

Pursuant to the authority vested in the Commissioner of Health by section 365-a of the Social Services Law and section 201(1)(v) of the Public Health 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:

Subdivision (d) of Section 505.3 is amended to read as follows:

(d) Prescription refills.

(1) A written order may not be refilled unless the practitioner has indicated the number of allowable refillings on the order.

(2) No written order for drugs may be refilled more than six months after the date of issuance, nor more than five times within a six month period, with the exception of prescription contraceptives for family planning purposes, which may be filled twelve times within one year after the date of issuance.

(3) Refills must bear the prescription number of the original written order.

Subparagraph (ii) of paragraph (2) of subdivision (e) of Section 505.3 is amended to read as follows:

(e) Prescribed quantities.

(1) Drugs must be ordered in a quantity consistent with the health needs of the patient and sound medical practice.

(2) Dispensing limits for drugs.

(i) Except as provided in subparagraph (ii) of this paragraph, the maximum quantity of

drugs dispensed is limited to the larger of:

(a) a 30 day supply; or

(b) 100 doses. One hundred doses is 100 units of a solid formulation.

(ii) The dispensing limit does not apply to long-term maintenance drugs. Long-term maintenance drugs are:

(a) drugs ordered or prescribed with one or more refills in quantities of a 30-day supply or greater. The quantity ordered or prescribed must be based on generally accepted medical practice. The ordering practitioner must be contacted if dispensing the supply specified in the prescription would result in the medical assistance recipient receiving a quantity of drugs which exceeds the manufacturer's labeling indications; or

(b) drugs ordered or prescribed without refills in quantities of a 60-day supply or greater. The quantity ordered or prescribed must be based on generally accepted medical practice. The ordering practitioner must be contacted if dispensing the supply specified in the prescription would result in the medical assistance recipient receiving a quantity of drugs which exceeds the manufacturer's labeling indications; or

(c) drugs ordered or prescribed for family planning purposes. The quantity ordered or prescribed must be based on generally accepted medical practice. Prescription contraceptives for family planning purposes may be dispensed in a twelve-month supply at one time; or

(d) prescriptions written and dispensed on the official New York State Prescription Form for up to a three-month supply when written in conformity with the Controlled Substance Act (Title IV of Article 33 of the Public Health Law).

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 1974 the legislature amended Section 365-a of the Social Services law to ensure the availability of family planning services and supplies for eligible persons of childbearing age who desire them. The proposed changes to section 505.3 would ensure timely access to prescription contraception, furthering the objectives of SSL 365-a.

Needs and Benefits:

In New York State, a written order for prescription medication for a Medicaid enrollee may not be filled more than 6 months after the date of issuance. This regulation change allows for a written order of prescription contraceptives for family planning purposes to be filled up to 12 months after the date of issuance. Specifically, Section 505.3(d)(2) of Title 18 is being amended to allow for a written order of prescription contraceptives for family planning purposes to be filled twelve times within one year after the date of issuance. Section 505.3(e)(2) is amended to allow for the dispensing of a 12-month supply at once.

Costs:

There is no fiscal impact to the New York State Medicaid program.

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:

A written order of prescription contraceptives for family planning purposes may be filled twelve times within one year after the date of issuance, or may be dispensed as a 12-month supply at once, upon publication of the Notice of Adoption of these regulations.

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm. 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

**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 amendments will allow for a written order of prescription contraceptives for family planning purposes to be filled twelve times within one year after the date of issuance; and will allow for the dispensing of a 12-month supply at once if needed.

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 allow for a written order of prescription contraceptives for family planning purposes to be filled twelve times within one year after the date of issuance; and will allow for the dispensing of a 12-month supply at once if needed.

ASSESSMENT OF PUBLIC COMMENT

Public comments were submitted to the NYS Department of Health (“Department”) in response to this regulation. The public comment period for this regulation ended on 09/24/2018. The Department received 13 comments.

These comments and the Department’s response are summarized below:

Comment: The organizations listed below stated that they fully support the proposed rulemaking in its entirety, and recommended swift adoption. They stated that the proposed regulations are critical due to persistent barriers to contraceptive access for low-income women and women of color. They stated that the proposed regulations will improve access to contraception for Medicaid members, and promote health equity by appropriately aligning the Medicaid program’s policies for the dispensing of contraceptive drugs with the regulations for commercial insurance.

The American College of Obstetricians and Gynecologists (ACOG), District II

Health Care for All New York (HCFANY)

The League of Women Voters of New York State

The National Women’s Law Center

New York Civil Liberties Union (NYCLU)

Physicians for Reproductive Health

Planned Parenthood Empire State Acts (PPESA)

Planned Parenthood of New York City (PPNYC)

Planned Parenthood of the Southern Finger Lakes

PowHer New York

Raising Women's Voices-New York (RWV-NY)

Reproductive Health Access Project

Women's Health and Reproductive Rights (WHARR)

Response: The Department acknowledges the comments in support of the proposed regulation.

No changes were made to the proposed regulation.