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February 2, 2015

**VIA EMAIL & FIRST CLASS MAIL**

Katherine Ceroalo  
New York State Department of Health  
Bureau of House Counsel  
Regulatory Affairs Unit  
Room 2438  
ESP Tower Building  
Albany, New York 12237

Re: Amendment of Section 505.2(l) of Title 18 of NYCRR

Dear Ms. Ceroalo:

The Transgender Legal Defense and Education Fund (“TLDEF”) submits these comments in response to the proposed rulemaking by the New York State Department of Health (“DOH”) regarding an amendment to Section 505.2(l) of Title 18 of the New York Codes, Rules and Regulations, ID No. HLT-50-14-00001-P (the “Proposed Rule”), part of New York State’s Medicaid program rules. TLDEF is committed to achieving equality – including equal access to health care – for transgender people. We have significant experience in matters related to ensuring access to appropriate care for gender dysphoria. Empire Justice Center joins these comments. Empire Justice Center is a statewide, multi-issue, multi-strategy public interest law firm focused on changing the systems within which poor and low income families live. We commend DOH for its proposal, which represents a significant step toward bringing New York State in line with medical understandings of treatment for gender dysphoria. The Proposed Rule would allow many New Yorkers with gender dysphoria to receive the care and treatment they need, which they are currently unable to access through New York State’s Medicaid program.

For the reasons described in detail in our March 22, 2013 letter advocating removal of restrictions on coverage for the treatment of gender dysphoria, we support the Proposed Rule. A copy of that letter is enclosed. However, we recommend modifications to make the Proposed Rule better reflect current treatment standards in transgender health care.

Our recommendations are based primarily on the Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, version 7, promulgated by the World Professional Association for Transgender Health (“WPATH”) (“Standards of Care”).<sup>1</sup> The American Medical Association has determined that “...the World Professional Association For Transgender Health, Inc. (“WPATH”) is the leading international, interdisciplinary professional organization devoted to the understanding and treatment of gender (dysphoria)...” WPATH’S Standards of Care are internationally accepted as the medical standards of care for treating individuals with gender dysphoria.<sup>2</sup> The Standards of Care provide guidance to health professionals about treating transsexual, transgender, and gender nonconforming individuals. The Standards of Care are based upon expert professional consensus and current medical standards. We also base some of our recommendations on the Endocrine Society’s Clinical Practice Guideline entitled, “Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline” (“Clinical Guideline”).<sup>3</sup> The Endocrine Society is the world’s oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology.

Our recommendations, discussed in detail below, consist of the following:

- (1) The Proposed Rule should allow for coverage for hormone therapy and certain surgical procedures for individuals under the age of 18;
- (2) Individuals between the ages of 18 and 21 should have access to the same medically necessary treatments as individuals over 21, including surgical procedures;
- (3) The Proposed Rule should require only one referral letter from a health professional for chest/breast surgeries, rather than two referral letters as currently written;

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<sup>1</sup> A copy of WPATH’s Standards of Care (SOC 7) is available here: [http://www.wpath.org/site\\_page.cfm?pk\\_association\\_webpage\\_menu=1351&pk\\_association\\_webpage=3926](http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1351&pk_association_webpage=3926).

<sup>2</sup> See American Medical Association House of Delegates’ Resolution 122, A-08, *Removing Financial Barriers to Care For Transgender Patients*, ¶ 4 (2008), available at <http://www.uclgbtia.org/AMA-TransInsuranceResolution.pdf>.

<sup>3</sup> The Endocrine Society: Clinical Guidelines. Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline. Updated 2009. <https://www.endocrine.org/education-and-practice-management/clinical-practice-guidelines>.

(4) The Proposed Rule should not require individuals to receive hormone therapy prior to undergoing all surgeries;

(5) Individuals should not be required to live for 12 months in a gender role congruent with the individual's gender identity for all surgeries;

(6) All medically necessary treatments should be covered. The Proposed Rule should not categorically exclude those procedures currently listed as "cosmetic" where those procedures are necessary for the treatment of gender dysphoria;

(7) The Proposed Rule should clarify the provision of coverage for medically necessary hysterectomy procedures;

(7) The Proposed Rule should evolve with the advancement of the Standards of Care and medical understanding of the treatment of gender dysphoria.

**I. The Proposed Rule Should Allow For Coverage of Hormone Therapy and Certain Surgical Procedures For Individuals Under the Age of 18**

Subdivision (2) of the Proposed Rule provides that "[h]ormone therapy, whether or not in preparation for gender reassignment surgery, may be covered for individuals 18 years of age or older." This subdivision excludes coverage for hormone therapy for individuals under the age of 18.

Subdivision (3) provides that "[g]ender reassignment surgery may be covered for those 18 years of age or older[.]" This subdivision similarly excludes coverage for all surgical treatments for gender dysphoria for individuals under the age of 18.

Recommendation

We recommend that the Proposed Rule be amended to align with the Standards of Care which recognize that hormone therapy and certain surgical procedures can be appropriate treatment for individuals under the age of 18.

*Hormone therapy:* The Standards of Care and the Clinical Guideline contemplate the use of puberty-suppressing hormone treatment for individuals under the age of 18, as soon as pubertal changes begin.<sup>4</sup> The Standards of Care and the Clinical Guideline further contemplate the provision of feminizing or masculinizing hormones to adolescents.<sup>5</sup> Use of puberty-suppressing hormones can provide an adolescent time to explore his or her gender identity while awaiting further treatment. They can also facilitate gender transition by preventing the development of secondary sex characteristics that are later more difficult or impossible to reverse.<sup>6</sup> Early intervention

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<sup>4</sup> SOC 7, at 18. Clinical Guideline, at Section 2.0.

<sup>5</sup> SOC 7, at 20. Clinical Guideline, at Section 2.0.

<sup>6</sup> SOC 7 at 19.

using hormone therapy can help to avoid negative social and emotional consequences – including stigmatization and abuse – for transgender adolescents. Early intervention can often treat gender dysphoria more effectively than use of hormone therapy at a later point.

*Gender Reassignment Surgery:* The Standards of Care recognize that chest surgery in female-to-male patients may be appropriate prior to the age of 18.<sup>7</sup> The Proposed Rule should be modified to allow for the provision of this treatment as medically necessary.

### Revision

Subsection (2) of the Proposed Rule should be revised as follows: “(2) Hormone therapy, whether or not in preparation for gender reassignment surgery, may be covered.”

The first sentence of Subsection (3) of the Proposed Rule should be revised to read “(3) Gender reassignment surgery may be covered.”

## **II. Individuals Between the Ages of 18 and 21 Should Have Access to the Same Medically Necessary Treatments as Individuals Over 21, Including Surgical Procedures**

Subsection (3) of the Proposed Rule provides that if gender reassignment surgery will result in sterilization, the individual undergoing surgery must be 21 years of age or older in order for the procedure to be covered by Medicaid. This subsection excludes from coverage adults who may require surgery that results in sterilization if they are between the ages of 18 and 21. There is no medical or scientific basis for excluding those who are between 18 and 21 from these treatments for gender dysphoria. Indeed, this restriction appears to be based on the federal reimbursement rules implemented to address concerns unrelated to the treatment of gender dysphoria.

### Recommendation

The Proposed Rule should be modified to provide coverage for medically necessary gender reassignment surgery for all adults even if the surgery results in sterilization.

Under existing federal law unrelated to treatment for gender dysphoria, the requirements for Medicaid reimbursement for procedures that will result in sterilization are: (a) the individual is at least 21 years old at the time consent is obtained; (b) the individual is not mentally incompetent; (c) the individual has given informed consent; (d) at least 30 days have passed between the date of informed consent and the date of the sterilization.<sup>8</sup>

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<sup>7</sup> SOC 7, at 21.

<sup>8</sup> 42 C.F.R. 441.253.

Under federal law, if New York State’s Medicaid plan provides coverage for procedures resulting in sterilization for individuals under age 21, it will not be reimbursed by the federal government for the costs of these procedures. But New York State has already opted to self-fund certain health care in other instances in which it will not be reimbursed by the federal government, and it should do the same for the treatment of gender dysphoria. For instance, New York State Medicaid will provide coverage for abortion procedures for which the federal government has restricted Medicaid reimbursement.<sup>9</sup> In so doing, New York made clear its commitment to the provision of medically necessary care, regardless of federal reimbursement rules. It should do the same here. There is no reasoned justification for denying coverage for surgical procedures for individuals between the ages of 18 and 21, but permitting coverage for those over 21 years old.

### Revision

The first sentence of Subsection (3) should be revised read: “(3) Gender reassignment surgery may be covered.”

### **III. The Proposed Rule Should Require Only One Referral Letter From a Health Professional For Chest/Breast Surgeries, Rather Than Two Referral Letters as Currently Written**

Subsection (3) of the Proposed Rule currently requires that surgery will be covered only if the individual has letters from two “qualified New York State licensed health professionals who have independently assessed the individual and are referring the individual for surgery.”

### Recommendation

WPATH’s criteria for surgeries in the Standards of Care are designed to promote optimal patient care.<sup>10</sup> Importantly, the Standards of Care make different recommendations for different surgeries, based on medical evidence and consensus.<sup>11</sup> To that end, the Standards of Care do not recommend requiring two referral letters for all surgeries. For chest/breast surgeries (mastectomy, chest reconstruction, and augmentation mammoplasty), the Standards of Care state that only one letter should be required.<sup>12</sup>

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<sup>9</sup> Compare 18 NYCRR 505.2(e) with Exec. Order No. 13,535, 3 C.F.R., 2010 Comp., p. 201 (2011) (Hyde Amendment).

<sup>10</sup> SOC 7, at 58.

<sup>11</sup> SOC 7, at 58.

<sup>12</sup> SOC 7, at 27.

## Revision

Subsection (3) should be revised as follows: “Gender reassignment surgery may be covered. Individuals should have letters from two qualified New York State licensed health professionals who have independently assessed the individual and are referring the individual for the surgery. For mastectomy, chest reconstruction, and augmentation mammoplasty procedures only one letter from a licensed health professional who has independently assessed the individual and is referring the individual for surgery shall be required.”

### **IV. The Proposed Rule Should Not Require Individuals to Receive Hormone Therapy Prior to Undergoing Surgery**

Subsection (3) (ii) of the Proposed Rule states that referral letters for gender reassignment surgery must include a statement that the individual “has received hormone therapy appropriate to the individual’s gender goals... unless such therapy is medically contraindicated or the individual is otherwise unable to take hormones.”

## Recommendation

The Proposed Rule should be clarified to state that hormone therapy is not a prerequisite to undergoing chest/breast surgery. As noted above, different surgeries are subject to different criteria under the Standards of Care. The Standards of Care do not require that an individual undergo hormone therapy in order to undergo surgical treatment related to the chest/ breast, including mastectomy and creation of a male chest in female-to-male patients and breast augmentation in male-to-female patients.<sup>13</sup>

The Proposed Rule should make clear that hormone therapy is not a prerequisite to all surgical treatment for gender dysphoria. There are a variety of personal and medical reasons that individuals do not undergo hormone therapy. Some transgender and gender non-conforming individuals seek to have surgery to alleviate their gender dysphoria, but do not seek hormone therapy, as it is unnecessary to address their gender dysphoria. This decision should be left to the individual, his or her surgeon, and his or her health professional providing the referral for treatment. To the extent that the phrase “medically contraindicated” is intended to encompass these various considerations, the Proposed Rule should be clarified to state that.

## Revision

Subsection (3)(ii) of the Proposed Rule should be revised as follows: “has received hormone therapy appropriate to the individual's gender goals, unless such therapy is medically contraindicated or the individual is otherwise unable to take

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<sup>13</sup> SOC 7, at 59. WPATH does suggest that hormone therapy can help to obtain better aesthetic surgical results in breast augmentation procedures. But it does not require such therapy as a prerequisite for this surgery.

hormones. Hormone therapy shall not be a prerequisite to obtaining coverage for mastectomy, chest reconstruction, or augmentation mammoplasty.”

**V. The Proposed Rule Should Not Require Individuals To Live For 12 Months in a Gender Role Congruent With the Individual’s Gender Identity For All Surgeries**

Subsection (3)(iii) of the Proposed Rule mandates that the required referral letters include a statement that the individual “has lived for 12 months in a gender role congruent with the individual’s gender identity....”

Recommendation

The Standards of Care do not require that individuals live for 12 months congruently with their gender identity prior to undergoing all surgical procedures. Additionally, the Proposed Rule’s requirement fails to account for the difficulties that many transgender individuals face when trying to live in congruence with their gender identity while undergoing gender transition, including transition-related medical care.

Specifically, the Standards of Care do not require individuals to live in congruence with their gender identity prior to undergoing chest/breast surgeries, hysterectomy, salpingo-oophorectomy, or orchiectomy.

The Standards of Care state that the requirement that an individual live for 12 months congruently with their gender identity is to allow the individual to experience and socially adjust to living in their gender role before taking further steps to transition.<sup>14</sup> It is very difficult for some transgender individuals to live congruently with their gender identity before surgical interventions. For example, some transgender males have difficulty living congruently with their gender identity before mastectomy and reconstruction. The Proposed Rule should be clarified to ensure that it does not exclude individuals from medically necessary treatment if they are not able to live congruently with their gender identity.

Revision

In line with the Standards of Care, the Proposed Rule should be revised to remove the requirement that individuals live in a gender role congruent with their gender identity for all surgeries except metoidioplasty, phalloplasty, or vaginoplasty. Additionally, the Proposed Rule should be revised to provide that the requirement that an individual live congruently with their gender identity before undergoing metoidioplasty, phalloplasty, or vaginoplasty should be a flexible one that takes into account the difficulties that transitioning individuals face in trying to satisfy this requirement.

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<sup>14</sup> SOC 7, at 60.

## **VI. The Proposed Rule Should Not Categorically Exclude Those Procedures Currently Listed As “Cosmetic” Where Those Procedures Are Necessary For the Treatment of Gender Dysphoria**

Subsection (4) of the Proposed Rule appears to exclude coverage for a range of medical treatments deemed “cosmetic” in the Proposed Rule. Many of these procedures can be medically necessary for the treatment of gender dysphoria. The Proposed Rule should be clarified to ensure that coverage is available for all medically necessary care for the treatment of gender dysphoria.

The Proposed Rule provides that “payment will not be made for the following services and procedures,” and follows with a list of specific services and procedures including “cosmetic surgery, services, and procedures, including but not limited to: (a) abdominoplasty, blepharoplasty, neck tightening, or removal of redundant skin; (b) breast augmentation; (c) breast, brow, face or forehead lifts; (d) calf, cheek, chin, nose, or pectoral implants; (e) collagen injections; (f) drugs to promote hair growth or loss; (g) electrolysis, unless required for vaginoplasty; (h) facial bone reconstruction, reduction, or sculpturing, including jaw shortening and rhinoplasty; (i) hair transplantation; (j) lip reduction; (k) liposuction; (l) thyroid chondroplasty; and (m) voice therapy, voice lessons, or voice modification surgery.”

Subdivision (5) then provides that, “For the purposes of this subdivision, cosmetic surgery, services and procedures refers to anything solely directed at improving an individual’s appearance.”

In addition, in relation to cosmetic services and procedures, the Regulatory Impact Statement states that “[t]he proposed amendments list services and procedures that would *generally* be considered cosmetic and ancillary to the GRS, and therefore not medically necessary.” (Emphasis supplied)

### Recommendation

The Proposed Rule is unclear and may be interpreted to operate as a blanket exclusion for the services and procedures listed under Subsection (4)(v), thereby interfering with or impeding proper treatment of gender dysphoria as determined by a doctor. The rule should be rewritten so as to permit coverage for these services and procedures listed where they are medically necessary to treat a patient’s gender dysphoria.

Federal and state laws limit Medicaid coverage to payment solely for medically necessary care, services, and supplies, and prohibit coverage of cosmetic procedures for Medicaid recipients. The procedures listed as “cosmetic” in the Proposed Rule are, in fact, medically necessary treatments for gender dysphoria for some individuals.

The Proposed Rule’s statement that the procedures listed in Subsection 4(v) are generally “cosmetic” is out of line with current medical consensus regarding the treatment of gender dysphoria. Certain procedures that are designated “cosmetic” interventions can have a profound beneficial effect in treating gender dysphoria and are

medically necessary in such cases.<sup>15</sup> For example, Subsection (4)(v)(b) excludes coverage for “breast augmentation.” However, the Standards of Care include breast augmentation (implants, lipofilling) as medically necessary treatment for some patients with gender dysphoria.<sup>16</sup>

Similarly, subsection (4)(v)(m) lists voice therapy, voice lessons, or voice modification as “cosmetic” services that would not be covered. However, the Standards of Care recognize that voice and communication therapy can be medically necessary treatments that may “help to alleviate gender dysphoria.”<sup>17</sup>

The Standards of Care also recognize “nongenital, nonbreast surgical interventions” as medically necessary treatments for gender dysphoria, including: “facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation (implants/lipofilling), [and] hair reconstruction.”

Removing the seemingly blanket treatment exclusions in the Proposed Rule will allow physicians to determine how best to treat individual patients. Accordingly, the Proposed Rule should be revised to cover all medically necessary treatments for gender dysphoria.

### Revision

The language currently found in Subsection (4) and Subsection (5) should be deleted in its entirety.

## **VII. The Proposed Rule Should Clarify Coverage for Medically Necessary Hysterectomy Procedures**

Subsection (6) of the Proposed Rule states that “[a]ll legal and program requirements related to providing and claiming reimbursement for sterilization procedures must be followed when transgender care involves sterilization.”

The Proposed Rule may refer to Federal Medicaid regulations which prohibit reimbursement for hysterectomies if they are performed solely for the purpose of rendering an individual incapable of reproducing or, even if there is another purpose, if the hysterectomy would not have been performed but for the purpose of rendering the individual incapable of reproducing.<sup>18</sup>

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<sup>15</sup> See SOC 7 at 58.

<sup>16</sup> SOC 7, at 59.

<sup>17</sup> SOC 7, at 52.

<sup>18</sup> 42 C.F.R. 441.255(a).

## Recommendation

The Proposed Rule should clarify that hysterectomy procedures will be covered when medically necessary for the treatment of gender dysphoria.

## Revision

The language currently found in Subsection (6) should be deleted in its entirety.

### **VIII. The Proposed Rule Should Respond to Continually Advancing WPATH Standards of Care**

Our final recommendation is that the Proposed Rule remain flexible in response to continually advancing understandings of appropriate treatment for gender dysphoria. As the Proposed Rule's Regulatory Impact Statement notes, since 1998, when the regulation was originally promulgated, "a body of credible medical evidence has been developed supporting the conclusion that GRS is a safe and effective treatment for gender dysphoria in medically necessary cases, and is no longer considered experimental." Transgender health care has made great strides in the past several decades, and will no doubt continue to evolve.

To remain current, the rule should be revised to provide specifically that it will comport with the most current Standards of Care. This would obviate the need to continually update the regulations as the relevant standards of care continue to change.<sup>19</sup>

### **IX. Conclusion**

We reiterate our support of the Proposed Rule and believe that it demonstrates laudable commitment to equal treatment for transgender New Yorkers. Our modifications include important changes to the Proposed Rule that will ensure that it comports with the most current medical understandings of the treatment for gender dysphoria. We would be happy to provide you with any additional information you might need as you consider our comments.

Very truly yours,



Ethan Boehme Rice

Encl.

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<sup>19</sup> At least one other state has adopted a similar approach in its state Medicaid program, providing that treatment for gender dysphoria is a covered benefit when medical necessity has been demonstrated and that "[t]reatment should follow the latest version of the World Professional Association for Transgender Health (WPATH) document, Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People." See Medi-Cal Update, General Medicine, No. 21. Policy Clarification: Gender Identity Disorder (March 2013), at <http://files.medi-cal.ca.gov/pubsdoco/bulletins/artfull/gm201303.asp#a21>.