



Memorandum

#16-090

TO: WIC Regional Directors
WIC Local Agency Directors

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

DATE: September 23, 2016

SUBJECT: revisions to WIC Policies *FD 13.0: Issuance of Contract Infant Formula, FD 16.0: Approval of Non-Contract Formulas, and FD 16.1: Issuance of Formula Food Packages.*

This memo announces revisions to WIC Policies *FD 13.0: Issuance of Contract Infant Formula, FD 16.0: Approval of Non-Contract Formulas, and FD 16.1: Issuance of Formula Food Packages.* These policy revisions have been made per USDA and reviewed by TALWD. The revised policies are effective October 1, 2016, monitoring will begin April 1, 2017, and reflect the following changes:

Summary of Changes

- 1) Policy Changes – for all 3 policies: Added non-contract infant formula definition and further clarified the definition for infant formula.
 - a. FD 13.0 – Issuance of Contract Formulas
 - i. Removed “Standard” from policy title and purpose
 - ii. Removed definition of “medical home” since it isn’t mentioned in the policy
 - iii. Under section on Alternate contract formula with prescription removed references to non-contract infant formula and side 1 and 2 references for the prescription form
 - iv. Addressed in-state transfers receiving an alternate contract formula requiring a prescription and provided guidance for issuing
 - v. Added some clarifying statements about trials and retrials of contract formula before issuing non-contract infant formula (when preconditions are met)
 - b. FD 16.0 – Approval of Non-Contract Formulas
 - i. Under “Approval Authority” changed reference to the type of formulas that can be approved by a WCS to “as designated in the Texas WIC Formulary” rather than Level 1

- ii. Under the section describing “Verbal Prescriptions” clarified under what circumstances they can be accepted and for how long
- iii. Limited prescription extensions to exempt/WIC eligible nutritionals only
- iv. Explained when a complete nutrition assessment is required. Referred staff to the Texas WIC Formulary for more details for specific formulas
- v. Clarified that at a minimum, approval of all non-contract formula requests require a review of formulas tried with symptoms
- vi. Added a section specific to approval of non-contract infant formula (when allowed)
 - 1. Moved sections referring to changes from non-contract infant formula back to contract formula to this section
 - 2. Eliminated the required contract formula retrial every 3 months. Instead, a retrial is required at the end of the RX period
- c. FD 16.1 – Issuance of Formula Food Packages
 - i. Removed “Requiring Medical Documentation” from the policy title
 - ii. Removed section referring to 6-11 months formula only food package which was discontinued
 - iii. Removed section on infant formula for religious eating patterns since non-contract infant formulas will not be authorized for newly enrolled Texas WIC participants
 - iv. Revised wording for transfers in all situations - out of state, in-state as well as prescriptions from other states

If you have any questions or require additional information regarding *Texas WIC Policies FD 13.0, 16.0, or 16.1*, please contact Sandra Brown, WIC Team Lead Formula/Food Specialist, Nutrition Education and Clinic Services Unit, at Sandra.Brown@dshs.state.tx.us or (512) 341-4576.

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Effective October 1, 2016

Policy No. FD:13.0

Issuance of Contract Infant Formula

Purpose

To ensure that participants needing milk-based and soy-based infant formula receive contract formula.

Authority

State Policy; 7CFR Part 246.10 (c)

Policy

Infants who receive formula shall be issued contract formula except in cases where a contract formula would be contraindicated and non-contract formula has been prescribed for valid medical reasons. Contract formula may be issued to participants older than one year of age for valid medical reasons.

Definitions

Infant formula – Also defined as non-exempt formula. A routine formula labelled for use by full term, generally healthy infants. Such formulas include but are not limited to; milk-based, soy-based, low-lactose or added rice starch products. Infant formula may be contract or non-contract.

Primary contract infant formula – The specific infant formula for which manufacturers submit a bid to a State Agency in response to a rebate solicitation and for which a contract is awarded by the State Agency as a result of that bid.

Alternate contract infant formula – Formulas other than the primary contract infant formulas available as a result of a rebate contract awarded by a State Agency.

Non-contract infant formula – Infant formula not covered under the current rebate contract for Texas WIC.

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Procedures

- I. Contract milk-based infant formula - The primary contract milk-based infant formula shall be issued to infants unless:
 - A. An infant is already using the contract soy formula and the parent/guardian wants to continue on that formula; or
 - B. An infant is experiencing difficulties with the formula and the parent/guardian is requesting a trial with the contract soy formula.
 - C. There is a request from the health care provider (HCP) for a different formula for medical reasons, (e.g. protein hydrolysate such as Alimentum for cow's milk protein allergy).

- II. Contract soy-based infant formula – The primary contract soy-based infant formula shall be issued to infants in cases where:
 - A. The family follows a vegan (vegetarian, no dairy) diet and requires soy formula; or
 - B. There is a strong family preference and/ or caregiver request for soy formula; or
 - C. There is a prescription from an infant's health care provider for a soy-based formula for a valid medical reason (e.g. cow's milk allergy, galactosemia).

- III. Guidelines for handling reported symptoms of intolerance
 - A. If intolerance to any of the contract formulas is reported, assess whether symptom(s) of intolerance may be caused by errors in feeding, preparation, and/or storage. If symptoms appear to be due to these errors, provide appropriate counseling.
 - B. If symptoms appear to be due to a common infant problem such as spitting up, fussiness, constipation, etc., provide appropriate counseling and educational material(s).
 - C. If a parent/guardian reports symptoms of diarrhea, bloody stools, vomiting, fever, or if an infant has weight loss, poor or no weight gain, a referral shall be made to the infant's healthcare provider. Document the referral in the participant's record.

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- D. A contract formula with prescription may be recommended to address the infant's symptoms.
- IV. Alternate contract formula with prescription
- A. An alternate contract milk-based infant formula shall be issued by prescription only, to infants where;
 - i. An infant has tried a primary contract formula and is experiencing intolerance symptoms such as but not limited to: colic, gas, constipation, vomiting or diarrhea.
 - ii. An infant has a medical contraindication which prevents a trial of a primary contract infant formula.
 - B. Medical Request Documentation
 - i. Completion of the Texas WIC Medical Request for Formula/Food form by the HCP permits a one-time request for up to the infant's first birthday.
 - ii. If a different form is presented, it can be accepted but the length of issuance, diagnosis and trial of a primary contract formula or medical contraindication must be documented.
 - iii. Measurements, dietary and medical assessments are not needed to approve alternate contract formulas.
 - C. Approval Authority
 - i. Certifying Authorities (CA) – Any CA may approve requests for contract formulas requiring a prescription.
 - ii. WIC Certification Specialist (WCS)
 - 1. If a completed Texas WIC Medical Request for Formula/Food form for an alternate contract formula is presented it may be approved.
 - 2. If another prescription form is presented or if the form is incomplete, refer the request to a CA for approval.
 - D. In-State Transfers – If a participant received an alternate contract formula with prescription and transfers to another local clinic in Texas, the gaining clinic may use the RX expiration date available in TWIN for future issuance. Example: An infant born 1/15/16 has a prescription for Similac Sensitive which was approved through the first birthday (expiration date 1/14/17).

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The gaining clinic can continue to issue until 1/14/17 based on the information from the losing clinic's TWIN data. A new prescription is not needed.

- V. Contract formula retrials prior to issuing/approving non-contract infant formula to participants that meet guidelines listed in Policy FD: 16.0 Approval of Non-Contract Formulas.
 - A. Contract formula retrials may be waived with documentation for medical contraindications such as:
 - i. Acute or chronic illness or injury/disability
 - ii. Recent or pending hospitalization or surgery
 - iii. Weight loss, failure to gain weight, and FTT
 - iv. Severe intolerance symptoms like vomiting, diarrhea, blood in the stool, etc.
 - v. Foster care placement
 - B. A primary contract formula retrial shall be met by one or more of the following options:
 - i. Documented adverse reaction(s) to the primary contract formula within the past 30 days. Verbal declaration by the parent/guardian is acceptable.
 - ii. A trial can be waived due to medical contraindications (see Procedure V. A. above).
 - C. An alternate contract formula (instead of the primary contract formula) may be offered for a retrial if the HCP provides medical documentation.
- VI. Issuance of contract formula to a participant older than one year of age requires a prescription, assessment, documentation and approval as described in Policy FD: 16.0 Approval of Non-Contract Formulas.
- VII. Concentrating (or altering standard dilution of) primary contract formula
 - A. A request from a prescriptive authority is required for WIC staff to provide instructions for mixing formula to concentrations other than the standard dilution. It is not necessary to contact the state office for approval to provide mixing instructions for contract formula. Document that mixing instructions were provided by WIC staff as requested by the HCP.

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- B. Mixing instructions for concentrating the primary contract formulas to 22, 24, 27, and 30 kcal/oz. can be accessed at: <http://dshs.texas.gov/wichd/nut/foods-nut.shtm>
- C. The maximum amount of formula issued shall not be increased due to the reduced volume resulting from concentration.
- D. Contact the formula pager at (512) 499-6814 for other issues related to formula dilution.

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Approval of Non-Contract Formulas

Purpose

To ensure that infant formulas, exempt 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 – Also defined as non-exempt 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. Infant formula may be contract or non-contract.

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

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

Non-Contract Infant Formula—Infant formula not covered under the current rebate contract for Texas WIC.

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 selected formulas as designated in the Texas WIC Formulary.

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 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*
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Metabolic Formula/Food both located at <http://dshs.texas.gov/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 in the "For WIC use only" section of the Medical Request form. The original prescription information shall not be altered.
- b. Verbal prescriptions are acceptable. Record the information that is received verbally on a Medical Request form and fax it to the HCP for a signature. Staff may accept the verbal RX and issue the requested formula for one month. After the signed form is received back from the HCP, the formula may continue to be issued for the length of time requested as specified in the Texas WIC Formulary. The Medical Request form shall be filed in the participant's chart.
- 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 for exempt formulas/WIC eligible nutritionals only 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.

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- 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. Non-WIC forms shall be official documents from the prescribing entity such as: hospital prescriptions, HCP prescription pad, discharge papers or summaries. These may be accepted if:
 - i. The documents contain all prescription requirements listed in section IA.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 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., ≤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
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- cannot be reached, call the State Agency (SA) formula pager at (512) 499-6814 if needed, for assistance.
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 Food Packages* 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 –
1. A complete nutrition assessment is required under the following circumstances:
 - a. When weight gain or growth need to be monitored.
Examples: Neosure or Enfacare for prematurity or low birth weight, and Pediasure or Kid Essentials for failure to thrive, etc.
 - b. When staff contact State Agency (SA) staff for a formula approval decision. This includes State Approval formulas excluding metabolic formulas.
 2. The following information shall be included in a nutrition assessment (when one is completed) and considered for the formula approval decision:
 - a. Anthropometric measurements – weight and length/height shall be plotted on the growth chart. Measurements can be
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- obtained from the HCP. Use the date the measurements were taken to plot on the growth chart.
- i. Measurements obtained from the HCP shall not be older than 30 days for infants, children, and women.
 - ii. It is best practice to use measurements that were taken within 7 days for infants.
 - iii. Current weight and height may be critical to the care of medically fragile infants or children diagnosed with failure-to-thrive.
 - iv. Use professional judgment when deciding whether to use measurements provided that are older than 7 days.
 - v. Contact the formula pager at (512) 499-6814 if measurements are beyond the 30 day timeframe.
 - vi. For preterm infants, corrected weight and length for age shall be plotted up until the infant/child is 2 years chronological age.
 - vii. 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, inadequate or no weight gain, or excessive weight gain.
- b. Dietary intake/dietary history (as needed for the approval decision)
 - c. Formula history
 - d. Pertinent medical history (as needed for the approval decision)
3. At a minimum, all non-contract formula approval requests shall include a formula history which consists of a review of formulas tried and symptoms experienced.
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4. Refer to the *Texas WIC Formulary* for the nutrition assessment requirements for each specific formula.
- 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 nutrition assessment (if completed).
 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.
 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* located at:
<http://dshs.texas.gov/wichd/nut/foods-nut.shtm>. Additional requirements may apply to specific formulas.
- II. Documentation for formula approval – The *Formula Approval Form* located at: <http://dshs.texas.gov/wichd/nut/foods-nut.shtm> (or locally developed form) may be used for formula approval documentation when indicated.
- A. Texas WIC information network (TWIN) documentation – the following fields shall be entered into TWIN:
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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.
 - D. Other formula approval considerations
 1. When an exempt formula/ WIC eligible nutritional 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.
 3. Prematurity classification – If the HCP does not write “prematurity or low birth weight” as the diagnosis for a formula
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typically requested for an infant less than or equal to 37 weeks gestation assume that prematurity is the diagnosis.

4. 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, if needed.

III. Approval of non-contract infant formula – Refer to the form “*Non-Contract Infant Formula Approval Guidance*” and/or the policy sections A-E below.

- A. New Texas WIC participants born (or initially certified) on or after 10/1/16 will no longer be eligible to receive non-contract infant formulas.
- B. Participants previously prescribed these formulas may continue to be eligible for them if they meet the following criteria:
 1. Date of birth (DOB) (or initially certified) on or prior to 9/30/16.
 2. Previous issuance of a non-contract infant formula from Texas WIC.
 3. Presentation of a completed prescription form with one or more qualifying medical conditions.
- C. After evaluation and approval by appropriate LA or SA staff, the formula may be issued until the prescription expiration date.
- D. Evaluation consists of review of the prescription form and comparison with the latest version of the *Texas WIC Formulary*.
- E. Contract formula retrials are no longer required every 3 months. Instead, a trial of contract formula is required after the end of the prescription expiration date, unless medically contraindicated.

Example: Enfamil AR was issued and approved prior to 10/1/16. A new RX was presented on 10/10/16 for 6 months (no benefits in hand). The retrial is now required in March 2017 prior to the next approval time period which begins in April 2017.

1. If a contract formula has not been tried since the last approval and no medical contraindication was provided, a primary
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contract formula or an alternate contract formula (with complete and valid prescription) may be provided.

2. If a contract formula has not been tried since the last approval and the parent or guardian refuses a retri al, contact the HCP for permission for a retri al or a medical contraindication to refuse the retri al.
3. If a participant requests to change from a non-contract infant formula to a contract infant formula and has a current valid prescription for the non-contract infant formula:
 - a. Attempt to 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.
 - 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://dshs.texas.gov/wichd/nut/foods-nut.shtm>.

IV. WIC staff formula approval authority information

- A. Reference materials can be found at <http://dshs.texas.gov/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. Description of product
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- c. Maximum length of issuance
 - d. Nutrition assessment instructions
 - 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
 - 1. Approval authorities shall approve any formula listed in the *Texas WIC Formulary* (with the exceptions listed in Section IV.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.
 - 3. The LA RD, using professional judgment, may approve these formulas (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 13 month old child, 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.
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Example: Similac Sensitive 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– For formulas requiring SA approval per the *Texas WIC Formulary* contact the SA before contacting the HCP.
1. Formulas that require state office approval are indicated in the *Texas WIC Formulary*. These include but are not limited to:
 - a. First time metabolic requests
 - b. Human milk fortifiers (HMF)
 - c. 24 calorie or higher ready-to-use (RTU) formulas for premature infants
 - d. Modular products
 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;
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c. For consultation or technical assistance any time.

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Policy No. FD:16.1

Issuance of Formula Food Packages

Purpose

To ensure that Texas WIC participants receive the infant formula, exempt formula, WIC-eligible nutritionals and supplemental foods that meet their nutritional needs.

Authority

7 CFR Part 246.10; State Policy

Policy

WIC participants may be issued non-contract formula 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 infant formulas, nutritional beverages, additives such as human milk fortifiers and modular products, nutritional supplements and WIC-eligible nutritional products.

Infant Formula – Also defined as non-exempt formula. A routine formula labeled for use by full term, generally healthy infants or toddlers. Such formulas include milk and soy-based, low-lactose, or added rice starch products. Infant formula may be contract or non-contract.

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

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

Approval Authority - Designated agency staff who are authorized 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 selected formulas as designated in the Texas WIC Formulary.

Non-Contract Infant Formula – Infant formula not covered under the current rebate contract for Texas WIC.

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 assistants (P.A.), and nurse practitioners (N.P.).

Medical Home - A healthcare professional or healthcare clinic that provides comprehensive medical care. Comprehensive care includes care of patients with illnesses and injuries, well-child exams, immunizations, and referrals for specialty care.

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

Procedures

- I. General requirements for the issuance of non-contract formula
 - A. Valid prescription approved by appropriate approval authority.
 - B. Food package, formula code, formula quantity, food(s) to omit and the formula expiration date determined by the appropriate approval authority.
 - C. Appropriate documentation provided in TWIN and participant chart. Reference materials can be found at: <http://dshs.texas.gov/wichd/nut/foods-nut.shtm>. The following documents shall be referred to when issuing formula:
 - 1. *Texas WIC Food Package Guide*
 - 2. *Formula Code List*
 - 3. *Texas WIC Formula Maximum Quantity Table*
- II. Formula and Food Package Issuance Information
 - A. *6-11 Months RX More Formula Only Package*
 - 1. Infants six months of age or older, whose medical condition (e.g., developmental delay) prevents them from consuming supplemental infant foods, are eligible to receive formula at the same monthly allowance as provided to infants ages 4 through 5 months.
 - 2. *The RX More Formula Only* food package shall be prescribed to those participants for whom the HCP has indicated "formula only", or has marked to omit both infant cereal and infant fruits/vegetables on the Medical Request form.
 - a. Developmentally delayed, premature and/or tube fed infants for whom the HCP has not indicated "formula only", shall be

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scheduled to return to the clinic no earlier than 3 months of age, but before 6 months of age to determine the appropriate food package to issue after they turn 6 months of age.

- b. *The RX More Formula Only* food package may be issued once staff receives this information from the HCP. This food package may be issued prior to 6 months of age.
- c. If supplemental food authorization cannot be obtained from the HCP, do not issue supplemental food or the RX More Formula Only food package instead, issue the standard 6-11 months formula food package and refuse the supplemental foods.

B. Formula Food Packages for Children and Women

- 1. Formula Only Food Package – Choose this package if all foods are to be omitted due to the child’s medical condition. No additional formula is provided in the absence of supplemental food.
- 2. Formula with Infant Cereal and Baby Food – This package provides the following foods:
 - a. Formula
 - b. Juice
 - c. Infant cereal
 - d. Fruits and vegetables cash value or baby fruits and vegetables. Parent/guardian may choose in consultation with staff.
- 3. Not all combinations of formula and food options are available. Choose the food package option that is closest to meeting the medical/nutritional needs of the child or woman. Individual supplemental foods can be refused at issuance if they are not needed or wanted by the participant and/or HCP.

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C. Metabolic Formula Approval and Issuance

1. Products prescribed for inborn-errors of metabolism (e.g., PKU) require a completed *Texas WIC Medical Request for Metabolic Formula/Food* from a DSHS approved metabolic center. This form is available on the web at:
<http://dshs.texas.gov/wichd/nut/foods-nut.shtm>
2. WIC staff are not to issue metabolic products to participants until their diagnosis has been confirmed by a metabolic geneticist. A list of recognized metabolic centers and metabolic dietitians can be found at: <http://dshs.texas.gov/wichd/nut/foods-nut.shtm>. Initial requests for metabolic products require state agency (SA) approval. Subsequent requests may be approved by a CA provided that the Metabolic Request form is completely filled out as described in II.C. 1 - 2 above.
3. Families with members who have metabolic disorders shall be given the option to participate in nutrition education, but are not required to do so. WIC staff shall not provide any individual counseling regarding appropriate metabolic diets for participants with metabolic disorders. Refer to WIC Policy *CR: 07.0 Provision of Services to Families with Special Health Care Needs*.

D. Concentrated Non-Contract Formulas

1. Federal regulations set a maximum formula allowance that cannot be exceeded regardless of the prescribed concentration rate.
 2. Refer to a LA RD or call the SA for technical assistance related to altering the standard dilution of non-contract formulas. The parent/guardian should be informed that the amount of formula provided by WIC may not be enough to last the entire month.
 3. When instructions for altering the dilution of formula are provided by the HCP, WIC staff are not required to do any
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additional approval or assessment. Place a copy of the mixing instructions provided by the HCP in the participant's chart. Determine if the parent is mixing correctly according to the instructions.

4. When instructions for altering the standard dilution of formula are provided by WIC staff, a prescription, assessment, and documentation are required.
- E. Goat's Milk, Rice Milk or Almond Milk are not authorized supplemental food items and cannot be issued.
- F. Supplemental Food Issuance With or Without Formula
1. Food without formula – If a participant is receiving formula from another assistance program (such as Medicaid, Newborn Screening, CHIP, etc.) and not from WIC, the HCP shall be consulted to determine the appropriate supplemental foods to issue for the medical condition. This may be obtained verbally and documented in the participant's chart.
 2. Interpretation of formula quantity when an exact amount is specified – When a HCP requests a specific number of containers of formula per month or ounces per day;
 - a. Infants – Issue maximum amount allowed or contact the SA for assistance if significantly less than maximum is requested.
 - b. Children – Provide the number of containers requested per day. You may round up to the nearest full packaging unit as long as this is less than the maximum amount allowed per month (e.g., round up to the nearest 6 pack).
 3. Selection of Appropriate Supplemental Foods –
 - a. The HCP can defer supplemental foods selection to the Nutritionist/RD when utilizing a version of the Texas Medical Request Form with the statement: "The RD/Nutritionist can
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determine the appropriate supplemental foods and amounts if left blank.”

- b. Unless otherwise noted by the HCP, the Nutritionist/RD can choose the appropriate supplemental foods, amounts and the length of issuance for the participant’s diagnosis, age, preferences, developmental readiness and food allergies.
- c. When accepting a form without the above or a similar statement the approval authority must contact the HCP if supplemental foods are not prescribed or indicated.
- d. The approval authority may obtain verbal authorization to make appropriate food selections from the HCP and document on the medical request form.

III. Transfers and Prescriptions from Other States and Foreign Countries

A. Out-of-State Transfers

1. Prescription available:

- a. Non-contract infant formula - these formulas are not allowed for first time Texas issuance. Issue a primary contract formula.
- b. Exempt/WIC eligible nutritionals or alternate contract formula – The prescription can be honored for up to 3 months. Alternate contract formula prescriptions can be honored as long as the prescription is valid (up to end of certification period).

2. No prescription available:

- a. Non-contract infant formula – Issue a primary contract formula.
 - b. Exempt/WIC eligible nutritional – may issue the food and formula previously issued in the other state for one month and refer them to a Texas HCP for a new prescription.
 - c. Contact the state agency if there are questions about the appropriate food package. Document formula and reason needed. Ensure the reason is comparable to the Texas WIC Formulary.
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B. In-State Transfers

1. Prescription or expiration date available:
 - a. Issue up to 3 months as appropriate. A new prescription will be needed at the next issuance period.
2. No prescription or expiration date available:
 - a. Attempt to contact previous HCP to verify medical need for formula.
 - b. May issue one month to allow time to connect with new local HCP.
3. Foster care – If there is no current prescription available and no documentation from the previous caregiver, issue one month of the requested formula until a new HCP can provide an updated prescription.

C. Prescriptions from Other States (Not transfers)

1. Prescriptions from other States may be accepted for up to 3 months to allow the participant time to obtain a new medical provider.
2. If allowed food information is not available, staff may contact the out-of-state medical provider to obtain it.
3. If staff cannot obtain this information, formula only may be provided.
4. If a participant's medical home is located in another state, prescriptions may be accepted from that location provided that they contain all required information. Approval time period is not limited to 3 months in these situations.

- D. Foreign Prescriptions - Prescriptions from foreign countries, including Mexico, may be approved by the SA for 1 month only. Thereafter, a current prescription from a local U.S. HCP shall be required.
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- IV. Coordination with Medicaid – WIC staff shall refer participants to Medicaid in the following situations:
 - A. When additional formula is needed beyond what WIC can supply.
 - B. If the needed formula is not on the Texas WIC Formulary and cannot be supplied by WIC.
 - C. If the participant is no longer categorically eligible.
 - D. Contact the formula pager for Medicaid referral assistance.
 - V. Maximum Quantities of Formula and Food
 - A. Do not exceed maximum issuance of formula. Formula issuance includes issuance, formula exchange, and any other transaction involving formula.
 - B. Refer to Policy *FD: 12.0 Food Packages* for maximum monthly allowances of formula and supplemental foods.
 - C. Medical documentation is needed for all contract formulas (other than the primary milk and soy-based formulas), non-contract formulas and supplemental foods that are issued with formula for infants.
 - D. Medical documentation is needed for all formula and supplemental foods (including whole milk) that are issued with formula for women and children one year of age and older.
 - VI. Non-Compliant Issuance of Non-Contract Formulas
 - A. LAs shall be required to reimburse the SA for non-compliant issuance of non-contract formula in accordance with this policy. The
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amount of reimbursement shall be equal to the dollar amount that was paid to the vendor.

- B. Non-compliant issuance of non-contract formula includes any one of the following:
1. A prescription or medical request form was not provided and no documentation exists to support the reason to issue non-contract formula.
 2. A prescription or medical request form was provided but the participant did not qualify to receive non-contract formula
 3. Formula was issued to the participant beyond the prescribed and authorized length of issuance.
 4. The amount of formula issued exceeded the maximum allowable amount for the form of the formula, infant's age, and feeding option.