Transgender Related Care and Services

Effective date: 12/7/16

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) (i) Hormone therapy, whether or not in preparation for gender reassignment surgery, [may] shall be covered [for individuals 18 years of age or older.] as follows:

(a) treatment with gonadotropin-releasing hormone agents (pubertal suppressants), based upon a determination by a qualified medical professional that an individual is eligible and ready for such treatment, i.e., that the individual:

(1) meets the criteria for a diagnosis of gender dysphoria;

(2) has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria;

(3) does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;

(4) has adequate psychological and social support during treatment; and

(5) demonstrates knowledge and understanding of the expected outcomes of treatment with pubertal suppressants and cross-sex hormones, as well as the medical and social risks and benefits of sex reassignment;

(b) treatment with cross-sex hormones for patients who are sixteen years of age and older, based upon a determination of medical necessity made by a qualified medical professional; patients who are under eighteen years of age must meet the applicable criteria set forth in clause (a).

(ii) Notwithstanding the requirement in clause (b) of subparagraph (i) of this paragraph that an individual be sixteen years of age or older, payment for cross-sex hormones for patients under sixteen years of age who otherwise meet the requirements of clause (b) of subparagraph (i) of this paragraph shall be made in specific cases if medical necessity is demonstrated and prior approval is received.

(3) (i) Gender reassignment surgery [may] shall 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, or licensed clinical social worker 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)] (a) has a persistent and well-documented case of gender dysphoria;

[(ii)] (b) 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)] (c) 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)] (d) 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)] (e) has the capacity to make a fully informed decision and to consent to the treatment.

(ii) Notwithstanding subparagraph (i) of this paragraph, payment for gender reassignment surgery, services, and procedures for patients under eighteen years of age may be made in specific cases if medical necessity is demonstrated and prior approval is received.

[(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.

(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:

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

(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;

(iii) breast, brow, face, or forehead lifts;

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

(v) collagen injections;

(vi) drugs to promote hair growth or loss;

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

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

(ix) hair transplantation;

(x) lip reduction;

(xi) liposuction;

(xii) thyroid chondroplasty; and

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

(4) For individuals meeting the requirements of paragraph (3) of this subdivision, Medicaid coverage will be available for the following gender reassignment surgeries, services, and procedures, based upon a determination of medical necessity made by a qualified medical professional:

(i) mastectomy, hysterectomy, salpingectomy, oophorectomy, vaginectomy, urethroplasty, metoidioplasty, phalloplasty, scrotoplasty, penectomy, orchiectomy, vaginoplasty, labiaplasty, clitoroplasty, and/or placement of a testicular prosthesis and penile prosthesis;

(ii) breast augmentation, provided that: the patient 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 patient is otherwise unable to take hormones;

(iii) electrolysis when required for vaginoplasty or phalloplasty; and

(iv) such other surgeries, services, and procedures as may be specified by the Department in billing guidance to providers.

[(6)] (5) [For purposes of this subdivision, cosmetic surgery, services, and procedures refers to anything solely directed at improving an individual's appearance.] For individuals meeting the requirements of paragraph (3) of this subdivision, surgeries, services, and procedures in connection with gender reassignment not specified in paragraph (4) of this subdivision, or to be performed in situations other than those described in such paragraph, including those done to change the patient's physical appearance to more closely conform secondary sex characteristics to those of the patient's identified gender, shall be covered if it is demonstrated that such surgery, service, or procedure is medically necessary to treat a particular patient's gender dysphoria, and prior approval is received. Coverage is not available for surgeries, services, or procedures that are purely cosmetic, i.e., that enhance a patient's appearance but are not medically necessary to treat the patient's underlying gender dysphoria.

[(7)] (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 amendments would revise the Department's existing regulations providing for Medicaid coverage of medically necessary treatments to address gender dysphoria (GD) to: provide coverage of such treatments for individuals under 18 years of age; specify gender reassignment surgeries, services, and procedures that the Medicaid program will cover without the need for the practitioner to obtain prior approval; reiterate that Medicaid will cover other surgeries, services, and procedures, including those done to change an individual's physical appearance to more closely conform secondary sex characteristics to those of the patient's

identified gender, if it is demonstrated that such surgery, service, or procedure is medically necessary to treat a particular patient's GD, and prior approval is received; and remove language in the regulation specifying certain coverage limitations, in favor of including that information in other Medicaid policy materials.

The existing regulation provides coverage for hormone therapy only for individuals 18 years of age or older. When the Department proposed the original regulation providing for Medicaid coverage of transgender care and services, it had reservations about the safety and efficacy, and thus the medical necessity, of hormone therapy for individuals under 18 with GD. For one thing, the use of hormone therapy to treat GD in individuals under the age of 18 is not approved by the federal Food and Drug Administration (FDA), nor is it indicated as an accepted off-label use by any of the pharmaceutical compendia relied on by the Medicaid program; this may be due to the apparent dearth of quality, longitudinal studies on the long term effects of providing such treatments to the under 18 population. In addition, at the time of the original regulation, virtually no other health care payer provided coverage of hormone therapy for individuals under age 18; this may have been due, in part, to the lack of FDA approval or pharmaceutical compendia support.

Since then, the Department has observed the beginning of a shift in payer policies with respect to treatment for the under 18 population, and has had the opportunity to talk to a number of practitioners who treat minors with GD, to benefit from their clinical experiences and to solicit their understanding of the current consensus in the medical profession, if any, with respect to such treatment.

All of these practitioners were of the opinion that the use of pubertal suppressants and cross-sex hormone therapy could be medically necessary in the treatment of GD in individuals

under age 18. They acknowledged that it would be ideal if more high quality studies were available on the long-term effects of the treatments, but all believed that the positive effects they have observed in the short term in improving the mental health of minors with GD outweigh the potential long-term risks. The practitioners were in agreement that pubertal suppressants do not need to be prescribed before an individual reaches Tanner stage 2 in pubertal development. With respect to the current standard of care for treating minors with GD, the practitioners were also generally consistent in stating that cross-sex hormone treatment typically is not started until the individual reaches 16 years of age, and surgical interventions to treat GD typically are not recommended before the individual reaches 18 years of age, although exceptions might be appropriate in particular cases. This is consistent with existing guidelines issued by the Endocrine Society with respect to the use of pubertal suppressants and cross-sex hormone therapy to treat GD in individuals under 18 years of age, and suggests that the Endocrine Society guidelines are reflective of a generally accepted standard of care for treating GD in this age group.

Therefore, the Department is proposing to amend the regulations to adopt criteria for Medicaid payment for pubertal suppressants and cross-sex hormones for individuals under age 18. These criteria are modeled closely after those set forth in the current Endocrine Society guidelines.

The proposed amendments would provide for coverage of pubertal suppressants in the treatment of GD based on the determination of a qualified medical professional that an individual is eligible and ready for the treatment. An individual would be considered eligible and ready for treatment with pubertal suppressants if the individual: meets the criteria for a diagnosis of GD; has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an

increase in gender dysphoria; does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment; has adequate psychological and social support during treatment; and demonstrates knowledge and understanding of the expected outcomes of treatment with pubertal suppressants and cross-sex hormones, as well as the medical and social risks and benefits of sex reassignment.

The proposed amendments would provide for coverage of treatment with cross-sex hormones for individuals who are 16 years of age or older, based on a determination of medical necessity by a qualified medical professional. An individual under 18 years of age would have to meet the same criteria as for treatment with pubertal suppressants, as applicable.

The proposed amendments would also provide for coverage of cross-sex hormones for individuals under age 16, and for coverage of gender reassignment surgeries, services, and procedures for individuals under age 18, in individual cases if medical necessity is demonstrated and prior approval is received.

The proposed changes therefore would make Medicaid coverage of transgender care and services available, regardless of an individual's age, when such care and services are medically necessary to treat the individual's gender dysphoria.

Commenters on the current regulation have objected to the designation of certain surgeries, services, and procedures as presumptively cosmetic, and to the inclusion in the regulation of information about coverage limitations related to cryopreservation of reproductive tissue and reversal of gender reassignment surgeries. The commenters contended that such provisions have the effect of treating individuals with GD differently than other Medicaid recipients, and imposing stricter prior approval standards on individuals with GD than are applied to individuals with other conditions or diagnoses. The Department does not agree with

the commenters on these points, but is proposing changes to the regulation in order to be sensitive to their concerns and to try to avoid any misconceptions about Medicaid's policy.

First, the proposed amendments would remove the list of presumptively cosmetic surgeries, services, and procedures from the regulation. Instead, the proposed amendments would specifically list gender reassignment surgeries, services, and procedures that Medicaid will cover without the need for prior approval. The proposed amendments would further provide that any surgeries, services, and procedures not on this list or otherwise specified by the Department in billing guidance to Medicaid providers, would be subject to prior approval and covered if medically necessary to treat the individual's gender dysphoria. This would include surgeries, services, and procedures for the purpose of changing an individual's appearance to more closely conform secondary sex characteristics to those of the patient's identified gender. The regulation would continue to provide that Medicaid coverage is not available for surgeries, services, and procedures that are purely cosmetic, i.e., that enhance an individual's appearance but are not medically necessary to treat the individual's underlying gender dysphoria.

Second, the proposed amendments would remove the language regarding cryopreservation of reproductive tissue and the reversal of gender reassignment surgeries; instead, the Department will provide this information in billing guidance to Medicaid providers or other policy materials.

Commenters had also requested that licensed clinical social workers be added to the list of licensed New York State health professionals, with whom an individual has an established and ongoing relationship, who can provide a letter referring the individual for gender reassignment surgery. Because licensed clinical social workers in New York State are qualified to diagnose

GD, the Department is comfortable adding them to this list. The proposed amendments would make this change.

Finally, the proposed amendments would make a number of minor, nonsubstantive changes to clarify existing regulatory language.

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:

There may be costs to the Medicaid program associated with increased use of pubertal suppressants. Generally, however, the proposed amendments do not expand the Medicaid benefit package, but simply allow Medicaid recipients to receive covered transition-related transgender care and services at a younger age, and thus should not generate significant additional costs to the program.

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 paperwork requirements.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

Given the Department's current understanding that the use of pubertal suppressants and cross-sex hormone therapy may be medically necessary in the treatment of GD in individuals under age 18, it has concluded that there is no alternative to changing its coverage policy and making necessary conforming amendments to the existing regulation.

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 regulation would, among other things: provide coverage of medically necessary treatments for gender dysphoria in individuals under 18 years of age; specify gender reassignment surgeries, services, and procedures that the Medicaid program will cover without the need for the practitioner to obtain prior approval; reiterate that Medicaid will cover other surgeries, services, and procedures if it is demonstrated that such surgery, service, or procedure is medically necessary to treat a particular patient's GD, and prior approval is received; and add licensed clinical social workers to the list of licensed NYS health professionals, with whom an individual has an established and ongoing relationship, who can provide a letter referring the individual for gender reassignment surgery (GRS). In short, the proposed changes would make Medicaid coverage of transgender care and services available, regardless of an individual's age, whenever such care and services are medically necessary to treat the individual's gender dysphoria.

Comments on the proposed rulemaking were received from a State senator (who was strongly supportive of the regulation and did not recommend any further revisions), a community health center with experience in transgender health care, a network of federally qualified health centers (FQHCs), a law firm representing a managed care organization, the LGBT Rights Committee of the New York City Bar Association, two legal aid organizations and a law firm commenting jointly, and 61 individuals.

Comment: Two commenters were opposed to Medicaid covering services for the treatment of gender dysphoria. One objected generally to medical intervention for a "delusion." The other contended that gender dysphoria does not meet the criteria set forth in Social Services Law section 365-a, which provides for Medicaid coverage of "medical, dental and remedial care,

services and supplies . . . which are necessary to prevent, diagnose, correct or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, interfere with such person's capacity for normal activity, or threaten some significant handicap."

Response: No changes were made to the proposed regulation as a result of these comments. Gender dysphoria is a condition recognized by the American Psychiatric Association in its Diagnostic and Statistical Manual of Mental Disorders. The Manual describes the condition, in part, as one which causes clinically significant distress or impairment in social, occupational, or other important areas of functioning. Therefore, the Department interprets the language of section 365-a of the Social Services Law (SSL) as encompassing the condition of gender dysphoria.

From the Department's standpoint, the question is not whether Medicaid should pay for treatment of gender dysphoria, but instead what treatments are medically necessary and what standards should such treatment meet in order to qualify for Medicaid reimbursement.

Sections 363 and 364 of the SSL make clear that the primary purpose of the Medicaid program is to ensure the availability of uniform, high-quality medical care to all New Yorkers. Section 363-a of the SSL designates the Department as the single State agency charged with the responsibility to supervise the administration of the Medicaid State plan in New York. Section 364 of the SSL further authorizes the Department to establish and maintain standards for medical care reimbursed through the program.

In this rulemaking, and in prior rulemakings, the Department has established standards intended to ensure Medicaid pays for high-quality care that is not medically contraindicated, is medically necessary to treat an individual's gender dysphoria, and is undertaken with the informed consent of the individual.

Comment: A commenter noted that although the Department indicates in the Regulatory Impact Statement for the proposed rulemaking that licensed clinical social workers are being added to the list of licensed NYS health professionals, with whom an individual has an established and ongoing relationship, who can provide a letter referring the individual for GRS, this is not reflected in the text of the regulation.

Response: The Department thanks the commenter for pointing out this oversight. The Department has added an explicit reference to licensed clinical social workers in the text of the regulation, as was intended.

Comment: The community health center and the FQHC network both expressed support for the proposed expansion of coverage to treatment of individuals under age 18, and the addition of licensed clinical social workers to the list of health professionals who can provide a letter referring an individual for GRS. However, they recommended that the list of referring professionals be further expanded to include licensed therapists, physician assistants, nurse practitioners, and family nurse practitioners.

Response: The list of health professionals who can supply referral letters for GRS strikes a balance between enabling access to services and ensuring that Medicaid coverage of GRS is based on determinations of medical necessity made by individuals qualified to make such determinations. The Department does not believe its policy will prevent transgender individuals from accessing necessary care, and is a valid exercise of the discretion granted to it as the single State Medicaid agency responsible for establishing standards to ensure high quality Medicaid services.

Comment: The community health center and the FQHC network also recommended that the following services be covered by Medicaid for the treatment of gender dysphoria, without the need to obtain prior approval: breast, brow, face, and forehead lifts; drugs to promote hair growth or loss; electrolysis for the entire body; facial bone reconstruction, reduction, or sculpturing; hair transplantation; vocal surgeries and coaching; and thyroid chondroplasty. The community health center went on in its comment to state that "these surgeries are all medically-necessary for an individual seeking gender affirmation."

Response: Not all individuals seek the full range of potential treatments for the symptoms of gender dysphoria, which belies the commenter's statement that all of the listed surgeries are medically necessary procedures for any individual seeking to transition. Whether one or more of the listed surgeries is medically necessary for an individual will depend on the circumstances of the particular case. Therefore the Department, as the single State agency charged with the responsibility of supervising the administration of the Medicaid program, finds it appropriate to require prior approval, based on a showing of medical necessity by the health practitioner in a particular case, as a prerequisite to payment for these services.

Comment: The bar association LGBT committee objected, among other things, to: requiring prior approval for hormone treatments provided to individuals under age 16 and surgical interventions undertaken prior to age 18; requiring two letters from health care practitioners referring an individual for GRS, rather than one; and requiring prior approval for any transition-related treatments, which the commenter contends is equivalent to labeling such treatments as "presumptively cosmetic." Instead, the commenter urges that the regulation be revised to simply state that any and all treatments for gender dysphoria consistent with contemporary standards of care must be covered.

Response: Decisions on discrete aspects of the coverage policy (prerequisites for Medicaid coverage of hormone therapy or GRS; two referral letters for GRS versus one; when and if prior approval is required) are appropriately made by the Department in its role as the single State Medicaid agency. The commenter suggested alternative policies, in order to give individuals with gender dysphoria maximum access to the services they seek. However, the Department's statutory obligation is not simply to provide access to desired services, but to make sure that Medicaid pays only for high-quality and medically necessary services. The Department believes the policy determinations it has made promote the receipt of high quality, medically necessary care by Medicaid recipients, are reasonable, and are fully within the discretion afforded to it by the Legislature when the Department was designated as the single State Medicaid agency.

The Department disagrees that the proposed regulation labels any services as presumptively cosmetic. Rather, the prior approval requirements in the proposed regulation reflect the Department's recognition that not all transition-related services will be medically necessary for every individual with gender dysphoria. As the commenter itself observed, citing the Standards of Care of the World Professional Association for Transgender Health, "what constitutes medically necessary treatment, is a highly individualized process that can vary significantly from one person to another. For some transgender people, hormones provide adequate treatment for gender dysphoria. For many others, surgery is essential and medically necessary to treat their gender dysphoria. What surgery is required will depend on the clinical needs and overall health of a particular person."

The commenter's suggestion that the criteria for Medicaid coverage of transgender services be any of multiple standards of care propounded by individual practitioners, medical

societies, and advocacy organizations, is untenable. It would create uncertainty among providers and recipients as to what Medicaid does and does not cover, and would be an abdication of the Department's responsibility to establish standards for the care, services, and supplies eligible for Medicaid reimbursement. No changes were made to the proposed regulation as a result of these comments.

Comment: One of the prerequisites for coverage of hormone therapy is that the individual does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment. The managed care organization recommends that the language be revised to refer to an untreated psychiatric comorbidity, based on its understanding that coverage of transgender care should be available if the psychiatric comorbidity has been addressed and the individual is stable.

Response: The Department disagrees with the commenter's assumption that undergoing treatment for a psychiatric comorbidity necessarily means that it has been addressed and that the individual is stable. The proposed regulatory language, which is identical to language in the Endocrine Society's standard of care, is intended to avoid transgender care being provided when an existing psychiatric comorbidity prevents or interferes with making a definitive diagnosis of gender dysphoria or with obtaining informed consent for transgender treatment. The fact that the individual is receiving treatment is not, by itself, dispositive as to whether the existing psychiatric comorbidity raises these concerns. No changes were made to the proposed regulation as a result of this comment.

Approximately 57 of the comments followed a common template and were virtually identical. These commenters expressed strong support for the proposed regulation to the extent that it: expands Medicaid coverage of pubertal suppressants and cross-sex hormones; includes

licensed clinical social workers in the list of health professionals who can provide a letter referring an individual for GRS; and continues to recognize that hormone therapy may be medically contraindicated for some individuals and is not part of every individual's transition. These commenters also expressed concerns about the proposed rulemaking, summarized below.

Comment: The proposed regulation contains a definition of "cosmetic services" that is different than the definition used elsewhere. The definition in the proposed regulation is "not accessible," "exclusionary," and will invite incorrect denials of care.

Response: The Department does not agree that there is any significance to slight differences in wording in references to cosmetic procedures in its regulations and policies. As the Department has stressed in previous rulemakings amending section 505.2(*l*), the language in question is intended to ensure that Medicaid pays only for medically necessary care, services, and supplies. The Medicaid program is statutorily constrained to do so, and therefore is prohibited from paying for care, services, or supplies whose purpose is not medical but cosmetic. No changes were made to the proposed regulation as a result of this comment.

Comment: The proposed regulation provides for the coverage of breast augmentation, without the requirement of obtaining prior approval, if an individual has completed 24 months of hormone therapy, during which time breast growth has been negligible. The term "negligible" is vague and undefined, may be used by insurance companies against persons with gender dysphoria, and does not affirm the need of many individuals to receive this care. A separate commenter suggested replacing negligible breast growth with "insufficient breast growth in proportion to the patient's body type such that it has failed to alleviate the patient's gender dysphoria as determined by the treating medical or mental health professional."

Response: The regulation intends to distinguish between a situation in which hormone therapy has failed to achieve the goal of conforming this sex characteristic to that of the individual's identified gender, and a situation where it has succeeded. In the former situation, breast augmentation will be covered, without the need to obtain prior approval, based on the reasonable judgment of the medical practitioner that breast growth has been negligible. In the latter, a question exists as to whether further, surgical augmentation is medically necessary to treat the individual's gender dysphoria, or is instead being sought for solely cosmetic reasons; therefore, breast augmentation will be covered only if medical necessity is demonstrated and prior approval received.

The Department shares the commenters' interest in clear Medicaid coverage standards and will take their comments under advisement in crafting billing guidance for providers and considering future amendments to the regulation.

Comment: The Department should continue to review the current medical consensus with respect to the treatment of gender dysphoria, and be cognizant of any changing opinions of leading medical professional organizations such as the Endocrine Society or the World Professional Association for Transgender Health.

Response: The Department will propose future amendments to the regulation if necessitated by an evolving medical consensus on medically necessary treatment of gender dysphoria.