

RULE MAKING ACTIVITIES

Each rule making is identified by an I.D. No., which consists of 13 characters. For example, the I.D. No. AAM-01-96-00001-E indicates the following:

AAM -the abbreviation to identify the adopting agency
01 -the *State Register* issue number
96 -the year
00001 -the Department of State number, assigned upon receipt of notice.
E -Emergency Rule Making—permanent action not intended (This character could also be: A for Adoption; P for Proposed Rule Making; RP for Revised Rule Making; EP for a combined Emergency and Proposed Rule Making; EA for an Emergency Rule Making that is permanent and does not expire 90 days after filing.)

Italics contained in text denote new material. Brackets indicate material to be deleted.

NOTICE OF ADOPTION

Certificate of Public Advantage

I.D. No. HLT-38-13-00007-A

Filing No. 985

Filing Date: 2014-12-02

Effective Date: 2014-12-17

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Addition of Subpart 83-1 to Title 10 NYCRR.

Statutory authority: Public Health Law, section 2999-bb

Subject: Certificate of Public Advantage.

Purpose: For the health care industry to obtain reasonable protections from antitrust liability through an active state oversight program.

Substance of final rule: The proposed rule would add a new Subpart 83-1 to 10 NYCRR titled Certificate of Public Advantage.

Section 83-1.1 Contains definitions for purposes of this Subpart, including definitions for “Attorney General,” “Certificate of Public Advantage,” “Cooperative Agreement,” “Federal or State Antitrust Laws,” “Health Care Provider,” “Mental Hygiene Agency,” “Person,” “Planning Process” and “Primary Service Area.”

Section 83-1.2 Certificate of Public Advantage. Describes the effect of obtaining a Certificate of Public Advantage (“COPA”) and sets forth the basic contents of an application.

Section 83-1.3 Public notice. Provides for public notice of an application, by both the department and each party to the agreement or proposed agreement for which approval is sought.

Section 83-1.4 Fees for applications and monitoring. Sets forth fees and costs to be paid in relation to applications and renewals.

Section 83-1.5 Review process. Sets forth the factors to be considered by the Department in its review of applications for a COPA.

Section 83-1.6 Issuance of a Certificate of Public Advantage. Provides for consultation with the Attorney General, the mental hygiene agencies (as appropriate), and the Public Health and Health Planning Council

(“PHHPC”) in the issuance of a COPA, sets forth examples of conditions which may be imposed in the issuance of a COPA, and provides for the period for which such COPA may be valid.

Section 83-1.7 Record keeping. Requires the Department to maintain a record of all Cooperative Agreements for which COPAs are in effect and a copy of the certificate, including any conditions imposed in it.

Section 83-1.8 Modification and termination. Provides that any material modification of an approved Cooperative Agreement is subject to the prior review and approval of the Department in consultation with the Attorney General, mental hygiene agencies (as appropriate), and the PHHPC, and that any party to a Cooperative Agreement covered by a COPA must file notice of such termination with the Department at least thirty days prior to the termination. The notice of termination will be provided by the Department to the Attorney General and the mental hygiene agencies (as appropriate).

Section 83-1.9 Periodic reports. Requires periodic filing of reports of activity pursuant to a COPA, and sets forth the frequency and contents of such reports.

Section 83-1.10 Review after issuance of Certificate of Public Advantage. Provides for Department review of reports, and includes provisions addressing corrective measures the Department may take under certain circumstances.

Section 83-1.11 Application for renewal. Provides for renewal of an approved COPA.

Section 83-1.12 Revocation. Provides for revocation of a COPA by the Department under certain circumstances, and a procedure for doing so.

Section 83-1.13 Hearing rights. Provides for a right of hearing prior to the Department’s revocation of a COPA.

Section 83-1.14 Voluntary surrender. Allows for the voluntary surrender of a COPA.

Section 83-1.15 Effect of consultation or recommendations. Clarifies treatment of input received pursuant to consultations with, or recommendations from, the Attorney General, mental hygiene agencies (as appropriate), or the PHHPC.

Section 83-1.16 Certificate of need and other requirements. Provides that nothing in this Subpart shall relieve parties from any responsibility for compliance with laws or regulations governing certificate of need or other approval or notice submission requirements.

A copy of the full text of the regulatory proposal is available on the Department of Health website (www.health.ny.gov).

Final rule as compared with last published rule: Nonsubstantive changes were made in sections 83-1.1(c)(2), 83-1.2(b)(2) and (3).

Revised rule making(s) were previously published in the State Register on August 27, 2014.

Text of rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of House Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqa@health.ny.gov

Revised Regulatory Impact Statement, Revised Regulatory Flexibility Analysis, Revised Rural Area Flexibility Analysis and Revised Job Impact Statement

Changes made to the last published rule do not necessitate revision to the previously published RIS, RFA, RAFA or JIS.

Assessment of Public Comment

A Notice of Proposed Rule Making was published in the State Register on September 18, 2013. The proposed regulations were revised in light of public comments received and a Notice of Revised Rule Making was published in the State Register on August 27, 2014. During the public comment period for the revised rulemaking, comments were received from hospitals, hospital associations, health plan associations, and a bar association. Clarifications and technical, non-substantive changes have been made to the regulations in light of the comments received. The regulations will take effect today pursuant to a Notice of Adoption filed in

today's State Register. The full text of the regulations and Assessment of Public Comment is available on the Department of Health's website.

All comments received were reviewed and evaluated. In response to comments, section 83-1.1(c)(2) has been revised to clarify certain types of transactions for which a COPA may be available. In addition, technical clarifications were made to section 83-1.2(b)(2) and (3). As explained below, other suggestions were not incorporated because they were inconsistent with the statutory authority underlying the proposed rulemaking or concerned issues outside the scope of the proposed rulemaking.

A number of comments related to the intersection of the Certificate of Public Advantage (COPA) and the Delivery System Reform Incentive Payment (DSRIP). As noted in the comments and responses, the Department has indicated that Performing Provider Systems (PPSs) may submit COPA applications along with their DSRIP Project Plan applications. In response to a number of comments, the Department advises that it soon will issue Frequently Asked Questions to assist PPSs in submitting COPA applications which will address the matters raised.

A number of comments expressed concern about the Attorney General's ability to seek retroactive enforcement of state antitrust laws, which they assert is inconsistent with the statutory purpose underlying the COPA regulations. In response, the Department notes that the proposed regulations achieve the statute's intent to provide state action immunity under the state and federal antitrust laws for collaborative arrangements that promote improved quality, efficiency of and access to health care services through the COPA process, while preserving the Attorney General's authority as authorized by law.

The Assessment of Public Comment is available on the Department of Health's website at www.health.ny.gov.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Transgender Related Care and Services

I.D. No. HLT-50-14-00001-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: Amendment of section 505.2(l) of Title 18 NYCRR.

Statutory authority: Public Health Law, sections 201 and 206; and Social Services Law, sections 363-a and 365-a(2)

Subject: Transgender Related Care and Services.

Purpose: To authorize Medicaid coverage for transgender related care and services.

Text of proposed rule: Subdivision (l) of section 505.2 is repealed and a new subdivision (l) is added to read as follows:

(l) *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.*

Text of proposed rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of House Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqa@health.ny.gov

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

This rule was not under consideration at the time this agency submitted its Regulatory Agenda for publication in the Register.

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 exist-

ing 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.

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.

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.

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.

Office of Mental Health

NOTICE OF ADOPTION

Clinic Treatment Programs

I.D. No. OMH-40-14-00007-A

Filing No. 977

Filing Date: 2014-12-02

Effective Date: 2014-12-17

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of Part 599 of Title 14 NYCRR.

Statutory authority: Mental Hygiene Law, sections 7.09, 31.04, 43.01 and 43.02; Social Services Law, sections 364, 364-a and 364-j

Subject: Clinic Treatment Programs.

Purpose: Adjust billing units associated with reimbursement of clinic services; allow flexibility in delivery of complex care management.

Text or summary was published in the October 8, 2014 issue of the Register, I.D. No. OMH-40-14-00007-P.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: Sue Watson, NYS Office of Mental Health, 44 Holland Avenue, Albany, NY 12229, (518) 474-1331, email: Sue.Watson@omh.ny.gov

Assessment of Public Comment

The agency received no public comment.

Office for People with Developmental Disabilities

NOTICE OF ADOPTION

HCBS Waiver Community Habilitation Services

I.D. No. PDD-41-14-00006-A

Filing No. 978

Filing Date: 2014-12-02

Effective Date: 2014-12-17

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of Subpart 635-10 of Title 14 NYCRR.

Statutory authority: Mental Hygiene Law, sections 13.07, 13.09(b) and 16.00

Subject: HCBS Waiver Community Habilitation Services.

Purpose: To amend proposed Community Habilitation regulations that were adopted on October 1, 2014.

Text or summary was published in the October 15, 2014 issue of the Register, I.D. No. PDD-41-14-00006-EP.

Final rule as compared with last published rule: No changes.

Text of rule and any required statements and analyses may be obtained from: Regulatory Affairs Unit, OPWDD, 44 Holland Avenue, 3rd Floor, Albany, NY 12229, (518) 474-1830, email: rau.unit@opwdd.ny.gov

Additional matter required by statute: Pursuant to the requirements of the State Environmental Quality Review Act, OPWDD, as lead agency, has determined that the action described herein will have no effect on the environment, and an E.I.S is not needed.

Assessment of Public Comment

The agency received no public comment.