



RULE-MAKING ORDER

CR-103E (July 2011)
(Implements RCW 34.05.350)

Agency: Health Care Authority, Washington Apple Health

Emergency Rule Only

Effective date of rule:

Emergency Rules

- Immediately upon filing.
- Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

- Yes
 - No
- If Yes, explain:

Purpose:

To add prior authorization requirements for providers prescribing thickeners to clients younger than one year of age.

Citation of existing rules affected by this order:

Repealed:
 Amended: 182-554-500
 Suspended:

Statutory authority for adoption: RCW 41.05.021, 41.05.160

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

- That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
- That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.
- That in order to implement the requirements or reductions in appropriations enacted in any budget for fiscal year 2009, 2010, 2011, 2012, or 2013, which necessitates the need for the immediate adoption, amendment, or repeal of a rule, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the fiscal needs or requirements of the agency.

Reasons for this finding:

The FDA has issued a warning not to give infants thickeners, particularly those born prematurely, because there is substantive evidence it puts them at risk of necrotizing enterocolitis. The recommendation is supported by American Academy of Pediatrics. This rule change is intended to follow the FDA's warning. The agency held a public hearing for this rule on January 5, 2016. As a result of comments received at the public hearing, the agency revised the rule. The agency held a 2nd public hearing on December 27, 2016. The agency amended the rule based on public hearing comments and the final rules were filed under WSR 17-08-008, effective May 1, 2017. This filing extends the current emergency filing until the permanent rules become effective.

Date adopted: March 24, 2017

NAME
Wendy Barcus

SIGNATURE

TITLE
HCA Rules Coordinator

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
 STATE OF WASHINGTON
 FILED

DATE: March 24, 2017
TIME: 11:37 AM
WSR 17-08-010

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	_____	Amended	_____	Repealed	_____
Federal rules or standards:	New	_____	Amended	<u>1</u>	Repealed	_____
Recently enacted state statutes:	New	_____	Amended	_____	Repealed	_____

The number of sections adopted at the request of a nongovernmental entity:

New	_____	Amended	_____	Repealed	_____
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The number of sections adopted in the agency's own initiative:

New	_____	Amended	_____	Repealed	_____
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	_____	Amended	<u>1</u>	Repealed	_____
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The number of sections adopted using:

Negotiated rule making:	New	_____	Amended	_____	Repealed	_____
Pilot rule making:	New	_____	Amended	_____	Repealed	_____
Other alternative rule making:	New	_____	Amended	<u>1</u>	Repealed	_____

WAC 182-554-500 Covered enteral nutrition products, equipment and related supplies—Orally administered—Clients twenty years of age and younger only.

(1) The department covers orally administered enteral nutrition products for clients twenty years of age and younger only, as follows:

(a) The client's nutritional needs cannot be met using traditional foods, baby foods, and other regular grocery products that can be pulverized or blenderized and used to meet the client's caloric and nutritional needs;

(b) The client is able to manage their feedings in one of the following ways:

(i) Independently; or

(ii) With a caregiver who can manage the feedings; and

(c) The client meets one of the following clinical criteria:

(i) Acquired immune deficiency syndrome (AIDS). Providers must obtain prior authorization to receive payment. The client must:

(A) Be in a wasting state;

(B) Have a weight-for-length less than or equal to the fifth percentile if the client is three years of age or younger; or

(C) Have a body mass index (BMI) of:

(I) Less than or equal to the fifth percentile if the client is four through seventeen years of age; or

(II) Less than or equal to 18.5 if the client is eighteen through twenty years of age; or

(D) Have a BMI of:

(I) Less than or equal to twenty-five; and

(II) An unintentional or unexplained weight loss of five percent in one month, seven and a half percent in three months, or ten percent in six months.

(ii) Amino acid, fatty acid, and carbohydrate metabolic disorders.

(A) The client must require a specialized nutrition product; and

(B) Providers must follow the department's expedited prior authorization process to receive payment.

(iii) Cancer(s).

(A) The client must be receiving chemotherapy and/or radiation therapy or post-therapy treatment;

(B) The department pays for orally administered nutritional products for up to three months following the completion of chemotherapy or radiation therapy; and

(C) Providers must follow the department's expedited prior authorization process to receive payment.

(iv) Chronic renal failure.

(A) The client must be receiving dialysis and have a fluid restrictive diet in order to use nutrition bars; and

(B) Providers must follow the department's expedited prior authorization process to receive payment.

(v) Decubitus pressure ulcers.

(A) The client must have stage three or greater decubitus pressure ulcers and an albumin level of 3.2 or below; and

(B) Providers must follow the department's expedited prior authorization process to receive a maximum of three month's payment.

(vi) Failure to thrive or malnutrition/malabsorption as a result of a stated primary diagnosed disease.

(A) The provider must obtain prior authorization to receive payment; and

(B) The client must have:

(I) A disease or medical condition that is only organic in nature and not due to cognitive, emotional, or psychological impairment; and

(II) A weight-for-length less than or equal to the fifth percentile if the client is two years of age or younger; or

(III) A BMI of:

(aa) Less than or equal to the fifth percentile if the client is three through seventeen years of age; or

(bb) Less than or equal to 18.5, an albumin level of 3.5 or below, and a cholesterol level of one hundred sixty or below if the client is age eighteen through twenty years of age; or

(IV) Have a BMI of:

(aa) Less than or equal to twenty-five; and

(bb) An unintentional or unexplained weight loss of five percent in one month, seven and a half percent in three months, or ten percent in six months.

(vii) Medical conditions (e.g., dysphagia) requiring a thickener.

(A) The client must be older than one year of age and:

(I) Require a thickener to aid in swallowing or currently be transitioning from tube feedings to oral feedings; and

(II) Be evaluated by a speech therapist or an occupational therapist who specializes in dysphagia. The report recommending a thickener must be in the client's chart in the prescriber's office.

(B) Providers must follow the ~~((department's))~~ agency's expedited prior authorization process to receive payment.

(C) If prescribing for a child younger than one year of age, providers must request prior authorization and:

(I) Include clinical documentation that supports the medical necessity of the request; and

(II) Include the report recommending a thickener from a speech therapist or occupational therapist who specializes in dysphagia.

(d) If four years of age or younger.

(i) The client must:

(A) Have a certified registered dietitian (RD) evaluation with recommendations which support the prescriber's order for oral enteral nutrition products or formulas; and

(B) Have a signed and dated written notification from WIC indicating one of the following:

(I) Client is not eligible for the women, infants, and children (WIC) program; or

(II) Client is eligible for WIC program, but the need for the oral enteral nutrition product or formula exceeds WIC's allowed amount; or

(III) The requested oral enteral nutrition product or formula is not available through the WIC program. Specific, detailed documentation of the tried and failed efforts of similar WIC products, or the medical need for alternative products must be in the prescriber's chart for the client; and

(C) Meet one of the following clinical criteria:

(I) Low birth weight (less than 2500 grams);

(II) A decrease across two or more percentile lines on the CDC growth chart, once a stable growth pattern has been established;

(III) Failure to gain weight on two successive measurements, despite dietary interventions; or

(IV) Documented specific, clinical factors that place the child at risk for a compromised nutrition and/or health status.

(ii) Providers must follow the department's expedited prior authorization process to receive payment.

(e) If five years of age through twenty years of age.

(i) The client must:

(A) Have a certified RD evaluation, for eligible clients, with recommendations which support the prescriber's order for oral enteral nutrition products; and

(B) Meet one of the following clinical criteria:

(I) A decrease across two or more percentile lines on the CDC growth chart, once a stable growth pattern has been established;

(II) Failure to gain weight on two successive measurements, despite dietary interventions; or

(III) Documented specific, clinical factors that place the child at risk for a compromised nutrition and/or health status.

(ii) Providers must follow the department's expedited prior authorization process to receive payment.

(2) Requests to the department for prior authorization for orally administered enteral nutrition products must include a completed Oral Enteral Nutrition Worksheet Prior Authorization Request (DSHS 13-743), available for download at: <http://www1.dshs.wa.gov/msa/forms/eforms.html>. The DSHS 13-743 form must be:

(a) Completed by the prescribing physician, advanced registered nurse practitioner (ARNP), or physician assistant-certified (PA-C), verifying all of the following:

(i) The client meets the requirements listed in this section;

(ii) The client's physical limitations and expected outcome;

(iii) The client's current clinical nutritional status, including the relationship between the client's diagnosis and nutritional need;

(iv) For a client eighteen through twenty years of age, the client's recent weight loss history and a comparison of the client's actual weight to ideal body weight and current body mass index (BMI);

(v) For a client younger than eighteen years of age, the client's growth history and a comparison to expected weight gain, and:

(A) An evaluation of the weight-for-length percentile if the client is three years of age or younger; or

(B) An evaluation of the BMI if the client is four through seventeen years of age.

(vi) The client's medical condition and the exact daily caloric amount of needed enteral nutrition product;

(vii) The reason why the client is unable to consume enough traditional food to meet nutritional requirements;

(viii) The medical reason the specific enteral nutrition product, equipment, and/or supply is prescribed;

(ix) Documentation explaining why less costly, equally effective products or traditional foods are not appropriate;

(x) The number of days or months the enteral nutrition products, equipment, and/or necessary supplies are required; and

(xi) The client's likely expected outcome if enteral nutritional support is not provided.

(b) Written, signed (including the prescriber's credentials), and dated by the prescriber on the same day and before delivery of the enteral nutrition product, equipment, or related supply. This form must not be back-dated; and

(c) Be submitted within three months from the date the prescriber signs the prescription.

(3) Clients twenty years of age and younger must be evaluated by a certified RD within thirty days of initiation of enteral nutrition products and periodically (at the discretion of the certified RD) while receiving enteral nutrition products. The certified RD must be a current provider with the department.