

## Transgender Related Care and Services

Effective date: 3/11/15

Pursuant to authority vested in the Commissioner of Health by Sections 201 and 206 of the Public Health Law and Sections 363-a and 365-a(2) of the Social Services Law, Section 505.2 of Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended as follows, to be effective upon, publication of a Notice of Adoption in New York State Register.

Subdivision (1) of section 505.2 is repealed and a new subdivision (1) is added to read as follows:

(1) Gender dysphoria treatment. As provided in this subdivision, payment is available for medically necessary hormone therapy and/or gender reassignment surgery for the treatment of gender dysphoria.

(2) Hormone therapy, whether or not in preparation for gender reassignment surgery, may be covered for individuals 18 years of age or older.

(3) Gender reassignment surgery may be covered for an individual who is 18 years of age or older, or 21 years of age or older if the surgery will result in sterilization, and has letters from two qualified New York State licensed health professionals who have independently assessed the individual and are referring the individual for the surgery. One of these letters must be from a psychiatrist or psychologist with whom the individual has an established and ongoing relationship. The other letter may be from a licensed psychiatrist, psychologist, physician or

licensed clinical social worker acting within the scope of his or her practice, who has only had an evaluative role with the individual. Together, the letters must establish that the individual:

(i) has a persistent and well-documented case of gender dysphoria;

(ii) has received hormone therapy appropriate to the individual's gender goals, which shall be for a minimum of 12 months in the case of an individual seeking genital surgery, unless such therapy is medically contraindicated or the individual is otherwise unable to take hormones;

(iii) has lived for 12 months in a gender role congruent with the individual's gender identity, and has received mental health counseling, as deemed medically necessary, during that time;

(iv) has no other significant medical or mental health conditions that would be a contraindication to gender reassignment surgery, or if so, that those are reasonably well-controlled prior to the gender reassignment surgery; and

(v) has the capacity to make a fully informed decision and to consent to the treatment.

(4) Payment will not be made for the following services and procedures:

(i) cryopreservation, storage, and thawing of reproductive tissue, and all related services and charges;

(ii) reversal of genital and/or breast surgery;

(iii) reversal of surgery to revise secondary sex characteristics;

(iv) reversal of any procedure resulting in sterilization; and

(v) 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.

(5) For purposes of this subdivision, cosmetic surgery, services, and procedures refers to anything solely directed at improving an individual's appearance.

(6) All legal and program requirements related to providing and claiming reimbursement for sterilization procedures must be followed when transgender care involves sterilization.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Social Services Law (SSL) section 363-a and Public Health Law section 201(1)(v) provide that the Department is the single State agency responsible for supervising the administration of the State's medical assistance ("Medicaid") program and for adopting such regulations, which shall be consistent with law, and as may be necessary to implement the State's Medicaid program. SSL section 365-a authorizes Medicaid coverage for specified medical care, services and supplies, together with such medical care, services and supplies as authorized in the regulations of the Department.

### **Legislative Objective:**

Section 365-a of the SSL requires Medicaid to pay for part or all of the cost of medical, dental, and remedial care, services, and supplies that are necessary to prevent, diagnose, correct or cure conditions that cause acute suffering, endanger life, result in illness or infirmity, interfere with a person's capacity for normal activity, or threaten some significant handicap.

### **Needs and Benefits:**

The proposed regulations would change Medicaid policy with respect to payment for treatments to address gender dysphoria. Gender dysphoria is the diagnosis given to persons whose gender at birth is contrary to the one they identify with, and who experience clinically significant distress as a result. Gender dysphoria may be manifested by a strong desire to be treated as the other gender or to be rid of one's sex characteristics, or by a strong conviction that one has feelings and reactions typical of the other gender.

Treatments for gender dysphoria include counseling, hormone therapy, and gender reassignment surgery. Gender reassignment surgery (GRS) is a term for the surgical procedures by which the physical appearance and function of a person's existing sexual characteristics are altered to resemble those of the other sex.

Section 505.2(l) of 18 NYCRR, related to Medicaid payment for physicians' services, currently prohibits payment for any care, services, drugs, or supplies rendered in connection with GRS. At the time the regulation was originally promulgated in 1998, there was a lack of consensus regarding the safety and efficacy of GRS, and many health care payers, including the federal Medicare program, considered it an experimental procedure requiring further long-term study.

Since that time, 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. Significantly, in May of 2014, the Federal Government through the Departmental Appeals Board of the Department of Health and Human Services ruled that Medicare could no longer deny coverage of GRS on the grounds that it is ineffective, unsafe, experimental, or controversial, that it has a high rate of complication or has not been subjected to controlled, long-term studies, or that the criteria for diagnosing gender dysphoria is inconsistent or problematic.

Given these developments, the Department is updating its Medicaid coverage policy. The proposed amendments would repeal the existing text of section 505.2(l) and replace it with a description of the express parameters within which the Medicaid program would now cover hormone therapy and/or GRS for the treatment of gender dysphoria.

Hormone therapy prescribed for adults with gender dysphoria would now be covered whether or not in preparation for GRS.

GRS would now be covered for persons who are referred for the treatment by two New York State licensed health professionals acting within the scope of their practices. The minimum age for coverage would be 18 years of age unless the GRS would result in sterilization, in which case federal Medicaid rules require a minimum age of 21. The health professionals would have to provide letters stating that the patient: has a persistent and well-documented case of gender dysphoria; has received hormone therapy appropriate to the patient's gender goals, which shall be for a minimum of 12 months in the case of genital surgery, unless such therapy is medically contradicted or the patient is unable to take hormones; has lived for 12 months in a gender role consistent with the individual's gender identity and has received mental health counseling, as deemed medically necessary, during that time; has no other significant medical or mental health conditions that would be a contraindication to GRS, or any such conditions are reasonably well-controlled; and has the capacity to provide informed consent for the treatment.

Medicaid would not pay to reverse gender reassignment surgeries or sterilization procedures. Further, Medicaid would not pay for the cryopreservation, storage, or thawing of reproductive tissue. Finally, Medicaid would not pay for cosmetic services and procedures that are solely directed at improving the patient's appearance. The proposed amendments list services and procedures that would generally be considered cosmetic and ancillary to the GRS, and therefore not medically necessary.

**Costs:**

**Costs to Regulated Parties:**

The proposed amendment would add a new covered benefit under the State's Medicaid program. The amendment would not increase costs to regulated parties.

**Costs to State Government:**

Adding coverage of transgender care and services to the Medicaid benefit package will increase costs to the State. To estimate these costs, the Department looked at the number of Medicaid recipients who receive mental health services based on a diagnosis of gender dysphoria (currently 353 natal males and 308 natal females). The Department estimated the percentage of natal males and natal females who would seek hormone therapy only, partial GRS, or full GRS. Then, using typical costs for the types of care and services that would be implicated (including mental health counseling, hormone therapy, laboratory services, and surgeries specific to male-to-female and female-to-male reassignment), the Department calculated the total, annual State share of expenditures related to the expansion of coverage for transgender care and services to be approximately \$6,737,000.

**Costs to Local Governments:**

Local social services districts' share of Medicaid costs is statutorily capped; therefore, there will be no additional costs to local governments as a result of the proposed amendment.

**Costs to the Department of Health:**

There will be no additional costs to the Department.

**Local Government Mandates:**

This amendment will not impose any program, service, duty, additional cost, or responsibility on any county, city, town, village, school district, fire district, or other special district.

**Paperwork:**

In order to perform and claim Medicaid reimbursement for GRS, physicians would have to receive letters from two qualified mental health professionals who independently assessed the patient and are referring him or her for the surgery. One of these letters would be from the patient's psychotherapist, with whom the patient has an established and ongoing relationship. The other letter could be from a mental health professional who has only had an evaluative role with the patient. These letters would need to establish that the patient meets the prerequisites set forth in the regulation for the surgery.

**Duplication:**

There are no duplicative or conflicting rules identified.

**Alternatives:**

Alternatives to the proposed amendment would not comply with existing New York law and current medical science. Specifically, one alternative to the proposed amendment would be to maintain the current prohibition on Medicaid payment for care, services, drugs, or supplies rendered in connection with GRS. However, SSL section 365-a authorizes Medicaid payment for medically necessary care to correct or cure conditions that can cause acute suffering and interfere with a person's capacity for normal activity, a criterion that gender dysphoria meets.

Another alternative would be to provide coverage for all services and procedures performed in connection with gender reassignment, even services and procedures that are solely



cosmetic. However, federal and State law limit Medicaid coverage to payment solely for medically necessary care, services, and supplies. Therefore the Department is required to make a distinction between surgical procedures that are primary to gender reassignment, and thus medically necessary and coverable, and procedures performed solely for cosmetic reasons, which are not. This is consistent with the State's broader Medicaid coverage policy, which prohibits coverage of cosmetic procedures for Medicaid recipients.

**Federal Standards:**

The proposed regulations do not exceed any minimum federal standards.

**Compliance Schedule:**

Regulated parties should be able to comply with the proposed regulations when they become effective.

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## **STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment would add a new covered benefit under the State's Medicaid program. It would not impose an adverse economic impact on small businesses or local governments, and it would not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

## **STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for the proposed amendment is not being submitted because the amendment would not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There would be no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

## **STATEMENT IN LIEU OF JOB IMPACT STATEMENT**

A Job Impact Statement for the proposed amendment is not being submitted because it is apparent from the nature and purpose of the amendment that it would not have a substantial adverse impact on jobs and/or employment opportunities.

## ASSESSMENT OF PUBLIC COMMENT

Public comment was received from 91 commenters: 64 advocacy organizations; 10 lawyers or legal organizations; eight mental or physical health care professionals; one New York State agency; one New York State Senator; one New York State Assembly member; one New York City agency, and five individuals who did not indicate any affiliation. Six commenters identified themselves as a transgender individual or a family member of a transgender individual. Over 50 of the comments were virtually identical, following a template provided by an advocacy organization.

Only two commenters opposed the elimination of the current prohibition on Medicaid coverage of care, services, and supplies rendered for the purpose of, or to promote, gender reassignment. Another commenter objected at length to the current prohibition on coverage in 18 NYCRR § 505.2(l), but offered no comments on the Department's proposed amendment to the regulation. One commenter advocated that section 505.2(l) simply be repealed, without replacement. The remaining 87 commenters supported the addition of transition-related transgender care and services to the Medicaid benefit package, but suggested changes to the proposed regulation.

**Comment:** The majority of commenters objected to the proposed regulation restricting coverage to individuals 18 years of age or older. Specifically, commenters recommended that Medicaid cover pubertal suppressants and cross-sex hormone therapy for children and adolescents under the age of 18.

**Response:** It is the policy of the New York State Medicaid program to only cover drugs that are for medically accepted indications. Federal Medicaid law at 42 U.S.C. 1396r-8(k)(6) defines "medically accepted indication" to mean any use approved by the Food and Drug

Administration (FDA) or supported by one or more citations in official pharmaceutical compendia listed in 42 U.S.C. 1396r-8(g)(1)(B)(i).

Pubertal suppressants are neither FDA-approved nor compendia-supported for the treatment of gender dysphoria at any age. Cross-sex hormone therapy is not FDA-approved for the treatment of gender dysphoria; however, there is compendia support for using cross-sex hormone therapy to treat gender dysphoria, but only for individuals 18 years of age and older. Because pharmaceutical treatments for gender dysphoria in children and adolescents do not meet the federal Medicaid standards for a “medically accepted indication,” no changes to the proposed regulation were made as a result of these comments.

**Comment:** Many commenters objected to the proposed regulation specifying a minimum age of 21 for sex reassignment surgery that would result in sterilization. It was suggested that the Department is incorrectly interpreting the provisions of a federal Medicaid regulation at 42 CFR 441.253, which requires individuals to be at least 21 years of age at the time they consent to sterilization in order for the procedure to be covered by Medicaid.

**Response:** The Department has reviewed the provisions of 42 CFR 441.253, and considered them in conjunction with another federal Medicaid regulation specifying the criteria for coverage of hysterectomies. The Department has concluded that these regulations do not clearly indicate whether Medicaid may cover a procedure performed on an individual under 21 years of age that results in sterilization, but was not performed solely for the purpose of rendering the individual incapable of reproducing. The Department intends to seek guidance from the Centers for Medicare and Medicaid Services on the correct interpretation of these regulations; if such procedures may be covered, the Department will revise its policy in a subsequent rulemaking.

**Comment:** A number of commenters objected to the exclusion of cosmetic services from the services that Medicaid will cover to treat gender dysphoria.

**Response:** Federal and State law limit Medicaid coverage to payment for medically necessary care, services, and supplies. For this reason, the New York State Medicaid program does not cover purely cosmetic procedures. The proposed regulation therefore distinguishes between surgical procedures that are primary to gender reassignment, and ancillary procedures directed solely at improving an individual's appearance. No changes to the proposed regulation were made as a result of these comments.

However, breast augmentation in male-to-female transitions may be primary to gender reassignment in certain limited circumstances. The Department plans to issue separate policy guidance setting forth criteria for coverage of breast augmentation, and will consider making a clarifying change to the regulation in a subsequent rulemaking.

**Comment:** Some commenters recommended that the Department strictly follow the standards of care recommended by the World Professional Association for Transgender Health (WPATH). Other commenters felt that the Department's policy on Medicaid coverage for transgender care and services should be even more expansive, and described the WPATH recommendations as unnecessarily burdensome. Some commenters asked that certain prerequisites to coverage of sex reassignment surgery in the proposed regulation be eliminated (being diagnosed as having gender dysphoria; receiving 12 months of hormone therapy if seeking genital surgery, unless medically contraindicated; living for 12 months in a gender role congruent with the individual's gender identity; or receiving mental health counseling, as deemed medically necessary). One commenter suggested that having the capacity to consent to the treatment should not be a prerequisite to an individual receiving care.

**Response:** In developing its policy, the Department reviewed standards of care recommended by professional organizations, including the WPATH, as well as those followed by commercial insurers and by the handful of other state Medicaid programs that cover transgender care and services. As the comments demonstrate, there is no universal agreement on one standard of care that should be followed. The proposed regulation sets forth a policy that will enable transgender individuals to receive medically necessary care, and that reflects the mainstream of current thinking with respect to transgender care and services. The proposed regulation also establishes reasonable prerequisites and criteria for coverage, designed to limit Medicaid payment to medically necessary care, and consistent with the Department's responsibility under section 364 of the Social Services Law to ensure that the medical care and services paid for by the Medicaid program are of the highest quality. No changes to the proposed regulation were made as a result of these comments.

**Comment:** A number of comments dealt with the requirement that gender reassignment surgery be supported by referral letters from two qualified, licensed health care professionals. Some commenters recommended that only one referral letter be required for breast surgery. Some commenters stated that additional types of professionals (e.g. licensed marriage and family therapists, or licensed mental health counselors) should be able to supply a referral letter.

**Response:** The requirement for an authoritative diagnosis of gender dysphoria is necessary to ensure that Medicaid pays only for medically necessary care. The Department is willing to consider expanding the list of referring professionals in the future, but believes the current requirement is reasonable and will not be a barrier to transgender individuals accessing necessary care. Likewise, the Department will consider adopting a policy of requiring one



referral letter for breast surgery, which is consistent with the policies of a number of other health insurance payers, but will address any such change in a subsequent rulemaking.

**Comment:** Some commenters raised a concern about gender-specific billing edits that might result in the rejection of Medicaid claims for non-transition-related care needed by transgender individuals (e.g., prostate-related care for a transgender individual whose assigned gender at birth was male but whose gender marker has been changed to female).

**Response:** This issue is beyond the intended scope of the regulation, and no changes were made to the proposed regulation in response to it. However, the Department will implement system edits to ensure access to non-transition-related care for individuals who are in the process of transitioning or have completed their transition.

**Comment:** Some commenters recommended that the Department establish an advisory committee to oversee implementation of the proposed regulation and/or develop and mandate transgender health competency training for its Medicaid providers.

**Response:** These comments address issues beyond the intended scope of the regulation, and no changes were made to the proposed regulation in response to them. However, the Department will take these comments under advisement.

