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Effective October 1, 2016

Policy No. FD:16.1

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### **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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<p style="text-align: center;"><b>Nutrition Services</b> <b>Department of State Health Services</b></p>
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Policy No. FD:16.1

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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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<p style="text-align: center;"><b>Nutrition Services</b> <b>Department of State Health Services</b></p>
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Policy No. FD:16.1

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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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---

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Policy No. FD:16.1

---

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.

<p style="text-align: center;"><b>Nutrition Services</b> <b>Department of State Health Services</b></p>
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Policy No. FD:16.1

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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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<p style="text-align: center;"><b>Nutrition Services</b> <b>Department of State Health Services</b></p>
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Effective October 1, 2016

Policy No. FD:16.1

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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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---

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Policy No. FD:16.1

---

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 nutritional 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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<p style="text-align: center;"><b>Nutrition Services</b> <b>Department of State Health Services</b></p>
---

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Policy No. FD:16.1

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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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<p style="text-align: center;"><b>Nutrition Services</b> <b>Department of State Health Services</b></p>
---

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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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---

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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.