

Pursuant to the authority vested in the Commissioner of Health by section 365-a(2)(ee) of the Social Services Law, Part 505 of Title 18 (Social Services) of the Official Compilation of Codes, Rules, and Regulations of the State of New York is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraph 1 of subdivision (a) of Section 505.1 is amended and a new subparagraph (iii) is added to read as follows:

Section 505.1 Scope of medical assistance. (a) Services available. (1) Medical care, services and supplies available to eligible persons must, except to the extent that such medical care, services and supplies are [either furnished solely to promote fertility or] certified as inappropriate, unnecessary or otherwise not authorized by the Commissioner of Health or his or her designee and except as provided in subdivision (b) of this section, include the following:

(i) services of qualified physicians, dentists, nurses, optometrists and other related professional personnel;

(ii) care, treatment, maintenance and nursing services in hospitals, skilled nursing facilities that qualify as, or have applications pending to become, providers in the Medicare program pursuant to title XVIII of the Federal Social Security Act, or other eligible institutions, and health-related care and services in intermediate care facilities, while such institutions and facilities are operated in compliance with applicable provisions of law and to the extent authorized by this Subchapter. However, no medical assistance payment will be authorized for care provided after

December 31, 1977 in skilled nursing facilities which have participated in title XIX since September 1, 1976, but for whom title XVIII certification is still lacking, except for those skilled nursing facilities providing solely pediatric care[.];

(iii) services to ensure improved outcomes of women ages 21 through 44 experiencing infertility, limited to ovulation enhancing drugs, office visits, hysterosalpingogram services, pelvic ultrasounds, and blood testing.

Paragraph 3 of subdivision (g) of Section 505.3 is amended to read as follows:

(3) No payment will be made for any drug which has weight reduction as its sole clinical use[, or for any drug when used to promote fertility]. Payment for drugs used to promote fertility is limited to bromocriptine, clomiphene citrate, letrozole and tamoxifen, when receiving services pursuant to section 505.1(a)(1)(iii) of this Title, and subject to the FDA recommended and/or compendia-supported uses and limitations.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Social Services Law (SSL) section 365-a and Public Health Law (PHL) section 201(l)(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 Objectives:

In 2017, the Legislature added a new paragraph (ee) to subdivision (2) of section 365-a of the SSL, to "include the coverage of a set of services to ensure improved outcomes of women who are in the process of ovulation enhancing drugs, limited to the provision of such treatment, office visits, hysterosalpingogram services, pelvic ultrasounds, and blood testing; services shall be limited to those necessary to monitor such treatment." These regulations implement the change in statute.

Needs and Benefits:

In New York State, women enrolled in Medicaid currently do not have access to insurance coverage for infertility benefits. This regulation implements a recent statutory change to extend Medicaid coverage to provide infertility benefits. Specifically, Section 505.1 of Title 18 is being amended to provide Medicaid eligible women ages 21 through 44 experiencing infertility, access to ovulation enhancing drugs, office visits, hysterosalpingogram services,

pelvic ultrasounds, and blood testing. Section 505.3 is amended to specify which drugs may be covered by Medicaid.

Costs:

As a Family Planning benefit under Medicaid, the cost of this coverage is 90% covered by the federal government, with 5% covered by New York State and 5% covered by local governments. However, because the local share is subject to a spending cap pursuant to Chapter 58 of the Laws of 2005, the State will be responsible for both the State and local share for this benefit, based on current budget projections. The cost to the New York State Medicaid program is expected to be \$5 million annually.

Local Government Mandates:

This rule imposes no mandates upon any county, city, town, village, school district, fire district, or other special district.

Paperwork:

This rule imposes no new reporting requirements, forms, or other new paperwork.

Duplication:

There are no relevant rules or other legal requirements of the Federal or State governments that duplicate, overlap, or conflict with this rule.

Alternatives:

This change conforms with a recent change in statute and, as such, no other alternatives were considered.

Federal Standards:

There are no federal standards associated with this rule.

Compliance Schedule:

Medicaid infertility benefits will be available to eligible members upon publication of the Notice of Adoption in the State Register.

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**STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS FOR SMALL
BUSINESSES AND LOCAL GOVERNMENTS**

A regulatory flexibility analysis is not required for this proposal since it will not impose any adverse economic impact or 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 is not required for this proposal since it will not impose any adverse economic impact or reporting, recordkeeping or other compliance requirements on rural areas. The proposed rules will allow Medicaid eligible women ages 21 through 44 diagnosed with infertility access to ovulation enhancing drugs, blood testing, ultrasounds, and office visits for treatment and monitoring.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A Job Impact Statement is not included because the proposed regulatory amendments will not have an adverse effect on jobs and employment opportunities. The proposed amendments will establish the reimbursement of infertility health care services provided to the New York State Medicaid population of women diagnosed with infertility.

ASSESSMENT OF PUBLIC COMMENT

Public comments were submitted to the NYS Department of Health (DOH) in response to the regulation. The public comment period for this regulation ended on October 22, 2018. The Department received a total of four comments from representatives of the provider community, including The American College of Obstetrics and Gynecology (ACOG), The American Society for Reproductive Medicine, from legal advisors on behalf of managed care insurance plans and Medicaid members. The comments resonated with positive enthusiasm and requests for coverage of assisted reproductive technology.

Three of the four comments were similar and positive, stating that the adoption of these regulations is an obvious benefit to the patients. Two of the four comments requested that the Department define infertility and suggest coverage is expanded to include assisted reproductive technology (ART) such as artificial insemination and in vitro fertilization.

Summarized below is the Department of Health's response to the comments:

COMMENT: A comment received inquired if transmasculine individuals will be able to utilize the infertility services coverage.

RESPONSE: Medicaid infertility benefits will be available to transmasculine individuals between the ages of 21 through 44.

COMMENT: Two comments were requests that infertility be defined.

RESPONSE: The Department will define infertility and include that definition in Medicaid program policy documents, including but not limited to the NYS Medicaid Update.

COMMENT: One comment expressed concern that assisted reproductive technology (ART) such as in vitro fertilization (IVF) and infertility evaluation or treatment for males (testis biopsies and semen analysis) will not be covered by Medicaid.

RESPONSE: Subparagraph (ee) of Section 365-a of Social Services Law as written only authorizes Medicaid coverage of ovulation enhancing drugs and appropriate monitoring of the women who receive ovulation enhancing drugs.

COMMENT: One comment expressed concern about limited formulary (only 4 drugs will be covered to promote fertility) and that the coverage does not include drugs for men.

RESPONSE: Subparagraph (ee) of Section 365-a of Social Services Law as written only authorizes Medicaid coverage of ovulation enhancing drugs and appropriate monitoring of the women who receive ovulation enhancing drugs. The listed drugs have FDA approval and compendia support for use in enhancing ovulation.

COMMENT: One comment expressed concern about excluding coverage for woman ages 45 and older experiencing infertility.

RESPONSE: The approved Medicaid State Plan Amendment limits this coverage to women ages 21 through age 44.