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RE: Responses to comments received from the public for GCR 19-021: Health Care Administrative Rules Update

All comments received were for HCAR 4.238, Gender Affirmation Surgery for the Treatment of Gender Dysphoria. A summary of the nearly 200 comments received on the proposed rule and the Agency of Human Services' responses to those comments is included below.

Comments have been summarized according to topic due to the volume received. Comments were received from the general public, health care providers, Outright Vermont, Vermont Department of Financial Regulation, Vermont Legal Aid, Inc., University of Vermont Children's Hospital Transgender Youth Program, the Transgender Legal Defense & Education Fund, and the National Center for Transgender Equality.

Comment 1:

The majority of comments received were in general support or opposition to the rule, with an emphasis on the lack of a stated age minimum of eligibility for coverage of these services. Many commenters opposing the rule cited one or more of the following reasons for their opposition:

- Young people (under various ages – 18, 21, or 25 years) are not capable of fully consenting to permanent surgeries that may render them incapable of reproducing.
- There is no such thing, medically, as being “transgender.”
- People experiencing gender dysphoria need mental health treatment, not surgery.
- There is a lack of evidence that these surgeries relieve gender dysphoria over time.
- Concern that those who undergo these surgeries experience regret and suicidal ideation.
- Children and adolescents will overcome gender dysphoria naturally, or identify as gender non-conforming instead of transgender, if they are not pushed by family/peers/counselors/society into medical treatments such as hormones and surgery.

Conversely, many commenters supported the rule for the following reasons:

- The previous age minimum of 21 years created an arbitrary barrier not supported by clinical practice, standards, and guidelines.
- The expansion of coverage for young people will save lives and improve health, and there is evidence to support this.

Response 1:

The State is finalizing this rule as proposed – without a stated age minimum. Vermont Medicaid provides medically necessary health care to eligible Vermonters. In doing so, the State relies on clinical standards of practice, guidelines, medical literature, and legal requirements to establish coverage rules and policies. The State also abides by federal Medicaid law, including its affirmative obligation to ensure that children under the age of 21 have access to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services. The EPSDT benefit is more comprehensive than the Medicaid benefit for adults and is designed to assure that children receive early detection and care, so that health problems are averted or diagnosed and treated as early as possible. A stated age minimum for coverage of surgical treatment for gender dysphoria would be arbitrary and in conflict with the State's obligations under EPSDT. All surgeries under this rule require prior authorization, which allows the State to ensure that the treating providers are following clinical standards of care and recommending developmentally appropriate treatment.

Comment 2:

Many comments were received on Section 4.238.7, Non-Covered Services. Commenters expressed that Section 4.238.7(a) excludes many services that may in some cases be medically necessary and essential to treating diagnosed gender dysphoria. The commenters objected to the designation of certain services as presumptively cosmetic, stating there is a difference between cosmetic procedures and medically necessary ones, and these should be reviewed on a case-by-case basis by medical personnel. For example, genital hair removal is necessary before genital surgery can be performed on trans-feminine patients.

Some commenters alleged that parts of Section 4.238.7 are discriminatory, as they have the effect of treating individuals with gender dysphoria differently than other Medicaid beneficiaries, and imposing stricter standards on individuals with gender dysphoria than are applied to individuals with other conditions or diagnoses.

Response 2:

The State does not agree that the rule as proposed is discriminatory, however the language has been modified for clarity. The State individually reviews each request for services for beneficiaries under age 21, in accordance with EPSDT. The State may place appropriate limits on services for adults and believes the services in this rule are sufficient in amount, duration, and scope to reasonably achieve its purpose. The proposed rule language at Section 4.238.7(a) listing examples of non-covered services has been removed. Language has been changed under Sections 4.238.2 and 4.238.7 to clarify that this rule is about surgeries only. Coverage of hair removal only as required for vaginoplasty and phalloplasty surgeries has been added to the final proposed rule. The State will provide further information on coverage of hair removal in clinical criteria or other sub-regulatory policy materials.

Comment 3:

One commenter stated that section 4.238.5(a)(1)(C)(i)(2) wrongly assumes that all individuals with gender dysphoria have interpersonal issues either as a result of their diagnosis or independently of it. It also requires that patients with gender dysphoria participate in treatment for a different issue in order to obtain medically necessary treatment for gender dysphoria. This requirement should be removed.

Response 3:

Section 4.238.5(a)(1)(C)(i)(2) has been removed in the final proposed rule.

Comment 4:

Several comments were received on Section 4.238.5(a)(4), hormonal therapy pre-requisites. Some commenters cited concerns that this language is not consistent with the *WPATH Standards of Care* and is exclusionary of individuals that do not wish to undergo hormone therapy but do need to have surgical procedures that are medically necessary to treat their gender dysphoria. Specifically, that it is exclusionary of non-binary identified individuals who are comfortable with their current hormones but do experience gender dysphoria for which surgery may be a necessary treatment. Another commenter argued that requiring 24 consecutive months of hormone therapy for augmentation mammoplasty is overly burdensome, not in line with *WPATH Standards of Care*, and therefore a discriminatory restriction, as a longer period of hormonal therapy is not medically indicated and delays surgery, which can exacerbate gender dysphoria.

Response 4:

Section 4.238.5(a)(4)(A) has been modified to no longer apply the pre-requisite of 12 consecutive months of hormonal therapy to all genital surgeries, but only metoidioplasty, phalloplasty, and vaginoplasty. The pre-requisite of hormonal therapy for breast augmentation mammoplasty has been changed from 24 months to 12 months. In addition, the terms “genital surgeries” and “breast surgeries” have been removed from section 4.238.2.

Comment 5:

Several comments indicated that the language, “written clinical evaluations” at Section 4.238.5(a)(1) is confusing and comprises an onerous barrier to accessing care, as the language suggests an hours-long, arms-length assessment process using a standardized tool or questionnaire that results in a structured product with assessment under the criteria. Expert professionals are unclear what this standardized evaluation would be.

Response 5:

Language was added to Section 4.238.5(a)(1) and 4.238.5(a)(1)(C)(v) to clarify this requirement. The “written clinical evaluation” language was not intended to be a substantive change from clinical criteria, nor was it to prescribe a certain format in which the information is to be conveyed to Vermont Medicaid for prior authorization. The written clinical evaluation may be in the form of a letter, and the qualified mental health professional who signs the letter should have assessed the patient face-to-face, not simply reviewed a chart or consulted with another treating qualified mental health professional.

Comment 6:

Several comments were received on 4.238.4, Qualified Providers. The requirement of “documented supervised training” is particularly onerous and is likely unnecessary for most procedures. This provision may leave recipients with few to no providers and amount to a constructive denial of care.

Response 6:

The rule has been amended to remove the “documented supervised training” requirement under section 4.238.4.

Comment 7:

Commenter pointed out that breast implants can deteriorate over time and replacements can be medically necessary where the implants cause discomfort or medical complications, therefore the last sentence at 4.238.5(b) should be eliminated. There are myriad medically necessary reasons why an individual might require more than one augmentation mammoplasty surgery in a lifetime, including revision or replacement.

Response 7:

The sentence “No more than one breast augmentation mammoplasty will be covered in a lifetime” has been removed from 4.238.5(b). The intention of this language was not to exclude coverage of further surgeries for medical complications or other medical reasons in connection to the original augmentation mammoplasty surgery. The words “or modification” have also been removed form 4.238.7(b).

Comment 8:

Commenter stated that the requirement at 4.238.5(a)(3) for individuals to live full-time for 12 months in a gender role should be eliminated or modified, as it is not in accordance with the *WPATH Standards of Care* and could exacerbate gender dysphoria and create safety concerns for some individuals, such as a transgender man who is on testosterone but must live with breasts.

Response 8:

The State is not eliminating this requirement – it remains in the final proposed rule. These surgeries are permanent and, in some cases, render the patient sterile. The *WPATH Standards of Care* contain the 12 months in a gender role criterion for genital surgeries. WPATH also notes that living in another gender role that is consistent with one’s gender identity is one of many therapeutic treatment options for gender dysphoria. Unlike surgery, this treatment option is not permanent nor medically invasive. The State feels that this pre-requisite to gender affirmation surgery, in combination with the rest of the rule, is appropriate. Section 4.238.5(a)(3) has been modified to remove the language “across a range of life experiences and events that may occur throughout the year” as there may be clinically appropriate reasons why an individual may not be able to transition in all contexts prior to surgery.