

<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:13.0

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### **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.