

POLICY MANUAL

5. NUTRITION AND BREASTFEEDING SERVICES.

5.08. Infant Formula.

A. POLICY OVERVIEW:

Pursuant to 42 U.S.C 1786(h)(8)(A)(i), the Pennsylvania Special Supplemental Nutrition Program for Women, Infants and Children (PA WIC) uses a competitive bidding system to procure infant formula. PA WIC uses a “single solicitation,” “single-supplier” competitive bidding system.

B. DEFINITIONS:

- a. Infant Formula: As defined in Section 201(z) of the Federal Food, Drug, and Cosmetic Act, *as amended by* the Infant Formula Act of 1980 (Pub. L. 96–359), (FDCA), 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.” 21 U.S.C. 321(z). U.S. Food and Drug Administration’s (FDA) regulations, 21 CFR, 105.3(e), mirror WIC definitions of an infant as persons not more than 12 months old.
- b. Exempt Formula: As defined by Section 412 of the FDCA, an exempt infant formula is “[a]ny infant formula which is represented and labeled for use by an infant-- (A) who has an inborn error of metabolism or low birth weight, or (B) who otherwise has an unusual medical or dietary problem[.]” 21 U.S.C. 350a(h)(1). See Policy 5.10, Exempt Infant Formula and WIC-Eligible Nutritionals, for more information.
- c. Contract Formula: Any infant formula that is provided to WIC participants through a rebate contract negotiated with an infant formula manufacturer.
 - (1) Primary Infant Formula: Defined as “[t]he 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.” 7 CFR 246.2;
 - (2) Alternate Infant Formula: any cow’s milk based or partially hydrolyzed formula (including lactose free formula and formula with added rice starch) intended for feeding infants who may have conditions as noted in section C.5.
- d. Non-Contract Formula: Any standard infant formula that is not covered by a rebate contract as described above.

C. POLICY:

1. A Competent Professional Authority (CPA) or a Competent Paraprofessional Authority (CPPA) shall be responsible for prescribing formula in Food Packages I and II. Refer to Policy 5.10, Exempt Infant Formula and WIC-Eligible Nutritionals, for prescribing formula in Food Package III.
2. Formulas shall be provided as concentrated liquid or powder. RTF formula may be authorized when the CPA determines a need as described in Section C.8.
3. Primary Infant Formula shall be provided as a first choice for infants requiring standard

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formula.

4. An Alternate Infant Formula falls under the contracted infant formulas and may be provided to accommodate a variety of infant conditions that include, but are not limited to: documented infant formula intolerances, food allergies, or inappropriate growth patterns that do not require the use of an exempt infant formula. Medical documentation may be needed.
5. Prescriptions may be faxed or provided electronically to the local agency or clinic. Verbal orders for Alternate Infant Formulas can be accepted by a CPA on a case-by-case basis. Written confirmation of the medical documentation must be obtained within one month after the phone call.
6. Once all appropriate Contract Formulas have been ruled out, Non-Contract Formula may be issued only when a Contract Formula would place the participant at medical risk because of a diagnosed condition as indicated on appropriate medical documentation. These instances must be approved by the SA on a case-by-case basis.
7. Refer participants to their physician before switching from milk-based to soy-based formula or vice versa.
 - a. Symptoms such as vomiting, diarrhea, or excessive gas may be caused by medical problems or inappropriate feeding practices rather than formula intolerance.
 - b. Many infants who are allergic to milk-based formulas are also allergic to soy and require a protein hydrolysate formula. Refer to Policy 5.10, Exempt Infant Formulas and WIC-Eligible Nutritionals.
 - c. Soy formulas are not appropriate for pre-term infants.
8. Provide RTF formula only when:
 - a. There is an unsanitary or restricted water supply; or
 - b. The participant's caregiver may have difficulty in correctly preparing the concentrated liquid or powder formula.
 - c. The formula is available in RTF only.
 - d. Powder is the only alternative to RTF formula and the infant is immunocompromised or at risk of infection from powder formula. Infants should be monitored monthly.
 - e. If a participant is experiencing homelessness or living in a shelter.
 - f. Additionally, the following justifications may be used to issue RTF formula in Food Package III:
 - (1) If a RTF formula better accommodates the participant's condition.

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- (2) If it improves the participant's compliance in consuming the prescribed WIC formula.
- g. Document the reason for providing RTF formula in the Management Information System (MIS). Written documentation from the health care provider is needed as justification.
- 9. Infant formulas may be provided to non-breastfed infants and breastfed infants who need supplemental formula. Refer to Policy 5.03, Formula Issuance for Breastfed Infants.
 - a. Infant formulas may be provided to children when a physician's prescription justifies the need, as described in Policy 5.10, Exempt Infant Formula and WIC-Eligible Nutritionals.

Reference(s):

1. 42 U.S.C 1786
2. Federal Food, Drug, and Cosmetic Act, *as amended by* the Infant Formula Act of 1980 (Pub. L. 96–359)
3. WIC Regulations: 7 CFR subparts 246.2; 246.10, including 246.10(e)(1)(iii); 246.16a.
4. Federal Food Drug and Cosmetic Act; Section 201 21 USC 321(z); Section 412, Section 350a (h)(1)
5. 21 CFR 105.3
6. USDA WIC Policy Memorandum #2014-1A, Clarification on Medical Documentation for Infant Formula Issued in Food Packages I and II (January 7, 2014)

Policy Status:

1. This Policy supersedes Policy Number 7.04 dated August 10, 2018.