and technicians when telemedicine is used: (a) The physician is responsible for, and retains the authority for, the safety and quality of services provided to patients by nonphysician providers through telemedicine. (b) Physician supervision (e.g. regarding protocols, conferencing, and medical record review) is required when nonphysician providers or technicians deliver services via telemedicine in all settings and circumstances. (c) Physicians should visit the sites where patients receive services from nonphysician providers or technicians through telemedicine, and must be knowledgeable regarding the competence and qualifications of the nonphysician providers utilized. (d) The supervising physician should have the capability to immediately contact nonphysician providers or technicians delivering, as well as patients receiving, services via telemedicine in any setting. (e) Nonphysician providers who deliver services via telemedicine should do so according to the applicable nonphysician practice acts in the state where the patient receives such services. (f) The extent of supervision provided by the physician should conform to the applicable medical practice act in the state where the patient receives services. (g) Mechanisms for the regular reporting, recording, and supervision of patient care delivered through telemedicine must be arranged and maintained between the supervising physician, nonphysician providers, and technicians. (h) The physician is responsible for providing and updating patient care protocols for all levels of telemedicine involving nonphysician providers or technicians.
(2) The AMA urges those who design or utilize telemedicine systems to make prudent and reasonable use of those technologies necessary to apply current or future confidentiality and privacy principles and requirements to telemedicine interactions.
(3) The AMA emphasizes to physicians their responsibility to ensure that their legal and ethical requirements with respect to patient confidentiality and data integrity are not compromised by the use of any particular telemedicine modality. (4) The AMA advocates that continuing medical education conducted using telemedicine adhere to the standards of the AMA's Physician Recognition Award and the Essentials and Standards of the Accreditation Council for Continuing Medical Education. (CME/CMS Rep., I-96; Reaffirmed: CMS Rep. 8, A-06)

H-480.974The Evolving Impact of Telemedicine
Our AMA: (1) will evaluate relevant federal legislation related to telemedicine;
(2) urges CMS and other concerned entities involved in telemedicine to fund demonstration projects to evaluate the effect of care delivered by physicians using telemedicine-related technology on costs, quality, and the physician-patient relationship;
(3) urges medical specialty societies involved in telemedicine to develop appropriate practice parameters to address the various applications of telemedicine and to guide quality assessment and liability issues related to telemedicine; (Reaffirmed by CME/CMS Rep. A-96)
(4) encourages the CPT Editorial Board to develop CPT codes or modifiers for telemedical services;
(5) will work with CMS and other payers to develop and test, through these demonstration projects, appropriate reimbursement mechanisms;
(6) will develop a means of providing appropriate continuing medical education credit, acceptable toward the Physician's Recognition Award, for educational consultations using telemedicine; and

(7) will work with the Federation of State Medical Boards and the state and territorial licensing boards to develop licensure guidelines for telemedicine practiced across state boundaries. (CMS/CME Rep., A-94; Reaffirmation A-01)

H-480.969 The Promotion of Quality Telemedicine
(1) It is the policy of the AMA that medical boards of states and territories should require a full and unrestricted license in that state for the practice of telemedicine, unless there are other appropriate state-based licensing methods, with no differentiation by specialty, for physicians who wish to practice telemedicine in that state or territory. This license category should adhere to the following principles: (a) application to situations where there is a telemedical transmission of individual patient data from the patient's state that results in either (i) provision of a written or otherwise documented medical opinion used for diagnosis or treatment or (ii) rendering of treatment to a patient within the board's state; (b) exemption from such a licensure requirement for traditional informal physician-to-physician consultations ("curbside consultations") that are provided without expectation of compensation; (c) exemption from such a licensure requirement for telemedicine practiced across state lines in the event of an emergent or urgent circumstance, the definition of which for the purposes of telemedicine should show substantial deference to the judgment of the attending and consulting physicians as well as to the views of the patient; and (d) application requirements that are non-burdensome, issued in an expeditious manner, have fees no higher than necessary to cover the reasonable costs of administering this process, and that utilize principles of reciprocity with the licensure requirements of the state in which the physician in question practices. (2) The AMA urges the FSMB and individual states to recognize that a physician practicing certain forms of telemedicine (e.g., teleradiology) must sometimes perform necessary functions in the licensing state (e.g., interaction with patients, technologists, and other physicians) and that the interstate telemedicine approach adopted must accommodate these essential quality-related functions. (3) The AMA urges national medical specialty societies to develop and implement practice parameters for telemedicine in conformance with: Policy 410.973 (which identifies practice parameters as "educational tools"); Policy 410.987 (which identifies practice parameters as "strategies for patient management that are designed to assist physicians in clinical decision making," and states that a practice parameter developed by a particular specialty or specialties should not preclude the performance of the procedures or treatments addressed in that practice parameter by physicians who are not formally credentialed in that specialty or specialties); and Policy 410.996 (which states that physician groups representing all appropriate specialties and practice settings should be involved in developing practice parameters, particularly those which cross lines of disciplines or specialties). (CME/CMS Rep., A-96; Amended: CME Rep. 7, A-99)

H-480.961 Teleconsultations and Medicare Reimbursement
Our AMA demands that CMS reimburse telemedicine services in a fashion similar to traditional payments for all other forms of consultation, which involves paying the various providers for their individual claims, and not by various "fee splitting" or "fee sharing" reimbursement schemes. (Res. 144, A-93; Reaffirmed: CMS Rep. 10, A-03; Reaffirmation A-07)

H-480.968 Telemedicine
AMA: (1) encourages all national specialty societies to work with their state societies to develop comprehensive practice standards and guidelines to address both the clinical and technological aspects of telemedicine; (2) will assist the national specialty societies in their efforts to develop these guidelines and standards; and urges national private accreditation organizations (e.g., URAC and JCAHO) to require that medical care organizations which establish ongoing arrangements for medical care delivery from remote sites require practitioners at those sites to

meet no less stringent credentialing standards and participate in quality review procedures that are at least equivalent to those at the site of care delivery. (Res. 117, I-96; Reaffirmed: CSAPH Rep. 3, A-06)

H-480.984 Technology Assessment in Medicine
(1) The AMA believes that technology assessment programs and coverage determinations should be based upon the following principles in order to assure sound clinical practice and equitable public policy: (a) The primary objective of health care technology assessment should be the development of accurate and complete information for physicians on safety, effectiveness, and clinical indications in order to enhance the appropriate utilization of health care technology. (b) The development of information on safety, effectiveness, and indications for use should be based upon a rigorous scientific methodology. (c) The primary responsibility for the conduct of technology assessment should rest with the medical profession, with participation from both the research and practice communities. Participation in such assessment by all appropriate medical specialties is important, particularly when use of the technology crosses specialties. (d) The pluralistic approach to technology assessment in both the public and private sectors should be strongly encouraged and continued. (e) The results of technology assessment must be communicated in an accurate and timely manner throughout the research and practice communities; specialty societies and other health care professional organizations should intensify efforts to disseminate such information. (f) Health care technologies should be re-evaluated on a continuing basis after their introduction, particularly if they are expensive or have the potential to cause serious harm if applied inappropriately. (g) Obsolete technologies should be identified and their further use should be discouraged. (h) Cost-effectiveness is an important consideration in technology assessment, but it should remain subordinate to considerations of safety and effectiveness. (i) Decisions as to the cost-effectiveness of technology can best be made by the physician on an individual patient basis, taking into consideration the needs of the individual and the results of cost-effectiveness analyses. Therefore, cost-effectiveness should not be used by payers to preclude or limit the availability of a safe and effective technology by either refusal to reimburse or by the provision of more limited reimbursement for such technology. (j) Payer determinations regarding coverage for health care technologies must be made with the involvement of the medical community and the public. Such determinations should be timely and responsive to the evolving information on safety and effectiveness. (k) Payer coverage policies for investigational technologies should be flexible and reviewed frequently so as to assure that the needs of individual patients are met. (l) Payers should integrate the concept of risk/benefit analysis into their decision-making and adapt their coverage policy accordingly. In serious and life-threatening illnesses, payers must recognize that patient and physician may agree upon a particular therapy, notwithstanding a lesser degree of certitude about that therapy's safety and effectiveness, if no other alternative therapies are available.
(2) The AMA should continue its efforts to educate the public about the contributions of innovations in health care technology to the health and well-being of all people and the prevention of disease.
(3) The AMA should emphasize access to effective technologies (and reimbursement for such technologies) which may be more appropriate for a subset of patients, even though other technologies may be more effective for the majority of patients for a given clinical condition, in order to protect physician judgment and patient preference in selection of therapy.
(4) When safety, effectiveness and availability have been established, cost should be a substantial determining factor in the choice of technology. (Joint CMS/CSA Rep., I-90; Reaffirmed: In Lieu of Res. 711, I-93; Amended: CSA Rep. 8, A-03)

H-275.955 Physician Licensure Legislation
Our AMA (1) reaffirms its policies opposing discrimination against physicians on the basis of being a graduate of a foreign medical school and supports state and territory responsibility for admitting physicians to practice; and (2) reaffirms earlier policy urging licensing jurisdictions to adopt laws and rules facilitating the movement of physicians between states, to move toward uniformity in requirements for the endorsement of licenses to practice medicine, and to base endorsement of medical licenses on an assessment of competence rather than on passing a written examination of cognitive knowledge. (CME Rep. B, A-90; Reaffirmation A-00)

H-275.962 Proposed Single Examination for Licensure
Our AMA: (1) endorses the concept of a single examination for medical licensure; (2) urges the NBME and the FSMB to place responsibility for developing Steps I and II of the new single examination for licensure with the faculty of U.S. medical schools working through the NBME; (3) continues its vigorous support of the LCME and its accreditation of medical schools and supports monitoring the impact of a single examination on the effectiveness of the LCME; (4) urges the NBME and the FSMB to establish a high standard for passing the examination, (5) strongly recommends and supports actively pursuing efforts to assure that the standard for passing be criterion-based; that is, that passing the examination indicate a degree of knowledge acceptable for practicing medicine; and (6) urges that appointing graduates of LCME accredited medical schools to accredited residency training not be dependent on their passing Steps I and II or the single examination for licensure. (CME Rep. B, I-89; Reaffirmed: Sunset Report, A-00)

H-275.967 Licensure by Endorsement
The AMA opposes national legislation which would mandate licensing reciprocity by all state licensing authorities. (Res. 42, A-88; Reaffirmed: Sunset Report, I-98)

H-275.978 Medical Licensure
The AMA: (1) urges directors of accredited residency training programs to certify the clinical competence of graduates of foreign medical schools after completion of the first year of residency training; however, program directors must not provide certification until they are satisfied that the resident is clinically competent; (2) encourages licensing boards to require a certificate of competence for full and unrestricted licensure; (3) urges licensing boards to review the details of application for initial licensure to assure that procedures are not unnecessarily cumbersome and that inappropriate information is not required. Accurate identification of documents and applicants is critical. It is recommended that boards continue to work cooperatively with the Federation of State Medical Boards to these ends; (4) will continue to provide information to licensing boards and other health organizations in an effort to prevent the use of fraudulent credentials for entry to medical practice; (5) urges those licensing boards that have not done so to develop regulations permitting the issuance of special purpose licenses. It is recommended that these regulations permit special purpose licensure with the minimum of educational requirements consistent with protecting the health, safety and welfare of the public; (6) urges licensing boards, specialty boards, hospitals and their medical staffs, and other organizations that evaluate physician competence to inquire only into conditions which impair a physician's current ability to practice medicine. (BOT Rep. I-93-13; CME Rep. 10 - I-94); (7) urges licensing boards to maintain strict confidentiality of reported information; (8) urges that the evaluation of information collected by licensing boards be undertaken only by persons experienced in medical licensure and competent to make judgments about physician competence. It is recommended that decisions concerning medical competence and discipline be made with the participation of physician members of the board; (9) recommends that if confidential information is improperly released by a licensing board about a physician, the board

take appropriate and immediate steps to correct any adverse consequences to the physician; (10) urges all physicians to participate in continuing medical education as a professional obligation; (11) urges licensing boards not to require mandatory reporting of continuing medical education as part of the process of reregistering the license to practice medicine; (12) opposes the use of written cognitive examinations of medical knowledge at the time of reregistration except when there is reason to believe that a physician's knowledge of medicine is deficient; (13) supports working with the Federation of State Medical Boards to develop mechanisms to evaluate the competence of physicians who do not have hospital privileges and who are not subject to peer review; (14) believes that licensing laws should relate only to requirements for admission to the practice of medicine and to assuring the continuing competence of physicians, and opposes efforts to achieve a variety of socioeconomic objectives through medical licensure regulation; (15) urges licensing jurisdictions to pass laws and adopt regulations facilitating the movement of licensed physicians between licensing jurisdictions; licensing jurisdictions should limit physician movement only for reasons related to protecting the health, safety and welfare of the public; (16) encourages the Federation of State Medical Boards and the individual medical licensing boards to continue to pursue the development of uniformity in the acceptance of examination scores on the Federation Licensing Examination and in other requirements for endorsement of medical licenses; (17) urges licensing boards not to place time limits on the acceptability of National Board certification or on scores on the United State Medical Licensing Examination for endorsement of licenses; (18) urges licensing boards to base endorsement on an assessment of physician competence and not on passing a written examination of cognitive ability, except in those instances when information collected by a licensing board indicates need for such an examination; (19) urges licensing boards to accept an initial license provided by another board to a graduate of a US medical school as proof of completion of acceptable medical education; (20) urges that documentation of graduation from a foreign medical school be maintained by boards providing an initial license, and that the documentation be provided on request to other licensing boards for review in connection with an application for licensure by endorsement; and (21) urges licensing boards to consider the completion of specialty training and evidence of competent and honorable practice of medicine in reviewing applications for licensure by endorsement. (CME Rep. A, A-87; Modified: Sunset Report, I-97; Reaffirmation A-04)

H-275.993 Examinations for Medical Licensure
Our AMA affirms its recommendation that medical school faculties continue to exercise the responsibilities inherent in their positions for the evaluation of students and residents, respectively. (CME Rep. B, I-81; Reaffirmed: CLRPD Rep. F, I-91; Modified: Sunset Report, I-01)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 318
(A-08)

Introduced by: Resident and Fellow Section

Subject: Protecting Patients and Residents by Reducing Extended Work Shifts

Referred to: Reference Committee C

Whereas, Five years have passed since both the American Medical Association (AMA) and the American Council on Graduate Medical Education (ACGME) adopted specific duty hour restrictions to protect residents, fellows, and patients[i,ii]; and

Whereas, The current duty hour restrictions continue to allow residents and fellows to work for up to 30 continuous hours with no dedicated time for sleep; and

Whereas, A growing body of literature published mostly in the past five years has shown that decreasing or eliminating extended work shifts (defined as shifts greater than 16 hours) may improve both resident quality of life and patient safety[iii,iv,v,vi,vii,viii,ix,x,xi,xii]; and

Whereas, This same body of literature also suggests that decreasing or eliminating extended shifts does not compromise resident education, even for residents in surgical programs[xiii,xiv,xv,xvi,xvii,xviii,xix,xx,xxi,xxii,xxiii]; and

Whereas, Despite the accumulated evidence, it would be premature to create a new mandate eliminating extended work shifts for residents and fellows at a time when many residency programs are still struggling to comply with the current duty hour restrictions; and

Whereas, Residency programs can instead be encouraged to voluntarily reduce or eliminate extended work shifts in order to improve resident quality of life and patient safety, allowing individual programs to move towards this goal at their own pace; and

Whereas, Decreasing or eliminating extended work shifts will require new team-based approaches to patient care as well as improvements in the way physicians communicate patient information to each other at the time of shift-change; therefore be it

RESOLVED, That our AMA reaffirm support of the current ACGME duty hour restrictions, and be it further

RESOLVED, That our AMA encourage the voluntary reduction or elimination of extended work shifts (>16 hours) for residents and fellows by academic medical centers and teaching hospitals while opposing a new ACGME mandate at this time, and be it further

RESOLVED, That our AMA continue to evaluate outcomes-based research on the impact of reductions in extended work shifts on (1) Patient Safety, (2) Resident Education, (3) Resident Safety, (4) Resident Quality of Life and (5) Professionalism in Transfer of Care, and be it further

RESOLVED, That our AMA develop specific prioritized research questions/objectives to further evaluate issues related to resident duty-hour reforms, such as best practices for signing out patients and organizing patient care teams.

[ii] H-310.927

[ii] ACGME Duty Hours, 2007. Accessed at http://www.acgme.org/acWebsite/dutyHours/dh_Lang703.pdf on March 21, 2008.

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[v] Goldstein, M.J., et al., *A 360 degrees evaluation of a night-float system for general surgery: a response to mandated work-hours reduction.* Current Surgery, 2004. **61**(5): p. 445-51.

[vi] Hutter, M.M., et al., *The impact of the 80-hour resident workweek on surgical residents and attending surgeons.* Annals of Surgery, 2006. **243**(6): p. 864-71; discussion 871-5.

[vii] Afessa, B., et al., *Introduction of a 14-hour work shift model for housestaff in the medical ICU.[see comment]*. Chest, 2005. **128**(6): p. 3910-5.

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[xi] Mann, F.A. and P.L. Danz, *The night stalker effect: quality improvements with a dedicated night-call rotation.* Investigative Radiology, 1993. **28**(1): p. 92-6.

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[xviii] Welling, R.E., et al., *Work hours compliance in a community hospital.* Current Surgery, 2004. **61**(2): p. 241-3.

[xix] McElearney, S.T., et al., *Effect of the 80-hour work week on cases performed by general surgery residents.* American Surgeon, 2005. **71**(7): p. 552-5; discussion 555-6.

[xx] de Virgilio, C., et al., *The 80-hour resident workweek does not adversely affect patient outcomes or resident education.* Current Surgery, 2006. **63**(6): p. 435-9; discussion 440.

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[xxii] Hutter, M.M., et al., *The impact of the 80-hour resident workweek on surgical residents and attending surgeons.* Annals of Surgery, 2006. **243**(6): p. 864-71; discussion 871-5.

[xxiii] Malangoni, M.A., et al., *Life after 80 hours: the impact of resident work hours mandates on trauma and emergency experience and work effort for senior residents and faculty.* Journal of Trauma-Injury Infection & Critical Care, 2005. **58**(4): p. 758-61; discussion 761-2.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 426
(A-08)

Introduced by: Resident and Fellow Section

Subject: Pediatric Suspected Intentional Trauma

Referred to: Reference Committee D

Whereas, More than 6,000,000 children were reported as maltreated and 899,000 were confirmed victims by child protective services in 2005,[1] and

Whereas, 62.8 percent of victims experienced neglect, 16.6 percent were physically abused, 9.3 percent were sexually abused, 7.1 percent were psychologically maltreated, and 2.0 percent were medically neglected,[1] and

Whereas, 1460 children died in 2005 from child abuse,[1] and

Whereas, Recent studies demonstrate that only 50-60% of abuse related deaths are reported making child abuse deaths as the least reported form of fatal maltreatment,[2] and

Whereas, Children who experience maltreatment are at increased risk for adverse health effects and behaviors as adults—including smoking, alcoholism, drug abuse, eating disorders, severe obesity, depression, suicide, sexual promiscuity, and certain chronic diseases,[3,4] and

Whereas, Maltreatment during infancy or early childhood can cause important regions of the brain to form improperly, leading to physical, mental, and emotional problems such as sleep disturbances, panic disorder, and attention-deficit/hyperactivity disorder,[5] and

Whereas, 25% to 30% of infant victims of shaken baby syndrome die from their injuries, and nonfatal consequences of shaken baby syndrome include varying degrees of visual impairment (e.g., blindness), motor impairment (e.g. cerebral palsy) and cognitive impairments,[6] and

Whereas, Victims of child maltreatment who were physically assaulted by caregivers are twice as likely to commit physical assault as adults, [7] and

Whereas, The direct costs (judicial, law enforcement, and health system responses to child maltreatment) are estimated at $24 billion each year. The indirect costs (long-term economic consequences of child maltreatment) exceed an estimated $69 billion annually, [8] and

Whereas, More than 53% of physicians do not report child abuse when they state they have a suspicion for abuse, [9] and

Whereas, Researchers found that 31% of traumatic head injuries were not recognized by the physicians who first evaluated these victims, [10] and

Whereas, Physicians serve on the front lines of detecting and diagnosing child abuse and yet less than 57% of physicians who are mandated reporters receive any training regarding child abuse reporting; therefore be it,[11]

RESOLVED, That our AMA support comprehensive reporting and investigation of all cases of reasonably suspected child abuse and neglect using an inclusive and interdisciplinary method in accordance with state and federal laws; and be it further

RESOLVED, That our AMA support the creation of a national standardized pediatric intentional trauma curriculum for medical students and residents.

Fiscal Note: Staff cost estimated at less than $500 to implement.

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Relevant AMA Policy

H-515.989 Evidence of Standards for Child Sexual Abuse
The AMA continues to support the standardization of evidence in child sexual abuse cases and urges that examination and treatment of child abuse victims be done by a physician. (Res. 78, I-87; Reaffirmed: Sunset Report, I-97)

H-60-990 Child Pornography
The AMA (1) supports reassembling an interdisciplinary panel of experts periodically to continue to address shared concerns and information relevant to the issue of child pornography; (2) encourages and promotes awareness of child pornography issues among physicians; (3) through physicians, encourages parents to use the educational textbook entitled, Sex Talk for a Safe Child; (4) promotes physician awareness of the need for follow-up psychiatric treatment for all victims of child pornography; (5) encourages research on child abuse (including risk factors, psychological and behavioral impact, and treatment efficacy) and dissemination of the findings; (6) wherever possible, encourages international cooperation among medical societies to be alert to and intervene in child pornography activities; and (7) cooperates with other national organizations and federal and local agencies in addressing the problem of child pornography. (BOT Rep. Z, A-88; Reaffirmed: Sunset Report, I-98)

H-60.961 HHS to Require the States to Repeal the Religious Exemption in the Child Abuse and Neglect Prevention Statutes
The AMA will petition the Secretary of HHS to remove the religious exemption in child abuse and neglect cases from the Code of Federal Regulations and to exercise administrative authority to urge state officials to repeal existing child abuse and neglect religious exemption provisions in state statutes, thereby restoring equal protection under the law for all children. (Sub. Res. 219, A-93; Reaffirmed by BOT Rep. 24, A-97)

H-75.991 Requirements or Incentives by Government for the Use of Long-Acting Contraceptives
(1) Involuntary use of long-acting contraceptives because of child abuse raises serious questions about a person's fundamental right to refuse medical treatment, to be free of cruel and unusual punishment, and to procreate. The state's compelling interest in protecting children from abuse may be served by less intrusive means than imposing contraception on parents who have committed child abuse. The needs of children may be better met by providing close supervision of the parents, appropriate treatment and social services, and foster placement care when necessary. There is not sufficient evidence to demonstrate that long-acting contraceptives are an effective social response to the problem of child abuse. Before long-acting contraceptives could be considered as a response to individual cases of child abuse, the issue would need to be addressed by society broadly. Society must be careful about taking shortcuts to save resources when constitutional rights are involved. (2) Serious questions are raised by plea bargains, or negotiations with child welfare authorities, that result in the use of long-acting contraceptives. Such agreements are made in inherently coercive environments that lack procedural safeguards. In addition, cultural and other biases may influence decisions by the state to seek the use of a long-acting contraceptive. (3) If welfare or other government benefits were based on the use of long-acting contraceptive agents, individuals would be required to assume a potentially serious health risk before receiving their benefits. Government benefits should not be made contingent on the acceptance of a health risk. (4) Individuals should not be denied access to effective contraception because of their indigence. Use of long-acting

contraceptives should be covered by Medicaid and other health insurance programs, both public and private. (5) Long-acting contraceptives may be medically contraindicated. Assessing the health risks of long-acting contraceptives is substantially outside the purview of courts and legislatures. (BOT Rep. EE, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmation A-04)

H-60.992 Missing and Exploited Children
To enhance physician involvement with issues related to missing and exploited children, the AMA supports the following statements and activities: (1) Child abductions and runaway behaviors are harmful and emotionally upsetting, divisive, and chaos-producing to victims and their families. Any disappearance of a child constitutes a family crisis with both victims and families at high risk for developing physical and emotional problems. Any child who is the object of a custody dispute is vulnerable to parental snatching, running away and/or being abused. (2) Medical interventions, including family therapy, should occur immediately after a child is reported missing; if the child returns home or is found dead, physicians and other health care professionals should continue to monitor the victim patient and/or the patient's family. (3) Children abducted by family members or strangers should be considered victims of child abuse and such occurrences should be designated as reportable instances of child abuse under state statutes. (4) Prevention efforts should focus on reducing family stress, combatting alcoholism and drug abuse, dealing with poor marital relationships including divorce mediation and counseling, and providing supportive services for families at risk. (5) All shelter services that are presently available to runaways and homeless youths should contain a high quality health care component. Comprehensive standards of health care should be developed for the national network of runaway centers. Physicians should be consultants to and work with governing boards of these agencies. (6) Children's medical records should be intelligible and include a complete medical history, distinguishing physical characteristics and detailed information, as outlined in the Child Identification Form developed by the AMA. The AMA encourages physicians to utilize this form in their practice settings. Pediatricians and family physicians should encourage parents to arrange for the speedy transfer of the child's previous medical records and physicians should respond promptly to such requests. The parent's refusal to comply with this request should warrant further questioning of the parents or a report of a possible missing child. (7) At prevention, diagnostic and treatment levels, physicians should attempt to identify troubled children and their families early and ensure that appropriate treatment takes place or that referrals are made to the other medical specialists or community resources. (8) The primary care physician, medical examiner and dentist are key members of the missing child identification team, and should be knowledgeable about the steps to be taken (completing the NCIC forms) immediately after a child is reported missing. (9) Physicians should actively promote the practice of obtaining clear and readable fingerprints and footprints as a technically useful way to document these unique physical characteristics of children. (10) State medical societies should consider establishing committees on child abuse and neglect, with the topic of missing and exploited children included in the charge of responsibilities. (11) The AMA supports continued research on abducted children (both parent and stranger abductions), runaways, homeless youth and their families, and how physicians can help them. (12) All levels of medical education should emphasize the diagnosis, comprehensive treatment and prevention of problems associated with families that suffer from stress and that may be related to problems of alcoholism, drug abuse, domestic violence and marital dysfunction. Educational programs should address the reactions of physicians to these complex and frustrating social problems. (13) The AMA supports cooperating with the American Academy of Pediatrics, the American Psychiatric Association, the American College of Obstetricians and Gynecologists, and the College of American Pathologists in developing and disseminating information about the health care needs of missing children and effective prevention strategies. (14) The AMA supports cooperating with the American Bar Association, the American Psychiatric Association, law enforcement agencies and the National Center for Missing and Exploited Children in

considering the problem of identifying and tracking perpetrators of child abductions. (BOT Rep. O, A-86; Reaffirmed: Sunset Report, I-96; Reaffirmed and Modified: CSAPH Rep. 3, A-06)

H-245.984 Treatment Decisions for Seriously Ill Newborns
Physicians should play an active role in advocating for changes in the Child Abuse Prevention Act as well as state laws that require physicians to violate the ethical guidelines stated in E-2.215 (Treatment Decisions for Seriously Ill Newborns). (CEJA Rep. I, A-92; Modified and Reaffirmed: CEJA Rep. 1, A-03)

H-515.988 Repeal of Religious Exemptions in Child Abuse and medical Practice statutes
Our AMA (1) reaffirms existing policy supporting repeal of the religious exemption from state child abuse statutes; (2) recognizes that constitutional barriers may exist with regard to elimination of the religious exemption from state medical practice acts; and (3) encourages state medical associations that are aware of problems with respect to spiritual healing practitioners in their areas to investigate such situations and pursue all solutions, including legislation where appropriate, to address such matters. (BOT Rep. H, A-90; Reaffirmed: Sunset Report, I-00)

H-515.983 Physicians and Family Violence
Ethical Considerations: (1) The medical profession must demonstrate a greater commitment to ending family violence and helping its victims. Physicians must play an active role in advocating increased services for victims and abusers. Protective services for abused children and elders need to be better funded and staffed, and follow-up services should be expanded. Shelters and safe homes for battered women and their children must be expanded and better funded. Mechanisms to coordinate the range of services, such as legal aid, employment services, welfare assistance, day care, and counseling, should be established in every community. Mandatory arrest of abusers and greater enforcement of protection orders are important law enforcement reforms that should be expanded to more communities. There should be more research into the effectiveness of rehabilitation and prevention programs for abusers.
(2) Informed consent for interventions should be obtained from competent victims of abuse. For minors who are not deemed mature enough to give informed consent, consent for emergency interventions need not be obtained from their parents. Physicians can obtain authorization for further interventions from a court order or a court-appointed guardian. (3) Physicians should inform parents of a child-abuse diagnosis and they should inform an elderly patient's representative when the patient clearly does not possess the capacity to make health care decisions. The safety of the child or elderly person must be ensured prior to disclosing the diagnosis when the parents or caretakers are potentially responsible for the abuse. For competent adult victims physicians must not disclose an abuse diagnosis to caregivers, spouses, or any other third party without the consent of the patient. (CEJA Rep. B, I-91; Reaffirmed: CSA Rep. 7, I-00; Modified and Reaffirmed: CEJA Rep. 1, A-03)

H-525.980 Expansion of AMA Policy on Female Genital Mutilation
The AMA (1) condemns the practice of female genital mutilation (FGM); (2) considers FGM a form of child abuse; (3) supports legislation to eliminate the performance of female genital mutilation in the United States and to protect young girls and women at risk of undergoing the procedure; and (4) supports that physicians who are requested to perform female genital mutilation on a patient provide culturally sensitive counseling to educate the patient and her family members about the negative health consequences of the procedure, and discourage them from having the procedure performed. Where possible, physicians should refer the patient to social support groups that can help them cope with changing societal mores. (CSA Rep. 5, I-94; Res. 513, A-96; Reaffirmed: CSAPH Rep. 3, A-06)

D-60.982 Long Term Effects of Early Abuse/Neglect on Brain Development

Our AMA will: (1) work with national organizations, e.g., American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, American College of Obstetricians and Gynecologists, and others involved with early brain research, child abuse and neglect and public education to make educational materials available to hospital infant and pediatric personnel, physicians, parents, other child care providers and educators and the public at large; (2) urge state and local medical societies to work with their legislators to put in place educational, and where appropriate, support programs for those involved with infants and young children, i.e., parents, students in junior and senior high school, child care providers, and early childhood educators; and (3) work with the federal government and pertinent agencies to make this issue--prevention of early abuse and brain damage with its devastating long term effects for individuals and society--a priority of our nation. (BOT Action in response to referred for decision Res. 526, A-02)

D-515-993 Support for Legislative Action and Improved Research on the Health Response to Violence and Abuse

Our AMA, in conjunction with other members of the Federation and the National Advisory Council on Violence and Abuse will: (1) identify and actively support state and federal legislative proposals designed to increase scientific knowledge, promote public and professional awareness, enhance recognition and ensure access to appropriate medical services for patients who have experienced violence and/or abuse; (2) actively support legislation and congressional authorizations designed to increase the nation's health care infrastructure addressing violence and abuse including proposals like the Health CARES (Child Abuse Research, Education and Services) Network; (3) actively support expanded funding for research on the primary prevention of violence and abuse, the cost of violence and abuse to the health care system, and the efficacy of interventions and methods utilized in the identification and treatment of victims of violence and abuse; (4) actively study the best practices in diagnosis and management of family violence (including an analysis of studies not reviewed in the recent US Preventive Services Task Force Recommendations on Screening for Family Violence) and present a report that identifies future research and practice recommendations; and (5) invite a Federation-wide task force to review and promote the best practices in the identification, management and prevention of family violence. (Res. 438, A-04)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 612
(A-08)

Introduced by: Resident and Fellow Section

Subject: Accuracy of Internet Physician Profiles

Referred to: Reference Committee A

Whereas, Various internet sites such as WebMD, VIMO and HealthGrades provide physician provider information such as education/training, practice type, location, board certification status, and disciplinary actions [1]; and

Whereas, Information provided in internet physician profiles is often obtained from third party sources and may contain erroneous information such as inaccurate listing of specialty or practice location, and these sites do not claim accuracy of the provided information [2, 3, 4]; and

Whereas, Physicians are not always notified that their provider information is being posted or provided open access to their full information profile, and may even be required to pay to see their full profile, and there is no mechanism for oversight of the physician profile information; and

Whereas, Patients are increasingly using the internet to review the credentials of their physicians [5], and may receive misinformation from these internet sites, therefore be it

RESOLVED, That the AMA investigate the publication of physician information on internet websites; and be it further

RESOLVED, That the AMA investigate potential solutions to erroneous physician information contained on Internet websites with report back at I-08.

Fiscal Note: Implement accordingly at estimated staff cost of $4,752.

References

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2. WebMD Legal disclaimer: "WebMD, its licensors, and its suppliers make no representations or warranties about the following: The accuracy, reliability, completeness, currentness, or timeliness of the Content, software, text, graphics, links, or communications provided on or through the use of the WebMD Site or WebMD" Accessed March 2, 2008 from http://www.webmd.com/policies/about-terms-and-conditions-of-use#part4.
3. VIMO legal disclaimer: "Vimo gathers data from a variety of different sources, public and private. While we strive to provide the most accurate, up-to-date information possible, we can't guarantee that our listings are completely without error" accessed March 2, 2008 from http://www.vimo.com/html/copyright.php.
4. HealthGrades legal disclaimer "HealthGrades obtains its information from sources it believes to be reliable. However, because of the possibility of human and mechanical error as well as other factors, HealthGrades makes no representations or warranties, express or implied, as to the accuracy or

timeliness of its information, and cannot be responsible or liable for any errors or omissions in its information or the results obtained from the use of such information." Accessed March 2, 2008 from http://www.healthgrades.com/consumer/index.cfm?fuseaction=modnw&modtype=content&modact=legal_disclaimer&tv_eng=home&tv=home.

5. Kaiser Family Foundation *Online Health Information Poised to Become Important Resource For Seniors, But Not There Yet* (January 12, 2005). Accessed March 2, 2008 from http://www.kff.org/entmedia/entmedia011205nr.cfm.

Relevant AMA Policy

H-406.996 Use and Release of Physician-Specific Health Care Data
(1) Our AMA advocates that third party payers, government entities and others that use and release physician-specific health care data adhere to the following principles: (a) Physicians under review and relevant physician organizations shall be provided with an adequate opportunity to review and respond to proposed physician-specific health care data interpretations and disclosures prior to their publication or release. (b) Effective safeguards to protect against the dissemination of inconsistent, incomplete, invalid, inaccurate or subjective physician-specific health care data shall be established. (c) Reliable administrative, technical, and physical safeguards to prevent the unauthorized use or disclosure of physician-specific health care data shall be developed. (d) Such safeguards shall treat all underlying physician-specific health care data and all analyses, proceedings, records, and minutes from quality review activities on physician-specific health care data as confidential, and provide that none of these documents shall be subject to discovery, or admitted into evidence in any judicial or administrative proceeding. (2) Our AMA supports release of severity-adjusted physician-specific health care data from carefully selected pilot projects where the data may be deemed accurate, reliable, and meaningful to physicians, consumers, and purchaser; (3) Our AMA urges that any published physician-specific health care data be limited to appropriate data concerning the quality of health care, access to health care, and the cost of health care; (4) Our AMA opposes the publication of physician-specific health care data collected outside of carefully selected pilot studies or where the data are not deemed accurate, reliable, or meaningful; (5) Our AMA urges that a copy of the information in any such profile be forwarded to the subject physician, and that the physician be given the right to review and certify adequacy of the information prior to any profile being distributed, including being placed on the Internet; and (6) Our AMA urges that the costs associated with creation of any such profiling system should not be paid for by physicians licensure fees. (BOT Rep. Q, I-92; BOT Rep. W, A-92; Reaffirmed: Res. 719, A-93; CMS Rep. 10, A-96; Appended: Res. 316, I-97; Reaffirmation A-01; Reaffirmation A-02; Reaffirmation A-05; Reaffirmed in lieu of Res. 724, A-05)

E-5.027 Use of Health-Related Online Sites
As Internet prevalence and access rapidly increases, individuals turn to the Internet to find health-related information quickly and efficiently. Online users can access innumerable informational or interactive online sites, many of which are maintained by physicians or rely on their services. Physician involvement should be guided by the following considerations: (1) Physicians responsible for the health-related content of an online site should ensure that the information is accurate, timely, reliable, and scientifically sound, and includes appropriate scientific references. (2) The provision of diagnostic or therapeutic services through interactive online sites, including advice to online users with whom the physician does not have a pre-existing relationship or the use of decision-support programs that generate personalized information directly transmitted to users, should be consistent with general and specialty-specific standards. General standards include truthfulness, protection of privacy, principles of informed consent, and disclosures such as limitations inherent in the technology. (3) When participating in interactive online sites that offer email communication, physicians should follow

guidelines established in Opinion 5.026, "The Use of Electronic Mail." (4) Physicians who establish or are involved in health-related online sites must minimize conflicts of interest and commercial biases. This can be achieved through safeguards for disclosure and honesty in funding and advertising. It also requires that physicians not place commercial interests ahead of patient health; therefore, physicians must not use health-related online sites to promote unnecessary services, refer patients to entities in which they have ownership interests, or sell products outside of established ethical guidelines. (See Opinions 2.19, "Unnecessary Services;" 8.032, "Conflicts of Interest: Health Facility Ownership by a Physician;" 8.062, "Sale of Non-Health-Related Goods from Physicians' Offices;" and 8.063, "Sale of Health-Related Products from Physicians' Offices"). Promotional claims on online sites must conform to Opinion 5.02, "Advertising and Publicity." (5) Physicians who establish or are involved in health-related online sites that use patient-specific information must provide high-level security protections, as well as privacy and confidentiality safeguards. (I, II, IV, V, VI) Issued December 2003 based on the report "Use of Health-Related Online Sites," adopted June 2003, (AJOB 2003; 3(3)).

H-478.999 An International Code of Ethics for Internet Health Sites
Our AMA supports of a universal code of ethics for Internet health sites. (Res. 615, A-00)

H-375.969 Physician Access to Performance Profile Data
AMA policy is that every physician should be given a copy of his/her practice performance profile information at least annually by each organization retaining such physician information. (Res. 827, A-98)

EXHIBIT D

2012 Agenda for the Reference Committee on Advocacy

National Conference of Special Constituencies—Sheraton Kansas City Hotel at Crown Center

Item No.	Resolution Title
1. Resolution No. 1008	Alternative Funding for Primary Care Graduate Medical Education
2. Resolution No. 1009	Stop State Legislators from Practicing Medicine Without a License
3. Resolution No. 1001	Expiration of Expirations
4. Resolution No. 1010	Resolution to Remove Barriers to Long Acting Reversible Contraceptive Devices Use
5. Resolution No. 1002	Anti-Bullying
6. Resolution No.1003	Lesbian, Gay, Bisexual and Transgender (LGBT) Demographic Information
7. Resolution No. 1004	Transgender Care
8. Resolution No. 1005	GLBT Foster Care and Adoption
9. Resolution No. 1006	In Sickness and in Health Equality for all Families

Resolution No. 1008

2012 National Conference of Special Constituencies—Sheraton Kansas City Hotel at Crown Center

Alternative Funding for Primary Care Graduate Medical Education

Submitted by: Lara D. Mashek, MD, Women
Kelly Jones, MD, Women
Rebecca Rodriquez, MD, Women
Allison Smith, MD, Women
Carolyn Forbes, MD, FAAFP, Women
Teresa Lovins, MD, FAAFP, Women
Russell Kohl, MD, FAAFP, GLBT
Ashby Wolfe, MD, MPH, MPP, New Physician
Ravi Grivois-Shah, MD, FAAFP, New Physician

WHEREAS, Over 60 million Americans lack adequate access to primary care due to a shortage of primary care physicians in their communities[1], and

WHEREAS, primarily due to lack of adequate funding, the number of residency positions is limited; and

WHEREAS, major funding for residency training positions comes from Federal and state governments, increases in which are limited due to budgetary constraints, and

WHEREAS, although 56% of patient visits in America are primary care, only 37% of physicians practice primary care medicine[2], and

WHEREAS, the American Academy of Family Physicians (AAFP) already supports encouraging and recognizing innovation in training that ensures future family physicians will meet the needs of their patients in the context of their communities[3], now, therefore, be it

RESOLVED, That the American Academy of Family Physicians (AAFP) work diligently with government and private entities to create alternative funding opportunities to help stabilize current primary care residency training positions and develop additional positions to address the critical shortage of primary care physicians in our country.

1. National Association of Community Health Centers http://www.nachc.com/client/documents/pressreleases/PrimaryCareAccessRPT.pdf accessed May 3, 2012
2. Halsey, A. June 20, 2009. Washington Post. http://www.washingtonpost.com/wp-dyn/content/article/2009/06/19/AR2009061903583_pf.html accessed May 3, 2012
3. AAFP Family Physicians Workforce and Residency Education (2009 COD) http://www.aafp.org/online/en/home/policy/policies/f/roleprod.html accessed on May 3, 2012

Resolution No. 1009

2012 National Conference of Special Constituencies—Sheraton Kansas City Hotel at Crown Center

Stop State Legislators from Practicing Medicine Without a License

Submitted by: Andrea Angelucci, DO, General Registrant
Cathleen London, MD, Women
Susan Hadley, MD, Women
Joanna Bisgrove, MD, New Physician
Tina Tanner, MD, Women

WHEREAS, The American Academy of Family Physicians (AAFP) states that, "Quality healthcare in family medicine is the achievement of optimal physical and mental health through accessible, safe, cost-effective care that is based on best evidence, responsive to the needs and preferences of patients and populations, and respectful of patients' families, personal values, and beliefs,"[1] and "supports the use of evidence-based and explicitly stated clinical practice guidelines" that are "developed using rigorous evidence-based methodology," [2] and

WHEREAS, family physicians undergo over 20,000 hours of clinical training before being permitted to practice independently[3] while state and federal legislators are not required to undergo any medical training or licensure, and

WHEREAS, recent legislation mandated that physicians give patients inaccurate medical information and inappropriately interfered with medical practice increasing cost without medical benefit in a time of escalating health care expenditures [4,5,6,7,8,9,10,11,12,] and

WHEREAS, under H.R. 358, dubbed the "Protect Life Act[13]" hospitals could refuse to care for a pregnant woman with a life-threatening complication, and

WHEREAS, although the above examples pertain to abortion care, a politically charged issue, they open the door for inappropriate legislation of other controversial aspects of the physician-patient relationship, and

WHEREAS, the AAFP "opposes legislation that infringes on the matter or breadth of information exchanged within the patient-physician relationship because of the potential harm it can cause to the health of the individual, family and community," and states that, "Physicians should be free to have open and honest communication with patients about all aspects of health and safety[14]," and

WHEREAS, the American Medical Association (AMA) "vigorously and actively defends the physician-patient-family relationship and actively opposes state and/or federal efforts to interfere in the content of communication in clinical care delivery between clinicians and patients," and "strongly condemns any interference by government or other third parties that compromise a physician's ability to use his or her medical judgment as to the information or treatment that is in the best interest of their patients[15]," now, therefore, be it

RESOLVED, That the American Academy of Family Physicians (AAFP) oppose interference by government or other third parties that compromise a physician's ability to use his or her medical judgment as to the information or treatment that is in the best interest of their patients, and be it further

RESOLVED, That the American Academy of Family Physicians (AAFP) condemn newly enacted federal laws that restrict the privacy of physician-patient-family relationships and/or that violate the First Amendment rights of physicians in their practice of the art and science of medicine, and be it further

RESOLVED, That the American Academy of Family Physicians (AAFP) send letters to all members of the Senate discouraging passage of H.R. 358, dubbed the "Protect Life Act" and be it further

RESOLVED, That the American Academy of Family Physicians (AAFP) provide constituent chapters with information regarding the potential for state legislation to restrict the privacy of physician-patient-family relationships and/or state legislation that violates the First Amendment rights of physicians in their practice of the art and science of medicine, and offer model language such as: The right to practice within the scope of a medical license supersedes any existing or future legislative act.

1. American Academy of Family Physicians. (2000) (2011 COD) "Quality Healthcare in Family Medicine." http://www.aafp.org/online/en/home/policy/policies/f/qualcare.html
2. AAFP Statement of Policy on Clinical Practice Guidelines. 1994, updated 2008 http://www.aafp.org/online/en/home/policy/policies/c/clinicalpractguidelines.html
3. American Academy of Family Physicians. "Family Physician and Nurse Practitioner Training." http://www.aafp.org/online/etc/medialib/aafp_org/documents/press/nurse-practicioners/np-training.Par.0001.File.tmp/NP_Info_FP-NPTraining-Compare-4pgs.pdf
4. Guttmacher Institute. "State Policies in Brief: An overview of abortion laws." 5/1/2012. http://www.guttmacher.org/statecenter/spibs/spib_OAL.pdf
5. National Cancer Institute." Fact Sheet: Abortion, Miscarriage, and Breast Cancer Risk." http://www.cancer.gov/cancertopics/factsheet/Risk/abortion-miscarriage
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8. Guttmacher Institute. "State Policies in Brief: Requirements for ultrasound." 5/1/2012. http://www.guttmacher.org/statecenter/spibs/spib_RFU.pdf
9. Clark W et al. "Medication abortion employing routine sequential measurements of serum hCG and sonography only when indicated." Contraception. 2007 Feb;75(2):131-5. http://www.ncbi.nlm.nih.gov/pubmed/17241843
10. Guttmacher Institute. "State Policies in Brief: Counseling and waiting periods for abortion." 5/1/2012. http://www.guttmacher.org/statecenter/spibs/spib_MWPA.pdf
11. Guttmacher Institute. "State Policies in Brief: State policies on later abortions." 5/1/2012. http://www.guttmacher.org/statecenter/spibs/spib_PLTA.pdf
12. Ibid.
13. http://www.govtrack.us/congress/bills/112/hr358

14. American Academy of Family Physicians. (2011 COD) “Infringement on Patient Physician Relationship.” http://www.aafp.org/online/en/home/policy/policies/i/infringementonpatphyrelat.html
15. American Medical Association. “Government Interference in Patient Counseling.” H-373.995. https://ssl3.ama-assn.org/apps/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-373.995.HTM

Resolution No. 1001

2012 National Conference of Special Constituencies—Sheraton Kansas City Hotel at Crown Center

Expiration of Expirations

Submitted by: Nkiruka Udejiofor, MD, New Physicians
Jody R. George, MD, New Physicians
Mary Krebs, MD, New Physicians

WHEREAS, Factors that lead to prescription prior authorization triggers on maintenance medications are not likely to change, and

WHEREAS, requiring repeated renewal of previously approved prior authorization of maintenance medications raises costs in staff time, decreases efficiency, and wastes resources in patient care, and

WHEREAS, insurance companies often have different procedures for previously approved prior authorization requests that change yearly, now, therefore, be it

RESOLVED, That the American Academy of Family Physicians (AAFP) advocate through its resources, including government advocacy, corporate relations or other means, to work toward the elimination of expiration dates of previously approved authorizations of maintenance medications.

Resolution No. 1010

2012 National Conference of Special Constituencies—Sheraton Kansas City Hotel at Crown Center

Resolution to Remove Barriers to Long Acting Reversible Contraceptive Devices Use

Submitted by: Andrea Angelucci, DO, New Physician
Cathleen London, MD, Women
Susan Hadley, MD, Women
Joanna Bisgrove, MD, New Physician
Susan Saucedo, MD, General Registrant

WHEREAS, Reproductive health care is part of comprehensive primary care and the American Academy of Family Physicians (AAFP) "is concerned about the sexual health of adults[1]," and

WHEREAS, the AAFP Policy on Reproductive Decisions states, "physicians should seek to, through extensive patient education and counseling, decrease the number of unwanted pregnancies," [2] but the disparity in unintended pregnancy in low income women increased by 29% between 1994 and 2001, and

WHEREAS, long acting reversible contraceptive devices are a cost-effective contraceptive method with a significant upfront cost[2,3], and

WHEREAS, copper and hormonal intra uterine devices (IUDs) were the most cost-effective reversible methods, with an estimated five-year cost of $647 and $930, respectively, and Implanon costs $650 -$700.

WHEREAS, oral contraceptives have an estimated total cost of $3,381 over a 5-year period[4], and

WHEREAS, there exists numerous recognized barriers to long acting reversible contraceptive devices use, including lack of clinician knowledge or skill,[5,6] low patient awareness of the method[7] and high upfront costs[8,9], and

WHEREAS, Gariepy (2011) found that 43% of women had no coverage for IUDs and that high out-of-pocket expense was highly associated with failure to obtain an IUD, with non-white women facing greater out-of pocket expense than white women[10] and whereas other research has shown that cost concerns are an important factor in contraceptive method choice and use[11], and

WHEREAS, unlike other medications or devices that usually decrease in cost the longer they are on the market, the cost of IUDs has been increasing. In March of 2010, the average wholesale price of the levonorgestrel IUD in the United States increased 43%, from $586 to $843[12], now, therefore, be it

RESOLVED, That the American Academy of Family Physicians (AAFP) reaffirm the Patient Protection and Affordable Care Act support of no out-of-pocket cost for any contraception and advocate for improved insurance coverage of IUDs, including adequate provider reimbursement

with regard to the current cost of the devices, and reduced out-of-pocket expenses for patients, thus reducing barriers to Intra Uterine Device (IUD) use as a first-line option for most women, and be it further

RESOLVED, That the American Academy of Family Physicians (AAFP) endorse increased resident and continuing medical education (CME) education on the use of intra uterine devices (IUDs).

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Resolution No. 1002

2012 National Conference of Special Constituencies—Sheraton Kansas City Hotel at Crown Center

Anti-Bullying

Submitted by: Luis Otero Jr., MD, FAAFP, GLBT
Sarah Balfour, MD, GLBT
Laura Jordhen, MD, GLBT
David Hoelting, MD, GLBT
Jeffrey Meiring, DO, GLBT
Benjamin Simmons, MD, GLBT
Beena Nagappala, MD, Minority
Theresa (Tess) Garcia, MD, Minority
Doreen Feldhouse, MD, FAAFP, Women
Jose Tiburcio, MD, Minority
Lori Carnsew, MD, FAAFP, Women
Kerry Pulliam, MD, New Physicians
Lara Mashek, MD, Women
S. Gail Martin, MD, Minority
Joanna T. Bisgrove, MD, New Physicians
Carolyn Forbes, MD, FAAFP, Women

WHEREAS, Bullying is a significant problem, with an estimation by the Centers for Disease Control and Prevention to be as high as 20% among high school students, and

WHEREAS, the public awareness of bullying has increased with the advent of the Internet and social media, and

WHEREAS, cyber bullying is being recognized as an increasing problem, and

WHEREAS, bullying can lead to serious academic, social, legal and emotional problems including suicide, now, therefore, be it

RESOLVED, That the American Academy of Family Physicians (AAFP) update the bullying policy to state: “Harassment and bullying in the school setting, on or off campus, including online forums, for reasons including, but not limited to ethnicity, socioeconomic status, religion, sexual orientation, gender identity, physical status, or other personal characteristics, have a significant harmful effect on students and should not be tolerated,” and be it further

RESOLVED, That the American Academy of Family Physicians (AAFP) make evidence-based resources to screen for and prevent bullying at patient and community levels available on a single page of the AAFP website and any other suitable venues (eg. Scientific Assembly, AAFP live clinical course, enduring materials).

Resolution No. 1003

2012 National Conference of Special Constituencies—Sheraton Kansas City Hotel at Crown Center

Lesbian, Gay, Bisexual and Transgender (LGBT) Demographic Information

Submitted by: Folashade Omole, MD, FAAFP, GLBT
Keisa Bennett, MD, GLBT

WHEREAS, The American Academy of Family Physicians (AAFP) recognizes a broad and diverse set of families, and

WHEREAS, the AAFP recognizes the importance of lesbian, gay, bisexual, and transgender (LGBT) health needs, now, therefore, be it

RESOLVED, That the American Academy of Family Physicians (AAFP) encourage all electronic health record vendors (EHR) structure demographic identifiers in an open-ended manner so that patients may self-identify both sexual orientation and gender.

Resolution No. 1004

2012 National Conference of Special Constituencies—Sheraton Kansas City Hotel at Crown Center

Transgender Care

Submitted by: Laura Ellis, MD, FAAFP, GLBT
Werner Brammer, MD, FAAFP, GLBT
Bruce Echols, MD, FAAFP, GLBT
Andrew Goodman, MD, GLBT

WHEREAS, Gender Identity Disorder is a medically recognized condition, and

WHEREAS, persons with Gender Identity Disorder who are not provided care can suffer serious psychological and physical issues including suicide, and

WHEREAS, care for Gender Identity Disorder is lifelong and multifaceted including surgical, hormonal, and psychological support and

WHEREAS, this care is expensive and out of reach of many people, and

WHEREAS, many insurers specifically exclude transgender care, and

WHEREAS, the American Academy of Family Physicians (AAFP) has already resolved that employers and health plans should not discriminate by actual or perceived gender in the provision of prescription drugs and devices, elective sterilization procedures, and diagnostic testing (2011 COD), now, therefore, be it

RESOLVED, That the American Academy of Family Physicians (AAFP) support efforts to require insurers to provide coverage for comprehensive care of transgendered individuals including medical care, screening tests based on medical need rather than gender, mental health care, and, when medically necessary, gender reassignment surgery.

Resolution No. 1005

2012 National Conference of Special Constituencies—Sheraton Kansas City Hotel at Crown Center

GLBT Foster Care and Adoption

Submitted by: Bernard Richard, MD, GLBT
Flora Sadri-Azarbayejani, DO, FAAFP, GLBT

WHEREAS, There is need for an increase in foster and adoptive parents, and

WHEREAS, there are over 500,000 children in foster care on any given day in the United States, and

WHEREAS, same gender couples are raising children in at least 96% of all United States counties, and

WHEREAS, 34.3% of lesbian couples and 22.3% of gay male couples are raising children compared with 45.6% of married heterosexual and 43.1% of unmarried heterosexual couples, and

WHEREAS, current AAFP policy on "Family" states that, "The family is a group of individuals with a continuing legal, genetic, and/or emotional relationship. Society relies on the family group to provide for the economic and protective needs of individuals, especially the children and the elderly," and

WHEREAS, the American Academy of Family Physicians (AAFP) Congress of Delegates adopted a policy where the AAFP will "establish policy and be supportive of legislation which promotes a safe and nurturing environment, including psychological and legal security, for all children, including those of adoptive parents, regardless of the parents' sexual orientation," and

WHEREAS, studies have shown there are no changes in outcomes with regards to children who are raised by gay, lesbian, bisexual, and transgender (GLBT) families including their sexual orientation, now, therefore, be it

RESOLVED, That the American Academy of Family Physicians (AAFP) support the allowance of adults to become foster or adoptive parents regardless of sexual orientation, and be it further

RESOLVED, That the American Academy of Family Physicians (AAFP) support legislation or policies allowing same gender couples to co-foster or co-adopt children.

Resolution No. 1006

2012 National Conference of Special Constituencies—Sheraton Kansas City Hotel at Crown Center

In Sickness and in Health Equality for all Families

Submitted by: Bruce Echols, MD, FAAFP, GLBT
Samuel Hanson Willis, MD, GLBT
Carlos Gonzales, MD, FAAFP, GLBT
Susan Pereira, MD, GLBT
Justin Ford, DO, GLBT
Russell Kohl, MD, FAAFP, GLBT
Chandra Hartman, MD, FAAFP, GLBT
Sarah Lamanuzzi, MD, Women
Susan Hadley, MD, Women
Rebecca Rodriguez, MD, Women

WHEREAS, The language of written federal law regarding unions and families, uses the word marriage in over 1,100 legal statutes, and

WHEREAS, the only way to achieve full legal equality for same gender families through our federal legal system is to be married, and

WHEREAS, the 2011 American Academy of Family Physicians (AAFP) Congress of Delegates passed a resolution in support of full legal equality for same-gender families to contribute to overall health and longevity, improved family stability, and to benefit children of Gay, Lesbian, Bisexual and Transgender (GLBT) families, now, therefore, be it

RESOLVED, That the American Academy of Family Physicians (AAFP) support civil marriage for same gender families in accordance with the 2011 Congress of Delegates resolution regarding full legal equality for same gender families.

EXHIBIT E

The American College of Obstetricians and Gynecologists
Women's Health Care Physicians

COMMITTEE OPINION

Number 512 • December 2011

Committee on Health Care for Underserved Women

This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Health Care for Transgender Individuals

ABSTRACT: Transgender individuals face harassment, discrimination, and rejection within our society. Lack of awareness, knowledge, and sensitivity in health care communities eventually leads to inadequate access to, underutilization of, and disparities within the health care system for this population. Although the care for these patients is often managed by a specialty team, obstetrician–gynecologists should be prepared to assist or refer transgender individuals with routine treatment and screening as well as hormonal and surgical therapies. The American College of Obstetricians and Gynecologists opposes discrimination on the basis of gender identity and urges public and private health insurance plans to cover the treatment of gender identity disorder.

The Spectrum of Transgender Identity

Transgender is a broad term used for people whose gender identity or gender expression differs from their assigned sex at birth (Box 1) (1). However, there is no universally accepted definition of the word "transgender" because of the lack of agreement regarding what groups of people are considered "transgender." In addition, definitions often vary by geographic region and by individual (2). The American Psychiatric Association *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, Text Revision, considers transgender individuals to be individuals with a disturbance in sexual or gender identity. Any combination of sexual and gender identity is possible for transgender individuals (Box 2). The diagnosis of gender identity disorder is only established for individuals with clinically significant distress and functional impairment caused by the persistent discomfort with one's assigned sex and primary and secondary sex characteristics. If untreated, gender identity disorder can result in psychologic dysfunction, depression, suicidal ideation, and even death (3).

Prevalence rates of transgender populations are not clearly established; however, studies suggest that transgender individuals constitute a small but substantial population (4). Additional research is needed among this population as outlined by the Institute of Medicine Report, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2).

The social and economic marginalization of transgender individuals is widespread. Harassment, discrimination, and rejection occur frequently within an individual's own family and affect educational, employment, and housing opportunities.

Transgender individuals, particularly young transgender individuals, are disproportionately represented in the homeless population (5). Once homeless, individuals may be denied access to shelters because of their gender or are placed in inappropriate housing. Subsequently, many homeless transgender individuals turn to survival sex (the exchange of sex for food, clothing, shelter, or other basic needs), which increases the risk of exposure to sexually transmitted infections and becoming victims of violence (6). In one small study, 35% of male-to-female transgender individuals tested positive for human immunodeficiency virus (HIV), 20% were homeless, and 37% reported physical abuse (7).

Barriers to Health Care

Within the medical community, transgender individuals face significant barriers to health care. This includes the failure of most health insurance plans to cover the cost of mental health services, cross-sex hormone therapy, or gender affirmation surgery. This barrier exists despite evidence that such treatments are safe and effective and that cross-gender behavior and gender identity issues are not an issue of choice for the individual and cannot be reversed with psychiatric treatment (8). With medical and psychiatric care that affirms transgender identity, the transgender individual can lead an enhanced, functional life (9).

Box 1. Transgender Definitions

Transsexual—an individual who strongly identifies with the other sex and seeks hormones or gender-affirmation surgery or both to feminize or masculinize the body; may live full-time in the crossgender role.*

Crossdresser—an individual who dresses in the clothing of the opposite sex for reasons that include a need to express femininity or masculinity, artistic expression, performance, or erotic pleasure, but do not identify as that gender. The term "transvestite" was previously used to describe a crossdresser, but it is now considered pejorative and should not be used.†

Bigendered—individuals who identify as both or alternatively male and female, as no gender, or as a gender outside the male or female binary.†

Intersex—individuals with a set of congenital variations of the reproductive system that are not considered typical for either male or female. This includes newborns with ambiguous genitalia, a condition that affects 1 in 2,000 newborns in the United States each year.‡

Female-to-male—refers to someone who was identified as female at birth but who identifies and portrays his gender as male. This term is often used after the individual has taken some steps to express his gender as male, or after medically transitioning through hormones or surgery. Also known as FTM or transman.†

Male-to-female—refers to someone who was identified as male at birth but who identifies and portrays her gender as female. This term is often used after the individual has taken some steps to express her gender as female, or after medically transitioning through hormones or surgery. Also known as MTF or transwoman.†

* The health of lesbian, gay, bisexual, and transgender people: building a foundation for better understanding. Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities, Board on the Health of Select Populations, Institute of Medicine of the National Academies. Washington, DC: National Academies Press; 2011. Available at: http://www.nap.edu/openbook.php?record_id=13128&page=R1. Retrieved August 8, 2011.

† Fenway Health. Glossary of gender and transgender terms. Boston (MA): Fenway Health; 2010. Available at: http://www.fenwayhealth.org/site/DocServer/Handout_7-C_Glossary_of_Gender_and_Transgender_Terms__fi.pdf. Retrieved July 22, 2011.

‡ Dreger AD. "Ambiguous sex"--or ambivalent medicine? Ethical issues in the treatment of intersexuality. Hastings Cent Rep 1998; 28:24–35.

Box 2. Sexual Identity and Gender Identity Definitions

Sex—designation of a person at birth as male or female based on anatomy and biology.*

Gender identity—a person's innate identification as a man, woman, or something else that may or may not correspond to the person's external body or assigned sex at birth.*

Gender expression—how individuals present themselves socially, including clothing, hairstyle, jewelry, and physical characteristics, including speech and mannerisms. This may not be the same gender in all settings.*

Sexual orientation—a person's physical, romantic, emotional, and/or spiritual attraction to individuals of the same (lesbian or gay), different (heterosexual), or both (bisexual) biologic sexes. Sexual orientation does not define the real-life sexual practices and behaviors of an individual.*

Sexual behavior—the sexual encounters and behaviors of the individual. This is likely to be the most important factor in assessing the risk of sexually transmitted infections. Sexual behavior differs from sexual orientation; for example, not all individuals who engage in same-sex behaviors view themselves as gay, lesbian, or bisexual.

Legal sex—sex as stated on legal identifications, forms, and documents. Transgender individuals may adopt a second name other than their legal name with which they may prefer to be addressed. Transgender persons should be asked for their preferred name, even if it differs from their legal name and sex. State regulations vary and it may be difficult or impossible for a transgender individual to meet that state's requirements to change their legal sex.†

* Fenway Health. Glossary of gender and transgender terms. Boston (MA): Fenway Health; 2010. Available at: http://www.fenwayhealth.org/site/DocServer/Handout_7-C_Glossary_of_Gender_and_Transgender_Terms__fi.pdf. Retrieved July 22, 2011.

† This is a significant issue for transgender individuals. Some states have adopted progressive laws that do not require gender-affirmation surgery or an original birth certificate; instead, these laws allow individuals to change their legal sex with a letter from their health care providers stating that the individuals live their lives as this gender. See the National Center for Transgender Equality (www.transequality.org) and the Transgender Law and Policy Institute (www.transgenderlaw.org) for more information, including descriptions of state laws.

The consequences of inadequate treatment are staggering. Fifty-four percent of transgender youth have attempted suicide and 21% resort to self-mutilation. More than 50% of persons identified as transgender have used injected hormones that were obtained illegally or used outside of conventional medical settings. Additionally, such individuals frequently resort to the illegal and dangerous use of self-administered silicone injections to spur masculine or feminine physiologic changes (5). The American College of Obstetricians and Gynecologists, therefore, urges public and private health insurance plans to cover the treatment of gender identity disorder.

Caring for Transgender Individuals

Obstetrician–gynecologists should be prepared to assist or refer transgender individuals for routine treatment

and screening as well as hormonal and surgical therapies. Basic preventive services, like sexually transmitted infection testing and cancer screening, can be provided without specific expertise in transgender care. Hormonal and surgical therapies for transgender patients may be requested, but should be managed in consultation with health care providers with expertise in specialized care and treatment of transgender patients (see Resources). Physical and emotional issues for transgender individuals and the effects of aging, as in all other individuals, affect the health status of this population and should be addressed. Health care providers who are morally opposed to providing care to this population should refer them elsewhere for care. For more information, a resource guide on health care for transgender individuals is available at www.acog.org/departments/dept_notice.cfm?recno=18&bulletin=5825.

Creating a Welcoming Environment

Health care providers' discomfort when treating transgender individuals may alienate patients and result in lower quality or inappropriate care as well as deter them from seeking future medical care (10). Excellent resources exist to facilitate the provision of culturally competent care for transgender patients (10). Adding a "transgender" option to check boxes on patient visit records can help to better capture information about transgender patients, and could be a sign of acceptance to that person (10). Questions should be framed in ways that do not make assumptions about gender identity, sexual orientation, or behavior. It is more appropriate for clinicians to ask their patients which terms they prefer (1). Language should be inclusive, allowing the patient to decide when and what to disclose. The adoption and posting of a nondiscrimination policy can also signal health care providers and patients alike that all persons will be treated with dignity and respect. Assurance of confidentiality can allow for a more open discussion, and confidentiality must be ensured if a patient is being referred to a different health care provider. Training staff to increase their knowledge and sensitivity toward transgender patients will also help facilitate a positive experience for the patient (10). It is important to prepare now to treat a future transgender patient. Additional guidelines for creating a welcoming office environment for transgender patients have been developed by the Gay and Lesbian Medical Association and can be found at http://www.glma.org/_data/n_0001/resources/live/GLMA%20guidelines%202006%20FINAL.pdf.

Gender Transition: World Professional Association for Transgender Health Guidelines

The World Professional Association for Transgender Health is a multidisciplinary professional society representing the specialties of medicine, psychology, social sciences, and law. Their published clinical guidelines about the psychiatric, psychologic, medical, and surgical management of gender identity disorders are widely used by specialists in transgender health care (11), but are not universally accepted by all members of the transgender health community because critics consider them to be overly restrictive and inflexible.

The World Professional Association for Transgender Health guidelines describe the transition from one gender to another in three stages: 1) living in the gender role consistent with gender identity; 2) the use of cross-sex hormone therapy after living in the new gender role for at least 3 months; 3) gender-affirmation surgery after living in the new gender role and using hormonal therapy for at least 12 months. Additional clinical guidelines have been published by the Endocrine Society (12).

Female-to-Male Transgender Individuals

Hormones

Methyltestosterone injections every 2 weeks are usually sufficient to suppress menses and induce masculine secondary sex characteristics (13). Before receiving androgen therapy, patients should be screened for medical contraindications and have periodic laboratory testing, including hemoglobin and hematocrit to evaluate for polycythemia, liver function tests, and serum testosterone level assessments (goal is a mid normal male range of 500 microgram/dL), while receiving the treatment.

Surgery

Hysterectomy, with or without salpingo-oophorectomy, is commonly part of the surgical process. An obstetrician–gynecologist who has no specialized expertise in transgender care may be asked to perform this surgery, and also may be consulted for routine reasons such as dysfunctional bleeding or pelvic pain. Reconstructive surgery should be performed by a urologist, gynecologist, plastic surgeon, or general surgeon who has specialized competence and training in this field.

Screening

Age-appropriate screening for breast cancer and cervical cancer should be continued unless mastectomy or removal of the cervix has occurred. For patients using androgen therapy who have not had a complete hysterectomy, there may be an increased risk of endometrial cancer and ovarian cancer (13).

Male-to-Female Transgender Individuals

Hormones

Estrogen therapy results in gynecomastia, reduced hair growth, redistribution of fat, and reduced testicular volume. All patients considering therapy should be screened for medical contraindications. After surgery, doses of estradiol, 2–4 mg/d, or conjugated equine estrogen, 2.5 mg/d, are often sufficient to keep total testosterone levels to normal female levels of less than 25 ng/dL. Nonoral therapy

also can be offered. It is recommended that male-to-female transgender patients receiving estrogen therapy have an annual prolactin level assessment and visual field examination to screen for prolactinoma (13).

Surgery

Surgery usually involves penile and testicular excision and the creation of a neovagina (14). Reported complications of surgery include vaginal and urethral stenosis, fistula formation, problems with remnants of erectile tissue, and pain. Vaginal dilation of the neovagina is required to maintain patency. Other surgical procedures that may be performed include breast implants and nongenital surgery, such as facial feminization surgery.

Screening

Age-appropriate screening for breast and prostate cancer is appropriate for male-to-female transgender patients. Opinion varies regarding the need for Pap testing in this population. In patients who have a neocervix created from the glans penis, routine cytologic examination of the neocervix may be indicated (15). The glans are more prone to cancerous changes than the skin of the penile shaft, and intraepithelial neoplasia of the glans is more likely to progress to invasive carcinoma than is intraepithelial neoplasia of other penile skin (14).

Conclusion

Obstetrician–gynecologists should be prepared to assist or refer transgender individuals. Physicians are urged to eliminate barriers to access to care for this population through their own individual efforts. An important step is to identify the sexual orientation and gender identity status of all patients as a routine part of clinical encounters and recognize that many transgender individuals may not identify themselves. The American College of Obstetricians and Gynecologists urges health care providers to foster nondiscriminatory practices and policies to increase identification and to facilitate quality health care for transgender individuals, both in assisting with the transition if desired as well as providing long-term preventive health care.

Resources

Select clinics with expertise in treating transgender individuals:

Fenway Community Health
www.fenwayhealth.org

University of Minnesota, Center for Sexual Health
www.phs.umn.edu/clinic/home.html

Callen-Lorde Community Health Center
www.callen-lorde.org

Tom Waddell Health Center
www.sfdph.org/dph/comupg/oservices/medSvs/hlthCtrs/TransgenderHlthCtr.asp

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Health care for transgender individuals. Committee Opinion No. 512. American College of Obstetricians and Gynecologists. Obstet Gynecol 2011;118:1454–8.

EXHIBIT F

Position Statement on Access to Care for Transgender and Gender Variant Individuals

Approved by the Board of Trustees, July 2012
Approved by the Assembly, May 2012

"Policy documents are approved by the APA Assembly and Board of Trustees…These are…position statements that define APA official policy on specific subjects…" – *APA Operations Manual*.

Issue: Significant and long-standing medical and psychiatric literature exists that demonstrates clear benefits of medical and surgical interventions to assist gender variant individuals seeking transition. However, private and public insurers often do not offer, or may specifically exclude, coverage for medically necessary treatments for gender transition. Access to medical care (both medical and surgical) positively impacts the mental health of transgender and gender variant individuals.

The APA's vision statement includes the phrase: "Its vision is a society that has available, accessible quality psychiatric diagnosis and treatment," yet currently, transgender and gender variant individuals frequently lack available and accessible treatment. In addition, APA's values include the following points:

- best standards of clinical practice
- patient-focused treatment decisions
- scientifically established principles of treatment
- advocacy for patients

Transgender and gender variant individuals currently lack access to the best standards of clinical practice, frequently do not have the opportunity to pursue patient-focused treatment decisions, do not receive scientifically established treatment and could benefit significantly from APA's advocacy.

APA Position:

Therefore, the American Psychiatric Association:

1. **Recognizes that appropriately evaluated transgender and gender variant individuals can benefit greatly from medical and surgical gender transition treatments.**
2. **Advocates for removal of barriers to care and supports both public and private health insurance coverage for gender transition treatment.**
3. **Opposes categorical exclusions of coverage for such medically necessary treatment when prescribed by a physician.**

Authors: Jack Drescher, M.D., Ellen Haller, M.D., APA Caucus of Lesbian, Gay and Bisexual Psychiatrists.

Background to the Position Statement

Transgender and gender variant people are frequently denied medical, surgical and psychiatric care related to gender transition despite significant evidence that appropriately evaluated individuals benefit from such care. It is often asserted that the DSM (and ICD) diagnoses provide the only pathways to insurance reimbursement for transgender individuals seeking medical assistance. However, to date, the APA has issued no treatment guidelines for gender identity disorder (GID) in either children or adults. This omission is in contrast to an increasing proliferation of APA practice guidelines for other DSM diagnoses (1).

The absence of a formal APA opinion about treatment of a diagnosis of its own creation has contributed to an ongoing problem of many health care insurers and other third party payers claiming that hormonal treatment and sex reassignment surgery (SRS) are "experimental treatments," "elective treatments," or "not medically necessary," and, therefore, not reimbursable or covered under most insurance plans. The lack of consistency in how a transgender condition is defined by some institutions further marginalizes these individuals based on their subjective, surgical and hormonal status (2). In addition, treatment is not always accessible to wards of governmental agencies, such as transgender and gender variant individuals in foster care and prison systems. In other words, the presence of the GID diagnosis in the DSM has not served its intended purpose of creating greater access to care--one of the major arguments for diagnostic retention (1).

Lack of access to care adversely impacts the mental health of transgender and gender variant people, and both hormonal and surgical treatment have been shown to be efficacious in these individuals (3-7). Practice guidelines have been developed based on peer-reviewed scientific studies and are published and available for clinicians to access (3, 8, 9). The American Medical Association and the American Psychological Association both have position statements stating the critical importance of access to care for transgender and gender variant individuals (10, 11).

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EXHIBIT G

AMERICAN PSYCHOLOGICAL ASSOCIATION

Transgender, Gender Identity, & Gender Expression Non-Discrimination

Adopted by the American Psychological Association Council of Representatives August, 2008.

Whereas transgender and gender variant people frequently experience prejudice and discrimination and psychologists can, through their professional actions, address these problems at both an individual and a societal level;

Whereas the American Psychological Association opposes prejudice and discrimination based on demographic characteristics including gender identity, as reflected in policies including the Hate Crimes Resolution (Paige, 2005), the Resolution on Prejudice Stereotypes and Discrimination (Paige, 2007), APA Bylaws (Article III, Section 2), the Ethical Principles of Psychologists and Code of Conduct (APA 2002, 3.01 and Principle E);

Whereas transgender and other gender variant people benefit from treatment with therapists with specialized knowledge of their issues (Lurie, 2005; Rachlin, 2002), and that the Ethical Principles of Psychologists and Code of Conduct state that when scientific or professional knowledge ...is essential for the effective implementation of their services or research, psychologists have or obtain the training....necessary to ensure the competence of their services..." (APA 2002, 2.01b);

Whereas discrimination and prejudice against people based on their actual or perceived gender identity or expression detrimentally affects psychological, physical, social, and economic well-being (Bockting et al., 2005; Coan et al., 2005; Clements-Nolle, 2006; Kenagy, 2005; Kenagy & Bostwick, 2005; Nemoto et al., 2005; Resolution on Prejudice Stereotypes and Discrimination, Paige, 2007; Riser et al., 2005; Rodriquez-Madera & Toro-Alfonso, 2005; Sperber et al., 2005; Xavier et al., 2005);

Whereas transgender people may be denied basic non-gender transition related health care (Bockting et al., 2005; Coan et al., 2005; Clements-Nolle, 2006; GLBT Health Access Project, 2000; Kenagy, 2005; Kenagy & Bostwick, 2005; Nemoto et al., 2005; Riser et al., 2005; Rodriquez-Madera & Toro-Alfonso, 2005; Sperber et al., 2005; Xavier et al., 2005);

Whereas gender variant and transgender people may be denied appropriate gender transition related medical and mental health care despite evidence that appropriately evaluated individuals benefit from gender transition treatments (De Cuypere et al., 2005; Kuiper & Cohen-Kettenis, 1988; Lundstrom, et al., 1984; Newfield, et al., 2006; Pfafflin & Junge, 1998; Rehman et al., 1999; Ross & Need, 1989; Smith et al., 2005);

Whereas gender variant and transgender people may be denied basic civil rights and protections (Minter, 2003; Spade, 2003) including: the right to civil marriage which confers a social status and important legal benefits, rights, and privileges (Paige, 2005); the right to obtain appropriate identity documents that are consistent with a post-transition identity; and the right to fair and safe and harassment-free institutional environments such as care facilities, treatment centers, shelters, housing, schools, prisons and juvenile justice programs;

Whereas transgender and gender variant people experience a disproportionate rate of homelessness (Kammerer et al., 2001), unemployment (APA, 2007) and job discrimination (Herbst et al., 2007), disproportionately report income below the poverty line (APA, 2007) and experience other financial disadvantages (Lev, 2004);

Whereas transgender and gender variant people may be at increased risk in institutional environments and facilities for harassment, physical and sexual assault (Edney, 2004; Minter, 2003; Peterson et al., 1996; Witten & Eyler, 2007) and inadequate medical care including denial of gender transition treatments such as hormone therapy (Edney, 2004; Peterson et al., 1996; Bockting et al., 2005; Coan et al., 2005; Clements-Nolle, 2006; Kenagy, 2005; Kenagy & Bostwick, 2005; Nemoto et al., 2005; Newfield et al., 2006; Riser et al., 2005; Rodriquez-Madera &Toro-Alfonso, 2005; Sperber et al., 2005; Xavier et al., 2005);

Whereas many gender variant and transgender children and youth face harassment and violence in school environments, foster care, residential treatment centers, homeless centers and juvenile justice programs (D'Augelli, Grossman, & Starks, 2006; Gay Lesbian and Straight Education Network, 2003; Grossman, D'Augelli, & Slater, 2006);

Whereas psychologists are in a position to influence policies and practices in institutional settings, particularly regarding the implementation of the Standards of Care published by the World Professional Association of Transgender Health (WPATH, formerly known as the Harry Benjamin International Gender Dysphoria Association) which recommend the

continuation of gender transition treatments and especially hormone therapy during incarceration (Meyer et al., 2001);

Whereas psychological research has the potential to inform treatment, service provision, civil rights and approaches to promoting the well-being of transgender and gender variant people;

Whereas APA has a history of successful collaboration with other organizations to meet the needs of particular populations, and organizations outside of APA have useful resources for addressing the needs of transgender and gender variant people;

Therefore be it resolved that APA opposes all public and private discrimination on the basis of actual or perceived gender identity and expression and urges the repeal of discriminatory laws and policies;

Therefore be it further resolved that APA supports the passage of laws and policies protecting the rights, legal benefits, and privileges of people of all gender identities and expressions;

Therefore be it further resolved that APA supports full access to employment, housing, and education regardless of gender identity and expression;

Therefore be it further resolved that APA calls upon psychologists in their professional roles to provide appropriate, nondiscriminatory treatment to transgender and gender variant individuals and encourages psychologists to take a leadership role in working against discrimination towards transgender and gender variant individuals;

Therefore be it further resolved that APA encourages legal and social recognition of transgender individuals consistent with their gender identity and expression, including access to identity documents consistent with their gender identity and expression which do not involuntarily disclose their status as transgender for transgender people who permanently socially transition to another gender role;

Therefore be it further resolved that APA supports access to civil marriage and all its attendant benefits, rights, privileges and responsibilities, regardless of gender identity or expression;

Therefore be it further resolved that APA supports efforts to provide fair and safe environments for gender variant and transgender people in institutional settings such as supportive living environments, long-term care facilities, nursing homes, treatment facilities, and shelters, as well as custodial settings such as prisons and jails;

Therefore be it further resolved that APA supports efforts to provide safe and secure educational environments, at all levels of education, as well as foster care environments and juvenile justice programs, that promote an understanding and acceptance of self and in which all youths, including youth of all gender identities and expressions, may be free from discrimination, harassment, violence, and abuse;

Therefore be it further resolved that APA supports the provision of adequate and necessary mental and medical health care treatment for transgender and gender variant individuals;

Therefore be it further resolved that APA recognizes the efficacy, benefit and medical necessity of gender transition treatments for appropriately evaluated individuals and calls upon public and private insurers to cover these medically necessary treatments;

Therefore be it further resolved that APA supports access to appropriate treatment in institutional settings for people of all gender identities and expressions; including access to appropriate health care services including gender transition therapies;

Therefore be it further resolved that APA supports the creation of educational resources for all psychologists in working with individuals who are gender variant and transgender;

Therefore be it further resolved that APA supports the funding of basic and applied research concerning gender expression and gender identity;

Therefore be it further resolved that APA supports the creation of scientific and educational resources that inform public discussion about gender identity and gender expression to promote public policy development, and societal and familial attitudes and behaviors that affirm the dignity and rights of all individuals regardless of gender identity or gender expression;

Therefore be it further resolved that APA supports cooperation with other organizations in efforts to accomplish these ends.

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EXHIBIT H

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Routledge
Taylor & Francis Group

Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7

Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., Fraser, L., Green, J., Knudson, G., Meyer, W. J., Monstrey, S., Adler, R. K., Brown, G. R., Devor, A. H., Ehrbar, R., Ettner, R., Eyler, E., Garofalo, R., Karasic, D. H., Lev, A. I., Mayer, G., Meyer-Bahlburg, H., Hall, B. P., Pfaefflin, F., Rachlin, K., Robinson, B., Schechter, L. S., Tangpricha, V., van Trotsenburg, M., Vitale, A., Winter, S., Whittle, S., Wylie, K. R., & Zucker, K.

ABSTRACT. The *Standards of Care* (*SOC*) *for the Health of Transsexual, Transgender, and Gender Nonconforming People* is a publication of the World Professional Association for Transgender Health (WPATH). The overall goal of the *SOC* is to provide clinical guidance for health professionals to assist transsexual, transgender, and gender nonconforming people with safe and effective pathways to achieving lasting personal comfort with their gendered selves, in order to maximize their overall health, psychological well-being, and self-fulfillment. This assistance may include primary care, gynecologic and urologic care, reproductive options, voice and communication therapy, mental health services (e.g., assessment, counseling, psychotherapy), and hormonal and surgical treatments. The *SOC* are based on the best available science and expert professional consensus. Because most of the research and experience in this field comes from a North American and Western European perspective, adaptations of the *SOC* to other parts of the world are necessary. The *SOC* articulate standards of care while acknowledging the role of making informed choices and the value of harm reduction approaches. In addition, this version of the *SOC* recognizes that treatment for gender dysphoria i.e., discomfort or distress that is caused by a discrepancy between persons gender identity and that persons sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) has become more individualized. Some individuals who present for care will have made significant self-directed progress towards gender role changes or other resolutions regarding their gender identity or gender dysphoria. Other individuals will require more intensive services. Health professionals can use the *SOC* to help patients consider the full range of health services open to them, in accordance with their clinical needs and goals for gender expression.

KEYWORDS. Transexual, transgender, gender dysphoria, *Standards of Care*

This is the seventh version of the *Standards of Care*. The original *SOC* were published in 1979. Previous revisions were in 1980, 1981, 1990, 1998, and 2001.

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I. PURPOSE AND USE OF THE STANDARDS OF CARE

The World Professional Association for Transgender Health (WPATH)[1] is an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, advocacy, public policy, and respect in transsexual and transgender health. The vision of WPATH is a world wherein transsexual, transgender, and gender-nonconforming people benefit from access to evidence-based health care, social services, justice, and equality.

One of the main functions of WPATH is to promote the highest standards of health care for individuals through the articulation of *Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender-Nonconforming People*. The *SOC* are based on the best available science and expert professional consensus.[2] Most of the research and experience in this field comes from a North American and Western European perspective; thus, adaptations of the *SOC* to other parts of the world are necessary. Suggestions for ways of thinking about cultural relativity and cultural competence are included in this version of the *SOC*.

The overall goal of the *SOC* is to provide clinical guidance for health professionals to assist transsexual, transgender, and gender-nonconforming people with safe and effective pathways to achieving lasting personal comfort with their gendered selves, in order to maximize their overall health, psychological well-being, and self-fulfillment. This assistance may include primary care, gynecologic and urologic care, reproductive options, voice and communication therapy, mental health services (e.g., assessment, counseling, psychotherapy), and hormonal and surgical treatments. While this is primarily a document for health professionals, the *SOC* may also be used by individuals, their families, and social institutions to understand how they can assist with promoting optimal health for members of this diverse population.

WPATH recognizes that health is dependent upon not only good clinical care but also social and political climates that provide and ensure social tolerance, equality, and the full rights of citizenship. Health is promoted through public policies and legal reforms that promote tolerance and equity for gender and sexual diversity and that eliminate prejudice, discrimination, and stigma. WPATH is committed to advocacy for these changes in public policies and legal reforms.

The Standards of Care *Are Flexible Clinical Guidelines*

The *SOC* are intended to be flexible in order to meet the diverse health care needs of transsexual, transgender, and gender-nonconforming people. While flexible, they offer standards for promoting optimal health care and guiding the treatment of people experiencing gender dysphoria—broadly defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) (Fisk, 1974; Knudson, De Cuypere, & Bockting, 2010b).

As in all previous versions of the *SOC*, the criteria put forth in this document 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

[1]Formerly the Harry Benjamin International Gender Dysphoria Association.

[2]*The Standards of Care (SOC), Version 7*, represents a significant departure from previous versions. Changes in this version are based upon significant cultural shifts, advances in clinical knowledge, and appreciation of the many health care issues that can arise for transsexual, transgender, and gender-nonconforming people beyond hormone therapy and surgery (Coleman, 2009a, 2009b, 2009c, 2009d).

valuable for the accumulation of new data, which can be retrospectively examined to allow for health care—and the *SOC*—to evolve.

The *SOC* articulate standards of care but also acknowledge the role of making informed choices and the value of harm-reduction approaches. In addition, this version of the *SOC* recognizes and validates various expressions of gender that may not necessitate psychological, hormonal, or surgical treatments. Some patients who present for care will have made significant self-directed progress towards gender role changes, transition, or other resolutions regarding their gender identity or gender dysphoria. Other patients will require more intensive services. Health professionals can use the *SOC* to help patients consider the full range of health services open to them, in accordance with their clinical needs and goals for gender expression.

II. GLOBAL APPLICABILITY OF THE STANDARDS OF CARE

While the *SOC* are intended for worldwide use, WPATH acknowledges that much of the recorded clinical experience and knowledge in this area of health care is derived from North American and Western European sources. From place to place, both across and within nations, there are differences in all of the following: social attitudes towards transsexual, transgender, and gender-nonconforming people; constructions of gender roles and identities; language used to describe different gender identities; epidemiology of gender dysphoria; access to and cost of treatment; therapies offered; number and type of professionals who provide care; and legal and policy issues related to this area of health care (Winter, 2009).

It is impossible for the *SOC* to reflect all of these differences. In applying these standards to other cultural contexts, health professionals must be sensitive to these differences and adapt the *SOC* according to local realities. For example, in a number of cultures, gender-nonconforming people are found in such numbers and living in such ways as to make them highly socially visible (Peletz, 2006). In settings such as these, it is common for people to initiate a change in their gender expression and physical characteristics while in their teens or even earlier. Many grow up and live in a social, cultural, and even linguistic context quite unlike that of Western cultures. Yet almost all experience prejudice (Peletz, 2006; Winter, 2009). In many cultures, social stigma towards gender nonconformity is widespread and gender roles are highly prescriptive (Winter et al., 2009). Gender-nonconforming people in these settings are forced to be hidden and, therefore, may lack opportunities for adequate health care (Winter, 2009).

The *SOC* are not intended to limit efforts to provide the best available care to all individuals. Health professionals throughout the world—even in areas with limited resources and training opportunities—can apply the many core principles that undergird the *SOC*. These principles include the following: Exhibit respect for patients with nonconforming gender identities (do not pathologize differences in gender identity or expression); provide care (or refer to knowledgeable colleagues) that affirms patients' gender identities and reduces the distress of gender dysphoria, when present; become knowledgeable about the health care needs of transsexual, transgender, and gender-nonconforming people, including the benefits and risks of treatment options for gender dysphoria; match the treatment approach to the specific needs of patients, particularly their goals for gender expression and need for relief from gender dysphoria; facilitate access to appropriate care; seek patients' informed consent before providing treatment; offer continuity of care; and be prepared to support and advocate for patients within their families and communities (schools, workplaces, and other settings).

Terminology is culturally and time-dependent and is rapidly evolving. It is important to use respectful language in different places and times, and among different people. As the *SOC* are translated into other languages, great care must be taken to ensure that the meanings of terms are accurately translated. Terminology in English may not be easily translated into other languages, and vice versa. Some languages do not have equivalent words to describe the various terms within this document; hence, translators should

be cognizant of the underlying goals of treatment and articulate culturally applicable guidance for reaching those goals.

III. THE DIFFERENCE BETWEEN GENDER NONCONFORMITY AND GENDER DYSPHORIA

Being Transsexual, Transgender, or Gender Nonconforming Is a Matter of Diversity, Not Pathology

WPATH released a statement in May 2010 urging the de-psychopathologization of gender nonconformity worldwide (WPATH Board of Directors, 2010). This statement noted that "the expression of gender characteristics, including identities, that are not stereotypically associated with one's assigned sex at birth is a common and culturally diverse human phenomenon [that] should not be judged as inherently pathological or negative."

Unfortunately, there is a stigma attached to gender nonconformity in many societies around the world. Such stigma can lead to prejudice and discrimination, resulting in "minority stress" (I. H. Meyer, 2003). Minority stress is unique (additive to general stressors experienced by all people), socially based, and chronic, and may make transsexual, transgender, and gender-nonconforming individuals more vulnerable to developing mental health problems such as anxiety and depression (Institute of Medicine, 2011). In addition to prejudice and discrimination in society at large, stigma can contribute to abuse and neglect in one's relationships with peers and family members, which in turn can lead to psychological distress. However, these symptoms are socially induced and are not inherent to being transsexual, transgender, or gender-nonconforming.

Gender Nonconformity Is Not the Same as Gender Dysphoria

Gender nonconformity refers to the extent to which a person's gender identity, role, or expression differs from the cultural norms prescribed for people of a particular sex (Institute of Medicine, 2011). *Gender dysphoria* refers to discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) (Fisk, 1974; Knudson, De Cuypere, & Bockting, 2010b). Only *some* gender-nonconforming people experience gender dysphoria at *some* point in their lives.

Treatment is available to assist people with such distress to explore their gender identity and find a gender role that is comfortable for them (Bockting & Goldberg, 2006). Treatment is individualized: What helps one person alleviate gender dysphoria might be very different from what helps another person. This process may or may not involve a change in gender expression or body modifications. Medical treatment options include, for example, feminization or masculinization of the body through hormone therapy and/or surgery, which are effective in alleviating gender dysphoria and are medically necessary for many people. Gender identities and expressions are diverse, and hormones and surgery are just two of many options available to assist people with achieving comfort with self and identity.

Gender dysphoria can in large part be alleviated through treatment (Murad et al., 2010). Hence, while transsexual, transgender, and gender-nonconforming people may experience gender dysphoria at some points in their lives, many individuals who receive treatment will find a gender role and expression that is comfortable for them, even if these differ from those associated with their sex assigned at birth, or from prevailing gender norms and expectations.

Diagnoses Related to Gender Dysphoria

Some people experience gender dysphoria at such a level that the distress meets criteria for a formal diagnosis that might be classified as a mental disorder. Such a diagnosis is not a license for stigmatization or for the deprivation of civil and human rights. Existing classification systems such as the *Diagnostic Statistical Manual of Mental Disorders (DSM)* (American Psychiatric Association, 2000) and the *International Classification of Diseases*

(*ICD*) (World Health Organization, 2007) define hundreds of mental disorders that vary in onset, duration, pathogenesis, functional disability, and treatability. All of these systems attempt to classify clusters of symptoms and conditions, not the individuals themselves. A disorder is a description of something with which a person might struggle, not a description of the person or the person's identity.

Thus, transsexual, transgender, and gender-nonconforming individuals are not inherently disordered. Rather, the distress of gender dysphoria, when present, is the concern that might be diagnosable and for which various treatment options are available. The existence of a diagnosis for such dysphoria often facilitates access to health care and can guide further research into effective treatments.

Research is leading to new diagnostic nomenclatures, and terms are changing in both the *DSM* (Cohen-Kettenis & Pfäfflin, 2010; Knudson, De Cuypere, & Bockting, 2010b; Meyer-Bahlburg, 2010; Zucker, 2010) and the *ICD*. For this reason, familiar terms are employed in the *SOC* and definitions are provided for terms that may be emerging. Health professionals should refer to the most current diagnostic criteria and appropriate codes to apply in their practice areas.

IV. EPIDEMIOLOGIC CONSIDERATIONS

Formal epidemiologic studies on the incidence[3] and prevalence[4] of transsexualism specifically or transgender and gender-nonconforming identities in general have not been conducted, and efforts to achieve realistic estimates are fraught with enormous difficulties (Institute of Medicine, 2011; Zucker & Lawrence, 2009). Even if epidemiologic studies established that a similar proportion of transsexual, transgender, or gender-nonconforming people existed all over the world, it is likely that cultural differences from one country to another would alter both the behavioral expressions of different gender identities and the extent to which gender dysphoria—distinct from one's gender identity—is actually occurring in a population. While in most countries, crossing normative gender boundaries generates moral censure rather than compassion, there are examples in certain cultures of gender-nonconforming behaviors (e.g., in spiritual leaders) that are less stigmatized and even revered (Besnier, 1994; Bolin, 1988; Chiñas, 1995; Coleman, Colgan, & Gooren, 1992; Costa & Matzner, 2007; Jackson & Sullivan, 1999; Nanda, 1998; Taywaditep, Coleman, & Dumronggittigule, 1997).

For various reasons, researchers who have studied incidence and prevalence have tended to focus on the most easily counted subgroup of gender-nonconforming individuals: transsexual individuals who experience gender dysphoria and who present for gender-transition-related care at specialist gender clinics (Zucker & Lawrence, 2009). Most studies have been conducted in European countries such as Sweden (Wålinder, 1968, 1971), the United Kingdom (Hoenig & Kenna, 1974), the Netherlands (Bakker, Van Kesteren, Gooren, & Bezemer, 1993; Eklund, Gooren, & Bezemer, 1988; van Kesteren, Gooren, & Megens, 1996), Germany (Weitze & Osburg, 1996), and Belgium (De Cuypere et al., 2007). One was conducted in Singapore (Tsoi, 1988).

De Cuypere and colleagues (2007) reviewed such studies, as well as conducted their own. Together, those studies span 39 years. Leaving aside two outlier findings from Pauly in 1965 and Tsoi in 1988, ten studies involving eight countries remain. The prevalence figures reported in these ten studies range from 1:11,900 to 1:45,000 for male-to-female individuals (MtF) and 1:30,400 to 1:200,000 for female-to-male (FtM) individuals. Some scholars have suggested that the prevalence is much higher, depending on the methodology used in the research (e.g., Olyslager & Conway, 2007).

Direct comparisons across studies are impossible, as each differed in their data collection methods and in their criteria for documenting a person as transsexual (e.g., whether or not a person had undergone genital reconstruction,

[3] *Incidence*—the number of new cases arising in a given period (e.g., a year).

[4] *Prevalence*—the number of individuals having a 4035 condition, divided by the number of people in the general population.

versus had initiated hormone therapy, versus had come to the clinic seeking medically supervised transition services). The trend appears to be towards higher prevalence rates in the more recent studies, possibly indicating increasing numbers of people seeking clinical care. Support for this interpretation comes from research by Reed and colleagues (2009), who reported a doubling of the numbers of people accessing care at gender clinics in the United Kingdom every five or six years. Similarly, Zucker and colleagues (2008) reported a four- to five-fold increase in child and adolescent referrals to their Toronto, Canada, clinic over a 30-year period.

The numbers yielded by studies such as these can be considered minimum estimates at best. The published figures are mostly derived from clinics where patients met criteria for severe gender dysphoria and had access to health care at those clinics. These estimates do not take into account that treatments offered in a particular clinic setting might not be perceived as affordable, useful, or acceptable by all self-identified gender dysphoric individuals in a given area. By counting only those people who present at clinics for a specific type of treatment, an unspecified number of gender dysphoric individuals are overlooked.

Other clinical observations (not yet firmly supported by systematic study) support the likelihood of a higher prevalence of gender dysphoria: (i) Previously unrecognized gender dysphoria is occasionally diagnosed when patients are seen with anxiety, depression, conduct disorder, substance abuse, dissociative identity disorders, borderline personality disorder, sexual disorders, and disorders of sex development (Cole, O'Boyle, Emory, & Meyer, 1997). (ii) Some cross-dressers, drag queens/kings or female/male impersonators, and gay and lesbian individuals may be experiencing gender dysphoria (Bullough & Bullough, 1993). (iii) The intensity of some people's gender dysphoria fluctuates below and above a clinical threshold (Docter, 1988). (iv) Gender nonconformity among FtM individuals tends to be relatively invisible in many cultures, particularly to Western health professionals and researchers who have conducted most of the studies on which the current estimates of prevalence and incidence are based (Winter, 2009).

Overall, the existing data should be considered a starting point, and health care would benefit from more rigorous epidemiologic study in different locations worldwide.

V. OVERVIEW OF THERAPEUTIC APPROACHES FOR GENDER DYSPHORIA

Advancements in the Knowledge and Treatment of Gender Dysphoria

In the second half of the 20th century, awareness of the phenomenon of gender dysphoria increased when health professionals began to provide assistance to alleviate gender dysphoria by supporting changes in primary and secondary sex characteristics through hormone therapy and surgery, along with a change in gender role. Although Harry Benjamin already acknowledged a spectrum of gender nonconformity (Benjamin, 1966), the initial clinical approach largely focused on identifying who was an appropriate candidate for sex reassignment to facilitate a physical change from male to female or female to male as completely as possible (e.g., Green & Fleming, 1990; Hastings, 1974). This approach was extensively evaluated and proved to be highly effective. Satisfaction rates across studies ranged from 87% of MtF patients to 97% of FtM patients (Green & Fleming, 1990), and regrets were extremely rare (1%–1.5% of MtF patients and $< 1\%$ of FtM patients; Pfäfflin, 1993). Indeed, hormone therapy and surgery have been found to be medically necessary to alleviate gender dysphoria in many people (American Medical Association, 2008; Anton, 2009; World Professional Association for Transgender Health, 2008).

As the field matured, health professionals recognized that while many individuals need both hormone therapy and surgery to alleviate their gender dysphoria, others need only one of these treatment options and some need neither (Bockting & Goldberg, 2006; Bockting, 2008; Lev, 2004). Often with the help of psychotherapy, some individuals integrate their trans- or cross-gender feelings into the gender role they were assigned at birth and do not feel the need to feminize or masculinize their body. For

others, changes in gender role and expression are sufficient to alleviate gender dysphoria. Some patients may need hormones, a possible change in gender role, but not surgery; others may need a change in gender role along with surgery but not hormones. In other words, treatment for gender dysphoria has become more individualized.

As a generation of transsexual, transgender, and gender-nonconforming individuals has come of age—many of whom have benefitted from different therapeutic approaches—they have become more visible as a community and demonstrated considerable diversity in their gender identities, roles, and expressions. Some individuals describe themselves not as gender-nonconforming but as unambiguously cross-sexed (i.e., as a member of the other sex; Bockting, 2008). Other individuals affirm their unique gender identity and no longer consider themselves to be either male or female (Bornstein, 1994; Kimberly, 1997; Stone, 1991; Warren, 1993). Instead, they may describe their gender identity in specific terms such as transgender, bigender, or genderqueer, affirming their unique experiences that may transcend a male/female binary understanding of gender (Bockting, 2008; Ekins & King, 2006; Nestle, Wilchins, & Howell, 2002). They may not experience their process of identity affirmation as a "transition," because they never fully embraced the gender role they were assigned at birth or because they actualize their gender identity, role, and expression in a way that does not involve a change from one gender role to another. For example, some youth identifying as genderqueer have always experienced their gender identity and role as such (genderqueer). Greater public visibility and awareness of gender diversity (Feinberg, 1996) have further expanded options for people with gender dysphoria to actualize an identity and find a gender role and expression that are comfortable for them.

Health professionals can assist gender dysphoric individuals with affirming their gender identity, exploring different options for expression of that identity, and making decisions about medical treatment options for alleviating gender dysphoria.

Options for Psychological and Medical Treatment of Gender Dysphoria

For individuals seeking care for gender dysphoria, a variety of therapeutic options can be considered. The number and type of interventions applied and the order in which these take place may differ from person to person (e.g., Bockting, Knudson, & Goldberg, 2006; Bolin, 1994; Rachlin, 1999; Rachlin, Green, & Lombardi, 2008; Rachlin, Hansbury, & Pardo, 2010). Treatment options include the following:

- Changes in gender expression and role (which may involve living part time or full time in another gender role, consistent with one's gender identity);
- Hormone therapy to feminize or masculinize the body;
- Surgery to change primary and/or secondary sex characteristics (e.g., breasts/chest, external and/or internal genitalia, facial features, body contouring);
- Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support; improving body image; or promoting resilience.

Options for Social Support and Changes in Gender Expression

In addition (or as an alternative) to the psychological- and medical-treatment options described above, other options can be considered to help alleviate gender dysphoria, for example:

- In person and online peer support resources, groups, or community organizations that provide avenues for social support and advocacy;
- In person and online support resources for families and friends;
- Voice and communication therapy to help individuals develop verbal and nonverbal communication skills that facilitate comfort with their gender identity;

- Hair removal through electrolysis, laser treatment, or waxing;
- Breast binding or padding, genital tucking or penile prostheses, padding of hips or buttocks;
- Changes in name and gender marker on identity documents.

VI. ASSESSMENT AND TREATMENT OF CHILDREN AND ADOLESCENTS WITH GENDER DYSPHORIA

There are a number of differences in the phenomenology, developmental course, and treatment approaches for gender dysphoria in children, adolescents, and adults. In children and adolescents, a rapid and dramatic developmental process (physical, psychological, and sexual) is involved and there is greater fluidity and variability in outcomes, particularly in prepubertal children. Accordingly, this section of the *SOC* offers specific clinical guidelines for the assessment and treatment of gender dysphoric children and adolescents.

Differences Between Children and Adolescents with Gender Dysphoria

An important difference between gender dysphoric children and adolescents is in the proportion for whom dysphoria persists into adulthood. Gender dysphoria during childhood does not inevitably continue into adulthood.[5] Rather, in follow-up studies of prepubertal children (mainly boys) who were referred to clinics for assessment of gender dysphoria, the dysphoria persisted into adulthood for only 6%–23% of children (Cohen-Kettenis, 2001; Zucker & Bradley, 1995). Boys in these studies were more likely to identify as gay in adulthood than as transgender (Green, 1987; Money & Russo, 1979; Zucker & Bradley, 1995; Zuger, 1984). Newer studies, also including girls, showed a 12%–27% persistence rate of gender dysphoria into adulthood (Drummond, Bradley, Peterson-Badali, & Zucker, 2008; Wallien & Cohen-Kettenis, 2008).

In contrast, the persistence of gender dysphoria into adulthood appears to be much higher for adolescents. No formal prospective studies exist. However, in a follow-up study of 70 adolescents who were diagnosed with gender dysphoria and given puberty-suppressing hormones, all continued with actual sex reassignment, beginning with feminizing/masculinizing hormone therapy (de Vries, Steensma, Doreleijers, & Cohen-Kettenis, 2010).

Another difference between gender dysphoric children and adolescents is in the sex ratios for each age group. In clinically referred, gender dysphoric children under age 12, the male/female ratio ranges from 6:1 to 3:1 (Zucker, 2004). In clinically referred, gender dysphoric adolescents older than age 12, the male/female ratio is close to 1:1 (Cohen-Kettenis & Pfäfflin, 2003).

As discussed in section IV and by Zucker and Lawrence (2009), formal epidemiologic studies on gender dysphoria—in children, adolescents, and adults—are lacking. Additional research is needed to refine estimates of its prevalence and persistence in different populations worldwide.

Phenomenology in Children

Children as young as age two may show features that could indicate gender dysphoria. They may express a wish to be of the other sex and be unhappy about their physical sex characteristics and functions. In addition, they may prefer clothes, toys, and games that are commonly associated with the other sex and prefer playing with other-sex peers. There appears to be heterogeneity in these features: Some children demonstrate extremely gender-nonconforming behavior and wishes, accompanied by persistent and severe discomfort with their primary sex characteristics. In other children, these characteristics are less intense or only partially present (Cohen-Kettenis et al., 2006; Knudson, De Cuypere, & Bockting, 2010a).

[5]Gender-nonconforming behaviors in children may continue into adulthood, but such behaviors are not necessarily indicative of gender dysphoria and a need for treatment. As described in section III, gender dysphoria is not synonymous with diversity in gender expression.

It is relatively common for gender dysphoric children to have coexisting internalizing disorders such as anxiety and depression (Cohen-Kettenis, Owen, Kaijser, Bradley, & Zucker, 2003; Wallien, Swaab, & Cohen-Kettenis, 2007; Zucker, Owen, Bradley, & Ameeriar, 2002). The prevalence of autism spectrum disorders seems to be higher in clinically referred, gender dysphoric children than in the general population (de Vries, Noens, Cohen-Kettenis, van Berckelaer-Onnes, & Doreleijers, 2010).

Phenomenology in Adolescents

In most children, gender dysphoria will disappear before, or early in, puberty. However, in some children these feelings will intensify and body aversion will develop or increase as they become adolescents and their secondary sex characteristics develop (Cohen-Kettenis, 2001; Cohen-Kettenis & Pfäfflin, 2003; Drummond et al., 2008; Wallien & Cohen-Kettenis, 2008; Zucker & Bradley, 1995). Data from one study suggest that more extreme gender nonconformity in childhood is associated with persistence of gender dysphoria into late adolescence and early adulthood (Wallien & Cohen-Kettenis, 2008). Yet many adolescents and adults presenting with gender dysphoria do not report a history of childhood gender-nonconforming behaviors (Docter, 1988; Landén, Wålinder, & Lundström, 1998). Therefore, it may come as a surprise to others (parents, other family members, friends, and community members) when a youth's gender dysphoria first becomes evident in adolescence.

Adolescents who experience their primary and/or secondary sex characteristics and their sex assigned at birth as inconsistent with their gender identity may be intensely distressed about it. Many, but not all, gender dysphoric adolescents have a strong wish for hormones and surgery. Increasing numbers of adolescents have already started living in their desired gender role upon entering high school (Cohen-Kettenis & Pfäfflin, 2003).

Among adolescents who are referred to gender identity clinics, the number considered eligible for early medical treatment—starting with GnRH analogues to suppress puberty in the first Tanner stages—differs among countries and centers. Not all clinics offer puberty suppression. If such treatment is offered, the pubertal stage at which adolescents are allowed to start varies from Tanner stage 2 to stage 4 (Delemarre-van de Waal & Cohen-Kettenis, 2006; Zucker et al., 2012). The percentages of treated adolescents are likely influenced by the organization of health care, insurance aspects, cultural differences, opinions of health professionals, and diagnostic procedures offered in different settings.

Inexperienced clinicians may mistake indications of gender dysphoria for delusions. Phenomenologically, there is a qualitative difference between the presentation of gender dysphoria and the presentation of delusions or other psychotic symptoms. The vast majority of children and adolescents with gender dysphoria are not suffering from underlying severe psychiatric illness such as psychotic disorders (Steensma, Biemond, de Boer, & Cohen-Kettenis, published online ahead of print January 7, 2011).

It is more common for adolescents with gender dysphoria to have coexisting internalizing disorders such as anxiety and depression, and/or externalizing disorders such as oppositional defiant disorder (de Vries et al., 2010). As in children, there seems to be a higher prevalence of autistic spectrum disorders in clinically referred, gender dysphoric adolescents than in the general adolescent population (de Vries et al., 2010).

Competency of Mental Health Professionals Working with Children or Adolescents with Gender Dysphoria

The following are recommended minimum credentials for mental health professionals who assess, refer, and offer therapy to children and adolescents presenting with gender dysphoria:

1. Meet the competency requirements for mental health professionals working with adults, as outlined in section VII;
2. Trained in childhood and adolescent developmental psychopathology;
3. Competent in diagnosing and treating the ordinary problems of children and adolescents.

Roles of Mental Health Professionals Working with Children and Adolescents with Gender Dysphoria

The roles of mental health professionals working with gender dysphoric children and adolescents may include the following:

1. Directly assess gender dysphoria in children and adolescents (see general guidelines for assessment, below).
2. Provide family counseling and supportive psychotherapy to assist children and adolescents with exploring their gender identity, alleviating distress related to their gender dysphoria, and ameliorating any other psychosocial difficulties.
3. Assess and treat any coexisting mental health concerns of children or adolescents (or refer to another mental health professional for treatment). Such concerns should be addressed as part of the overall treatment plan.
4. Refer adolescents for additional physical interventions (such as puberty-suppressing hormones) to alleviate gender dysphoria. The referral should include documentation of an assessment of gender dysphoria and mental health, the adolescent's eligibility for physical interventions (outlined below), the mental health professional's relevant expertise, and any other information pertinent to the youth's health and referral for specific treatments.
5. Educate and advocate on behalf of gender dysphoric children, adolescents, and their families in their community (e.g., day care centers, schools, camps, other organizations). This is particularly important in light of evidence that children and adolescents who do not conform to socially prescribed gender norms may experience harassment in school (Grossman, D'Augelli, Howell, & Hubbard, 2006; Grossman, D'Augelli, & Salter, 2006; Sausa, 2005), putting them at risk for social isolation, depression, and other negative sequelae (Nuttbrock et al., 2010).
6. Provide children, youth, and their families with information and referral for peer support, such as support groups for parents of gender-nonconforming and transgender children (Gold & MacNish, 2011; Pleak, 1999; Rosenberg, 2002).

Assessment and psychosocial interventions for children and adolescents are often provided within a multidisciplinary gender identity specialty service. If such a multidisciplinary service is not available, a mental health professional should provide consultation and liaison arrangements with a pediatric endocrinologist for the purpose of assessment, education, and involvement in any decisions about physical interventions.

Psychological Assessment of Children and Adolescents

When assessing children and adolescents who present with gender dysphoria, mental health professionals should broadly conform to the following guidelines:

1. Mental health professionals should not dismiss or express a negative attitude towards nonconforming gender identities or indications of gender dysphoria. Rather, they should acknowledge the presenting concerns of children, adolescents, and their families; offer a thorough assessment for gender dysphoria and any coexisting mental health concerns; and educate clients and their families about therapeutic options, if needed. Acceptance, and alleviation of secrecy, can bring considerable relief to gender dysphoric children/adolescents and their families.
2. Assessment of gender dysphoria and mental health should explore the nature and characteristics of a child's or adolescent's gender identity. A psychodiagnostic and psychiatric assessment—covering the areas of emotional functioning, peer and other social relationships, and intellectual functioning/school achievement—should be performed. Assessment should include an evaluation of the strengths and weaknesses of family functioning. Emotional and behavioral problems are relatively

common, and unresolved issues in a child's or youth's environment may be present (de Vries, Doreleijers, Steensma, & Cohen-Kettenis, 2011; Di Ceglie & Thümmel, 2006; Wallien et al., 2007).

3. For adolescents, the assessment phase should also be used to inform youth and their families about the possibilities and limitations of different treatments. This is necessary for informed consent and also important for assessment. The way that adolescents respond to information about the reality of sex reassignment can be diagnostically informative. Correct information may alter a youth's desire for certain treatment, if the desire was based on unrealistic expectations of its possibilities.

Psychological and Social Interventions for Children and Adolescents

When supporting and treating children and adolescents with gender dysphoria, health professionals should broadly conform to the following guidelines:

1. Mental health professionals should help families to have an accepting and nurturing response to the concerns of their gender dysphoric child or adolescent. Families play an important role in the psychological health and well-being of youth (Brill & Pepper, 2008; Lev, 2004). This also applies to peers and mentors from the community, who can be another source of social support.
2. Psychotherapy should focus on reducing a child's or adolescent's distress related to the gender dysphoria and on ameliorating any other psychosocial difficulties. For youth pursuing sex reassignment, psychotherapy may focus on supporting them before, during, and after reassignment. Formal evaluations of different psychotherapeutic approaches for this situation have not been published, but several counseling methods have been described (Cohen-Kettenis, 2006; de Vries, Cohen-Kettenis, & Delemarre-van de Waal, 2006; Di Ceglie & Thümmel, 2006; Hill, Menvielle, Sica, & Johnson, 2010; Malpas, 2011; Menvielle & Tuerk, 2002; Rosenberg, 2002; Vanderburgh, 2009; Zucker, 2006).

   Treatment aimed at trying to change a person's gender identity and expression to become more congruent with sex assigned at birth has been attempted in the past without success (Gelder & Marks, 1969; Greenson, 1964), particularly in the long term (Cohen-Kettenis & Kuiper, 1984; Pauly, 1965). Such treatment is no longer considered ethical.
3. Families should be supported in managing uncertainty and anxiety about their child's or adolescent's psychosexual outcomes and in helping youth to develop a positive self-concept.
4. Mental health professionals should not impose a binary view of gender. They should give ample room for clients to explore different options for gender expression. Hormonal or surgical interventions are appropriate for some adolescents but not for others.
5. Clients and their families should be supported in making difficult decisions regarding the extent to which clients are allowed to express a gender role that is consistent with their gender identity, as well as the timing of changes in gender role and possible social transition. For example, a client might attend school while undergoing social transition only partly (e.g., by wearing clothing and having a hairstyle that reflects gender identity) or completely (e.g., by also using a name and pronouns congruent with gender identity). Difficult issues include whether and when to inform other people of the client's situation, and how others in their lives might respond.
6. Health professionals should support clients and their families as educators and advocates in their interactions with community members and authorities such as teachers, school boards, and courts.
7. Mental health professionals should strive to maintain a therapeutic relationship with

gender-nonconforming children/adolescents and their families throughout any subsequent social changes or physical interventions. This ensures that decisions about gender expression and the treatment of gender dysphoria are thoughtfully and recurrently considered. The same reasoning applies if a child or adolescent has already socially changed gender role prior to being seen by a mental health professional.

Social Transition in Early Childhood

Some children state that they want to make a social transition to a different gender role long before puberty. For some children, this may reflect an expression of their gender identity. For others, this could be motivated by other forces. Families vary in the extent to which they allow their young children to make a social transition to another gender role. Social transitions in early childhood do occur within some families with early success. This is a controversial issue, and divergent views are held by health professionals. The current evidence base is insufficient to predict the long-term outcomes of completing a gender role transition during early childhood. Outcomes research with children who completed early social transitions would greatly inform future clinical recommendations.

Mental health professionals can help families to make decisions regarding the timing and process of any gender-role changes for their young children. They should provide information and help parents to weigh the potential benefits and challenges of particular choices. Relevant in this respect are the previously described relatively low persistence rates of childhood gender dysphoria (Drummond et al., 2008; Wallien & Cohen-Kettenis, 2008). A change back to the original gender role can be highly distressing and even result in postponement of this second social transition on the child's part (Steensma & Cohen-Kettenis, 2011). For reasons such as these, parents may want to present this role change as an exploration of living in another gender role rather than an irreversible situation. Mental health professionals can assist parents in identifying potential in-between solutions or compromises (e.g., only when on vacation). It is also important that parents explicitly let the child know that there is a way back.

Regardless of a family's decisions regarding transition (timing, extent), professionals should counsel and support them as they work through the options and implications. If parents do not allow their young child to make a gender-role transition, they may need counseling to assist them with meeting their child's needs in a sensitive and nurturing way, ensuring that the child has ample possibilities to explore gender feelings and behavior in a safe environment. If parents do allow their young child to make a gender-role transition, they may need counseling to facilitate a positive experience for their child. For example, they may need support in using correct pronouns, maintaining a safe and supportive environment for their transitioning child (e.g., in school, peer group settings), and communicating with other people in their child's life. In either case, as a child nears puberty, further assessment may be needed as options for physical interventions become relevant.

Physical Interventions for Adolescents

Before any physical interventions are considered for adolescents, extensive exploration of psychological, family, and social issues should be undertaken, as outlined above. The duration of this exploration may vary considerably depending on the complexity of the situation.

Physical interventions should be addressed in the context of adolescent development. Some identity beliefs in adolescents may become firmly held and strongly expressed, giving a false impression of irreversibility. An adolescent's shift towards gender conformity can occur primarily to please the parents and may not persist or reflect a permanent change in gender dysphoria (Hembree et al., 2009; Steensma et al., published online ahead of print January 7, 2011).

Physical interventions for adolescents fall into three categories or stages (Hembree et al., 2009):

1. *Fully reversible interventions*. These involve the use of GnRH analogues to suppress estrogen or testosterone production

and consequently delay the physical changes of puberty. Alternative treatment options include progestins (most commonly medroxyprogesterone) or other medications (such as spironolactone) that decrease the effects of androgens secreted by the testicles of adolescents who are not receiving GnRH analogues. Continuous oral contraceptives (or depot medroxyprogesterone) may be used to suppress menses.

2. *Partially reversible interventions*. These include hormone therapy to masculinize or feminize the body. Some hormone-induced changes may need reconstructive surgery to reverse the effect (e.g., gynaecomastia caused by estrogens), while other changes are not reversible (e.g., deepening of the voice caused by testosterone).
3. *Irreversible interventions.* These are surgical procedures.

A staged process is recommended to keep options open through the first two stages. Moving from one stage to another should not occur until there has been adequate time for adolescents and their parents to assimilate fully the effects of earlier interventions.

Fully Reversible Interventions

Adolescents may be eligible for puberty-suppressing hormones as soon as pubertal changes have begun. In order for adolescents and their parents to make an informed decision about pubertal delay, it is recommended that adolescents experience the onset of puberty to at least Tanner Stage 2. Some children may arrive at this stage at very young ages (e.g., 9 years of age). Studies evaluating this approach have only included children who were at least 12 years of age (Cohen-Kettenis, Schagen, Steensma, de Vries, & Delemarre-van de Waal, 2011; de Vries, Steensma et al., 2010; Delemarre-van de Waal, van Weissenbruch, & Cohen Kettenis, 2004; Delemarre-van de Waal & Cohen-Kettenis, 2006).

Two goals justify intervention with puberty-suppressing hormones: (i) their use gives adolescents more time to explore their gender nonconformity and other developmental issues and (ii) their use may facilitate transition by preventing the development of sex characteristics that are difficult or impossible to reverse if adolescents continue on to pursue sex reassignment.

Puberty suppression may continue for a few years, at which time a decision is made to either discontinue all hormone therapy or transition to a feminizing/masculinizing hormone regimen. Pubertal suppression does not inevitably lead to social transition or to sex reassignment.

Criteria for Puberty-Suppressing Hormones

In order for adolescents to receive puberty-suppressing hormones, the following minimum criteria must be met:

1. The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed);
2. Gender dysphoria emerged or worsened with the onset of puberty;
3. Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment;
4. The adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process.

Regimens, Monitoring, and Risks for Puberty Suppression

For puberty suppression, adolescents with male genitalia should be treated with GnRH analogues, which stop luteinizing hormone secretion and therefore testosterone secretion. Alternatively, they may be treated with progestins (such as medroxyprogesterone) or with other medications that block testosterone secretion and/or neutralize testosterone action.

Adolescents with female genitalia should be treated with GnRH analogues, which stop the production of estrogens and progesterone. Alternatively, they may be treated with progestins (such as medroxyprogesterone). Continuous oral contraceptives (or depot medroxyprogesterone) may be used to suppress menses. In both groups of adolescents, use of GnRH analogues is the preferred treatment (Hembree et al., 2009), but their high cost is prohibitive for some patients.

During pubertal suppression, an adolescent's physical development should be carefully monitored—preferably by a pediatric endocrinologist—so that any necessary interventions can occur (e.g., to establish an adequate gender appropriate height, to improve iatrogenic low bone mineral density) (Hembree et al., 2009).

Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. Intervention in early adolescence should be managed with pediatric endocrinological advice, when available. Adolescents with male genitalia who start GnRH analogues early in puberty should be informed that this could result in insufficient penile tissue for penile inversion vaginoplasty techniques (alternative techniques, such as the use of a skin graft or colon tissue, are available).

Neither puberty suppression nor allowing puberty to occur is a neutral act. On the one hand, functioning in later life can be compromised by the development of irreversible secondary sex characteristics during puberty and by years spent experiencing intense gender dysphoria. On the other hand, there are concerns about negative physical side effects of GnRH analogue use (e.g., on bone development and height). Although the very first results of this approach (as assessed for adolescents followed over 10 years) are promising (Cohen-Kettenis et al., 2011; Delemarre-van de Waal & Cohen-Kettenis, 2006), the long-term effects can only be determined when the earliest-treated patients reach the appropriate age.

Partially Reversible Interventions

Adolescents may be eligible to begin feminizing/masculinizing hormone therapy, preferably with parental consent. In many countries, 16-year-olds are legal adults for medical decision-making and do not require parental consent. Ideally, treatment decisions should be made among the adolescent, the family, and the treatment team.

Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults (Hembree et al., 2009). The hormone regimens for youth are adapted to account for the somatic, emotional, and mental development that occurs throughout adolescence (Hembree et al., 2009).

Irreversible Interventions

Genital surgery should not be carried out until (i) patients reach the legal age of majority to give consent for medical procedures in a given country and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with their gender identity. The age threshold should be seen as a minimum criterion and not an indication in and of itself for active intervention.

Chest surgery in FtM patients could be carried out earlier, preferably after ample time of living in the desired gender role and after one year of testosterone treatment. The intent of this suggested sequence is to give adolescents sufficient opportunity to experience and socially adjust in a more masculine gender role, before undergoing irreversible surgery. However, different approaches may be more suitable, depending on an adolescent's specific clinical situation and goals for gender identity expression.

Risks of Withholding Medical Treatment for Adolescents

Refusing timely medical interventions for adolescents might prolong gender dysphoria and contribute to an appearance that could provoke abuse and stigmatization. As the level of gender-related abuse is strongly associated with the degree of psychiatric distress during adolescence (Nuttbrock et al., 2010), withholding puberty-suppression and subsequent feminizing or masculinizing hormone therapy is not a neutral option for adolescents.

VII. MENTAL HEALTH

Transsexual, transgender, and gender-nonconforming people might seek the assistance of a mental health professional for any number of reasons. Regardless of a person's reason for seeking care, mental health professionals should have familiarity with gender nonconformity, act with appropriate cultural competence, and exhibit sensitivity in providing care.

This section of the *SOC* focuses on the role of mental health professionals in the care of adults seeking help for gender dysphoria and related concerns. Professionals working with gender dysphoric children, adolescents, and their families should consult section VI.

Competency of Mental Health Professionals Working with Adults Who Present with Gender Dysphoria

The training of mental health professionals competent to work with gender dysphoric adults rests upon basic general clinical competence in the assessment, diagnosis, and treatment of mental health concerns. Clinical training may occur within any discipline that prepares mental health professionals for clinical practice, such as psychology, psychiatry, social work, mental health counseling, marriage and family therapy, nursing, or family medicine with specific training in behavioral health and counseling. The following are recommended minimum credentials for mental health professionals who work with adults presenting with gender dysphoria:

1. A master's degree or its equivalent in a clinical behavioral science field. This degree, or a more advanced one, should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country.
2. Competence in using the *Diagnostic Statistical Manual of Mental Disorders* and/or the *International Classification of Diseases* for diagnostic purposes.
3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria.
4. Documented supervised training and competence in psychotherapy or counseling.
5. Knowledge about gender-nonconforming identities and expressions, and the assessment and treatment of gender dysphoria.
6. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

In addition to the minimum credentials above, it is recommended that mental health professionals develop and maintain cultural competence to facilitate their work with transsexual, transgender, and gender-nonconforming clients. This may involve, for example, becoming knowledgeable about current community, advocacy, and public policy issues relevant to these clients and their families. Additionally, knowledge about sexuality, sexual health concerns, and the assessment and treatment of sexual disorders is preferred.

Mental health professionals who are new to the field (irrespective of their level of training and other experience) should work under the supervision of a mental health professional with established competence in the assessment and treatment of gender dysphoria.

Tasks of Mental Health Professionals Working with Adults Who Present with Gender Dysphoria

Mental health professionals may serve transsexual, transgender, and gender-nonconforming individuals and their families in many ways, depending on a client's needs. For example, mental health professionals may serve as a psychotherapist, counselor, or family therapist, or as a diagnostician/assessor, advocate, or educator.

Mental health professionals should determine a client's reasons for seeking professional

assistance. For example, a client may be presenting for any combination of the following health care services: psychotherapeutic assistance to explore gender identity and expression or to facilitate a coming-out process; assessment and referral for feminizing/masculinizing medical interventions; psychological support for family members (partners, children, extended family); psychotherapy unrelated to gender concerns; or other professional services.

Below are general guidelines for common tasks that mental health professionals may fulfill in working with adults who present with gender dysphoria.

Tasks Related to Assessment and Referral

1. Assess Gender Dysphoria

Mental health professionals assess clients' gender dysphoria in the context of an evaluation of their psychosocial adjustment (Bockting et al., 2006; Lev, 2004, 2009). The evaluation includes, at a minimum, assessment of gender identity and gender dysphoria, history and development of gender dysphoric feelings, the impact of stigma attached to gender nonconformity on mental health, and the availability of support from family, friends, and peers (for example, in-person or online contact with other transsexual, transgender, or gender-nonconforming individuals or groups). The evaluation may result in no diagnosis, in a formal diagnosis related to gender dysphoria, and/or in other diagnoses that describe aspects of the client's health and psychosocial adjustment. The role of mental health professionals includes making reasonably sure that the gender dysphoria is not secondary to, or better accounted for, by other diagnoses.

Mental health professionals with the competencies described above (hereafter called "a qualified mental health professional") are best prepared to conduct this assessment of gender dysphoria. However, this task may instead be conducted by another type of health professional who has appropriate training in behavioral health and is competent in the assessment of gender dysphoria, particularly when functioning as part of a multidisciplinary specialty team that provides access to feminizing/masculinizing hormone therapy. This professional may be the prescribing hormone-therapy provider or a member of that provider's health care team.

2. Provide Information Regarding Options for Gender Identity and Expression and Possible Medical Interventions

An important task of mental health professionals is to educate clients regarding the diversity of gender identities and expressions and the various options available to alleviate gender dysphoria. Mental health professionals then may facilitate a process (or refer elsewhere) in which clients explore these various options, with the goals of finding a comfortable gender role and expression and becoming prepared to make a fully informed decision about available medical interventions, if needed. This process may include referral for individual, family, and group therapy and/or to community resources and avenues for peer support. The professional and the client discuss the implications, both short- and long-term, of any changes in gender role and use of medical interventions. These implications can be psychological, social, physical, sexual, occupational, financial, and legal (Bockting et al., 2006; Lev, 2004).

This task is also best conducted by a qualified mental health professional, but may be conducted by another health professional with appropriate training in behavioral health and with sufficient knowledge about gender-nonconforming identities and expressions and about possible medical interventions for gender dysphoria, particularly when functioning as part of a multidisciplinary specialty team that provides access to feminizing/masculinizing hormone therapy.

3. Assess, Diagnose, and Discuss Treatment Options for Coexisting Mental Health Concerns

Clients presenting with gender dysphoria may struggle with a range of mental health concerns (Gómez-Gil, Trilla, Salamero, Godás, & Valdés, 2009; Murad et al., 2010) whether related or unrelated to what is often a long history of gender dysphoria and/or chronic minority stress. Possible concerns include anxiety, depression, self-harm, a history of abuse and neglect,

compulsivity, substance abuse, sexual concerns, personality disorders, eating disorders, psychotic disorders, and autistic spectrum disorders (Bockting et al., 2006; Nuttbrock et al., 2010; Robinow, 2009). Mental health professionals should screen for these and other mental health concerns and incorporate the identified concerns into the overall treatment plan. These concerns can be significant sources of distress and, if left untreated, can complicate the process of gender identity exploration and resolution of gender dysphoria (Bockting et al., 2006; Fraser, 2009a; Lev, 2009). Addressing these concerns can greatly facilitate the resolution of gender dysphoria, possible changes in gender role, the making of informed decisions about medical interventions, and improvements in quality of life.

Some clients may benefit from psychotropic medications to alleviate symptoms or treat coexisting mental health concerns. Mental health professionals are expected to recognize this and either provide pharmacotherapy or refer to a colleague who is qualified to do so. The presence of coexisting mental health concerns does not necessarily preclude possible changes in gender role or access to feminizing/masculinizing hormones or surgery; rather, these concerns need to be optimally managed prior to, or concurrent with, treatment of gender dysphoria. In addition, clients should be assessed for their ability to provide educated and informed consent for medical treatments.

Qualified mental health professionals are specifically trained to assess, diagnose, and treat (or refer to treatment for) these coexisting mental health concerns. Other health professionals with appropriate training in behavioral health, particularly when functioning as part of a multidisciplinary specialty team providing access to feminizing/masculinizing hormone therapy, may also screen for mental health concerns and, if indicated, provide referral for comprehensive assessment and treatment by a qualified mental health professional.

4. If Applicable, Assess Eligibility, Prepare, and Refer for Hormone Therapy

The *SOC* provide criteria to guide decisions regarding feminizing/masculinizing hormone therapy (outlined in section VIII and Appendix C). Mental health professionals can help clients who are considering hormone therapy to be both psychologically prepared (e.g., client has made a fully informed decision with clear and realistic expectations; is ready to receive the service in line with the overall treatment plan; has included family and community as appropriate) and practically prepared (e.g., has been evaluated by a physician to rule out or address medical contraindications to hormone use; has considered the psychosocial implications). If clients are of childbearing age, reproductive options (section IX) should be explored before initiating hormone therapy.

It is important for mental health professionals to recognize that decisions about hormones are first and foremost a client's decisions—as are all decisions regarding health care. However, mental health professionals have a responsibility to encourage, guide, and assist clients with making fully informed decisions and becoming adequately prepared. To best support their clients' decisions, mental health professionals need to have functioning working relationships with their clients and sufficient information about them. Clients should receive prompt and attentive evaluation, with the goal of alleviating their gender dysphoria and providing them with appropriate medical services.

Referral for feminizing/masculinizing hormone therapy. People may approach a specialized provider in any discipline to pursue feminizing/masculinizing hormone therapy. However, transgender health care is an interdisciplinary field, and coordination of care and referral among a client's overall care team is recommended.

Hormone therapy can be initiated with a referral from a qualified mental health professional. Alternatively, a health professional who is appropriately trained in behavioral health and competent in the assessment of gender dysphoria may assess eligibility of, prepare, and refer the patient for hormone therapy, particularly in the absence of significant coexisting mental health concerns and when working in the context of a multidisciplinary specialty team. The referring health professional should provide

documentation—in the chart and/or referral letter—of the patient's personal and treatment history, progress, and eligibility. Health professionals who recommend hormone therapy share the ethical and legal responsibility for that decision with the physician who provides the service.

The recommended content of the referral letter for feminizing/masculinizing hormone therapy is as follows:

1. The client's general identifying characteristics;
2. Results of the client's psychosocial assessment, including any diagnoses;
3. The duration of the referring health professional's relationship with the client, including the type of evaluation and therapy or counseling to date;
4. An explanation that the criteria for hormone therapy have been met and a brief description of the clinical rationale for supporting the client's request for hormone therapy;
5. A statement that informed consent has been obtained from the patient;
6. A statement that the referring health professional is available for coordination of care and welcomes a phone call to establish this.

For providers working within a multidisciplinary specialty team, a letter may not be necessary; rather, the assessment and recommendation can be documented in the patient's chart.

5. If Applicable, Assess Eligibility, Prepare, and Refer for Surgery

The *SOC* also provide criteria to guide decisions regarding breast/chest surgery and genital surgery (outlined in section XI and Appendix C). Mental health professionals can help clients who are considering surgery to be both psychologically prepared (e.g., client has made a fully informed decision with clear and realistic expectations; is ready to receive the service in line with the overall treatment plan; has included family and community as appropriate) and practically prepared (e.g., has made an informed choice about a surgeon to perform the procedure; has arranged aftercare). If clients are of childbearing age, reproductive options (section IX) should be explored before undergoing genital surgery.

The *SOC* do not state criteria for other surgical procedures, such as feminizing or masculinizing facial surgery; however, mental health professionals can play an important role in helping their clients to make fully informed decisions about the timing and implications of such procedures in the context of the overall coming-out or transition process.

It is important for mental health professionals to recognize that decisions about surgery are first and foremost a client's decisions—as are all decisions regarding health care. However, mental health professionals have a responsibility to encourage, guide, and assist clients with making fully informed decisions and becoming adequately prepared. To best support their clients' decisions, mental health professionals need to have functioning working relationships with their clients and sufficient information about them. Clients should receive prompt and attentive evaluation, with the goal of alleviating their gender dysphoria and providing them with appropriate medical services.

Referral for surgery. Surgical treatments for gender dysphoria can be initiated by a referral (one or two, depending on the type of surgery) from a qualified mental health professional. The mental health professional provides documentation—in the chart and/or referral letter—of the patient's personal and treatment history, progress, and eligibility. Mental health professionals who recommend surgery share the ethical and legal responsibility for that decision with the surgeon.

- One referral from a qualified mental health professional is needed for breast/chest surgery (e.g., mastectomy, chest reconstruction, or augmentation mammoplasty).
- Two referrals—from qualified mental health professionals who have independently assessed the patient—are needed for genital surgery (i.e., hysterectomy/

salpingo-oophorectomy, orchiectomy, genital reconstructive surgeries). If the first referral is from the patient's psychotherapist, the second referral should be from a person who has only had an evaluative role with the patient. Two separate letters, or one letter signed by both (e.g., if practicing within the same clinic) may be sent. Each referral letter, however, is expected to cover the same topics in the areas outlined below.

- No letter is required for hysterectomy/salpingo-oophorectomy or orchiectomy to be performed for reasons unrelated to gender dysphoria or due to other diagnoses.

The recommended content of the referral letters for surgery is as follows:

1. The client's general identifying characteristics;
2. Results of the client's psychosocial assessment, including any diagnoses;
3. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date;
4. 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;
5. A statement that informed consent has been obtained from the patient;
6. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.

For providers working within a multidisciplinary specialty team, a letter may not be necessary, rather, the assessment and recommendation can be documented in the patient's chart.

Relationship of Mental Health Professionals with Hormone-Prescribing Physicians, Surgeons, and Other Health Professionals

It is ideal for mental health professionals to perform their work and periodically discuss progress and obtain peer consultation from other professionals (both in mental health care and other health disciplines) who are competent in the assessment and treatment of gender dysphoria. The relationship among professionals involved in a client's health care should remain collaborative, with coordination and clinical dialogue taking place as needed. Open and consistent communication may be necessary for consultation, referral, and management of postoperative concerns.

Tasks Related to Psychotherapy

Psychotherapy Is Not an Absolute Requirement for Hormone Therapy and Surgery

A mental health screening and/or assessment as outlined above is needed for referral to hormonal and surgical treatments for gender dysphoria. In contrast, psychotherapy—although highly recommended—is not a requirement.

The *SOC* do not recommend a minimum number of psychotherapy sessions prior to hormone therapy or surgery. The reasons for this are multifaceted (Lev, 2009). First, a minimum number of sessions tends to be construed as a hurdle, which discourages the genuine opportunity for personal growth. Second, mental health professionals can offer important support to clients throughout all phases of exploration of gender identity, gender expression, and possible transition—not just prior to any possible medical interventions. Third, clients and their psychotherapists differ in their abilities to attain similar goals in a specified time period.

Goals of Psychotherapy for Adults with Gender Concerns

The general goal of psychotherapy is to find ways to maximize a person's overall psychological well-being, quality of life, and self-fulfillment. Psychotherapy is not intended to alter a person's gender identity; rather, psychotherapy can help an individual to explore gender concerns and find ways to alleviate gender dysphoria, if present (Bockting et al., 2006; Bockting & Coleman, 2007; Fraser, 2009a; Lev,

2004). Typically, the overarching treatment goal is to help transsexual, transgender, and gender-nonconforming individuals achieve long-term comfort in their gender identity expression, with realistic chances for success in their relationships, education, and work. For additional details, see Fraser (Fraser, 2009c).

Therapy may consist of individual, couple, family, or group psychotherapy, the latter being particularly important to foster peer support.

Psychotherapy for Transsexual, Transgender, and Gender-Nonconforming Clients, Including Counseling and Support for Changes in Gender Role

Finding a comfortable gender role is, first and foremost, a psychosocial process. Psychotherapy can be invaluable in assisting transsexual, transgender, and gender-nonconforming individuals with all of the following: (i) clarifying and exploring gender identity and role, (ii) addressing the impact of stigma and minority stress on one's mental health and human development, and (iii) facilitating a coming-out process (Bockting & Coleman, 2007; Devor, 2004; Lev, 2004), which for some individuals may include changes in gender role expression and the use of feminizing/masculinizing medical interventions.

Mental health professionals can provide support and promote interpersonal skills and resilience in individuals and their families as they navigate a world that often is ill-prepared to accommodate and respect transgender, transsexual, and gender-nonconforming people. Psychotherapy can also aid in alleviating any coexisting mental health concerns (e.g., anxiety, depression) identified during screening and assessment.

For transsexual, transgender, and gender-nonconforming individuals who plan to change gender roles permanently and make a social gender role transition, mental health professionals can facilitate the development of an individualized plan with specific goals and timelines. While the experience of changing one's gender role differs from person to person, the social aspects of the experience are usually challenging—often more so than the physical aspects. Because changing gender role can have profound personal and social consequences, the decision to do so should include an awareness of what the familial, interpersonal, educational, vocational, economic, and legal challenges are likely to be, so that people can function successfully in their gender role.

Many transsexual, transgender, and gender-nonconforming people will present for care without ever having been related to, or accepted in, the gender role that is most congruent with their gender identity. Mental health professionals can help these clients to explore and anticipate the implications of changes in gender role, and to pace the process of implementing these changes. Psychotherapy can provide a space for clients to begin to express themselves in ways that are congruent with their gender identity and, for some clients, overcome fears about changes in gender expression. Calculated risks can be taken outside of therapy to gain experience and build confidence in the new role. Assistance with coming out to family and community (friends, school, workplace) can be provided.

Other transsexual, transgender, and gender-nonconforming individuals will present for care already having acquired experience (minimal, moderate, or extensive) living in a gender role that differs from that associated with their birth-assigned sex. Mental health professionals can help these clients to identify and work through potential challenges and foster optimal adjustment as they continue to express changes in their gender role.

Family Therapy or Support for Family Members

Decisions about changes in gender role and medical interventions for gender dysphoria have implications for, not only clients, but also their families (Emerson & Rosenfeld, 1996; Fraser, 2009a; Lev, 2004). Mental health professionals can assist clients with making thoughtful decisions about communicating with family members and others about their gender identity and treatment decisions. Family therapy may include work with spouses or partners, as well

as with children and other members of a client's extended family.

Clients may also request assistance with their relationships and sexual health. For example, they may want to explore their sexuality and intimacy-related concerns.

Family therapy might be offered as part of the client's individual therapy and, if clinically appropriate, by the same provider. Alternatively, referrals can be made to other therapists with relevant expertise for working with family members or to sources of peer support (e.g., in person or offline support networks of partners or families).

Follow-Up Care Throughout Life

Mental health professionals may work with clients and their families at many stages of their lives. Psychotherapy may be helpful at different times and for various issues throughout the life cycle.

E-therapy, Online Counseling, or Distance Counseling

Online or e-therapy has been shown to be particularly useful for people who have difficulty accessing competent in-person psychotherapeutic treatment and who may experience isolation and stigma (Derrig-Palumbo & Zeine, 2005; Fenichel et al., 2004; Fraser, 2009b). By extrapolation, e-therapy may be a useful modality for psychotherapy with transsexual, transgender, and gender-nonconforming people. E-therapy offers opportunities for potentially enhanced, expanded, creative, and tailored delivery of services; however, as a developing modality it may also carry unexpected risk. Telemedicine guidelines are clear in some disciplines in some parts of the United States (Fraser, 2009b; Maheu, Pulier, Wilhelm, McMenamin, & Brown-Connolly, 2005) but not all; the international situation is even less well defined (Maheu et al., 2005). Until sufficient evidence-based data on this use of e-therapy is available, caution in its use is advised.

Mental health professionals engaging in e-therapy are advised to stay current with their particular licensing board, professional association, and country's regulations, as well as the most recent literature pertaining to this rapidly evolving medium. A more thorough description of the potential uses, processes, and ethical concerns related to e-therapy has been published (Fraser, 2009b).

Other Tasks of the Mental Health Professionals

Educate and Advocate on Behalf of Clients Within Their Community (Schools, Workplaces, Other Organizations) and Assist Clients with Making Changes in Identity Documents

Transsexual, transgender, and gender-nonconforming people may face challenges in their professional, educational, and other types of settings as they actualize their gender identity and expression (Lev, 2004, 2009). Mental health professionals can play an important role by educating people in these settings regarding gender nonconformity and by advocating on behalf of their clients (Currah, Juang, & Minter, 2006; Currah & Minter, 2000). This role may involve consultation with school counselors, teachers, and administrators, human resources staff, personnel managers and employers, and representatives from other organizations and institutions. In addition, health providers may be called upon to support changes in a client's name and/or gender marker on identity documents such as passports, driver's licenses, birth certificates, and diplomas.

Provide Information and Referral for Peer Support

For some transsexual, transgender, and gender-nonconforming people, an experience in peer support groups may be more instructive regarding options for gender expression than anything individual psychotherapy could offer (Rachlin, 2002). Both experiences are potentially valuable, and all people exploring gender issues should be encouraged to participate in community activities, if possible. Resources for peer support and information should be made available.

Culture and Its Ramifications for Assessment and Psychotherapy

Health professionals work in enormously different environments across the world. Forms of distress that cause people to seek professional assistance in any culture are understood and classified by people in terms that are products of their own cultures (Frank & Frank, 1993). Cultural settings also largely determine how such conditions are understood by mental health professionals. Cultural differences related to gender identity and expression can affect patients, mental health professionals, and accepted psychotherapy practice. WPATH recognizes that the *SOC* have grown out of a Western tradition and may need to be adapted depending on the cultural context.

Ethical Guidelines Related to Mental Health Care

Mental health professionals need to be certified or licensed to practice in a given country according to that country's professional regulations (Fraser, 2009b; Pope & Vasquez, 2011). Professionals must adhere to the ethical codes of their professional licensing or certifying organizations in all of their work with transsexual, transgender, and gender-nonconforming clients.

Treatment aimed at trying to change a person's gender identity and lived gender expression to become more congruent with sex assigned at birth has been attempted in the past (Gelder & Marks, 1969; Greenson, 1964), yet without success, particularly in the long-term (Cohen-Kettenis & Kuiper, 1984; Pauly, 1965). Such treatment is no longer considered ethical.

If mental health professionals are uncomfortable with, or inexperienced in, working with transsexual, transgender, and gender-nonconforming individuals and their families, they should refer clients to a competent provider or, at minimum, consult with an expert peer. If no local practitioners are available, consultation may be done via telehealth methods, assuming local requirements for distance consultation are met.

Issues of Access to Care

Qualified mental health professionals are not universally available; thus, access to quality care might be limited. WPATH aims to improve access and provides regular continuing education opportunities to train professionals from various disciplines to provide quality, transgender-specific health care. Providing mental health care from a distance through the use of technology may be one way to improve access (Fraser, 2009b).

In many places around the world, access to health care for transsexual, transgender, and gender-nonconforming people is also limited by a lack of health insurance or other means to pay for needed care. WPATH urges health insurance companies and other third-party payers to cover the medically necessary treatments to alleviate gender dysphoria (American Medical Association, 2008; Anton, 2009; World Professional Association for Transgender Health, 2008).

When faced with a client who is unable to access services, referral to available peer-support resources (offline and online) is recommended. Finally, harm-reduction approaches might be indicated to assist clients with making healthy decisions to improve their lives.

VIII. HORMONE THERAPY

Medical Necessity of Hormone Therapy

Feminizing/masculinizing hormone therapy —the administration of exogenous endocrine agents to induce feminizing or masculinizing changes—is a medically necessary intervention for many transsexual, transgender, and gender-nonconforming individuals with gender dysphoria (Newfield, Hart, Dibble, & Kohler, 2006; Pfäfflin & Junge, 1998). Some people seek maximum feminization/ masculinization, while others experience relief with an androgynous presentation resulting from hormonal minimization of existing secondary sex characteristics (Factor & Rothblum, 2008). Evidence for the psychosocial outcomes of hormone therapy is summarized in Appendix D.

Hormone therapy must be individualized based on a patient's goals, the risk/benefit ratio of medications, the presence of other medical conditions, and consideration of social and economic issues. Hormone therapy can provide significant comfort to patients who do not wish to make a social gender role transition or undergo surgery, or who are unable to do so (Meyer, 2009). Hormone therapy is a recommended criterion for some, but not all, surgical treatments for gender dysphoria (see section XI and Appendix C).

Criteria for Hormone Therapy

Initiation of hormone therapy may be undertaken after a psychosocial assessment has been conducted and informed consent has been obtained by a qualified health professional, as outlined in section VII of the *SOC*. A referral is required from the mental health professional who performed the assessment, unless the assessment was done by a hormone provider who is also qualified in this area.
The criteria for hormone therapy are as follows:

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* outlined in section VI);
4. If significant medical or mental health concerns are present, they must be reasonably well-controlled.

As noted in section VII of the *SOC*, the presence of coexisting mental health concerns does not necessarily preclude access to feminizing/masculinizing hormones; rather, these concerns need to be managed prior to, or concurrent with, treatment of gender dysphoria.

In selected circumstances, it can be acceptable practice to provide hormones to patients who have not fulfilled these criteria. Examples include facilitating the provision of monitored therapy using hormones of known quality as an alternative to illicit or unsupervised hormone use or to patients who have already established themselves in their affirmed gender and who have a history of prior hormone use. It is unethical to deny availability of or eligibility for hormone therapy solely on the basis of blood seropositivity for blood-borne infections such as HIV or hepatitis B or C.

In rare cases, hormone therapy may be contraindicated due to serious individual health conditions. Health professionals should assist these patients with accessing nonhormonal interventions for gender dysphoria. A qualified mental health professional familiar with the patient is an excellent resource in these circumstances.

Informed Consent

Feminizing/masculinizing hormone therapy may lead to irreversible physical changes. Thus, hormone therapy should be provided only to those who are legally able to provide informed consent. This includes people who have been declared by a court to be emancipated minors, incarcerated people, and cognitively impaired people who are considered competent to participate in their medical decisions (Bockting et al., 2006). Providers should document in the medical record that comprehensive information has been provided and understood about all relevant aspects of the hormone therapy, including both possible benefits and risks and the impact on reproductive capacity.

Relationship Between the Standards of Care and Informed Consent Model Protocols

A number of community health centers in the United States have developed protocols for providing hormone therapy based on an approach that has become known as the Informed Consent Model (Callen Lorde Community Health Center, 2000, 2011; Fenway Community Health Transgender Health Program, 2007; Tom Waddell Health Center, 2006). These protocols are consistent with the guidelines presented in the WPATH *Standards of Care, Version 7*. The *SOC* are flexible clinical guidelines; they allow for tailoring of interventions to the needs of the

individual receiving services and for tailoring of protocols to the approach and setting in which these services are provided (Ehrbar & Gorton, 2010).

Obtaining informed consent for hormone therapy is an important task of providers to ensure that patients understand the psychological and physical benefits and risks of hormone therapy, as well as its psychosocial implications. Providers prescribing the hormones or health professionals recommending the hormones should have the knowledge and experience to assess gender dysphoria. They should inform individuals of the particular benefits, limitations, and risks of hormones, given the patient's age, previous experience with hormones, and concurrent physical or mental health concerns.

Screening for and addressing acute or current mental health concerns is an important part of the informed consent process. This may be done by a mental health professional or by an appropriately trained prescribing provider (see section VII of the *SOC*). The same provider or another appropriately trained member of the health care team (e.g., a nurse) can address the psychosocial implications of taking hormones when necessary (e.g., the impact of masculinization/feminization on how one is perceived and its potential impact on relationships with family, friends, and coworkers). If indicated, these providers will make referrals for psychotherapy and for the assessment and treatment of coexisting mental health concerns such as anxiety or depression.

The difference between the Informed Consent Model and *SOC, Version 7,* is that the *SOC* puts greater emphasis on the important role that mental health professionals can play in alleviating gender dysphoria and facilitating changes in gender role and psychosocial adjustment. This may include a comprehensive mental health assessment and psychotherapy, when indicated. In the Informed Consent Model, the focus is on obtaining informed consent as the threshold for the initiation of hormone therapy in a multidisciplinary, harm-reduction environment. Less emphasis is placed on the provision of mental health care until the patient requests it, unless significant mental health concerns are identified that would need to be addressed before hormone prescription.

Physical Effects of Hormone Therapy

Feminizing/masculinizing hormone therapy will induce physical changes that are more congruent with a patient's gender identity.

- In FtM patients, the following physical changes are expected to occur: deepened voice, clitoral enlargement (variable), growth in facial and body hair, cessation of menses, atrophy of breast tissue, and decreased percentage of body fat compared to muscle mass.
- In MtF patients, the following physical changes are expected to occur: breast growth (variable), decreased erectile function, decreased testicular size, and increased percentage of body fat compared to muscle mass.

Most physical changes, whether feminizing or masculinizing, occur over the course of two years. The amount of physical change and the exact timeline of effects can be highly variable. Tables 1a and 1b outline the approximate time course of these physical changes.

TABLE 1a. Effects and Expected Time Course of Masculinizing Hormones[a]

Effect	Expected onset[b]	Expected maximum effect[b]
Skin oiliness/acne	1–6 months	1–2 years
Facial/body hair growth	3–6 months	3–5 years
Scalp hair loss	>12 months[c]	Variable
Increased muscle mass/strength	6–12 months	2–5 years[d]
Body fat redistribution	3–6 months	2–5 years
Cessation of menses	2–6 months	n/a
Clitoral enlargement	3–6 months	1–2 years
Vaginal atrophy	3–6 months	1–2 years
Deepened voice	3–12 months	1–2 years

[a] Adapted with permission from Hembree et al. (2009). Copyright 2009, The Endocrine Society.
[b] Estimates represent published and unpublished clinical observations.
[c] Highly dependent on age and inheritance; may be minimal.
[d] Significantly dependent on amount of exercise.

TABLE 1b. Effects and Expected Time Course of Feminizing Hormones[a]

Effect	Expected onset[b]	Expected maximum effect [b]
Body fat redistribution	3–6 months	2–5 years
Decreased muscle mass/strength	3–6 months	1–2 years[c]
Softening of skin/decreased oiliness	3–6 months	Unknown
Decreased libido	1–3 months	1–2 years
Decreased spontaneous erections	1–3 months	3–6 months
Male sexual dysfunction	Variable	Variable
Breast growth	3–6 months	2–3 years
Decreased testicular volume	3–6 months	2–3 years
Decreased sperm production	Variable	Variable
Thinning and slowed growth of body and facial hair	6–12 months	$>$ 3 years[d]
Male pattern baldness	No regrowth, loss stops 1–3 months	1–2 years

[a] Adapted with permission from Hembree et al. (2009). Copyright 2009, The Endocrine Society.
[b] Estimates represent published and unpublished clinical observations.
[c] Significantly dependent on amount of exercise.
[d] Complete removal of male facial and body hair requires electrolysis, laser treatment, or both.

The degree and rate of physical effects depends in part on the dose, route of administration, and medications used, which are selected in accordance with a patient's specific medical goals (e.g., changes in gender-role expression, plans for sex reassignment) and medical risk profile. There is no current evidence that response to hormone therapy—with the possible exception of voice deepening in FtM persons—can be reliably predicted based on age, body habitus, ethnicity, or family appearance. All other factors being equal, there is no evidence to suggest that any medically approved type or method of administering hormones is more effective than any other in producing the desired physical changes.

Risks of Hormone Therapy

All medical interventions carry risks. The likelihood of a serious adverse event is dependent on numerous factors: the medication itself, dose, route of administration, and a patient's clinical characteristics (age, comorbidities, family history, health habits). It is thus impossible to predict whether a given adverse effect will happen in an individual patient.

The risks associated with feminizing/masculinizing hormone therapy for the transsexual, transgender, and gender-nonconforming population as a whole are summarized in Table 2. Based on the level of evidence, risks are categorized as follows: (i) likely increased risk with hormone therapy, (ii) possibly increased risk with hormone therapy, or (iii) inconclusive or no increased risk. Items in the last category include those that may present risk but for which the evidence is so minimal that no clear conclusion can be reached.

Additional detail about these risks can be found in Appendix B, which is based on two comprehensive, evidence-based literature reviews of masculinizing/feminizing hormone therapy (Feldman & Safer, 2009; Hembree et al., 2009), along with a large cohort study (Asscheman et al., 2011). These reviews can serve as detailed references for providers, along with other widely recognized, published clinical materials (Dahl, Feldman, Goldberg, & Jaberi, 2006; Ettner, Monstrey, & Eyler, 2007).

Competency of Hormone-Prescribing Physicians, Relationship with Other Health Professionals

Feminizing/masculinizing hormone therapy is best undertaken in the context of a complete approach to health care that includes comprehensive primary care and a coordinated approach to psychosocial issues (Feldman & Safer, 2009). While psychotherapy or ongoing counseling is not required for the initiation of hormone therapy, if a therapist is involved, then regular

TABLE 2. Risks Associated with Hormone Therapy

Risk level	Feminizing hormones	Masculinizing hormones
Likely increased risk	• **Venous thromboembolic disease**[a] • Gallstones • Elevated liver enzymes • Weight gain • **Hypertriglyceridemia**	• **Polycythemia** • Weight gain • Acne • Androgenic alopecia (balding) • Sleep apnea
Likely increased risk with presence of additional risk factors[b]	• **Cardiovascular disease**	
Possible increased risk	• **Hypertension** • Hyperprolactinemia or prolactinoma	• Elevated liver enzymes • **Hyperlipidemia**
Possible increased risk with presence of additional risk factors [b]	• **Type 2 diabetes**[a]	• **Destabilization of certain psychiatric disorders**[c] • **Cardiovascular disease** • **Hypertension** • **Type 2 diabetes**
No increased risk or inconclusive	• **Breast cancer**	• Loss of bone density • **Breast cancer** • **Cervical cancer** • **Ovarian cancer** • **Uterine cancer**

Note. Bolded items are clinically significant.
[a] Risk is greater with oral estrogen administration than with transdermal estrogen administration.
[b] Additional risk factors include age.
[c] Includes bipolar, schizoaffective, and other disorders that may include manic or psychotic symptoms. This adverse event appears to be associated with higher doses or supraphysiologic blood levels of testosterone.

communication among health professionals is advised (with the patient's consent) to ensure that the transition process is going well, both physically and psychosocially.

With appropriate training, feminizing/masculinizing hormone therapy can be managed by a variety of providers, including nurse practitioners, physician assistants, and primary care physicians (Dahl et al., 2006). Medical visits relating to hormone maintenance provide an opportunity to deliver broader care to a population that is often medically underserved (Clements, Wilkinson, Kitano, & Marx, 1999; Feldman, 2007; Xavier, 2000). Many of the screening tasks and management of comorbidities associated with long-term hormone use, such as cardiovascular risk factors and cancer screening, fall more uniformly within the scope of primary care rather than specialist care (American Academy of Family Physicians, 2005; Eyler, 2007; World Health Organization, 2008), particularly in locations where dedicated gender teams or specialized physicians are not available.

Given the multidisciplinary needs of transsexual, transgender, and gender-nonconforming people seeking hormone therapy, as well as the difficulties associated with fragmentation of care in general (World Health Organization, 2008), WPATH strongly encourages the increased training and involvement of primary care providers in the area of feminizing/masculinizing hormone therapy. If hormones are prescribed by a specialist, there should be close communication with the patient's primary care provider. Conversely, an experienced hormone provider or endocrinologist should be involved if the primary care physician has no experience with this type of hormone therapy or if the patient has a preexisting metabolic or endocrine disorder that could be affected by endocrine therapy.

While formal training programs in transgender medicine do not yet exist, hormone providers have a responsibility to obtain appropriate

knowledge and experience in this field. Clinicians can increase their experience and comfort in providing feminizing/masculinizing hormone therapy by comanaging care or consulting with a more experienced provider, or by providing more limited types of hormone therapy before progressing to initiation of hormone therapy. Because this field of medicine is evolving, clinicians should become familiar and keep current with the medical literature and discuss emerging issues with colleagues. Such discussions might occur through networks established by WPATH and other national/local organizations.

Responsibilities of Hormone-Prescribing Physicians

In general, clinicians who prescribe hormone therapy should engage in the following tasks:

1. Perform an initial evaluation that includes discussion of a patient's physical transition goals, health history, physical examination, risk assessment, and relevant laboratory tests.
2. Discuss with patients the expected effects of feminizing/masculinizing medications and the possible adverse health effects. These effects can include a reduction in fertility (Feldman & Safer, 2009; Hembree et al., 2009). Therefore, reproductive options should be discussed with patients before starting hormone therapy (see section IX).
3. Confirm that patients have the capacity to understand the risks and benefits of treatment and are capable of making an informed decision about medical care.
4. Provide ongoing medical monitoring, including regular physical and laboratory examination to monitor hormone effectiveness and side effects.
5. Communicate as needed with a patient's primary care provider, mental health professional, and surgeon.
6. If needed, provide patients with a brief written statement indicating that they are under medical supervision and care that includes feminizing/masculinizing hormone therapy. Particularly during the early phases of hormone treatment, a patient may wish to carry this statement at all times to help prevent difficulties with the police and other authorities.

Depending on the clinical situation for providing hormones (see below), some of these responsibilities are less relevant. Thus, the degree of counseling, physical examinations, and laboratory evaluations should be individualized to a patient's needs.

Clinical Situations for Hormone Therapy

There are circumstances in which clinicians may be called upon to provide hormones without necessarily initiating or maintaining long-term feminizing/masculinizing hormone therapy. By acknowledging these different clinical situations (see below, from least to highest level of complexity), it may be possible to involve clinicians in feminizing/masculinizing hormone therapy who might not otherwise feel able to offer this treatment.

1. Bridging

Whether prescribed by another clinician or obtained through other means (e.g., purchased over the Internet), patients may present for care already on hormone therapy. Clinicians can provide a limited (1–6 month) prescription for hormones while helping patients find a provider who can prescribe long-term hormone therapy. Providers should assess a patient's current regimen for safety and drug interactions and substitute safer medications or doses when indicated (Dahl et al., 2006; Feldman & Safer, 2009). If hormones were previously prescribed, medical records should be requested (with the patient's permission) to obtain the results of baseline examinations and laboratory tests and any adverse events. Hormone providers should also communicate with any mental health professional who is currently involved in a patient's care. If a patient has never had a psychosocial assessment as recommended by the *SOC* (see section VII), clinicians should refer the patient to a qualified mental health professional if appropriate and feasible (Feldman & Safer, 2009). Providers who prescribe bridging hormones

need to work with patients to establish limits as to the duration of bridging therapy.

2. Hormone Therapy Following Gonad Removal

Hormone replacement with estrogen or testosterone is usually continued lifelong after an oophorectomy or orchiectomy, unless medical contraindications arise. Because hormone doses are often decreased after these surgeries (Basson, 2001; Levy, Crown, & Reid, 2003; Moore, Wisniewski, & Dobs, 2003) and only adjusted for age and comorbid health concerns, hormone management in this situation is quite similar to hormone replacement in any hypogonadal patient.

3. Hormone Maintenance Prior to Gonad Removal

Once patients have achieved maximal feminizing/masculinizing benefits from hormones (typically two or more years), they remain on a maintenance dose. The maintenance dose is then adjusted for changes in health conditions, aging, or other considerations such as lifestyle changes (Dahl et al., 2006). When a patient on maintenance hormones presents for care, the provider should assess the patient's current regimen for safety and drug interactions and substitute safer medications or doses when indicated. The patient should continue to be monitored by physical examinations and laboratory testing on a regular basis, as outlined in the literature (Feldman & Safer, 2009; Hembree et al., 2009). The dose and form of hormones should be revisited regularly with any changes in the patient's health status and available evidence on the potential long-term risks of hormones (see *Hormone Regimens*, below).

4. Initiating Hormonal Feminization/ Masculinization

This clinical situation requires the greatest commitment in terms of provider time and expertise. Hormone therapy must be individualized based on a patient's goals, the risk/benefit ratio of medications, the presence of other medical conditions, and consideration of social and economic issues. Although a wide variety of hormone regimens have been published (Dahl et al., 2006; Hembree et al., 2009; Moore et al., 2003), there are no published reports of randomized clinical trials comparing safety and efficacy. Despite this variation, a reasonable framework for initial risk assessment and ongoing monitoring of hormone therapy can be constructed, based on the efficacy and safety evidence presented above.

Risk Assessment and Modification for Initiating Hormone Therapy

The initial evaluation for hormone therapy assesses a patient's clinical goals and risk factors for hormone-related adverse events. During the risk assessment, the patient and clinician should develop a plan for reducing risks wherever possible, either prior to initiating therapy or as part of ongoing harm reduction.

All assessments should include a thorough physical exam, including weight, height, and blood pressure. The need for breast, genital, and rectal exams, which are sensitive issues for most transsexual, transgender, and gender-nonconforming patients, should be based on individual risks and preventive health care needs (Feldman & Goldberg, 2006; Feldman, 2007).

Preventive Care

Hormone providers should address preventive health care with patients, particularly if a patient does not have a primary care provider. Depending on a patient's age and risk profile, there may be appropriate screening tests or exams for conditions affected by hormone therapy. Ideally, these screening tests should be carried out prior to the start of hormone therapy.

Risk Assessment and Modification for Feminizing Hormone Therapy (MtF)

There are no absolute contraindications to feminizing therapy per se, but absolute contraindications exist for the different feminizing agents, particularly estrogen. These include previous venous thrombotic events related to an underlying hypercoagulable condition, history of estrogen-sensitive neoplasm, and end-stage chronic liver disease (Gharib et al., 2005).

Other medical conditions, as noted in Table 2 and Appendix B, can be exacerbated by estrogen or androgen blockade and, therefore, should be evaluated and reasonably well controlled prior to starting hormone therapy (Feldman & Safer, 2009; Hembree et al., 2009. Dhejne et al., 2011). Clinicians should particularly attend to tobacco use, as it is associated with increased risk of venous thrombosis, which is further increased with estrogen use. Consultation with a cardiologist may be advisable for patients with known cardio- or cerebrovascular disease.

Baseline laboratory values are important to both assess initial risk and evaluate possible future adverse events. Initial labs should be based on the risks of feminizing hormone therapy outlined in Table 2, as well as individual patient risk factors, including family history. Suggested initial lab panels have been published (Feldman & Safer, 2009; Hembree et al., 2009). These can be modified for patients or health care systems with limited resources and in otherwise healthy patients.

Risk Assessment and Modification for Masculinizing Hormone Therapy (FtM)

Absolute contraindications to testosterone therapy include pregnancy, unstable coronary artery disease, and untreated polycythemia with a hematocrit of 55% or higher (Carnegie, 2004). Because the aromatization of testosterone to estrogen may increase risk in patients with a history of breast or other estrogen-dependent cancers (Moore et al., 2003), consultation with an oncologist may be indicated prior to hormone use. Comorbid conditions likely to be exacerbated by testosterone use should be evaluated and treated, ideally prior to starting hormone therapy (Feldman & Safer, 2009; Hembree et al., 2009). Consultation with a cardiologist may be advisable for patients with known cardio- or cerebrovascular disease (Dhejne et al., 2011).

An increased prevalence of polycystic ovarian syndrome (PCOS) has been noted among FtM patients even in the absence of testosterone use (Baba et al., 2007; Balen, Schachter, Montgomery, Reid, & Jacobs, 1993; Bosinski et al., 1997). While there is no evidence that PCOS is related to the development of a transsexual, transgender, or gender-nonconforming identity, PCOS is associated with increased risk of diabetes, cardiac disease, high blood pressure, and ovarian and endometrial cancers (Cattrall & Healy, 2004). Signs and symptoms of PCOS should be evaluated prior to initiating testosterone therapy, as testosterone may affect many of these conditions. Testosterone can affect the developing fetus (*Physicians' Desk Reference,* 2010), and patients at risk of becoming pregnant require highly effective birth control.

Baseline laboratory values are important to both assess initial risk and evaluate possible future adverse events. Initial labs should be based on the risks of masculinizing hormone therapy outlined in Table 2, as well as individual patient risk factors, including family history. Suggested initial lab panels have been published (Feldman & Safer, 2009; Hembree et al., 2009). These can be modified for patients or health care systems with limited resources and in otherwise healthy patients.

Clinical Monitoring During Hormone Therapy for Efficacy and Adverse Events

The purpose of clinical monitoring during hormone use is to assess the degree of feminization/masculinization and the possible presence of adverse effects of medication. However, as with the monitoring of any long-term medication, monitoring should take place in the context of comprehensive health care. Suggested clinical monitoring protocols have been published (Feldman & Safer, 2009; Hembree et al., 2009). Patients with comorbid medical conditions may need to be monitored more frequently. Healthy patients in geographically remote or resource-poor areas may be able to use alternative strategies, such as telehealth, or cooperation with local providers such as nurses and physician assistants. In the absence of other indications, health professionals may prioritize monitoring for those risks that are either likely to be increased by hormone therapy or possibly increased by hormone therapy but clinically serious in nature.

Efficacy and Risk Monitoring During Feminizing Hormone Therapy (MtF)

The best assessment of hormone efficacy is clinical response: Is a patient developing a feminized body while minimizing masculine characteristics consistent with that patient's gender goals? In order to more rapidly predict the hormone dosages that will achieve clinical response, one can measure testosterone levels for suppression below the upper limit of the normal female range and estradiol levels within a premenopausal female range but well below supraphysiologic levels (Feldman & Safer, 2009; Hembree et al., 2009).

Monitoring for adverse events should include both clinical and laboratory evaluation. Follow-up should include careful assessment for signs of cardiovascular impairment and venous thromboembolism (VTE) through measurement of blood pressure, weight, and pulse; heart and lung exams; and examination of the extremities for peripheral edema, localized swelling, or pain (Feldman & Safer, 2009). Laboratory monitoring should be based on the risks of hormone therapy described above, a patient's individual comorbidities and risk factors, and the specific hormone regimen itself. Specific lab-monitoring protocols have been published (Feldman & Safer, 2009; Hembree et al., 2009).

Efficacy and Risk Monitoring During Masculinizing Hormone Therapy (FtM)

The best assessment of hormone efficacy is clinical response: Is a patient developing a masculinized body while minimizing feminine characteristics consistent with that patient's gender goals? Clinicians can achieve a good clinical response with the least likelihood of adverse events by maintaining testosterone levels within the normal male range while avoiding supraphysiological levels (Dahl et al., 2006; Hembree et al., 2009). For patients using intramuscular (IM) testosterone cypionate or enanthate, some clinicians check trough levels while others prefer midcycle levels (Dahl et al., 2006; Hembree et al., 2009; Tangpricha, Turner, Malabanan, & Holick, 2001; Tangpricha, Ducharme, Barber, & Chipkin, 2003).

Monitoring for adverse events should include both clinical and laboratory evaluation. Follow-up should include careful assessment for signs and symptoms of excessive weight gain, acne, uterine break-through bleeding, and cardiovascular impairment, as well as psychiatric symptoms in at-risk patients. Physical examinations should include measurement of blood pressure, weight, pulse, and skin, as well as and heart and lung exams (Feldman & Safer, 2009). Laboratory monitoring should be based on the risks of hormone therapy described above, a patient's individual comorbidities and risk factors, and the specific hormone regimen itself. Specific lab monitoring protocols have been published (Feldman & Safer, 2009; Hembree et al., 2009).

Hormone Regimens

To date, no controlled clinical trials of any feminizing/masculinizing hormone regimen have been conducted to evaluate safety or efficacy in producing physical transition. As a result, wide variation in doses and types of hormones have been published in the medical literature (Moore et al., 2003; Tangpricha et al., 2003; van Kesteren, Asscheman, Megens, & Gooren, 1997). In addition, access to particular medications may be limited by a patient's geographical location and/or social or economic situations. For these reasons, WPATH does not describe or endorse a particular feminizing/masculinizing hormone regimen. Rather, the medication classes and routes of administration used in most published regimens are broadly reviewed.

As outlined above, there are demonstrated safety differences in individual elements of various regimens. The Endocrine Society Guidelines (Hembree et al., 2009) and Feldman and Safer (2009) provide specific guidance regarding the types of hormones and suggested dosing to maintain levels within physiologic ranges for a patient's desired gender expression (based on goals of full feminization/masculinization). It is strongly recommended that hormone providers regularly review the literature for new information and use those medications that safely meet individual patient needs with available local resources.

Regimens for Feminizing Hormone Therapy (MtF)

Estrogen. Use of oral estrogen, and specifically ethinyl estradiol, appears to increase the risk of VTE. Because of this safety concern, ethinyl estradiol is not recommended for feminizing hormone therapy. Transdermal estrogen is recommended for those patients with risk factors for VTE. The risk of adverse events increases with higher doses, particularly doses resulting in supraphysiologic levels (Hembree et al., 2009). Patients with comorbid conditions that can be affected by estrogen should avoid oral estrogen if possible and be started at lower levels. Some patients may not be able to safely use the levels of estrogen needed to get the desired results. This possibility needs to be discussed with patients well in advance of starting hormone therapy.

Androgen-reducing medications ("anti-androgens"). A combination of estrogen and "anti-androgens" is the most commonly studied regimen for feminization. Androgen-reducing medications, from a variety of classes of drugs, have the effect of reducing either endogenous testosterone levels or testosterone activity and, thus, diminishing masculine characteristics such as body hair. They minimize the dosage of estrogen needed to suppress testosterone thereby reducing the risks associated with high-dose exogenous estrogen (Prior, Vigna, Watson, Diewold, & Robinow, 1986; Prior, Vigna, & Watson, 1989).

Common anti-androgens include the following:

- Spironolactone, an antihypertensive agent, directly inhibits testosterone secretion and androgen binding to the androgen receptor. Blood pressure and electrolytes need to be monitored because of the potential for hyperkalemia.
- Cyproterone acetate is a progestational compound with anti-androgenic properties. This medication is not approved in the United States because of concerns over potential hepatotoxicity, but it is widely used elsewhere (De Cuypere et al., 2005).
- GnRH agonists (e.g., goserelin, buserelin, triptorelin) are neurohormones that block the gonadtropin-releasing hormone receptor, thus blocking the release of follicle stimulating hormone and luteinizing hormone. This leads to highly effective gonadal blockade. However, these medications are expensive and only available as injectables or implants.
- 5-alpha reductase inhibitors (finasteride and dutasteride) block the conversion of testosterone to the more active agent, 5-alpha-dihydrotestosterone. These medications have beneficial effects on scalp hair loss, body hair growth, sebaceous glands, and skin consistency.

Cyproterone and spironolactone are the most commonly used anti-androgens and are likely the most cost-effective.

Progestins. With the exception of cyproterone, the inclusion of progestins in feminizing hormone therapy is controversial (Oriel, 2000). Because progestins play a role in mammary development on a cellular level, some clinicians believe that these agents are necessary for full breast development (Basson & Prior, 1998; Oriel, 2000). However, a clinical comparison of feminization regimens with and without progestins found that the addition of progestins neither enhanced breast growth nor lowered serum levels of free testosterone (Meyer et al., 1986). There are concerns regarding potential adverse effects of progestins, including depression, weight gain, and lipid changes (Meyer et al., 1986; Tangpricha et al., 2003). Progestins (especially medroxyprogesterone) are also suspected to increase breast cancer risk and cardiovascular risk in women (Rossouw et al., 2002). Micronized progesterone may be better tolerated and have a more favorable impact on the lipid profile than medroxyprogesterone does (de Lignières, 1999; Fitzpatrick, Pace, & Wiita, 2000).

Regimens for Masculinizing Hormone Therapy (FtM)

Testosterone. Testosterone generally can be given orally, transdermally, or parenterally (IM), although buccal and implantable preparations are also available. Oral testosterone

undecanoate, available outside the United States, results in lower serum testosterone levels than nonoral preparations and has limited efficacy in suppressing menses (Feldman, 2005, April; Moore et al., 2003). Because intramuscular testosterone cypionate or enanthate are often administered every 2–4 weeks, some patients may notice cyclic variation in effects (e.g., fatigue and irritability at the end of the injection cycle, aggression or expansive mood at the beginning of the injection cycle), as well as more time outside the normal physiologic levels (Dhejne et al., 2011; Jockenhövel, 2004). This may be mitigated by using a lower but more frequent dosage schedule or by using a daily transdermal preparation (Dobs et al., 1999; Jockenhövel, 2004; Nieschlag et al., 2004). Intramuscular testosterone undecanoate (not currently available in the United States) maintains stable, physiologic testosterone levels over approximately 12 weeks and has been effective in both the setting of hypogonadism and in FtM individuals (Mueller, Kiesewetter, Binder, Beckmann, & Dittrich, 2007; Zitzmann, Saad, & Nieschlag, 2006). There is evidence that transdermal and intramuscular testosterone achieve similar masculinizing results, although the timeframe may be somewhat slower with transdermal preparations (Feldman, 2005, April). Especially as patients age, the goal is to use the lowest dose needed to maintain the desired clinical result, with appropriate precautions being made to maintain bone density.

Other agents. Progestins, most commonly medroxyprogesterone, can be used for a short period of time to assist with menstrual cessation early in hormone therapy. GnRH agonists can be used similarly, as well as for refractory uterine bleeding in patients without an underlying gynecological abnormality.

Bioidentical and Compounded Hormones

As discussion surrounding the use of bioidentical hormones in postmenopausal hormone replacement has heightened, interest has also increased in the use of similar compounds in feminizing/masculinizing hormone therapy. There is no evidence that custom compounded bioidentical hormones are safer or more effective than government-agency-approved bioidentical hormones (Sood, Shuster, Smith, Vincent, & Jatoi, 2011). Therefore, it has been advised by the North American Menopause Society (2010) and others to assume that, whether the hormone is from a compounding pharmacy or not, if the active ingredients are similar, it should have a similar side-effect profile. WPATH concurs with this assessment.

IX. REPRODUCTIVE HEALTH

Many transgender, transsexual, and gender-nonconforming people will want to have children. Because feminizing/masculinizing hormone therapy limits fertility (Darney, 2008; Zhang, Gu, Wang, Cui, & Bremner, 1999), it is desirable for patients to make decisions concerning fertility before starting hormone therapy or undergoing surgery to remove/alter their reproductive organs. Cases are known of people who received hormone therapy and genital surgery and later regretted their inability to parent genetically related children (De Sutter, Kira, Verschoor, & Hotimsky, 2002).

Health care professionals—including mental health professionals recommending hormone therapy or surgery, hormone-prescribing physicians, and surgeons—should discuss reproductive options with patients prior to initiation of these medical treatments for gender dysphoria. These discussions should occur even if patients are not interested in these issues at the time of treatment, which may be more common for younger patients (De Sutter, 2009). Early discussions are desirable, but not always possible. If an individual has not had complete sex reassignment surgery, it may be possible to stop hormones long enough for natal hormones to recover, allowing the production of mature gametes (Payer, Meyer, & Walker, 1979; Van den Broecke, Van der Elst, Liu, Hovatta, & Dhont, 2001).

Besides debate and opinion papers, very few research papers have been published on the reproductive health issues of individuals receiving different medical treatments for gender dysphoria. Another group who faces the need to preserve reproductive function in light of

loss or damage to their gonads are people with malignancies that require removal of reproductive organs or use of damaging radiation or chemotherapy. Lessons learned from that group can be applied to people treated for gender dysphoria.

MtF patients, especially those who have not already reproduced, should be informed about sperm-preservation options and encouraged to consider banking their sperm prior to hormone therapy. In a study examining testes that were exposed to high-dose estrogen (Payer et al., 1979), findings suggest that stopping estrogen may allow the testes to recover. In an article reporting on the opinions of MtF individuals towards sperm freezing (De Sutter et al., 2002), the vast majority of 121 survey respondents felt that the availability of freezing sperm should be discussed and offered by the medical world. Sperm should be collected before hormone therapy or after stopping the therapy until the sperm count rises again. Cryopreservation should be discussed even if there is poor semen quality. In adults with azoospermia, a testicular biopsy with subsequent cryopreservation of biopsied material for sperm is possible, but may not be successful.

Reproductive options for FtM patients might include oocyte (egg) or embryo freezing. The frozen gametes and embryo could later be used with a surrogate woman to carry to pregnancy. Studies of women with polycystic ovarian disease suggest that the ovary can recover in part from the effects of high testosterone levels (Hunter & Sterrett, 2000). Stopping the testosterone briefly might allow for ovaries to recover enough to release eggs; success likely depends on the patient's age and duration of testosterone treatment. While not systematically studied, some FtM individuals are doing exactly that, and some have been able to become pregnant and deliver children (More, 1998).

Patients should be advised that these techniques are not available everywhere and can be very costly. Transsexual, transgender, and gender-nonconforming people should not be refused reproductive options for any reason.

A special group of individuals are prepubertal or pubertal adolescents who will never develop reproductive function in their natal sex due to blockers or cross-gender hormones. At this time there is no technique for preserving function from the gonads of these individuals.

X. VOICE AND COMMUNICATION THERAPY

Communication, both verbal and nonverbal, is an important aspect of human behavior and gender expression. Transsexual, transgender, and gender-nonconforming people might seek the assistance of a voice and communication specialist to develop vocal characteristics (e.g., pitch, intonation, resonance, speech rate, phrasing patterns) and nonverbal communication patterns (e.g., gestures, posture/movement, facial expressions) that facilitate comfort with their gender identity. Voice and communication therapy may help to alleviate gender dysphoria and be a positive and motivating step towards achieving one's goals for gender role expression.

Competency of Voice and Communication Specialists Working with Transsexual, Transgender, and Gender-Nonconforming Clients

Specialists may include speech-language pathologists, speech therapists, and speech-voice clinicians. In most countries the professional association for speech-language pathologists requires specific qualifications and credentials for membership. In some countries the government regulates practice through licensing, certification, or registration processes (American Speech-Language-Hearing Association, 2011; Canadian Association of Speech-Language Pathologists and Audiologists; Royal College of Speech & Language Therapists, United Kingdom; Speech Pathology Australia).

The following are recommended minimum credentials for voice and communication specialists working with transsexual, transgender, and gender-nonconforming clients:

1. Specialized training and competence in the assessment and development of communication skills in transsexual, transgender, and gender-nonconforming clients.

2. A basic understanding of transgender health, including hormonal and surgical treatments for feminization/masculinization and trans-specific psychosocial issues as outlined in the *SOC*, and familiarity with basic sensitivity protocols such as the use of preferred gender pronoun and name (Canadian Association of Speech-Language Pathologists and Audiologists; Royal College of Speech & Language Therapists, United Kingdom; Speech Pathology Australia).
3. Continuing education in the assessment and development of communication skills in transsexual, transgender, and gender-nonconforming clients. This may include attendance at professional meetings, workshops, or seminars; participation in research related to gender-identity issues; independent study; or mentoring from an experienced, certified clinician.

Other professionals such as vocal coaches, theater professionals, singing teachers, and movement experts may play a valuable adjunct role. Such professionals will ideally have experience working with, or be actively collaborating with, speech-language pathologists.

Assessment and Treatment Considerations

The overall purpose of voice and communication therapy is to help clients adapt their voice and communication in a way that is both safe and authentic, resulting in communication patterns that clients feel are congruent with their gender identity and that reflect their sense of self (Adler, Hirsch, & Mordaunt, 2006). It is essential that voice and communication specialists be sensitive to individual communication preferences. Communication—style, voice, choice of language, etc.—is personal. Individuals should not be counseled to adopt behaviors with which they are not comfortable or which do not feel authentic. Specialists can best serve their clients by taking the time to understand a person's gender concerns and goals for gender-role expression (American Speech-Language-Hearing Association, 2011; Canadian Association of Speech-Language Pathologists and Audiologists; Royal College of Speech & Language Therapists, United Kingdom; Speech Pathology Australia).

Individuals may choose the communication behaviors that they wish to acquire in accordance with their gender identity. These decisions are also informed and supported by the knowledge of the voice and communication specialist and by the assessment data for a specific client (Hancock, Krissinger, & Owen, 2010). Assessment includes a client's self-evaluation and a specialist's evaluation of voice, resonance, articulation, spoken language, and nonverbal communication (Adler et al., 2006; Hancock et al., 2010).

Voice-and-communication treatment plans are developed by considering the available research evidence, the clinical knowledge and experience of the specialist, and the client's own goals and values (American Speech-Language-Hearing Association, 2011; Canadian Association of Speech-Language Pathologists and Audiologists; Royal College of Speech & Language Therapists, United Kingdom; Speech Pathology Australia). Targets of treatment typically include pitch, intonation, loudness and stress patterns, voice quality, resonance, articulation, speech rate and phrasing, language, and nonverbal communication (Adler et al., 2006; Davies & Goldberg, 2006; de Bruin, Coerts, & Greven, 2000; Gelfer, 1999; McNeill, 2006; Oates & Dacakis, 1983). Treatment may involve individual and/or group sessions. The frequency and duration of treatment will vary according to a client's needs. Existing protocols for voice-and-communication treatment can be considered in developing an individualized therapy plan (Carew, Dacakis, & Oates, 2007; Dacakis, 2000; Davies & Goldberg, 2006; Gelfer, 1999; McNeill, Wilson, Clark, & Deakin, 2008; Mount & Salmon, 1988).

Feminizing or masculinizing the voice involves nonhabitual use of the voice production mechanism. Prevention measures are necessary to avoid the possibility of vocal misuse and long-term vocal damage. All voice and communication therapy services should therefore include a vocal health component (Adler et al., 2006).

Vocal Health Considerations After Voice Feminization Surgery

As noted in section XI, some transsexual, transgender, and gender-nonconforming people will undergo voice feminization surgery. (Voice deepening can be achieved through masculinizing hormone therapy, but feminizing hormones do not have an impact on the adult MtF voice.) There are varying degrees of satisfaction, safety, and long-term improvement in patients who have had such surgery. It is recommended that individuals undergoing voice feminization surgery also consult a voice and communication specialist to maximize the surgical outcome, help protect vocal health, and learn nonpitch related aspects of communication. Voice surgery procedures should include follow-up sessions with a voice and communication specialist who is licensed and/or credentialed by the board responsible for speech therapists/speech-language pathologists in that country (Kanagalingam et al., 2005; Neumann & Welzel, 2004).

XI. SURGERY

Sex Reassignment Surgery Is Effective and Medically Necessary

Surgery—particularly genital surgery—is often the last and the most considered step in the treatment process for gender dysphoria. While many transsexual, transgender, and gender-nonconforming individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender dysphoria (Hage & Karim, 2000). For the latter group, relief from gender dysphoria cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity. Moreover, surgery can help patients feel more at ease in the presence of sex partners or in venues such as physicians' offices, swimming pools, or health clubs. In some settings, surgery might reduce risk of harm in the event of arrest or search by police or other authorities.

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; Gijs & Brewaeys, 2007; Klein & Gorzalka, 2009; Pfäfflin & Junge, 1998). Additional information on the outcomes of surgical treatments are summarized in Appendix D.

Ethical Questions Regarding Sex Reassignment Surgery

In ordinary surgical practice, pathological tissues are removed to restore disturbed functions, or alterations are made to body features to improve a patient's self image. Some people, including some health professionals, object on ethical grounds to surgery as a treatment for gender dysphoria, because these conditions are thought not to apply.

It is important that health professionals caring for patients with gender dysphoria feel comfortable about altering anatomically normal structures. In order to understand how surgery can alleviate the psychological discomfort and distress of individuals with gender dysphoria, professionals need to listen to these patients discuss their symptoms, dilemmas, and life histories. The resistance against performing surgery on the ethical basis of "above all do no harm" should be respected, discussed, and met with the opportunity to learn from patients themselves about the psychological distress of having gender dysphoria and the potential for harm caused by denying access to appropriate treatments.

Genital and breast/chest surgical treatments for gender dysphoria are not merely another set of elective procedures. Typical elective procedures involve only a private mutually consenting contract between a patient and a surgeon. Genital and breast/chest surgeries as medically necessary treatments for gender dysphoria are to be undertaken only after assessment of the patient by qualified mental health professionals, as outlined in section VII of the *SOC*. These surgeries may be performed once there is written documentation that this assessment has occurred and that the person has met the criteria for a specific surgical treatment. By following this procedure, mental health professionals,

surgeons, and patients share responsibility for the decision to make irreversible changes to the body.

It is unethical to deny availability or eligibility for sex reassignment surgeries solely on the basis of blood seropositivity for blood-borne infections such as HIV or hepatitis C or B.

Relationship of Surgeons with Mental Health Professionals, Hormone-Prescribing Physicians (if Applicable), and Patients (Informed Consent)

The role of a surgeon in the treatment of gender dysphoria is not that of a mere technician. Rather, conscientious surgeons will have insight into each patient's history and the rationale that led to the referral for surgery. To that end, surgeons must talk at length with their patients and have close working relationships with other health professionals who have been actively involved in their clinical care.

Consultation is readily accomplished when a surgeon practices as part of an interdisciplinary health care team. In the absence of this, a surgeon must be confident that the referring mental health professional(s), and if applicable the physician who prescribes hormones, is/are competent in the assessment and treatment of gender dysphoria, because the surgeon is relying heavily on his/her/their expertise.

Once a surgeon is satisfied that the criteria for specific surgeries have been met (as outlined below), surgical treatment should be considered and a preoperative surgical consultation should take place. During this consultation, the procedure and postoperative course should be extensively discussed with the patient. Surgeons are responsible for discussing all of the following with patients seeking surgical treatments for gender dysphoria:

- The different surgical techniques available (with referral to colleagues who provide alternative options);
- The advantages and disadvantages of each technique;
- The limitations of a procedure to achieve "ideal" results; surgeons should provide a full range of before-and-after photographs of their own patients, including both successful and unsuccessful outcomes;
- The inherent risks and possible complications of the various techniques; surgeons should inform patients of their own complication rates with respect to each procedure.

These discussions are the core of the informed-consent process, which is both an ethical and legal requirement for any surgical procedure. Ensuring that patients have a realistic expectation of outcomes is important in achieving a result that will alleviate their gender dysphoria.

All of this information should be provided to patients in writing, in a language in which they are fluent, and in graphic illustrations. Patients should receive the information in advance (possibly via the Internet) and given ample time to review it carefully. The elements of informed consent should always be discussed face-to-face prior to the surgical intervention. Questions can then be answered and written informed consent can be provided by the patient. Because these surgeries are irreversible, care should be taken to ensure that patients have sufficient time to absorb information fully before they are asked to provide informed consent. A minimum of 24 hours is suggested.

Surgeons should provide immediate aftercare and consultation with other physicians serving the patient in the future. Patients should work with their surgeon to develop an adequate aftercare plan for the surgery.

Overview of Surgical Procedures for the Treatment of Patients with Gender Dysphoria

For the Male-to-Female (MtF) Patient, Surgical Procedures May Include the Following:

1. Breast/chest surgery: augmentation mammoplasty (implants/lipofilling);
2. Genital surgery: penectomy, orchiectomy, vaginoplasty, clitoroplasty, vulvoplasty;
3. Nongenital, nonbreast surgical interventions: facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation

(implants/lipofilling), hair reconstruction, and various aesthetic procedures.

For the Female-to-Male (FtM) Patient, Surgical Procedures May Include the Following:

1. Breast/chest surgery: subcutaneous mastectomy, creation of a male chest;
2. Genital surgery: hysterectomy/salpingo-oophorectomy, reconstruction of the fixed part of the urethra, which can be combined with a metoidioplasty or with a phalloplasty (employing a pedicled or free vascularized flap), vaginectomy, scrotoplasty, and implantation of erection and/or testicular prostheses;
3. Nongenital, nonbreast surgical interventions: voice surgery (rare), liposuction, lipofilling, pectoral implants, and various aesthetic procedures.

Reconstructive Versus Aesthetic Surgery

The question of whether sex reassignment surgery should be considered "aesthetic" surgery or "reconstructive" surgery is pertinent not only from a philosophical point of view, but also from a financial point of view. Aesthetic or cosmetic surgery is mostly regarded as not medically necessary and therefore is typically paid for entirely by the patient. In contrast, reconstructive procedures are considered medically necessary—with unquestionable therapeutic results—and thus paid for partially or entirely by national health systems or insurance companies.

Unfortunately, in the field of plastic and reconstructive surgery (both in general and specifically for gender-related surgeries), there is no clear distinction between what is purely reconstructive and what is purely cosmetic. Most plastic surgery procedures actually are a mixture of both reconstructive and cosmetic components.

While most professionals agree that genital surgery and mastectomy cannot be considered purely cosmetic, opinions diverge as to what degree other surgical procedures (e.g., breast augmentation, facial feminization surgery) can be considered purely reconstructive. Although it may be much easier to see a phalloplasty or a vaginoplasty as an intervention to end lifelong suffering, for certain patients an intervention like a reduction rhinoplasty can have a radical and permanent effect on their quality of life and, therefore, is much more medically necessary than for somebody without gender dysphoria.

Criteria for Surgeries

As for all of the *SOC*, the criteria for initiation of surgical treatments for gender dysphoria were developed to promote optimal patient care. While the *SOC* allow for an individualized approach to best meet a patient's health care needs, a criterion for all breast/chest and genital surgeries is documentation of persistent gender dysphoria by a qualified mental health professional. For some surgeries, additional criteria include preparation and treatment consisting of feminizing/masculinizing hormone therapy and one year of continuous living in a gender role that is congruent with one's gender identity.

These criteria are outlined below. Based on the available evidence and expert clinical consensus, different recommendations are made for different surgeries.

The *SOC* do not specify an order in which different surgeries should occur. The number and sequence of surgical procedures may vary from patient to patient, according to their clinical needs.

Criteria for Breast/Chest Surgery (One Referral)

Criteria for 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 prerequisite.

Criteria for 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)

The criteria for genital surgery are specific to the type of surgery being requested.

Criteria for hysterectomy and salpingo-oophorectomy in FtM patients and for orchiectomy in MtF patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to give 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 hormones are not clinically indicated for the individual).

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

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

Criteria for metoidioplasty or phalloplasty in FtM patients and for 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 hormones are not clinically indicated for the individual).
6. 12 continuous months of living in a gender role that is congruent with the patient's identity.

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

Rationale for a preoperative, 12-month experience of living in an identity-congruent gender role. 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. As noted in section VII, the social aspects of changing one's gender role are usually challenging—often more so than the physical aspects. Changing gender role can have profound personal and social consequences, and the decision to do so should include an awareness of what the familial, interpersonal, educational, vocational, economic, and legal challenges are likely to be, so that people can function successfully in their gender role. Support from a qualified mental health professional and from

peers can be invaluable in ensuring a successful gender role adaptation (Bockting, 2008).

The duration of 12 months allows for a range of different life experiences and events that may occur throughout the year (e.g., family events, holidays, vacations, season-specific work or school experiences). During this time, patients should present consistently, on a day-to-day basis and across all settings of life, in their desired gender role. This includes coming out to partners, family, friends, and community members (e.g., at school, work, other settings).

Health professionals should clearly document a patient's experience in the gender role in the medical chart, including the start date of living full-time for those who are preparing for genital surgery. In some situations, if needed, health professionals may request verification that this criterion has been fulfilled: They may communicate with individuals who have related to the patient in an identity-congruent gender role or request documentation of a legal name and/or gender-marker change, if applicable.

Surgery for People with Psychotic Conditions and Other Serious Mental Illnesses

When patients with gender dysphoria are also diagnosed with severe psychiatric disorders and impaired reality testing (e.g., psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated (Dhejne et al., 2011). Reevaluation by a mental health professional qualified to assess and manage psychotic conditions should be conducted prior to surgery, describing the patient's mental status and readiness for surgery. It is preferable that this mental health professional be familiar with the patient. No surgery should be performed while a patient is actively psychotic (De Cuypere & Vercruysse, 2009).

Competency of Surgeons Performing Breast/Chest or Genital Surgery

Physicians who perform surgical treatments for gender dysphoria should be urologists, gynecologists, plastic surgeons, or general surgeons, and board-certified as such by the relevant national and/or regional association. Surgeons should have specialized competence in genital reconstructive techniques as indicated by documented supervised training with a more experienced surgeon. Even experienced surgeons must be willing to have their surgical skills reviewed by their peers. An official audit of surgical outcomes and publication of these results would be greatly reassuring to both referring health professionals and patients. Surgeons should regularly attend professional meetings where new techniques are presented. The Internet is often effectively used by patients to share information on their experience with surgeons and their teams.

Ideally, surgeons should be knowledgeable about more than one surgical technique for genital reconstruction so that they, in consultation with patients, can choose the ideal technique for each individual. Alternatively, if a surgeon is skilled in a single technique and this procedure is either not suitable for or desired by a patient, the surgeon should inform the patient about other procedures and offer referral to another appropriately skilled surgeon.

Breast/Chest Surgery Techniques and Complications

Although breast/chest appearance is an important secondary sex characteristic, breast presence or size is not involved in the legal definitions of sex and gender and is not necessary for reproduction. The performance of breast/chest operations for treatment of gender dysphoria should be considered with the same care as beginning hormone therapy, as both produce relatively irreversible changes to the body.

For the MtF patient, a breast augmentation (sometimes called "chest reconstruction") is not different from the procedure in a natal female patient. It is usually performed through implantation of breast prostheses and occasionally with the lipofilling technique. Infections and capsular fibrosis are rare complications of augmentation mammoplasty in MtF patients (Kanhai, Hage, Karim, & Mulder, 1999).

For the FtM patient, a mastectomy or "male chest contouring" procedure is available. For

many FtM patients, this is the only surgery undertaken. When the amount of breast tissue removed requires skin removal, a scar will result and the patient should be so informed. Complications of subcutaneous mastectomy can include nipple necrosis, contour irregularities, and unsightly scarring (Monstrey et al., 2008).

Genital Surgery Techniques and Complications

Genital surgical procedures for the MtF patient may include orchiectomy, penectomy, vaginoplasty, clitoroplasty, and labiaplasty. Techniques include penile skin inversion, pedicled colosigmoid transplant, and free skin grafts to line the neovagina. Sexual sensation is an important objective in vaginoplasty, along with creation of a functional vagina and acceptable cosmesis.

Surgical complications of MtF genital surgery may include complete or partial necrosis of the vagina and labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, and vaginas that are either too short or too small for coitus. While the surgical techniques for creating a neovagina are functionally and aesthetically excellent, anorgasmia following the procedure has been reported, and a second stage labiaplasty may be needed for cosmesis (Klein & Gorzalka, 2009; Lawrence, 2006).

Genital surgical procedures for FtM patients may include hysterectomy, salpingo-oophorectomy, vaginectomy, metoidioplasty, scrotoplasty, urethroplasty, placement of testicular prostheses, and phalloplasty. For patients without former abdominal surgery, the laparoscopic technique for hysterectomy and salpingo-oophorectomy is recommended to avoid a lower-abdominal scar. Vaginal access may be difficult as most patients are nulliparous and have often not experienced penetrative intercourse. Current operative techniques for phalloplasty are varied. The choice of techniques may be restricted by anatomical or surgical considerations and by a client's financial considerations. If the objectives of phalloplasty are a neophallus of good appearance, standing micturition, sexual sensation, and/or coital ability, patients should be clearly informed that there are several separate stages of surgery and frequent technical difficulties, which may require additional operations. Even metoidioplasty, which in theory is a one-stage procedure for construction of a microphallus, often requires more than one operation. The objective of standing micturition with this technique can not always be ensured (Monstrey et al., 2009).

Complications of phalloplasty in FtMs may include frequent urinary tract stenoses and fistulas, and occasionally necrosis of the neophallus. Metoidioplasty results in a micropenis, without the capacity for standing urination. Phalloplasty, using a pedicled or a free vascularized flap, is a lengthy, multi-stage procedure with significant morbidity that includes frequent urinary complications and unavoidable donor site scarring. For this reason, many FtM patients never undergo genital surgery other than hysterectomy and salpingo-oophorectomy (Hage & De Graaf, 1993).

Even patients who develop severe surgical complications seldom regret having undergone surgery. The importance of surgery can be appreciated by the repeated finding that quality of surgical results is one of the best predictors of the overall outcome of sex reassignment (Lawrence, 2006).

Other Surgeries

Other surgeries for assisting in body feminization include reduction thyroid chondroplasty (reduction of the Adam's apple), voice modification surgery, suction-assisted lipoplasty (contour modeling) of the waist, rhinoplasty (nose correction), facial bone reduction, face-lift, and blepharoplasty (rejuvenation of the eyelid). Other surgeries for assisting in body masculinization include liposuction, lipofilling, and pectoral implants. Voice surgery to obtain a deeper voice is rare but may be recommended in some cases, such as when hormone therapy has been ineffective.

Although these surgeries do not require referral by mental health professionals, such professionals can play an important role in assisting clients in making a fully informed decision about the timing and implications of

such procedures in the context of the social transition.

Although most of these procedures are generally labeled "purely aesthetic," these same operations in an individual with severe gender dysphoria can be considered medically necessary, depending on the unique clinical situation of a given patient's condition and life situation. This ambiguity reflects reality in clinical situations, and allows for individual decisions as to the need and desirability of these procedures.

XII. POSTOPERATIVE CARE AND FOLLOW-UP

Long-term postoperative care and follow-up after surgical treatments for gender dysphoria are associated with good surgical and psychosocial outcomes (Monstrey et al., 2009). Follow-up is important to a patient's subsequent physical and mental health and to a surgeon's knowledge about the benefits and limitations of surgery. Surgeons who operate on patients coming from long distances should include personal follow-up in their care plan and attempt to ensure affordable local long-term aftercare in their patients' geographic region.

Postoperative patients may sometimes exclude themselves from follow-up by specialty providers, including the hormone-prescribing physician (for patients receiving hormones), not recognizing that these providers are often best able to prevent, diagnose, and treat medical conditions that are unique to hormonally and surgically treated patients. The need for follow-up equally extends to mental health professionals, who may have spent a longer period of time with the patient than any other professional and therefore are in an excellent position to assist in any postoperative adjustment difficulties. Health professionals should stress the importance of postoperative follow-up care with their patients and offer continuity of care.

Postoperative patients should undergo regular medical screening according to recommended guidelines for their age. This is discussed more in the next section.

XIII. LIFELONG PREVENTIVE AND PRIMARY CARE

Transsexual, transgender, and gender-nonconforming people need health care throughout their lives. For example, to avoid the negative secondary effects of having a gonadectomy at a relatively young age and/or receiving long-term, high-dose hormone therapy, patients need thorough medical care by providers experienced in primary care and transgender health. If one provider is not able to provide all services, ongoing communication among providers is essential.

Primary care and health maintenance issues should be addressed before, during, and after any possible changes in gender role and medical interventions to alleviate gender dysphoria. While hormone providers and surgeons play important roles in preventive care, every transsexual, transgender, and gender-nonconforming person should partner with a primary care provider for overall health care needs (Feldman, 2007).

General Preventive Health Care

Screening guidelines developed for the general population are appropriate for organ systems that are unlikely to be affected by feminizing/masculinizing hormone therapy. However, in areas such as cardiovascular risk factors, osteoporosis, and some cancers (breast, cervical, ovarian, uterine, and prostate), such general guidelines may either over- or underestimate the cost-effectiveness of screening individuals who are receiving hormone therapy.

Several resources provide detailed protocols for the primary care of patients undergoing feminizing/masculinizing hormone therapy, including therapy that is provided after sex reassignment surgeries (Center of Excellence for Transgender Health, UCSF, 2011; Feldman & Goldberg, 2006; Feldman, 2007; Gorton, Buth, & Spade, 2005). Clinicians should consult their national evidence-based guidelines and discuss screening with their patients in light of the effects of hormone therapy on their baseline risk.

Cancer Screening

Cancer screening of organ systems that are associated with sex can present particular medical and psychosocial challenges for transsexual, transgender, and gender-nonconforming patients and their health care providers. In the absence of large-scale prospective studies, providers are unlikely to have enough evidence to determine the appropriate type and frequency of cancer screenings for this population. Over-screening results in higher health care costs, high false positive rates, and often unnecessary exposure to radiation and/or diagnostic interventions such as biopsies. Under-screening results in diagnostic delay for potentially treatable cancers. Patients may find cancer screening gender affirming (such as mammograms for MtF patients) or both physically and emotionally painful (such as Pap smears offer continuity of care for FtM patients).

Urogenital Care

Gynecologic care may be necessary for transsexual, transgender, and gender-nonconforming people of both sexes. For FtM patients, such care is needed predominantly for individuals who have not had genital surgery. For MtF patients, such care is needed after genital surgery. While many surgeons counsel patients regarding postoperative urogenital care, primary care clinicians and gynecologists should also be familiar with the special genital concerns of this population.

All MtF patients should receive counseling regarding genital hygiene, sexuality, and prevention of sexually transmitted infections; those who have had genital surgery should also be counseled on the need for regular vaginal dilation or penetrative intercourse in order to maintain vaginal depth and width (van Trotsenburg, 2009). Due to the anatomy of the male pelvis, the axis and the dimensions of the neovagina differ substantially from those of a biologic vagina. This anatomic difference can affect intercourse if not understood by MtF patients and their partners (van Trotsenburg, 2009).

Lower-urinary-tract infections occur frequently in MtF patients who have had surgery because of the reconstructive requirements of the shortened urethra. In addition, these patients may suffer from functional disorders of the lower urinary tract; such disorders may be caused by damage of the autonomous nerve supply of the bladder floor during dissection between the rectum and the bladder, and by a change of the position of the bladder itself. A dysfunctional bladder (e.g., overactive bladder, stress or urge urinary incontinence) may occur after sex reassignment surgery (Hoebeke et al., 2005; Kuhn, Hiltebrand, & Birkhauser, 2007).

Most FtM patients do not undergo vaginectomy (colpectomy). For patients who take masculinizing hormones, despite considerable conversion of testosterone to estrogens, atrophic changes of the vaginal lining can be observed regularly and may lead to pruritus or burning. Examination can be both physically and emotionally painful, but lack of treatment can seriously aggravate the situation. Gynecologists treating the genital complaints of FtM patients should be aware of the sensitivity that patients with a male gender identity and masculine gender expression might have around having genitals typically associated with the female sex.

XIV. APPLICABILITY OF THE STANDARDS OF CARE *TO PEOPLE LIVING IN INSTITUTIONAL ENVIRONMENTS*

The *SOC* in their entirety apply to all transsexual, transgender, and gender-nonconforming people, irrespective of their housing situation. People should not be discriminated against in their access to appropriate health care based on where they live, including institutional environments such as prisons or long-/intermediate-term health care facilities (Brown, 2009). Health care for transsexual, transgender, and gender-nonconforming people living in an institutional environment should mirror that which would be available to them if they were living in a noninstitutional setting within the same community.

All elements of assessment and treatment as described in the *SOC* can be provided to people living in institutions (Brown, 2009). Access to these medically necessary treatments should not

be denied on the basis of institutionalization or housing arrangements. If the in-house expertise of health professionals in the direct or indirect employ of the institution does not exist to assess and/or treat people with gender dysphoria, it is appropriate to obtain outside consultation from professionals who are knowledgeable about this specialized area of health care.

People with gender dysphoria in institutions may also have coexisting mental health conditions (Cole et al., 1997). These conditions should be evaluated and treated appropriately.

People who enter an institution on an appropriate regimen of hormone therapy should be continued on the same, or similar, therapies and monitored according to the *SOC*. A "freeze frame" approach is not considered appropriate care in most situations (*Kosilek v. Massachusetts Department of Corrections/Maloney*, C.A. No. 92-12820-MLW, 2002). People with gender dysphoria who are deemed appropriate for hormone therapy (following the *SOC*) should be started on such therapy. The consequences of abrupt withdrawal of hormones or lack of initiation of hormone therapy when medically necessary include a high likelihood of negative outcomes such as surgical self-treatment by autocastration, depressed mood, dysphoria, and/or suicidality (Brown, 2010).

Reasonable accommodations to the institutional environment can be made in the delivery of care consistent with the *SOC*, if such accommodations do not jeopardize the delivery of medically necessary care to people with gender dysphoria. An example of a reasonable accommodation is the use of injectable hormones, if not medically contraindicated, in an environment where diversion of oral preparations is highly likely (Brown, 2009). Denial of needed changes in gender role or access to treatments, including sex reassignment surgery, on the basis of residence in an institution are not reasonable accommodations under the *SOC* (Brown, 2010).

Housing and shower/bathroom facilities for transsexual, transgender, and gender-nonconforming people living in institutions should take into account their gender identity and role, physical status, dignity, and personal safety. Placement in a single-sex housing unit, ward, or pod on the sole basis of the appearance of the external genitalia may not be appropriate and may place the individual at risk for victimization (Brown, 2009).

Institutions where transsexual, transgender, and gender-nonconforming people reside and receive health care should monitor for a tolerant and positive climate to ensure that residents are not under attack by staff or other residents.

XV. APPLICABILITY OF THE STANDARDS OF CARE *TO PEOPLE WITH DISORDERS OF SEX DEVELOPMENT*

Terminology

The term *disorder of sex development* (DSD) refers to a somatic condition of atypical development of the reproductive tract (Hughes, Houk, Ahmed, Lee, & LWPES/ESPE Consensus Group, 2006). DSDs include the condition that used to be called *intersexuality*. Although the terminology was changed to DSD during an international consensus conference in 2005 (Hughes et al., 2006), disagreement about language use remains. Some people object strongly to the "disorder" label, preferring instead to view these congenital conditions as a matter of diversity (Diamond, 2009) and to continue using the terms *intersex* or *intersexuality*. In the *SOC*, WPATH uses the term DSD in an objective and value-free manner, with the goal of ensuring that health professionals recognize this medical term and use it to access relevant literature as the field progresses. WPATH remains open to new terminology that will further illuminate the experience of members of this diverse population and lead to improvements in health care access and delivery.

Rationale for Addition to the SOC

Previously, individuals with a DSD who also met the *DSM-IV-TR's* behavioral criteria for Gender Identity Disorder (American Psychiatric Association, 2000) were excluded from that general diagnosis. Instead, they were categorized as having a "Gender Identity Disorder-Not

Otherwise Specified." They were also excluded from the WPATH *Standards of Care*.

The current proposal for *DSM-5* (www.dsm5.org) is to replace the term *gender identity disorder* with *gender dysphoria*. Moreover, the proposed changes to the *DSM* consider gender dysphoric people with a DSD to have a subtype of gender dysphoria. This proposed categorization—which explicitly differentiates between gender dysphoric individuals with and without a DSD—is justified: In people with a DSD, gender dysphoria differs in its phenomenological presentation, epidemiology, life trajectories, and etiology (Meyer-Bahlburg, 2009).

Adults with a DSD and gender dysphoria have increasingly come to the attention of health professionals. Accordingly, a brief discussion of their care is included in this version of the *SOC*.

Health History Considerations

Health professionals assisting patients with both a DSD and gender dysphoria need to be aware that the medical context in which such patients have grown up is typically very different from that of people without a DSD.

Some people are recognized as having a DSD through the observation of gender-atypical genitals at birth. (Increasingly this observation is made during the prenatal period by way of imaging procedures such as ultrasound.) These infants then undergo extensive medical diagnostic procedures. After consultation among the family and health professionals—during which the specific diagnosis, physical and hormonal findings, and feedback from long-term outcome studies (Cohen-Kettenis, 2005; Dessens, Slijper, & Drop, 2005; Jurgensen, Hiort, Holterhus, & Thyen, 2007; Mazur, 2005; Meyer-Bahlburg, 2005; Stikkelbroeck et al., 2003; Wisniewski, Migeon, Malouf, & Gearhart, 2004) are considered—the newborn is assigned a sex, either male or female.

Other individuals with a DSD come to the attention of health professionals around the age of puberty through the observation of atypical development of secondary sex characteristics. This observation also leads to a specific medical evaluation.

The type of DSD and severity of the condition has significant implications for decisions about a patient's initial sex assignment, subsequent genital surgery, and other medical and psychosocial care (Meyer-Bahlburg, 2009). For instance, the degree of prenatal androgen exposure in individuals with a DSD has been correlated with the degree of masculinization of gender-related *behavior* (that is, *gender role and expression*); however, the correlation is only moderate, and considerable behavioral variability remains unaccounted for by prenatal androgen exposure (Jurgensen et al., 2007; Meyer-Bahlburg, Dolezal, Baker, Ehrhardt, & New, 2006). Notably, a similar correlation of prenatal hormone exposure with gender *identity* has not been demonstrated (e.g., Meyer-Bahlburg, Dolezal, et al., 2004). This is underlined by the fact that people with the same (core) gender identity can vary widely in the degree of masculinization of their gender-related behavior.

Assessment and Treatment of Gender Dysphoria in People with Disorders of Sex Development

Very rarely are individuals with a DSD identified as having gender dysphoria *before* a DSD diagnosis has been made. Even so, a DSD diagnosis is typically apparent with an appropriate history and basic physical exam—both of which are part of a medical evaluation for the appropriateness of hormone therapy or surgical interventions for gender dysphoria. Mental health professionals should ask their clients presenting with gender dysphoria to have a physical exam, particularly if they are not currently seeing a primary care (or other health care) provider.

Most people with a DSD who are born with genital ambiguity do not develop gender dysphoria (e.g., Meyer-Bahlburg, Dolezal, et al., 2004; Wisniewski et al., 2004). However, some people with a DSD will develop chronic gender dysphoria and even undergo a change in their birth-assigned sex and/or their gender role (Meyer-Bahlburg, 2005; Wilson, 1999; Zucker, 1999). If there are persistent and strong indications that gender dysphoria is present, a comprehensive

evaluation by clinicians skilled in the assessment and treatment of gender dysphoria is essential, irrespective of the patient's age. Detailed recommendations have been published for conducting such an assessment and for making treatment decisions to address gender dysphoria in the context of a DSD (Meyer-Bahlburg, 2011). Only after thorough assessment should steps be taken in the direction of changing a patient's birth-assigned sex or gender role.

Clinicians assisting these patients with treatment options to alleviate gender dysphoria may profit from the insights gained from providing care to patients without a DSD (Cohen-Kettenis, 2010). However, certain criteria for treatment (e.g., age, duration of experience with living in the desired gender role) are usually not routinely applied to people with a DSD; rather, the criteria are interpreted in light of a patient's specific situation (Meyer-Bahlburg, 2011). In the context of a DSD, changes in birth-assigned sex and gender role have been made at any age between early-elementary-school age and middle adulthood. Even genital surgery may be performed much earlier in these patients than in gender dysphoric individuals without a DSD if the surgery is well justified by the diagnosis, by the evidence-based gender-identity prognosis for the given syndrome and syndrome severity, and by the patient's wishes.

One reason for these treatment differences is that genital surgery in individuals with a DSD is quite common in infancy and adolescence. Infertility may already be present due to either early gonadal failure or to gonadectomy because of a malignancy risk. Even so, it is advisable for patients with a DSD to undergo a full social transition to another gender role only if there is a long-standing history of gender-atypical behavior, and if gender dysphoria and/or the desire to change one's gender role has been strong and persistent for a considerable period of time. Six months is the time period of full symptom expression required for the application of the gender dysphoria diagnosis proposed for *DSM-5* (Meyer-Bahlburg, 2011).

Additional Resources

The gender-relevant medical histories of people with a DSD are often complex. Their histories may include a great variety of inborn genetic, endocrine, and somatic atypicalities, as well as various hormonal, surgical, and other medical treatments. For this reason, many additional issues need to be considered in the psychosocial and medical care of such patients, regardless of the presence of gender dysphoria. Consideration of these issues is beyond what can be covered in the *SOC*. The interested reader is referred to existing publications (e.g., Cohen-Kettenis & Pfäfflin, 2003; Meyer-Bahlburg, 2002, 2008). Some families and patients also find it useful to consult or work with community support groups.

There is a very substantial medical literature on the medical management of patients with a DSD. Much of this literature has been produced by high-level specialists in pediatric endocrinology and urology, with input from specialized mental health professionals, especially in the area of gender. Recent international consensus conferences have addressed evidence-based care guidelines (including issues of gender and of genital surgery) for DSD in general (Hughes et al., 2006) and specifically for Congenital Adrenal Hyperplasia (Joint LWPES/ESPE CAH Working Group et al., 2002; Speiser et al., 2010). Others have addressed the research needs for DSD in general (Meyer-Bahlburg & Blizzard, 2004) and for selected syndromes such as 46, XXY (Simpson et al., 2003).

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APPENDIX A: GLOSSARY

Terminology in the area of health care for transsexual, transgender, and gender-nonconforming people is rapidly evolving; new terms are being introduced, and the definitions of existing terms are changing. Thus, there is often misunderstanding, debate, or disagreement about language in this field. Terms that may be unfamiliar or that have specific meanings in the *SOC* are defined below for the purpose of this document only. Others may adopt these definitions, but WPATH acknowledges that these terms may be defined differently in different cultures, communities, and contexts.

WPATH also acknowledges that many terms used in relation to this population are not ideal. For example, the terms *transsexual* and *transvestite*—and, some would argue, the more recent term *transgender*—have been applied to people in an objectifying fashion. Yet such terms have been more or less adopted by many people who are making their best effort to make themselves understood. By continuing to use these terms, WPATH intends only to ensure that concepts and processes are comprehensible, in order to facilitate the delivery of quality health care to transsexual, transgender, and gender-nonconforming people. WPATH remains open to new terminology that will further illuminate the experience of members of this diverse population and lead to improvements in health care access and delivery.

Bioidentical hormones: Hormones that are *structurally* identical to those found in the human body (ACOG Committee of Gynecologic Practice, 2005). The hormones used in bioidentical hormone therapy (BHT) are generally derived from plant sources and are structurally similar to endogenous human hormones, but they need to be commercially processed to become bioidentical.

Bioidentical compounded hormone therapy (BCHT): Use of hormones that are prepared, mixed, assembled, packaged, or labeled as a drug by a pharmacist and custom-made for a patient according to a physician's specifications. Government-drug-agency approval is not possible for each compounded product made for an individual consumer.

Cross-dressing (transvestism): Wearing clothing and adopting a gender role presentation that, in a given culture, is more typical of the other sex.

Disorders of sex development (DSD): Congenital conditions in which the development of chromosomal, gonadal, or anatomic sex is atypical. Some people strongly object to the "disorder" label and instead view these conditions as a matter of diversity (Diamond, 2009), preferring the terms *intersex* and *intersexuality*.

Female-to-male (FtM): Adjective to describe individuals assigned female at birth who are changing or who have changed their body and/or gender role from birth-assigned female to a more masculine body or role.

Gender dysphoria: Distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) (Fisk, 1974; Knudson, De Cuypere, & Bockting, 2010b).

Gender identity: A person's intrinsic sense of being male (a boy or a man), female (a girl or a woman), or an alternative gender (e.g., boygirl, girlboy, transgender, genderqueer, eunuch) (Bockting, 1999; Stoller, 1964).

Gender identity disorder: Formal diagnosis set forth by the *Diagnostic Statistical Manual of Mental Disorders, 4th Edition, Text Rev. (DSM IV-TR)* (American Psychiatric Association, 2000). Gender identity disorder is characterized by a strong and persistent cross-gender identification and a persistent discomfort with one's sex or sense of inappropriateness in the gender role of that sex, causing clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Gender-nonconforming: Adjective to describe individuals whose gender identity, role, or expression differs from what is normative for their assigned sex in a given culture and historical period.

Gender role or expression: Characteristics in personality, appearance, and behavior that in a given culture and historical period are designated as masculine or feminine (that is, more typical of the male or female social role) (Ruble, Martin, & Berenbaum, 2006). While most individuals present socially in clearly masculine or feminine gender roles, some people present in an alternative gender role such as genderqueer or specifically transgender. All people tend to incorporate both masculine and feminine characteristics in their gender expression in varying ways and to varying degrees (Bockting, 2008).

Genderqueer: Identity label that may be used by individuals whose gender identity and/or role does not conform to a binary understanding of gender as limited to the categories of man or woman, male or female (Bockting, 2008).

Internalized transphobia: Discomfort with one's own transgender feelings or identity as a result of internalizing society's normative gender expectations.

Male-to-female (MtF): Adjective to describe individuals assigned male at birth who are changing or who have changed their body and/or gender role from birth-assigned male to a more feminine body or role.

Natural hormones: Hormones that are derived from natural *sources* such as plants or animals. Natural hormones may or may not be bioidentical.

Sex: Sex is assigned at birth as male or female, usually based on the appearance of the external genitalia. When the external genitalia are ambiguous, other components of sex (internal genitalia, chromosomal and hormonal sex) are considered in order to assign sex (Grumbach, Hughes, & Conte, 2003; MacLaughlin & Donahoe, 2004; Money & Ehrhardt, 1972; Vilain, 2000). For most people, gender identity and expression are consistent with their sex assigned at birth; for transsexual, transgender, and gender-nonconforming individuals, gender identity or expression differ from their sex assigned at birth.

Sex reassignment surgery (gender affirmation surgery): Surgery to change primary and/or secondary sex characteristics to affirm a person's gender identity. Sex reassignment surgery can be an important part of medically necessary treatment to alleviate gender dysphoria.

Transgender: Adjective to describe a diverse group of individuals who cross or transcend culturally defined categories of gender. The gender identity of transgender people differs to varying degrees from the sex they were assigned at birth (Bockting, 1999).

Transition: Period of time when individuals change from the gender role associated with their sex assigned at birth to a different gender role. For many people, this involves learning how to live socially in another gender role; for others this means finding a gender role and expression that is most comfortable for them. Transition may or may not include feminization or masculinization of the body through hormones or other medical procedures. The nature and duration of transition is variable and individualized.

Transsexual: Adjective (often applied by the medical profession) to describe individuals who seek to change or who have changed their primary and/or secondary sex characteristics through femininizing or masculinizing medical interventions (hormones and/or surgery), typically accompanied by a permanent change in gender role.

APPENDIX B: OVERVIEW OF MEDICAL RISKS OF HORMONE THERAPY

The risks outlined below are based on two comprehensive, evidence-based literature reviews of masculinizing/feminizing hormone therapy (Feldman & Safer, 2009; Hembree et al., 2009), along with a large cohort study (Asscheman et al., 2011). These reviews can serve as detailed references for providers, along with other widely recognized, published clinical materials (e.g., Dahl et al., 2006; Ettner et al., 2007).

Risks of Feminizing Hormone Therapy (MTF)

Likely Increased Risk

Venous thromboembolic disease

- Estrogen use increases the risk of venous thromboembolic events (VTE), particularly in patients who are over age 40, smokers, highly sedentary, obese, and who have underlying thrombophilic disorders.
- This risk is increased with the additional use of third generation progestins.
- This risk is decreased with use of the transdermal (versus oral) route of estradiol administration, which is recommended for patients at higher risk of VTE.

Cardiovascular, cerebrovascular disease

- Estrogen use increases the risk of cardiovascular events in patients over age 50 with underlying cardiovascular risk factors. Additional progestin use may increase this risk.

Lipids

- Oral estrogen use may markedly increase triglycerides in patients, increasing the risk of pancreatitis and cardiovascular events.
- Different routes of administration will have different metabolic effects on levels of HDL cholesterol, LDL cholesterol, and lipoprotein(a).
- In general, clinical evidence suggests that MtF patients with preexisting lipid disorders may benefit from the use of transdermal rather than oral estrogen.

Liver/gallbladder

- Estrogen and cyproterone acetate use may be associated with transient liver-enzyme elevations and, rarely, clinical hepatotoxicity.
- Estrogen use increases the risk of cholelithiasis (gall stones) and subsequent cholecystectomy.

Possible Increased Risk

Type 2 diabetes mellitus

- Feminizing hormone therapy, particularly estrogen, may increase the risk of type 2 diabetes, particularly among patients with a family history of diabetes or other risk factors for this disease.

Hypertension

- Estrogen use may increase blood pressure, but the effect on incidence of overt hypertension is unknown.
- Spironolactone reduces blood pressure and is recommended for at-risk or hypertensive patients desiring feminization.

Prolactinoma

- Estrogen use increases the risk of hyperprolactinemia among MtF patients in the first year of treatment, but this risk is unlikely thereafter.
- High-dose estrogen use may promote the clinical appearance of preexisting but clinically unapparent prolactinoma.

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.

Breast cancer

- MtF persons who have taken feminizing hormones do experience breast cancer, but it is unknown how their degree of risk compares to that of persons born with female genitalia.
- Longer duration of feminizing hormone exposure (i.e., number of years taking estrogen preparations), family history of breast cancer, obesity (BMI >35), and the use of progestins likely influence the level of risk.

Other Side Effects of Feminizing Therapy

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

Fertility and sexual function

- Feminizing hormone therapy may impair fertility.
- Feminizing hormone therapy may decrease libido.
- Feminizing hormone therapy reduces nocturnal erections, with variable impact on sexually stimulated erections.

Risks of Anti-androgen Medications

Feminizing hormone regimens often include a variety of agents that affect testosterone production or action. These include GnRH agonists, progestins (including cyproterone acetate), spironolactone, and 5-alpha reductase inhibitors. An extensive discussion of the specific risks of these agents is beyond the scope of the *SOC*. However, both spironolactone and cyproterone acetate are widely used and deserve some comment.

Cyproterone acetate is a progestational compound with anti-androgenic properties (Gooren, 2005; Levy et al., 2003). Although widely used in Europe, it is not approved for use in the United States because of concerns about hepatotoxicity (Thole, Manso, Salgueiro, Revuelta, & Hidalgo, 2004). Spironolactone is commonly used as an anti-androgen in feminizing hormone therapy, particularly in regions where cyproterone is not approved for use (Dahl et al., 2006; Moore et al., 2003; Tangpricha et al., 2003). Spironolactone has a long history of use in treating hypertension and congestive heart failure. Its common side effects include hyperkalemia, dizziness, and gastrointestinal symptoms (*Physicians' Desk Reference*, 2007).

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.

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, unless other risk factors are present.
- 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.

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 give 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.

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 give 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 prerequisite.

Breast Augmentation (Implants/Lipofilling) in MtF Patients

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to give 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 Salpingo-oophorectomy in FtM Patients and Orchiectomy in MtF Patients

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to give 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 hormones are not clinically indicated for the individual).

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 give 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 hormones are not clinically indicated for the individual);
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—that is, 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 posttreatment 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 had undergone 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, 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 been 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).

Two long-term observational studies, both retrospective, compared the mortality and psychiatric morbidity of transsexual adults to those

of general population samples (Asscheman et al., 2011; Dhejne et al., 2011). An analysis of data from the Swedish National Board of Health and Welfare information registry found that individuals who had received sex reassignment surgery (191 MtF and 133 FtM) had significantly higher rates of mortality, suicide, suicidal behavior, and psychiatric morbidity than those for a nontranssexual control group matched on age, immigrant status, prior psychiatric morbidity, and birth sex (Dhejne et al., 2011). Similarly, a study in the Netherlands reported a higher total mortality rate, including incidence of suicide, in both pre- and postsurgery transsexual patients (966 MtF and 365 FtM) than in the general population of that country (Asscheman et al., 2011). Neither of these studies questioned the efficacy of sex reassignment; indeed, both lacked an adequate comparison group of transsexuals who either did not receive treatment or who received treatment other than genital surgery. Moreover, transexual people in these studies were treated as far back as the 1970's. However, these findings do emphasize the need to have good long-term psychological and psychiatric care available for this population. More studies are needed that focus on the outcomes of current assessment and treatment approaches for gender dysphoria.

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 areas 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 De Sutter, 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 coauthors 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, an *SOC* 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 revisions. 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 iterations 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.

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.

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†All members of the *Standards of Care, Version 7*, Revision Committee donated their time to work on this revision.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF DOCKETING

17-1460 - Fulcher v. Secretary of Veterans Affairs

Date of docketing: January 9, 2017

Petition for review of: United States Department of Veterans Affairs, pursuant to 38 U.S.C. Sec. 502

Petitioner(s): Dee Fulcher, Giuliano Silva, Transgender American Veterans Association

Critical dates include:

- Date of docketing. See Fed. Cir. R. 12 and 15.
- Certified list. See Fed. Cir. R. 17.
- Entry of appearance. (*Due within 14 days of the date of docketing.*) See Fed. Cir. R. 47.3.
- Certificate of interest. (*Due within 14 days of the date of docketing.*) See Fed. Cir. R. 47.4.
- Docketing Statement. (*Due within 30 days of the date of docketing.*) [See Fed. Cir. R. 33.1 and the mediation guidelines available at www.cafc.uscourts.gov.]
- Requests for extensions of time. See Fed. Cir. R. 26 and 27. **N.B. Delayed requests are not favored by the court**.
- Briefs. See Fed. Cir. R. 31. **N.B. You will not receive a separate briefing schedule from the Clerk's Office**.
- **ORAL ARGUMENT SCHEDULE CONFLICTS:** Counsel should advise the clerk in writing within 30 days once briefing is completed of potential scheduling conflicts or as soon as they are known and should not wait until an actual conflict arises. Once scheduled, a case will not be postponed except on motion showing **compelling reasons**. See Practice Note following Fed. Cir. R. 34.

The official caption is reflected on the electronic docket under the listing of the parties and counsel. The Rules of Practice and required forms are available at www.cafc.uscourts.gov.

Peter R. Marksteiner
Clerk of Court

cc:

Secretary, Department of Veterans Affairs
Director, Commercial Litigation Branch, Civil Division, U.S. Department of Justice, P.O. Box 480, Ben Franklin Station, Washington, DC 20044
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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

DEE FULCHER, GIULIANO SILVA, and TRANSGENDER AMERICAN VETERANS ASSOCIATION, Petitioners, v. SECRETARY OF VETERANS AFFAIRS, Respondent.	**PETITION FOR REVIEW PURSUANT TO 38 U.S.C. § 502**

Pursuant to 38 U.S.C. § 502 and Federal Circuit Rule 47.12, Dee Fulcher ("Ms. Fulcher"), Giuliano Silva ("Mr. Silva"), and the Transgender American Veterans Association ("TAVA") (collectively "Petitioners") hereby petition this Court for review of the denial of their petition for rulemaking by the U.S. Department of Veterans Affairs (the "Department" or "VA"). The petition for rulemaking, *see* Exhibit 1 ("Pet."), requested that the Department initiate rulemaking to amend or repeal rules and regulations excluding sex reassignment surgery as a covered medical benefit for transgender veterans and, in particular, to amend or repeal 38 C.F.R. § 17.38(c)(4) (the "Regulation"), which categorically excludes coverage for "gender alterations."

STATEMENT OF THE CASE

On May 9, 2016, Petitioners filed a petition for rulemaking pursuant to 5 U.S.C. § 553(e), requesting that the VA "amend or repeal the rules and regulations, including 38 C.F.R. § 17.38(c)(4) and any implementing directives, that exclude medically necessary sex reassignment surgery for transgender veterans from the medical benefits package provided to veterans under the health care system of the [Department], and to promulgate regulations expressly including medically necessary sex reassignment surgery for transgender veterans in that medical benefits package." Pet. 1. The Department acknowledged receipt of the petition.

Later in the spring of 2016, the Department announced in the Unified Agenda of Federal Regulatory and Deregulatory Actions, a semiannual compilation of regulatory actions under development in the federal government, that it was considering issuance of a notice of proposed rulemaking to remove the regulation that prohibits the VA from providing medical services that are considered gender alterations.

On November 10, 2016, the Department informed members of Congress that it was withdrawing consideration of that possible rulemaking from its regulatory agenda. *See* Exhibit 2. Although the Department stated that it "will continue to explore a regulatory change that would allow VA to perform gender alteration surgery and a change in the medical benefits package, when appropriated funding

is available," it made clear that any rulemaking that would allow the VA to perform or pay for such treatment is "not imminent." *Id.* The VA's letter amounts to a denial of the petition. *See Nat'l Parks Conservation Ass'n v. U.S. Dep't of Interior*, 794 F. Supp. 2d 39, 46 (D.D.C. 2011) (holding in part that an agency's letter response, which stated that the agency may engage in future rulemaking but would not initiate rulemaking at that time, constituted a denial of the plaintiffs' petition for rulemaking).

This petition for review is timely because it is filed within 60 days of the VA's letter as required by Federal Circuit Rule 47.12. This Court has jurisdiction pursuant to 38 U.S.C. § 502 to review the VA's denial of the petition for rulemaking. *See Preminger v. Sec'y of Veterans Affairs*, 632 F.3d 1345, 1352 (Fed. Cir. 2011).

PETITIONERS

Pursuant to Federal Circuit Rule 47.12, Petitioners state that each has been adversely affected by the VA's denial of the petition for rulemaking.

Ms. Fulcher is a transgender veteran of the U.S. Marine Corps who has been diagnosed with gender dysphoria and whose VA clinicians have recommended sex reassignment surgery as treatment. Pet. 6. Because of the Regulation, Ms. Fulcher cannot obtain medically necessary procedures that her clinicians have prescribed. Pet. 6.

Mr. Silva is a transgender man who has also been diagnosed with gender dysphoria. He is a veteran of the U.S. Army. Pet. 6. Mr. Silva would undergo both a mastectomy and reconstructive surgery but cannot obtain both because of the Regulation. Pet. 6.

Both Ms. Fulcher and Mr. Silva are members of TAVA, which is a 501(c)(3) organization dedicated "to ensuring that transgender veterans receive appropriate and necessary medical care." Pet. 4. Members of TAVA have been denied access to sex reassignment surgery by the Regulation. TAVA has independent standing to bring this petition because its members are directly harmed by the Regulation, the petition is germane to TAVA's purpose, and the participation of individual members is not required for the relief sought. *See Disabled Am. Veterans v. Gober*, 234 F.3d 682, 689 (Fed. Cir. 2000) (citing *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977)). Specifically, at least one veteran is a member of TAVA, Pet. 6; advocacy relating to healthcare for transgender veterans is consistent with TAVA's mission, Pet. 5; and, although individual TAVA members are participating in this appeal, their participation is not necessary to obtain the desired relief—namely, an order requiring the VA to engage in the requested rulemaking.

RELIEF SOUGHT

For the foregoing reasons, Petitioners request that this Court review the Department's denial of the petition for rulemaking and direct the VA to undertake a rulemaking to amend or repeal the Regulation.

Dated: January 6, 2017

Respectfully submitted,

/s/ Paul R.Q. Wolfson

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DEPARTMENT OF VETERANS AFFAIRS 8320-01

38 CFR Part 17

RIN 2900-AP69

Removing Exclusion of Gender Alterations from the Medical Benefits Package

AGENCY: Department of Veterans Affairs

ACTION: Proposed Rule

SUMMARY: This rulemaking proposes to remove the exclusion of medical services that are considered “gender alterations” from the Department of Veterans Affairs (VA) medical benefits package regulation. In the past, gender transition surgeries were considered treatment for gender dysphoria, previously referred to as transsexualism or gender identity disorder, but they required further research to assure their safety and reliability. Increased understanding of both gender dysphoria and surgical techniques in this area have improved significantly, and surgical procedures are now widely accepted in the medical community as medically necessary treatment for gender dysphoria. Additionally, recent medical research shows that the failure to provide transition surgeries to certain patients suffering from gender dysphoria can have severe medical consequences. In light of these medical advances and the evolving standard of care, VA would revise its medical benefits package regulation to remove this exclusion. VA would instead make medical decisions about what surgical procedures are medically necessary to treat a Veteran’s gender dysphoria on a case-by-case basis consistent with the requirements of 38 CFR 17.38(b) (which apply to all care provided under the medical benefits package).

DATES: Comment Date: Comments must be received on or before [Insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted through www.Regulations.gov; by mail or hand-delivery to Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue, NW, Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to ["RIN 2900-AP69– Removing Exclusion of Gender Alterations from the Medical Benefits Package."] Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at www.Regulations.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Jillian Shipherd or Dr. Michael Kauth Directors of the LGBT Program for Patient Care Services, Department of Veterans Affairs, LGBTProgram@va.gov or 857-364-4660, 150 South Huntington Ave. Boston, MA 02130. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Section 1710 of title 38 United States Code (U.S.C.) requires VA to "furnish hospital care and medical services which the Secretary

determines to be needed" for eligible veterans. In 1999, VA promulgated 38 CFR § 17.38, establishing the Department's medical benefits package for veterans enrolled in VA's health care system. 64 FR 54207 (Oct. 6, 1999). The regulation described the types of medically needed care and services available for such veterans, as well as certain exclusions. The regulation specifically excluded medical services considered to be "gender alterations." 38 CFR § 17.38(c)(4). Although not specifically explained in the preambles to the original proposed and final rules, the rationale for all exclusions in § 17.38(c) was generally that such services were not considered medically needed. As VA explained in proposing the medical benefits package, "medically needed" care is "care that . . . appropriate healthcare professionals [determine] to be needed to promote, preserve, or restore the health of the individual and to be in accord with generally accepted standards of medical practice." 63 FR 37299, 37300 (July 10, 1998). All care included in the package is intended to meet these criteria. In addition, the proposed rule defined the terms "promote," "preserve," and "restore" in §§17.38(b)(1)-(3), respectively. While other provisions of this regulation have been modified over the years, this exclusion has to date remained unchanged.

VA has generally interpreted § 17.38(c)(4) as barring only gender transition surgeries and gender alterations in the form of plastic reconstructive surgeries performed for strictly cosmetic purposes. See e.g. VHA Directive 2013-003, Providing Health Care for Transgender and Intersex Veterans (February 8, 2013).

Medical science and surgical techniques supporting gender transitioning have, however, steadily improved since then. Based on the medical literature, we now believe that surgical procedures currently available to aid individuals in gender transitioning may be reasonably determined by a treating VA healthcare provider to be care that is in accord with generally accepted standards of medical practice and medically necessary to promote, preserve, or restore a particular Veteran's health. In other words, we would permit the treating VA healthcare provider to determine, in the exercise of his or her clinical judgment, that such services are medically necessary in a particular clinical case and so offer them to the patient. Before VA permits this, however, we first must remove the current exclusion of gender alterations from the medical benefits package. 38 CFR § 17.38(c)(4). We will also renumber the paragraphs in subsection (c) accordingly.

The rationale for this substantive change is two-fold. First, based on the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM 5) , we now know that gender dysphoria is a clinical condition of gender incongruence associated with a strong desire to be treated as another gender, to be rid of one's birth sex characteristics, or a strong conviction that one has feelings and reactions typical of another gender, "which can have "clinically significant distress or impairment in social occupational, or other important areas of functioning." DSM 5 452-53 (2013). According to the American Medical Association House of Delegates, Resolution 122:A-08, gender dysphoria is a serious condition that, left untreated, can lead to serious medical problems, including "clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate

medical care and treatment, suicidality and death." American Medical Association (2008); see also Whittle, et al., WPATH Clarification on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage for Transgender and Transsexual People Worldwide (2008), http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1352&pk_association_webpage=3947 (last visited Apr. 21, 2016). Second, related to gender transition surgery specifically, multiple medical professional organizations, including the American Psychological Association, the American Psychiatric Association, the American Academy of Family Physicians, the American Congress of Obstetricians and Gynecologists, and the World Professional Association for Transgender Health have all issued statements affirming that transition surgery is medically necessary care for some patients. See Proceedings of the American Psychological Association, American Psychologist 64:372–453 (2009), https://www.apa.org/about/policy/transgender.pdf (last visited Apr. 21, 2016); Drescher et al., APA official actions: Position Statement on Access to Care for Transgender and Gender Variant Individuals (2012), https://www.psychiatry.org/file%20library/about-apa/organization-documents-policies/policies/position-2012-transgender-gender-variant-access-care.pdf (last visited Apr. 21, 2016); American Academy of Family Physicians, Resolution 64:22 (2007); American College of Obstetricians and Gynecologists, Committee Opinion 118:1454-8 (2011) http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals (last visited Apr. 21, 2016).

Additionally, a 2014 U.S. Department of Health and Human Services Departmental Appeals Board ("Appeals Board") decision reviewed the medical data on gender transition surgeries and stated that the "surgery relieves, and very often completely eliminates, gender dysphoria." Department of Health and Human Services Departmental Appeals Board Decision No. 2576 ("NCD Decision") at 16 (May 30, 2014). Other studies cited by the Appeals Board noted that providing sex reassignment surgical interventions alleviated suffering and dysfunction, significantly reduced suicidality, and improved virtually every part of a patient's life. Id. at 17.

Having deliberated on all the information above, we propose to remove "gender alterations" from the list of exclusions under § 17.38(c). As discussed above, a VA healthcare provider's decision to offer and provide surgical gender alteration services (as VA defines such services) to a particular patient would still need to meet all of the requirements for care in § 17.38(b). In other words, they would only be available if clinically determined to be medically necessary by the VA treating provider.

To effectuate this change, we propose to remove § 17.38(c)(4) in its entirety, to renumber current § 17.38(c)(5) as § 17.38(c)(4), and to renumber current § 17.38(c)(6) as § 17.38(c)(5).

Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by this proposed rulemaking, represents the exclusive legal authority on this subject. No contrary rules or procedures would be authorized. All existing or subsequent VA guidance, including

VHA Directive 2013-003, would be read to conform with this rulemaking if possible or, if not possible, such guidance would be superseded by this rulemaking.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This proposed rule will directly affect only individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking would be exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory

Planning and Review) defines a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as "any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order."

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at http://www.regulations.gov, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at http://www.va.gov/orpm/, by following the link for "VA Regulations Published From FY 2004 Through FY to Date."

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any

rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.009, Veterans Medical Care Benefits; 64.042, VHA Inpatient Surgery.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. [NAME AND TITLE OF APPROVING OFFICIAL] approved this document on [DATE] for publication.

List of Subjects in 38 CFR Part 17

Medical benefits package.

Approved:

_____

For the reasons described in the preamble, Department of Veterans Affairs proposes to amend 38 CFR part 17 as follows:

PART 17 – MEDICAL

1. The authority citation for part 17 continues to read as follows:

AUTHORITY: 38 U.S.C. 501, and as noted in specific sections.

2. Amend § 17.38 to remove paragraph (c)(4) and redesignate paragraphs (c)(5) and (c)(6) as paragraphs (c)(4) and (c)(5), respectively.

Congress of the United States
Washington, DC 20515

June 22, 2016

The Honorable Robert McDonald
Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue NW
Washington, D.C. 20420

Dear Secretary McDonald:

We write today with serious concerns regarding the Department of Veterans Affairs' (VA) Spring 2016 Notice of Proposed Rulemaking entitled "Removing Gender Alterations Restriction From the Medical Benefits Package," which seeks to change current VA policies regarding coverage for certain gender alteration procedures. More specifically, the proposal aims to reverse a long-standing prohibition on the use of VA funds to pay for gender alteration surgeries.

Currently, the Veterans Health Administration (VHA) employs classification groups to help ensure the Department's limited resources are focused first on veterans with service-connected disabilities. Many veterans struggle to receive appropriate and timely treatment for service-connected conditions, such as Post-Traumatic Stress Disorder (PTSD), due to significant backlogs and inadequate access within the VA's health care system. While we are aware that Gender Dysphoria is not classified as a service-connected condition, and would therefore not be factored as part of a service-connection rating determination, we do not believe the VA should be discussing the potential coverage of gender alteration surgeries as the Agency faces challenges in delivering health care to those veterans whose service directly resulted in their need for medical treatments.

Additionally, you will recall that in 2015, the VA's financial mismanagement led to a budget crisis that resulted in Congress passing, and the President enacting, the *Surface Transportation and Veterans Health Care Choice Improvement Act of 2015* (P.L. 114-41), in order to shore up the $3.3 billion needed to pay for veterans' health care through the remainder of the fiscal year. This is a clear demonstration that the VA is struggling to manage payments for currently-authorized medical services, and we do not believe policies should be altered to allow for gender reassignment surgeries in this environment.

Finally, current VHA policy on the provision of health care to transgender and intersex veterans delineates that the VA cover only those treatments deemed "medically necessary" (VHA Directive 2013-003). The proposed rule references "recent medical research" that has demonstrated "severe medical consequences for certain patients if transition-related surgeries and procedures are not provided," however the research used to come to that conclusion is not formally cited in the proposal. If the VA is proposing this misguided potential policy change, we strongly believe the agency should at least provide the relevant research reviewed during its consideration.

We respectfully request the VA withdraw this notice immediately. Additionally, we ask that the VA provide us with the "recent medical research" referred to, but not cited, in the proposal's language. Thank you for your consideration in this matter.

Sincerely,

Charles W. Boustany, Jr., M.D.
Member of Congress

Brian Babin
Member of Congress

Warren Davidson
Member of Congress

Mike Kelly
Member of Congress

Joe Pitts
Member of Congress

Walter B. Jones
Member of Congress

John Fleming, M.D.
Member of Congress

Duncan Hunter
Member of Congress

Tim Huelskamp
Member of Congress

Trent Kelly
Member of Congress

David Brat
Member of Congress

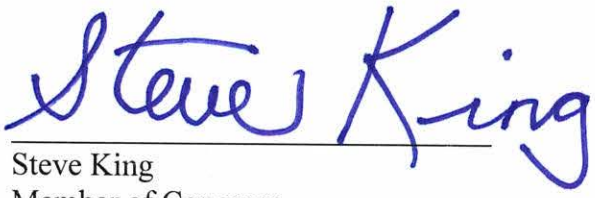
Vicky Hartzler
Member of Congress

Chuck Fleischmann
Member of Congress

Diane Black
Member of Congress

Doug LaMalfa
Member of Congress

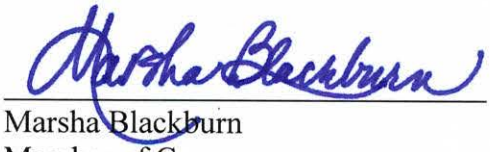
Doug Lamborn
Member of Congress



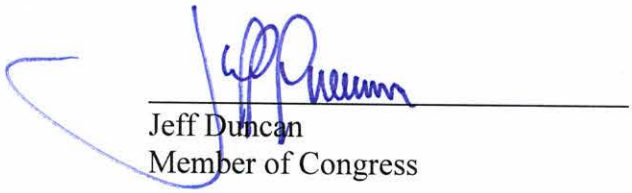
Steve King
Member of Congress

Kevin Cramer
Member of Congress

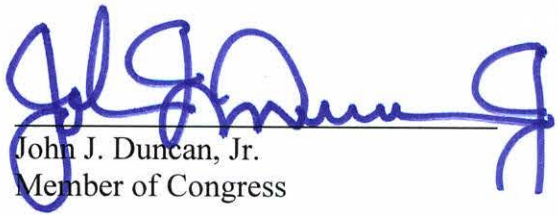
Peter J. Roskam
Member of Congress



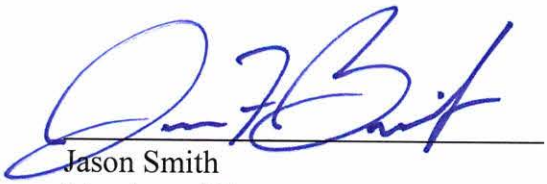
Marsha Blackburn
Member of Congress



Jeff Duncan
Member of Congress



John J. Duncan, Jr.
Member of Congress



Jason Smith
Member of Congress

Tom Rice
Member of Congress

Steven M. Palazzo
Member of Congress

Bill Flores
Member of Congress

Stephen Fincher
Member of Congress

Thomas Massie
Member of Congress

Andy Harris, M.D.
Member of Congress

Todd Rokita
Member of Congress

VA | U.S. Department of Veterans Affairs

Office of the Secretary
Washington DC 20420

In Reply Refer To: **00REG**

Date: July 29, 2016

Subj: Economic Impact Analysis for RIN 2900- AP69, Removing Gender Alterations Restriction from the Medical Benefits Package

I have reviewed this rulemaking package and determined the following.

1. This rulemaking will not have an annual effect on the economy of $100 million or more, as set forth in Executive Order 12866.

2. This rulemaking will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601-612.

3. This rulemaking will not result in the expenditure of $100 million or more by State, local, and tribal governments, in the aggregate, or by the private sector, under the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

4. Attached please find the relevant cost impact documents.

(Attachment 1): Agency's Impact Analysis, dated June 22, 2016
(Attachment 2): CFO Concurrence memo, dated July 24, 2016

Approved by:
Michael P. Shores, MSRC
Acting, Director Regulation Policy & Management (00REG)
Office of the Secretary

(Attachment 1)

Impact Analysis for RIN 2900 AP69/WP2015-003

Title of Regulation: Removing Gender Alterations Restriction from the Medical Benefits Package

Purpose: To determine the economic impact of this rulemaking. This impact analysis describes a cost allocation pilot for the additional services that will be provided by the rule change. This costing pilot will allow for data acquisition to improve projections of ongoing costs by utilizing actual costs for services associated with this rule change.

The Need for the Regulatory Action: Section 1710 of title 38 United States Code (U.S.C.) requires VA to "furnish hospital care and medical services which the Secretary determines to be needed" for eligible veterans. VA has established a "medical benefits package" in 38 CFR 17.38, which describes the types of medically needed care and services available for such eligible veterans, as well as certain exclusions. Services that are considered "gender alterations" are specifically excluded from being provided as part of the medical benefits package under 38 CFR 17.38(c)(4).

This rulemaking proposes to remove a restriction in Department of Veterans Affairs (VA) regulation that prohibits VA from providing medical services that are considered "gender alterations." In the past, gender dysphoria, previously referred to as transsexualism or gender identity disorder, was a disorder for which transition-related surgeries and procedures were considered treatment, but such surgeries and procedures required further research to assure their safety and reliability. Due to the prior limited knowledge about both gender dysphoria and effective transition-related procedures, surgical procedures in particular were not deemed to be medically necessary. However, increased understanding of both gender dysphoria and surgical techniques in this area have improved significantly, and surgical procedures are now widely accepted in the medical community as medically necessary treatment for gender dysphoria (e.g., American Medical Association, the American Psychological Association, the American Psychiatric Association, the American Academy of Family Physicians). Additionally, recent medical research shows that gender dysphoria is a serious condition that has had severe medical consequences for certain patients if transition-related surgeries and procedures are not provided[1]. In 2014, the U.S. Department of Health and Human Services (HHS) lifted its ban on transition-related care for Medicare patients.[2] In 2015, the Office of Personnel Management (OPM) required that insurance plans for the Federal Employees Health Benefits Program include coverage for all transition-related care.[3] A new HHS rule (effective July 18, 2016) requires health care plans under the Affordable Care Act (ACA) to be inclusive of comprehensive transgender care.[4] This

[1] See Padula, W.V. Heru, S., & Campbell, J.D. Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A cost-effectiveness Analyses (2015) J. of Gen. Intern. Medicine DOI 10.1007/s11606-015-3529-6

[2] See Decision No. 2576, Department of Health and Human Services, Departmental Appeals Board (May 30, 2014), available at http://www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf.

[3] U.S. Office of Personnel Management, FEHB Program Carrier Letter, Letter No. 2015-12 (June 23, 2015), *available at* https://www.opm.gov/healthcare-insurance/healthcare/carriers/2015/2015-12.pdf.

[4] See Section 1557 of the Patient Protections and Affordable Care Act (May 13. 2016) available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-11458.pdf

rule change prohibits denial of health services based on gender identity, such as denying gender alteration procedures. In light of medical advances, recent research, and the standard in insurance coverage at the federal level, VA would revise its regulation to remove the prohibition on medical services that are considered "gender alterations." In this way, medical decisions would be made on a case-by-case basis; determining which procedures are medically necessary to treat gender dysphoria for the individual being treated.

VHA already provides transgender care under Directive 2013-003: Currently, VHA provides most services for transgender veterans including cross-sex hormones, psychotherapy, pre and post-operative care, including evaluations of readiness for surgical procedures and care associated with post-surgery complications.

Added benefits if "gender alteration" exclusion is removed from the Medical Benefits Package: Treatment decisions would be made by the medical team working with each unique Veteran. If this change is made, when transition-related procedures are indicated and deemed medically necessary by the treatment team, services would be provided and/or paid for by the VHA. This could include a variety of procedures that are currently disallowed (e.g., hysterectomy, penectomy, phalloplasty or metoidioplasty with urethral extension, vaginectomy, vaginoplasty, scrotoplasty, breast augmentation or reduction and reconstruction, electrolysis, facial feminization/masculinization, tracheal shave/ chondrolaryngoplasty). For ease of communication, these are described below as feminizing procedures and masculinizing procedures.

Utilization of transition-related procedures outside VHA: Very little published data exists on transgender healthcare utilization and/or costs. However, some recent research suggests that for large, civilian employers whose insurance plans offer transition-related care (including surgeries listed above), an average of .044 per thousand employees file claims for transition care annually.[5] This means that on average, one out of every 22,727 employees file claims for transition-related care each year.[6] This care can include any type of transition-related care, including hormones, gender counseling, surgeries, etc.

However, transgender people are over-represented in the veteran population by a factor of at least two.[7] The over-representation of transgender people in the veteran

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[5] *See Jody L. Herman (2013), Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers (Los Angeles: Williams Institute). The .044 figure cited above was derived from data from a subset of the largest employers.*

[6] *For additional research on utilization rates of transition-related care, see City and County of San Francisco and San Francisco Human Rights Commission (2007), San Francisco City and County Transgender Health Benefit; Department of Insurance, State of California (2012), Economic Impact Assessment: Gender Nondiscrimination in Health Insurance; Human Rights Campaign, (no date), Transgender-Inclusive Benefits: Medical Treatment Cost and Utilization; Jamison Green & Associates (2012), Transgender-Inclusive Health Benefits: Data for Cost Calculation. Presented by Andre Wilson of Jamison Green & Associates to the Department of Insurance, State of California, February 2012.*

[7] *According to a recent report, there are an estimated 134,300 veterans who self-identify as transgender out of a total veteran population of 21,999,108. Thus, individuals who self-identify as transgender make up 0.61% of the overall veteran population, as compared to 0.3% of the nation's civilian adult population. The percent of veterans who self-identify as transgender may be .0061/.003 = 2x greater than the percent of non-veterans who self-identify as transgender. See Gary J. Gates and Jody L. Herman (2014), Transgender Military Service in the United States (Los Angeles: Williams Institute). The total population of veterans is from Table 1L: VETPOP2014 Living Veterans by Age Group, Gender, 2013-2014, available at http://www.va.gov/vetdata/Veteran_Population.asp (last accessed November 28, 2014). For the percent*

population can be explained by developmental theories that argue the appeal of structured environments (such as the military) during periods of identity confusion or denial. By extension, transgender individuals are twice as likely to be enrolled in the VHA as to work for civilian organizations such as the large employers from which the .044 figure was derived. Thus, the average VHA utilization rate is expected to be at least twice as high as in the civilian study.

It is not known exactly how many transgender veterans use VHA services. However, using data from 2013 and the .044 figure from above, VHA can estimate that 687 unique VHA-utilizing veterans will require transition-related care.[8] Given that transition-related care is highly individualized, it is not possible to know what aspects of care will be required for each unique veteran. Again, it is important to note that the majority of this care is already covered by VHA including hormones and gender identity counseling. Fortunately, the addition of medically necessary transition-related procedures is viewed as an event-based expense per unique veteran, rather than ongoing medical expense to the system, especially since post-operative complications and care are already covered benefits. The proposed change would add transition-related procedures deemed medically necessary by the unique veteran's VHA treatment team to the existing benefits.

We have predicted that 687 unique VHA utilizing veterans will require transition-related care each year. As a check on the validity of the estimate, consider that researchers determined recently that the number of new transgender diagnoses in the VHA system increased from 226 in 2006 to 522 in 2013.[9] Once VHA removes its surgery exclusion, and after a period of adjustment during which VHA will meet the surgical needs of veterans who already have transgender diagnoses and who are already enrolled in the system, the annual number of VHA enrollees seeking transition-related surgery should not, in general, exceed the number of new transgender diagnoses each year.

Unadjusted annual costs of providing transition-related procedures to each unique transgender Veteran: When estimating the costs of added benefits, the figure of 687 unique veterans per year was used. In addition, while many of these veterans will not have any surgical interventions, these unadjusted projections assume that everyone will access all the services newly available to them. In this way, we offer the most conservative (highest) cost projection possible.

As with many healthcare services, determining actual costs of procedures is difficult. To generate these figures we relied on two sources: 1) For procedures not currently conducted within VHA (facial feminization procedures and electrolysis), we used recently (2013) published data on average costs of each intervention[10]. For these

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of adult Americans who self-identify as transgender, See Gary J. Gates (2011), How Many People Are Lesbian, Gay, Bisexual and Transgender (Los Angeles: Williams Institute).

[8] *The 2013 VHA population was 7,809,269. The 687 figure was derived as follows: 2013 VHA Population/1000 * (average utilization rate per thousand civilians * transgender veteran prevalence factor), or 7,809,269/1000 * (.044*2) = 687.*

[9] Michael R. Kauth, Jillian C. Shipherd, Jan Lindsay, John R. Blosnich, George R. Brown, and Kenneth T. Jones (2014), Access to Care for Transgender Veterans in the Veterans Health Administration: 2006-2013, American Journal of Public Health 104, S4, 533.

[10] From Meier SC & Lubuski CM. (2013). The demographics of the transgender population (pp. 289-327). In AK Baumle (ed), The International Handbook on the Demography of Sexuality. Springer. Because there were no VHA data on electrolysis or facial feminization, the average figures reported for these two procedures were included despite these costs being from procedures conducted in civilian clinics.

procedures we utilized the average of costs reported for each procedure in civilian clinics. 2) Actual VHA cost data was used for procedures that are currently being performed by VHA staff for reasons other than gender transition (e.g., genital reconstruction due to blast injuries, mastectomies and breast reconstruction following a cancer diagnosis)[11]. Data were gathered from FY2008 through Q2 of FY2015 and averaged across years. For any breast-related procedures, costs were doubled with the assumption that both breasts would be modified for transition purposes.

For these cost estimates, it was assumed that two-thirds of the 687 transgender veterans would seek feminizing procedures and one-third would seek masculinizing procedures. This assumption is based on the statistically higher number of veterans with a male birth sex (relative to female sex at birth). Thus, in these estimates we anticipate that 458 unique VHA using Veterans would receive all feminizing procedures and 229 veterans would receive all masculinizing procedures. The figures described below do not include travel that may be associated with the listed procedures.

Feminizing Procedures

Procedure	Cost per person	Unique Veterans	Unadjusted Cost to VHA
Breast augmentation[11]	$10,199	458	$4,671,142
Genital reconstruction[11]	$56,019	458	$25,656,702
Facial feminization[10]	$52,500	458	$24,045,000
Electrolysis[10]	$2,900	458	$1,328,200
	Per person		**Unadjusted Cost Overall**
Totals	$121,618		$55,701,044

Masculinizing Procedures

Procedure	Cost per person	Unique Veterans	Unadjusted Cost to VHA
Breast reduction/chest reconstruction[11]	$15,286	229	$3,500,494
Hysterectomy/ Genital reconstruction[11]	$80,731	229	$18,487,399

[11] Data was derived from the following CPT Coded procedures performed within VHA FY2008 through April FY2015. All breast procedure costs were doubled, with the assumption that the procedure would be done on both sides to facilitate transition. Costs were averaged across all procedures/years. The number of procedures included in the calculation of costs are listed below for each included code:

	Per person		Unadjusted Cost Overall
Totals	$96,017		$21,987,893

Feminization procedures: Code 19325 Enlarge breast with implant (data from 147 procedures); Code 54125 Removal of penis (data from 88 procedures); Code 54520 Removal of testis (data from 1979 procedures); Code 54660 Revision of testis (data from 85 procedures); Code 54690 Laparoscopy orchiectomy (data from 15 procedures); Code 55180 Revision of scrotum (data from 24 procedures); Code 57291 Construction of vagina (data from 1 procedure); Code 57292 Construction of vagina with graft (data from 1 procedure); Code 57295 Revision of vaginal graft via vagina (data from 57 procedures); Code 57296 Revision of vaginal graft open abdomen (data from 2 procedures); Code 57426 Revision of vaginal graft laparoscopic (data from 2 procedures).

Masculinization procedures: Code 58150 Total hysterectomy (data from 2918 procedures); Code 58552 Laparoscopic vaginal hysterectomy incl T/O (data from 362 procedures); Code 58554 Laparoscopic vaginal hysterectomy incl W/T/O complete (data from 26 procedures); Code 58571 TLH W/T/O uterus 250 G or less (data from 238 procedures); Code 58573 TLH W/T/O uterus over 250 G (data from 33 procedures); Code 56625 Complete removal of vulva (data from 9 procedures); Code 56800 Repair of vagina (data from 5 procedures); Code 56805 Repair of clitoris (data from 1 procedure); Code 57110 Remove vagina wall complete (data from 2 procedures); Code 19350 Breast reconstruction (data from 5 procedures); Code 19371 Removal of breast capsule (data from 22 procedures).

There is no way to know how many unique VHA-utilizing veterans will seek and be medically cleared for these transition-related procedures. There are many personal and medical reasons why veterans may not seek or receive any or all of these procedures. However, to be conservative these unadjusted estimates assume that all of the unique 687 VHA utilizing veterans will receive all of these interventions. Using this approach, the maximum estimated per person costs range between $96,017 and $121,618 per veteran. If each unique veteran sought and attained every service available to them in VHA, the range of total unadjusted costs to VHA would be potentially as high as $77,690,998 each year to include both feminizing ($55,700,128) and masculinizing (21,990,870) procedures to 687 veterans. However, this figure assumes that every veteran would receive every possible procedure, an assumption that is highly unlikely due to the various personal and medical reasons why a veteran might not seek or receive any given procedure.

Adjusted costs of providing transition-related surgery: Using similar methodology as described above, the City and County of San Francisco estimated that offering transition-related care to its employees would cost $1.75 million per year, but the actual cost over five years averaged $77,283 per year. In other words, San Francisco's estimate was more than 22x too high.[12] Therefore, in our adjusted projected costs, we have divided these figures by a factor of 22 in order to have real-world, data-driven estimates of adjusted projected costs.

Feminizing Procedures

Procedure	Potential Cost to VHA	Adjusted Costs*
Breast augmentation	$4,675,264	$212,512
Genital reconstruction	$25,653,496	$1,166,068
Facial feminization	$24,041,336	$1,092,788
Electrolysis	$1,330,032	$60,456

[12] *Jody L. Herman (2013), Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers (Los Angeles: Williams Institute), 11.*

	Overall	Adjusted Cost Overall
Totals	$55,700,128	$2,531,824

*Adjusted costs are divided by 22

Masculinizing Procedures

Procedure	Potential Cost to VHA	Adjusted Costs*
Breast reduction/chest reconstruction	$3,501,410	$159,155
Hysterectomy/Genital reconstruction	$18,489,460	$840,430
	Overall	**Adjusted Cost Overall**
Totals	$21,990,870	$999,585

*Adjusted costs are divided by 22

Summary of Projected Costs using Unadjusted and Adjusted Projections:

FY	Cost per person	Unadjusted Annual Costs	Adjusted Annual Costs
2018	$96,017- $121,618	$77,690,998	$3,531,409

Thus, based on available data, the projected cost impact of adding these services to the Medical Benefits Package varies widely from a low of just over $3.5 million dollars annually ($2,531,824 Feminizing; $999,585 Masculinizing) a high of nearly $78 million per year. The wide variability in adjusted and unadjusted costs makes it difficult to project annual costs appropriately. As such, this proposal includes a three year cost allocation pilot to gather data on actual costs associated with this care. In this way, it will be possible to determine accurate cost allocations for care beyond the costing pilot.

Limitations of this cost projection: As with many healthcare related costs, determining the costs of associated procedures can be difficult. There were several data-driven assumptions that underlie the cost projections regarding the number of unique VHA utilizing veterans who may attain transition-related procedures. There are very few published reports or publically available data on transition-related costs. Moreover, the costs per procedure in this report were based on published data from the private sector, but are not necessarily the most current or applicable. In addition, where VHA data was used it is important to realize that the procedures were not for the purposes of gender transition but for other medical causes. Thus, even though these are the most relevant figures to generate cost estimates, it is not known how or if costs will differ for similar procedures conducted for gender transition purposes. In addition, in some cases there were only a few procedures conducted, and sometimes only one, which contributes to higher costs due to the infrequency of the procedure. These estimates were generated from the best available published data and from VHA data sources to assure the most accurate projections.

Importantly, VHA currently must pay for post-operative care and complications from transition surgeries performed outside the system. By ensuring that the entire transition process is handled within the VHA system, we have better continuity of care and better control of pricing. Many Veterans are enduring post-operative complications related to international travel from surgical centers and poor surgical care; by increasing access through VHA processes for this care these types of complications can be reduced and continuity of care will be enhanced. On more than one occasion we have learned of veterans who sought transition-related surgeries outside of the U.S. and then returned home, sitting on the surgical site for an extended airline trip. These veterans then presented to VHA emergency rooms seeking assistance. Outcomes are poorer than when there has been planned post-surgical care.

Finally, transition-related surgery has been proven effective at mitigating serious health conditions including suicidality, substance abuse and dysphoria that, left untreated, impose treatment costs on the VHA.[13],[14]

Cost allocation pilot: Given the limitations of the data as described above, and the resulting wide variability in cost estimates, a three year costing pilot is being proposed with this rule change. Annual review of actual incurred costs of these added benefits will improve each successive year's budget projections. By the end of the pilot it will be possible to provide data-driven cost projections to inform future budget planning.

In the initial months of access to these procedures, techniques that are more commonly performed at many VA facilities (e.g., removal of testes or uterus) for other medical purposes (e.g., cancer treatment) will be newly available for the purposes of transition-related care, but likely accessed by only a small number of veterans for minimal costs. In FY 2018, it is anticipated that systems of referral for more complex transition-related procedures will become widely available and costs will begin to increase as veterans are referred for this care. In FY2018 we anticipate meeting the lower projected cost estimates of 3.5 million, in FY 2019 and 2020, we predict a greater demand for services from previously identified veterans and also new veterans seeking services, potentially resulting in a doubling of demand and costs.

Feminizing Procedures

Procedure	Cost per person	Adjusted cost	Unique Veterans	Adjusted Cost to VHA
Breast augmentation	$10,199	$464	458	$212,512
Genital reconstruction	$56,019	$2,546	458	$1,166,068
Facial feminization	$52,500	$2,386	458	$1,092,788

[13] *For a review of the evidence of the efficacy of transition-related surgery, see Department of Health and Human Services Departmental Appeals Board Decision No. 2576 (May 30, 2014). For an analysis of cost savings that would be accrued by offering transition-related surgery, see Department of Insurance, State of California (2012), Economic Impact Assessment: Gender Nondiscrimination in Health Insurance, 9-12.*

[14] For a review of the cost-effectiveness analysis where provider both cost per quality-adjusted life year (QUALY) for successful transition reducing negative outcomes (e.g., HIV, depression, suicidality, drug abuse, mortality) with an incremental cost-effectiveness ratio of $9314/QUALY. Estimations are that costs of adding comprehensive transgender care (over no benefits) is $0.016 per member per month.

Electrolysis	$2,900	$132	458	$60,456
Totals				**$2,532,824**

Masculinizing Procedures

Procedure	Cost per person	Adjusted cost	Unique Veterans	Adjusted Cost to VHA
Breast reduction/chest reconstruction	$15,286	$695	229	$159,155
Hysterectomy/Genital reconstruction	$80,371	$3,670	229	$840,430
Totals				**$999,585**

Total of All Procedures FY 2018	**$3,531,409**

*** adjusted costs divided by 22 per published results from San Francisco example**

Feminizing Procedures

Procedure	Cost per person	Adjusted cost	Unique Veterans	Adjusted Cost to VHA
Breast augmentation	$10,199	$928	458	$425,024
Genital reconstruction	$56,019	$5,092	458	$2,332,136
Facial feminization	$52,500	$4,772	458	$2,185,576
Electrolysis	$2,900	$264	458	$120,912
Totals				**$5,063,648**

Masculinizing Procedures

Procedure	Cost per person	Adjusted cost	Unique Veterans	Adjusted Cost to VHA
Breast reduction/chest reconstruction	$15,286	$1,390	229	$318,310
Hysterectomy/Genital reconstruction	$80,371	$7,340	229	$1,680,860
Totals				**$1,999,170**

Total of All Procedures FY 2019	**$7,062,818**
Total for All Procedures FY 2020 (FY 2019*3.9%)	**$7,338,268**

*** adjusted costs for FY 2018-FY 2019 multiplied by 2 to account for potential doubling of demand**

FY	Projected Costs
2018	$3,531,409
2019	$7,062,818
2020	$7,338,268
Projected Costs	**$17,932,495**

Estimated Impact: VA has determined that there are costs associated with this rulemaking. The costs estimated during the budget pilot from the publication of the rule through the first 3 years to be just over $17.9 million. Annual review of actual incurred costs of these added benefits will improve each successive year's budget projections. Should demand for the services outstrip the cost allocations per year, the Under Secretary for Health has the authority to adjust budget allocations to assure access to care. This analysis sets forth the basic assumptions, methods, and data underlying the analysis and discusses the uncertainties associated with the estimates.

Submitted by:
Jillian C. Shipherd, Ph.D. and
Michael R. Kauth, Ph.D.
Directors, LGBT Program (10P4Y)
Patient Care Service
Department of Veterans Affairs
June 22, 2016

(Attachment 2)

Memorandum

Department of Veterans Affairs

Date: July 24, 2016

From: VHA Chief Financial Officer (10A3)

Subj: Impact Analysis for RIN 2900-AP69, Removing Gender Alterations Restriction from the Medical Benefits Package; Lesbian, Gay, Bisexual, and Transgender (LGBT) Program

To: Chief Impact Analyst, Office of Regulation Policy and Management, Office of the General Counsel (02REG)

1. The VHA Chief Financial Officer concurs with the costs associated with the attached impact analysis for RIN 2900-AP69, Removing Gender Alterations Restriction from the Medical Benefits Package, LGBT Program (10P4Y). However, VHA would require additional appropriated funds to support the proposed change in regulation(s).

2. The VHA Chief Financial Officer concurs with the attached impact analysis to remove a restriction in Department of Veterans Affairs (VA) regulation that prohibits VA from providing medical services that are considered "gender alterations." In the past, gender dysphoria, previously referred to as transsexualism or gender identity disorder, was a disorder for which transition-related surgeries and procedures were considered treatment, but such surgeries and procedures required further research to assure their safety and reliability. Due to the prior limited knowledge about both gender dysphoria and effective transition-related procedures, surgical procedures in particular were not deemed to be medically necessary. However, increased understanding of both gender dysphoria and surgical techniques in this area have improved significantly, and surgical procedures are now widely accepted in the medical community as medically necessary treatment for gender dysphoria. Implementation of the proposal would be subject to appropriation of additional funds.

3. This impact analysis describes a cost allocation three year pilot for the additional services that will be provided by the rule change. This costing pilot will allow for data acquisition to improve projections of ongoing costs by utilizing actual costs for services associated with this rule change.

4. Questions regarding this cost analysis may be directed to Ed Bernard, Acting AsCFO, Office of Resource Management, at (202) 443-5078.

Mark Yow

Congress of the United States
Washington, DC 20515

September 12, 2016

Secretary Robert A. McDonald
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington D.C., 20420

Dear Secretary McDonald:

We write today as members of the Congressional LGBT Equality Caucus Transgender Equality Task Force to urge the Department of Veterans Affairs (VA) to move swiftly to ensure access to medically necessary surgical care for transgender veterans.

We commend the Department for considering a repeal of the current blanket exclusion in its Spring 2016 Regulatory Agenda (RIN: 2900-AP69). We urge you to move forward with publishing a proposed rule to remove the arbitrary and outdated restriction that prohibits VA from providing medical services to treat gender dysphoria. Your attention to this issue is especially urgent given the Obama Administration's forward thinking policy changes to lift policies that discriminate against LGBT people across the federal government.

It is our understanding that under current VA regulations (38 C.F.R. § 17.38(c)(4)), VHA is prohibited from covering transition-related surgeries for transgender veterans, without regard to medical necessity. We also understand that this rule runs counter to steps being taken by OPM, HHS/OCR, CMS, and DOD to eliminate blanket exclusions for surgical care for the treatment of gender dysphoria. The experience of states and employers,[1] and a significant body of research, demonstrates that providing surgical care for gender dysphoria based on individual medical necessity has extremely little to no net cost, and potentially provides long-term savings to government as a result of preventing future medical and mental health care costs (such as treatment of suicide attempts).[2] Both HHS[3] and Department of Labor (DOL)[4] echoed these findings in final regulations, finding a de minimis cost impact.

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[1] *See, e.g.,* Or. Health Review Comm'n, Value-based Benefits Subcommittee, http://www.oregon.gov/oha/herc/CommitteeMeetingMaterials/VbBS%20Materials%206-12-2014.pdf (June 12, 2014) (estimating a 0.003% increase in non-administrative costs for Oregon Medicaid, before accounting for cost savings); Jody L. Herman, Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefit Plans: Findings from a Survey of Employers (2013) (finding "zero or very low costs [and] low utilization by employees," with employers reporting costs were "negligible," "minimal," or 0.004% of health care expenditures, and reviewing similar findings on municipal and university employee coverage), http://williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf; Cal. Dep't of Ins., Economic Impact Assessment: Gender Nondiscrimination in Health Insurance (2012) (concluding cost impacts for California health plans are "very insignificant" and likely to offset by savings).

[2] William V. Padula et al., Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis, 31 JOURNAL OF GENERAL INTERNAL MEDICINE 394 (2015) (finding that the cost of covering transition-related procedures is about $0.016 per plan member per month).

As you know, the existing regulation was adopted in 1999 and is not required by any statute. This exclusion denies transgender veterans critically important medical care currently available to VA employees, Medicare beneficiaries and, most recently, active duty military service members. This blanket exclusion, without regard to medical necessity, discriminates against transgender veterans in violation of Section 1557 of the Affordable Care Act, which applies to "any program or activity that is administered by an Executive Agency."[5]

This past year has proved historic for transgender equality and visibility. At no other time in our nation's history has the transgender community better or more publicly advocated for full inclusion throughout all parts of society and equal protection under the law. We've made significant gains, yet more work remains to be done and call on you to continue moving towards VA adoption of the proposed rule to permit surgical care for transgender veterans.

Our veterans earn the benefits provided to them through dedicated service to the protection of our country. It is our collective responsibility to ensure that *all* of our veterans are able to access the healthcare they have dutifully earned. We look forward to and eagerly await your response.

Sincerely,

Mike Quigley
Member of Congress

Michael M. Honda
Member of Congress

Jackie Speier
Member of Congress

Raúl M. Grijalva
Member of Congress

Bonnie Watson Coleman
Member of Congress

Eleanor Holmes Norton
Member of Congress

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[3] In the preamble to its final regulation on Section 1557 of the ACA, HHS stated: "Based on the [existing research], we estimate that providing transgender individuals nondiscriminatory insurance coverage and treatment will impact a very small segment of the population due to the fact that the number of transgender individuals (and particularly those who seek surgical procedures in connection with their gender transition) in the general population is small, and consequently will have de minimis impact on the overall cost of care and on health insurance premiums." *Nondiscrimination in Health Programs and Activities; Final Rule, 81 Fed. Reg. 31375, 31457 (May 18, 2016).*

[4] In the preamble to its final regulation on sex discrimination by federal contractors, DOL OFFCP also said that the rule required the elimination of trans gender exclusions. Both DOL and HHS consulted the same body of research, and concluded: "OFCCP determines that the cost of adding nondiscriminatory health-care benefits is most likely to be de minimis." *81 Fed. Reg. 39107, 39148 (June 15, 2016).*

[5] 42 U.S. Code § 18116.

CC: Dr. Michael Kauth
Dr. Jillian Shipherd

United States Senate
WASHINGTON, DC 20510

September 22, 2016

Secretary Robert A. McDonald
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington D.C., 20420

Dear Secretary McDonald:

We write today to urge the Department of Veterans Affairs (VA) to move swiftly to ensure that all those who have served our nation so bravely have access to medically necessary care, including surgical treatment for gender dysphoria. Numerous federal agencies have taken steps to remove barriers to healthcare access for transgender people and it is critical that the Department do so as well.

We applaud the Department for its efforts to date to review this issue and explore a regulatory change to the current blanket exclusion for such care.[1] However, as we swiftly approach the end of the calendar year, it is crucial that the VA move forward with publishing a proposed rule to remove the arbitrary and outdated restriction that prohibits the VA from providing medical services to treat gender dysphoria.

Under current VA regulations (38 C.F.R. § 17.38(c)(4)), the Veterans Health Administration is prohibited from covering transition-related surgeries for transgender veterans, without regard to medical necessity. However, the understanding of the medical community regarding the healthcare needs of transgender people has advanced significantly since this regulation was adopted more than fifteen years ago, and today it is inconsistent with basic standards of medical care. Furthermore, it is out of step with efforts undertaken by the Office of Personnel Management, the Department of Health and Human Services (HHS), the Centers for Medicare and Medicaid Services and the Department of Defense to eliminate blanket exclusions for surgical care for the treatment of gender dysphoria. In addition, an increasing number of state and local governments and private sector employers have taken steps to ensure this care is available and their experience demonstrates that there is little to no net cost in doing so. Both HHS and the Department of Labor have recognized this de minimis fiscal impact in findings in final regulations prohibiting such exclusions for Marketplace health plans and for employee plans of federal contractors.[2]

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[1] Department of Veteran's Affairs Spring 2016 Regulatory Agenda (RIN: 2900-AP69).
[2] *Nondiscrimination in Health Programs and Activities; Final Rule, 81 Fed. Reg. 31375, 31457 (May 18, 2016); Discrimination on the Basis of Sex; Final Rule, 81 Fed. Reg. 39107, 39148 (June 15, 2016).*

This exclusion denies transgender veterans critically important medical care currently available to VA civilian employees, Medicare beneficiaries and active duty service members. It is also in contravention of the requirements of Section 1557 of the Affordable Care Act, which bars discrimination based on sex in healthcare programs and applies to programs administered by Executive Branch agencies.

Our veterans, through proud service and sacrifice for their country, have earned our respect, admiration and every one of the benefits provided to them through the Department. They all deserve access to medically necessary care through the VA and it is imperative that you act swiftly to remove the outdated and unjustified exclusion that denies many transgender veterans the treatment that they need. We look forward to your response.

Sincerely,

Tammy Baldwin
United States Senator

Sherrod Brown
United States Senator

Jeffrey A. Merkley
United States Senator

Al Franken
United States Senator

Bernard Sanders
United States Senator

Patty Murray
United States Senator

Barbara Boxer
United States Senator

Edward J. Markey
United States Senator

Richard J. Durbin
United States Senator

Ron Wyden
United States Senator

Elizabeth Warren
United States Senator

CC: Drs. Michael Kauth and Jillian Shipherd, Co-Directors, Lesbian, Gay, Bisexual, and Transgender (LGBT) Program, Office of Patient Care Services, Veterans Health Administration

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

DEE FULCHER, GIULIANO SILVA, and TRANSGENDER AMERICAN VETERANS ASSOCIATION,	)	
Petitioners,	)	
	)	17-1460
v.	)	
SECRETARY OF VETERANS AFFAIRS,	)	
Respondent.	)	

NOTICE OF FILING OF INDEX OF RECORD

Pursuant to Federal Circuit Rule 17(b)(3), David J. Shulkin, Secretary of Veterans Affairs, files the attached index of the record relating to the agency's consideration of petitioners' May 9, 2016 petition for rulemaking.

Respectfully submitted,

CHAD A. READLER
Acting Assistant Attorney General

ROBERT E. KIRSCHMAN, JR.
Director

/s/Allison Kidd-Miller
ALLISON KIDD-MILLER
Assistant Director

/s/Eric P. Bruskin
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Attorneys for Respondent

March 21, 2017

Index Of Record Of Department Of Veterans Affairs'
Consideration Of Petitioners' May 9, 2017 Petition For Rulemaking

1. Petition For Rulemaking To Promulgate Regulations Governing Provision Of Sex Reassignment Surgery To Transgender Veterans, May 9, 2016.

2. Department of Veterans Affairs, RIN 2900-AP69, "Removing Exclusion of Gender Alterations from the Medical Benefits Package," Spring 2016.

3. Letter from 30 members of Congress to The Honorable Robert McDonald, Secretary, U.S. Department of Veterans Affairs, June 22, 2016.

4. Office of the Secretary, 00REG, "Economic Impact Analysis for RIN 2900-AP69, Removing Gender Alterations Restriction from the Medical Benefits Package," July 29, 2016.

    a. Attachment 1: Impact Analysis for RIN 2900 AP69/WP2015-003, June 22, 2016.

    b. Attachment 2: Department of Veterans Affairs Memorandum from VHA Chief Financial Officer to Chief Impact Analyst, Office of Regulation Policy and Management, Office of the General Counsel, "Impact Analysis for RIN 2900-AP69, Removing Gender Alterations Restriction from the Medical Benefits Package; Lesbian, Gay, Bisexual, and Transgender (LGBT) Program," July 24, 2016.

5. Letter from six members of the House of Representatives to The Honorable Robert McDonald, Secretary, U.S. Department of Veterans Affairs, September 12, 2016.

6. Letter from 11 members of the Senate to The Honorable Robert McDonald, Secretary, U.S. Department of Veterans Affairs, September 12, 2016.

7. Collection of letters from David J. Shulkin to members of Congress, November 10, 2016.

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on this 21st day of March, 2017, a copy of the foregoing "NOTICE OF FILING OF INDEX OF RECORD" was filed electronically.

X This filing was served electronically to all parties by operation of the Court's electronic filing system.

/s/Eric P. Bruskin

CERTIFICATE OF SERVICE

I hereby certify that, on this 3rd day of January, 2018 I filed the foregoing Joint Appendix with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

/s/ Alan E. Schoenfeld
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