

Non-prescription Emergency Contraceptives Drugs

Effective date: 3/1/17

Pursuant to the authority vested in the Commissioner of Health by section 201(1)(v) of the Public Health Law, sections 363-a(2) and 367-a(9)(b) of the Social Services Law, section 505.3 of Title 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to read as follows, to be effective upon publication of a Notice of Adoption in the New York State Register:

Paragraph (1) of subdivision (b) of Section 505.3 is amended to read as follows:

(1) Drugs may be obtained only upon the written order of a practitioner, except for non-prescription emergency contraceptive drugs as described in subparagraph (i) of this paragraph, and for telephone and electronic orders for drugs filled in compliance with this section and 10 NYCRR Part 910.

(i) Non-prescription emergency contraceptive drugs for females may be obtained without a written order subject to a utilization frequency limit of 6 courses of treatment in any 12-month period.

[(i)] (ii) The ordering/prescribing of drugs is limited to the practitioner's scope of practice.

[(ii)] (iii) The ordering/prescribing of drugs is limited to practitioners not excluded from participating in the medical assistance program.

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, not inconsistent with law, as may be necessary to implement the program. In addition, SSL section 365-a(4) authorizes the Department to adopt regulations specifying certain non-prescription drugs that will be covered under the Medicaid program.

Legislative Objectives:

Section 365-a of the SSL provides for Medicaid coverage of medically necessary medical, dental and remedial care, services and supplies, to the extent that such coverage is authorized in the State Medicaid statutes or in the regulations of the Department.

Needs and Benefits:

The proposed amendments would restore a provision, inadvertently removed from 18 NYCRR § 505.3(b) by a previous regulatory amendment, allowing coverage of non-prescription emergency contraceptive drugs without a written order.

In addition to changing the regulatory language to once again reflect a Medicaid coverage policy that has been in effect since 2007, the proposed amendments would conform to case law and to guidelines issued by the Food and Drug Administration and the Centers for Medicare and Medicaid Services, making non-prescription emergency contraceptive drugs available without age or point-of-sale restrictions.

As a result of the unintentional removal of language from the regulation, paragraph (1) of section 505.3(b) currently provides Medicaid coverage only for drugs obtained upon the written order of a practitioner. The proposed regulation would amend paragraph (1) to restore the exception to this rule with respect to non-prescription emergency contraceptive drugs. In addition, the proposed regulation would renumber subparagraphs (i) and (ii) of paragraph (1) as (ii) and (iii), respectively, and add a new subparagraph (i) to specify that coverage of non-prescription emergency contraceptive drugs for females is subject to a utilization frequency limit of 6 courses of treatment in any 12-month period.

Costs:

Costs for the Implementation of, and Continuing Compliance with this Regulation to Regulated Entity:

There are no direct costs associated with compliance.

Costs to State and Local Government:

This amendment will not increase costs to the State or local government. The proposed amendment would merely conform the regulation to existing policy.

Local Government Mandates:

The proposed regulation imposes no new mandates on any county, city, town or village government; or school, fire or other special district.

Paperwork:

The Department of Health anticipates no additional record keeping requirements.

Duplication:

The proposed regulation does not duplicate, overlap or conflict with any other state or federal law or regulations.

Alternatives:

Because the existing regulation does not conform to current Medicaid policy, as a result of the unintentional removal of language from the regulation in a previous amendment, no alternatives were considered.

Federal Standards:

This amendment does not exceed any minimum standards of the Federal government for the same or similar subject areas.

Compliance Schedule:

The proposed amendment will become effective upon promulgation.

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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.

JOB IMPACT STATEMENT

A Job Impact Statement is not required. The proposed rule will not have an adverse impact on jobs and employment opportunities based upon its nature and purpose. The proposed regulations will allow non-prescription emergency contraceptive drugs to be obtained without a written order. The proposed regulations have no implications for job opportunities.

ASSESSMENT OF PUBLIC COMMENT

The Department received one set of comments during the public comment period from the New York State Academy of Family Physicians.

Comment:

Proposed § 505.3(b)(1)(i) allows recipients to obtain non-prescription emergency contraceptive drugs “subject to a utilization frequency limit of 6 courses of treatment in any 12-month period”. Women should have access to the full spectrum of birth control options to meet their needs. These limitations are contrary to the protection of women’s choice, and should be removed.

Response:

The regulations were not revised to include this change. Emergency contraception is indicated for the prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. Per the U.S. Food and Drug Administration (FDA) approved prescribing information, emergency contraception is not indicated for routine use as a contraceptive. Based on this information, the utilization frequency limit is deemed appropriate.

Comment:

It is recommended that the same provisions be made for the other emergency contraceptive pill, Ella or ulipristal acetate. This medication is effective in women with a BMI over 25, while Plan B is not.

Response:

The regulations were not revised to include this change. This regulation relates to non-prescription emergency contraceptive drugs, as approved by the FDA. Ella or

ulipristal acetate has not been approved by the FDA as a non-prescription drug.

Although it continues to be available when prescribed by a physician, it cannot be made available without a prescription, in accordance with Federal and New York State law.