WIC FORMULAS

Human milk is the most appropriate food for infants and breastfeeding is the natural method for feeding infants. Infant formula is inherently nutritionally inferior. The WIC Program has an obligation and unique opportunity to provide pregnant women and new mothers with the information they need to make an informed feeding decision and the support they need to reach their breastfeeding goals.

For breastfed infants who may need a supplement to the breast milk they receive, and for infants whose mothers/caretakers choose not to breastfeed, WIC can provide infant formula. The CPA, together with the participant’s caregiver, should determine the type of food package which best meets the participant’s needs. Formulas available through WIC include standard contract formula, exempt infant formula, and medical foods. Only USDA-approved formulas may be provided. The most common infant formulas consumed by infants are made from modified cows’ milk with added carbohydrate (usually lactose), vegetable oils, and vitamins and minerals.

The WIC Program is a supplemental nutrition program. As such, the amount of formula available through WIC might not be enough to meet the nutrition needs of an infant, particularly as an infant grows and requires more calories and nutrients. The amount of formula provided must not exceed the monthly maximums of the Minnesota WIC Program which are governed by WIC Federal Regulations. It is important that WIC staff inform caregivers who choose to formula-feed, that they may need to purchase additional formula.

Background and Definitions

- **Infant formula** is “a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk”. The Food, Drug, and Cosmetic Act mandates that all infant formulas marketed in the U.S. provide the same nutrition for healthy, full-term infants.

- **Infant Formula Rebate**: All WIC state agencies are required by WIC federal regulations to enter into cost-containment contracts for the purchase of infant formula. Competitive bidding is used to award the contract to a manufacturer of infant formula for the exclusive right to provide its product to WIC participants in that State, in exchange for a monetary rebate on the formula, which reduces the cost to WIC. Since the rebate money is used to support additional WIC participation, it is important that all infants receiving formula from WIC be provided the contract brands of formula unless there is a specific condition requiring an exempt formula or medical food.

- **Standard Formula**: Standard formulas are those nutritionally suitable for the majority of generally healthy infants who are supplemented with formula or fully formula fed.
- **Primary Contract Formulas** - are those that meet the federal requirements for formula and for which MN WIC receives rebate under the state’s formula contract.

- **Alternate Contract Formulas** – are those included in the state’s formula contract that do not need federal requirements (e.g., because of a lower caloric density), and therefore require medical documentation.

- **Standard Non-Contract Formula**: Any brand of standard formula not covered by the contract.

- **Exempt infant formula**: An exempt infant formula is an infant formula intended for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems.

- **Medical food**: The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)) is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

### 7.5.1 Contract Formula

**References**: 7CFR 246.10(c)(1)(i); 246.16a

**Policy**: If infant formula is requested by the parent/caretaker of an infant, and the CPA determines that formula is appropriate, the CPA must provide through the appropriate food package, a contract formula.

**Purpose**: To meet the federal mandate requiring all states to contain the cost of infant formula.

**Procedures**:

1. Breastfeeding is the normal method for feeding infants and every mother must be encouraged to breastfeed. All requests for infant formula by a breastfeeding mother must be assessed by a CPA to determine the appropriateness of supplementing the infant. See **Section 7.4, Supporting Breastfeeding with the WIC Food Package**.

2. Participants requesting formula must be informed of and offered a primary contract formula. If conditions warrant, CPAs may offer an alternate contract formula, but must obtain medical documentation. **Section 7.6, Medical Documentation** and **Exhibit 7-B, WIC Formula Summary**.

3. If parent/caretaker requests a standard non-contract infant formula, the CPA must explain the policy prohibiting the issuance of any infant formula other than standard contract formula.
4. A participant over 12 months of age (i.e., either a child or a woman) prescribed a standard contract formula by a Health Care Provider must meet the criteria for Food Package 3. Medical documentation is required. See Section 7.6, Medical Documentation.

5. Standard contract formula may be provided in either powder or concentrate form, depending on the caregiver’s preference.
   - CPAs must encourage breastfeeding mothers for whom supplementation is determined necessary, to choose powdered formula to minimize the amount of formula that is prepared at one time, and therefore to better support breastfeeding and reduce the amount that is wasted.
   - CPAs may issue Ready-to-Feed standard contract formula only if circumstances meet criteria described in Section 7.5.2 Ready-to-Feed/Use Formula.

6. If an exempt infant formula or a medical food is requested by a Health Care Provider, criteria described for Food Package 3 must be met. See Section 7.9, Food Package 3.

Guidance:
1. The American Academy of Pediatrics (AAP) and other professional health groups recommend breastfeeding. Full breastfeeding (without supplementation) is considered the norm for infant feeding.

2. For infants receiving formula, the AAP Committee on Nutrition, states that any standard iron-fortified infant formula is an appropriate source of nutrition for healthy infants birth to 12 months.

3. In compliance with federal regulations, the MN WIC Program contracts with a formula manufacturer for the exclusive right to provide its product to WIC participants in exchange for a monetary rebate on the formula WIC provides. Rebate received from the formula contractor allows MN WIC to serve additional participants. It is expected that CPAs will issue a standard contract formula if formula is determined to be appropriate.

4. If the parent/caregiver reports intolerance to the primary contract formula, assess formula preparation, feeding and storage practices. Use Exhibit 7-C, Assessment of Infant Formula Feeding, as a guide.
   - If feeding and/or storage problems are identified, provide appropriate education and counseling, and refer if necessary. Continue issuing primary contract milk- or soy-based formula and schedule follow-up appointment to reassess.
   - If it appears that the infant has an intolerance to primary contract formulas, an alternate infant formula (e.g., alternate contract formula or exempt infant formula) might be warranted. See related policies: Section 7.6, Medical Documentation, Section 7.7 Food Package 1 for Infants 0-5 Months; Section 7.8 Food Package 2 for Infants 6-11 Months, and Section 7.9 Food Package 3.

5. Powdered formula is the most appropriate form for the following participants:
   - Breastfeeding infants who are being fed any formula.
- Homeless participants who do not breastfeed. With powdered formula, participants can prepare the amount needed, limiting unnecessary waste and need for refrigeration. Ready-to-Feed formula may be appropriate in some cases (e.g., if storage is a problem). See policy on Ready-to-Feed Formula, Section 7.5.2.

6. **Soy Formula**

The AAP updated its review on the use of soy formulas in 2008. All soy formulas on the market are iron-fortified and meet USDA and AAP guidelines for vitamin, mineral, and electrolyte content. Soy formulas do not contain cows’ milk protein or lactose. The protein is a soy isolate and the carbohydrate sources are corn maltodextrin, corn syrup solids, and sucrose.

Concerns have been raised about the phytoestrogens and isoflavones in soy formula and their potential negative effects on human development, reproduction, and/or endocrine function. Other studies have suggested that isoflavones may play a protective role in some diseases such as coronary heart disease. Although studied extensively, there is no conclusive evidence that soy isoflavones are contraindicated.

**Soy formula usage:** Soy formula may be used to provide nutrition for full-term infants, however, **there are few indications for its use** in place of cow’s milk-based formula.

**Indications for use include:**
- Infants with galactosemia,
- Infants with hereditary lactase deficiency, and
- Vegan diets

**Soy formula is not indicated for:**
- Infants with documented cow milk protein allergy.
  For infants with a documented cow milk protein allergy, an extensively hydrolyzed protein formula such as Nutramigen should be considered. See Section 7.9, Food Package 3.
- Pre-term infants
- Prevention of colic or fussiness -- There is no proven value in using soy-formula.

For more information, refer to the AAP Clinical Report: *Use of Soy Protein-Based Formulas in Infant Feeding*.

### 7.5.2 Ready-to-Feed/Use Formula

**References:** 7CFR 246.10(c)(1)(i)

**Policy:** CPAs may issue ready-to-feed (RTF) or ready-to-use (RTU) formula in the following situations only:
• **Infants: Food Packages 1 and 2**
  - Water supply is unsanitary or restricted due to emergency circumstances (e.g., in flooding);
  - Refrigeration is inadequate;
  - Participant/caregiver might have difficulty preparing formula; or
  - The particular formula needed is available only as RTU.

• **Infants, Children, Women: Food Package 3**
  - All of the above reasons, and/or
  - The RTU form better accommodates the participant’s condition (e.g., premature infants at risk of Enterobacter Sakazakii);
  - The RTU form improves the participant’s compliance in consuming the prescribed formula.

**Purpose:**
- To meet the federal mandate to contain cost of infant formulas, and
- To assure that participants receive the formula that meets their medical and/or nutritional needs and special circumstances.

**Procedures:**
1. CPAs must assess the need for RTU formula and determine appropriateness.
2. CPAs must document the reason for issuance of RTU formula in the participant record.

**Guidance:**
1. If a participant has unsanitary water or is uncertain of its safety:
   • Encourage and support breastfeeding.
     - Full breastfeeding does not require water for washing bottles or bottle nipples, and provides protection against illness for the breastfed infant.
     - Encourage a return to full breastfeeding for women who are supplementing.
     - Explore interest in and feasibility of re-lactating or inducing lactation for women who are not breastfeeding.
   • Issue one month’s supply of RTU formula, if appropriate.
   • Assist the participant in determining how to obtain safe water (e.g., purchasing bottled water or acquiring water from a safe municipal water supply).
   • Refer the participant to the agency in the county that tests water.

2. If refrigeration is inadequate:
   • Refer as needed to local housing assistance programs.
   • Encourage and support breastfeeding.
     - Encourage a return to full breastfeeding for women who are supplementing.
     - Explore interest in and feasibility of re-lactating or inducing lactation for women who are not breastfeeding.

3. If a participant returns RTU formula to the local agency and the formula cannot be used by another participant in your agency, contact the State WIC
agency to request that a notice of availability be included in the WIC Wednesday Update.

7.5.3 Standard Non-Contract Formula

References: 7CFR 246.10(c)(1)(i); 246.16a

Policy: CPAs may not issue any standard non-contract formula.

Purpose: To meet the federal mandate to contain food costs by issuing standard contract formula, and to enable Minnesota WIC to serve more participants with funds recovered through rebates for contract formula.

Definition: Non-contract formulas are “standard infant formulas” not included in the Minnesota WIC Formula Rebate Contract.

Procedures:
1. There are no circumstances for which a standard non-contract milk- or soy-based formula may be provided. For a list of standard contract formulas, see Exhibit 7-B, WIC Formula Summary.

Guidance:
- Although there are small differences in protein, fat, and carbohydrates among all standardized formulas, there are no medically proven advantages of one formula brand over another.
- WIC CPAs need to work with the family and their primary care provider in transitioning to a standard contract formula.
- If it appears the infant has a “true” intolerance to standard contract formulas, an exempt infant formula might be warranted. See related policy Section 7.9, Food Package 3.

7.5.4 Medically Prescribed Formula

See Section 7.9, Food Package 3.

7.5.5 Use of Formula Returned by Participants

References: Federal Bill Emerson Good Samaritan Food Donation Act
**Policy:** The State Agency recommends that Local Agencies redistribute infant formula returned to the WIC clinic by a participant when the formula is determined to be in good condition and the expiration date of the formula is at least 30 days beyond the redistribution date.

If the returned formula is determined to be in good condition and has not yet expired, and the Local Agency decides not to redistribute the formula to participants, the formula should be donated to a food shelf or homeless center. The *Bill Emerson Good Samaritan Food Donation Act* protects “donors” from liability when donating food in apparently good condition and donated “in good faith”.

**Purpose:** This policy and guidance are intended to assist local agencies in deciding how best to handle formula returned to WIC clinics by participants. Because formula is a valuable commodity for which there is great need and because local agencies have limited storage space, formula which is returned to clinic by a participant needs to be handled in a responsible manner.

**Background:** The actual condition of formula cannot be known with certainty, regardless of the source – whether shipped directly from the manufacturer, purchased from a grocery store, or returned by participants. At this time neither USDA nor FDA has established policy prohibiting the redistribution of returned formula.

**Procedures:**

1. **Assessing Returned Formula** – Local agency staff must assess the condition of the formula being returned. Local staff should ask and/or assess the following:
   - **Reason for the return**
   - **Condition of the cans**
     - A can should be unopened and not damaged in any way, with the original label intact.
     - A can is considered damaged if there is any sign of bulging or leaking, or if the can is dented, punctured, or cracked.
   - **Where and how the formula was stored** (see Guidance) and
   - **Expiration date** (see Guidance)

2. **Formula in Good Condition**
   **Standard milk- and soy-based infant formulas:** If assessed by staff to be in good condition, your agency may:
   - Redistribute to another participant. The formula may be provided:
     - In exchange, can-for-can, for formula being returned, in lieu of reissuing vouchers;
     - As a formula sample to assist in transitioning an infant to another formula;
     - To another WIC participant using the same formula, in lieu of vouchers.
     - To ensure that the participant is “counted” in the agency’s caseload, a voucher must be issued. If the infant is not receiving other food (e.g., infant cereal), you should issue a voucher with at least one can of formula, and provide the rest of the formula from stock.
• Returned infant formula must be prescribed just as with any other formula and may be prescribed only by a CPA.

• Donate to a food shelf/pantry or homeless center, if your agency anticipates not being able to redistribute the formula to a participant before it expires. Refer to the Bill Emerson Good Samaritan Food Donation Act which may relieve your agency of liability.

• Destroy the formula if it has expired or check on the possibility of donating the expired formula to the Humane Society or other animal shelter.

Exempt Infant Formula / Medical Foods: If assessed by staff to be in good condition, your agency may:
• Provide the formula to another participant with the same prescription in lieu of vouchers.
• Offer to another Local Agency if the formula is not needed by your agency(you can contact the State WIC office to post a notice in the WIC Wednesday Update).
• If your agency can not use the formula and it is still in the original case packaging, arrange to have it sent back to the State WIC office for redistribution.
• If the number of cans is less than a complete case, offer it to a local hospital or clinic in your area.

Note: Because exempt infant formula and medical foods are intended to be used only by participants with special needs, do not donate medical formula to a food pantry, homeless shelter, or Humane Society.

3. Formula Not in Good Condition
If local agency staff determines that the formula being returned has expired or is about to expire, or is not in good condition (e.g., the can is damaged in some way, or upon questioning, it is learned that the formula has been exposed to extreme temperatures), the local agency should destroy it.

4. Documentation of the disposition of returned formula is required.
• Document what was done with the returned formula (e.g., reissued, destroyed or donated) using the Tracking Log for Returned Formula, Exhibit 7-I.

• If the formula is redistributed to a participant, document this in the record of the participant to whom it was given if it is important to their care (e.g., if it is formula being used to transition the infant to another type of formula). Document:
  o Type of formula
  o Quantity issued
  o Reason for issuance, and
  o Name of CPA issuing the formula

Guidance:
• Unless there is good reason to suspect that the formula product is not in “good” condition (e.g., damaged packaging, etc.), you should assume that it is.

• WIC participants receiving formula should routinely be instructed to carefully examine formula prior to use. Any formula that has an unusual appearance, color or odor should be reported to the manufacturer at the phone number listed on the product label.

• When assessing formula returned to clinic, consider:
  o **Where and how the formula was stored:**
    Unopened powder and liquid formulas should be stored at “normal” room temperature (i.e., 68-80 degrees F). Shelf life is based on the best estimate of the time during which certain changes may occur at normal temperatures. The shelf life is selected to assure that the ingredients will satisfy the label claim at expiration date. Excessive heat or freezing should be avoided. Many of the normal chemical and physical changes that occur over time at room temperature will be accelerated at constantly elevated temperatures, such as near a furnace or a water heater. Long term exposure to heat may cause the fat to separate in liquid formulas and may cause powder formula to darken and change odor. Generally, freezing does not affect the nutritional quality, but it may break down the fatty acids. It also may affect the appearance and functionality (separation, increased sedimentation or lumps). If a product is for a tube feeding, it could clog the tubing.
  
  o **Expiration date:**
    The format used for the expiration date is: day of month/month/year. The day of the month is always the first day of the month. Depending on the manufacturer, the number “1” may or may not be included (e.g., 1FEB2012, 1MAR12 or 08/2011).
    ▪ A product may be used until that date.
    ▪ It should not be used the day of expiration or past that date.

• **Storage of Formula in Clinic**
  o Store out-of-sight of WIC participants to avoid undermining breastfeeding.
  o Store in a secure, locked cabinet or room.
  o Rotate stock so that “older” product is used first, and product doesn’t expire.
  o Protect from temperature extremes to maintain product quality.