

Department of Health

NOTICE OF ADOPTION

Tanning Facilities

I.D. No. HLT-46-19-00003-A

Filing No. 1275

Filing Date: 2021-12-17

Effective Date: 2022-01-05

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

Action taken: Amendment of Subpart 72-1 of Title 10 NYCRR.

Statutory authority: Public Health Law, sections 3551 and 3554

Subject: Tanning Facilities.

Purpose: To prohibit the use of indoor tanning facilities by individuals less than 18 years of age.

Text or summary was published in the November 13, 2019 issue of the Register, I.D. No. HLT-46-19-00003-P.

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

Revised rule making(s) were previously published in the State Register on October 13, 2021.

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

Initial Review of Rule

As a rule that requires a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2025, which is no later than the 3rd year after the year in which this rule is being adopted.

Assessment of Public Comment

The Department of Health (Department) received one comment regarding the proposed amendments to Subpart 72-1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York.

The comment, from the New York State Society of Dermatology and Dermatologic Surgery (NYSSDDS), supports the proposed regulations. The Department acknowledges this support.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Prescription Refills

I.D. No. HLT-01-22-00004-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 505.3(d)(2) of Title 18 NYCRR.

Statutory authority: Public Health Law, section 201(1)(v); Social Services Law, sections 363-a(2) and 367-a(9)(b)

Subject: Prescription Refills.

Purpose: Limits Medicaid FFS prescriptions to a maximum of 12 fills within one year from the date the prescriber initiates a prescription.

Text of proposed rule: 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 refills 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.]

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

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

Public comment will be received until: 60 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, 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.

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.

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.

Office of Mental Health

EMERGENCY RULE MAKING

Covid-19 Masking Program

I.D. No. OMH-40-21-00007-E
Filing No. 1267
Filing Date: 2021-12-15
Effective Date: 2021-12-15

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

Action taken: Addition of Part 556 to Title 14 NYCRR.

Statutory authority: Mental Hygiene Law, sections 7.07, 7.09 and 31.04

Finding of necessity for emergency rule: Preservation of public health and general welfare.

Specific reasons underlying the finding of necessity: The immediate adoption of this rule is necessary for the preservation of health, safety, and welfare.

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal. According to Johns Hopkins' Coronavirus Resource Center, as of July 14, 2021, there have been over 188 million cases and over 4 million deaths worldwide, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions. Given the disproportionate adverse health impacts of COVID-19 for older adults and those with comorbidities, many of whom reside in New York's facilities, it is imperative that these facilities facilitate the appropriate masking of their staff. Based on the foregoing, the Office has made the determination that this emergency regulation is necessary to best protect the residents of New York's facilities.

For all of the reasons outlined above, this rule is being adopted on an Emergency basis until such time as it has been formally adopted through the SAPA rule promulgation process.

Subject: Covid-19 Masking Program.

Purpose: To implement Covid-19 Mask Program.

Text of emergency rule: A new Part 556 titled COVID-19 Mask Requirement, is added to read as follows:

556.1 Background and Intent.

(a) COVID-19 is an unpredictable disease that can cause serious illnesses and death. In response to this increased public health threat, New York must take active steps to prevent and control transmission of COVID-19. The seriousness of the continuing threat and the failure to achieve acceptable vaccination rates through voluntary programs necessitate further action.

556.2 Legal Base.

(a) Section 7.07 of the Mental Hygiene Law charges the Office of Mental Health with the responsibility for seeing that persons with mental illness are provided with care and treatment, and that such care, treatment and rehabilitation is of high quality and effectiveness.

(b) Section 7.09 of the Mental Hygiene Law gives the Commissioner of the Office of Mental Health the power and responsibility to adopt regulations that are necessary and proper to implement matters under the Commissioner's jurisdiction.

(c) Section 31.04 of the Mental Hygiene Law grants the Commissioner of Mental Health the power and responsibility to adopt regulations to effectuate the provisions and purposes of Article 31 of the Mental Hygiene Law, including procedures for the issuance and amendment of operating certificates, and for setting standards of quality and adequacy of facilities.

556.3 Applicability.

(a) This Part applies to:

(1) any provider of services which operates or proposes to operate a facility, or a residential program licensed, certified, designated or funded by the Office of Mental Health,

(2) hospitals, facilities, corrections-based programs, and residential programs operated by the Office of Mental Health.

556.4 Definitions Pertaining to this Part.

(a) Facility shall mean:

(1) a Hospital as defined hereinafter,

(2) a provider of services which operates or proposes to operate a congregate residential program licensed, certified, or funded by the Office of Mental Health, or

(3) an out-patient program licensed, certified, designated or funded by the Office of Mental Health.

(b) Hospital shall mean a hospital named in Mental Hygiene Law section 7.17(b), or operated pursuant to Parts 580, 582, or 590 of this Title, and any provider of services co-located within such hospital campus.

(c) Staff shall mean all persons employed or affiliated with a Facility, whether paid or unpaid, including but not limited to employees, corrections-based staff, members of the medical, nursing, and other treatment staff, contract staff, students, and volunteers, who engage in activities such that if they were infected with COVID-19 they could potentially expose patients to the disease.

556.5 Requirements for All Facilities.

(a) Effective immediately, all Programs shall have policies and procedures in place to ensure all staff, visitors and individuals receiving services regardless of vaccination status wear appropriate masks, consistent with any infection control guidance issued by this Office.

(b) As determined by the Commissioner based on COVID-19 incidence and prevalence, as well as any other public health and/or clinical risk factors related to COVID-19 disease spread, all Hospital and Facility staff, contractors, vendors, visitors, patients, residents, clients, and all other individuals who enter the indoor premises of such Hospital or Facility, must wear masks at all times regardless of vaccination status, except when alone in an office or room, or actively eating or drinking.

(c) For purposes of this section face-coverings shall include, but are not limited to, cloth masks, surgical masks, and N-95 respirators that are worn to completely cover a person's nose and mouth.

(d) Face coverings are not required to be worn by:

(1) children under two years of age,

(2) a person with a disability who cannot wear a mask, or cannot safely wear a mask, for reasons related to the disability, or

(3) a person for whom wearing a mask would create a risk to workplace health, safety, or job duty as determined by an Occupational Health and Safety Administration workplace risk assessment.

556.6 Enforcement.

(a) The Office will enforce the provisions of this Part pursuant to its oversight authority in Mental Hygiene Law Articles 7 and 31.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously submitted to the Department of State a notice of proposed rule making, I.D. No. OMH-40-21-00007-EP, Issue of October 6, 2021. The emergency rule will expire February 12, 2022.

Text of rule and any required statements and analyses may be obtained from: Sara Paupini, Esq., Office of Mental Health, 44 Holland Avenue, Albany, New York 12229, (518) 474-1331, email: regs@omh.ny.gov

Regulatory Impact Statement

(1) Statutory Authority:

(a) Section 7.07 of the Mental Hygiene Law (MHL) charges the Office