Transgender Related Care and Services

Effective date: 8/31/16

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 (*l*) of section 505.2 is amended to read as follows:

(*l*) Gender dysphoria treatment.

(1) 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 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, psychologist, or psychiatric nurse practitioner with whom the individual has an established and ongoing relationship. The other letter may be from a licensed psychiatrist, psychologist, physician, psychiatric nurse practitioner, 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; and

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

(5) Payment will not be made for any surgery, services, or procedures that are performed solely for the purpose of improving an individual's appearance (cosmetic procedures). The following surgery, services, and procedures will be presumed to be cosmetic and will not be covered, unless justification of medical necessity is provided and prior approval is received:

[(v) cosmetic surgery, services, and procedures, including but not limited to:]

[(a)] (i) abdominoplasty, blepharoplasty, neck tightening, or removal of redundant skin;

[(b)] (ii) breast augmentation, unless the individual has completed a minimum of 24 months of hormone therapy during which time breast growth has been negligible, or hormone therapy is medically contraindicated or the individual is otherwise unable to take hormones;

[(c)] (iii) breast, brow, face, or forehead lifts;

[(d)] (iv) calf, cheek, chin, nose, or pectoral implants;

[(e)] (v) collagen injections;

[(f)] (vi) drugs to promote hair growth or loss;

[(g)] (vii) electrolysis, unless required for vaginoplasty or phalloplasty;

[(h)] (viii) facial bone reconstruction, reduction, or sculpturing, including jaw shortening and rhinoplasty;

[(i)] (ix) hair transplantation;

[(j)] (x) lip reduction;

[(k)] (xi) liposuction;

[(l)] (xii) thyroid chondroplasty; and

[(m)] (xiii) voice therapy, voice lessons, or voice modification surgery.

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

[(6)] (7) 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 amendments would revise the Department's existing regulations providing for Medicaid coverage of treatments to address gender dysphoria, to clarify the policy with respect to coverage for presumptively cosmetic surgery, services, and procedures.

The existing regulation provides that Medicaid will not pay for surgery, services, or procedures performed in connection with GRS that are purely cosmetic, and defines "cosmetic surgery, services, and procedures" as anything solely directed at improving an individual's appearance. However, the existing regulation may not be clear that an ostensibly cosmetic

procedure listed in the regulation may be covered if it is established that it is medically necessary in a particular case and not solely directed at improving appearance. Therefore, consistent with the Department's published written guidance interpreting the regulation, the proposed amendments would add language clarifying that the listed surgery, services or procedures are presumed to be cosmetic, i.e., performed solely for the purpose of improving appearance, and will not be covered unless justification of medical necessity is provided and prior approval is granted. The proposed amendments would renumber paragraphs (5) and (6) of § 505.2(*l*) as paragraphs (6) and (7), and place the list of presumptively cosmetic procedures and the clarifying language into a new paragraph (5).

Similarly, the newly numbered § 505.2(*l*)(5) would be amended to reflect and refine interpretative guidance issued by the Department with respect to the coverage of breast augmentation and the coverage of electrolysis. The proposed amendments would provide that: breast augmentation will be covered, without the need for prior approval, if an individual has completed a minimum of 24 months of hormone therapy during which time breast growth has been negligible, or hormone therapy is medically contraindicated or the individual is otherwise unable to take hormones; and that necessary electrolysis will be covered, without the need for prior approval, as part of the Medicaid payment for both vaginoplasty and phalloplasty.

Costs:

Costs to Regulated Parties:

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

Costs to State Government:

The proposed amendments would not change the Department's current policy with respect to the availability of Medicaid coverage for ostensibly cosmetic procedures in connection with GRS, but would simply clarify regulatory language to more clearly state that policy. There will be no additional costs to the Medicaid program as a result of making these clarifications.

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:

The proposed amendments would not increase the paperwork requirements for a medical provider to document the need for hormone therapy or GRS.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

Advocates for individuals with gender dysphoria and a federal court have both interpreted the existing regulatory language, as regards the availability of Medicaid coverage for ostensibly cosmetic procedures in connection with GRS, inconsistently with the Department's intent.

Therefore the Department concluded that there is no alternative to clarifying the regulatory language.

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 pertains to a 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 amendments is not being submitted because the amendments 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 amendments 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

The proposed amendments would revise the Department's existing regulations at 18 NYCRR § 505.2(*l*) pertaining to Medicaid coverage of transgender related care and services. Section 505.2(*l*)(5) of the proposed regulation lists certain surgery, services, and procedures presumed to be cosmetic (i.e. performed solely for the purpose of improving appearance); coverage of these services would be available if prior approval is received based on a finding of medical necessity. Seven comments were received: two from lawyers or legal organizations; one from a health center; and four from individuals, one of whom is transgender.

Comment: Some commenters took the position that all gender affirming services for individuals with gender dysphoria (GD) constitute medically necessary treatment.

Response: The Department disagrees, and contends that individuals with GD, like anyone else, may in some instances desire to change their appearance for purely cosmetic reasons, and not for the purpose of treating their GD. For example, an individual with GD who has received medically necessary treatment and has successfully transitioned to the opposite gender, may nevertheless wish to undergo additional procedures, not because it is necessary to address the symptoms of their GD, but simply to enhance their appearance. The Medicaid program is limited to paying for medically necessary care, and thus cannot pay for procedures whose purpose is not medical but cosmetic. No changes were made to the proposed regulation as a result of this comment.

Comment: Some commenters contended that the proposed amendment imposes a stricter standard for obtaining prior approval of the procedures listed in §505.2(*l*)(5) to treat GD than is applied to the same procedures when used to treat other conditions or diagnoses. As support for this contention, they pointed to: the proposed regulatory presumption that these services are

cosmetic; and the fact that the regulation defines cosmetic procedures as those "performed solely for the purpose of improving an individual's appearance", while in other contexts cosmetic procedures are described as those "provided only because of the enrollee's personal preference".

Response: As always, it is the Department's intent only to ensure that Medicaid pays for medically necessary care, services, and supplies. No change was made to the proposed regulation as a result of this comment, but the Department will take it under advisement, and will consider whether the presumption language should be eliminated or modified in a subsequent rulemaking, in order to dispel any misconception that the Department is setting a stricter standard for coverage of these procedures in the context of transgender care.

Comment: Some commenters urged the Department to eliminate what they referred to as the list of "exclusions" in the regulation.

Response: The services listed in §505.2(*l*)(5) are not excluded from coverage. They will be covered if medically necessary and prior approval is received. Nevertheless, the Department will consider whether specifying in the regulation procedures that are subject to prior approval is contributing to the misconception that a stricter standard is being set for coverage of these procedures in the context of transgender care. If the Department decides to omit the list from the regulation, it will do so in a subsequent rulemaking.

Comment: A number of comments addressed topics outside of the scope of the proposed amendments, including the current limitation on coverage of hormone therapy and gender reassignment surgery (GRS) to individuals 18 years of age or older, and the types of practitioners who can provide referral letters for GRS.

Response: Because these comments do not pertain to the amendments proposed in the current rulemaking, no changes were made in response to these comments. However, the

Department is considering these comments outside the context of the current rulemaking, and if the Department determines policy changes are advisable, it will address them in a separate rulemaking.