

Pursuant to authority vested in the Commissioner of Health by Section 201(1)(v) of the Public Health Law and Sections 363-a and 365-a (2) (g) of the Social Services Law, Section 505.5 of Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended as follows, to be effective upon publication of a Notice of Adoption in the New York State Register:

Subdivision (g) of Section 505.5 of Title 18 is amended to read as follows:

(g) ~~[Benefit-limitations]~~ Defined Benefits. The department shall establish defined benefits ~~[limits]~~ for certain Medicaid services as part of its Medicaid State Plan. ~~[The department shall not allow exceptions to defined benefit limitations. The department has established defined benefit limits on enteral nutritional formulas.]~~

(1) Enteral nutritional formula. Enteral nutritional formulas [is] are a defined benefit through the department's automated authorization system ~~[are limited to coverage]~~ for:

~~[(1) i)~~ tube-fed individuals who cannot chew or swallow food and must obtain nutrition through formula via tube;

~~[(2) ii)~~ individuals with rare inborn metabolic disorders requiring specific medical formulas to provide essential nutrients not available through any other means;

~~[(3) iii)~~ children under age 21 when caloric and dietary nutrients from food cannot be absorbed or metabolized; and

~~[(4) iv)~~ persons with a diagnosis of HIV infection, AIDS, or HIV-related illness, or other disease or condition, who are oral-fed and who:

~~[(i) a)~~ require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index under 18.5 as defined by the Centers for Disease Control, up to ~~[1,000]~~ 1250 calories per day; or

([ii] *b*) require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index under 22 as defined by the Centers for Disease Control and a documented, unintentional weight loss of 5 percent or more within the previous 6 month period, up to [1,000]~~1250~~ calories per day; [or]

([iii] *c*) require total nutritional support, have a permanent structural limitation that prevents the chewing of food, and the placement of a feeding tube is medically contraindicated[.]; or

(d) if approved for oral-fed supplementation, person demonstrates the continued ability to maintain a body mass index of 18.5 to 24.9 while continuing oral-fed supplemental nutrition.

(v) Nutritional needs required over the defined benefit shall be reviewed for medical necessity on a case-by-case basis.

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. In addition, SSL section 365-a(2)(g) authorizes the Commissioner of the Department to establish standards related to enteral formula therapy and nutritional supplements for persons with nasogastric, jejunostomy, or gastrostomy tube feeding, for treatment of an inborn metabolic disorder, or to address growth and development problems in children, or, subject to standards established by the commissioner, for persons with a diagnosis of HIV infection, AIDS or HIV-related illness or other diseases and conditions.

Legislative Objective:

The legislative objective of this authority is to provide supplemental nutrition for the maintenance of a healthy weight for persons with complex medical conditions and severe diseases who require formula therapy or nutritional supplements under Medicaid. This ensures that the nutritional and health needs of vulnerable populations are adequately addressed through appropriate formula therapies and supplements, consistent with established medical standards.

Needs and Benefits:

Enteral nutritional formulas are ordered by practitioners and dispensed by pharmacy or durable medical equipment providers. Medicaid reimburses the cost of enteral formulas for administration via tube, or for oral nutrition when used for treatment of an inborn metabolic disorder, or to address growth and development issues in children, for persons with a diagnosis

of HIV infection, AIDS, or HIV-related illness, or for persons with other diseases and conditions, subject to standards established by the Commissioner of the Department.

The proposed amendment seeks to increase the enteral nutrition defined benefit calorie limit from 1,000 calories to 1,250 calories per day for members who require supplemental nutrition, demonstrate documented compliance with an appropriate medical and nutritional plan of care, and have a body mass index under 22 as defined by the Centers for Disease Control and a documented, unintentional weight loss of 5 percent or more within the previous 6-month period. The change also allows for continuation of oral supplementation for maintaining a healthy weight if approved for an initial weight loss.

Advantages of the proposed amendment to increase the enteral nutrition defined benefit calorie limit threshold from 1,000 calories to 1,250 calories per day for members with qualifying conditions include streamlining approval process for providers and members by reducing administrative burden on healthcare professionals, enhancing efficiency with a more agile approval process for impacted requests, cost savings potential for providers and New York State through reduced manual workload of paper submissions and reviews, and allowing for a broader range of nutritional needs within the automated approval systems.

Costs:

Costs to the State and Local Government:

The changes to the enteral nutrition defined benefit calorie limits are estimated to be cost neutral to Medicaid expenditures due to the current manual review process authorizing requests to exceed calorie limits.

Costs to Private Regulated Parties:

Regulated entities will not incur any costs as a result of this rule.

Costs to the Regulatory Agency:

DOH will incur an estimated cost of \$3,200 to implement necessary changes to the automated phone authorization system and the web-based Enteral Authorization Portal, which process most enteral related authorizations for providers.

Local Government Mandates:

The proposed regulation does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

This amendment will not require additional paperwork for practitioners and dispensers beyond the existing paperwork required to obtain authorizations for providing enteral formula to eligible individuals.

Duplication:

This regulation does not duplicate any existing federal, State, or local government regulation.

Alternatives:

The Department could maintain previously established enteral nutrition defined benefit calorie limits, however the proposed amendment represents a cost-effective means to improve health outcomes, enhance authorization process efficiency, and increase equity and access to healthcare.

Federal Standards:

This amendment does not exceed any minimum standards of the federal government for the same or similar subject areas and does not result in reimbursement by Medicaid at a higher level than established federal reimbursement for enterals.

Compliance Schedule:

It is anticipated that regulated persons would be able to comply with the rule upon publication of a Notice of Adoption in the New York State Register.

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

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment that applies to the enteral nutrition defined benefit calorie limit 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

No rural area flexibility analysis is required pursuant to section 202 bb(4)(a), of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on facilities in rural areas, and it does not impose reporting, record keeping or other compliance requirements on facilities in rural areas.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A job impact statement is not being submitted with rule because it is evident from the nature and purpose of these amendments that the regulation will not have a substantial adverse impact on jobs and/or employment opportunities.