



## Memorandum

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**#14-137**

**TO:** WIC Regional Directors  
WIC Local Agency Directors

**FROM:** Amanda Hovis, Director  
Nutrition Education/Clinic Services Unit  
Nutrition Services Section

**DATE:** November 25, 2014

**SUBJECT:** Policy Memo –Revised Policy: *Texas WIC Policy FD:16.0 Approval of Non-Contract Formulas*

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This memo announces revisions to the subject policy as follows. The policy is effective December 1, 2014. At that time they will be posted and you may update your *Policy and Procedures Manual* by accessing the *WIC Website* at:

[http://www.dshs.state.tx.us/wichd/policy/table\\_of\\_contents.shtm](http://www.dshs.state.tx.us/wichd/policy/table_of_contents.shtm)

### Summary of Revisions

*Texas WIC Policy FD:16.0 Approval of Non-Contract Formulas*

- Title change: “Approval of Non-Contract Formulas”.
- Changed definition of Non-Exempt Formulas to Infant Formulas.
- Changed definition of Medical Foods to WIC-eligible Nutritionals (final food rules).
- Clarified that measurements that were taken within 7 days for nutrition assessment is for infants.
- Revised other formula approval considerations - If a comparable contract formula has not been tried since the last approval and no medical contraindication was provided on the *Texas WIC Medical Request for Formula/Food*, a comparable contract formula may be provided *but a prescription may be needed prior to issuance*.
- Added information about the optional form Texas WIC Formula Change Form when switching from non-contract to contract.
- Removed Quick Reference for Formula Approval reference.

If you have any questions or require additional information regarding *Texas WIC Policy FD:16.0 Approval of Non-Contract Formulas*, please contact Sandra Brown, Food Formula Specialist, at [sandra.brown@dshs.state.tx.us](mailto:sandra.brown@dshs.state.tx.us) or (512) 341-4576.

Attachments

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## **Approval of Non-Contract Formulas**

### **Purpose**

To ensure that infant formulas, exempt infant formula and WIC-eligible nutritionals requiring medical documentation are approved for appropriate medical reasons in compliance with WIC regulations

### **Authority**

7 CFR Part 246.10; State Policy

### **Policy**

Non-contract formula may be approved for valid medical conditions when the use of WIC contract formula is contraindicated.

### **Definitions**

Formula(s) – The term “formula(s)” used throughout this policy refers to all contract and non-contract formulas, including milk and soy-based, low-lactose formulas, nutritional beverages, additives such as human milk fortifiers and modular products, nutritional supplements and WIC-eligible nutritionals.

Infant Formula - A routine formula labeled for use by full term, generally healthy infants or toddlers. Such formulas include milk-based, soy-based, low-lactose, or added rice starch products.

Exempt Formula - Therapeutic formula intended and labeled for use by individuals with specific medical and/or dietary conditions.

WIC-Eligible Nutritionals - Certain enteral products that are specifically formulated to provide nutritional support for individuals with a qualifying condition, when the use of conventional foods is precluded, restricted, or inadequate. Such WIC-eligible nutritionals must serve the purpose of a food, meal or diet (may be nutritionally complete or incomplete) and provide a source of calories and one or more nutrients; be designed for enteral

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digestion via an oral or tube feeding; and may not be a conventional food, drug, flavoring, or enzyme (e.g., Pediasure).

Approval Authority - Designated agency staff who are authorized by criteria outlined in this policy to approve formula; e.g., L.V.N., R.N., L.D., R.D., Nutritionist, and other Certifying Authorities (C.A.) as specified in policy CS: 15.0 *Certifying Authority*. Certified WIC Certification Specialists (WCS's) are authorized to approve formula after successful completion of the state WCS formula approval training and with local agency (LA) WIC director and preceptor approval. The Certified WCS must be designated "formula certified" to approve Level 1 formulas.

Health Care Provider (HCP) - Also referred to as "prescriptive authority"; a medical professional who may legally diagnose medical conditions and write prescriptions. In Texas, prescriptive authorities include but are not limited to: medical doctors (M.D.), doctors of osteopathy (D.O.), physician's assistants (P.A.), and nurse practitioners (N.P.).

Prescription(s) - Medical documentation required to approve formula.

### Procedures

- I. Formula approval requirements
  - A. Prescription
    1. Prescription documentation - *The Texas WIC Medical Request for Formula/Food F13-06-13152* (hereafter referred to as Medical Request form), and the *Texas WIC Medical Request for Metabolic Formula/Food* both located at [www.dshs.state.tx.us/wichd/nut/foods-nut.shtm](http://www.dshs.state.tx.us/wichd/nut/foods-nut.shtm) are required to provide medical documentation for formula. LA developed forms are not permitted.
      - a. Incomplete written prescriptions shall be followed up with a phone call to the HCP to obtain any missing information provided the prescription has the signature/ stamp of the prescriptive authority. Missing information shall be documented. The "For WIC use only" section of the Medical Request form may be used to document additional

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- information. The original prescription information shall not be altered.
- b. Verbal prescriptions may be accepted but will be valid for no longer than one month. The verbal information provided shall be recorded on a Medical Request form and faxed to the HCP for their signature. After the verbal prescription is signed by the HCP and received it shall be filed in the participant's chart prior to a second issuance.
  - c. Changes (such as a different formula or a new diagnosis), obtained after discussion with the HCP may be documented in the "for WIC use only" section of the Medical Request form.
  - d. Extending an existing written medical request – A recently expired medical request may be extended by contacting the HCP for verbal approval. This extension may occur once and for up to 6 months under the following select circumstances:
    - i. The previous medical request is no more than 30 days past the expiration date.
    - ii. The diagnosis and formula requested have not changed.
    - iii. Documentation in the "for WIC use only" section of the Medical Request form includes:
      - 1) New length of issuance
      - 2) Name of HCP providing verbal authorization
      - 3) Date of phone conversation
      - 4) Signature of CA
  - e. Faxed/electronic prescriptions are acceptable.
  - f. Requests for formula received on non-WIC forms. Examples include but are not limited to: hospital prescriptions, HCP prescription pad, discharge papers or summaries. These may be accepted if:
    - i. The documents contain all prescription requirements listed in section I.A.2. of this policy or;
    - ii. The participant is an infant less than 6 months of age and supplemental foods are not an option during the

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issuance time frame and all other needed information is available or:

- iii. One of the above documents is presented and the HCP cannot be contacted, the formula may be approved for one month if the document contains at least the following information:
  - 1) Date
  - 2) Hospital name or other identifying information
  - 3) Name of formula
  - 4) Patient or guardian name
  - 5) Reason for issuance can be clearly inferred (e.g.,  $\leq 37$  weeks gestation or birth weight less than or equal to 5lbs. 8oz.)
- g. If a prescription is received that requires additional information, clarification, discussion etc. and the HCP cannot be reached, call the State Agency (SA) formula pager at (512) 499-6814 for assistance, if needed.
- 2. Prescription requirements - Completed written prescriptions include the following information:
  - a. Name of participant
  - b. Name of formula
  - c. Amount needed per day and/or;
  - d. Authorized prescribed amount of formula and/or supplemental foods and their amounts (see Policy *FD: 12.0* for maximum amounts)
  - e. Requested length of issuance
  - f. Medical diagnosis or reason(s) for which formula or food is prescribed
  - g. Contact information of the prescriptive authority
  - h. Signature of the prescriptive authority (signature and/or medical office stamps are acceptable)
  - i. Date prescription was written
- B. Nutrition assessment – The following information shall be included in an assessment and considered for formula approval:
  - 1. Anthropometric measurements – weight and length/height shall be plotted on the growth chart. Measurements can be obtained

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from the HCP. Use the date the measurements were taken to plot on the growth chart.

- a. Measurements obtained from the HCP shall not be older than 30 days for infants, children, and women.
  - b. It is best practice to use measurements that were taken within 7 days for infants.
  - c. Current weight and height may be critical to the care of medically fragile infants or children diagnosed with failure-to-thrive.
  - d. Use professional judgment when deciding whether to use measurements provided that are older than 7 days.
  - e. Contact the formula pager at (512) 499-6814 if measurements are beyond the 30 day timeframe.
  - f. For preterm infants, corrected weight and length for age shall be plotted up until the infant/child is 2 years chronological age.
  - g. If a growth problem is identified during an assessment, the participant's HCP shall be notified (by phone, fax, or letter) if the HCP has not assessed the participant since the formula was last prescribed. A growth problem is defined as weight loss or inadequate or no weight gain or excessive weight gain.
2. Dietary intake/dietary history
  3. Formula history
  4. Pertinent medical history
- C. Length of approval
1. The approval authority shall determine how long a formula shall be issued based on length of time a formula is requested, the participant's health history and nutritional assessment.
  2. A prescription may be approved for the full length of time requested.
  3. It may also be approved for a shorter length of time than requested. The original prescription is still valid if approved for a shorter length of time.

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4. Prescriptions that cross certification expiration dates may be extended for the remaining length of the request at the time of certification.  
**Example:** Neocate Jr. is approved January 2nd for 6 months. The approval time period is January through June. The certification expires at the end of February. Initial issuance is for 2 months (January – February). Four additional months may be issued after the certification is entered in February. No further formula approval is needed at that time.
  5. Specific details on length of issuance can be found in the *Texas WIC Formulary and Medical Reasons for Issuance* (hereafter referred to as the *Texas WIC Formulary*) [www.dshs.state.tx.us/wichd/nut/formula-nut.shtm](http://www.dshs.state.tx.us/wichd/nut/formula-nut.shtm). Additional requirements may apply to specific formulas.
- II. Documentation for formula approval – The *Formula Approval Form* located at: <http://www.dshs.state.tx.us/wichd/nut/foods-nut.shtm> (or locally developed form) shall be used for formula approval documentation.
- A. Texas WIC information network (TWIN) documentation – the following fields shall be entered into TWIN:
    1. Food package code
    2. Formula code
    3. Prescription expiration date (the last day of the month for which the formula is approved)
    4. Restricted supplemental foods shall be refused if appropriate
  - B. Participant record documentation
    1. Name of the appropriate LA or SA staff approval person
    2. Date the formula is approved
    3. Reason(s) for denial, if appropriate
    4. Notification of denial, if applicable
    5. Any additional useful information to support approval or denial of formula
  - C. Notifying HCP – Staff shall notify the HCP if the requested formula cannot be issued or is not approved by WIC. This notification may be by phone, fax or email.

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- D. Other formula approval considerations
1. When a formula has been prescribed for a valid medical condition, do not challenge with or issue a different formula without first obtaining approval from the prescriptive authority.  
**Example:** Neocate DHA/ARA was prescribed for severe multiple allergies including cow and soymilk allergies. Do not issue a protein hydrolysate (e.g., Nutramigen LGG) without HCP approval.
  2. A participant does not need to be challenged on contract formula prior to issuing an exempt formula/WIC-eligible nutritional.  
**Example:** Nutramigen LGG was prescribed for cow milk allergy. A trial of contract soy formula does not need to occur first. Requests for standard milk or soy-based non-contract formula shall follow the challenge guidelines indicated in the *Texas WIC Formulary*.
  3. If a comparable contract formula has not been tried since the last approval and no medical contraindication was provided on the *Texas WIC Medical Request for Formula/Food*, a comparable contract formula may be provided but a prescription may be needed prior to issuance.
  4. When a participant requests to change from a non-contract formula to a contract formula and has a current valid prescription:
    - a. Verify the change with the HCP that wrote the original prescription. This may be accepted verbally.
    - b. If the HCP cannot be reached, inform the HCP of the formula change via fax. The faxed form used to inform the HCP must include:
      - i. Name of participant and date of birth
      - ii. Clinic name and contact information
      - iii. The names of the current formula and the new formula requested
      - iv. A signed statement from the participant indicating acknowledgement of the requested formula change

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- c. One final month of the original formula may be provided pending any possible medical objections from the HCP.
    - d. An optional form has been created for this purpose. It is entitled "Texas WIC Formula Change Form" and can be found at: <http://www.dshs.state.tx.us/wichd/nut/foods-nut.shtm>
  - 5. Prematurity classification – If the HCP does not write "prematurity or low birth weight" as the diagnosis for a formula typically requested for an infant less than or equal to 37 weeks gestation assume that prematurity is the diagnosis.
  - 6. Special accommodations for an assessment shall be offered to families with special health care needs (refer to Policy CR: 07.0). If a physical presence waiver is in place, use the most recent measurements when available.
- III. WIC staff formula approval authority information
  - A. Reference materials can be found at <http://www.dshs.state.tx.us/wichd/nut/foods-nut.shtm>. The following documents shall be referred to when approving formula:
    - 1. *Texas WIC Formulary* – The formulary includes:
      - a. Reasons for issuance
      - b. Packaging
      - c. Maximum length of issuance
    - 2. *Formula Maximum Quantity Table* – For maximum quantities of formula by age and feeding option
    - 3. *Formula Code List* – For formula codes and other information regarding packaging and ordering formula
  - B. LA Approvals (Levels 1 – 3)
    - 1. Approval authorities shall approve any formula listed in the *Texas WIC Formulary* (with the exceptions listed in Section III.C.) under the following conditions:
      - a. Prescription is complete, signed and does not require any clarification by the HCP.
      - b. Qualifying condition or medical reason is the same as that listed in the *Texas WIC Formulary*.
    - 2. If the formula is requested for a reason not found in the Texas WIC formulary, consult with a LA RD or SA.

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3. The LA RD, using professional judgment, may approve a Level 1-3 formula (with the exception of metabolic formulas) for valid medical reasons **not** listed in the *Texas WIC Formulary*. Documentation of the reason for approval is required.  
**Example:** The following situation would be outside the guidelines for this formula as described in the Texas WIC Formulary - EnfaCare request for a 10 month old infant, born at 34 weeks gestation who was 4 lbs. at birth, developmentally delayed and not eating baby food. The LA RD could make a determination and decision without contacting the SA for approval. A brief description of the reason for the decision is to be included in the formula approval documentation.
  4. Formulary approval exceptions by LA RD's may not conflict with other policy restrictions.  
**Example:** Enfamil AR RTU due to intolerance symptoms on powder is in conflict with *FD: 15.0 Issuance of Ready-to-Use Formula*. Such medical exceptions are to be referred to SA formula approval staff.
  5. If information is missing on the Medical Request form, appropriate LA staff shall contact the HCP to obtain the information.
  6. If the missing information is limited to length of issuance, date, or signature, any staff member may call the HCP or fax back the request to be signed.
  7. If any other aspect of the request requires discussion with the HCP, refer to the LA nutritionist, RD or SA for guidance before calling the HCP.
  8. WCS may not contact the HCP to discuss or clarify requests unless so directed by a CA.
- C. SA Approval (Level 4) – For Level 4 requests, contact the SA before contacting the HCP.
1. Formulas that require state office approval are indicated in the *Texas WIC Formulary* as Level 4. These include but are not limited to:
    - a. First time metabolic requests

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- b. Human milk fortifiers (HMF)
- c. 24 calorie ready-to-use (RTU) formulas for premature infants
- 2. The SA shall also be contacted:
  - a. When a LA RD is not available
  - b. When prescribed formula is:
    - i. prescribed for reasons other than those listed in the *Texas WIC Formulary* and the LA RD needs assistance;
    - ii. not listed in the *Texas WIC Formulary* and/or;
    - iii. not described in any guidelines or memos issued by the SA
  - c. For consultation or technical assistance any time.