



PROPOSED RULE MAKING

CR-102 (June 2004)

(Implements RCW 34.05.320)

Do **NOT** use for expedited rule making

Agency: Department of Social and Health Services, Health and Recovery Services Administration

- Preproposal Statement of Inquiry was filed as WSR 09-06-080; or
- Expedited Rule Making--Proposed notice was filed as WSR _____; or
- Proposal is exempt under RCW 34.05.310(4).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

Title of rule and other identifying information: (Describe Subject)

The department is amending chapter 388-554 WAC – Enteral Nutrition Program.

Hearing location(s):

Blake Office Park East – Rose Room
4500 – 10th Ave. SE
Lacey, Washington 98503
(One block north of the intersection of Pacific Ave. SE and Alhadeff Lane. A map or directions are available at <http://www.dshs.wa.gov/msa/rpau/docket.html> or by calling 360-664-6094)

Date: **October 27, 2009** Time: **10:00 a.m.**

Submit written comments to:

Name: DSHS Rules Coordinator
Address: PO Box 45850, Olympia WA, 98504-5850
Delivery: 4500 – 10th Ave. SE, Lacey, Washington 98503
E-mail: DSHSRPAURulesCoordinator@dshs.wa.gov
Fax: (360) 664-6185

by
5 p.m. on October 27, 2009

Assistance for persons with disabilities: Contact Jennisha Johnson, DSHS Rules Consultant by October 6, 2009

Date of intended adoption: Not sooner than October 28, 2009 (Note: This is **NOT** the effective date)

TTY (360) 664-6178 or (360) 664-6094 or
by e-mail at johnsil4@dshs.wa.gov

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

See Attachment

Reasons supporting proposal:

This amendment is necessary for the department to fully meet the legislatively mandated appropriation reduction in Chapter 564, Laws of 2009 § 1109 (ESHB 1244) for durable medical equipment (DME) for fiscal years 2010-2011 and to further clarify the Department's coverage policy for enteral nutrition.

Statutory authority for adoption:

Chapter 564, Laws of 2009 § 1109 (ESHB 1244);
RCW 74.04.050, RCW 74.08.090

Statute being implemented:

Chapter 564, Laws of 2009 § 1109 (ESHB 1244)

Is rule necessary because of a:

- | | | |
|-------------------------|------------------------------|--|
| Federal Law? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| Federal Court Decision? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| State Court Decision? | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |

If yes, CITATION:

DATE

August 27, 2009

NAME (type or print)

Stephanie Vaughn

SIGNATURE

TITLE

DSHS Rules Coordinator

CODE REVISER USE ONLY

**OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED**

DATE: September 01, 2009

TIME: 12:11 PM

WSR 09-18-093

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:
None.

Name of proponent: (person or organization) Department of Social and Health Services

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Wendy L. Boedigheimer	PO Box 45504, Olympia WA 98504-5504	(360) 725-1306
Implementation....Maureen Guzman	PO Box 45506, Olympia WA 98504-5506	(360) 725-2033
Enforcement.....Maureen Guzman	PO Box 45506, Olympia WA 98504-5506	(360) 725-2033

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone ()

fax ()

e-mail

No. Explain why no statement was prepared.

The Department analyzed the proposed rule amendments and concludes that they will impose no new costs on small businesses. The preparation of a comprehensive SBEIS is not required.

Is a cost-benefit analysis required under RCW 34.05.328?

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: Maureen Guzman, Enteral Program Manager

Address: DSHS/HRSA/Division of Healthcare Services

PO Box 45506

Olympia WA 98504-5506

phone (360) 725-2330

fax (360) 586-9727

e-mail guzmam@dshs.wa.gov

No: Please explain:

ATTACHMENT to CR 102

Major change

The Department is no longer covering orally-administered enteral nutrition for clients twenty-one years of age and older.

Other changes/updates to the Enteral Nutrition chapter include:

- Reorganized the chapter to mirror other recently reorganized medical program chapters.
- Changed references from “MAA” to the “department.”
- Clarified when the Department will pay for enteral nutrition products.
- Updated the definition for “Women, infants, and children (WIC) program” to match the Department of Health’s current definition.
- Added Children’s Healthcare Programs as defined in WAC 388-505-0210 to the list of eligible clients.
- Clarified that “Emergency Medical Only Programs” are eligible only when the services are necessary to treat the client’s emergency medical condition.
- Removed language that the Department would pay separately for oral enteral nutrition for a client who resides in a nursing facility when the client’s need for enteral nutrition meets 100% of the client’s nutritional needs. Adult family homes, assisted living facilities, boarding homes, or any other residence where the provision of food is part of the per diem rate are required to provide food for their clients.
- Added the “client’s caregiver” as a sufficient person for providers to confirm with whether the client’s next months delivery of authorized orally administered enteral nutrition products is necessary. Current language states that the provider must confirm with the client.
- Clarified that when a client has indicated that he or she is not using the enteral nutrition product as prescribed, in addition to notifying the client’s physician, the provider must also document the notification in the client’s file.
- Clarified what the Department means by a “valid” prescription.
- Clarified that providers must request prior authorization for covered orally-administered enteral nutrition products and tube-delivered enteral equipment and related supplies as required in the chapter or when the clinical criteria is not met. Requests for prior authorization must be submitted to the Department on DSHS 13-743 form [Oral Enteral Nutrition Worksheet Prior Authorization Request].
- Codified expedited prior authorization (EPA) criteria for oral enteral nutrition for clients 20 years of age and younger.
- Created a new noncovered section [WAC 388-554-800] to include orally-administered enteral nutrition for clients 21 years of age and older and nonmedical equipment, supplies, and related services, including but not limited to, back-packs, pouches, bags, baskets, or other carrying containers. The Department does not pay for these items but needed to codify this.

AMENDATORY SECTION (Amending WSR 05-04-059, filed 1/28/05, effective 3/1/05)

WAC 388-554-100 Enteral nutrition ((program))--General.

~~((The medical assistance administration's (MAA's) enteral nutrition program covers the products, equipment, and supplies to provide medically necessary enteral nutrition to eligible medical assistance clients))~~ (1) The department covers the enteral nutrition products, equipment, and related supplies listed in this chapter, according to department rules and subject to the limitations and requirements in this chapter.

(2) The department pays for enteral nutrition products, equipment and related supplies when they are:

(a) Covered;

(b) Within the scope of the eligible client's medical care program;

(c) Medically necessary as defined under WAC 388-500-0005;

(d) Authorized, as required within this chapter, chapters 388-501 and 388-502 WAC, and the department's published billing instructions and numbered memoranda; and

(e) Billed according to this chapter, chapters 388-501 and 388-502, and the department's published billing instructions and numbered memoranda.

(3) The department requires prior authorization for covered enteral nutrition products, equipment and related supplies when the clinical criteria set forth in this chapter are not met, including the criteria associated with the expedited prior authorization process. The department evaluates requests requiring prior authorization on a case-by-case basis to determine whether they are medically necessary, according to the process found in WAC 388-501-0165.

(4) The department evaluates a request for a service that is in a covered category, but has been determined to be experimental or investigational per WAC 388-531-0550, under the provisions of WAC 388-501-0165.

(5) The department terminates a provider's participation with the department according to chapter 388-502 WAC.

AMENDATORY SECTION (Amending WSR 05-04-059, filed 1/28/05, effective 3/1/05)

WAC 388-554-200 Enteral nutrition ((program))--Definitions.

The following terms and definitions and those found in WAC 388-500-0005 apply to ~~((the enteral nutrition program))~~ this chapter:

"BMI" see **"body mass index."**

"Body mass index (BMI)" ~~((is))~~ - A number that shows body

weight ((adjusted by)) relative to height, and is calculated using inches and pounds or meters and kilograms.

"Department" - The department of social and health services (DSHS).

"Enteral nutrition" ((means))- The use of medically necessary nutritional products alone, or in combination with traditional food, when a client is unable to consume enough traditional food to meet nutritional requirements. Enteral nutritional solutions can be given orally or via feeding tubes.

"Enteral nutrition equipment" ((means))- Durable medical feeding pumps and intravenous (IV) poles used in conjunction with nutrition supplies to dispense formula to a client.

"Enteral nutrition product" ((means))- Enteral nutrition formulas and/or products.

"Enteral nutrition supplies" ((means))- The supplies, such as nasogastric, gastrostomy and jejunostomy tubes, necessary to allow nutritional support via the alimentary canal or any route connected to the gastrointestinal system.

"Growth chart" ((is))- A series of percentile curves that illustrate the distribution of select body measurements (i.e., height, weight, and age) in children published by the Centers for Disease Control and Prevention, National Center for Health Statistics. CDC growth charts: United States. <http://www.cdc.gov/growthcharts/>

"Nonfunctioning digestive tract" ((is))- Caused by a condition that affects the body's alimentary organs and their ability to break down ((and)) digest, and absorb nutrients.

"Orally administered enteral nutrition products" ((means)) - Enteral nutrition solutions and products that a client consumes orally for nutritional support.

"Tube-delivery" ((means))- The provision of nutritional requirements through a tube into the stomach or small intestine.

~~((**"WIC program"** (Women, infants and children (WIC) program) is a special supplemental nutrition program managed by the department of health (DOH) that serves to safeguard the health of children up to age five, and low-income pregnant and breastfeeding women who are at nutritional risk by providing them with healthy, nutritious foods to supplement diets, information on healthy eating, and referral to health care.))~~

"Women, infants and children (WIC) program((-))" ((~~See "WIC program."~~)) (Also known as WIC program) - A special supplemental nutrition program managed by the department of health (DOH) that serves to safeguard the health of children up to age five and low-income pregnant and breastfeeding women who are at nutritional risk, by providing them with healthy, nutritious foods to supplement diets, information on healthy eating, and referral to health care.

AMENDATORY SECTION (Amending WSR 05-04-059, filed 1/28/05, effective 3/1/05)

WAC 388-554-300 Enteral nutrition ((program))--Client

eligibility. (1) ~~((Clients in the following medical assistance programs are eligible))~~ To receive oral or tube-delivered enteral nutrition products ((and tube-delivered enteral nutrition products and necessary)), equipment, and related supplies, ((subject to the limitations in this chapter and other applicable WAC)) clients must be eligible for one of the following medical assistance programs:

- (a) ~~Categorically needy program (CN or CNP);~~
- (b) ~~Categorically needy program - state children's health insurance program (CNP-SCHIP) ((same scope of coverage as CNP));~~
- (c) ~~((General assistance - Unemployable (GA-U)))~~ Children's healthcare programs as defined in WAC 388-505-0210;
- (d) ~~Limited casualty program - Medically needy program (LCP-MNP);~~
- (e) ~~((Alien emergency medical program - CNP))~~ General assistance (GAU/ADATSA); and
- (f) ~~((Alien emergency medical program - LCP-MNP))~~ Emergency medical only programs when the services are necessary to treat the client's emergency medical condition.

(2) ~~((All clients younger than age twenty-one must be evaluated by a certified dietitian with a current provider number within thirty days of initiation of enteral nutrition products, and periodically (at the discretion of the certified dietitian) while receiving enteral nutrition products. See WAC 388-554-400 (2)(h) for provider requirements.~~

(3) ~~Clients enrolled in an MAA managed care plan are eligible for oral enteral nutrition products and tube-delivered enteral nutrition products and necessary equipment and supplies through that plan. If a client becomes enrolled in a managed care plan before MAA completes the purchase (or rental, if applicable) of prescribed enteral products, necessary equipment and supplies:~~

- (a) ~~MAA rescinds the purchase until the managed care primary care provider (PCP) evaluates the client; and~~
- (b) ~~The managed care plan's applicable reimbursement policies apply to the purchase of the products, equipment, or supplies, or rental of the equipment, as applicable.~~

(4) ~~To receive orally administered enteral nutrition products, a client must:~~

(a) ~~Have a valid written physician order from a physician, advanced registered nurse practitioner (ARNP), or physician assistant-certified (PA-C) for all enteral nutrition products;~~

(b) ~~When required, have the provider obtain prior authorization as described in WAC 388-554-700;~~

(c) ~~Meet the conditions in this section and other applicable WAC;~~

(d) ~~Be able to manage their feedings in one of the following ways:~~

(i) ~~Independently; or~~

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

(e) ~~Have at least one of the following medical conditions, subject to the criteria listed:~~

(i) ~~Malnutrition/malabsorption as a result of a stated primary diagnosed disease. The client must have:~~

(A) ~~A weight-for-length less than or equal to the fifth percentile if the client is younger than age three; or~~

(B) ~~A body mass index (BMI) of:~~

(I) ~~Less than or equal to the fifth percentile if the client~~

~~is older than age three and younger than age eighteen; or~~
~~(ii) Less than or equal to 18.5 if the client is age eighteen or older.~~
~~(iii) Acquired immune deficiency syndrome (AIDS). The client must be in a wasting state and have:~~
~~(A) A weight-for-length less than or equal to the fifth percentile if the client is younger than age three; or~~
~~(B) A BMI of:~~
~~(i) Less than or equal to the fifth percentile if the client is older than age three and younger than age eighteen; or~~
~~(ii) Less than or equal to 18.5 if the client is age eighteen or older.~~
~~(iv) Amino acid, fatty acid, and carbohydrate metabolic disorders;~~
~~(v) Dysphagia. The client must:~~
~~(A) Need to transition from tube feedings to oral feedings or require thickeners to aid swallowing; and~~
~~(B) Be evaluated by:~~
~~(i) A speech therapist; or~~
~~(ii) An occupational therapist who specializes in dysphagia.~~
~~(vi) Chronic renal failure. The client:~~
~~(A) Must be receiving dialysis; and~~
~~(B) Have a fluid restrictive diet in order to use nutrition bars.~~
~~(vii) Malignant cancer(s). The client must be receiving chemotherapy.~~
~~(viii) Decubitus pressure ulcers. The client must have:~~
~~(A) Stage three or greater decubitus pressure ulcers; and~~
~~(B) An albumin level of 3.2 or below.~~
~~(ix) Failure to thrive. The client must have a disease or medical condition that is only organic in nature and not due to cognitive, emotional, or psychological impairment. In addition, the client must have:~~
~~(A) A weight-for-length less than or equal to the fifth percentile if the client is younger than age three;~~
~~(B) A BMI of less than or equal to the fifth percentile if the client is at least age three but younger than age eighteen; and~~
~~(C) A BMI of 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 or older.~~
~~(5) A client is eligible to receive delivery of orally administered enteral nutrition products in quantities sufficient to meet the client's medically authorized needs, not to exceed a one-month supply. To receive the next month's delivery of authorized products, the client's record must show documentation of the need to refill the products. See WAC 388-554-400 for provider requirements.~~
~~(6) To receive tube-delivered enteral nutrition products, necessary equipment and supplies, a client must:~~
~~(a) Have a valid written physician order from a physician, ARNP, or PA-C;~~
~~(b) Meet the conditions in this section and other applicable WAC; and~~
~~(c) Be able to manage their tube feedings in one of the following ways:~~

~~(i) Independently; or
(ii) With a caregiver who can manage the feedings; and
(d) Have at least one of the following medical conditions,~~
subject to the criteria listed:

~~(i) A nonfunction or disease of the structures that normally permit food to reach the small bowel; or~~

~~(ii) A disease or condition of the small bowel that impairs digestion and absorption of an oral diet, either of which requires tube feedings to provide sufficient nutrients to maintain weight and strength that is properly proportioned to the client's overall health status)) Clients who are enrolled in a department-contracted managed care organization (MCO) must arrange for enteral nutrition products, equipment, and related supplies directly through his or her department-contracted MCO.~~

~~(3) For clients who reside in a nursing facility, adult family home, assisted living facility, boarding home, or any other residence where the provision of food is included in the daily rate, oral enteral nutrition products are the responsibility of the facility to provide in accordance with chapters 388-76, 388-97 and 388-78A WAC.~~

~~(4) For clients who reside in a state-owned facility (i.e. state school, developmental disabilities (DD) facility, mental health facility, Western State Hospital, and Eastern State Hospital) enteral nutrition products, equipment, and related supplies are the responsibility of the state-owned facility to provide.~~

~~(5) Clients who have elected and are eligible to receive the department's hospice benefit must arrange for enteral nutrition products, equipment and related supplies directly through the hospice benefit.~~

~~(6) Children who qualify for supplemental nutrition from the women, infants, and children (WIC) program must receive supplemental nutrition directly from that program unless the client meets the limited circumstances in WAC 388-554-500(1)(d).~~

AMENDATORY SECTION (Amending WSR 05-04-059, filed 1/28/05, effective 3/1/05)

WAC 388-554-400 Enteral nutrition ((program))--Provider requirements. (1) ~~((A provider of all oral enteral nutrition products and tube-delivered enteral nutrition products and necessary equipment and supplies must)) The following providers are eligible to enroll/contract with the department to provide orally-administered enteral nutrition products and tube-delivered enteral nutrition products, equipment, and related supplies:~~

~~(a) ((Have a current core provider agreement with the medical assistance administration (MAA); and~~

~~(b) Be one of the following provider types:~~

~~(i)) Pharmacy provider; or~~

~~((+ii)) (b) Durable medical equipment (DME) provider.~~

~~(2) To ((be paid for oral enteral nutrition products and tube-delivered enteral nutrition products and necessary equipment~~

~~and supplies, an eligible)) receive payment for orally-administered enteral nutrition products and tube-delivered enteral nutrition products, equipment and related supplies, a provider must:~~

~~(a) Meet the requirements in ((WAC 388-502-0020 and other applicable)) chapters 388-501 and 388-502 WAC;~~

~~(b) ((Obtain prior authorization (PA), if required, before delivery to the client and before billing MAA. See WAC 388-554-700 for PA requirements)) Provide only those services that are within the scope of the provider's license;~~

~~(c) ((Deliver orally administered enteral nutrition products in quantities sufficient to meet a client's medically authorized needs, not to exceed a one-month supply)) Obtain prior authorization from the department, if required, before delivery to the client and before billing the department;~~

~~(d) ((Bill MAA for the authorized products and submit a claim for payment to MAA with a date of service being the same as the shipping date)) Deliver enteral nutritional products in quantities sufficient to meet the client's authorized needs, not to exceed a one-month supply;~~

~~(e) Confirm with the client ((and document in the client's record)) or the client's caregiver that the next month's delivery of authorized orally administered enteral nutrition products is necessary ((see WAC 388-554-300(5))) and document the confirmation in the client's file. ((MAA will not reimburse)) The department does not pay for automatic periodic delivery of products;~~

~~(f) ((Notify and inform the client's physician if the client has indicated the product is not being used as prescribed)) Furnish clients with new or used equipment that includes full manufacturer and dealer warranties for at least one year; and~~

~~(g) ((Keep legible, accurate, and complete charts in the client's record to justify the medical necessity of the items provided and include:~~

~~(i) For each item billed, a copy of the prescription. The prescription must:~~

~~(A) Be signed and dated by the prescribing physician;~~

~~(B) List the client's medical condition and exact daily caloric amount of needed enteral product; and~~

~~(C) State the reason why the client is unable to consume enough traditional food to meet nutritional requirements.~~

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

~~(iii) For a client who meets the women, infants and children (WIC) program's target population as defined in WAC 388-554-200, verification from the WIC program that the client:~~

~~(A) Is not eligible for WIC program services;~~

~~(B) Is eligible for WIC program services, but nutritional needs exceed the WIC program's maximum per calendar month allotment; or~~

~~(C) The WIC program cannot provide the prescribed product.~~

~~(h) For a client younger than age twenty-one, retain a copy of each required certified dietitian evaluation, as described in WAC 388-554-300(2).~~

~~(3) MAA may recoup any payment made to a provider for authorized enteral nutrition products if the requirements in subsection (2) of this section and other applicable WAC are not~~

met)) Notify the client's physician if the client has indicated the enteral nutrition product is not being used as prescribed and document the notification in the client's file.

AMENDATORY SECTION (Amending WSR 06-24-036, filed 11/30/06, effective 1/1/07)

WAC 388-554-500 ((Orally administered)) Covered enteral nutrition products, equipment and related supplies--((Coverage, limitations, and reimbursement))Orally-administered--Clients twenty years of age and younger only. (1) ((The enteral nutrition program covers and reimburses medically necessary orally administered enteral nutrition products, subject to:

- (a) Prior authorization requirements under WAC 388-554-700;
- (b) Duration periods determined by the department;
- (c) Delivery requirements under WAC 388-554-400(2); and
- (d) The provisions in other applicable WAC.

(2) Except as provided in subsection (3) of this section, the department does not pay separately for orally administered enteral nutrition products:

(a) When a client resides in a state-owned facility (i.e., state school, developmental disabilities (DD) facility, mental health facility, Western State Hospital, and Eastern State Hospital).

(b) When a client has elected and is eligible to receive the department's hospice benefit, unless both of the following apply:

- (i) The client has a preexisting medical condition that requires enteral nutritional support; and
- (ii) The preexisting medical condition is not related to the diagnosis that qualifies the client for hospice.

(3) The department pays separately for a client's orally administered enteral nutrition products when the client:

- (a) Resides in a nursing facility;
- (b) Meets the criteria in WAC 388-554-300; and
- (c) Needs enteral nutrition products to meet one hundred percent of the client's nutritional needs.

(4) The department does not cover or pay for orally administered enteral nutrition products when the client's nutritional need can 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.

(5) The department:

(a) Determines reimbursement for oral enteral nutrition products according to a set fee schedule;

(b) Considers medicare's current fee schedule when determining maximum allowable fees;

(c) Considers vendor rate increases or decreases as directed by the Legislature; and

(d) Evaluates and updates the maximum allowable fees for oral enteral nutrition products at least once per year.

(6) The department evaluates a request for orally administered

~~enteral nutrition products that are in excess of the enteral nutrition program's limitations or restrictions, according to the provisions of WAC 388-501-0165 and 388-501-0169.~~

~~(7) The department evaluates a request for orally administered enteral nutrition products that are listed as noncovered in this chapter according to the provisions of WAC 388-501-0160)) The department covers orally-administered enteral nutrition products only for clients twenty years of age and younger 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:

(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 expedited prior authorization process to receive payment.

(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 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.

AMENDATORY SECTION (Amending WSR 06-24-036, filed 11/30/06, effective 1/1/07)

WAC 388-554-600 ((~~Tube-delivered~~)) ~~Covered enteral nutrition products, equipment and related ((equipment and)) supplies - - ((Coverage, limitations, and reimbursement))~~ **Tube-delivered.** (1) ((The enteral nutrition program covers and reimburses the following, subject to the limitations listed in this section and the provisions in other applicable WAC:

~~(a) Tube-delivered enteral nutrition products;~~

~~(b) Tube-delivery supplies;~~

~~(c) Enteral nutrition pump rental and purchase;~~

~~(d) Nondisposable intravenous (IV) poles required for enteral nutrition product delivery; and~~

~~(e) Repairs to equipment.~~

~~(2) The department covers up to twelve months of rental payments for enteral nutrition equipment. After twelve months of rental, the department considers the equipment purchased and it becomes the client's property.~~

~~(3) The department requires a provider to furnish clients new or used equipment that includes full manufacturer and dealer warranties for one year.~~

~~(4) The department covers only one:~~

~~(a) Purchased pump per client in a five year period; and~~

~~(b) Purchased nondisposable IV pole per client for that client's lifetime.~~

~~(5) The department's reimbursement for covered enteral nutrition equipment and necessary supplies includes all of the following:~~

~~(a) Any adjustments or modifications to the equipment that are required within three months of the date of delivery. This does not apply to adjustments required because of changes in the client's medical condition;~~

~~(b) Fitting and set-up; and~~

~~(c) Instruction to the client or the client's caregiver in the appropriate use of the equipment and necessary supplies.~~

~~(6) A provider is responsible for any costs incurred to have another provider repair equipment if all of the following apply:~~

~~(a) Any equipment that the department considers purchased requires repair during the applicable warranty period;~~

~~(b) The provider is unable to fulfill the warranty; and~~

~~(c) The client still needs the equipment.~~

~~(7) If a rental equipment the department considers to have been purchased must be replaced during the warranty period, the department recoups fifty percent of the total amount previously paid toward rental and eventual purchase of the equipment delivered to the client. All of the following must apply:~~

- ~~(a) The provider is unable to fulfill the warranty; and~~
- ~~(b) The client still needs the equipment.~~

~~(8) The department rescinds any authorization for prescribed equipment if the equipment was not delivered to the client before the client:~~

- ~~(a) Loses medical eligibility;~~
- ~~(b) Becomes covered by a hospice agency and the equipment is used in the treatment of the terminal diagnosis or related condition(s);~~
- ~~(c) Becomes eligible for a department-contracted managed care plan; or~~
- ~~(d) Dies.~~

~~(9) Except as provided in subsection (10) of this section, the department does not pay separately for tube-delivered enteral nutrition products or necessary equipment or supplies when a client:~~

~~(a) Resides in a state-owned facility (i.e., state school, developmental disabilities (DD) facility, mental health facility, Western State Hospital, and Eastern State Hospital).~~

~~(b) Has elected and is eligible to receive the department's hospice benefit, unless both of the following apply:~~

~~(i) The client has a preexisting medical condition that requires enteral nutritional support; and~~

~~(ii) The preexisting medical condition is not related to the diagnosis that qualifies the client for hospice.~~

~~(10) The department pays separately for a client's tube-delivered enteral nutrition products and necessary equipment and supplies when:~~

~~(a) The client resides in a nursing facility;~~

~~(b) The client meets the eligibility criteria in WAC 388-554-300; and~~

~~(c) Use of enteral nutrition products meets one hundred percent of the client's nutritional needs.~~

~~(11) The department determines reimbursement for tube-delivered enteral nutrition products and necessary equipment and supplies using the same criteria described in WAC 388-554-500(5).~~

~~(12) The department evaluates a request for tube-delivered enteral nutrition products and necessary equipment and supplies that are in excess of the enteral nutrition program's limitations or restrictions, according to the provisions of WAC 388-501-0165 and 388-501-0169.~~

~~(13) The department evaluates a request for tube-delivered enteral nutrition products and necessary equipment and supplies, that are listed as noncovered in this chapter, under the provision of WAC 388-501-0160)) The department covers tube-delivered enteral nutrition products, equipment, and related supplies, without prior authorization, for eligible clients regardless of age, as follows:~~

~~(a) When the client meets the following clinical criteria:~~

~~(i) The client has a valid prescription;~~

~~(A) To be valid, a prescription must:~~

(I) Be written by a physician, advanced registered nurse practitioner (ARNP), or physician's assistant certified (PA-C);

(II) Be written, signed (including the prescriber's credentials), and dated by the prescriber on the same day and before delivery of the supply, equipment, or device. Prescriptions must not be back-dated;

(III) Be submitted within three months from the date the prescriber signs the prescription; and

(IV) State the specific product requested, diagnosis, estimated length of need (months), and quantity.

(ii) The client is able to manage his or her tube feedings in one of the following ways:

(A) Independently; or

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

(iii) The client has at least one of the following medical conditions:

(A) A nonfunction or disease or clinical condition that impairs the client's ability to ingest sufficient calories and nutrients from products orally or does not permit sufficient calories and nutrients from food to reach the gastrointestinal tract; or

(B) A disease or condition of the small bowel that impairs digestion and absorption of an oral diet, either of which requires tube feedings to provide sufficient nutrients to maintain weight and strength that is properly proportioned to the client's overall health status.

(b) With the following limitations:

(i) One purchased pump, per client, in a five-year period; and

(ii) One purchased nondisposable intravenous pole required for enteral nutrition product delivery, per client, per lifetime.

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

(2) The department pays for up to twelve months of rental payments for tube-delivered enteral nutrition equipment. After twelve months of rental, the department considers the equipment purchased and it becomes the client's property.

(3) The department pays for replacement parts for tube-delivered enteral nutrition equipment, with prior authorization, when:

(a) Owned by the client;

(b) Less than five years old; and

(c) No longer under warranty.

AMENDATORY SECTION (Amending WSR 05-04-059, filed 1/28/05, effective 3/1/05)

WAC 388-554-700 Enteral nutrition products, equipment and related supplies--((Prior)) Authorization ((requirements)). (1) ~~((All requests for oral enteral nutrition products, repairs to equipment, and replacement of necessary supplies for tube-delivery of enteral nutrition products require prior authorization as described in this section. See also WAC 388-501-0165.~~

~~(2) When MAA receives an initial request for prior authorization, the prescription(s) for those items cannot be older than three months from the date MAA receives the request.~~

~~(3) MAA may authorize orally administered enteral nutrition products that are listed in MAA's published issuances, including billing instructions and numbered memoranda, only if medical necessity is established and the provider furnishes all of the following information to MAA:~~

~~(a) A copy of the signed and dated physician order completed by the prescribing physician, advanced registered nurse practitioner (ARNP), or physician assistant-certified (PA-C), which includes client's medical condition and exact daily caloric amount of prescribed enteral nutrition product;~~

~~(b) Documentation from the client's physician, ARNP, or PA-C that verifies all of the following:~~

~~(i) The client has one of the medical conditions listed in WAC 388-554-300 (4) (e);~~

~~(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 age eighteen or older, 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 age eighteen, 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 younger than age three; or~~

~~(B) An evaluation of the BMI if the client is older than age three and younger than age eighteen.~~

~~(v) Documentation explaining why less costly, equally effective products or traditional foods are not appropriate (see WAC 388-554-500(4));~~

~~(vi) The client's likely expected outcome if enteral nutritional support is not provided; and~~

~~(vii) Number of days or months the enteral nutrition products, equipment, and/or necessary supplies are required.~~

~~(4) A provider may resubmit a request for prior authorization for oral enteral nutrition products or replacement of necessary supplies for tube-delivery of enteral nutrition products that MAA has denied. MAA requires the provider to include new documentation that is relevant to the request.) The department requires providers to obtain authorization for covered orally-administered enteral nutrition products, and tube-delivered enteral equipment and related supplies as required in this chapter and in published department billing instructions and/or numbered memoranda or when the clinical criteria required in this chapter are not met.~~

~~(a) For prior authorization (PA), a provider must submit a written request to the department as specified in WAC 388-554-500(2).~~

~~(b) For expedited prior authorization (EPA), a provider must establish that the client's condition meets the clinically appropriate EPA criteria outlined in this chapter and in the department's published enteral nutrition billing instructions. The appropriate EPA number must be used when the provider bills the department.~~

(c) Upon request, a provider must provide documentation to the department showing how the client's condition met the criteria for PA or EPA.

(2) Authorization requirements in this chapter are not a denial of service for the client.

(3) When an oral enteral nutrition product or tube-delivered enteral nutrition equipment or related-supply requires authorization, the provider must properly request authorization in accordance with the department's rules, billing instructions, and numbered memoranda.

(4) When authorization is not properly requested, the department rejects and returns the request to the provider for further action. The department does not consider the rejection of the request to be a denial of service.

(5) The department's authorization does not necessarily guarantee payment.

(6) The department evaluates requests for authorization for covered enteral nutrition products, equipment, and related-supplies that exceed limitations in this chapter on a case-by-case basis in accordance with WAC 388-501-0169.

(7) The department may recoup any payment made to a provider if the department later determines that the service was not properly authorized or did not meet the EPA criteria. Refer to WAC 388-502-0100(1)(c).

(8) If a fee-for-service client enrolls in a department-contracted MCO before the department completes the purchase or rental of prescribed enteral nutrition products, necessary equipment and supplies:

(a) The department rescinds the authorization of the purchase or rental;

(b) The department stops paying for any equipment on the last day of the month preceding the month in which the client becomes enrolled in the managed care plan; and

(c) The department-contracted MCO determines the client's continuing need for the equipment and is then responsible for the client.

(9) The department rescinds any authorization for prescribed equipment if the equipment was not delivered to the client before the client:

(a) Loses medical eligibility;

(b) Becomes covered by a hospice agency and the equipment is used in the treatment of the terminal diagnosis or related condition(s);

(c) Becomes eligible for a department-contracted managed care plan; or

(d) Dies.

AMENDATORY SECTION (Amending WSR 05-04-059, filed 1/28/05, effective 3/1/05)

WAC 388-554-800 ~~Noncovered-Enteral nutrition~~ ((program requirements for ~~WIC program-eligible clients~~) ~~products,~~

equipment, and related-supplies. ((Clients who qualify for supplemental nutrition from the women, infants, and children (WIC) program must receive supplemental nutrition through that program. The medical assistance administration (MAA) may cover the enteral nutrition products and supplies for WIC program-eligible clients only when all of the following are met:

(1) The provider requests prior authorization for the enteral nutrition product or supply;

(2) Documentation from the WIC program is attached to the request form that verifies:

(a) The client's enteral nutrition need is in excess of WIC program allocations; or

(b) The WIC program cannot supply the prescribed product; and

(3) The client meets the enteral nutrition program requirements in this chapter)) (1) The department does not cover the following:

(a) Nonmedical equipment, supplies, and related services, including but not limited to, back-packs, pouches, bags, baskets, or other carrying containers; and

(b) Orally administered enteral nutrition products for clients twenty-one years of age and older.

(2) An exception to rule (ETR), as described in WAC 388-501-0160, may be requested for a noncovered service.

(3) When EPSDT applies, the department evaluates a noncovered service, equipment, or supply according to the process in WAC 388-501-0165 to determine if it is medically necessary, safe, effective, and not experimental (see WAC 388-534-0100 for EPSDT rules).

NEW SECTION

WAC 388-554-900 Reimbursement-Enteral nutrition products, equipment, and related-supplies. (1) The department:

(a) Determines reimbursement for enteral nutrition products, equipment, and related-supplies according to a set fee schedule;

(b) Considers medicare's current fee schedule when determining maximum allowable fees;

(c) Considers vendor rate increases or decreases as directed by the legislature; and

(d) Evaluates and updates the maximum allowable fees for enteral nutrition products, equipment, and related-supplies at least once per year.

(2) The department's payment for covered enteral nutrition products, equipment and related supplies includes all of the following:

(a) Any adjustments or modifications to the equipment required within three months of the date of delivery. This does not apply to adjustments required because of changes in the client's medical condition;

(b) Instructions to the client and/or caregiver on the safe and proper use of equipment provided;

(c) Full service warranty;

(d) Delivery and pick-up; and

(e) Fitting and adjustments.

(3) If changes in circumstance occur during the rental period, such as death or ineligibility, the department discontinues payment effective on the date of the change in circumstance.

(4) The department does not pay for simultaneous rental and a purchase of any item.

(5) The department does not reimburse providers for equipment that is supplied to them at no cost through suppliers/manufacturers.

(6) The provider who furnishes enteral nutrition equipment to a client is responsible for any costs incurred to have another provider repair equipment if all of the following apply:

(a) Any equipment that the department considers purchased requires repair during the applicable warranty period;

(b) The provider refuses or is unable to fulfill the warranty; and

(c) The client still needs the equipment.

(7) If the rental equipment must be replaced during the warranty period, the department recoups fifty percent of the total amount previously paid toward rental and eventual purchase of the equipment delivered to the client if:

(a) The provider is unwilling or unable to fulfill the warranty; and

(b) The client still needs the equipment.