

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 State Register:

(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] twelve months after the date of issuance, nor more than [five] eleven times within a [six] twelve-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.]

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 State's Medicaid program.

Legislative Objectives:

The legislative objective is to provide the Department of Health the authority to allow a maximum of 12 fills within one year from the date the prescriber initiates a prescription for the Medicaid Fee-for-Service Program, as it is necessary to implement the State's Medicaid program. Further, the enacted budget of SFY 2021-2022 directs the Department to transition the pharmacy benefit from Managed Care to the Medicaid Fee-For-Service (FFS) program effective April 1, 2023, which will increase the FFS claims by nearly 800%. Additionally, the regulations would align with industry standards for Medicaid Managed Care and Commercial payors. Subsequently, making this change would avoid creating unnecessary burdens to prescribers, patients, and pharmacists. By allowing the prescription to be filled up to 12 times within one year from the prescription's written date, additional refill and prior authorization requests will be reduced, therefore, improving access to medications.

Needs and Benefits:

Section 505.3 describes the administration of the pharmacy benefit for Fee-for-Service (FFS)

Medicaid members. This request is to amend 505.3(d)(2), which limits Medicaid FFS prescriptions to a maximum of five fills within 6 months after the date the prescriber initiates a prescription. Applicable State and federal controlled substance rules regarding fill limits will still apply.

Section 505.3 (d)(2) will be amended to limit Medicaid FFS prescriptions to a maximum of 12 fills within one year from the date the prescriber initiates a prescription. This change will encourage prescriber monitoring and follow up with the patient at the one-year mark, which aligns with standard of practice and it eliminates unnecessary prescriber interruptions and delays at the pharmacy counter. Additionally, with the system improvements that have been implemented since this regulation went into effect, the Department of Health is able to take a more targeted approach to identify potential drug utilization issues so that only those claims for which there is evidence in the patient's claims history of potential drug utilization issues are intervened on, for follow up with the prescriber and/or patient.

Lastly, with the implementation of the SFY 2021-22 budget initiative to transition the pharmacy benefit from Managed Care to the Medicaid FFS Pharmacy program effective April 1, 2023, FFS claims volume will increase from ~12 million paid claims per year to ~90 million paid claims per year. Therefore, it becomes more imperative that regulations align to allow for a seamless transition of refills greater than five to be processed by the Medicaid Fee-For-Service program. Additionally, the regulations would align with industry standards for Medicaid Managed Care and Commercial payors. This would avoid the unnecessary burden of obtaining a new prescription, additional refills and prior authorizations due to the current five refill limitation on

prescriptions, in advance of the transition.

Costs:

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

There are no direct costs associated with compliance.

Costs to State and Local Governments:

This amendment will not increase costs to the State or local government.

Costs to the Department of Health:

This amendment will not increase cost to the Department of Health.

Local Government Mandates:

This amendment will not increase costs to the State or local government.

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:

There is one alternative, follow the regulation as it currently stands; however, this is contrary to current industry standards for prescription refills. This regulatory change supports the pharmacy carve-out and will reduce pharmacy service disruption.

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 publication of a Notice of Adoption in the State Register.

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

**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 does not impose an adverse economic impact on small businesses or local governments, and it does 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 these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are 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 Medicaid FFS patients to have prescriptions written for a maximum of twelve fills within one year from the date written by the prescriber. The proposed regulations have no implications for job opportunities.