

## POLICY AND PROCEDURE MANUAL

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### 7. FOOD SUPPLEMENTS

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#### 7.08 Exempt Infant Formula and WIC-Eligible Nutritionals

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##### A. POLICY:

PA WIC shall issue infant formula, exempt infant formula or WIC-eligible nutritionals to women, infant or child participants with a documented qualifying condition as noted in the definitions in section B below.

##### B. DEFINITIONS:

Exempt Infant Formula: As defined by the FD&C Act Section 412, Section 350a(h)(1), an exempt infant formula is "Any infant formula which is represented and labeled for use by an infant who has an inborn error of metabolism or low birth weight, or who otherwise has an unusual medical or dietary problem."

Phenylketonuria (PKU): Persons with phenylketonuria (PKU) cannot metabolize the amino acid phenylalanine. They must restrict dietary protein to prevent toxic accumulation of phenylalanine that can cause intellectual and developmental disabilities and neurological problems. Participants with PKU require formulas that are free of phenylalanine. Participants with PKU receive medical care, diet prescription and nutritional counseling at one of the following state contracted PKU Treatment Centers (PTCs) in Pennsylvania: Children's Hospital of Philadelphia, St. Christopher's Hospital for Children in Philadelphia, Children's Hospital of Pittsburgh, Geisinger Medical Center, or Hershey Medical Center. Follow-up care is provided by community health nurses and the metabolic dietitian at the PTCs. The PKU Treatment Centers refer potentially eligible PKU patients to the PA WIC Program.

WIC-Eligible Nutritionals: Certain enteral products that are specifically formulated to provide nutritional support for individuals with a qualifying 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 feed; and may not be a conventional food, drug, flavoring, or enzyme. (CFR 246.10(12) Table 4).

##### C. PROCEDURE:

1. Requests for exempt infant formulas or WIC-eligible nutritionals shall be handled by a nutritionist or a competent professional authority (CPA). If a nutritionist or CPA is not in the clinic, clinic staff shall consult a nutritionist or CPA at a different site or the local agency (LA) Nutrition Education Coordinator or his/her designee. Document the consultation in chart. See attachment 1 for basic guidance for issuance of formula to children.
2. The amount of formula specified in a physician's prescription shall be used to determine the quantity of formula provided to the WIC participant. However, the amount provided cannot exceed the maximum amount allowed by the Federal WIC Regulations (See Reference 1). For quantities prescribed that exceed the WIC maximum amount, refer to attachments 2 and 3.
3. Participants eligible to receive exempt infant formula or WIC-eligible nutritionals must have one or more qualifying conditions, as determined by a health care professional licensed to write medical prescriptions under Pennsylvania State law, which include but are not limited to premature birth, low birth weight, failure to thrive, inborn errors of metabolism and metabolic disorders, gastrointestinal disorders, malabsorption syndromes, immune system disorders, severe food allergies that require an elemental

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formula, and life threatening disorders, diseases and medical conditions that impair ingestion, digestion, absorption or the utilization of nutrients that could adversely affect the participant's nutrition status.

Note: These products may not be issued solely for the purpose of enhancing nutrient intake or managing body weight. For a partial list of authorized products approved for use in Pennsylvania, please refer to Attachments 4a and 4b.

4. Exempt infant formulas or WIC-eligible nutritionals may be provided to women, infants and children when a physician documents that the participant has a medical condition that precludes or restricts the use of conventional foods or standard formulas. These products must be provided to participants in accordance with the following model food package:

Food Package III – Women, children and infants with special dietary needs.

5. Formula may be provided for oral use or for administration via an enteral tube feeding (i.e. nasogastric tube, gastrostomy, or jejunostomy tube). Formulas administered parenterally (via peripheral or central venous catheter) are not allowed.
6. Formula shall normally be provided as concentrated liquid or powder. However, ready-to-feed exempt infant formula or WIC-eligible nutritionals may be authorized when the CPA determines that any of the following conditions exist:
  - a. There is an unsanitary or restricted water supply or poor refrigeration.
  - b. The participant's caregiver may have difficulty in correctly diluting concentrated liquid or powdered formula.
  - c. The formula is available in ready-to-feed only.  
Powder is the only alternative to ready-to-feed formula and the participant is immunocompromised as determined by the doctor. These participants may be at risk of *Chronobacter sakazakii* (*C. sakazakii*) infection from powdered formula since powdered formula is not sterile.
7. Additionally, the following justifications may be used to issue ready-to-feed in Food Package III:
  - a. If a ready-to-feed formula better accommodates the participant's condition
  - b. If it improves the participant's compliance in consuming the prescribed WIC formula
8. Obtain a written prescription before issuing exempt infant formula or WIC-eligible nutritionals. The prescription may be written on a physician's prescription blank or the Pennsylvania WIC Program Formula Authorization Form (attachment 5). The prescription shall include:
  - a. The name of the participant receiving formula(s)
  - b. The name(s) and quantity(ies) of formula(s) being prescribed
  - c. The medical condition and ICD-10 code
  - d. Any special instructions related to the preparation, amount of formula(s) and/or feeding frequency of the formula(s)
  - e. The signature of the health care provider - physician, Certified Registered Nurse Practitioner (CRNP), Physician's Assistant (PA) or Certified Nurse Midwife

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- (CNM) prescribing the formula(s)
- f. Current date
  - g. The length of time formula(s) is needed; monthly renewal is required for premature (pre-discharge) formulas.
  - h. Supplemental foods authorized in Food Package III include infant cereal, infant fruits and vegetables, milk and milk alternatives (including whole milk), cheese, eggs, canned fish, fruits and vegetables, breakfast cereal, whole wheat bread, tortilla or other whole grains, juice, beans and peanut butter. The health care provider prescribing the formula should indicate which WIC foods should be restricted from issuance as well as the length of restriction on the prescription form.
  - i. Food Package III is not authorized for infants, women and children whose only condition is food allergy/intolerance to lactose, sucrose, milk protein or soy protein which does not require the use of an exempt infant formula or WIC-eligible nutritional but can be managed with one of the other WIC food packages.
  - j. Any participant presenting a prescription requesting exempt infant formula or WIC-eligible nutritionals solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying condition will not be able to receive exempt infant formula or WIC-eligible nutritionals from WIC.
9. Formulas may be issued individually or in combination with another formula according to a physician's prescription to best accommodate the participant's nutritional needs. However, the combined total quantity of these products issued monthly may not exceed the regulatory maximum monthly allowance.
  10. Prescriptions may be faxed or provided electronically to the LA or clinic. Verbal orders for exempt infant formulas and WIC-eligible nutritionals can be accepted by a CPA on a case-by-case basis. Written confirmation of the medical documentation must be obtained within two weeks after the phone call.
  11. Some formulas will be provided through any authorized WIC vendor unless they are not available in a WIC-authorized store. If a product is not available in grocery stores within a reasonable distance, it may be obtained through the Special Formula Distribution Center (SFDC).
  12. Exempt infant formula or WIC-eligible nutritionals will be sent to the clinic, or when requested, shipped to the participant's home, after the electronic order is placed through the SFDC. See P&P 4.05, B.2.a(4) and B.2.c (for formula being shipped to the participant's home).
  13. If the formula is to be obtained from the SFDC, refer to P&P 4.05 for specific instructions on ordering and delivering the formula.
  14. To provide a combination of two or more formulas, refer to the physician's prescription for amounts of each formula, including the contract brand (see P&P 7.04), being requested. (If amounts are not specified, contact the physician.)
  15. Prescriptions for exempt infant formula or WIC-eligible nutritionals shall be renewed at least every 6 months; with the exception of premature (pre-discharge) formulas packaged in nursette bottles, which shall be renewed at least once a month.

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16. If a health care provider prescribes a formula not on the WIC-approved formula list, mail or fax the following to the State Agency (SA):
  - a. A WIC Formula Authorization Form or valid health care provider's prescription form.
  - b. If requested by the SA staff, fax a completed Bottle Feeding Checklist (attachment 2 to P&P 7.04). A Bottle Feeding Checklist should be completed with the caregiver to assess correct formula preparation and infant feeding.
  - c. The LA clinic should call the SA to discuss a comparable product already in the system. If none exists, the SA will add the new product to the list of formulas in the system. It may require 24-48 hours before the LA staff may be able to order the formula through the warehouse.
  - d. After reviewing the information received, the SA may approve the formula for the specific client by adding the product to the MIS, and LA WIC staff will be notified when the new product is available for ordering.  
Note: Low-calorie formulas solely for the purpose of managing body weight are not authorized.
17. Formulas are not to be provided to participants while they are hospitalized.
18. PKU Formula Issuance Procedure
  - a. All referrals of PKU patients to the PA WIC Program and their formula prescriptions for PKU formula shall be directed to the SA. The SA shall provide LA staff with instructions for providing formula and other services to these clients.
  - b. WIC may provide PKU participants of 6 months of age with infant cereal, infant fruit and infant vegetables unless otherwise specified on the Formula Authorization Form. WIC may provide women and children with cereal, juice, farmer's market coupons and cash value vouchers. WIC shall not provide infant meats, milk (cow or soy), tofu, eggs, peanut butter, beans, cheese or tuna fish to any PKU participant.
  - c. WIC does not provide diet education contacts to PKU participants. Diet education is provided by the metabolic dietitian at the PKU Treatment Center. WIC nutrition education contacts are still required for appropriate topics such as breastfeeding support, physical activity, and shopping on a budget.
  - d. All endorsers and/or proxies of PKU participants shall come to WIC at least tri-monthly for benefits for allowed foods and/or standard infant formula. Endorsers shall be seen by a CPA at each visit.
  - e. The metabolic dietitian at the PKU Treatment Center will contact the SA to refer the PKU patient to WIC and mail or fax a copy of the Referral of PKU Patient to WIC form (attachment 6) and the Formula Authorization Form (attachment 5) to the SA.
  - f. The Nutritionist at the SA will review the Formula Authorization Form to determine the amount and type of formula that WIC should provide. The metabolic dietitian at the PKU Treatment Center will be consulted if necessary (attachment 7).
  - g. The Nutritionist at the SA will contact the WIC clinic where the participant will be seen and mail or fax a copy of the referral form, the completed Formula Authorization Form and the PKU Quick Reference for WIC Staff (attachments 5, 6 and 8).
  - h. The LA will do the following:

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- (1) Contact the patient referred to WIC for PKU formula to schedule the WIC appointment and follow up by sending a postcard to the patient designating the time and location of the appointment and what to bring. If the patient misses the appointment, contact him or her to reschedule. If the patient attends the appointment, but is ineligible, provide a Notice of Ineligibility. Notify the Nutritionist at the SA who will notify the metabolic dietitian at the Patient Treatment Center of the patient's ineligibility.
- (2) When PKU prescription formula is being issued, it will not be obtained from the SFDC and will instead be purchased and distributed by the PA Department of Health.
- (3) When the PKU patient attends the appointment and is eligible, the staff shall enroll the person in WIC:
  - (a) Complete and have the endorser sign the Participant Data Form.
  - (b) Use MIS to issue benefits payable to Vendor #45000 (PA Department of Health, Division of Newborn Screening and Genetic Services) for the amount and type of PKU formula shown on the Formula Authorization Form (see attachment 5). Have the participant sign the digital signature pad. Mail the food instruments to the following address:

**PA Department of Health  
Bureau of WIC  
625 Forster Street  
7<sup>th</sup> Floor, West Wing  
Health & Welfare Building  
Harrisburg, PA 17120**
  - (c) If applicable, use the MIS to issue benefits payable to any authorized vendor of participant's choice for their prescribed food benefit package. Handle these benefits as you normally would.
    1. If another formula is issued in addition to PKU formula, WIC will prioritize the provision of that formula over the PKU formula but will cover the PKU formula to the extent that additional formula funding is allowed. The total amount of all formula (non-PKU and PKU) provided by WIC shall not exceed the USDA allowable maximum.
    2. Age-eligible participants may receive cereal, juice, infant fruits and vegetables, or cash value vouchers and farmer's market coupons.
  - (d) A CPA should evaluate the client's food package at each nutrition follow-up appointment to make sure it is consistent with the most recent and current Formula Authorization Form. WIC prescriptions for PKU formula are good for 6 months unless otherwise specified on the form.

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Attachment(s):

1. Criteria for Usage of Formula for Children
2. Medical Assistance (MA) Coverage of Exempt Infant Formula and WIC-Eligible Nutritionals
3. Other Possible Sources of Special Formula
- 4a. Formulas and Maximum Amounts
- 4b. Formulas and Maximum Amounts for PBF Infants
5. Pennsylvania WIC Program Formula Authorization Form
6. Referral of PKU Patient to WIC
7. PKU Treatment Center Addresses & Phone Numbers
8. PKU Quick Reference for WIC Staff

Reference(s):

1. WIC Regulation: 7 CFR part 246.10 [c], [e] (3)
2. FNS-268: WIC Eligible Formulas and Medical Foods or Products
3. FD&C Act Section 412, Section 350a(h)(1)
4. WIC Services to Eligible PKU Patients: Memorandum of Understanding Revised September 1994.

Policy and Procedure Status:

1. This P&P supersedes P&P Number 7.08, dated June 29, 2015.