

January 2, 2015

RE: National Coverage Determination for Gender Dysphoria and Gender Reassignment Surgery

On behalf of the National Center for Transgender Equality, Transgender Law Center and Justice in Aging, we appreciate the opportunity to comment on the proposed NCD for Gender Reassignment Surgery. While we have joined separate comments addressing in detail the clinical evidence for covering these procedures, these comments address CMS's responsibility to ensure that the NCD comply with the legal requirements of the Affordable Care Act.

The NCD must comply with the nondiscrimination requirements of the Affordable Care Act.

The NCD must be consistent not only with current medical research, but also with the nondiscrimination principles and standards of Section 1557 of the Affordable Care Act. HHS has affirmed that Section 1557 prohibits health coverage practices that result in discrimination on the basis of gender identity.¹ Its recent proposed rule implementing Section 1557 enumerated a range of coverage policies and practices that arbitrarily and discriminatorily single out transgender people by denying them benefits provided to non-transgender people and limiting their access to essential care solely based on their gender identity.² The requirements set out in the proposed nondiscrimination rule apply to health programs administered by CMS, including Medicare,³ as well as recipients of Medicare funds apart from Medicare Part B payments.⁴ Issuing an NCD is necessary to ensure uniform compliance with these nondiscrimination requirements.

Section 1557 prohibits automatic exclusions of medically necessary treatments for Gender Dysphoria.

HHS has recognized that many restrictions on coverage for treatments of Gender Dysphoria unlawfully discriminate against transgender people, in violation of Section 1557. For example, a covered entity may not categorically exclude any and all care related to gender transition.⁵ The Department of Appeals Board's 2014 decision striking down Medicare's categorical exclusion of surgical treatments for Gender Dysphoria brought the Medicare program closer in line with both the overwhelming medical

¹ Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172 (proposed Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 92).

² *Id.* To date, 12 states (California, Colorado, Connecticut, Illinois, Massachusetts, Minnesota, New York, Nevada, Oregon, Rhode Island, Vermont, and Washington State) and the District of Columbia have adopted similar interpretations of the ACA and/or their own state nondiscrimination laws with respect to health insurance.

³ *Id.* at 54,195.

⁴ *Id.* at 54,194.

⁵ *Id.* at 54,219.

evidence regarding the safety, efficacy and medical necessity of such treatment and with CMS's legal obligations under Section 1557.⁶

HHS further clarified that, even in the absence of a blanket exclusion of transition-related care, certain coverage exclusions of specific services may also constitute illegal discrimination.⁷ For example, the proposed rule made clear that Section 1557 prohibits policies that deny coverage for services used in the treatment of Gender Dysphoria when similar services are covered for the purpose of treating other conditions.⁸ Most therapeutic services used in the treatment of Gender Dysphoria are analogous to therapeutic services that are regularly covered under Medicare for other medical conditions for non-transgender individuals.⁹ For example, Medicare covers mastectomies and reconstructive surgeries for the treatment of breast cancer¹⁰ and reconstructive facial surgeries to repair serious injuries.¹¹ Denying coverage for substantially similar reconstructive surgeries simply because those procedures are used for the treatment of Gender Dysphoria would constitute unlawful discrimination against transgender people in violation of Section 1557.

In some circumstances, implementing a nondiscriminatory coverage policy based on medical necessity will require coverage of services for treating Gender Dysphoria that are usually considered cosmetic and therefore not covered for other conditions. For example, procedures such as augmentation mammoplasty or permanent hair removal, which are cosmetic in most contexts and excluded from coverage, may be medically necessary in the context of Gender Dysphoria. The essential purpose of transition-related treatment, whether it is genital reconstructive surgery or any other gender reassignment procedure, is to therapeutically treat Gender Dysphoria, not to improve a person's appearance.

A coverage policy that classifies these often life-saving treatments as cosmetic and makes coverage of those treatments subject to the same exclusion as procedures that are cosmetic when performed on non-transgender people misconstrues the nature of transition-related care. Such a policy unlawfully discriminates against transgender people: whereas non-transgender people affected by the policy are merely denied coverage for aesthetic, non-essential services, transgender people under the same policy are denied coverage for medically necessary care that is inherently tied to their transgender status.¹² The automatic classification of certain treatments of Gender

⁶ See Dep't of Health & Human Serv., NCD 140.3, Transsexual Surgery, 11 (2014).

⁷ See Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. at 54220.

⁸ *Id.* at 54,190. State nondiscrimination laws applicable to insurance have been interpreted similarly. See, e.g., 10 Cal. Admin. Code § 2561.2(a)(4) (prohibiting exclusion of services for gender transition "if coverage is available for those services under the policy when the services are not related to gender transition"); Oregon Insurance Division Bulletin INS 2012-1 ("A health insurer may not deny or limit coverage or deny a claim for a procedure provided for [gender dysphoria] if the same procedure is allowed in the treatment of another [non-GD] condition").

⁹ See Dep't of Health and Human Servs., NCD 140.3, Transsexual Surgery, 11 (2014).

¹⁰ Dep't of Health and Human Servs., NCD 140.2, Breast Reconstruction Following Mastectomy (1997).

¹¹ See Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage; 120 - Cosmetic Surgery.

¹² *Cf.*, e.g., EEOC on Coverage of Contraception, (Dec. 14, 2000) (holding that exclusion of hormonal contraceptive discriminates against women because virtually all persons affected are women),

Dysphoria, in spite a physician's determination of medical necessity for any particular individual, is a denial of coverage that clearly results in discrimination against transgender beneficiaries and is a direct violation of Section 1557.

Distinguishing procedures that can be medically necessary in the context of treating dysphoria from superficially comparable procedures used for cosmetic purposes is consistent with existing Medicare policy of providing coverage for procedures that are normally considered cosmetic when those services are used for medically necessary purposes:

Cosmetic surgery includes any surgical procedure directed at improving appearance, except when required for the...repair of accidental injury or for the improvement of the functioning of a malformed body member. For example, this exclusion does not apply to surgery in connection with treatment of severe burns or repair of the face following a serious automobile accident, or to surgery for therapeutic purposes which coincidentally also serves some cosmetic purpose.¹³

Accordingly, the NCD should clarify that no procedures recognized by the WPATH Standards as potentially medically necessary for the treatment of Gender Dysphoria are to automatically be classified as cosmetic and therefore excluded from coverage, regardless of whether they are cosmetic in most other contexts or have an incidental function of changing an individual's appearance. Rather, the NCD must allow for the coverage of these procedures when they are clinically indicated for the treatment of Gender Dysphoria, as determined by a qualified health care professional based on the patient's clinical history and presentation and the most up-to-date version of the WPATH Standards of Care.

The NCD should set nondiscriminatory and clinically supported standards for medical necessity.

HHS has recognized that the nondiscrimination requirements of Section 1557 apply not only to the outright exclusion of services related to gender transition, but also to any limitation on coverage that "results in discrimination against a transgender individual."¹⁴ A covered entity may not circumvent the nondiscrimination protections in the Affordable Care Act by employing discriminatory benefit designs and policies that create onerous and unjustifiable barriers to coverage that make it impossible or highly impractical for transgender people to access essential care. For example, a covered entity cannot impose arbitrary and excessive standards that are not supported by sound medical evidence for determining eligibility or medical necessity of transition-related procedures, such as by requiring mandatory waiting periods or hormone treatment before covering chest

<http://www.eeoc.gov/policy/docs/decisioncontraception.html>; *Cooley v. Daimler Chrysler Corp.*, 281 F.Supp.2d 979 (E.D. Mo. 2003) (same).

¹³ Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage; 120 - Cosmetic Surgery.

¹⁴ Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. at 54220.

reconstructive surgery¹⁵ or a minimum period of psychotherapy before covering hormonal or surgical interventions.¹⁶

While some commercial insurance policies still retain these criteria, the medical community has long since recognized that these prerequisites to care have no clinical basis, but rather developed out of outdated perceptions of transgender identities as disordered, abnormal and frequently illusory. Denying coverage based on widely discredited assumptions about transgender people rather than sound clinical practice is inherently discriminatory. In order to comply with the requirements of Section 1557 and prevent unlawfully discriminatory limitations and denials, the NCD should recognize that determinations of medical necessity must be based on mainstream clinical literature and the most recent version of the WPATH Standards of Care, rather than past or present commercial insurance practices or biased assumptions about transgender people or their health needs.¹⁷

By issuing an NCD based on the well-established medical standards regarding the treatment of Gender Dysphoria and the determination of medical necessity for each individual, CMS can comply with its legal obligations under the ACA and prevent the misapplication or inconsistent interpretation of the law in local coverage determinations by individual contractors. Ensuring that the NCD does not run afoul of the nondiscrimination provisions of Section 1557—such as by excluding treatments for Gender Dysphoria that are covered for other conditions, basing an exclusion of medically necessary treatments on their classification as cosmetic in unrelated contexts, or imposing criteria for coverage that are not clinically supported—CMS can ensure compliance with the ACA and avoid the possibility of nondiscrimination complaints or litigation against CMS or its contractors.

¹⁵ See World Prof. Ass’n for Transgender Health, *Standards of Care of the Health of Transsexual, Transgender, and Gender Nonconforming People*, Seventh Edition, 34, 59 (2011) [hereinafter SOC 7] (indicating that no minimum period of living as one’s identified gender is required before chest reconstructive surgery, and that “[h]ormone therapy is not a prerequisite” to masculine chest reconstructive surgery and recommended but not required for feminine chest reconstructive surgery)

¹⁶ See Stephen B. Levine et al., *Harry Benjamin International Gender Dysphoria Association’s The Standards of Care for Gender Identity Disorders*, Fifth Edition 20 (1998) (eliminating psychotherapy as a requirement for any transition-related therapy: “[t]he SOC committee is wary of insistence on some minimum number of psychotherapy sessions for the real life experience, hormones, or surgery, [because] patients differ widely in their abilities to attain similar goals in a specified time [and] minimum number of sessions tend to be construed as a hurdle which tends to be devoid of the genuine opportunity for personal growth.”); see also SOC 7, *supra* note 15, at 1 n. 2 (emphasizing that treatment for Gender Dysphoria should not be determined based on previous version of the Standards of Care: “*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....”).

¹⁷ See, e.g. Minn. Dep’t of Commerce and Minn. Dep’t of Health, Admin. Bulletin 2015-5 (pursuant to state nondiscrimination law, “[d]etermination of medical necessity and prior authorization protocols for gender dysphoria-related treatment must be based on the most recent, published medical standards set forth by nationally recognized medical experts in the transgender health field”), <http://mn.gov/commerce-stat/pdfs/bulletin-insurance-2015-5.pdf>.

We thank you for your work to ensure that all Medicare beneficiaries have access to medically necessary gender reassignment surgery and for your consideration of our comments.

Sincerely,

National Center for Transgender Equality
Justice in Aging
Transgender Law Center