

will support the objective of certifying only those children eligible for free or reduced price meals. No later than April 15, 2005 and by April 15 each year thereafter, each State agency must report to FNS the verification information in a consolidated electronic file that has been reported to it as required under §245.6a(c), by local educational agency, and any ameliorative actions the State agency has taken or intends to take in local educational agencies with high levels of applications changed due to verification. Contingent upon new funding to support this purpose, FNS will also require each State agency to report the aggregate number of students who were terminated as a result of verification but who were reinstated as of February 15th. The first report containing this data element would be required in the school year beginning July 1, 2005 and each school year thereafter. State agencies are encouraged to collect and report any or all verification data elements before the required dates.

(Secs. 801, 803, 812; Pub. L. 97-35, 95 Stat. 521-535 (42 U.S.C. 1753, 1758, 1759(a), 1773, 1778))

[35 FR 14065, Sept. 4, 1970, as amended at 38 FR 14958, June 7, 1973; Amdt. 8, 40 FR 57208, Dec. 8, 1975; 44 FR 1364, Jan. 5, 1979; 46 FR 51368, Oct. 20, 1981; 48 FR 12511, Mar. 25, 1983; 52 FR 19276, May 22, 1987; 64 FR 50744, Sept. 20, 1999; 64 FR 72474, Dec. 28, 1999; 66 FR 48333, Sept. 20, 2001; 68 FR 53490, Sept. 11, 2003; 72 FR 63796, Nov. 13, 2007]

EFFECTIVE DATE NOTE: At 68 FR 53490, Sept. 11, 2003, §245.11(i) was added. This paragraph contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 245.12 Fraud penalties.

(a) Whoever embezzles, willfully misapplies, steals, or obtains by fraud any funds, assets, or property provided under this part, whether received directly or indirectly from the Department, shall—

(1) If such funds, assets, or property are of a value of \$100 or more, be fined not more than \$25,000 or imprisoned not more than five years of both; or

(2) If such funds, assets, or property are of a value of less than \$100, be fined not more than \$1,000 or imprisoned not more than one year or both.

(b) Whoever receives, conceals, or retains to his use or gain funds, assets, or property provided under this part, whether received directly or indirectly from the Department, knowing such funds, assets, or property have been embezzled, willfully misapplied, stolen, or obtained by fraud, shall be subject to the same penalties provided in paragraph (a) of this section.

(Sec. 10(a), Pub. L. 95-627, 92 Stat. 3623 (42 U.S.C. 1760); sec. 14, Pub. L. 95-627, 92 Stat. 3625-3626)

[Amdt. 14, 44 FR 37901, June 29, 1979, as amended at 64 FR 50744, Sept. 20, 1999]

§ 245.13 Information collection/record-keeping—OMB assigned control numbers.

7 CFR section where requirements are described	Current OMB control number
245.3 (a), (b)	0584-0026
245.4	0584-0026
245.5 (a), (b)	0584-0026
245.6 (a), (b), (c), (e)	0584-0026
245.7(a)	0584-0026
245.9 (a), (b), (c)	0584-0026
245.10 (a), (d), (e)	0584-0026
245.11 (a), (a-1), (b), (c), (d), (f)	0584-0026
245.13(a)-(c)	0584-0026

[72 FR 68985, Dec. 6, 2007, as amended at 73 FR 11312, Mar. 3, 2008]

PART 246—SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN

Subpart A—General

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- 246.1 General purpose and scope.
- 246.2 Definitions.
- 246.3 Administration.

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- 246.24 Procurement and property management.
- 246.25 Records and reports.
- 246.26 Other provisions.
- 246.27 Program information.
- 246.28 OMB control numbers.

AUTHORITY: 42 U.S.C. 1786.

SOURCE: 50 FR 6121, Feb. 13, 1985, unless otherwise noted.

Subpart A—General

§ 246.1 General purpose and scope.

This part announces regulations under which the Secretary of Agriculture shall carry out the Special Supplemental Nutrition Program for Women, Infants and Children (WIC Program). Section 17 of the Child Nutrition Act of 1966, as amended, states in part that the Congress finds that substantial numbers of pregnant, postpartum and breastfeeding women, infants and young children from families with inadequate income are at special risk with respect to their physical and mental health by reason of inadequate nutrition or health care, or both. The purpose of the Program is to provide supplemental foods and nutrition education through payment of cash grants to State agencies which administer the Program through local agencies at no cost to eligible persons.

The Program shall serve as an adjunct to good health care during critical times of growth and development, in order to prevent the occurrence of health problems, including drug and other harmful substance abuse, and to improve the health status of these persons. The program shall be supplementary to the Food Stamp Program; any program under which foods are distributed to needy families in lieu of food stamps; and receipt of food or meals from soup kitchens, or shelters, or other forms of emergency food assistance.

[50 FR 6121, Feb. 13, 1985, as amended at 54 FR 51294, Dec. 14, 1989; 58 FR 11506, Feb. 26, 1993]

§ 246.2 Definitions.

For the purpose of this part and all contracts, guidelines, instructions, forms and other documents related hereto, the term:

7 CFR part 3016 means the Department's Uniform Federal Assistance Regulations. Part 3016 implements the policies established by the Office of Management and Budget (OMB) in Circulars A-21, A-87, A-102, A-110, and A-122, as well as OMB Guidance on Implementation of the Federal Grant and Cooperative Agreement Act of 1977.

7 CFR part 3017 means the Department's Common Rule regarding Governmentwide Debarment and Suspension (Non-procurement). Part 3017 implements the requirements established by Executive Order 12549 (February 18, 1986).

7 CFR part 3018 means the Department's Common Rule regarding Governmentwide New Restrictions on Lobbying. Part 3018 implements the requirements established by section 319 of the 1990 Appropriations Act for the Department of Interior and Related Agencies (Pub. L. 101-121).

7 CFR part 3021 means the Department's Common Rule regarding Governmentwide Requirements for Drug-Free Workplace. Part 3021 implements the requirements established in section 5151-5160 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690).

Above-50-percent vendors means vendors that derive more than 50 percent of their annual food sales revenue from WIC food instruments, and new vendor

applicants expected to meet this criterion under guidelines approved by FNS.

Affirmative Action Plan means that portion of the State Plan which describes how the Program will be initiated and expanded within the State's jurisdiction in accordance with § 246.4(a).

A-130 means Office of Management and Budget Circular A-130, which provides guidance for the coordinated development and operation of information systems.

Applicants means pregnant women, breastfeeding women, postpartum women, infants, and children who are applying to receive WIC benefits, and the breastfed infants of applicant breastfeeding women. Applicants include individuals who are currently participating in the program but are re-applying because their certification period is about to expire.

Authorized supplemental foods means those supplemental foods authorized by the State or local agency for issuance to a particular participant.

Breastfeeding means the practice of feeding a mother's breastmilk to her infant(s) on the average of at least once a day.

Breastfeeding women means women up to one year postpartum who are breastfeeding their infants.

Cash-value voucher means a fixed-dollar amount check, voucher, electronic benefit transfer (EBT) card or other document which is used by a participant to obtain authorized fruits and vegetables.

Categorical eligibility means persons who meet the definitions of pregnant women, breastfeeding women, postpartum women, or infants or children.

Certification means the implementation of criteria and procedures to assess and document each applicant's eligibility for the Program.

Children means persons who have had their first birthday but have not yet attained their fifth birthday.

Clinic means a facility where applicants are certified.

Competent professional authority means an individual on the staff of the local agency authorized to determine nutritional risk and prescribe supple-

mental foods. The following persons are the only persons the State agency may authorize to serve as a competent professional authority: Physicians, nutritionists (bachelor's or master's degree in Nutritional Sciences, Community Nutrition, Clinical Nutrition, Dietetics, Public Health Nutrition or Home Economics with emphasis in Nutrition), dietitians, registered nurses, physician's assistants (certified by the National Committee on Certification of Physician's Assistants or certified by the State medical certifying authority), or State or local medically trained health officials. This definition also applies to an individual who is not on the staff of the local agency but who is qualified to provide data upon which nutritional risk determinations are made by a competent professional authority on the staff of the local agency.

Competitive bidding means a procurement process under which FNS or the State agency selects a single source (such as a single infant formula manufacturer offering the lowest price), as determined by the submission of sealed bids, for a product for which bids are sought for use in the Program.

Compliance buy means a covert, on-site investigation in which a representative of the Program poses as a participant, parent or caretaker of an infant or child participant, or proxy, transacts one or more food instruments or cash-value vouchers, and does not reveal during the visit that he or she is a program representative.

Contract brand infant formula means all infant formulas (except exempt infant formulas) produced by the manufacturer awarded the infant formula cost containment contract. If under a single solicitation the manufacturer subcontracts for soy-based infant formula, then all soy-based infant formulas covered by the subcontract are also considered contract brand infant formulas (see § 246.16a(c)(1)(i)). If a State agency elects to solicit separate bids for milk-based and soy-based infant formulas, all infant formulas issued under each contract are considered the contract brand infant formula (see § 246.16a(c)(1)(ii)). For example, all of the milk-based infant formulas issued by a State agency that are produced by the manufacturer that was

awarded the milk-based contract are considered contract brand infant formulas. Similarly, all of the soy-based infant formulas issued by a State agency that are produced by the manufacturer that was awarded the soy-based contract are also considered to be contract brand infant formulas. Contract brand infant formulas also include all infant formulas (except exempt infant formulas) introduced after the contract is awarded.

Cost containment measure means a competitive bidding, rebate, direct distribution, or home delivery system implemented by a State agency as described in its approved State Plan of operation and administration.

CSFP means the Commodity Supplemental Food Program administered by the Department, authorized by section 5 of the Agriculture and Consumer Protection Act of 1973, as amended, and governed by part 247 of this title.

Days means calendar days.

Department means the U.S. Department of Agriculture.

Discount means, with respect to a State agency that provides Program foods to participants without the use of retail grocery stores (such as a State agency that provides for the home delivery or direct distribution of supplemental food), the amount of the price reduction or other price concession provided to any State agency by the manufacturer or supplier of the particular food product as the result of the purchase of Program food by each such State agency, or its representative, from the manufacturer or supplier.

Disqualification means the act of ending the Program participation of a participant, authorized food vendor, or authorized State or local agency, whether as a punitive sanction or for administrative reasons.

Documentation means the presentation of written documents which substantiate statements made by an applicant or participant or a person applying on behalf of an applicant.

Drug means:

- (a) A beverage containing alcohol;
- (b) A controlled substance (having the meaning given it in section 102(6) of the Controlled Substance Act (21 U.S.C. 802(6)); or

(c) A controlled substance analogue (having the meaning given it in section 102(32) of the Controlled Substance Act (21 U.S.C. 802(32))).

Dual participation means simultaneous participation in the Program in one or more than one WIC clinic, or participation in the Program and in the CSFP during the same period of time.

Electronic signature means an electronic sound, symbol, or process, attached to or associated with an application or other record and executed and or adopted by a person with the intent to sign the record.

Employee fraud and abuse means the intentional conduct of a State, local agency or clinic employee which violates program regulations, policies, or procedures, including, but not limited to, misappropriating or altering food instruments or cash-value vouchers, entering false or misleading information in case records, or creating case records for fictitious participants.

Exempt infant formula means an infant formula that meets the requirements for an exempt infant formula under section 412(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(h)) and the regulations at 21 CFR parts 106 and 107.

Family means a group of related or nonrelated individuals who are living together as one economic unit, except that residents of a homeless facility or an institution shall not all be considered as members of a single family.

Farmer means an individual authorized by the State agency to sell eligible fruits and vegetables to participants at a farmers' market or roadside stands. Individuals who exclusively sell produce grown by someone else, such as wholesale distributors, cannot be authorized.

Fiscal year means the period of 12 calendar months beginning October 1 of any calendar year and ending September 30 of the following calendar year.

FNS means the Food and Nutrition Service of the U.S. Department of Agriculture.

Food costs means the costs of supplemental foods, determined in accordance with §246.14(b).

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Food delivery system means the method used by State and local agencies to provide supplemental foods to participants.

Food instrument means a voucher, check, electronic benefits transfer card (EBT), coupon or other document which is used by a participant to obtain supplemental foods.

Food sales means sales of all Food Stamp Program eligible foods intended for home preparation and consumption, including meat, fish, and poultry; bread and cereal products; dairy products; fruits and vegetables. Food items such as condiments and spices, coffee, tea, cocoa, and carbonated and non-carbonated drinks may be included in food sales when offered for sale along with foods in the categories identified above. Food sales do not include sales of any items that cannot be purchased with food stamp benefits, such as hot foods or food that will be eaten in the store.

Health services means ongoing, routine pediatric and obstetric care (such as infant and child care and prenatal and postpartum examinations) or referral for treatment.

High-risk vendor means a vendor identified as having a high probability of committing a vendor violation through application of the criteria established in §246.12(j)(3) and any additional criteria established by the State agency.

Home food delivery contractor means a sole proprietorship, partnership, cooperative association, corporation, or other business entity that contracts with a State agency to deliver authorized supplemental foods to the residences of participants under a home food delivery system.

Homeless facility means the following types of facilities which provide meal service. A supervised publicly or privately operated shelter (including a welfare hotel or congregate shelter) designed to provide temporary living accommodations; a facility that provides a temporary residence for individuals intended to be institutionalized; or a public or private place not designed for, or normally used as, a regular sleeping accommodation for human beings.

Homeless individual means a woman, infant or child:

(a) Who lacks a fixed and regular nighttime residence; or

(b) Whose primary nighttime residence is:

(1) A supervised publicly or privately operated shelter (including a welfare hotel, a congregate shelter, or a shelter for victims of domestic violence) designated to provide temporary living accommodation;

(2) An institution that provides a temporary residence for individuals intended to be institutionalized;

(3) A temporary accommodation of not more than 365 days in the residence of another individual; or

(4) A public or private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings.

IHS means the Indian Health Service of the U.S. Department of Health and Human Services.

Individual with disabilities means a handicapped person as defined in 7 CFR 15b.3.

Infant formula means a food that meets the definition of an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and that meets the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) and the regulations at 21 CFR parts 106 and 107.

Institution means any residential accommodation which provides meal service, except private residences and homeless facilities.

Infants means persons under one year of age.

Inventory audit means the examination of food invoices or other proofs of purchase to determine whether a vendor has purchased sufficient quantities of supplemental foods to provide participants the quantities specified on food instruments redeemed by the vendor during a given period of time.

Local agency means: (a) A public or private, nonprofit health or human service agency which provides health services, either directly or through contract, in accordance with §246.5; (b) an IHS service unit; (c) an Indian tribe, band or group recognized by the Department of the Interior which operates a health clinic or is provided

health services by an IHS service unit; or (d) an intertribal council or group that is an authorized representative of Indian tribes, bands or groups recognized by the Department of the Interior, which operates a health clinic or is provided health services by an IHS service unit.

Members of populations means persons with a common special need who do not necessarily reside in a specific geographic area, such as off-reservation Indians or migrant farmworkers and their families.

Migrant farmworker means an individual whose principal employment is in agriculture on a seasonal basis, who has been so employed within the last 24 months, and who establishes, for the purposes of such employment, a temporary abode.

Net price means the difference between an infant formula manufacturer's lowest national wholesale price per unit for a full truckload of infant formula and the rebate level or the discount offered or provided by the manufacturer under an infant formula cost containment contract.

Non-contract brand infant formula means all infant formula, including exempt infant formula, that is not covered by an infant formula cost containment contract awarded by that State agency.

Nonprofit agency means a private agency which is exempt from income tax under the Internal Revenue Code of 1954, as amended.

Nutrition education means individual and group sessions and the provision of materials that are designed to improve health status and achieve positive change in dietary and physical activity habits, and that emphasize the relationship between nutrition, physical activity, and health, all in keeping with the personal and cultural preferences of the individual.

Nutrition Services and Administration (NSA) Costs means those direct and indirect costs, exclusive of food costs, as defined in §246.14(c), which State and local agencies determine to be necessary to support Program operations. Costs include, but are not limited to, the costs of Program administration, start-up, monitoring, auditing, the development of and accountability for

food delivery systems, nutrition education and breastfeeding promotion and support, outreach, certification, and developing and printing food instruments and cash-value vouchers.

Nutritional risk means: (a) Detrimental or abnormal nutritional conditions detectable by biochemical or anthropometric measurements; (b) Other documented nutritionally related medical conditions; (c) Dietary deficiencies that impair or endanger health; (d) Conditions that directly affect the nutritional health of a person, including alcoholism or drug abuse; or (e) Conditions that predispose persons to inadequate nutritional patterns or nutritionally related medical conditions, including, but not limited to, homelessness and migrancy.

OIG means the Department's Office of the Inspector General.

Other harmful substances means other substances such as tobacco, prescription drugs and over-the-counter medications that can be harmful to the health of the WIC population, especially the pregnant woman and her fetus.

Partially-redeemed food instrument means a paper food instrument which is redeemed for less than all of the supplemental foods authorized for that food instrument.

Participants means pregnant women, breastfeeding women, postpartum women, infants and children who are receiving supplemental foods or food instruments or cash-value vouchers under the Program, and the breastfed infants of participant breastfeeding women.

Participant violation means any intentional action of a participant, parent or caretaker of an infant or child participant, or proxy that violates Federal or State statutes, regulations, policies, or procedures governing the Program. Participant violations include intentionally making false or misleading statements or intentionally misrepresenting, concealing, or withholding facts to obtain benefits; exchanging cash-value vouchers, food instruments or supplemental foods for cash, credit, non-food items, or unauthorized food items, including supplemental foods in excess of those listed on the participant's food instrument; threatening to

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harm or physically harming clinic, farmer or vendor staff; and dual participation.

Participation means the sum of:

(1) The number of persons who received supplemental foods or food instruments during the reporting period;

(2) The number of infants who did not receive supplemental foods or food instruments but whose breastfeeding mother received supplemental foods or food instruments during the report period; and

(3) The number of breastfeeding women who did not receive supplemental foods or food instruments but whose infant received supplemental foods or food instruments during the report period.

Postpartum women means women up to six months after termination of pregnancy.

Poverty income guidelines means the poverty income guidelines prescribed by the Department of Health and Human Services. These guidelines are adjusted annually by the Department of Health and Human Services, with each annual adjustment effective July 1 of each year. The poverty income guidelines prescribed by the Department of Health and Human Services shall be used for all States, as defined in this section, except for Alaska and Hawaii. Separate poverty income guidelines are prescribed for Alaska and Hawaii.

Pregnant women means women determined to have one or more embryos or fetuses in utero.

Price adjustment means an adjustment made by the State agency, in accordance with the vendor agreement, to the purchase price on a food instrument after it has been submitted by a vendor for redemption to ensure that the payment to the vendor for the food instrument complies with the State agency's price limitations.

Primary contract infant formula means 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.

Program means the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) authorized

by section 17 of the Child Nutrition Act of 1966, as amended.

Proxy means any person designated by a woman participant, or by a parent or caretaker of an infant or child participant, to obtain and transact food instruments or cash-value vouchers or to obtain supplemental foods on behalf of a participant. The proxy must be designated consistent with the State agency's procedures established pursuant to §246.12(r)(1). Parents or caretakers applying on behalf of child and infant participants are not proxies.

Rebate means the amount of money refunded under cost containment procedures to any State agency from the manufacturer of the particular food product as the result of the purchase of the supplemental food with a voucher or other purchase instrument by a participant in each State agency's program. Such rebates shall be payments made subsequent to the exchange of a food instrument for food.

Remote Indian or Native village means an Indian or Native village that is located in a rural area, has a population of less than 5,000 inhabitants, and is not accessible year-round by means of a public road (as defined in 23 U.S.C. 101).

Routine monitoring means overt, on-site monitoring during which program representatives identify themselves to vendor personnel.

Secretary means the Secretary of Agriculture.

SFPD means the Supplemental Food Programs Division of the Food and Nutrition Service of the U.S. Department of Agriculture.

Sign or signature means a handwritten signature on paper or an electronic signature. If the State agency chooses to use electronic signatures, the State agency must ensure the reliability and integrity of the technology used and the security and confidentiality of electronic signatures collected in accordance with sound management practices, and applicable Federal law and policy, and the confidentiality requirements in §246.26.

State means any of the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, or the

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Commonwealth of the Northern Mariana Islands.

State agency means the health department or comparable agency of each State; an Indian tribe, band or group recognized by the Department of the Interior; an intertribal council or group which is an authorized representative of Indian tribes, bands or groups recognized by the Department of the Interior and which has an ongoing relationship with such tribes, bands or groups for other purposes and has contracted with them to administer the Program; or the appropriate area office of the IHS.

State alliance means two or more State agencies that join together for the purpose of procuring infant formula under the Program by soliciting competitive bids for infant formula.

State Plan means a plan of Program operation and administration that describes the manner in which the State agency intends to implement and operate all aspects of Program administration within its jurisdiction in accordance with § 246.4.

Supplemental foods means those foods containing nutrients determined by nutritional research to be lacking in the diets of pregnant, breastfeeding and postpartum women, infants, and children, and foods that promote the health of the population served by the WIC Program as indicated by relevant nutrition science, public health concerns, and cultural eating patterns, as prescribed by the Secretary in § 246.10.

Vendor means a sole proprietorship, partnership, cooperative association, corporation, or other business entity operating one or more stores authorized by the State agency to provide authorized supplemental foods to participants under a retail food delivery system. Each store operated by a business entity constitutes a separate vendor and must be authorized separately from other stores operated by the business entity. Each store must have a single, fixed location, except when the authorization of mobile stores is necessary to meet the special needs described in the State agency's State Plan in accordance with § 246.4(a)(14)(xiv).

Vendor authorization means the process by which the State agency assesses,

selects, and enters into agreements with stores that apply or subsequently reapply to be authorized as vendors.

Vendor limiting criteria means criteria established by the State agency to determine the maximum number and distribution of vendors it authorizes pursuant to § 246.12(g)(2).

Vendor overcharge means intentionally or unintentionally charging the State agency more for authorized supplemental foods than is permitted under the vendor agreement. It is not a vendor overcharge when a vendor submits a food instrument for redemption and the State agency makes a price adjustment to the food instrument.

Vendor peer group system means a classification of authorized vendors into groups based on common characteristics or criteria that affect food prices, for the purpose of applying appropriate competitive price criteria to vendors at authorization and limiting payments for food to competitive levels.

Vendor selection criteria means the criteria established by the State agency to select individual vendors for authorization consistent with the requirements in § 246.12(g)(3) and (g)(4).

Vendor violation means any intentional or unintentional action of a vendor's current owners, officers, managers, agents, or employees (with or without the knowledge of management) that violates the vendor agreement or Federal or State statutes, regulations, policies, or procedures governing the Program.

WIC means the Special Supplemental Nutrition Program for Women, Infants and Children authorized by section 17 of the Child Nutrition Act of 1966, 42 U.S.C. 1786.

WIC-eligible medical foods means 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 medical foods 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; and may not be a conventional food,

drug, flavoring, or enzyme. WIC-eligible medical foods include many, but not all, products that meet the definition of medical food in Section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)).

[50 FR 6121, Feb. 13, 1985; 50 FR 8098, Feb. 28, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 246.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 246.3 Administration.

(a) *Delegation to FNS.* Within the Department, FNS shall act on behalf of the Department in the administration of the Program. Within FNS, SFPD and the Regional Offices are responsible for Program administration. FNS shall provide assistance to State and local agencies and evaluate all levels of Program operations to ensure that the goals of the Program are achieved in the most effective and efficient manner possible.

(b) *Delegation to the State agency.* The State agency is responsible for the effective and efficient administration of the Program in accordance with the requirements of this part; the Department's regulations governing non-discrimination (7 CFR parts 15, 15a, and 15b); governing administration of grants (7 CFR part 3016); governing nonprocurement debarment/suspension (7 CFR part 3017); governing restrictions on lobbying (7 CFR part 3018); and governing the drug-free workplace requirements (7 CFR 3021); FNS guidelines; and, instructions issued under the FNS Directives Management System. The State agency shall provide guidance to local agencies on all aspects of Program operations.

(c) *Agreement and State Plan.* (1) Each State agency desiring to administer the Program shall annually submit a State Plan and enter into a written agreement with the Department for administration of the Program in the jurisdiction of the State agency in accordance with the provisions of this part.

(2) The written agreement shall include a certification regarding lobbying and, if applicable, a disclosure of

lobbying activities, as required by 7 CFR part 3018.

(d) *State agency eligibility.* A State agency shall be ineligible to participate in the WIC Program if State or local sales tax is collected on WIC food purchases in the area in which it administers the program, except that, if sales tax is collected on WIC food purchases by sovereign Indian entities which are not State agencies, the State agency shall remain eligible if any vendors collecting such tax are disqualified.

(e) *State staffing standards.* Each State agency shall ensure that sufficient staff is available to administer an efficient and effective Program including, but not limited to, the functions of nutrition education, certification, food delivery, fiscal reporting, monitoring, and training. Based on the June participation of the previous fiscal year, each State agency, as a minimum, shall employ the following staff:

(1) A full-time or equivalent administrator when the monthly participation level exceeds 1,500, or a half-time or equivalent administrator when the monthly participation exceeds 500.

(2) At least one full-time or equivalent Program specialist for each 10,000 participants above 1,500, but the State agency need not employ more than eight Program specialists unless the State agency considers it necessary. Program specialists should be utilized for providing fiscal management and technical assistance, monitoring vendors, reviewing local agencies, training, and nutritional services, or other Program duties as assigned by the State agency.

(3) For nutrition-related services, one full-time or equivalent nutritionist when the monthly participation is above 1,500, or a half-time or equivalent nutritionist when the monthly participation exceeds 500. The nutritionist shall be named State WIC Nutrition Coordinator and shall meet State personnel standards and qualifications in paragraphs (e)(3) (i), (ii), (iii), (iv), or (v) of this section and have the qualifications in paragraph (e)(3)(vi) of this section. Upon request, an exception to these qualifications may be granted by FNS. The State WIC Nutrition Coordinator shall—

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(i) Hold a Master's degree with emphasis in food and nutrition, community nutrition, public health nutrition, nutrition education, human nutrition, nutrition science or equivalent and have at least two years responsible experience as a nutritionist in education, social service, maternal and child health, public health, nutrition, or dietetics; or

(ii) Be registered or eligible for registration with the American Dietetic Association and have at least two years experience; or

(iii) Have at least a Bachelor of Science or Bachelor of Arts degree, from an accredited four-year institution, with emphasis in food and nutrition, community nutrition, public health nutrition, nutrition education, human nutrition, nutrition science or equivalent and have at least three years of responsible experience as a nutritionist in education, social service, maternal and child health, public health nutrition, or dietetics; or

(iv) Be qualified as a Senior Public Health Nutritionist under the Department of Health and Human Services guidelines; or

(v) Meet the IHS standards for a Public Health Nutritionist; and

(vi) Have at least one of the following: Program development skills, education background and experience in the development of educational and training resource materials, community action experience, counseling skills or experience in participant advocacy.

(4) A designated breastfeeding promotion coordinator, to coordinate breastfeeding promotion efforts identified in the State plan in accordance with the requirement of § 246.4(a)(9) of this part. The person to whom the State agency assigns this responsibility may perform other duties as well.

(5) A staff person designated for food delivery system management. The person to whom the State agency assigns this responsibility may perform other duties as well.

(6) The State agency shall enforce hiring practices which comply with the nondiscrimination criteria set forth in § 246.8. The hiring of minority staff is encouraged.

(f) *Delegation to local agency.* The local agency shall provide Program benefits to participants in the most effective and efficient manner, and shall comply with this part, the Department's regulations governing non-discrimination (7 CFR parts 15, 15a, 15b), the Department's regulations governing the administration of grants (7 CFR part 3016), Office of Management and Budget Circular A-130, and State agency and FNS guidelines and instructions.

[50 FR 6121, Feb. 13, 1985; 50 FR 8098, Feb. 28, 1985, as amended at 52 FR 21236, June 4, 1987; 59 FR 11499, Mar. 11, 1994; 65 FR 83277, Dec. 29, 2000; 71 FR 56728, Sept. 27, 2006]

Subpart B—State and Local Agency Eligibility

§ 246.4 State plan.

(a) *Requirements.* By August 15 of each year, each State agency shall submit to FNS for approval a State Plan for the following fiscal year as a prerequisite to receiving funds under this section. The State agency may submit the State Plan in the format provided by FNS guidance. Alternatively, the State agency may submit the Plan in combination with other federally required planning documents or develop its own format, provided that the information required below is included. FNS requests advance notification that a State agency intends to use an alternative format. The State Plan shall be signed by the State designated official responsible for ensuring that the Program is operated in accordance with the State Plan. FNS will provide written approval or denial of a completed State Plan or amendment within 30 days of receipt. Within 15 days after FNS receives an incomplete Plan, FNS will notify the State agency that additional information is needed to complete the Plan. Any disapproval will be accompanied by a statement of the reasons for the disapproval. After receiving approval of the State Plan, each State agency shall only submit to FNS for approval substantive changes in the State Plan. A complete and approved Plan shall include:

(1) An outline of the State agency's goals and objectives for improving Program operations.

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(2) A budget for nutrition services and administration funds, and an estimate of food expenditures.

(3) An estimate of Statewide participation for the coming fiscal year by category of women, infants and children.

(4) The State agency staffing pattern.

(5) An Affirmative Action Plan which includes—

(i) A list of all areas and special populations, in priority order based on relative need, within the jurisdiction of the State agency, the State agency's plans to initiate or expand operations under the Program in areas most in need of supplemental foods, including plans to inform nonparticipating local agencies of the availability and benefits of the Program and the availability of technical assistance in implementing the Program, and a description of how the State agency will take all reasonable actions to identify potential local agencies and encourage agencies to implement or expand operations under the Program within the following year in the neediest one-third of all areas unserved or partially served;

(ii) An estimate of the number of potentially eligible persons in each area and a list of the areas in the Affirmative Action Plan which are currently operating the Program and their current participation, which participant priority levels as specified in §246.7 are being reached in each of these areas, and which areas in the Affirmative Action Plan are currently operating CSFP and their current participation; and

(iii) A list of the names and addresses of all local agencies.

(6) Plans to provide program benefits to eligible migrant farmworkers and their families, to Indians, and to homeless individuals.

(7) The State agency's plans, to be conducted in cooperation with local agencies, for informing eligible persons of the availability of Program benefits, including the eligibility criteria for participation, the location of local agencies operating the Program, and the institutional conditions of §246.7(n)(1)(i) of this part, with emphasis on reaching and enrolling eligible women in the early months of preg-

nancy and migrants. Such information shall be publicly announced by the State agency and by local agencies at least annually. Such information shall also be distributed to offices and organizations that deal with significant numbers of potentially eligible persons, including health and medical organizations, hospitals and clinics, welfare and unemployment offices, social service agencies, farmworker organizations, Indian tribal organizations, organizations and agencies serving homeless individuals, and religious and community organizations in low-income areas.

(8) A description of how the State agency plans to coordinate program operations with other services or programs that may benefit participants in, or applicants for, the program.

(9) The State agency's nutrition education goals and action plans, including a description of the methods that will be used to provide drug and other harmful substance abuse information, promote breastfeeding, and to meet the special nutrition education needs of migrant farmworkers and their families, Indians, and homeless persons.

(10) For Indian State or local agencies that wish to apply for the alternate income determination procedure in accordance with §246.7(d)(2)(vii), documentation that the majority of Indian household members have incomes below eligibility criteria.

(11) A copy of the procedure manual developed by the State agency for guidance to local agencies in operating the Program. The manual shall include—

(i) Certification procedures, including:

(A) A list of the specific nutritional risk criteria by priority level which explains how a person's nutritional risk is determined;

(B) Hematological data requirements including timeframes for the collection of such data;

(C) The procedures for requiring proof of pregnancy, consistent with §246.7(c)(2)(ii), if the State agency chooses to require such proof;

(D) The State agency's income guidelines for Program eligibility;

(E) Adjustments to the participant priority system (see §246.7(e)(4)) to accommodate high-risk postpartum

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women or the addition of Priority VII; and,

(F) Alternate language for the statement of rights and responsibilities which is provided to applicants, parents, or caretakers when applying for benefits as outlined in § 246.7(i)(10) and (j)(2)(i) through (j)(2)(iii). This alternate language must be approved by FNS before it can be used in the required statement.

(ii) Methods for providing nutrition education to participants. Nutrition education will include information on drug abuse and other harmful substances. Participants will include homeless individuals.

(iii) Instructions concerning all food delivery operations performed at the local level, including the list of acceptable foods and their maximum monthly quantities as required by § 246.10(b)(1).

(iv) Instructions for providing all records and reports which the State agency requires local agencies to maintain and submit; and

(v) Instructions on coordinating operations under the program with drug and other harmful substance abuse counseling and treatment services.

(12) A description of the State agency's financial management system.

(13) A description of how the State agency will distribute nutrition services and administration funds, including start-up funds, to local agencies operating under the Program.

(14) A description of the food delivery system as it operates at the State agency level, including—

(i) *Type of system.* All food delivery systems in use within the State agency's jurisdiction;

(ii) *Vendor limiting and selection criteria.* Vendor limiting criteria, if used by the State agency, and the vendor selection criteria established by the State agency consistent with the requirements in § 246.12(g)(3) and (g)(4);

(iii) *A sample vendor and farmer, if applicable, agreement.* The sample vendor agreement must include the sanction schedule, the process for notification of violations in accordance with § 246.12(l)(3), and the State agency's policies and procedures on incentive items in accordance with § 246.12(g)(3)(iv), which may be incorporated as attachments or, if the sanc-

tion schedule, the process for notification of violations, or policies on incentive items are in the State agency's regulations, through citations to the regulations. State agencies that intend to delegate signing of vendor agreements to local agencies must describe the State agency supervision and instruction that will be provided to ensure the uniformity and quality of local agency activities;

(iv) *Vendor monitoring.* The system for monitoring vendors to ensure compliance and prevent fraud, waste, and program noncompliance, and the State agency's plans for improvement in the coming year in accordance with § 246.12(j). The State agency must also include the criteria it will use to determine which vendors will receive routine monitoring visits. State agencies that intend to delegate any aspect of vendor monitoring responsibilities to a local agency or contractor must describe the State agency supervision and instruction that will be provided to ensure the uniformity and quality of vendor monitoring;

(v) *Options regarding trafficking convictions.* The option exercised by the State agency to sanction vendors pursuant to § 246.12(k)(1)(i).

(vi) *Food instruments and cash-value vouchers.* A facsimile of the food instrument and cash-value voucher, if used, and a description of the system the State agency will use to account for the disposition of food instruments and cash value vouchers in accordance with § 246.12(q);

(vii) *Names of contractors.* The names of companies, excluding authorized vendors, with whom the State agency has contracted to participate in the operation of the food delivery system;

(viii) *Nutrition services and administration funds conversion.* For State agencies applying for authority to convert food funds to nutrition services and administration funds under § 246.16(g), a full description of their proposed cost-cutting system or system modification;

(ix) *Homeless participants.* If the State agency plans to adapt its food delivery system to accommodate the needs of homeless individuals, a description of such adaptations;

(x) *Infant formula cost containment.* A description of any infant formula cost

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containment system. A State agency must submit a State Plan or Plan amendment if it is attempting to structure and justify a system that is not a single-supplier competitive bidding system for infant formula in accordance with §246.16a(d); is requesting a waiver for an infant formula cost containment system under §246.16a(e); or, is planning to change or modify its current system or implement a system for the first time. The amendment must be submitted at least 90 days before the proposed effective date of the system change. The plan amendment must include documentation for requests for waivers based on interference with efficient or effective program operations; a cost comparison analysis conducted under §246.16a(d)(2); and a description of the proposed cost containment system. If FNS disputes supporting plan amendment documentation, it will deem the Plan amendment incomplete under this paragraph (a), and will provide the State agency with a statement outlining disputed issues within 15 days of receipt of the Plan amendment. The State agency may not enter into any infant formula cost containment contract until the disputed issues are resolved and FNS has given its consent. If necessary, FNS may grant a postponement of implementation of an infant formula cost containment system under §246.16a(f). If at the end of the postponement period issues remain unresolved the State agency must proceed with a cost containment system judged by FNS to comply with the provisions of this part. If the State agency does not comply, it will be subject to the penalties set forth in §246.16a(i);

(xi) *Vendor and farmer training.* The procedures the State agency will use to train vendors in accordance with §246.12(i) and farmers. State agencies that intend to delegate any aspect of training to a local agency, contractor, or vendor representative must describe the State agency supervision and instructions that will be provided to ensure the uniformity and quality of vendor training.

(xii) *Food instrument and cash-value voucher security.* A description of the State agency's system for ensuring food instrument and cash-value vouch-

er security in accordance with §246.12(p);

(xiii) *Participant access determination criteria.* A description of the State agency's participant access determination criteria consistent with §246.12(1); and

(xiv) *Mobile stores.* The special needs necessitating the authorization of mobile stores, if the State agency chooses to authorize such stores.

(xv) *Vendor cost containment.* A description of the State agency's vendor peer group system, competitive price criteria, and allowable reimbursement levels that demonstrates that the State agency is in compliance with the cost containment provisions in §246.12(g)(4); information on non-profit above-50-percent vendors that the State agency has exempted from competitive price criteria and allowable reimbursement levels in §246.12(g)(4)(iv); a justification and documentation supporting the State agency's request for an exemption from the vendor peer group requirement in §246.12(g)(4), if applicable; and, if the State agency authorizes any above-50-percent vendors, information required by FNS to determine whether the State agency's vendor cost containment system meets the requirements in §246.12(g)(4)(i).

(xvi) *Other cost containment systems.* A description of any other food cost containment systems (such as juice and cereal rebates and food item restrictions).

(xvii) *List of infant formula wholesalers, distributors, and retailers.* The policies and procedures for compiling and distributing to authorized WIC retail vendors, on an annual or more frequent basis, as required by §246.12(g)(11), a list of infant formula wholesalers, distributors, and retailers licensed in the State in accordance with State law (including regulations), and infant formula manufacturers registered with the Food and Drug Administration (FDA) that provide infant formula. The vendor may provide only the authorized infant formula which the vendor has obtained from a source included on the list described in §246.12(g)(11) to participants in exchange for food instruments specifying infant formula.

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(15) The State agency's procedures for accepting and processing vendor applications outside of its established timeframes if the State agency determines there will otherwise be inadequate participant access to the WIC Program.

(16) The State agency's plans to prevent and identify dual participation in accordance with § 246.7(1)(1)(i) and (1)(1)(ii). In States where the Program and the CSFP operate in the same area, or where an Indian State agency operates a Program in the same area as a geographic State agency, a copy of the written agreement between the State agencies for the detection and prevention of dual participation shall be submitted.

(17) A description of the procedures the State will use to comply with the civil rights requirements described in § 246.8, including the processing of discrimination complaints.

(18) A copy of the State agency's fair hearing procedures for participants and the administrative appeal procedures for local agencies and food vendors.

(19) The State agency's plan to reach and enroll migrants, and eligible women in the early months of pregnancy.

(20) The State agency's plan to establish, to the extent practicable, that homeless facilities, and institutions if it chooses to make the Program available to them, meet the conditions established in § 246.7(n)(1)(i) of this part, if residents of such accommodations are to be eligible to receive WIC Program benefits.

(21) A plan to provide program benefits to unserved infants and children under the care of foster parents, protective services, or child welfare authorities, including infants exposed to drugs perinatally.

(22) A plan to improve access to the Program for participants and prospective applicants who are employed or who reside in rural areas, by addressing their special needs through the adoption or revision of procedures and practices to minimize the time participants and applicants must spend away from work and the distances participants and applicants must travel. The State agency shall also describe any plans for issuance of food instruments and cash-

value vouchers to employed or rural participants, or to any other segment of the participant population, through means other than direct participant pick-up, pursuant to § 246.12(r)(4). Such description shall also include measures to ensure the integrity of Program services and fiscal accountability. The State agency will also describe its policy for approving transportation of participants to and from WIC clinics.

(23) Assurance that each local agency and any subgrantees of the State agency and/or local agencies are in compliance with the requirements of 7 CFR part 3017 regarding nonprocurement debarment/suspension.

(24) A description of the State agency's plans to provide and maintain a drug-free workplace in compliance with requirements in 7 CFR part 3021.

(25) A list of all organizations with which the State agency or its local agencies has executed or intends to execute a written agreement pursuant to § 246.26(h) authorizing the use and disclosure of confidential applicant and participant information for non-WIC purposes.

(26) The State agency's policies and procedures for preventing conflicts of interest at the local agency or clinic level in a reasonable manner. At a minimum, this plan must prohibit the following WIC certification practices by local agency or clinic employees, or provide effective alternative policies and procedures when such prohibition is not possible:

(i) Certifying oneself;

(ii) Certifying relatives or close friends; or,

(iii) One employee determining eligibility for all certification criteria and issuing food instruments, cash-value vouchers or supplemental food for the same participant.

(27) The State agency's plan for collecting and maintaining information on cases of participant and employee fraud and abuse. Such information should include the nature of the fraud detected and the associated dollar losses.

(28) The State agency's Universal Identifier number.

(b) *Public comment.* The State agency shall establish a procedure under which

members of the general public are provided an opportunity to comment on the development of the State agency plan.

(c) *Amendments.* At any time after approval, the State agency may amend the State Plan to reflect changes. The State agency shall submit the amendments to FNS for approval. The amendments shall be signed by the State designated official responsible for ensuring that the Program is operated in accordance with the State Plan.

(d) *Retention of copy.* A copy of the approved State Plan or the WIC portion of the State's composite plan of operations shall be kept on file at the State agency for public inspection.

[50 FR 6121, Feb. 13, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 246.4, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 246.5 Selection of local agencies.

(a) *General.* This section sets forth the procedures the State agency shall perform in the selection of local agencies and the expansion, reduction, and disqualification of local agencies already in operation. In making decisions to initiate, continue, and discontinue the participation of local agencies, the State agency shall give consideration to the need for Program benefits as delineated in the Affirmative Action Plan.

(b) *Application of local agencies.* The State agency shall require each agency, including subdivisions of the State agency, which desires approval as a local agency, to submit a written local agency application. After the receipt of an incomplete application, the State agency shall provide written notification to the applicant agency of the additional information needed. After the receipt of a complete application, the State agency shall notify the applicant agency in writing of the approval or disapproval of its application. When an application is disapproved, the State agency shall advise the applicant agency of the reasons for disapproval and of the right to appeal as set forth in § 246.18. When an agency submits an application and there are no funds to serve the area, the applicant agency

shall be notified that there are currently no funds available for Program initiation or expansion. The applicant agency shall be notified by the State agency when funds become available.

(c) *Program initiation and expansion.* The State agency shall meet the following requirements concerning Program initiation and expansion:

(1) The State agency will consider the Affirmative Action Plan (see § 246.4(a)(5)) when funding local agencies and expanding existing operations, and may consider how much of the current need is being met at each priority level. The selection criteria cited in paragraph (d)(1) of this section shall be applied to each area or special population before eliminating that area from consideration and serving the next area of special population. The State agency shall consider the number of participants in each priority level being served by existing local agencies in determining when it is appropriate to move into additional areas in the Affirmative Action Plan or to expand existing operations in an area. Additionally, the State agency shall consider the total number of people potentially eligible in each area compared to the number being served.

(2) The State agency shall provide a written justification to FNS for not funding an agency to serve the highest priority area or special population. Such justification may include its inability to administer the Program, lack of interest expressed for operating the Program, or for those areas or special populations which are under consideration for expansion of an existing operation, a determination by the State agency that there is a greater need for funding an agency serving an area or special population not operating the Program. The State agency shall use the participant priority system in § 246.7 as a measurement of greater need in such determination.

(3) The State agency may fund more than one local agency to serve the same area or special population as long as more than one local agency is necessary to serve the full extent of need in that area or special population.

(d) *Local agency priority system.* The State agency shall establish standards for the selection of new local agencies.

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Such standards shall include the following considerations:

(1) The State agency shall consider the following priority system, which is based on the relative availability of health and administrative services, in the selection of local agencies:

(i) First consideration shall be given to a public or a private nonprofit health agency that will provide ongoing, routine pediatric and obstetric care and administrative services.

(ii) Second consideration shall be given to a public or a private nonprofit health or human service agency that will enter into a written agreement with another agency for either ongoing, routine pediatric and obstetric care or administrative services.

(iii) Third consideration shall be given to a public or private nonprofit health agency that will enter into a written agreement with private physicians, licensed by the State, in order to provide ongoing, routine pediatric and obstetric care to a specific category of participants (women, infants or children).

(iv) Fourth consideration shall be given to a public or private nonprofit human service agency that will enter into a written agreement with private physicians, licensed by the State, to provide ongoing, routine pediatric and obstetric care.

(v) Fifth consideration shall be given to a public or private nonprofit health or human service agency that will provide ongoing, routine pediatric and obstetric care through referral to a health provider.

(2) The State agency must, when seeking new local agencies, publish a notice in the local media (unless it has received an application from a local public or nonprofit private health agency that can provide adequate services). The notice will include a brief explanation of the Program, a description of the local agency priority system (outlined in this paragraph (d)), and a request that potential local agencies notify the State agency of their interest. In addition, the State agency will contact all potential local agencies to make sure they are aware of the opportunity to apply. If an application is not submitted within 30 days, the State agency may then select a local agency

in another area. If sufficient funds are available, a State agency will give notice and consider applications outside the local area at the same time.

(e) *Disqualification of local agencies.* (1) The State agency may disqualify a local agency—

(i) When the State agency determines noncompliance with Program regulations;

(ii) When the State's Program funds are insufficient to support the continued operation of all its existing local agencies at their current participation level; or

(iii) When the State agency determines, following a review of local agency credentials in accordance with paragraph (f) of this section, that another local agency can operate the Program more effectively and efficiently.

(2) The State agency may establish its own criteria for disqualification of local agencies. The State agency shall notify the local agency of any State-established criteria. In addition to any State established criteria, the State agency shall consider, at a minimum—

(i) The availability of other community resources to participants and the cost efficiency and cost effectiveness of the local agency in terms of both food and nutrition services and administration costs;

(ii) The percentages of participants in each priority level being served by the local agency and the percentage of need being met in each participant category;

(iii) The relative position of the area or special population served by the local agency in the Affirmative Action Plan;

(iv) The local agency's place in the priority system in paragraph (d)(1) of this section; and

(v) The capability of another local agency or agencies to accept the local agency's participants.

(3) When disqualifying a local agency under the Program, the State agency shall—

(i) Make every effort to transfer affected participants to another local agency without disruption of benefits;

(ii) Provide the affected local agency with written notice not less than 60 days in advance of the pending action which includes an explanation of the

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reasons for disqualification, the date of disqualification, and, except in cases of the expiration of a local agency's agreement, the local agency's right to appeal as set forth in § 246.18; and

(iii) Ensure that the action is not in conflict with any existing written agreements between the State and the local agency.

(f) *Periodic review of local agency qualifications.* The State agency may conduct periodic reviews of the qualifications of authorized local agencies under its jurisdiction. Based upon the results of such reviews the State agency may make appropriate adjustments among the participating local agencies, including the disqualification of a local agency when the State agency determines that another local agency can operate the Program more effectively and efficiently. In conducting such reviews, the State agency shall consider the factors listed in paragraph (e)(2) of this section in addition to whatever criteria it may develop. The State agency shall implement the procedures established in paragraph (e)(3) of this section when disqualifying a local agency.

[50 FR 6121, Feb. 13, 1985; 50 FR 8098, Feb. 28, 1985; 65 FR 53527, Sept. 5, 2000; 71 FR 56728, Sept. 27, 2006]

§ 246.6 Agreements with local agencies.

(a) *Signed written agreements.* The State agency shall enter into a signed written agreement with each local agency, including subdivisions of the State agency, which sets forth the local agency's responsibilities for Program operations as prescribed in this part. Copies of the agreement shall be kept on file at both the State and local agencies for purposes of review and audit in accordance with §§ 246.19 and 246.20. Neither the State agency nor the local agency has an obligation to renew the agreement. The expiration of an agreement is not subject to appeal. The State agency shall provide local agencies with advance written notice of the expiration of an agreement as required under §§ 246.5(e)(3)(i) and 246.18(b)(1).

(b) *Provisions of agreement.* The agreement between the State agency and each local agency shall ensure that the local agency—

(1) Complies with all the fiscal and operational requirements prescribed by the State agency pursuant to this part, 7 CFR part 3016, the debarment and suspension requirements of 7 CFR part 3017, if applicable, the lobbying restrictions of 7 CFR part 3018, and FNS guidelines and instructions, and provides on a timely basis to the State agency all required information regarding fiscal and Program information;

(2) Has a competent professional authority on the staff of the local agency and the capabilities necessary to perform the certification procedures;

(3) Makes available appropriate health services to participants and informs applicants of the health services which are available;

(4) Prohibits smoking in the space used to carry out the WIC Program during the time any aspect of WIC services are performed;

(5) Has a plan for continued efforts to make health services available to participants at the clinic or through written agreements with health care providers when health services are provided through referral;

(6) Provides nutrition education services to participants, in compliance with § 246.11 and FNS guidelines and instructions;

(7) Implements a food delivery system prescribed by the State agency pursuant to § 246.12 and approved by FNS;

(8) Maintains complete, accurate, documented and current accounting of all Program funds received and expended;

(9) Maintains on file and has available for review, audit, and evaluation all criteria used for certification, including information on the area served, income standards used, and specific criteria used to determine nutritional risk; and

(10) Does not discriminate against persons on the grounds of race, color, national origin, age, sex or handicap; and compiles data, maintains records and submits reports as required to permit effective enforcement of the non-discrimination laws.

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(c) *Indian agencies.* Each Indian State agency shall ensure that all local agencies under its jurisdiction serve primarily Indian populations.

(d) *Health and human service agencies.* When a health agency and a human service agency comprise the local agency, both agencies shall together meet all the requirements of this part and shall enter into a written agreement which outlines all Program responsibilities of each agency. The agreement shall be approved by the State agency during the application process and shall be on file at both the State and local agency. No Program funds shall be used to reimburse the health agency for the health services provided. However, costs of certification borne by the health agency may be reimbursed.

(e) *Health or human service agencies and private physicians.* When a health or human service agency and private physician(s) comprise the local agency, all parties shall together meet all of the requirements of this part and shall enter into a written agreement which outlines the inter-related Program responsibilities between the physician(s) and the local agency. The agreement shall be approved by the State agency during the application process and shall be on file at both agencies. The local agency shall advise the State agency on its application of the name(s) and address(es) of the private physician(s) participating and obtain State agency approval of the written agreement. A competent professional authority on the staff of the health or human service agency shall be responsible for the certification of participants. No Program funds shall be used to reimburse the private physician(s) for the health services provided. However, costs of certification data provided by the physician(s) may be reimbursed.

(f) *Outreach/Certification In Hospitals.* The State agency shall ensure that each local agency operating the program within a hospital and/or that has a cooperative arrangement with a hospital:

(1) Advises potentially eligible individuals that receive inpatient or outpatient prenatal, maternity, or postpartum services, or that accompany a child under the age of 5 who re-

ceives well-child services, of the availability of program services; and

(2) To the extent feasible, provides an opportunity for individuals who may be eligible to be certified within the hospital for participation in the WIC Program.

[50 FR 6121, Feb. 13, 1985, as amended at 59 FR 11500, Mar. 11, 1994; 63 FR 63974, Nov. 18, 1998]

Subpart C—Participant Eligibility

§ 246.7 Certification of participants.

(a) *Integration with health services.* To lend administrative efficiency and participant convenience to the certification process, whenever possible, Program intake procedures shall be combined with intake procedures for other health programs or services administered by the State and local agencies. Such merging may include verification procedures, certification interviews, and income computations. Local agencies shall maintain and make available for distribution to all pregnant, postpartum, and breastfeeding women and to parents or caretakers of infants and children applying for and participating in the Program a list of local resources for drug and other harmful substance abuse counseling and treatment.

(b) *Program referral and access.* State and local agencies shall provide WIC Program applicants and participants or their designated proxies with information on other health-related and public assistance programs, and when appropriate, shall refer applicants and participants to such programs.

(1) The State agency shall provide each local WIC agency with materials showing the maximum income limits, according to family size, applicable to pregnant women, infants, and children up to age 5 under the medical assistance program established under Title XIX of the Social Security Act (in this section, referred to as the “Medicaid Program”). The local agency shall, in turn, provide to adult individuals applying or reapplying for the WIC Program for themselves or on behalf of others, written information about the Medicaid Program. If such individuals are not currently participating in Medicaid but appear to have family income below the applicable maximum income

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limits for the program, the local agency shall also refer these individuals to Medicaid, including the referral of infants and children to the appropriate entity in the area authorized to determine eligibility for early and periodic screening, diagnostic, and treatment (EPSDT) services, and, the referral of pregnant women to the appropriate entity in the area authorized to determine presumptive eligibility for the Medicaid Program, if such determinations are being offered by the State.

(2) State agencies shall provide WIC services at community and migrant health centers, Indian Health Services facilities, and other federally health care supported facilities established in medically underserved areas to the extent feasible.

(3) Local agencies may provide information about other potential sources of food assistance in the local area to adult individuals applying or reapplying in person for the WIC Program for themselves or on behalf of others, when such applicants cannot be served because the Program is operating at capacity in the local area.

(4) Each local agency that does not routinely schedule appointments shall schedule appointments for employed adult individuals seeking to apply or reapply for participation in the WIC Program for themselves or on behalf of others so as to minimize the time such individuals are absent from the workplace due to such application.

(5) Each local agency shall attempt to contact each pregnant woman who misses her first appointment to apply for participation in the Program in order to reschedule the appointment. At the time of initial contact, the local agency shall request an address and telephone number where the pregnant woman can be reached.

(c) *Eligibility criteria and basic certification procedures.* (1) To qualify for the Program, infants, children, and pregnant, postpartum, and breastfeeding women must:

(i) Reside within the jurisdiction of the State (except for Indian State agencies). Indian State agencies may establish a similar requirement. All State agencies may determine a service area for any local agency, and may require that an applicant reside within

the service area. However, the State agency may not use length of residency as an eligibility requirement.

(ii) Meet the income criteria specified in paragraph (d) of this section.

(iii) Meet the nutritional risk criteria specified in paragraph (e) of this section.

(2)(i) At certification, the State or local agency must require each applicant to present proof of residency (i.e., location or address where the applicant routinely lives or spends the night) and proof of identity. The State or local agency must also check the identity of participants, or in the case of infants or children, the identity of the parent or guardian, or proxies when issuing food, cash-value vouchers or food instruments. The State agency may authorize the certification of applicants when no proof of residency or identity exists (such as when an applicant or an applicant's parent is a victim of theft, loss, or disaster; a homeless individual; or a migrant farmworker). In these cases, the State or local agency must require the applicant to confirm in writing his/her residency or identity. Further, an individual residing in a remote Indian or Native village or an individual served by an Indian tribal organization and residing on a reservation or pueblo may establish proof of residency by providing the State agency their mailing address and the name of the remote Indian or Native village.

(ii) For a State agency opting to require proof of pregnancy, the State agency may issue benefits to applicants who claim to be pregnant (assuming that all other eligibility criteria are met) but whose conditions (as pregnant) are not visibly noticeable and do not have documented proof of pregnancy at the time of the certification interview and determination. The State agency should then allow a reasonable period of time, not to exceed 60 days, for the applicant to provide the requested documentation. If such documentation is not provided as requested, the woman can no longer be considered categorically eligible, and the local agency would then be justified in terminating the woman's WIC participation in the middle of a certification period.

(3) A State, a State agency, and an Indian Tribal Organization (including, an Indian tribe, band, or group recognized by the Department of the Interior; or an intertribal council or group which is an authorized representative of Indian tribes, bands or groups recognized by the Department of the Interior and which has an ongoing relationship with such tribes, bands or groups for other purposes and has contracted with them to administer the Program) serving as a State agency, may limit WIC participation to United States citizens, nationals, and qualified aliens as these terms are defined in the Immigration and Nationality Laws (8 U.S.C. 1101 et seq.). State agencies that implement this option shall inform FNS of their intentions and provide copies of the procedures they will establish regarding the limitation of WIC services to United States citizens, nationals, and qualified aliens.

(4) The certification procedure shall be performed at no cost to the applicant.

(d) *Income criteria and income eligibility determinations.* The State agency shall establish, and provide local agencies with, income guidelines, definitions, and procedures to be used in determining an applicant's income eligibility for the Program.

(1) *Income eligibility guidelines.* The State agency may prescribe income guidelines either equaling the income guidelines established under section 9 of the National School Lunch Act for reduced-price school meals or identical to State or local guidelines for free or reduced-price health care. However, in conforming Program income guidelines to health care guidelines, the State agency shall not establish Program guidelines which exceed the guidelines for reduced-price school meals or are less than 100 percent of the revised poverty income guidelines issued annually by the Department of Health and Human Services. Program applicants who meet the requirements established by paragraph (d)(2)(vi)(A) of this section shall not be subject to the income limits established by State agencies under this paragraph.

(i) *Local agency income eligibility guidelines.* Different guidelines may be prescribed for different local agencies

within the State provided that the guidelines are the ones used by the local agencies for determining eligibility for free or reduced-price health care.

(ii) *Annual adjustments in the income guidelines.* On or before June 1 each year, FNS will announce adjustments in the income guidelines for reduced-price meals under section 9 of the National School Lunch Act, based on annual adjustments in the revised poverty income guidelines issued by the Department of Health and Human Services.

(iii) *Implementation of the income guidelines.* On or before July 1 each year, each State agency shall announce and transmit to each local agency the State agency's family size income guidelines, unless changes in the poverty income guidelines issued by the Department of Health and Human Services do not necessitate changes in the State or local agency's income guidelines. The State agency may implement revised guidelines concurrently with the implementation of income guidelines under the Medicaid program established under Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.). The State agency shall ensure that conforming adjustments are made, if necessary, in local agency income guidelines. The local agency shall implement (revised) guidelines not later than July 1 of each year for which such guidelines are issued by the State.

(2) *Income eligibility determinations.* The State agency shall ensure that local agencies determine income through the use of a clear and simple application form provided or approved by the State agency.

(i) *Timeframes for determining income.* In determining the income eligibility of an applicant, the State agency may instruct local agencies to consider the income of the family during the past 12 months and the family's current rate of income to determine which indicator more accurately reflects the family's status. However, persons from families with adult members who are unemployed shall be eligible based on income during the period of unemployment if the loss of income causes the current rate of income to be less than

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the State or local agency's income guidelines for Program eligibility.

(ii) *Definition of "Income"*. If the State agency uses the National School Lunch reduced-priced meal income guidelines, as specified in paragraph (d)(1) of this section, it shall use the following definition of income: Income for the purposes of this part means gross cash income before deductions for income taxes, employees' social security taxes, insurance premiums, bonds, etc. Income includes the following—

(A) Monetary compensation for services, including wages, salary, commissions, or fees;

(B) Net income from farm and non-farm self-employment;

(C) Social Security benefits;

(D) Dividends or interest on savings or bonds, income from estates or trusts, or net rental income;

(E) Public assistance or welfare payments;

(F) Unemployment compensation;

(G) Government civilian employee or military retirement or pensions or veterans' payments;

(H) Private pensions or annuities;

(I) Alimony or child support payments;

(J) Regular contributions from persons not living in the household;

(K) Net royalties; and

(L) Other cash income. Other cash income includes, but is not limited to, cash amounts received or withdrawn from any source including savings, investments, trust accounts and other resources which are readily available to the family.

(iii) *Use of a State or local health care definition of "Income"*. If the State agency uses State or local free or reduced-price health care income guidelines, it will ensure that the definitions of income (see paragraph (d)(2)(ii) of this section), family (see § 246.2) and allowable exclusions from income (see paragraph (d)(2)(iv) of this section) are used uniformly to determine an applicant's income eligibility. This ensures that households with a gross income in excess of 185 percent of the Federal income guidelines (see paragraph (d)(1) of this section) are not eligible for Program benefits. The exception to this requirement is persons who are also income eligible under other programs

(see paragraph (d)(2)(vi) of this section).

(iv) *Income exclusions*. (A) In determining income eligibility, the State agency may exclude from consideration as income any:

(1) Basic allowance for housing received by military services personnel residing off military installations or in privatized housing, whether on- or off-base; and

(2) Cost-of-living allowance provided under 37 U.S.C. 405, to a member of a uniformed service who is on duty outside the contiguous states of the United States.

(B) The value of inkind housing and other inkind benefits, shall be excluded from consideration as income in determining an applicant's eligibility for the program.

(C) Loans, not including amounts to which the applicant has constant or unlimited access.

(D) Payments or benefits provided under certain Federal programs or acts are excluded from consideration as income by legislative prohibition. The payments or benefits which must be excluded from consideration as income include, but are not limited to:

(1) Reimbursements from the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Pub. L. 91-646, sec. 216, 42 U.S.C. 4636);

(2) Any payment to volunteers under Title I (VISTA and others) and Title II (RSVP, foster grandparents, and others) of the Domestic Volunteer Service Act of 1973 (Pub. L. 93-113, sec. 404(g), 42 U.S.C. 5044(g)) to the extent excluded by that Act;

(3) Payment to volunteers under section 8(b)(1)(B) of the Small Business Act (SCORE and ACE) (Pub. L. 95-510, sec. 101, 15 U.S.C. 637(b)(1)(D));

(4) Income derived from certain submarginal land of the United States which is held in trust for certain Indian tribes (Pub. L. 94-114, sec. 6, 25 U.S.C. 459e);

(5) Payments received under the Job Training Partnership Act (Pub. L. 97-300, sec. 142(b), 29 U.S.C. 1552(b));

(6) Income derived from the disposition of funds to the Grand River Band of Ottawa Indians (Pub. L. 94-540, sec. 6);

(7) Payments received under the Alaska Native Claims Settlement Act (Pub. L. 100-241, sec. 15, 43 U.S.C. sec. 1626(c));

(8) The value of assistance to children or their families under the National School Lunch Act, as amended (Pub. L. 94-105, sec. 9(d), 42 U.S.C. sec. 1760(e)), the Child Nutrition Act of 1966 (Pub. L. 89-642, sec. 11(b), 42 U.S.C. sec. 1780(b)), and the Food Stamp Act of 1977 (Pub. L. 95-113, sec. 1301, 7 U.S.C. sec. 2017(b));

(9) Payments by the Indian Claims Commission to the Confederated Tribes and Bands of the Yakima Indian Nation or the Apache Tribe of the Mesquero Reservation (Pub. L. 95-433, sec. 2, 25 U.S.C. 609c-1);

(10) Payments to the Passamaquoddy Tribe and the Penobscot Nation or any of their members received pursuant to the Maine Indian Claims Settlement Act of 1980 (Pub. L. 96-420, sec. 6, 9(c), 25 U.S.C. 1725(i), 1728(c));

(11) Payments under the Low-income Home Energy Assistance Act, as amended (Pub. L. 99-125, sec. 504(c), 42 U.S.C. sec. 8624(f));

(12) Student financial assistance received from any program funded in whole or part under Title IV of the Higher Education Act of 1965, including the Pell Grant, Supplemental Educational Opportunity Grant, State Student Incentive Grants, National Direct Student Loan, PLUS, College Work Study, and Byrd Honor Scholarship programs, which is used for costs described in section 472 (1) and (2) of that Act (Pub. L. 99-498, section 479B, 20 U.S.C. 1087uu). The specified costs set forth in section 472 (1) and (2) of the Higher Education Act are tuition and fees normally assessed a student carrying the same academic workload as determined by the institution, and including the costs for rental or purchase of any equipment, materials, or supplies required of all students in the same course of study; and an allowance for books, supplies, transportation, and miscellaneous personal expenses for a student attending the institution on at least a half-time basis, as determined by the institution. The specified costs set forth in section 472 (1) and (2) of the Act are those costs which are related to the costs of attendance at the edu-

cational institution and do not include room and board and dependent care expenses;

(13) Payments under the Disaster Relief Act of 1974, as amended by the Disaster Relief and Emergency Assistance Amendments of 1989 (Pub. L. 100-707, sec. 105(i), 42 U.S.C. sec. 5155(d));

(14) Effective July 1, 1991, payments received under the Carl D. Perkins Vocational Education Act, as amended by the Carl D. Perkins Vocational and Applied Technology Education Act Amendments of 1990 (Pub. L. 101-392, sec. 501, 20 U.S.C. sec. 2466d);

(15) Payments pursuant to the Agent Orange Compensation Exclusion Act (Pub. L. 101-201, sec. 1);

(16) Payments received for Wartime Relocation of Civilians under the Civil Liberties Act of 1988 (Pub. L. 100-383, sec. 105(f)(2), 50 App. U.S.C. sec. 1989b-4(f)(2));

(17) Value of any child care payments made under section 402(g)(1)(E) of the Social Security Act, as amended by the Family Support Act (Pub. L. 100-485, sec. 301, 42 U.S.C. sec. 602 (g)(1)(E));

(18) Value of any "at-risk" block grant child care payments made under section 5081 of Pub. L. 101-508, which amended section 402(i) of the Social Security Act;

(19) Value of any child care provided or paid for under the Child Care and Development Block Grant Act, as amended (Pub. L. 102-586, Sec. 8(b)), 42 U.S.C. 9858q;

(20) Mandatory salary reduction amount for military service personnel which is used to fund the Veteran's Educational Assistance Act of 1984 (GI Bill), as amended (Pub. L. 99-576, sec. 303(a)(1), 38 U.S.C. sec. 1411 (b));

(21) Payments received under the Old Age Assistance Claims Settlement Act, except for per capita shares in excess of \$2,000 (Pub. L. 98-500, sec. 8, 25 U.S.C. sec. 2307);

(22) Payments received under the Cranston-Gonzales National Affordable Housing Act, unless the income of the family equals or exceeds 80 percent of the median income of the area (Pub. L. 101-625, sec. 522(i)(4), 42 U.S.C. sec. 1437f nt);

(23) Payments received under the Housing and Community Development Act of 1987, unless the income of the

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family increases at any time to not less than 50 percent of the median income of the area (Pub. L. 100-242, sec. 126(c)(5)(A), 25 U.S.C. sec. 2307);

(24) Payments received under the Sac and Fox Indian claims agreement (Pub. L. 94-189, sec. 6);

(25) Payments received under the Judgment Award Authorization Act, as amended (Pub. L. 97-458, sec. 4, 25 U.S.C. sec. 1407 and Pub. L. 98-64, sec. 2(b), 25 U.S.C. sec. 117b(b));

(26) Payments for the relocation assistance of members of Navajo and Hopi Tribes (Pub. L. 93-531, sec. 22, 22 U.S.C. sec. 640d-21);

(27) Payments to the Turtle Mountain Band of Chippewas, Arizona (Pub. L. 97-403, sec. 9);

(28) Payments to the Blackfeet, Grosventre, and Assiniboine tribes (Montana) and the Papago (Arizona) (Pub. L. 97-408, sec. 8(d));

(29) Payments to the Assiniboine Tribe of the Fort Belknap Indian community and the Assiniboine Tribe of the Fort Peck Indian Reservation (Montana) (Pub. L. 98-124, sec. 5);

(30) Payments to the Red Lake Band of Chippewas (Pub. L. 98-123, sec. 3);

(31) Payments received under the Saginaw Chippewa Indian Tribe of Michigan Distribution of Judgment Funds Act (Pub. L. 99-346, sec. 6(b)(2));

(32) Payments to the Chippewas of Mississippi (Pub. L. 99-377, sec. 4(b));

(33) Payments received by members of the Armed Forces and their families under the Family Supplemental Subsistence Allowance from the Department of Defense (Pub. L. 109-163, sec. 608); and

(34) Payments received by property owners under the National Flood Insurance Program (Pub. L. 109-64).

(v) *Are applicants required to document income eligibility?* (A) *Adjectively/automatically income eligible applicants.* The State or local agency must require applicants determined to be adjunctively or automatically income eligible to document their eligibility for the program that makes them income eligible as set forth in paragraph (d)(2)(vi) of this section.

(B) *Other applicants.* The State or local agency must require all other applicants to provide documentation of family income at certification.

(C) *Exceptions.* The income documentation requirement does not apply to an individual for whom the necessary documentation is not available or an individual such as a homeless woman or child for whom the agency determines the income documentation requirement would present an unreasonable barrier to participation. Examples of individuals for whom the necessary documentation is not available include those with no income or no proof of income (such as an applicant or applicant's parent who is a migrant farmworker or other individual who works for cash). These are the only exceptions that may be used. When using these exceptions, the State or local agency must require the applicant to sign a statement specifying why he/she cannot provide documentation of income. Such a statement is not required when there is no income.

(D) *Verification.* The State or local agency may require verification of information it determines necessary to confirm income eligibility for Program benefits.

(vi) *Adjunct or automatic income eligibility.* (A) The State agency shall accept as income-eligible for the Program any applicant who documents that he/she is:

(1) Certified as fully eligible to receive food stamps under the Food Stamp Act of 1977, or certified as fully eligible, or presumptively eligible pending completion of the eligibility determination process, to receive Temporary Assistance for Needy Families (TANF) under Part A of Title IV of the Social Security Act or Medical Assistance (i.e., Medicaid) under Title XIX of the Social Security Act; or

(2) A member of a family that is certified eligible to receive assistance under TANF, or a member of a family in which a pregnant woman or an infant is certified eligible to receive assistance under Medicaid.

(B) The State agency may accept, as evidence of income within Program guidelines, documentation of the applicant's participation in State-administered programs not specified in this paragraph that routinely require documentation of income, provided that those programs have income eligibility

guidelines at or below the State agency's Program income guidelines.

(C) Persons who are adjunctively income eligible, as set forth in paragraphs (d)(2)(vi)(A) of this section, shall not be subject to the income limits established under paragraph (d)(1) of this section.

(vii) *Income eligibility of pregnant women.* A pregnant woman who is ineligible for participation in the program because she does not meet income guidelines shall be considered to have satisfied the income guidelines if the guidelines would be met by increasing the number of individuals in her family by the number of embryos or fetuses in utero. The same increased family size may also be used for any of the pregnant woman's categorically eligible family members. The State agency shall allow applicants to waive this increase in family size.

(viii) *Income eligibility of Indian applicants.* If an Indian State agency (or a non-Indian State agency which acts on behalf of a local agency operated by an Indian organization or the Indian Health Service) submits census data or other reliable documentation demonstrating to FNS that the majority of the Indian households in a local agency's service area have incomes at or below the State agency's income eligibility guidelines, FNS may authorize the State agency to approve the use of an income certification system under which the local Indian agency shall inform each Indian applicant household of the maximum family income allowed for that applicant's family size. The local agency shall ensure that the applicant, or the applicant's parent or caretaker, signs a statement that the applicant's family income does not exceed the maximum. The local agency may verify the income eligibility of any Indian applicant.

(ix) *Are instream migrant farmworkers and their family members required to document income eligibility?* Certain instream migrant farmworkers and their family members with expired Verification of Certification cards shall be declared to satisfy the State agency's income standard and income documentation requirements. Such cases include when income of that instream migrant farmworker is determined at

least once every 12 months. Such families shall satisfy the income criteria in any State for any subsequent certification while the migrant is instream during the 12-month period following the determination. The determination can occur either in the migrant's home base area before the migrant has entered the stream for a particular agricultural season, or in an instream area during the agricultural season.

(e) *Nutritional risk.* To be certified as eligible for the Program, applicants who meet the Program's eligibility standards specified in paragraph (c) of this section must be determined to be at nutritional risk. A competent professional authority on the staff of the local agency shall determine if a person is at nutritional risk through a medical and/or nutritional assessment. This determination may be based on referral data submitted by a competent professional authority not on the staff of the local agency. Nutritional risk data shall be documented in the participant's file and shall be used to assess an applicant's nutritional status and risk, tailor the food package to address nutritional needs, design appropriate nutrition education, and make referrals to health and social services for follow-up, as necessary and appropriate.

Except as stated in paragraph (e)(1)(v) of this section, at least one determination of nutritional risk must be documented at the time of certification in order for an income eligible applicant to receive WIC benefits.

(1) *Determination of nutritional risk.* (i) *Required nutritional risk data.* (A) At a minimum, height or length and weight measurements shall be performed and/or documented in the applicant's file at the time of certification. In addition, a hematological test for anemia such as a hemoglobin, hematocrit, or free erythrocyte protoporphyrin test shall be performed and/or documented at certification for applicants with no other nutritional risk factor present. For applicants with a qualifying nutritional risk factor present at certification, such test shall be performed and/or documented within 90 days of the date of certification. However, for breastfeeding women 6–12 months postpartum, such hematological tests

are not required if a test was performed after the termination of their pregnancy. In addition, such hematological tests are not required, but are permitted, for infants under nine months of age. All infants nine months of age and older (who have not already had a hematological test performed or obtained, between the ages of six and nine months), shall have a hematological test performed between nine and twelve months of age or obtained from referral sources. This hematological test does not have to occur within 90 days of the date of certification. Only one test is required for children between 12 and 24 months of age, and this test should be done 6 months after the infant test, if possible. At the State or local agency's discretion, the hematological test is not required for children ages two and older who were determined to be within the normal range at their last certification. However, the hematological test shall be performed on such children at least once every 12 months. Hematological test data submitted by a competent professional authority not on the staff of the local agency may be used to establish nutritional risk. However, such referral hematological data must:

(1) Be reflective of a woman applicant's category, meaning the test must have been taken for pregnant women during pregnancy and for postpartum or breastfeeding women following termination of pregnancy;

(2) Conform to the anemia screening schedule for infants and children as outlined in paragraph (e)(1)(ii)(B) of this section; and

(3) Conform to recordkeeping requirements as outlined in paragraph (i)(4) of this section.

(B) Height or length and weight measurements and, with the exceptions specified in paragraph (e)(1)(v) of this section, hematological tests, shall be obtained for all participants, including those who are determined at nutritional risk based solely on the established nutritional risk status of another person, as provided in paragraphs (e)(1)(iv) and (e)(1)(v) of this section.

(ii) *Timing of nutritional risk data.* (A) *Weight and height or length.* Weight and height or length shall be measured not

more than 60 days prior to certification for program participation.

(B) *Hematological test for anemia.* (1) For pregnant, breastfeeding, and postpartum women, and child applicants, the hematological test for anemia shall be performed or obtained from referral sources at the time of certification or within 90 days of the date of certification. The hematological test for anemia may be deferred for up to 90 days from the time of certification for applicants who have at least one qualifying nutritional risk factor present at the time of certification. If no qualifying risk factor is identified, a hematological test for anemia must be performed or obtained from referral sources (with the exception of presumptively eligible pregnant women).

(2) Infants nine months of age and older (who have not already had a hematological test performed, between six and nine months of age, by a competent professional authority or obtained from referral sources), shall between nine and twelve months of age have a hematological test performed or obtained from referral sources. Such a test may be performed more than 90 days after the date of certification.

(3) For pregnant women, the hematological test for anemia shall be performed during their pregnancy. For persons certified as postpartum or breastfeeding women, the hematological test for anemia shall be performed after the termination of their pregnancy. For breastfeeding women who are 6-12 months postpartum, no additional blood test is necessary if a test was performed after the termination of their pregnancy. The participant or parent/guardian shall be informed of the test results when there is a finding of anemia, and notations reflecting the outcome of the tests shall be made in the participant's file. Nutrition education, food package tailoring, and referral services shall be provided to the participant or parent/guardian, as necessary and appropriate.

(iii) *Breastfeeding dyads.* A breastfeeding woman may be determined to be a nutritional risk if her breastfed infant has been determined to be a nutritional risk. A breastfed infant can be certified based on the

mother's medical and/or nutritional assessment. A breastfeeding mother and her infant shall be placed in the highest priority level for which either is qualified.

(iv) *Infants born to WIC mothers or women who were eligible to participate in WIC.* An infant under six months of age may be determined to be at nutritional risk if the infant's mother was a Program participant during pregnancy or of medical records document that the woman was at nutritional risk during pregnancy because of detrimental or abnormal nutritional conditions detectable by biochemical or anthropometric measurements or other documented nutritionally related medical conditions.

(v) *Presumptive eligibility for pregnant women.* A pregnant woman who meets the income eligibility standards may be considered presumptively eligible to participate in the program, and may be certified immediately without an evaluation of nutritional risk for a period up to 60 days. A nutritional risk evaluation of such woman shall be completed not later than 60 days after the woman is certified for participation. A hematological test for anemia is not required to be performed within the 60-day period, but rather within 90 days, unless the nutritional risk evaluation performed does not identify a qualifying risk factor. If no qualifying risk factor is identified, a hematological test for anemia must be performed or obtained from referral sources before the 60-day period elapses. Under the subsequent determination process, if the woman does not meet any qualifying nutritional risk criteria, including anemia criteria, the woman shall be determined ineligible and may not participate in the program for the reference pregnancy after the date of the determination. Said applicant may subsequently reapply for program benefits and if found to be both income eligible and at qualifying nutritional risk may participate in the program. Persons found ineligible to participate in the program under this paragraph shall be advised in writing of the ineligibility, of the reasons for the ineligibility, and of the right to a fair hearing. The reasons for the ineligibility shall be properly documented and shall

be retained on file at the local agency. In addition, if the nutritional risk evaluation is not completed within the 60-day timeframe, the woman shall be determined ineligible.

(vi) *Regression.* A WIC participant who is reapplying for WIC benefits may be considered to be at nutritional risk in the next certification period if the competent professional authority determines that the applicant's nutritional status may regress to the nutritional risk condition(s) certified for in the previous certification period without supplemental foods and/or WIC nutrition services, and if the nutritional risk condition(s) certified for in the previous certification period is/are appropriate to the category of the participant in the subsequent certification based on regression. However, such applicants shall not be considered at nutritional risk based on the possibility of regression for consecutive certification periods. Applicants who are certified based on the possibility of regression should be placed either in the same priority for which they were certified in the previous certification period; a priority level lower than the priority level assigned in the previous certification period, consistent with § 246.7(e)(4); or in Priority VII, if the State agency is using that priority level.

(2) *Nutritional risk criteria.* The following are examples of nutritional risk conditions which may be used as a basis for certification. These examples include—

(i) Detrimental or abnormal nutritional conditions detectable by biochemical or anthropometric measurements, such as anemia, underweight, overweight, abnormal patterns of weight gain in a pregnant woman, low birth weight in an infant, or stunting in an infant or child;

(ii) Other documented nutritionally related medical conditions, such as clinical signs of nutritional deficiencies, metabolic disorders, pre-eclampsia in pregnant women, failure to thrive in an infant, chronic infections in any person, alcohol or drug abuse or mental retardation in women, lead poisoning, history of high risk pregnancies or factors associated with high risk pregnancies (such as smoking;

conception before 16 months postpartum; history of low birth weight, premature births, or neonatal loss; adolescent pregnancy; or current multiple pregnancy) in pregnant women, or congenital malformations in infants or children, or infants born of women with alcohol or drug abuse histories or mental retardation.

(iii) Dietary deficiencies that impair or endanger health, such as inadequate dietary patterns assessed by a 24-hour dietary recall, dietary history, or food frequency checklist; and

(iv) Conditions that predispose persons to inadequate nutritional patterns or nutritionally related medical conditions, such as homelessness or migrancy.

(3) *Nutritional risk priorities.* In determining nutritional risk, the State agency shall develop and include in its State Plan, specific risk conditions by priority level with indices for identifying these conditions. The criteria shall be used statewide and in accordance with the priority system as set forth in paragraph (e)(4) of this section.

(4) *Nutritional risk priority system.* The competent professional authority shall fill vacancies which occur after a local agency has reached its maximum participation level by applying the following participant priority system to persons on the local agency's waiting list. Priorities I through VI shall be utilized in all States. The State agency may, at its discretion, expand the priority system to include Priority VII. The State agency may set income or other sub-priority levels within any of these seven priority levels. The State agency may expand Priority III, IV, or V to include high-risk postpartum women. The State agency may place pregnant or breastfeeding women and infants who are at nutritional risk solely because of homelessness or migrancy in Priority IV; children who are at nutritional risk solely because of homelessness or migrancy in Priority V; and postpartum women who are at nutritional risk solely because of homelessness or migrancy in Priority VI, *OR*, the State agency may place pregnant, breastfeeding or postpartum women, infants, and children who are at nutritional risk solely because of

homelessness or migrancy in Priority VII.

(i) *Priority I.* Pregnant women, breastfeeding women and infants at nutritional risk as demonstrated by hematological or anthropometric measurements, or other documented nutritionally related medical conditions which demonstrate the need for supplemental foods.

(ii) *Priority II.* Except those infants who qualify for Priority I, infant up to six months of age of Program participants who participated during pregnancy, and infants up to six months of age born of women who were not Program participants during pregnancy but whose medical records document that they were at nutritional risk during pregnancy due to nutritional conditions detectable by biochemical or anthropometric measurements or other documented nutritionally related medical conditions which demonstrated the person's need for supplemental foods.

(iii) *Priority III.* Children at nutritional risk as demonstrated by hematological or anthropometric measurements or other documented medical conditions which demonstrate the child's need for supplemental foods.

(iv) *Priority IV.* Pregnant women, breastfeeding women, and infants at nutritional risk because of an inadequate dietary pattern.

(v) *Priority V.* Children at nutritional risk because of an inadequate dietary pattern.

(vi) *Priority VI.* Postpartum women at nutritional risk.

(vii) *Priority VII.* Individuals certified for WIC solely due to homelessness or migrancy and, at State agency option, in accordance with the provisions of paragraph (e)(1)(vi) of this section, previously certified participants who might regress in nutritional status without continued provision of supplemental foods.

(f) *Processing standards.* The local agencies shall process applicants within the following timeframes:

(1) *Waiting lists.* When the local agency is serving its maximum caseload, the local agency shall maintain a waiting list of individuals who visit the local agency to express interest in receiving Program benefits and who are likely to be served. However, in no case

shall an applicant who requests placement on the waiting list be denied inclusion. State agencies may establish a policy which permits or requires local agencies to accept telephone requests for placement on the waiting list. The waiting list shall include the person's name, address or phone number, status (e.g., pregnant, breastfeeding, age of applicant), and the date he or she was placed on the waiting list. Individuals shall be notified of their placement on a waiting list within 20 days after they visit the local agency during clinic office hours to request Program benefits. For those State agencies establishing procedures to accept telephone requests for placement on a waiting list, individuals shall be notified of their placement on a waiting list within 20 days after contacting the local agency by phone. The competent professional authority shall apply the participant priority system as specified in paragraph (e)(4) of this section to the waiting list to ensure that the highest priority persons become Program participants first when caseload slots become available.

(2) *Timeframes for processing applicants.* (i) When the local agency is not serving its maximum caseload, the local agency shall accept applications, make eligibility determinations, notify the applicants of the decisions made and, if the applicants are to be enrolled, issue food, cash-value vouchers or food instruments. All of these actions shall be accomplished within the timeframes set forth below.

(ii) The processing timeframes shall begin when the individual visits the local agency during clinic office hours to make an oral or written request for Program benefits. To ensure that accurate records are kept of the date of such requests, the local agency shall, at the time of each request, record the applicant's name, address and the date. The remainder of the information necessary to determine eligibility shall be obtained by the time of certification. Medical data taken prior to certification may be used as provided in paragraph (g)(4) of this section.

(iii) The local agency shall act on applications within the following timeframes:

(A) Special nutritional risk applicants shall be notified of their eligibility or ineligibility within 10 days of the date of the first request for Program benefits; except that State agencies may provide an extension of the notification period to a maximum of 15 days for those local agencies which make written request, including a justification of the need for an extension. The State agency shall establish criteria for identifying categories of persons at special nutritional risk who require expedited services. At a minimum, however, these categories shall include pregnant women eligible as Priority I participants, and migrant farmworkers and their family members who soon plan to leave the jurisdiction of the local agency.

(B) All other applicants shall be notified of their eligibility or ineligibility within 20 days of the date of the first request for Program benefits.

(iv) Each local agency using a retail purchase system shall issue a food instrument(s) and if applicable cash-value voucher(s) to the participant at the same time as notification of certification. Such food instrument(s) and cash-value vouchers shall provide benefits for the current month or the remaining portion thereof and shall be redeemable immediately upon receipt by the participant. Local agencies may mail the initial food instrument(s) and if applicable cash-value vouchers with the notification of certification to those participants who meet the criteria for the receipt of food instruments through the mail, as provided in § 246.12(r)(4).

(v) Each local agency with a direct distribution or home delivery system shall issue the supplemental foods to the participant within 10 days of issuing the notification of certification.

(g) *Certification periods.* (1) Program benefits will be based upon certifications established in accordance with the following timeframes:

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A/an:	Will be certified:
(i) Pregnant woman	For the duration of her pregnancy, and up to the last day of the month in which the infant becomes six weeks old or the pregnancy ends (for example, if the infant is born June 4, six weeks after birth would be July 16, and certification would end July 31).
(ii) Postpartum woman	Up to the last day of the sixth month after the baby is born or the pregnancy ends (postpartum).
(iii) Breastfeeding woman	Approximately every six months. The State agency may permit its local agencies to certify a breastfeeding woman up to the last day of the month in which her infant turns 1 year old, or until the woman ceases breastfeeding, whichever occurs first.
(iv) Infant	Approximately every six months. The State agency may permit its local agencies to certify an infant under six months of age up to the last day of the month in which the infant turns 1 year old, provided the quality and accessibility of health care services are not diminished.
(v) Child	Approximately every six months ending with the last day of the month in which a child reaches his/her fifth birthday.

(2) The State agency may authorize local agencies under its jurisdiction to establish shorter certification periods than outlined in paragraph (g)(1) of this section on a case-by-case basis. If the State agency exercises this option, it shall issue guidance for use by local agencies in establishing the shorter periods.

(3) In cases where there is difficulty in appointment scheduling for persons referenced in paragraphs (g)(1) (iii), (iv) and (v) of this section, the certification period may be shortened or extended by a period not to exceed 30 days.

(h) *Mandatory and optional mid-certification actions.* Mid-certification actions are either mandatory or optional as follows:

(1) *Mandatory reassessment of income eligibility mid-certification.* (i) The local agency must reassess a participant's income eligibility during the current certification period if the local agency receives information indicating that the participant's household income has changed. However, such assessments are not required in cases where sufficient time does not exist to effect the change. Sufficient time means 90 days or less before the expiration of the certification period.

(ii) *Mandatory disqualification mid-certification for income ineligibility.* The local agency must disqualify a participant and any other household members currently receiving WIC benefits who are determined ineligible based on the mid-certification income reassessment. However, adjunctively-eligible WIC participants (as defined in paragraphs (d)(2)(vi)(A) or (d)(2)(vi)(B) of this section) may not be disqualified from the

WIC Program solely because they, or certain family members, no longer participate in one of the other specified programs. The State agency will ensure that such participants and other household members currently receiving WIC benefits are disqualified during a certification period only after their income eligibility has been reassessed based on the income screening procedures used for applicants who are not adjunctively eligible.

(2) *Mandatory sanctions or other actions for participant violations.* The local agency must impose disqualifications, or take other actions in accordance with the procedures set forth in §246.12(u), in response to participant violations including, but not limited to, the violations listed in the definition of *Participant violation* in §246.2.

(3) *Optional mid-certification actions.* A participant may be disqualified during a certification period for the following reasons:

(i) A State agency may allow local agencies to disqualify a participant for failure to obtain food instruments, cash-value vouchers or supplemental foods for several consecutive months. As specified by the State agency, proof of such failure includes failure to pick up supplemental foods, cash-value vouchers or food instruments, non-receipt of food instruments or cash-value vouchers (when mailed instruments or vouchers are returned), or failure to have an electronic benefit transfer card revalidated for purchase of supplemental foods; or

(ii) If a State agency experiences funding shortages, it may be necessary to discontinue Program benefits to

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some certified participants. The State agency must explore alternatives (such as elimination of new certifications) before taking such action. In discontinuing benefits, the State agency will affect the least possible number of participants and those whose nutritional and health status would be least impaired by the action. When a State agency elects to discontinue benefits due to insufficient funds, it will not enroll new participants during that period. The State may discontinue benefits by:

(A) Disqualifying a group of participants; and/or,

(B) Withholding benefits from a group with the expectation of providing benefits again when funds are available.

(i) *Certification forms.* All certification data for each person certified shall be recorded on a form (or forms) which are provided by the State agency. The information on the forms shall include—

(1) Name and address;

(2) Date of initial visit to apply for participation;

(3) An indication of whether the applicant was physically present at certification and, if not, the reason why an exception was granted or a copy of the document(s) in the file which explains the reason for the exception;

(4) A description of the document(s) used to determine residency and identity or a copy of the document(s) used or the applicant's written statement when no documentation exists;

(5) Information regarding income eligibility for the Program as specified in paragraph (d) of this section as follows:

(i) A description of the document(s) used to determine income eligibility or a copy of the document(s) in the file;

(ii) An indication that no documentation is available and the reason(s) why or a copy of the applicant's written statement explaining such circumstances; or

(iii) An indication that the applicant has no income.

(6) The date of certification and the date nutritional risk data were taken if different from the date of certification;

(7) Height or length, weight, and hematological test results;

(8) The specific nutritional risk conditions which established eligibility for the supplemental foods. Documentation should include health history when appropriate to the nutritional risk condition, with the applicant's or applicant's parent's or caretaker's consent;

(9) The signature and title of the competent professional authority making the nutritional risk determination, and, if different, the signature and title of the administrative person responsible for determining income eligibility under the Program; and

(10) A statement of the rights and obligations under the Program. The statement must contain a signature space, and must be read by or to the applicant, parent, or caretaker. It must contain the following language or alternate language as approved by FNS (see § 246.4(a)(11)(i)), and be signed by the applicant, parent, or caretaker after the statement is read:

I have been advised of my rights and obligations under the Program. I certify that the information I have provided for my eligibility determination is correct, to the best of my knowledge. This certification form is being submitted in connection with the receipt of Federal assistance. Program officials may verify information on this form. I understand that intentionally making a false or misleading statement or intentionally misrepresenting, concealing, or withholding facts may result in paying the State agency, in cash, the value of the food benefits improperly issued to me and may subject me to civil or criminal prosecution under State and Federal law.

(11) If the State agency exercises the authority to use and disclose confidential applicant and participant information for non-WIC purposes pursuant to § 246.26(d)(2), a statement that:

(i) Notifies applicants that the chief State health officer (or the governing authority, in the case of an Indian State agency) may authorize the use and disclosure of information about their participation in the WIC Program for non-WIC purposes;

(ii) Must indicate that such information will be used by State and local WIC agencies and public organizations only in the administration of their programs that serve persons eligible for the WIC Program; and,

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(iii) Will be added to the statement required under paragraph (i)(10) of this section. This statement must also indicate that such information can be used by the recipient organizations only for the following:

(A) To determine the eligibility of WIC applicants and participants for programs administered by such organizations;

(B) To conduct outreach for such programs;

(C) To enhance the health, education, or well-being of WIC applicants and participants currently enrolled in those programs;

(D) To streamline administrative procedures in order to minimize burdens on participants and staff; and,

(E) To assess and evaluate a State's health system in terms of responsiveness to participants' health care needs and health care outcomes.

(j) *Notification of participant rights and responsibilities.* In order to inform applicants and participants or their parents or caretakers of Program rights and responsibilities, the following information shall be provided. Where a significant number or proportion of the population eligible to be served needs the information in a language other than English, reasonable steps shall be taken to provide the information in appropriate languages to such persons, considering the scope of the Program and the size and concentration of such population.

(1) During the certification procedure, every Program applicant, parent or caretaker shall be informed of the illegality of dual participation.

(2) At the time of certification, each Program participant, parent or caretaker must read, or have read to him or her, the statement provided in paragraph (i)(10) of this section (or an alternate statement as approved by FNS). In addition, the following sentences (or alternate sentences as approved by FNS) must be read:

(i) "Standards for eligibility and participation in the WIC Program are the same for everyone, regardless of race, color, national origin, age, handicap, or sex."

(ii) "You may appeal any decision made by the local agency regarding your eligibility for the Program."

(iii) "The local agency will make health services and nutrition education available to you, and you are encouraged to participate in these services."

(3) If the State agency implements the policy of disqualifying a participant for not picking up supplemental foods, cash-value vouchers or food instruments in accordance with paragraph (h)(3)(i) of this section, it shall provide notice of this policy and of the importance of regularly picking up cash-value vouchers, food instruments or supplemental foods to each participant, parent or caretaker at the time of each certification.

(4) At least during the initial certification visit, each participant, parent or caretaker shall receive an explanation of how the local food delivery system operates and shall be advised of the types of health services available, where they are located, how they may be obtained and why they may be useful.

(5) Persons found ineligible for the Program during a certification visit shall be advised in writing of the ineligibility, of the reasons for the ineligibility, and of the right to a fair hearing. The reasons for ineligibility shall be properly documented and shall be retained on file at the local agency.

(6) A person who is about to be suspended or disqualified from program participation at any time during the certification period shall be advised in writing not less than 15 days before the suspension or disqualification. Such notification shall include the reasons for this action, and the participant's right to a fair hearing. Further, such notification need not be provided to persons who will be disqualified for not picking up cash-value vouchers, supplemental foods or food instruments in accordance with paragraph (h)(3)(i) of this section.

(7) When a State or local agency pursues collection of a claim pursuant to § 246.23(c) against an individual who has been improperly issued benefits, the person shall be advised in writing of the reason(s) for the claim, the value of the improperly issued benefits which must be repaid, and of the right to a fair hearing.

(8) Each participant, parent or caretaker shall be notified not less than 15

days before the expiration of each certification period that certification for the Program is about to expire.

(9) If a State agency must suspend or terminate benefits to any participant during the participant's certification period due to a shortage of funds for the Program, it shall issue a notice to such participant in advance, as stipulated in paragraph (j)(6) of this section.

(k) *Transfer of certification.* (1) Each State agency shall ensure issuance of a Verification of Certification card to every participant who is a member of a family in which there is a migrant farmworker or any other participant who is likely to be relocating during the certification period. Certifying local agencies shall ensure that Verification of Certification cards are fully completed.

(2) The State agency shall require the receiving local agency to accept Verification of Certification cards from participants, including participants who are migrant farmworkers or members of their families, who have been participating in the Program in another local agency within or outside of the jurisdiction of the State agency. A person with a valid Verification of Certification card shall not be denied participation in the receiving State because the person does not meet that State's particular eligibility criteria.

(3) The Verification of Certification card is valid until the certification period expires, and shall be accepted as proof of eligibility for Program benefits. If the receiving local agency has waiting lists for participation, the transferring participant shall be placed on the list ahead of all waiting applicants.

(4) The Verification of Certification card shall include the name of the participant, the date the certification was performed, the date income eligibility was last determined, the nutritional risk condition of the participant, the date the certification period expires, the signature and printed or typed name of the certifying local agency official, the name and address of the certifying local agency and an identification number or some other means of accountability. The Verification of Certification card shall be uniform

throughout the jurisdiction of the State agency.

(1) *Dual participation.* The State agency is responsible for the following:

(1) In conjunction with WIC local agencies, the prevention and identification of dual participation within each local agency and between local agencies under the State agency's jurisdiction, including actions to identify suspected instances of dual participation at least semiannually. The State or local agency must take follow-up action within 120 days of detecting instances of suspected dual participation;

(2) In areas where a local agency serves the same population as an Indian State agency or a CSFP agency, and in areas where geographical or other factors make it likely that participants travel regularly between contiguous local service areas located across State agency borders, entering into an agreement with the other agency for the detection and prevention of dual participation. The agreement must be made in writing and included in the State Plan;

(3) Immediate termination from participation in one of the programs or clinics for participants found in violation due to dual participation; and

(4) In cases of dual participation resulting from intentional misrepresentation, the collection of improperly issued benefits in accordance with § 246.23(c)(1) and disqualification from both programs in accordance with § 246.12(u)(2).

(m) *Certification of persons in homeless facilities and institutions.* (1) Pregnant, breastfeeding, and postpartum women, infants or children who meet the requirements of paragraph (c) of this section, and who reside in a homeless facility, shall be considered eligible for the Program and shall be treated equally with all other eligible applicants at the local agency where they apply for WIC benefits, Provided that: the State or local agency has taken reasonable steps to:

(i) Establish, to the extent practicable, that the homeless facility meets the following conditions with respect to resident WIC participants:

(A) The homeless facility does not accrue financial or in-kind benefit from a person's participation in the Program,

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e.g., by reducing its expenditures for food service because its residents are receiving WIC foods;

(B) Foods provided by the WIC Program are not subsumed into a communal food service, but are available exclusively to the WIC participant for whom they were issued;

(C) The homeless facility places no constraints on the ability of the participant to partake of the supplemental foods and nutrition education available under the Program;

(ii) Contact the homeless facility periodically to ensure continued compliance with these conditions; and

(iii) Request the homeless facility to notify the State or local agency if it ceases to meet any of these conditions.

(2) The State agency may authorize or require local agencies to make the Program available to applicants who meet the requirements of paragraph (c) of this section, but who reside in institutions which meet the conditions of paragraphs (n)(1)(i)(A)–(C) of this section with respect to resident WIC participants.

(3) The State or local agency shall attempt to establish to the best of its ability, whether a homeless facility or institution complies with the conditions of paragraphs (n)(1)(i)(A)–(C) of this section with respect to WIC participants. If caseload slots are available, full certification periods shall be provided to the following:

(i) Participants who are residents of a homeless facility or institution which has been found to be in compliance with the conditions of paragraph (n)(1)(i)(A)–(C) of this section;

(ii) Participants who are residents of a homeless facility or institution whose compliance with the conditions of paragraphs (n)(1)(i)(A)–(C) of this section has not yet been established; and

(iii) Participants for whom no other shelter alternative is available in the local agency's service delivery area.

(4) If a homeless facility or institution has been determined to be non-compliant during the course of a participant's initial certification period, participants applying for continued benefits may be certified again, but the State agency shall discontinue issuance of WIC foods, except infant

formula, to the participant in such accommodation until the accommodation's compliance is achieved or alternative shelter arrangements are made. If certified, such participants shall continue to be eligible to receive all other WIC benefits, such as nutrition education and health care referral services.

(5) The State agency shall continue to the end of their certification periods the participation of residents of a homeless facility or institution which ceases to comply with the conditions of paragraphs (n)(1)(i)(A)–(C) of this section.

(6) As soon as the State or local agency determines that a homeless facility/institution does not meet the conditions of paragraphs (n)(1)(i)(A)–(C) of this section, it shall refer all participants using such accommodation to any other accommodations in the area which meet these conditions.

(n) *Drug and other harmful substance abuse screening.* When a State agency determines that screening is necessary to fulfill the referral requirements in this part, the State agency must require screening for the use of drugs and other harmful substances. When such screening is required, it shall:

(1) Be limited to the extent the State agency deems necessary to fulfill the referral requirement of § 246.4(a)(8) of this part and the drug and other harmful substance abuse information requirement of § 246.11(a)(3) of this part; and

(2) Be integrated into certification process as part of the medical or nutritional assessment.

(o) *Are applicants required to be physically present at certification?*—(1) *In general.* The State or local agency must require all applicants to be physically present at each WIC certification.

(2) *Exceptions*—(i) *Disabilities.* The State or local agency must grant an exception to applicants who are qualified individuals with disabilities and are unable to be physically present at the WIC clinic because of their disabilities or applicants whose parents or caretakers are individuals with disabilities that meet this standard. Examples of such situations include:

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(A) A medical condition that necessitates the use of medical equipment that is not easily transportable;

(B) A medical condition that requires confinement to bed rest; and

(C) A serious illness that may be exacerbated by coming in to the WIC clinic.

(ii) *Receiving ongoing health care.* The State agency may exempt from the physical presence requirement, if being physically present would pose an unreasonable barrier, an infant or child who was present at his/her initial WIC certification and is receiving ongoing health care.

(iii) *Working parents or caretakers.* The State agency may exempt from the physical presence requirement an infant or child who was present at his/her initial WIC certification and was present at a WIC certification or recertification determination within the 1-year period ending on the date of the most recent certification or recertification determination and is under the care of one or more working parents or one or more primary working caretakers whose working status presents a barrier to bringing the infant or child in to the WIC clinic.

(iv) *Infants under 8 weeks of age.* The State agency may exempt from the physical presence requirement an infant under eight (8) weeks of age who cannot be present at certification for a reason determined appropriate by the local agency, and for whom all necessary certification information is provided.

(p) *Certification of qualified aliens.* In those cases where a person sponsors a qualified alien, (as the term is defined in the Immigration and Nationality Laws (8 U.S.C.1101 et seq.)), i.e., signs an affidavit of support, the sponsor's income, including the income of the sponsor's spouse, shall not be counted in determining the income eligibility of the qualified alien except when the alien is a member of the sponsor's family or economic unit. Sponsors of qualified aliens are not required to reimburse the State or local agency or the Federal government for WIC Program benefits provided to sponsored aliens. Further, qualified aliens are eligible for the WIC Program without regard to

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the length of time in the qualifying status.

[50 FR 6121, Feb. 13, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 246.7, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 246.8 Nondiscrimination.

(a) *Civil rights requirements.* The State agency shall comply with the requirements of title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, Department of Agriculture regulations on nondiscrimination (7 CFR parts 15, 15a and 15b), and FNS instructions to ensure that no person shall, on the grounds of race, color, national origin, age, sex or handicap, be excluded from participation in, be denied benefits of, or be otherwise subjected to discrimination under the Program. Compliance with title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, and regulations and instructions issued thereunder shall include, but not be limited to:

(1) Notification to the public of the nondiscrimination policy and complaint rights of participants and potentially eligible persons;

(2) Review and monitoring activity to ensure Program compliance with the nondiscrimination laws and regulations;

(3) Collection and reporting of racial and ethnic participation data as required by title VI of the Civil Rights Act of 1964, which prohibits discrimination in federally assisted programs on the basis of race, color, or national origin; and

(4) Establishment of grievance procedures for handling complaints based on sex and handicap.

(b) *Complaints.* Persons seeking to file discrimination complaints should write to USDA, Director, Office of Adjudication and Compliance, 1400 Independence Avenue, SW., Washington, DC 20250-9410, or call (800) 795-3272 (voice) or (202) 720-6382 (TTY). All complaints received by State or local agencies which allege

discrimination based on race, color, national origin, or age shall be referred to the Secretary of Agriculture or Director, Office of Equal Opportunity. A State or local agency may process complaints which allege discrimination based on sex or handicap if grievance procedures are in place.

(c) *Non-English materials.* Where a significant number or proportion of the population eligible to be served needs service or information in a language other than English in order effectively to be informed of or to participate in the Program, the State agency shall take reasonable steps considering the size and concentration of such population, to provide information in appropriate languages to such persons. This requirement applies with regard to required Program information except certification forms which are used only by local agency staff. The State agency shall also ensure that all rights and responsibilities listed on the certification form are read to these applicants in the appropriate language.

[50 FR 6121, Feb. 13, 1985, as amended at 73 FR 11312, Mar. 3, 2008]

§ 246.9 Fair hearing procedures for participants.

(a) *Availability of hearings.* The State agency shall provide a hearing procedure through which any individual may appeal a State or local agency action which results in a claim against the individual for repayment of the cash value of improperly issued benefits or results in the individual's denial of participation or disqualification from the Program.

(b) *Hearing system.* The State agency shall provide for either a hearing at the State level or a hearing at the local level which permits the individual to appeal a local agency decision to the State agency. The State agency may adopt local level hearings in some areas, such as those with large case-loads, and maintain only State level hearings in other areas.

(c) *Notification of appeal rights.* At the time of a claim against an individual for improperly issued benefits or at the time of participation denial or of disqualification from the Program, the State or local agency shall inform each individual in writing of the right to a

fair hearing, of the method by which a hearing may be requested, and that any positions or arguments on behalf of the individual may be presented personally or by a representative such as a relative, friend, legal counsel or other spokesperson. Such notification is not required at the expiration of a certification period.

(d) *Request for hearing.* A request for a hearing is defined as any clear expression by the individual, the individual's parent, caretaker, or other representative, that he or she desires an opportunity to present his or her case to a higher authority. The State or local agency shall not limit or interfere with the individual's freedom to request a hearing.

(e) *Time limit for request.* The State or local agency shall provide individuals a reasonable period of time to request fair hearings; provided that, such time limit is not less than 60 days from the date the agency mails or gives the applicant or participant the notice of adverse action.

(f) *Denial or dismissal of request.* The State and local agencies shall not deny or dismiss a request for a hearing unless—

(1) The request is not received within the time limit set by the State agency in accordance with paragraph (e) of this section;

(2) The request is withdrawn in writing by the appellant or a representative of the appellant;

(3) The appellant or representative fails, without good cause, to appear at the scheduled hearing; or

(4) The appellant has been denied participation by a previous hearing and cannot provide evidence that circumstances relevant to Program eligibility have changed in such a way as to justify a hearing.

(g) *Continuation of benefits.* Participants who appeal the termination of benefits within the 15 days advance adverse action notice period provided by § 246.7(j)(6) must continue to receive Program benefits until the hearing official reaches a decision or the certification period expires, whichever occurs first. This does not apply to applicants denied benefits at initial certification, participants whose certification periods have expired, or participants who

become categorically ineligible for benefits. Applicants who are denied benefits at initial certification, participants whose certification periods have expired, or participants who become categorically ineligible during a certification period may appeal the denial or termination within the timeframes set by the State agency in accordance with paragraph (e) of this section, but must not receive benefits while awaiting the hearing or its results.

(h) *Rules of procedure.* State and local agencies shall process each request for a hearing under uniform rules of procedure and shall make these rules of procedure available for public inspection and copying. At a minimum, such rules shall include: The time limits for requesting and conducting a hearing; all advance notice requirements; the rules of conduct at the hearing; and the rights and responsibilities of the appellant. The procedures shall not be unduly complex or legalistic.

(i) *Hearing official.* Hearings shall be conducted by an impartial official who does not have any personal stake or involvement in the decision and who was not directly involved in the initial determination of the action being contested. The hearing official shall—

(1) Administer oaths or affirmations if required by the State;

(2) Ensure that all relevant issues are considered;

(3) Request, receive and make part of the hearing record all evidence determined necessary to decide the issues being raised;

(4) Regulate the conduct and course of the hearing consistent with due process to ensure an orderly hearing;

(5) Order, where relevant and necessary, an independent medical assessment or professional evaluation from a source mutually satisfactory to the appellant and the State agency; and

(6) Render a hearing decision which will resolve the dispute.

(j) *Conduct of the hearing.* The State or local agency shall ensure that the hearing is accessible to the appellant and is held within three weeks from the date the State or local agency received the request for a hearing. The State or local agency shall provide the appellant with a minimum of 10 days advance written notice of the time and

place of the hearing and shall enclose an explanation of the hearing procedure with the notice. The State or local agency shall also provide the appellant or representative an opportunity to—

(1) Examine, prior to and during the hearing, the documents and records presented to support the decision under appeal;

(2) Be assisted or represented by an attorney or other persons;

(3) Bring witnesses;

(4) Advance arguments without undue interference;

(5) Question or refute any testimony or evidence, including an opportunity to confront and cross-examine adverse witnesses; and

(6) Submit evidence to establish all pertinent facts and circumstances in the case.

(k) *Fair hearing decisions.* (1) Decisions of the hearing official shall be based upon the application of appropriate Federal law, regulations and policy as related to the facts of the case as established in the hearing record. The verbatim transcript or recording of testimony and exhibits, or an official report containing the substance of what transpired at the hearing, together with all papers and requests filed in the proceeding, constitute the exclusive record for a final decision by hearing official. The State or local agency shall retain the hearing record in accordance with § 246.25 and make these records available, for copying and inspection, to the appellant or representative at any reasonable time.

(2) The decision by the hearing official shall summarize the facts of the case, specify the reasons for the decision, and identify the supporting evidence and the pertinent regulations or policy. The decision shall become a part of the record.

(3) Within 45 days of the receipt of the request for the hearing, the State or local agency shall notify the appellant or representative in writing of the decision and the reasons for the decision in accordance with paragraph (k)(2) of this section. If the decision is in favor of the appellant and benefits were denied or discontinued, benefits shall begin immediately. If the decision concerns disqualification and is in

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favor of the agency, as soon as administratively feasible, the local agency shall terminate any continued benefits, as decided by the hearing official. If the decision regarding repayment of benefits by the appellant is in favor of the agency, the State or local agency shall resume its efforts to collect the claim, even during pendency of an appeal of a local-level fair hearing decision to the State agency. The appellant may appeal a local hearing decision to the State agency, provided that the request for appeal is made within 15 days of the mailing date of the hearing decision notice. If the decision being appealed concerns disqualification from the Program, the appellant shall not continue to receive benefits while an appeal to the State agency of a decision rendered on appeal at the local level is pending. The decision of a hearing official at the local level is binding on the local agency and the State agency unless it is appealed to the State level and overturned by the State hearing official.

(4) The State and local agency shall make all hearing records and decisions available for public inspection and copying; however, the names and addresses of participants and other members of the public shall be kept confidential.

(1) *Judicial review.* If a State level decision upholds the agency action and the appellant expresses an interest in pursuing a higher review of the decision, the State agency shall explain any further State level review of the decision and any State level rehearing process. If these are either unavailable or have been exhausted, the State agency shall explain the right to pursue judicial review of the decision.

[50 FR 6121, Feb. 13, 1985, as amended at 52 FR 21236, June 4, 1987; 59 FR 11503, Mar. 11, 1994; 71 FR 56730, Sept. 27, 2006; 73 FR 11312, Mar. 3, 2008]

Subpart D—Participant Benefits

§ 246.10 Supplemental foods.

(a) *General.* This section prescribes the requirements for providing supplemental foods to participants. The State agency must ensure that local agencies comply with this section.

(b) *State agency responsibilities.* (1) State agencies may:

(i) Establish criteria in addition to the minimum Federal requirements in Table 4 of paragraph (e)(12) of this section, except that the State agency may not establish further restrictions on the eligible fruits and vegetables, for the supplemental foods in their States. These State criteria could address, but not be limited to, other nutritional standards, competitive cost, State-wide availability, and participant appeal; and

(ii) Make food package adjustments to better accommodate participants who are homeless. At the State agency's option, these adjustments would include, but not be limited to, issuing authorized supplemental foods in individual serving-size containers to accommodate lack of food storage or preparation facilities.

(2) State agencies must:

(i) Identify the brands of foods and package sizes that are acceptable for use in the Program in their States in accordance with the requirements of this section. State agencies must also provide to local agencies, and include in the State Plan, a list of acceptable foods and their maximum monthly allowances as specified in Tables 1 through 4 of paragraphs (e)(9) through (e)(12) of this section; and

(ii) Ensure that local agencies:

(A) Make available to participants the maximum monthly allowances of authorized supplemental foods, except as noted in paragraph (c) of this section, and abide by the authorized substitution rates for WIC food substitutions as specified in Tables 1 through 3 of paragraphs (e)(9) through (e)(11) of this section;

(B) Make available to participants more than one food from each WIC food category except for the categories of peanut butter and eggs, and any of the WIC-eligible fruits and vegetables (fresh or processed) in each authorized food package as listed in paragraph (e) of this section;

(C) Authorize only a competent professional authority to prescribe the categories of authorized supplemental foods in quantities that do not exceed the regulatory maximum and are appropriate for the participant, taking

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into consideration the participant's age and nutritional needs; and

(D) Advise participants or their caretaker, when appropriate, that the supplemental foods issued are only for their personal use. However, the supplemental foods are not authorized for participant use while hospitalized on an in-patient basis. In addition, consistent with § 246.7(m)(1)(i)(B), supplemental foods are not authorized for use in the preparation of meals served in a communal food service. This restriction does not preclude the provision or use of supplemental foods for individual participants in a nonresidential setting (e.g., child care facility, family day care home, school, or other educational program); a homeless facility that meets the requirements of § 246.7(m)(1); or, at the State agency's discretion, a residential institution (e.g., home for pregnant teens, prison, or residential drug treatment center) that meets the requirements currently set forth in § 246.7(m)(1) and (m)(2).

(c) *Nutrition tailoring.* The full maximum monthly allowances of all supplemental foods in all food packages must be made available to participants if medically or nutritionally warranted. Reductions in these amounts cannot be made for cost-savings, administrative convenience, caseload management, or to control vendor abuse. Reductions in these amounts cannot be made for categories, groups or subgroups of WIC participants. The provision of less than the maximum monthly allowances of supplemental foods to an individual WIC participant in all food packages is appropriate only when:

(1) Medically or nutritionally warranted (e.g., to eliminate a food due to a food allergy);

(2) A participant refuses or cannot use the maximum monthly allowances; or

(3) The quantities necessary to supplement another programs' contribution to fill a medical prescription would be less than the maximum monthly allowances.

(d) *Medical documentation*—(1) *Supplemental foods requiring medical documentation.* Medical documentation is required for the issuance of the following supplemental foods:

(i) Any non-contract brand infant formula;

(ii) Any infant formula prescribed to a child or adult who receives Food Package III;

(iii) Any exempt infant formula;

(iv) Any WIC-eligible medical food;

(v) Any authorized supplemental food issued to participants who receive Food Package III;

(vi) Any authorized soy-based beverage or tofu issued to children who receive Food Package IV;

(vii) Any additional authorized cheese issued to children who receive Food Package IV that exceeds the maximum substitution rate;

(viii) Any additional authorized tofu and cheese issued to women who receive Food Packages V and VII that exceeds the maximum substitution rate; and

(ix) Any contract brand infant formula that does not meet the requirements in Table 4 of paragraph (e)(12) of this section.

(2) *Supplemental foods not requiring medical documentation.* (i) State agencies may authorize local agencies to issue a non-contract brand infant formula that meets the requirements in Table 4 of paragraph (e)(12) of this section without medical documentation in order to meet religious eating patterns; and

(ii) The State agency has the discretion to require medical documentation for any contract brand infant formula other than the primary contract infant formula and may decide that some contract brand infant formula may not be issued under any circumstances.

(3) *Medical Determination.* For purposes of this program, medical documentation means that a health care professional licensed to write medical prescriptions under State law has:

(i) Made a medical determination that the participant has a qualifying condition as described in paragraphs (e)(3) through (e)(7) of this section that dictates the use of the supplemental foods, as described in paragraph (d)(1) of this section; and

(ii) Provided the written documentation that meets the technical requirements described in paragraphs (d)(4)(ii) and (d)(4)(iii) of this section.

(4) *Technical Requirements*—(i) *Location*. All medical documentation must be kept on file (electronic or hard copy) at the local clinic. The medical documentation kept on file must include the initial telephone documentation, when received as described in paragraph (d)(4)(iii)(B) of this section.

(ii) *Content*. All medical documentation must include the following:

(A) The name of the authorized WIC formula (infant formula, exempt infant formula, WIC-eligible medical food) prescribed, including amount needed per day;

(B) The authorized supplemental food(s) appropriate for the qualifying condition(s) and their prescribed amounts;

(C) Length of time the prescribed WIC formula and/or supplemental food is required by the participant;

(D) The qualifying condition(s) for issuance of the authorized supplemental food(s) requiring medical documentation, as described in paragraphs (e)(3) through (e)(7) of this section; and

(E) Signature, date and contact information (or name, date and contact information), if the initial medical documentation was received by telephone and the signed document is forthcoming, of the health care professional licensed by the State to write prescriptions in accordance with State laws.

(iii) *Written confirmation*—(A) *General*. Medical documentation must be written and may be provided as an original written document, an electronic document, by facsimile or by telephone to a competent professional authority until written confirmation is received.

(B) *Medical documentation provided by telephone*. Medical documentation may be provided by telephone to a competent professional authority who must promptly document the information. The collection of the required information by telephone for medical documentation purposes may only be used until written confirmation is received from a health care professional licensed to write medical prescriptions and used only when absolutely necessary on an individual participant basis. The local clinic must obtain written confirmation of the medical documentation within a reasonable amount of time (i.e., one or two week's

time) after accepting the initial medical documentation by telephone.

(5) *Medical supervision requirements*. Due to the nature of the health conditions of participants who are issued supplemental foods that require medical documentation, close medical supervision is essential for each participant's dietary management. The responsibility remains with the participant's health care provider for this medical oversight and instruction. This responsibility cannot be assumed by personnel at the WIC State or local agency. However, it would be the responsibility of the WIC competent professional authority to ensure that only the amounts of supplemental foods prescribed by the participant's health care provider are issued in the participant's food package.

(e) *Food packages*. There are seven food packages available under the Program that may be provided to participants. The authorized supplemental foods must be prescribed from food packages according to the category and nutritional needs of the participant. The food packages are as follows:

(1) *Food Package I—Infants birth through 5 months*—(i) *Participant category served*. This food package is designed for issuance to infant participants from birth through age 5 months who do not have a condition qualifying them to receive Food Package III.

(ii) *Infant feeding categories*—(A) *Birth to one month*. Three infant feeding options are available during the first month after birth—fully breastfeeding, i.e., the infant receives no infant formula from the WIC Program; partially breastfeeding, i.e., the infant receives not more than 104 reconstituted fluid ounces of formula; or fully formula-feeding. Infant formula is not provided during the first month after birth to fully breastfed infants to support the successful establishment of breastfeeding.

(B) *One through 5 months*. Three infant feeding options are available from 1 months through 5 months—fully breastfeeding, fully formula-feeding, or partially breastfeeding, i.e., the infant is breastfed but also receives infant formula from the WIC Program in an amount not to exceed approximately

half the amount of infant formula allowed for a fully formula fed infant.

(iii) *Infant formula requirements.* This food package provides iron-fortified infant formula that is not an exempt infant formula. The issuance of any contract brand or noncontract brand infant formula that contains less than 10 milligrams of iron per liter at standard dilution (i.e., approximately 20 kilocalories per fluid ounce of prepared formula) is prohibited. Except as specified in paragraph (d) of this section, local agencies must issue as the first choice of issuance the primary contract infant formula, as defined in §246.2, with all other infant formulas issued as an alternative to the primary contract infant formula.

(iv) *Physical forms.* Local agencies must issue all WIC formulas (WIC formulas mean all infant formula, exempt infant formula and WIC-eligible medical foods) in concentrated liquid or powder physical forms. Ready-to-feed WIC formulas may be authorized when the competent professional authority determines and documents that:

(A) The participant's household has an unsanitary or restricted water supply or poor refrigeration;

(B) The person caring for the participant may have difficulty in correctly diluting concentrated or powder forms; or

(C) The WIC infant formula is only available in ready-to-feed.

(v) *Authorized category of supplemental foods.* Infant formula is the only category of supplemental foods authorized in this food package. Exempt infant formulas and WIC-eligible medical foods are authorized only in Food Package III.

(2) *Food Package II—Infants 6 through 11 months—(i) Participant category served.* This food package is designed for issuance to infant participants from 6 through 11 months of age who do not have a condition qualifying them to receive Food Package III.

(ii) *Infant feeding options.* Three infant feeding options are available—fully breastfeeding, fully formula-feeding, or partially breastfeeding.

(iii) *Infant formula requirements.* The requirements for issuance of infant formula in Food Package I, specified in paragraphs (e)(1)(iii) and (e)(1)(iv) of

this section, also apply to the issuance of infant formula in Food Package II.

(iv) *Authorized categories of supplemental foods.* Infant formula, infant fruits and vegetables, infant meat, and infant cereal are the categories of supplemental foods authorized in this food package.

(3) *Food Package III—Participants with qualifying conditions—(i) Participant category served and qualifying conditions.* This food package is reserved for issuance to women, infants and child participants who have a documented qualifying condition that requires the use of a WIC formula (infant formula, exempt infant formula or WIC-eligible medical food) because the use of conventional foods is precluded, restricted, or inadequate to address their special nutritional needs. Medical documentation must meet the requirements described in paragraph (d) of this section. Participants who are eligible to receive this food package must have one or more qualifying conditions, as determined by a health care professional licensed to write medical prescriptions under State law. The qualifying conditions 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 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. This food package may not be issued solely for the purpose of enhancing nutrient intake or managing body weight.

(ii) *Non-authorized issuance of Food Package III.* This food package is not authorized for:

(A) Infants whose only condition is:

(1) A diagnosed formula intolerance or food allergy to lactose, sucrose, milk protein or soy protein that does not require the use of an exempt infant formula; or

(2) A non-specific formula or food intolerance.

(B) Women and children who have a food intolerance to lactose or milk protein that can be successfully managed

with the use of one of the other WIC food packages (i.e., Food Packages IV–VII); or

(C) Any participant solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying condition.

(iii) *Restrictions on the issuance of WIC formulas in ready-to-feed (RTF) forms.* WIC State agencies must issue WIC formulas (infant formula, exempt infant formula and WIC-eligible medical foods) in concentrated liquid or powder physical forms unless the requirements for issuing RTF are met as described in paragraph (e)(1)(iv) of this section. In addition to those requirements, there are two additional conditions which may be used to issue RTF in Food Package III:

(A) If a ready-to-feed form better accommodates the participant's condition; or

(B) If it improves the participant's compliance in consuming the prescribed WIC formula.

(iv) *Unauthorized WIC costs.* All apparatus or devices (e.g., enteral feeding tubes, bags and pumps) designed to administer WIC formulas are not allowable WIC costs.

(v) *Authorized categories of supplemental foods.* The supplemental foods authorized in this food package require medical documentation for issuance and include infant formula (for children or women), exempt infant formula, WIC-eligible medical foods, infant cereal, infant food fruits and vegetables, milk and milk alternatives, cheese, eggs, canned fish, fruits and vegetables, breakfast cereal, whole wheat bread or other whole grains, juice, legumes and/or peanut butter.

(vi) *Coordination with medical payors and other programs that provide or reimburse for formulas.* WIC State agencies must coordinate with other Federal, State or local government agencies or with private agencies that operate programs that also provide or could reimburse for exempt infant formulas and WIC-eligible medical foods benefits to mutual participants. At a minimum, a WIC State agency must coordinate with the State Medicaid Program for the provision of exempt infant formulas and WIC-eligible medical foods that are authorized or could be author-

ized under the State Medicaid Program for reimbursement and that are prescribed for WIC participants who are also Medicaid recipients. The WIC State agency is responsible for providing up to the maximum amount of exempt infant formulas and WIC-eligible medical foods under Food Package III in situations where reimbursement is not provided by another entity.

(4) *Food Package IV—Children 1 through 4 years—(i) Participant category served.* This food package is designed for issuance to participants 1 through 4 years of age who do not have a condition qualifying them to receive Food Package III.

(ii) *Authorized categories of supplemental foods.* Milk, breakfast cereal, juice, fruits and vegetables, whole wheat bread or other whole grains, eggs, and legumes or peanut butter are the categories of supplemental foods authorized in this food package. Cheese may be substituted for milk in amounts described in Table 2 of paragraph (e)(10) of this section. Substitutions exceeding the maximum substitution allowance of cheese, up to the maximum allowance for fluid milk, may be allowed with medical documentation of the qualifying condition. Soy-based beverage and tofu can be substituted for milk only with medical documentation in this food package, in amounts described in Table 2 of paragraph (e)(10) of this section. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that a child cannot drink milk and requires soy-based beverage, tofu, or additional cheese as a substitute for milk. Such determination can be made for situations that include, but are not limited to, milk allergy, severe lactose maldigestion, and vegan diets. Medical documentation must meet the requirements described in paragraph (d) of this section.

(5) *Food Package V—Pregnant and partially breastfeeding women—(i) Participant category served.* This food package is designed for issuance to women participants with singleton pregnancies who do not have a condition qualifying them to receive Food Package III. This food package is also designed for

issuance to breastfeeding women participants, up to 1 year postpartum, who do not have a condition qualifying them to receive Food Package III and whose partially breastfed infants receive formula from the WIC program in amounts that do not exceed the maximum allowances described in Table 1 of paragraph (e)(9) of this section. Women participants breastfeeding more than one infant, and women participants pregnant with more than one fetus, are eligible to receive Food Package VII as described in paragraph (e)(7) of this section.

(ii) *Authorized categories of supplemental foods.* Milk, breakfast cereal, juice, fruits and vegetables, whole wheat bread or other whole grains, eggs, legumes and peanut butter are the categories of supplemental foods authorized in this food package. Cheese or calcium-set tofu may be substituted for milk in amounts described in Table 2 of paragraph (e)(10) of this section. Amounts of cheese or calcium-set tofu exceeding the maximum substitution allowances may be allowed with medical documentation of the qualifying condition, up to the maximum allowance for fluid milk. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that a woman cannot drink milk and requires additional cheese or calcium-set tofu. Such determination can be made for situations that include, but are not limited to, milk allergy or severe lactose maldigestion. Medical documentation must meet the requirements described in paragraph (d) of this section.

(6) *Food Package VI—Postpartum women—(i) Participant category served.* This food package is designed for issuance to women up to 6 months postpartum who are not breastfeeding their infants, and to breastfeeding women up to 6 months postpartum whose participating infant receives more than the maximum amount of formula allowed for partially breastfed infants as described in Table 1 of paragraph (e)(9) of this section.

(ii) *Authorized categories of supplemental foods.* Milk, breakfast cereal, juice, fruits and vegetables, eggs, and legumes or peanut butter are the cat-

egories of supplemental foods authorized in this food package. Cheese or calcium-set tofu may be substituted for milk in amounts described in Table 2 of paragraph (e)(10) of this section. Amounts of cheese or calcium-set tofu exceeding the maximum substitution allowances may be allowed with medical documentation of the qualifying condition, up to the maximum allowance for fluid milk. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that a woman cannot drink milk and requires additional cheese or calcium-set tofu. Such determination can be made for situations that include, but are not limited to, milk allergy or severe lactose maldigestion. Medical documentation must meet the requirements described in paragraph (d) of this section.

(7) *Food Package VII—Fully breastfeeding—(i) Participant category served.* This food package is designed for issuance to breastfeeding women up to 1 year postpartum whose infants do not receive infant formula from WIC (these breastfeeding women are assumed to be fully breastfeeding their infants). This food package is also designed for issuance to women participants pregnant with two or more fetuses, and women participants partially breastfeeding multiple infants. Women participants fully breastfeeding multiple infants receive 1.5 times the supplemental foods provided in Food Package VII.

(ii) *Authorized categories of supplemental foods.* Milk, cheese, breakfast cereal, juice, fruits and vegetables, whole wheat bread or other whole grains, eggs, legumes, peanut butter, and canned fish are the categories of supplemental foods authorized in this food package. Cheese or calcium-set tofu may be substituted for milk in amounts described in Table 2 of paragraph (e)(10) of this section. Amounts of cheese or calcium-set tofu exceeding the maximum substitution allowances may be allowed with medical documentation of the qualifying condition, up to the maximum allowance for fluid

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milk. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that a woman cannot drink milk and requires additional cheese or calcium-set tofu. Such determination can be made for situations that include, but are not limited to, milk allergy or severe lactose maldigestion. Medical documentation must meet the requirements described in paragraph (d) of this section.

(8) *Supplemental Foods—Maximum monthly allowances, options and substitution rates, and minimum requirements.*

Tables 1 through 3 of paragraphs (e)(9) through (e)(11) of this section specify the maximum monthly allowances of foods in WIC food packages and identify WIC food options and substitution rates. Table 4 of paragraph (e)(12) of this section describes the minimum requirements and specifications of supplemental foods in the WIC food packages.

(9) *Maximum monthly allowances of supplemental foods for infants.* The maximum monthly allowances, options and substitution rates of supplemental foods for infants in Food Packages I, II and III are stated in Table 1 as follows:

TABLE 1—MAXIMUM MONTHLY ALLOWANCES OF SUPPLEMENTAL FOODS FOR INFANTS IN FOOD PACKAGES I, II AND III

Foods ¹	Fully formula fed (FF)		Partially breastfed (BF/FF)		Fully breastfed (BF)	
	Food packages I-FF & II-FF A: 0 through 3 months B: 4 through 5 months	Food packages II-FF & III-FF 6 through 11 months	Food packages I-BF/FF & III BF/FF A: 0 to 1 month ² B: 1 through 3 months ² C: 4 through 5 months	Food packages II- BF/FF & III BF/FF 6 through 11 months	Food package I-BF 0 through 5 months	Food package II-BF 6 through 11 months
WIC Formula ^{4 5 6 7}	A: 806 fl oz reconstituted liquid concentrate or 832 fl. oz. RTF or 870 fl oz reconstituted powder. B: 884 fl oz reconstituted liquid concentrate or 896 fl. oz. RTF or 960 fl oz reconstituted powder.	624 fl. oz. reconstituted liquid concentrate or 640 fl. oz. RTF or 696 fl oz reconstituted powder.	A: 104 fl oz reconstituted powder ³ B: 364 fl oz reconstituted liquid concentrate or 384 fl oz RTF or 435 fl oz reconstituted powder. C: 442 fl. oz. reconstituted liquid concentrate or 448 fl. oz. RTF or 522 fl oz reconstituted powder.	312 fl. oz. reconstituted liquid concentrate or 320 fl. oz. RTF or 384 fl oz reconstituted powder.		
Infant cereal ⁸
Infant food fruits and vegetables ^{9 10}
Infant food meat ^{9 10}
		24 oz 128 oz		24 oz 128 oz		24 oz 256 oz 77.5 oz.

Table 1 Footnotes: (Abbreviations in order of appearance in table): FF = fully formula fed; BF/FF = partially breastfed (i.e., the infant is breastfed but also receives formula from the WIC Program); BF = fully breastfed (i.e., the infant receives no formula through the WIC program).

¹ Table 4 describes the minimum requirements and specifications for the supplemental foods.

² The powder form is the form recommended for partially breastfed infants ages 0 through 3 months in Food Package I.

³ Liquid concentrate and ready-to-feed (RTF) may be substituted at rates that provide comparable nutritive value.

⁴ WIC formula means infant formula, exempt infant formula, or WIC-eligible medical food. Only infant formula may be issued for infants in Food Packages I and II. Exempt infant formula may only be issued for infants in Food Package III.

⁵ The maximum monthly allowance is specified in reconstituted fluid ounces for liquid concentrate, RTF liquid, and powder forms of infant formula and exempt infant formula. Reconstituted fluid ounce is the form prepared for consumption as directed on the container.

⁶ If powder infant formula is provided, State agencies must provide at least the number of reconstituted fluid ounces as the maximum allowance for the liquid concentrate form of the same product in the same Food Package up to the maximum monthly allowance for powder. State agencies must issue whole containers that are all the same size.

⁷ State agencies may round up and disperse whole containers of infant formula over the food package timeframe to allow participants to receive the full authorized nutritional benefit (FNB). State agencies must use the methodology described in accordance with paragraph (h)(1) of this section.

⁸ State agencies may round up and disperse whole containers of infant foods (infant cereal, fruits and vegetables, and meat) over the Food Package timeframe. State agencies must use the methodology described in accordance with paragraph (h)(2) of this section.

⁹ Fresh banana may replace up to 16 ounces of infant food fruit at a rate of 1 pound of bananas per 8 ounces of infant food fruit.

¹⁰ In lieu of infant foods (cereal, fruit and vegetables, and meat), infants greater than 6 months of age in Food Package III may receive exempt infant formula or WIC-eligible medical foods at the same maximum monthly allowance as infants ages 4 through 5 months of age or the same feeding option.

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(10) *Maximum monthly allowances of supplemental foods in Food Packages IV through VII.* The maximum monthly allowances, options and substitution rates of supplemental foods for children and women in Food Package IV through VII are stated in Table 2 as follows:

TABLE 2—MAXIMUM MONTHLY ALLOWANCES OF SUPPLEMENTAL FOODS FOR CHILDREN AND WOMEN IN FOOD PACKAGES IV, V, VI AND VII

Foods ¹	Children		Women	
	Food Package IV 1 through 4 years	Food Package V: Pregnant and partially breastfeeding (up to 1 year postpartum) ²	Food Package VI: Postpartum (up to 6 months postpartum) ³	Food Package VII: Fully breastfeeding (up to 1 year postpartum) ^{4,5}
Juice, single strength ⁶	128 fl oz	144 fl oz	96 fl oz	144 fl oz
Milk, fluid	16 qt ^{7,8,9,10}	22 qt ^{7,8,11,12}	16 qt ^{7,8,11,12}	24 qt ^{7,8,11,12}
Breakfast cereal ¹³	36 oz	36 oz	36 oz	36 oz
Cheese	N/A	N/A	N/A	1 lb.
Eggs	1 dozen	1 dozen	1 dozen	2 dozen
Fruits and vegetables ^{14,15}	\$6.00 in cash value vouchers	\$10.00 in cash value vouchers	\$10.00 in cash value vouchers	\$10.00 in cash value vouchers.
Whole wheat bread or other whole grains ¹⁶	2 lb	1 lb	N/A	1 lb.
Fish (canned)	N/A	N/A	N/A	30 oz.
Legumes, dry ¹⁷	1 lb	1 lb	1 lb	1 lb.
And/or	Or	And	Or	And
Peanut butter	18 oz	18 oz	18 oz	18 oz.

Table 2 Footnotes: N/A = the supplemental food is not authorized in the corresponding food package.
¹ Table 4 of paragraph (e)(12) of this section describes the minimum requirements and specifications for the supplemental foods.
² Food Package V is issued to two categories of WIC participants: Women participants with singleton pregnancies and breastfeeding women whose partially breastfed infants receive formula from the WIC Program in amounts that do not exceed the maximum formula allowances for Food Packages I–BF/FF–A, I–BF/FF–B, I–BF/FF–C, or II–BF/FF, as appropriate for the age of the infant as described in Table 1 of paragraph (e)(9) of this section.
³ Food Package VI is issued to two categories of WIC participants: Non-breastfeeding postpartum women and breastfeeding postpartum women whose partially breastfed infants receive more than the maximum infant formula allowances for Food Packages I–BF/FF–A, I–BF/FF–B, I–BF/FF–C, or II–BF/FF, as appropriate for the age of the infant as described in Table 1 of paragraph (e)(9) of this section.
⁴ Food Package VII is issued to three categories of WIC participants: Fully breastfeeding women whose infants do not receive formula from the WIC Program; women pregnant with two or more fetuses; and women fully or partially breastfeeding multiple infants.
⁵ Women fully breastfeeding multiple infants are prescribed 1.5 times the maximum allowances.
⁶ Combinations of single-strength and concentrated juices may be issued provided that the total volume does not exceed the maximum monthly allowance for single-strength juice.
⁷ Whole milk, as specified in FDA standards, is the only type of milk allowed for 1-year-old children (12 through 23 months). Reduced fat milks, as specified in FDA standards, i.e., 2% milk fat, are the only types of milk allowed for children ≥ 24 months of age and women.
⁸ Evaporated milk may be substituted at the rate of 16 fluid ounces of evaporated milk per 32 fluid ounces of fluid milk or a 1:2 fluid ounce substitution ratio. Dry milk may be substituted at an equal reconstituted rate to fluid milk. When a combination of different milk forms is provided, the full maximum monthly fluid milk allowance must be provided.
⁹ For children, cheese may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk. No more than 1 lb. of cheese may be substituted for milk. With medical documentation, additional amounts of cheese may be substituted in cases of lactose intolerance or other qualifying conditions, up to the maximum allowance for fluid milk.
¹⁰ For children, soy-based beverage and calcium-set tofu may be substituted for milk only with medical documentation for qualifying conditions. Soy-based beverage may be substituted for milk, with medical documentation, for children in Food Package IV at the rate of 1 quart of tofu per 1 quart of milk up to the total maximum allowance of milk. Tofu may be substituted for milk, with medical documentation, for children in Food Package IV at the rate of 1 pound of tofu per 1 quart of milk up to the total maximum allowance of milk.
¹¹ For women, cheese or calcium-set tofu may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk or 1 pound of tofu per 1 quart of milk. A maximum of 4 quarts of milk can be substituted in this manner in Food Package VII; therefore, no more than 1 pound of cheese may be substituted for milk. With medical documentation, additional amounts of cheese or tofu may be substituted, up to the maximum allowances for fluid milk, in cases of lactose intolerance or other qualifying conditions.
¹² For women, soy-based beverage may be substituted for milk at the rate of 1 quart of soy-based beverage for 1 quart of milk up to the total maximum monthly allowance of milk.
¹³ At least one-half of the total number of breakfast cereals on the State agency's authorized food list must have whole grain as the primary ingredient and meet labeling requirements for making a health claim as a "whole grain food with moderate fat content" as defined in Table 4 of paragraph (e)(12) of this section.
¹⁴ Processed (canned, frozen, dried) fruits and vegetables may be substituted for fresh fruits and vegetables. Dried fruit and dried vegetables are not authorized for children in Food Package IV.
¹⁵ The monthly value of the fruit/vegetable cash-value vouchers will be adjusted annually for inflation as described in §246.16(f).
¹⁶ Brown rice, bulgur (cracked wheat), oatmeal, whole-grain barley, soft corn or whole wheat tortillas may be substituted for whole wheat bread on an equal weight basis.

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¹⁷ Canned legumes may be substituted for dried legumes at the rate of 64 oz. of canned beans for 1 lb. dried beans. Under Food Packages V and VII, two additional combinations of dry or canned beans/peas are authorized: 1 lb. Dry and 64 oz. Canned beans/peas (and no peanut butter); or 2 lb. Dry or 128 oz. Canned beans/peas (and no peanut butter) or 36 oz. peanut butter (and no beans).

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(11) *Maximum monthly allowances of supplemental foods for children and women with qualifying conditions in Food Package III.* The maximum monthly allowances, options and substitution

rates of supplemental foods for participants with qualifying conditions in Food Package III are stated in Table 3 as follows:

TABLE 3—MAXIMUM MONTHLY ALLOWANCES OF SUPPLEMENTAL FOODS FOR CHILDREN AND WOMEN IN FOOD PACKAGE III

Foods ¹	Children		Women	
	1 through 4 years	Pregnant and partially breastfeeding (up to 1 year postpartum) ²	Postpartum (up to 6 months postpartum) ³	Fully breastfeeding (up to 1 year postpartum) ^{4,5}
Juice, single strength ⁶	128 fl oz	144 fl oz	96 fl oz	144 fl oz
WIC Formula ^{7,8}	455 fl oz liquid concentrate	455 fl oz liquid concentrate	455 fl oz liquid concentrate	455 fl oz liquid concentrate
Milk	16 qt ^{9,10,11,12}	22 qt ^{9,10,13,14}	16 qt ^{9,10,13,14}	24 qt ^{9,10,13,14}
Breakfast cereal	36 oz	36 oz	36 oz	36 oz
Cheese	N/A	N/A	N/A	N/A
Eggs	1 dozen	1 dozen	1 dozen	2 dozen
Fruits and vegetables ^{17,18}	\$6.00 in cash value vouchers	\$10.00 in cash value vouchers	\$10.00 in cash value vouchers	\$10.00 in cash value vouchers
Whole wheat bread ¹⁹	2 lb	1 lb	N/A	1 lb
Fish (canned)	N/A	N/A	N/A	30 oz
Legumes, dry ²⁰	1 lb	1 lb	1 lb	1 lb
And/or	Or	And	Or	And
Peanut butter	18 oz	18 oz	18 oz	18 oz

Table 3 Footnotes: N/A = the supplemental food is not authorized in the corresponding food package.

¹ Table 4 of paragraph (e)(12) of this section describes the minimum requirements and specifications for the supplemental foods.

² Food Package V is issued to two categories of WIC participants—women participants with singleton pregnancies and breastfeeding women whose partially breastfed infants receive formula from the WIC Program in amounts that do not exceed the maximum formula allowances for Food Packages I–BF/FF–A, I–BF/FF–B, I–BF/FF–C, or II–BF/FF, as appropriate for the age of the infant as described in Table 1 of paragraph (e)(9) of this section.

³ Food Package VI is issued to two categories of WIC participants—non-breastfeeding postpartum women and breastfeeding postpartum women whose partially breastfed infants receive more than the maximum formula allowances for Food Packages I–BF/FF–A, I–BF/FF–B, I–BF/FF–C or II–BF/FF, as appropriate for the age of the infant as described in Table 1 of paragraph (e)(9) of this section.

⁴ Food Package VII is issued to three categories of WIC participants—fully breastfeeding women whose infants do not receive formula from the WIC Program; women pregnant with two or more fetuses; and women fully or partially breastfeeding multiple infants.

⁵ Women fully breastfeeding multiple infants are prescribed 1.5 times the maximum allowances.

⁶ Combinations of single-strength and concentrated juices may be issued provided that the total volume does not exceed the maximum monthly allowance for single-strength juice.

⁷ WIC formula means infant formula, exempt infant formula, or WIC-eligible medical food.

⁸ Powder and Ready-to-Feed may be substituted at rates that provide comparable nutritive value.

⁹ Whole milk, as specified in FDA standards, is the only type of milk allowed for 1-year-old children (12 through 23 months). Reduced fat milks, as specified in FDA standards, i.e., 2% milk fat, are the only types of milk allowed for children > 24 months of age and women. With medical documentation, whole milk may be substituted for reduced fat milk for children > 24 months of age and women.

¹⁰ Evaporated milk may be substituted at the rate of 16 fluid ounces of evaporated milk per 32 fluid ounces of fluid milk or a 1:2 fluid ounce substitution ratio. Dry milk may be substituted at an equal reconstituted rate to fluid milk. When a combination of different milk forms is provided, the full maximum monthly fluid milk allowance must be provided.

¹¹ For children, cheese may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk. No more than 1 lb. of cheese may be substituted for milk. With medical documentation, additional amounts of cheese may be substituted in cases of lactose intolerance or other qualifying conditions, up to the maximum allowance for fluid milk.

¹² For children, soy-based beverage and tofu may be substituted for milk only with medical documentation for qualifying conditions. Soy-based beverage may be substituted for milk, with medical documentation, for children in Food Package IV on a quart for quart basis up to the total maximum allowance of milk. Tofu may be substituted for milk, with medical documentation, for children in Food Package IV at the rate of 1 pound of tofu per 1 quart of milk up to the total maximum allowance of milk.

¹³ For women, cheese or calcium-set tofu may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk or 1 pound of tofu per 1 quart of milk. A maximum of 4 quarts of milk can be substituted in this manner in Food Package VII; therefore, no more than 1 pound of cheese may be substituted for milk. A maximum of 6 quarts of milk can be substituted in this manner in Food Package VII; therefore, no more than 2 lbs. of cheese may be substituted for milk. With medical documentation, additional amounts of cheese or tofu may be substituted, up to the maximum allowances for fluid milk, in cases of lactose intolerance or other qualifying conditions.

¹⁴ For women, soy-based beverage may be substituted for milk at the rate of 1 quart of soy-based beverage for 1 quart of milk up to the total maximum monthly allowance of milk.

¹⁵ 32 dry ounces of infant cereal may be substituted for 36 ounces of breakfast cereal.

¹⁶ At least one half of the total number of breakfast cereals on the State agency's authorized food list must have whole grain as the primary ingredient and meet labeling requirements for making a health claim as a "whole grain food with moderate fat content" as defined in Table 4 of paragraph (e)(12) of this section.

¹⁷ Processed (canned, frozen, dried) fruits and vegetables may be substituted for fresh fruits and vegetables. Dried fruit and dried vegetables are not authorized for children.

¹⁸ The monthly value of the fruit/vegetable cash-value vouchers will be adjusted annually for inflation as described in §246.16(f).

¹⁹ Brown rice, bulgur (cracked wheat), oatmeal, whole-grain barley, soft corn or whole wheat tortillas may be substituted for whole wheat bread on an equal weight basis.

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²⁰ Canned legumes may be substituted for dried legumes at the rate of 64 oz. of canned beans for 1 lb dried beans. Issuance of two additional combinations of dry or canned beans/peas is authorized for the Pregnant and Partially Breastfeeding (up to 1 year postpartum) category and Fully Breastfeeding (Enhanced) (up to 1 year postpartum) category: 1 lb. Dry and 64 oz. Canned beans/peas (and no peanut butter); or 2 lb. Dry or 128 oz. Canned beans/peas (and no peanut butter) or 36 oz. peanut butter (and no beans).

(12) *Minimum requirements and specifications for supplemental foods.* Table 4 describes the minimum requirements and specifications for supplemental foods in all food packages:

TABLE 4—MINIMUM REQUIREMENTS AND SPECIFICATIONS FOR SUPPLEMENTAL FOODS

Categories/foods	Minimum requirements and specifications
WIC formula:	
Infant formula	<p>All authorized infant formulas must (1) meet the definition for an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and meet the requirements for an infant formula under section 412 of the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 350a) and the regulations at 21 CFR parts 106 and 107;</p> <p>(2) Be designed for enteral digestion via an oral or tube feeding;</p> <p>(3) Provide at least 10 mg iron per liter (at least 1.8 mg iron/100 kilocalories) at standard dilution;</p> <p>(4) Provide at least 67 kilocalories per 100 milliliters (approximately 20 kilocalories per fluid ounce) at standard dilution.</p> <p>(5) Not require the addition of any ingredients other than water prior to being served in a liquid state.</p>
Exempt infant formula	<p>All authorized exempt infant formula must (1) meet the definition and requirements for an exempt infant formula under section 412(h) of the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 350a(h)) and the regulations at 21 CFR Parts 106 and 107; and</p> <p>2) Be designed for enteral digestion via an oral or tube feeding.</p>
WIC-eligible medical foods. ¹	<p>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 medical foods 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; and may not be a conventional food, drug, flavoring, or enzyme.</p> <p>WIC-eligible medical foods include many, but not all, products that meet the definition of medical food in Section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)).</p>
Milk and milk alternatives:	
Cow's milk	<p>Must conform to FDA standard of identity for whole, reduced fat, low-fat, or non-fat milks (21 CFR 131.110). Must be pasteurized and contain at least 400 IU of vitamin D per quart (100 IU per cup) and 2000 IU of vitamin A per quart (500 IU per cup).</p> <p>May be flavored or unflavored. May be fluid, shelf-stable, evaporated (21 CFR 131.130), or dried (i.e., powder) (21 CFR 131.147).²</p> <p>Cultured Milks. Must conform to FDA standard of identity for cultured milk (21 CFR 131.112—cultured buttermilk, kefir cultured milk, acidophilus cultured milk).</p>
Goat milk	<p>Must conform to FDA standard of identity for whole, reduced fat, low-fat, or non-fat milks (21 CFR part 131). Must be pasteurized and contain at least 400 IU of vitamin D per quart (100 IU per cup) and 2000 IU of vitamin A per quart (500 IU per cup) following FDA fortification standards (21 CFR part 131). May be flavored or unflavored. May be fluid, shelf-stable, evaporated (21 CFR 131.130), or dried (i.e., powdered) (21 CFR 131.147).²</p>
Cheese	<p>Domestic cheese made from 100 percent pasteurized milk. Must conform to FDA standard of identity (21 CFR Part 133); Monterey Jack, Colby, natural Cheddar, Swiss, Brick, Muenster, Provolone, part-skim or whole Mozzarella, pasteurized processed American, or blends of any of these cheeses are authorized.</p> <p>Cheeses that are labeled low, free, reduced, less or light in the nutrients of sodium, fat or cholesterol are WIC-eligible.³</p>
Tofu	<p>Calcium-set tofu prepared with only calcium salts (e.g., calcium sulfate). May not contain added fats, sugars, oils, or sodium.</p>
Soy-based beverage	<p>Must be fortified to meet the following nutrient levels: 276 mg calcium per cup, 8 g protein per cup, 500 IU vitamin A per cup, 100 IU vitamin D per cup, 24 mg magnesium per cup, 222 mg phosphorus per cup, 349 mg potassium per cup, 0.44 mg riboflavin per cup, and 1.1 mcg vitamin B12 per cup, in accordance with fortification guidelines issued by FDA.</p>
Juice	<p>Must be pasteurized 100% unsweetened fruit juice. Must conform to FDA standard of identity (21 CFR part 146) or vegetable juice must conform to FDA standard of identity (21 CFR part 156) and contain at least 30 mg of vitamin C per 100 mL of juice. With the exception of 100 percent citrus juices, State agencies must verify the vitamin C content of all State-approved juices. Juices that are fortified with other nutrients may be allowed at the State agency's option. Juice may be fresh, from concentrate, frozen, canned, or shelf-stable.</p> <p>Vegetable juice may be regular or lower in sodium.³</p>
Eggs	<p>Fresh shell domestic hens' eggs or dried eggs mix (must conform to FDA standard of identity in 21 CFR 160.105) or pasteurized liquid whole eggs (must conform to FDA standard of identity in 21 CFR 160.115).</p>

TABLE 4—MINIMUM REQUIREMENTS AND SPECIFICATIONS FOR SUPPLEMENTAL FOODS—Continued

Categories/foods	Minimum requirements and specifications
Breakfast cereal	<p>Hard boiled eggs, where readily available for purchase in small quantities, may be provided for homeless participants.</p> <p>Breakfast cereals as defined by FDA in 21 CFR 170.3(n)(4) for ready-to-eat and instant and regular hot cereals.</p> <p>Must contain a minimum of 28 mg iron per 100 g dry cereal.</p> <p>Must contain ≤ 21.2 g sucrose and other sugars per 100 g dry cereal (≤ 6 g per dry oz).</p> <p>At least half of the cereals authorized on a State agency's food list must have whole grain as the primary ingredient by weight AND meet labeling requirements for making a health claim as a "whole grain food with moderate fat content":⁴</p> <p>(1) Contain a minimum of 51% whole grains (using dietary fiber as the indicator);</p> <p>(2) Meet the regulatory definitions for "low saturated fat" at 21 CFR 101.62 (≤ 1 g saturated fat per RACC) and "low cholesterol" (≤ 20 mg cholesterol per RACC);</p> <p>(3) Bear quantitative trans fat labeling; and</p> <p>(4) Contain ≤ 6.5 g total fat per RACC and ≤ 0.5 g trans fat per RACC.</p>
Fruits and Vegetables (fresh and processed).	<p>Any variety of fresh whole or cut fruit without added sugars.⁵</p> <p>Any variety of fresh whole or cut vegetable, except white potatoes, without added sugars, fats, or oils (orange yams and sweet potatoes are allowed).⁵</p> <p>Any variety of canned⁶ fruits (must conform to FDA standard of identity (21 CFR part 145); including applesauce, juice pack or water pack without added sugars, fats, oils, or salt (i.e. sodium). Any variety of frozen fruits without added sugars.⁷</p> <p>Any variety of canned⁶ or frozen vegetables (must conform to FDA standard of identity (21 CFR part 155)) except white potatoes (orange yams and sweet potatoes are allowed); without added sugars, fats, or oils. May be regular or lower in sodium.^{3,7}</p> <p>Any type of dried fruits or dried vegetable without added sugars, fats, oils, or salt (i.e., sodium).⁵</p>
Whole wheat bread/Whole grain bread/ Other whole unprocessed grains.	<p style="text-align: center;"><i>Bread</i></p> <p><i>Whole wheat bread</i> must conform to FDA standard of identity (21 CFR 136.180). (Includes whole wheat buns and rolls.)</p> <p>AND</p> <p>Whole wheat must be the primary ingredient by weight in all whole wheat bread products.</p> <p><i>Whole grain bread</i> must meet labeling requirements for making a health claim as a "whole grain food with moderate fat content":⁴</p> <p>(1) Contain a minimum of 51% whole grains (using dietary fiber as the indicator);</p> <p>(2) Meet the regulatory definitions for "low saturated fat" at 21 CFR 101.62 (≤ 1 g saturated fat per RACC) and "low cholesterol" (≤ 20 mg cholesterol per RACC);</p> <p>(3) Bear quantitative trans fat labeling; and</p> <p>(4) Contain ≤ 6.5 g total fat per RACC and ≤ 0.5 g trans fat per RACC.</p> <p>AND</p> <p>Whole grain must be the primary ingredient by weight in all whole grain bread products.</p>
	<p style="text-align: center;"><i>Other Whole Unprocessed Grains</i></p> <p>Brown rice, bulgur (cracked wheat), oatmeal, and whole-grain barley without added sugars, fats, oils, or salt (i.e., sodium). May be instant-, quick-, or regular-cooking.</p> <p>Soft corn or whole wheat tortillas may be allowed at the State agency's option.</p>
Canned fish ⁶	<p>Whole grain must be the primary ingredient by weight.</p> <p>Canned only:</p> <p>Light tuna (must conform to FDA standard of identity (21 CFR 161.190));</p> <p>Salmon (must conform to FDA standard of identity (21 CFR 161.170));</p> <p>Sardines;</p> <p>Mackerel (N. Atlantic <i>Scomber scombrus</i>, or Chub Pacific <i>Scomber japonicus</i>);</p> <p>May be packed in water or oil. Pack may include bones or skin. May be regular or lower in sodium content.³</p>
Mature legumes (dry beans and peas)	<p>Any type of mature dry beans, peas, or lentils in dry-packaged or canned⁶ forms. Examples include but are not limited to black beans ("turtle beans"), blackeye peas (cowpeas of the blackeye variety, "cow beans"), garbanzo beans (chickpeas), great northern beans, kidney beans, lima beans ("butter beans"), navy beans, pinto beans, soybeans, split peas, and lentils. All categories exclude soups. May not contain added sugars, fats, oils or meat as purchased. Canned legumes may be regular or lower in sodium content.^{3,8}</p>
Peanut butter	<p>Baked beans may be provided for participants with limited cooking facilities.⁸</p> <p>Peanut butter and reduced fat peanut butter (must conform to FDA Standard of Identity (21 CFR 164.150)); creamy or chunky, regular or reduced fat, salted or unsalted³ forms are allowed.</p>
Infant Foods: Infant cereal	<p>Infant cereal must contain a minimum of 45 mg of iron per 100 g of dry cereal.⁹</p>
Infant fruits	<p>Any variety of single ingredient commercial infant food fruit without added sugars, starches, or salt (i.e., sodium). Texture may range from strained through diced.¹⁰</p>

TABLE 4—MINIMUM REQUIREMENTS AND SPECIFICATIONS FOR SUPPLEMENTAL FOODS—Continued

Categories/foods	Minimum requirements and specifications
Infant vegetables	Any variety of single ingredient commercial infant food vegetables without added sugars, starches, or salt (i.e., sodium). Texture may range from strained through diced. ¹¹
Infant meat	Any variety of commercial infant food meat or poultry, as a single major ingredient, with added broth or gravy. Added sugars or salt (i.e. sodium) are not allowed. Texture may range from pureed through diced. ¹²

Table 4 Footnotes: FDA = Food and Drug Administration of the U.S. Department of Health and Human Services; RACC = reference amount customarily consumed.

¹ The following are not considered a WIC eligible medical food: Formulas used solely for the purpose of enhancing nutrient intake, managing body weight, addressing picky eaters or used for a condition other than a qualifying condition (e.g., vitamin pills, weight control products, etc.); medicines or drugs, as defined by the Food, Drug and Cosmetic Act (21 U.S.C. 350a) as amended; enzymes, herbs, or botanicals; oral rehydration fluids or electrolyte solutions; flavoring or thickening agents; and feeding utensils or devices (e.g., feeding tubes, bags, pumps) designed to administer a WIC-eligible formula.

² All authorized milks must confirm to FDA, DHHS standards of identity for milks as defined by 21 CFR part 131 and meet WIC's requirements for vitamin fortification as stated above. Additional authorized milks include, but are not limited to: calcium-fortified, lactose-reduced and lactose-free, acidified, and UHT pasteurized milks. Other milks are permitted at the State agency's discretion provided that the State agency determines that the milk meets the minimum requirements for authorized milk.

³ Any of the following lower sodium forms are allowable:

Sodium-free—less than 5 mg sodium per serving;

Very low sodium—35 mg sodium or less per serving or, if the serving is 30 g or less or 2 tablespoons or less, 35 mg sodium or less per 50 g of the food;

Low-sodium—140 mg sodium or less per serving or, if the serving is 30 g or less or 2 tablespoons or less, 140 mg sodium or less per 50 g of the food;

Light in sodium—at least 50 percent less sodium per serving than average reference amount for same food with no sodium reduction;

Lightly salted—at least 50 percent less sodium per serving than reference amount (If the food is not "low in sodium," the statement "not a low-sodium food" must appear on the same panel as the Nutrition Facts panel.); and

Reduced or less sodium—at least 25 percent less sodium per serving than reference food.

⁴ Food and Drug Administration (FDA), *Health Claim Notification for Whole Grain Foods with Moderate Fat Content* at <http://www.cfsan.fda.gov/~dms/flgrain2.html>

⁵ Herbs or spices; edible blossoms and flowers, e.g., squash blossoms (broccoli, cauliflower and artichokes are allowed); creamed or sauced vegetables; vegetable-grain (pasta or rice) mixtures; fruit-nut mixtures; breaded vegetables; fruits and vegetables for purchase on salad bars; peanuts; ornamental and decorative fruits and vegetables such as chili peppers on a string; garlic on a string; gourds; painted pumpkins; fruit baskets and party vegetable trays; and items such as blueberry muffins and other baked goods are not authorized. Mature legumes (dry beans and peas) and juices are provided as separate food WIC categories and are not authorized under the fruit and vegetable category.

⁶ "Canned" refers to processed food items in cans or other shelf-stable containers, e.g., jars, pouches.

⁷ Excludes white potatoes; catsup or other condiments; pickled vegetables, olives; soups; juices; and fruit leathers and fruit roll-ups.

⁸ The following canned mature legumes are not authorized: soups; immature varieties of legumes, such as those used in canned green peas, green beans, snap beans, orange beans, and wax beans; baked beans with meat; e.g., beans and franks; and beans containing added sugars (with the exception of baked beans), fats, meat, or oils.

⁹ Infant cereals containing infant formula, milk, fruit, or other non-cereal ingredients are not allowed.

¹⁰ Mixtures with cereal or infant food desserts (e.g., peach cobbler) are not authorized; however, combinations of single ingredients (e.g., apple-banana) are allowed.

¹¹ Combinations of single ingredients (e.g., peas and carrots) are allowed.

¹² No infant food combinations (e.g., meat and vegetables) or dinners (e.g., spaghetti and meatballs) are allowed.

(f) *USDA purchase of commodity foods.*

(1) At the request of a State agency, FNS may purchase commodity foods for the State agency using funds allocated to the State agency. The commodity foods purchased and made available to the State agency must be equivalent to the foods specified in Table 4 of paragraph (e)(12) of this section.

(2) The State agency must:

(i) Distribute the commodity foods to its local agencies or participants; and

(ii) Ensure satisfactory storage facilities and conditions for the commodity foods, including documentation of proper insurance.

(g) *Infant formula manufacturer registration.* Infant formula manufacturers supplying formula to the WIC Program must be registered with the Secretary

of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). Such manufacturers wishing to bid for a State contract to supply infant formula to the program must certify with the State health department that their formulas comply with the Federal Food, Drug, and Cosmetic Act and regulations issued pursuant to the Act.

(h) *Rounding up.* State agencies may round up to the next whole container for either infant formula or infant foods (infant cereal, fruits, vegetables and meat). State agencies that use the rounding up option must calculate the amount of infant formula or infant foods provided according to the requirements and methodology as described in this section.

(1) *Infant Formula.* State agencies must use the maximum monthly allowance of reconstituted fluid ounces of liquid concentrate infant formula as specified in Table 1 of paragraph (e)(9) of this section as the full nutritional benefit (FNB) provided by infant formula for each food package category and infant feeding option (e.g., Food Package I A fully formula fed, IA–FF).

(i) For State agencies that use rounding up of infant formula, the FNB is determined over the timeframe (the number of months) that the participant receives the food package. In any given month of the timeframe, the monthly issuance of reconstituted fluid ounces of infant formula may exceed the maximum monthly allowance or fall below the FNB; however, the cumulative average over the timeframe may not fall below the FNB. In addition, the State agency must:

(A) Use the methodology described in paragraph (h)(1)(ii) of this section for calculating and dispersing the rounding up option;

(B) Issue infant formula in whole containers that are all the same size; and

(C) Disperse the number of whole containers as evenly as possible over the timeframe with the largest monthly issuances given in the beginning of the timeframe.

(ii) The methodology to calculate rounding up and dispersing infant formula to the next whole container over the food package timeframe is as follows:

(A) Multiply the FNB amount for the appropriate food package and feeding option (e.g. Food Package I A fully formula fed, IA–FF) by the timeframe the participant will receive the food package to determine the total amount of infant formula to be provided.

(B) Divide the total amount of infant formula to be provided by the yield of the container (in reconstituted fluid ounces) issued by the State agency to determine the total number of containers to be issued during the timeframe that the food package is prescribed.

(C) If the number of containers to be issued does not result in a whole number of containers, the State agency must round up to the next whole con-

tainer in order to issue whole containers.

(2) *Infant foods.* (i) State agencies may use the rounding up option to the next whole container of infant food (infant cereal, fruits, vegetables and meats) when the maximum monthly allowance cannot be issued due to varying container sizes of authorized infant foods.

(ii) State agencies that use the rounding up option for infant foods must:

(A) Use the methodology described in paragraph (h)(2)(iii) of this section for calculating and dispersing the rounding up option;

(B) Issue infant foods in whole containers; and

(C) Disperse the number of whole containers as evenly as possible over the timeframe (the number of months the participant will receive the food package).

(iii) The methodology to round up and disperse infant food is as follows:

(A) Multiply the maximum monthly allowance for the infant food by the timeframe the participant will receive the food package to determine the total amount of food to be provided.

(B) Divide the total amount of food provided by the container size issued by the State agency (e.g., ounces) to determine the total number of food containers to be issued during the timeframe that the food package is prescribed.

(C) If the number of containers to be issued does not result in a whole number of containers, the State agency must round up to the next whole container in order to issue whole containers.

(i) *Plans for substitutions.* (1) The State agency may submit to FNS a plan for substitution of food(s) acceptable for use in the Program to allow for different cultural eating patterns. The plan shall provide the State agency's justification, including a specific explanation of the cultural eating pattern and other information necessary for FNS to evaluate the plan as specified in paragraph (1)(2) of this section.

(2) FNS will evaluate a State agency's plan for substitution of foods for different cultural eating patterns based on the following criteria:

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(i) Any proposed substitute food must be nutritionally equivalent or superior to the food it is intended to replace.

(ii) The proposed substitute food must be widely available to participants in the areas where the substitute is intended to be used.

(iii) The cost of the substitute food must be equivalent to or less than the cost of the food it is intended to replace.

(3) FNS will make a determination on the proposed plan based on the evaluation criteria specified in paragraph (i)(2) of this section, as appropriate. The State agency shall substitute foods only after receiving the written approval of FNS.

[50 FR 6121, Feb. 13, 1985 as amended at 73 FR 11312, Mar. 3, 2008; 74 FR 48845, Sept. 25, 2009; 74 FR 69245, Dec. 31, 2009]

§ 246.11 Nutrition education.

(a) *General.* (1) Nutrition education shall be considered a benefit of the Program, and shall be made available at no cost to the participant. Nutrition education shall be designed to be easily understood by participants, and it shall bear a practical relationship to participant nutritional needs, household situations, and cultural preferences including information on how to select food for themselves and their families. Nutrition education shall be thoroughly integrated into participant health care plans, the delivery of supplemental foods, and other Program operations.

(2) The State agency shall ensure that nutrition education is made available to all participants. Nutrition education may be provided through the local agencies directly, or through arrangements made with other agencies. At the time of certification, the local agency shall stress the positive, long-term benefits of nutrition education and encourage the participant to attend and participate in nutrition education activities. However, individual participants shall not be denied supplemental foods for failure to attend or participate in nutrition education activities.

(3) As an integral part of nutrition education, the State agency shall ensure that local agencies provide drug and other harmful substance abuse information to all pregnant, postpartum,

and breastfeeding women and to parents or caretakers of infants and children participating in the program. Drug and other harmful substance abuse information may also be provided to pregnant, postpartum, and breastfeeding women and to parents or caretakers of infants and children participating in local agency services other than the Program.

(b) *Goals.* Nutrition education shall be designed to achieve the following two broad goals:

(1) Emphasize the relationship between nutrition, physical activity and health with special emphasis on the nutritional needs of pregnant, postpartum, and breastfeeding women, infants and children under five years of age, and raise awareness about the dangers of using drugs and other harmful substances during pregnancy and while breastfeeding.

(2) Assist the individual who is at nutritional risk in improving health status and achieving a positive change in dietary and physical activity habits, and in the prevention of nutrition-related problems through optimal use of the supplemental foods and other nutritious foods. This is to be taught in the context of the ethnic, cultural and geographic preferences of the participants and with consideration for educational and environmental limitations experienced by the participants.

(c) *State agency responsibilities.* The State agency shall perform the following activities in carrying out nutrition education responsibilities:

(1) Develop and coordinate the nutrition education component of Program operations with consideration of local agency plans, needs and available nutrition education resources.

(2) Provide in-service training and technical assistance for professional and para-professional personnel involved in providing nutrition education to participants at local agencies. The State agency shall also provide training on the promotion and management of breastfeeding to staff at local agencies who will provide information and assistance on this subject to participants.

(3) Identify or develop resources and educational materials for use in local

agencies, including breastfeeding promotion and instruction materials, taking reasonable steps to include materials in languages other than English in areas where a significant number or proportion of the population needs the information in a language other than English, considering the size and concentration of such population and, where possible, the reading level of participants.

(4) Develop and implement procedures to ensure that nutrition education is offered to all adult participants and to parents and guardians of infant or child participants, as well as child participants, whenever possible.

(5) Monitor local agency activities to ensure compliance with provisions set forth in paragraphs (c)(7), (d), and (e) of this section.

(6) Establish standards for participant contacts that ensure adequate nutrition education in accordance with paragraph (e) of this section.

(7) Establish standards for breastfeeding promotion and support which include, at a minimum, the following:

(i) A policy that creates a positive clinic environment which endorses breastfeeding as the preferred method of infant feeding;

(ii) A requirement that each local agency designate a staff person to coordinate breastfeeding promotion and support activities;

(iii) A requirement that each local agency incorporate task-appropriate breastfeeding promotion and support training into orientation programs for new staff involved in direct contact with WIC clients; and

(iv) A plan to ensure that women have access to breastfeeding promotion and support activities during the prenatal and postpartum periods.

(d) *Local agency responsibilities.* Local agencies shall perform the following activities in carrying out their nutrition education responsibilities:

(1) Make nutrition education available or enter into an agreement with another agency to make nutrition education available to all adult participants, and to parents or caretakers of infant and child participants, and whenever possible, to child participants. Nutrition education may be pro-

vided through the use of individual or group sessions. Educational materials designed for Program participants may be utilized to provide education to pregnant, postpartum, and breastfeeding women and to parents or caretakers of infants and children participating in local agency services other than the program.

(2) Develop an annual local agency nutrition education plan consistent with the State's nutrition education component of Program operations and in accordance with this part and FNS guidelines. The local agency shall submit its nutrition education plan to the State agency by a date specified by the State agency.

(e) *Participant contacts.* (1) The nutrition education contacts shall be made available through individual or group sessions which are appropriate to the individual participant's nutritional needs. All pregnant participants shall be encouraged to breastfeed unless contraindicated for health reasons.

(2) During each six-month certification period, at least two nutrition contacts shall be made available to all adult participants and the parents or caretakers of infant and child participants, and wherever possible, the child participants themselves.

(3) Nutrition education contacts shall be made available at a quarterly rate, but not necessarily taking place within each quarter, to parents or caretakers of infant participants certified for a period in excess of six months.

(4) The local agency shall document in each participant's certification file that nutrition education has been given to the participant in accordance with State agency standards, except that the second or any subsequent nutrition education contact during a certification period that is provided to a participant in a group setting may be documented in a masterfile. Should a participant miss a nutrition education appointment, the local agency shall, for purposes of monitoring and further education efforts, document this fact in the participant's file, or, at the local agency's discretion, in the case of a second or subsequent missed contact where the nutrition education was offered in a group setting, document this fact in a master file.

(5) An individual care plan shall be provided for a participant based on the need for such plan as determined by the competent professional authority, except that any participant, parent, or caretaker shall receive such plan upon request.

(6) Contacts shall be designed to meet different cultural and language needs of Program participants.

[50 FR 6121, Feb. 13, 1985; 50 FR 8098, Feb. 28, 1985, as amended at 58 FR 11507, Feb. 26, 1993; 59 FR 11503, Mar. 11, 1994; 65 FR 53528, Sept. 5, 2000; 71 FR 56731, Sept. 27, 2006; 73 FR 11312, Mar. 3, 2008]

Subpart E—State Agency Provisions

§ 246.12 Food delivery systems.

(a) *General.* This section sets forth design and operational requirements for food delivery systems. In recognition of emergent electronic benefits transfer (EBT) technology, FNS may, on a case-by-case basis, modify regulatory provisions to the extent FNS determines the particular EBT system provides adequate safeguards that serve the purpose of the provisions being modified.

(1) *Management.* The State agency is responsible for the fiscal management of, and accountability for, food delivery systems under its jurisdiction. The State agency may permit only authorized vendors and farmers, home food delivery contractors, and direct distribution sites to accept food instruments and cash-value vouchers.

(2) *Design.* The State agency must design all food delivery systems to be used by its local agencies.

(3) *FNS oversight.* FNS may, for a stated cause and by written notice, require revision of a proposed or operating food delivery system and will allow a reasonable time for the State agency to effect such a revision.

(4) *Part 3016.* All contracts or agreements entered into by the State or local agency for the management or operation of food delivery systems must conform to the requirements of part 3016 of this title.

(b) *Uniform food delivery systems.* The State agency may operate up to three types of food delivery systems under its jurisdiction—retail, home delivery,

or direct distribution. Each system must be procedurally uniform throughout the jurisdiction of the State agency and must ensure adequate participant access to supplemental foods. When used, food instruments must be uniform within each type of system.

(c) *No charge for authorized supplemental foods.* The State agency must ensure that participants receive their authorized supplemental foods free of charge.

(d) *Compatibility of food delivery system.* The State agency must ensure that the food delivery system(s) selected is compatible with the delivery of health and nutrition education services to participants.

(e) *Retail food delivery systems: General.* Retail food delivery systems are systems in which participants, parents or caretakers of infant and child participants, and proxies obtain authorized supplemental foods by submitting a food instrument or cash-value voucher to an authorized vendor.

(f) *Retail food delivery systems: Food instrument and cash-value voucher requirements—(1) General.* State agencies using retail food delivery systems must use food instruments and cash-value vouchers that comply with the requirements of paragraph (f)(2) of this section.

(2) *Printed food instruments and cash-value vouchers.* Each printed food instrument and cash-value voucher must clearly bear on its face the following information:

(i) *Authorized supplemental foods.* The supplemental foods authorized to be obtained with the food instrument or cash-value voucher;

(ii) *First date of use.* The first date on which the food instrument or cash-value voucher may be used to obtain supplemental foods;

(iii) *Last date of use.* The last date on which the food instrument or cash-value vouchers may be used to obtain authorized supplemental foods. This date must be a minimum of 30 days from the first date on which it may be used, except for the participant's first month of issuance, when it may be the end of the month or cycle for which the food instrument or cash-value voucher

is valid. Rather than entering a specific last date of use on each instrument or cash-value voucher, all instruments or cash-value vouchers may be printed with a notice that the participant must transact them within a specified number of days after the first date on which the food instrument or cash-value voucher may be used;

(iv) *Redemption period.* The date by which the vendor must submit the food instrument or cash-value voucher for redemption. This date must be no more than 60 days from the first date on which the food instrument or cash-value voucher may be used. If the date is fewer than 60 days, then the State agency must ensure that the allotted time provides the vendor sufficient time to submit the food instrument or cash-value voucher for redemption without undue burden;

(v) *Serial number.* A unique and sequential serial number;

(vi) *Purchase price.* A space for the purchase price to be entered. At the discretion of the State agency, a maximum price may be printed on the food instrument that is higher than the expected purchase price of the authorized supplemental foods for which it will be used, but that is low enough to protect against potential loss of funds. When a maximum price is printed on the food instrument, the space for the purchase price must be clearly distinguishable from the maximum price. For example, the words “purchase price” or “actual amount of sale” could be printed larger and in a different area of the food instrument than the maximum price; and

(vii) *Signature space.* A space where participants, parents or caretakers of infant or child participants, or proxies must sign.

(3) *Vendor identification.* The State agency must implement procedures to ensure each food instrument and cash-value voucher submitted for redemption can be identified by the vendor or farmer that submitted the food instrument or cash-value voucher. Each vendor operated by a single business entity must be identified separately. The State agency may identify vendors by requiring that all authorized vendors stamp their names and/or enter a vendor identification number on all food instruments or cash-value vouchers

prior to submitting them for redemption.

(g) *Retail food delivery systems: Vendor authorization—(1) General.* The State agency must authorize an appropriate number and distribution of vendors in order to ensure the lowest practicable food prices consistent with adequate participant access to supplemental foods and to ensure effective State agency management, oversight, and review of its authorized vendors.

(2) *Vendor limiting criteria.* The State agency may establish criteria to limit the number of stores it authorizes. The State agency must apply its limiting criteria consistently throughout its jurisdiction. Any vendor limiting criteria used by the State agency must be included in the State Plan in accordance with § 246.4(a)(14)(ii).

(3) *Vendor selection criteria.* The State agency must develop and implement criteria to select stores for authorization. The State agency must apply its selection criteria consistently throughout its jurisdiction. The State agency may reassess any authorized vendor at any time during the vendor's agreement period using the vendor selection criteria in effect at the time of the reassessment and must terminate the agreements with those vendors that fail to meet them. The vendor selection criteria must include the following categories and requirements and must be included in the State Plan in accordance with § 246.4(a)(14)(ii).

(i) *Minimum variety and quantity of supplemental foods.* The State agency must establish minimum requirements for the variety and quantity of supplemental foods that a vendor applicant must stock to be authorized. These requirements include that the vendor stock at least two varieties of fruits, two varieties of vegetables, and at least one whole grain cereal authorized by the State agency. The State agency may not authorize a vendor applicant unless it determines that the vendor applicant meets these minimums. The State agency may establish different minimums for different vendor peer groups. The State agency may not authorize a vendor applicant unless it determines that the vendor applicant obtains infant formula only from sources

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included on the State agency's list described in paragraph (g)(11) of this section.

(ii) *Business integrity.* The State agency must consider the business integrity of a vendor applicant. In determining the business integrity of a vendor applicant, the State agency may rely solely on facts already known to it and representations made by the vendor applicant on its vendor application. The State agency is not required to establish a formal system of background checks for vendor applicants. Unless denying authorization of a vendor applicant would result in inadequate participant access, the State agency may not authorize a vendor applicant if during the last six years the vendor applicant or any of the vendor applicant's current owners, officers, or managers have been convicted of or had a civil judgment entered against them for any activity indicating a lack of business integrity. Activities indicating a lack of business integrity include fraud, antitrust violations, embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, receiving stolen property, making false claims, and obstruction of justice. The State agency may add other types of convictions or civil judgments to this list.

(iii) *Current Food Stamp Program disqualification or civil money penalty for hardship.* Unless denying authorization of a vendor applicant would result in inadequate participant access, the State agency may not authorize a vendor applicant that is currently disqualified from the Food Stamp Program or that has been assessed a Food Stamp Program civil money penalty for hardship and the disqualification period that would otherwise have been imposed has not expired.

(iv) *Provision of incentive items.* The State agency may not authorize or continue the authorization of an above-50-percent vendor, or make payments to an above-50-percent vendor, which provides or indicates an intention to provide prohibited incentive items to customers. Evidence of such intent includes, but is not necessarily limited to, advertising the availability of prohibited incentive items.

(A) The State agency may approve any of the following incentive items to be provided by above-50-percent vendors to customers, at the discretion of the State agency:

(1) Food, merchandise, or services obtained at no cost to the vendor, subject to documentation;

(2) Food, merchandise, or services of nominal value, i.e., having a per item cost of less than \$2, subject to documentation;

(3) Food sales and specials which involve no cost or less than \$2 in cost to the vendor for the food items involved, subject to documentation, and do not result in a charge to a WIC food instrument for foods in excess of the foods listed on the food instrument;

(4) Minimal customary courtesies of the retail food trade, such as helping the customer to obtain an item from a shelf or from behind a counter, bagging food for the customer, and assisting the customer with loading the food into a vehicle.

(B) The following incentive items are prohibited for above-50-percent vendors to provide to customers:

(1) Services which result in a conflict of interest or the appearance of such conflict for the above-50-percent vendor, such as assistance with applying for WIC benefits;

(2) Lottery tickets provided to customers at no charge or below face value;

(3) Cash gifts in any amount for any reason;

(4) Anything made available in a public area as a complimentary gift which may be consumed or taken without charge;

(5) An allowable incentive item provided more than once per customer per shopping visit, regardless of the number of customers or food instruments involved, unless the incentive items had been obtained by the vendor at no cost or the total value of multiple incentive items provided during one shopping visit would not exceed the less-than-\$2 nominal value limit;

(6) Food, merchandise or services of greater than nominal value provided to the customer;

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(7) Food, merchandise sold to customers below cost, or services purchased by customers below fair market value;

(8) Any kind of incentive item which incurs a liability for the WIC Program;

(9) Any kind of incentive item which violates any Federal, State, or local law or regulations.

(C) For-profit goods or services offered by the above-50-percent vendor to WIC participants at a fair market value based on comparable for-profit goods or services of other businesses are not incentive items subject to approval or prohibition, except that such goods or services must not constitute a conflict of interest or result in a liability for the WIC Program.

(4) *Vendor selection criteria: competitive price.* The State agency must establish a vendor peer group system and distinct competitive price criteria and allowable reimbursement levels for each peer group. The State agency must use the competitive price criteria to evaluate the prices a vendor applicant charges for supplemental foods as compared to the prices charged by other vendor applicants and authorized vendors, and must authorize vendors selected from among those that offer the program the most competitive prices. The State agency must consider a vendor applicant's shelf prices or the prices it bids for supplemental foods, which may not exceed its shelf prices. In establishing competitive price criteria and allowable reimbursement levels, the State agency must consider participant access by geographic area. The State agency must inform all vendors of the criteria for peer groups, and must inform each individual vendor of its peer group assignment.

(i) *Vendors that meet the above-50-percent criterion.* Vendors that derive more than 50 percent of their annual food sales revenue from WIC food instruments, and new vendor applicants expected to meet this criterion under guidelines approved by FNS, are defined as above-50-percent vendors. Each State agency annually must implement procedures approved by FNS to identify authorized vendors and vendor applicants as either above-50-percent vendors or regular vendors, in accordance with paragraphs (g)(4)(i)(E) and

(g)(4)(i)(F) of this section. The State agency must receive FNS certification of its vendor cost containment system under section 246.12(g)(4)(vi) prior to authorizing any above-50-percent vendors. The State agency that chooses to authorize any above-50-percent vendors:

(A) Must distinguish these vendors from other authorized vendors in its peer group system or its alternative cost containment system approved by FNS by establishing separate peer groups for above-50-percent vendors or by placing above-50-percent vendors in peer groups with other vendors and establishing distinct competitive price selection criteria and allowable reimbursement levels for the above-50-percent vendors;

(B) Must reassess the status of new vendors within six months after authorization to determine whether or not the vendors are above-50-percent vendors, and must take necessary follow-up action, such as terminating vendor agreements or reassigning vendors to the appropriate peer group;

(C) Must compare above-50-percent vendors' prices against the prices of vendors that do not meet the above-50-percent criterion in determining whether the above-50-percent vendors have competitive prices and in establishing allowable reimbursement levels for such vendors; and

(D) Must ensure that the prices of above-50-percent vendors do not inflate the competitive price criteria and allowable reimbursement levels for the peer groups or result in higher total food costs if program participants transact their food instruments at above-50-percent vendors rather than at other vendors that do not meet the above-50-percent criterion. To comply with this requirement, the State agency must compare the average cost of each type of food instrument redeemed by above-50-percent vendors against the average cost of the same type of food instrument redeemed by regular vendors. The average cost per food instrument may be weighted to reflect the relative proportion of food instruments redeemed by each category of vendors in the peer group system. The State agency must compute statewide average costs per food instrument at

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least quarterly to monitor compliance with this requirement. If average payments per food instrument for above-50-percent vendors exceed average payments per food instrument to regular vendors, then the State agency must take necessary action to ensure compliance, such as adjusting payment levels. Where EBT systems are in use, it may be more appropriate to compare prices of individual WIC food items to ensure that average payments to above-50-percent vendors do not exceed average payments for the same food item to comparable vendors. If FNS determines that a State agency has failed to ensure that above-50-percent vendors do not result in higher costs to the program than if participants transact their food instruments at regular vendors, FNS will establish a claim against the State agency to recover excess food funds expended and will require remedial action.

(E) Must determine whether vendor applicants are expected to be above-50-percent vendors. The State agency must ask vendor applicants whether they expect to derive more than 50 percent of their annual revenue from the sale of food items from transactions involving WIC food instruments. This question applies whether or not the State agency chooses to authorize above-50-percent vendors. A vendor who answers in the affirmative must be treated as an above-50-percent vendor. The State agency must further assess a vendor who answers in the negative, by first calculating WIC redemptions as a percent of total food sales in existing WIC-authorized stores owned by the vendor applicant. Second, the State agency must calculate or request from the vendor applicant the percentage of anticipated food sales by type of payment, *i.e.*, cash, Supplemental Nutrition Assistance Program, WIC, and credit/debit card. Third, the State agency must review either the inventory invoices for food items, or the actual food items present at the preauthorization visit required by paragraph (g)(5) of this section, or both. Fourth, the State agency must determine whether WIC authorization is required in order for the store to open for business. If the vendor would be expected to be an above-50-percent

vendor under any of these criteria, then the vendor must be treated as an above-50-percent vendor. State agencies may use additional data sources and methodologies, if approved by FNS.

(F) Must determine whether a currently authorized vendor meets the above-50-percent criterion, based on the State agency's calculation of WIC redemptions as a percent of the vendor's total foods sales for the same period. If WIC redemptions are more than 50 percent of the total food sales, the vendor must be deemed to be an above-50-percent vendor. As an initial step in identifying above-50-percent vendors, the State agency may compare each vendor's WIC redemptions to Supplemental Nutrition Assistance Program redemptions for the same period. If more than one WIC State agency authorizes a particular vendor, then each State agency must obtain and add the WIC redemptions for each State agency that authorizes the vendor to derive the total WIC redemptions. If Supplemental Nutrition Assistance Program redemptions exceed WIC redemptions, no further assessment is required since the vendor would not be an above-50-percent vendor. For vendors whose WIC redemptions exceed their Supplemental Nutrition Assistance Program redemptions, or if this comparison of redemptions was not made, the State agency must obtain from these vendors a statement of the total amount of revenue derived from the sale of foods that could be purchased using Supplemental Nutrition Assistance Program benefits. The State agency must also obtain from these vendors documentation (such as tax documents or other verifiable documentation) to support the amount of food sales claimed by the vendor. After evaluating the documentation received from the vendor, the State agency must calculate WIC redemptions as a percent of total food sales and classify the vendor as meeting or not meeting the above-50-percent criterion. State agencies may use additional methods, if approved by FNS.

(ii) *Implementing effective peer groups.* The State agency's methodology for establishing a vendor peer group system must include the following:

(A) At least two criteria for establishing peer groups, one of which must be a measure of geography, such as metropolitan or other statistical areas that form distinct labor and products markets, unless the State agency receives FNS approval to use a single criterion;

(B) Routine collection of vendor shelf prices at least every six months following authorization to monitor vendor compliance with paragraphs (g)(4)(i)(C), (g)(4)(ii)(C), and (g)(4)(iii) of this section and to ensure State agency policies and procedures dependent on shelf price data are efficient and effective. FNS may grant an exemption from this shelf price collection requirement if the State agency demonstrates to FNSs' satisfaction that an alternative methodology for monitoring vendor compliance with paragraphs (g)(4)(i)(C), (g)(4)(ii)(C), and (g)(4)(iii) of this section is efficient and effective and other State agency policies and procedures are not dependent on frequent collection of shelf price data. Such exemption would remain in effect until the State agency no longer meets the conditions on which the exemption was based, until FNS revokes the exemption, or for three years, whichever occurs first;

(C) Assessment of the effectiveness of the peer groupings and competitive price criteria at least every three years and modification, as necessary, to enhance system performance. The State agency may change a vendor's peer group whenever the State agency determines that placement in an alternate peer group is warranted.

(iii) *Subsequent price increases.* The State agency must establish procedures to ensure that a vendor selected for participation in the program does not, subsequent to selection, increase prices to levels that would make the vendor ineligible for authorization.

(iv) *Exceptions to competitive price criteria.* The State agency may except from the competitive price criteria and allowable reimbursement levels pharmacy vendors that supply only exempt infant formula and/or WIC-eligible medical foods, and non-profit vendors for which more than 50 percent of their annual revenue from food sales consists of revenue derived from WIC food in-

struments. A State agency that elects to exempt non-profit vendors from competitive price criteria and/or allowable reimbursements levels must notify FNS, in writing, at least 30 days prior to the effective date of the exemption. The State agency's notification must indicate the reason for the exemption, including whether the vendor is needed to ensure participant access, why other vendors that are subject to competitive price criteria and allowable reimbursement levels cannot provide the required supplemental foods, the benefits to the program of exempting the non-profit vendor from the competitive price criteria and/or allowable reimbursement levels, the criteria the State agency used to assess the competitiveness of the non-profit vendor's prices, and how the State agency will determine the reimbursement level for the non-profit vendor. This notification requirement does not apply to State agency contracts and agreements with non-profit health and/or human service agencies or organizations.

(v) *Exemptions from the vendor peer group system requirement.* With prior written approval from FNS, a State agency may use a vendor cost containment approach other than a peer group system if it meets certain conditions. A State agency that obtains an exemption from the peer group requirement still must establish competitive pricing criteria for vendor selection and allowable reimbursement levels. An exemption from the peer group requirement would remain in effect until the State agency no longer meets the conditions on which the exemption was based, until FNS revokes the exemption, or for three years, whichever occurs first. During the period of the exemption, the State agency must provide annually to FNS documentation that it either authorizes no above-50-percent vendors, or that such vendors' redemptions continue to represent less than five percent of total WIC redemptions, depending on the terms of the exemption. The conditions for obtaining an exemption from the vendor peer group system are as follows:

(A) The State agency chooses not to authorize any vendors that derive more than 50 percent of their revenue from

food sales from WIC food instruments, and the State agency demonstrates to FNS that establishing a vendor peer group system would be inconsistent with efficient and effective operation of the program, or that its alternative cost containment system would be as effective as a peer group system; or

(B) The State agency determines that food instruments redeemed by vendors that meet the above-50-percent criterion comprise less than five percent of the total WIC redemptions in the State in the fiscal year prior to a fiscal year in which the exemption is effective; and the State agency demonstrates to FNS that its alternative vendor cost containment system would be as effective as a vendor peer group system and would not result in higher costs if program participants redeem food instruments at vendors that meet the above-50-percent criterion rather than at vendors that do not meet this criterion.

(vi) *Cost containment certification.* If a State agency elects to authorize any above-50-percent vendors, the State agency must submit information, in accordance with guidance provided by FNS, to demonstrate that its competitive price criteria and allowable reimbursement levels do not result in average payments per food instrument to these vendors that are higher than average payments per food instrument to comparable vendors that are not above-50-percent vendors. To calculate average payments per food instrument, the State agency must include either all food instruments redeemed by all authorized vendors or a representative sample of the redeemed food instruments. The State agency must add the redemption amounts for all redeemed food instruments of the same type and divide the sum by the number of food instruments of that type. If the State agency does not designate food instruments by type, it must calculate the average payment for each distinct combination of foods prescribed on the food instrument. The State agency may calculate average payments per food instrument type for groups of vendors that meet the above-50-percent criterion and comparable vendors, or the State agency may calculate average payments for each food instrument

type for each vendor. State agencies with EBT systems must compare the average cost of each WIC food purchased by participants at above-50-percent vendors with the average cost of each food purchased from comparable vendors. If FNS determines, based on its review of the information provided by the State agency and any other relevant data, that the requirements in this paragraph have been met, FNS will certify that the State agency's competitive price criteria and allowable reimbursement levels established for above-50-percent vendors do not result in higher average payments per food instrument (or higher costs for each WIC food item in EBT systems). If the State agency's methodology for establishing competitive price criteria and allowable reimbursement levels fails to meet the requirement of this section regarding average food instrument payments to above-50-percent vendors, FNS will disapprove the State agency's request to authorize above-50-percent vendors. At least every three years following initial certification, the State agency must submit information which demonstrates that it continues to meet the requirements of this section relative to average payments to above-50-percent vendors. FNS may require annual updates of selected food instrument redemption data.

(vii) *Limitation on private rights of action.* The competitive pricing provisions of this paragraph do not create a private right of action.

(5) *No imposition of EBT costs on retail vendors.* The State agency may not impose the costs of EBT equipment, systems, or processing required for electronic benefit transfers on any retail store authorized to transact food instruments, as a condition for authorization or participation in the program. The State agency may allow retailers to contribute to such costs on a voluntary basis.

(6) *On-site preauthorization visit.* The State agency must conduct an on-site visit prior to or at the time of a vendor's initial authorization.

(7) *Sale of store to circumvent WIC sanction.* The State agency may not authorize a vendor applicant if the State agency determines the store has been

sold by its previous owner in an attempt to circumvent a WIC sanction. The State agency may consider such factors as whether the store was sold to a relative by blood or marriage of the previous owner(s) or sold to any individual or organization for less than its fair market value.

(8) *Impact on small businesses.* The State agency is encouraged to consider the impact of authorization decisions on small businesses.

(9) *Application periods.* The State agency may limit the periods during which applications for vendor authorization will be accepted and processed, except that applications must be accepted and processed at least once every three years. The State agency must develop procedures for processing vendor applications outside of its timeframes when it determines there will be inadequate participant access unless additional vendors are authorized.

(10) *Data collection at authorization.* At the time of application, the State agency must collect the vendor applicant's Food Stamp Program authorization number if the vendor applicant is authorized in that program. In addition, the State agency must collect the vendor applicant's current shelf prices for supplemental foods.

(11) *List of infant formula wholesalers, distributors, and retailers licensed under State law or regulations, and infant formula manufacturers registered with the Food and Drug Administration (FDA).* The State agency must provide a list in writing or by other effective means to all authorized WIC retail vendors of the names and addresses of infant formula wholesalers, distributors, and retailers licensed in the State in accordance with State law (including regulations), and infant formula manufacturers registered with the Food and Drug Administration (FDA) that provide infant formula, on at least an annual basis.

(i) *Notification to vendors.* The State agency is required to notify vendors that they must purchase infant formula only from a source included on the State agency's list, or from a source on another State agency's list if the vendor's State agency permits this, and must only provide such infant formula to participants in exchange for food instruments specifying infant for-

mula. For the purposes of paragraph (g)(11) of this section, "infant formula" means *Infant formula, Contract brand infant formula* and *Non-contract brand infant formula* as defined in § 246.2, and infant formula covered by a waiver granted under § 246.16a(e).

(ii) *Type of license.* If more than one type of license applies, the State agency may choose which one to use.

(iii) *Exclusions from list.* The State agency may not exclude a State-licensed entity from the list except when:

(A) Specifically required or authorized by State law or regulations; or

(B) The entity does not carry infant formula.

(h) *Retail food delivery systems: Vendor agreements—(1) General—(i) Entering into agreements.* The State agency must enter into written agreements with all authorized vendors. The agreements must be for a period not to exceed three years. The agreement must be signed by a representative who has legal authority to obligate the vendor and a representative of the State agency. When the vendor representative is obligating more than one vendor, the agreement must specify all vendors covered by the agreement. When more than one vendor is specified in the agreement, the State agency may add or delete an individual vendor without affecting the remaining vendors. The State agency must require vendors to reapply at the expiration of their agreements and must provide vendors with not less than 15 days advance written notice of the expiration of their agreements.

(ii) *Delegation to local agencies.* The State agency may delegate to its local agencies the authority to sign vendor agreements if the State agency indicates its intention to do so in its State Plan in accordance with § 246.4(a)(14)(iii). In such cases, the State agency must provide supervision and instruction to ensure the uniformity and quality of local agency activities.

(2) *Standard vendor agreement.* The State agency must use a standard vendor agreement throughout its jurisdiction, although the State agency may

make exceptions to meet unique circumstances provided that it documents the reasons for such exceptions.

(3) *Vendor agreement provisions.* The vendor agreement must contain the following specifications, although the State agency may determine the exact wording to be used:

(i) *Acceptance of food instruments and cash value vouchers.* The vendor may accept food instruments and cash-value vouchers only from participants, parents or caretakers of infant and child participants, or proxies.

(ii) *No substitutions, cash, credit, refunds, or exchanges.* The vendor may provide only the authorized supplemental foods listed on the food instrument and cash-value voucher.

(A) The vendor may not provide unauthorized food items, nonfood items, cash, or credit (including rain checks) in exchange for food instruments or cash-value vouchers. The vendor may not provide refunds or permit exchanges for authorized supplemental foods obtained with food instruments or cash-value vouchers, except for exchanges of an identical authorized supplemental food item when the original authorized supplemental food item is defective, spoiled, or has exceeded its "sell by," "best if used by," or other date limiting the sale or use of the food item. An identical authorized supplemental food item means the exact brand and size as the original authorized supplemental food item obtained and returned by the participant.

(B) The vendor may provide only the authorized infant formula which the vendor has obtained from sources included on the list described in paragraph (g)(11) of this section to participants in exchange for food instruments specifying infant formula.

(iii) *Treatment of participants, parents/caretakers, and proxies.* The vendor must offer program participants, parents or caretakers of infant of child participants, and proxies the same courtesies offered to other customers.

(iv) *Time periods for transacting food instruments and cash-value vouchers.* The vendor may accept a food instrument or cash-value voucher only within the specified time period.

(v) *Purchase price on food instruments and cash-value vouchers.* The vendor

must ensure that the purchase price is entered on food instruments and cash-value vouchers in accordance with the procedures described in the vendor agreement. The State agency has the discretion to determine whether the vendor or the participant enters the purchase price. The purchase price must include only the authorized supplemental food items actually provided and must be entered on the food instrument or cash-value voucher before it is signed.

(vi) *Signature on food instruments and cash-value vouchers.* For printed food instruments and cash-value vouchers, the vendor must ensure the participant, parent or caretaker of an infant or child participant, or proxy signs the food instrument or cash-value voucher in the presence of the cashier. In EBT systems, a Personal Identification Number (PIN) may be used in lieu of a signature.

(vii) *Sales tax prohibition.* The vendor may not collect sales tax on authorized supplemental foods obtained with food instruments.

(viii) *Food instrument redemption.* The vendor must submit food instruments for redemption in accordance with the redemption procedures described in the vendor agreement. The vendor may redeem a food instrument only within the specified time period. As part of the redemption procedures, the State agency may make price adjustments to the purchase price on food instruments submitted by the vendor for redemption to ensure compliance with the price limitations applicable to the vendor. As part of the redemption procedures, the State agency must establish and apply limits on the amount of reimbursement allowed for food instruments based on a vendor's peer group and competitive price criteria. In setting allowable reimbursement levels, the State agency must consider participant access in a geographic area and may include a factor to reflect fluctuations in wholesale prices. In establishing allowable reimbursement levels for above-50-percent vendors the State agency must ensure that reimbursements do not result in higher food costs than if participants transacted their food instruments at vendors that are not above-50-percent vendors, or in

higher average payments per food instrument to above-50-percent vendors than average payments to comparable vendors. The State agency may make price adjustments to the purchase price on food instruments submitted by the vendor for redemption to ensure compliance with the allowable reimbursement level applicable to the vendor. A vendor's failure to remain price competitive is cause for termination of the vendor agreement, even if actual payments to the vendor are within the maximum reimbursement amount. The State agency may exempt vendors that supply only exempt infant formula and/or WIC-eligible medical foods and non-profit above-50-percent vendors from the allowable reimbursement limits.

(ix) *Vendor claims.* When the State agency determines the vendor has committed a vendor violation that affects the payment to the vendor, the State agency will delay payment or establish a claim. The State agency may delay payment or establish a claim in the amount of the full purchase price of each food instrument or cash-value voucher that contained the vendor overcharge or other error. The State agency will provide the vendor with an opportunity to justify or correct a vendor overcharge or other error. The vendor must pay any claim assessed by the State agency. In collecting a claim, the State agency may offset the claim against current and subsequent amounts to be paid to the vendor. In addition to denying payment or assessing a claim, the State agency may sanction the vendor for vendor overcharges or other errors in accordance with the State agency's sanction schedule.

(x) *No charge for authorized supplemental foods or restitution from participants.* The vendor may not charge participants, parents or caretakers of infant and child participants, or proxies for authorized supplemental foods obtained with food instruments or cash-value vouchers. In addition, the vendor may not seek restitution from these individuals for food instruments or cash-value vouchers not paid or partially paid by the State agency. The State agency may, however, allow participants, parents or caretakers of child participants to pay the difference when

the purchase of authorized fruits and vegetables exceeds the value of the cash-value voucher.

(xi) *Training.* At least one representative of the vendor must participate in training annually. Annual vendor training may be provided by the State agency in a variety of formats, including newsletters, videos, and interactive training. The State agency will have sole discretion to designate the date, time, and location of all interactive training, except that the State agency will provide the vendor with at least one alternative date on which to attend such training.

(xii) *Vendor training of staff.* The vendor must inform and train cashiers and other staff on program requirements.

(xiii) *Accountability for owners, officers, managers, and employees.* The vendor is accountable for its owners, officers, managers, agents, and employees who commit vendor violations.

(xiv) *Monitoring.* The vendor may be monitored for compliance with program requirements.

(xv) *Recordkeeping.* The vendor must maintain inventory records used for Federal tax reporting purposes and other records the State agency may require for the period of time specified by the State agency in the vendor agreement. Upon request, the vendor must make available to representatives of the State agency, the Department, and the Comptroller General of the United States, at any reasonable time and place for inspection and audit, all food instruments and cash-value vouchers in the vendor's possession and all program-related records.

(xvi) *Termination.* The State agency will immediately terminate the agreement if it determines that the vendor has provided false information in connection with its application for authorization. Either the State agency or the vendor may terminate the agreement for cause after providing advance written notice of a period of not less than 15 days to be specified by the State agency.

(xvii) *Change in ownership or location or cessation of operations.* The vendor must provide the State agency advance written notification of any change in vendor ownership, store location, or

cessation of operations. In such instances, the State agency will terminate the vendor agreement, except that the State agency may permit vendors to move short distances without terminating the agreement. The State agency has the discretion to determine the length of advance notice required for vendors reporting changes under this provision, whether a change in location qualifies as a short distance, and whether a change in business structure constitutes a change in ownership.

(xviii) *Sanctions*. In addition to claims collection, the vendor may be sanctioned for vendor violations in accordance with the State agency's sanction schedule. Sanctions may include administrative fines, disqualification, and civil money penalties in lieu of disqualification. The State agency must notify a vendor in writing when an investigation reveals an initial incidence of a violation for which a pattern of incidences must be established in order to impose a sanction, before another such incidence is documented, unless the State agency determines, in its discretion, on a case-by-case basis, that notifying the vendor would compromise an investigation.

(xix) *Conflict of interest*. The State agency will terminate the agreement if the State agency identifies a conflict of interest, as defined by applicable State laws, regulations, and policies, between the vendor and the State agency or its local agencies.

(xx) *Criminal penalties*. A vendor who commits fraud or abuse in the Program is liable to prosecution under applicable Federal, State or local laws. Those who have willfully misapplied, stolen or fraudulently obtained program funds will be subject to a fine of not more than \$25,000 or imprisonment for not more than five years or both, if the value of the funds is \$100 or more. If the value is less than \$100, the penalties are a fine of not more than \$1,000 or imprisonment for not more than one year or both.

(xxi) *Not a license/property interest*. The vendor agreement does not constitute a license or a property interest. If the vendor wishes to continue to be authorized beyond the period of its current agreement, the vendor must reapply for authorization. If a vendor is

disqualified, the State agency will terminate the vendor's agreement, and the vendor will have to reapply in order to be authorized after the disqualification period is over. In all cases, the vendor's new application will be subject to the State agency's vendor selection criteria and any vendor limiting criteria in effect at the time of the reapplication.

(xxii) *Compliance with vendor agreement, statutes, regulations, policies, and procedures*. The vendor must comply with the vendor agreement and Federal and State statutes, regulations, policies, and procedures governing the Program, including any changes made during the agreement period.

(xxiii) *Nondiscrimination regulations*. The vendor must comply with the nondiscrimination provisions of Departmental regulations (Parts 15, 15a and 15b of this title).

(xxiv) *Compliance with vendor selection criteria*. The vendor must comply with the vendor selection criteria throughout the agreement period, including any changes to the criteria. Using the current vendor selection criteria, the State agency may reassess the vendor at any time during the agreement period. The State agency will terminate the vendor agreement if the vendor fails to meet the current vendor selection criteria.

(xxv) *Reciprocal Food Stamp Program disqualification for WIC Program disqualifications*. Disqualification from the WIC Program may result in disqualification as a retailer in the Food Stamp Program. Such disqualification may not be subject to administrative or judicial review under the Food Stamp Program.

(4) *Purchase price and redemption procedures*. The State agency must describe in the vendor agreement its purchase price and redemption procedures. The redemption procedures must ensure that the State agency does not pay a vendor more than the price limitations applicable to the vendor.

(5) *Sanction schedule*. The State agency must include its sanction schedule in the vendor agreement or as an attachment to it. The sanction schedule must include all mandatory and State agency vendor sanctions and must be consistent with paragraph (1) of this

section. If the sanction schedule is in State law or regulations or in a document provided to the vendor at the time of authorization, the State agency instead may include an appropriate cross-reference in the vendor agreement.

(6) *Actions subject to administrative review and review procedures.* The State agency must include the adverse actions a vendor may appeal and those adverse actions that are not subject to administrative review. The State agency also must include a copy of the State agency's administrative review procedures in the vendor agreement or as an attachment to it or must include a statement that the review procedures are available upon request and the applicable review procedures will be provided along with an adverse action subject to administrative review. These items must be consistent with § 246.18. If these items are in State law or regulations or in a document provided to the vendor at the time of authorization, the State agency instead may include an appropriate cross-reference in the vendor agreement.

(7) *Notification of program changes.* The State agency must notify vendors of changes to Federal or State statutes, regulations, policies, or procedures governing the Program before the changes are implemented. The State agency should give as much advance notice as possible.

(8) *Allowable and prohibited incentive items for above-50-percent vendors.* The vendor agreement for an above-50-percent vendor, or another document provided to the vendor and cross-referenced in the agreement, must include the State agency's policies and procedures for allowing and prohibiting incentive items to be provided by an above-50-percent vendor to customers, consistent with paragraph (g)(3)(iv) of this section.

(i) The State agency must provide written approval or disapproval (including by electronic means such as electronic mail or facsimile) of requests from above-50-percent vendors for permission to provide allowable incentive items to customers;

(ii) The State agency must maintain documentation for the approval process, including invoices or similar docu-

ments showing that the cost of each item is either less than the \$2 nominal value limit, or obtained at no cost, unless the State agency provides the vendor with a list of pre-approved incentive items at the time of authorization; and

(iii) The State agency must define prohibited incentive items.

(i) *Retail food delivery systems: Vendor training—(1) General requirements.* The State agency must provide training annually to at least one representative of each vendor. Prior to or at the time of a vendor's initial authorization, and at least once every three years thereafter, the training must be in an interactive format that includes a contemporaneous opportunity for questions and answers. The State agency must designate the date, time, and location of the interactive training and the audience (e.g., managers, cashiers, etc.) to which the training is directed. The State agency must provide vendors with at least one alternative date on which to attend interactive training. Examples of acceptable vendor training include on-site cashier training, off-site classroom-style train-the-trainer or manager training, a training video, and a training newsletter. All vendor training must be designed to prevent program errors and noncompliance and improve program service.

(2) *Content.* The annual training must include instruction on the purpose of the Program, the supplemental foods authorized by the State agency, the minimum varieties and quantities of authorized supplemental foods that must be stocked by vendors, the requirement that vendors obtain infant formula only from sources included on a list provided by the State agency, the procedures for transacting and redeeming food instruments and cash-value vouchers, the vendor sanction system, the vendor complaint process, the claims procedures, the State agency's policies and procedures regarding the use of incentive items, and any changes to program requirements since the last training.

(3) *Delegation.* The State agency may delegate vendor training to a local agency, a contractor, or a vendor representative if the State agency indicates its intention to do so in its State

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Plan in accordance with § 246.4(a)(14)(xi). In such cases, the State agency must provide supervision and instruction to ensure the uniformity and quality of vendor training.

(4) *Documentation.* The State agency must document the content of and vendor participation in vendor training.

(j) *Retail food delivery systems: Monitoring vendors and identifying high-risk vendors—(1) General requirements.* The State agency must design and implement a system for monitoring its vendors for compliance with program requirements. The State agency may delegate vendor monitoring to a local agency or contractor if the State agency indicates its intention to do so in its State Plan in accordance with § 246.4(a)(14)(iv). In such cases, the State agency must provide supervision and instruction to ensure the uniformity and quality of vendor monitoring.

(2) *Routine monitoring.* The State agency must conduct routine monitoring visits on a minimum of five percent of the number of vendors authorized by the State agency as of October 1 of each fiscal year in order to survey the types and levels of abuse and errors among authorized vendors and to take corrective actions, as appropriate. The State agency must develop criteria to determine which vendors will receive routine monitoring visits and must include such criteria in its State Plan in accordance with § 246.4(a)(14)(iv).

(3) *Identifying high-risk vendors.* The State agency must identify high-risk vendors at least once a year using criteria developed by FNS and/or other statistically-based criteria developed by the State agency. FNS will not change its criteria more frequently than once every two years and will provide adequate advance notification of changes prior to implementation. The State agency may develop and implement additional criteria. All State agency-developed criteria must be approved by FNS.

(4) *Compliance investigations.* (i) *High-risk vendors.* The State agency must conduct compliance investigations of a minimum of five percent of the number of vendors authorized by the State agency as of October 1 of each fiscal year. The State agency must conduct

compliance investigations on all high-risk vendors up to the five percent minimum. The State agency may count toward this requirement a compliance investigation of a high-risk vendor conducted by a Federal, State, or local law enforcement agency. The State agency also may count toward this requirement a compliance investigation conducted by another WIC State agency provided that the State agency implements the option to establish State agency sanctions based on mandatory sanctions imposed by the other WIC State agency, as specified in paragraph (1)(2)(iii) of this section. A compliance investigation of a high-risk vendor may be considered complete when the State agency determines that a sufficient number of compliance buys have been conducted to provide evidence of program noncompliance, when two compliance buys have been conducted in which no program violations are found, or when an inventory audit has been completed.

(ii) *Randomly selected vendors.* If fewer than five percent of the State agency's authorized vendors are identified as high-risk, the State agency must randomly select additional vendors on which to conduct compliance investigations sufficient to meet the five-percent requirement. A compliance investigation of a randomly selected vendor may be considered complete when the State agency determines that a sufficient number of compliance buys have been conducted to provide evidence of program noncompliance, when two compliance buys are conducted in which no program violations are found, or when an inventory audit has been completed.

(iii) *Prioritization.* If more than five percent of the State agency's vendors are identified as high-risk, the State agency must prioritize such vendors so as to perform compliance investigations of those determined to have the greatest potential for program noncompliance and/or loss of funds.

(5) *Monitoring report.* For each fiscal year, the State agency must send FNS a summary of the results of its vendor monitoring containing information stipulated by FNS. The report must be sent by February 1 of the following fiscal year. Plans for improvement in the

coming year must be included in the State Plan in accordance with §246.4(a)(14)(iv).

(6) *Documentation*—(i) *Monitoring visits*. The State agency must document the following information for all monitoring visits, including routine monitoring visits, inventory audits, and compliance buys:

(A) the date of the monitoring visit, inventory audit, or compliance buy;

(B) the name(s) and signature(s) of the reviewer(s); and

(C) the nature of any problem(s) detected.

(ii) *Compliance buys*. For compliance buys, the State agency must also document:

(A) the date of the buy;

(B) a description of the cashier involved in each transaction;

(C) the types and quantities of items purchased, current shelf prices or prices charged other customers, and price charged for each item purchased, if available. Price information may be obtained prior to, during, or subsequent to the compliance buy; and

(D) the final disposition of all items as destroyed, donated, provided to other authorities, or kept as evidence.

(k) *Retail food delivery systems: Vendor claims*—(1) *System to review food instruments and cash-value vouchers for vendor claims*. The State agency must design and implement a system to review food instruments and cash-value vouchers submitted by vendors for redemption to ensure compliance with the applicable price limitations and to detect questionable food instruments or cash-value vouchers, suspected vendor overcharges, and other errors. This review must examine either all or a representative sample of the food instruments and cash-value vouchers and may be done either before or after the State agency makes payments on the food instruments or cash-value vouchers. The review of food instruments must include a price comparison or other edit designed to ensure compliance with the applicable price limitations and to assist in detecting vendor overcharges. For printed food instruments and cash-value vouchers the system also must detect the following errors—purchase price missing; participant, parent/caretaker, or proxy signature missing; ven-

dor identification missing; food instruments or cash-value vouchers transacted or redeemed after the specified time periods; and, as appropriate, altered purchase price. The State agency must take follow-up action within 120 days of detecting any questionable food instruments or cash-value vouchers, suspected vendor overcharges, and other errors and must implement procedures to reduce the number of errors when possible.

(2) *Delaying payment and establishing a claim*. When the State agency determines the vendor has committed a vendor violation that affects the payment to the vendor, the State agency must delay payment or establish a claim. Such vendor violations may be detected through compliance investigations, food instrument or cash-value voucher reviews, or other reviews or investigations of a vendor's operations. The State agency may delay payment or establish a claim in the amount of the full purchase price of each food instrument or cash-value voucher that contained the vendor overcharge or other error.

(3) *Opportunity to justify or correct*. When payment for a food instrument or cash-value voucher is delayed or a claim is established, the State agency must provide the vendor with an opportunity to justify or correct the vendor overcharge or other error. If satisfied with the justification or correction, the State agency must provide payment or adjust the proposed claim accordingly.

(4) *Timeframe and offset*. The State agency must deny payment or initiate claims collection action within 90 days of either the date of detection of the vendor violation or the completion of the review or investigation giving rise to the claim, whichever is later. Claims collection action may include offset against current and subsequent amounts owed to the vendor.

(5) *Food instruments and cash-value vouchers redeemed after the specified period*. With justification and documentation, the State agency may pay vendors for food instruments and cash-value vouchers submitted for redemption after the specified period for redemption. If the total value of such

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food instruments or cash-value vouchers submitted at one time exceeds \$500.00, the State agency must obtain the approval of the FNS Regional Office before payment.

(1) *Retail food delivery systems: Vendor sanctions*—(1) *Mandatory vendor sanctions*—(i) *Permanent disqualification*. The State agency must permanently disqualify a vendor convicted of trafficking in food instruments or cash-value vouchers or selling firearms, ammunition, explosives, or controlled substances (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) in exchange for food instruments or cash-value vouchers. A vendor is not entitled to receive any compensation for revenues lost as a result of such violation. If reflected in its State Plan, the State agency may impose a civil money penalty in lieu of a disqualification for this violation when it determines, in its sole discretion, and documents that:

(A) Disqualification of the vendor would result in inadequate participant access; or

(B) The vendor had, at the time of the violation, an effective policy and program in effect to prevent trafficking; and the ownership of the vendor was not aware of, did not approve of, and was not involved in the conduct of the violation.

(ii) *Six-year disqualification*. The State agency must disqualify a vendor for six years for:

(A) One incidence of buying or selling food instruments for cash (trafficking); or

(B) One incidence of selling firearms, ammunition, explosives, or controlled substances as defined in 21 U.S.C. 802, in exchange for food instruments or cash-value vouchers.

(iii) *Three-year disqualification*. The State agency must disqualify a vendor for three years for:

(A) One incidence of the sale of alcohol or alcoholic beverages or tobacco products in exchange for food instruments or cash-value vouchers;

(B) A pattern of claiming reimbursement for the sale of an amount of a specific supplemental food item which exceeds the store's documented inventory of that supplemental food item for a specific period of time;

(C) A pattern of vendor overcharges;

(D) A pattern of receiving, transacting and/or redeeming food instruments or cash-value vouchers outside of authorized channels, including the use of an unauthorized vendor and/or an unauthorized person;

(E) A pattern of charging for supplemental food not received by the participant; or

(F) A pattern of providing credit or non-food items, other than alcohol, alcoholic beverages, tobacco products, cash, firearms, ammunition, explosives, or controlled substances as defined in 21 U.S.C. 802, in exchange for food instruments or cash-value vouchers.

(iv) *One-year disqualification*. The State agency must disqualify a vendor for one year for:

(A) A pattern of providing unauthorized food items in exchange for food instruments or cash-value vouchers, including charging for supplemental foods provided in excess of those listed on the food instrument; or

(B) A pattern of an above-50-percent vendor providing prohibited incentive items to customers as set forth in paragraph (g)(3)(iv) of this section, in accordance with the State agency's policies and procedures required by paragraph (h)(8) of this section.

(v) *Second mandatory sanction*. When a vendor, who previously has been assessed a sanction for any of the violations in paragraphs (1)(1)(ii) through (1)(1)(iv) of this section, receives another sanction for any of these violations, the State agency must double the second sanction. Civil money penalties may only be doubled up to the limits allowed under paragraph (1)(1)(x)(C) of this section.

(vi) *Third or subsequent mandatory sanction*. When a vendor, who previously has been assessed two or more sanctions for any of the violations listed in paragraphs (1)(1)(ii) through (1)(1)(iv) of this section, receives another sanction for any of these violations, the State agency must double the third sanction and all subsequent sanctions. The State agency may not impose civil money penalties in lieu of disqualification for third or subsequent

sanctions for violations listed in paragraphs (1)(1)(ii) through (1)(1)(iv) of this section.

(vii) *Disqualification based on a Food Stamp Program disqualification.* The State agency must disqualify a vendor who has been disqualified from the Food Stamp Program. The disqualification must be for the same length of time as the Food Stamp Program disqualification, may begin at a later date than the Food Stamp Program disqualification, and is not subject to administrative or judicial review under the WIC Program.

(viii) *Voluntary withdrawal or non-renewal of agreement.* The State agency may not accept voluntary withdrawal of the vendor from the Program as an alternative to disqualification for the violations listed in paragraphs (1)(1)(i) through (1)(1)(iv) of this section, but must enter the disqualification on the record. In addition, the State agency may not use nonrenewal of the vendor agreement as an alternative to disqualification.

(ix) *Participant access determinations.* Prior to disqualifying a vendor for a Food Stamp Program disqualification pursuant to paragraph (1)(1)(vii) of this section or for any of the violations listed in paragraphs (1)(1)(ii) through (1)(1)(iv) of this section, the State agency must determine if disqualification of the vendor would result in inadequate participant access. The State agency must make the participant access determination in accordance with paragraph (1)(8) of this section. If the State agency determines that disqualification of the vendor would result in inadequate participant access, the State agency must impose a civil money penalty in lieu of disqualification. However, as provided in paragraph (1)(1)(vi) of this section, the State agency may not impose a civil money penalty in lieu of disqualification for third or subsequent sanctions for violations in paragraphs (1)(1)(ii) through (1)(1)(iv) of this section. The State agency must include documentation of its participant access determination and any supporting documentation in the file of each vendor who is disqualified or receives a civil money penalty in lieu of disqualification.

(x) *Civil money penalty formula.* For each violation subject to a mandatory sanction, the State agency must use the following formula to calculate a civil money penalty imposed in lieu of disqualification:

(A) Determine the vendor's average monthly redemptions for at least the 6-month period ending with the month immediately preceding the month during which the notice of adverse action is dated;

(B) Multiply the average monthly redemptions figure by 10 percent (.10);

(C) Multiply the product from paragraph (1)(1)(x)(B) of this section by the number of months for which the store would have been disqualified. This is the amount of the civil money penalty, provided that the civil money penalty shall not exceed the maximum amount specified in §3.91(b)(3)(v) of this title for each violation. For a violation that warrants permanent disqualification, the amount of the civil money penalty shall be the maximum amount specified in §3.91(b)(3)(v) of this title for each violation. When during the course of a single investigation the State agency determines a vendor has committed multiple violations, the State agency must impose a CMP for each violation. The total amount of civil money penalties imposed for violations investigated as part of a single investigation may not exceed the amount specified in §3.91(b)(3)(v) of this title as the maximum penalty for violations occurring during a single investigation.

(xi) *Notification to FNS.* The State agency must provide the appropriate FNS office with a copy of the notice of adverse action and information on vendors it has either disqualified or imposed a civil money penalty in lieu of disqualification for any of the violations listed in paragraphs (1)(1)(i) through (1)(1)(iv) of this section. This information must include the name of the vendor, address, identification number, the type of violation(s), and the length of disqualification or the length of the disqualification corresponding to the violation for which the civil money penalty was assessed, and must be provided within 15 days after the vendor's opportunity to file

for a WIC administrative review has expired or all of the vendor's WIC administrative reviews have been completed.

(xii) *Multiple violations during a single investigation.* When during the course of a single investigation the State agency determines a vendor has committed multiple violations (which may include violations subject to State agency sanctions), the State agency must disqualify the vendor for the period corresponding to the most serious mandatory violation. However, the State agency must include all violations in the notice of administration action. If a mandatory sanction is not upheld on appeal, then the State agency may impose a State agency-established sanction.

(2) *State agency vendor sanctions.* (i) *General requirements.* The State agency may impose sanctions for vendor violations that are not specified in paragraphs (1)(1)(i) through (1)(1)(iv) of this section as long as such vendor violations and sanctions are included in the State agency's sanction schedule. State agency sanctions may include disqualifications, civil money penalties assessed in lieu of disqualification, and administrative fines. The total period of disqualification imposed for State agency violations investigated as part of a single investigation may not exceed one year. A civil money penalty or fine may not exceed a maximum amount specified in § 3.91(b)(3)(v) of this title for each violation. The total amount of civil money penalties and administrative fines imposed for violations investigated as part of a single investigation may not exceed an amount specified in § 3.91(b)(3)(v) of this title as the maximum penalty for violations occurring during a single investigation. A State agency vendor sanction must be based on a pattern of violative incidences.

(ii) *Food Stamp Program civil money penalty for hardship.* The State agency may disqualify a vendor that has been assessed a civil money penalty for hardship in the Food Stamp Program, as provided under § 278.6 of this chapter. The length of such disqualification must correspond to the period for which the vendor would otherwise have been disqualified in the Food Stamp Program. If a State agency decides to

exercise this option, the State agency must:

(A) Include notification that it will take such disqualification action in its sanction schedule; and

(B) Determine if disqualification of the vendor would result in inadequate participant access in accordance with paragraph (1)(8) of this section. If the State agency determines that disqualification of the vendor would result in inadequate participant access, the State agency may not disqualify the vendor or impose a civil money penalty in lieu of disqualification. The State agency must include documentation of its participant access determination and any supporting documentation in each vendor's file.

(iii) *A mandatory sanction by another WIC State agency.* The State agency may disqualify a vendor that has been disqualified or assessed a civil money penalty in lieu of disqualification by another WIC State agency for a mandatory vendor sanction. The length of the disqualification must be for the same length of time as the disqualification by the other WIC State agency or, in the case of a civil money penalty in lieu of disqualification assessed by the other WIC State agency, for the same length of time for which the vendor would otherwise have been disqualified. The disqualification may begin at a later date than the sanction imposed by the other WIC State agency. If a State agency decides to exercise this option, the State agency must:

(A) Include notification that it will take such action in its sanction schedule; and

(B) Determine if disqualification of the vendor would result in inadequate participant access in accordance with paragraph (1)(8) of this section. If the State agency determines that disqualification of the vendor would result in inadequate participant access, the State agency must impose a civil money penalty in lieu of disqualification, except that the State agency may not impose a civil money penalty in situations in which the vendor has been assessed a civil money penalty in lieu of disqualification by the other WIC State agency. Any civil money penalty in lieu of disqualification must

be calculated in accordance with paragraph (1)(2)(x) of this section. The State agency must include documentation of its participant access determination and any supporting documentation in each vendor's file.

(3) *Notification of violations.* The State agency must notify a vendor in writing when an investigation reveals an initial incidence of a violation for which a pattern of incidences must be established in order to impose a sanction, before another such incidence is documented, unless the State agency determines, in its discretion, on a case-by-case basis, that notifying the vendor would compromise an investigation. This notification requirement applies to the violations set forth in paragraphs (1)(1)(iii)(C) through (1)(1)(iii)(F), (1)(1)(iv), and (1)(2)(i) of this section.

(i) Prior to imposing a sanction for a pattern of violative incidences, the State agency must either provide such notice to the vendor, or document in the vendor file the reason(s) for determining that such notice would compromise an investigation.

(ii) The State agency may use the same method of notification which the State agency uses to provide a vendor with adequate advance notice of the time and place of an administrative review in accordance with § 246.18(b)(3).

(iii) If notification is provided, the State agency may continue its investigation after the notice of violation is received by the vendor, or presumed to be received by the vendor, consistent with the State agency's procedures for providing such notice.

(iv) All of the incidences of a violation occurring during the first compliance buy visit must constitute only one incidence of that violation for the purpose of establishing a pattern of incidences.

(v) A single violative incidence may only be used to establish the violations set forth in paragraphs (1)(1)(ii)(A), (1)(1)(ii)(B), and (1)(1)(iii)(A) of this section.

(4) *Administrative reviews.* The State agency must provide administrative reviews of sanctions to the extent required by § 246.18.

(5) *Installation plans.* The State agency may use installation plans for the

collection of civil money penalties and administrative fines.

(6) *Failure to pay a civil money penalty.* If a vendor does not pay, only partially pays, or fails to timely pay a civil money penalty assessed in lieu of disqualification, the State agency must disqualify the vendor for the length of the disqualification corresponding to the violation for which the civil money penalty was assessed (for a period corresponding to the most serious violation in cases where a mandatory sanction included the imposition of multiple civil money penalties as a result of a single investigation).

(7) *Actions in addition to sanctions.* Vendors may be subject to actions in addition to the sanctions in this section, such as claims pursuant to paragraph (k) of this section and the penalties set forth in § 246.23(c) in the case of deliberate fraud.

(8) *Participant access determination criteria.* The State agency must develop participant access criteria. When making participant access determinations, the State agency must consider the availability of other authorized vendors in the same area as the violative vendor and any geographic barriers to using such vendors.

(9) *Termination of agreement.* When the State agency disqualifies a vendor, the State agency must also terminate the vendor agreement.

(m) *Home food delivery systems.* Home food delivery systems are systems in which authorized supplemental foods are delivered to the participant's home. Home food delivery systems must provide for:

(1) *Procurement.* Procurement of supplemental foods in accordance with § 246.24, which may entail measures such as the purchase of food in bulk lots by the State agency and the use of discounts that are available to States.

(2) *Accountability.* The accountable delivery of authorized supplemental foods to participants. The State agency must ensure that:

(i) Home food delivery contractors are paid only after the delivery of authorized supplemental foods to participants;

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(ii) A routine procedure exists to verify the correct delivery of authorized supplemental foods to participants, and, at a minimum, such verification occurs at least once a month after delivery; and

(iii) Records of delivery of supplemental foods and bills sent or payments received for such supplemental foods are retained for at least three years. Federal, State, and local authorities must have access to such records.

(n) *Direct distribution food delivery systems.* Direct distribution food delivery systems are systems in which participants, parents or caretakers of infant or child participants, or proxies pick up authorized supplemental foods from storage facilities operated by the State agency or its local agencies. Direct distribution food delivery systems must provide for:

(1) *Storage and insurance.* Adequate storage and insurance coverage that minimizes the danger of loss due to theft, infestation, fire, spoilage, or other causes;

(2) *Inventory.* Adequate inventory control of supplemental foods received, in stock, and issued;

(3) *Procurement.* Procurement of supplemental foods in accordance with § 246.24, which may entail measures such as purchase of food in bulk lots by the State agency and the use of discounts that are available to States;

(4) *Availability.* The availability of program benefits to participants and potential participants who live at great distance from storage facilities; and

(5) *Accountability.* The accountable delivery of authorized supplemental foods to participants.

(o) *Participant, parent/caretaker, proxy, vendor, farmer and home food delivery contractor complaints.* The State agency must have procedures to document the handling of complaints by participants, parents or caretakers of infant or child participants, proxies, vendors, farmers, home food delivery contractors, and direct distribution contractors. Complaints of civil rights discrimination must be handled in accordance with § 246.8(b).

(p) *Food instrument and cash-value voucher security.* The State agency must develop standards for ensuring

the security of food instruments and cash-value vouchers from the time the food instruments and cash-value vouchers are created to the time they are issued to participants, parents/caretakers, or proxies. For pre-printed food instruments or cash-value vouchers, these standards must include maintenance of perpetual inventory records of food instruments or cash-value vouchers throughout the State agency's jurisdiction; monthly physical inventory of food instruments or cash-value vouchers on hand throughout the State agency's jurisdiction; reconciliation of perpetual and physical inventories of food instruments and cash-value vouchers; and maintenance of all food instruments and cash-value vouchers under lock and key, except for supplies needed for immediate use. For EBT and print-on-demand food instruments and cash-value vouchers, the standards must provide for the accountability and security of the means to manufacture and issue such food instruments and cash-value vouchers.

(q) *Food instrument and cash-value voucher disposition.* The State agency must account for the disposition of all food instruments and cash-value vouchers as either issued or voided, and as either redeemed or unredeemed. Redeemed food instruments and cash-value vouchers must be identified as validly issued, lost, stolen, expired, duplicate, or not matching valid enrollment and issuance records. In an EBT system, evidence of matching redeemed food instruments to valid enrollment and issuance records may be satisfied through the linking of the Primary Account Number (PAN) associated with the electronic transaction to valid enrollment and issuance records. This process must be performed within 120 days of the first valid date for participant use of the food instruments and must be conducted in accordance with the financial management requirements of § 246.13. The State agency will be subject to claims as outlined in § 246.23(a)(4) for redeemed food instruments or cash-value vouchers that do not meet the conditions established in paragraph (q) of this section.

(r) *Issuance of food instruments, cash-value vouchers and authorized supplemental foods.* The State agency must:

(1) *Parents/caretakers and proxies.* Establish uniform procedures that allow parents and caretakers of infant and child participants and proxies to obtain and transact food instruments and cash-value vouchers or obtain authorized supplemental foods on behalf of a participant. In determining whether a particular participant or parent/caretaker should be allowed to designate a proxy or proxies, the State agency must require the local agency or clinic to consider whether adequate measures can be implemented to provide nutrition education and health care referrals to that participant or, in the case of an infant or child participant, to the participant's parent or caretaker;

(2) *Signature requirement.* Ensure that the participant, parent or caretaker of an infant or child participant, or proxy signs for receipt of food instruments, cash-value vouchers or authorized supplemental foods, except as provided in paragraph (r)(4) of this section;

(3) *Instructions.* Ensure that participants, parents or caretakers of infant and child participants, and proxies receive instructions on the proper use of food instruments and cash-value vouchers, or on the procedures for obtaining authorized supplemental foods when food instruments or cash-value vouchers are not used. The State agency must also ensure that participants, parents or caretakers of infant and child participants, and proxies are notified that they have the right to complain about improper vendor, farmer and home food delivery contractor practices with regard to program responsibilities;

(4) *Food instrument and cash-value voucher pick up.* Require participants, parents and caretakers of infant and child participants, and proxies to pick up food instruments and cash-value vouchers in person when scheduled for nutrition education or for an appointment to determine whether participants are eligible for a second or subsequent certification period. However, in all other circumstances the State agency may provide for issuance through an alternative means such as EBT or mailing, unless FNS determines that such actions would jeopardize the integrity of program services or program accountability. If a State agency opts

to mail food instruments and cash-value vouchers, it must provide justification, as part of its alternative issuance system in its State Plan, as required in §246.4(a)(21), for mailing food instruments and cash-value voucher to areas where food stamps are not mailed. State agencies that opt to mail food instruments and cash-value vouchers must establish and implement a system that ensures the return of food instruments and cash-value vouchers to the State or local agency if a participant no longer resides or receives mail at the address to which the food instruments and cash-value vouchers were mailed; and

(5) *Maximum issuance of food instruments and cash-value voucher.* Ensure that no more than a three-month supply of food instruments and cash-value vouchers or a one-month supply of authorized supplemental foods is issued at any one time to any participant, parent or caretaker of an infant or child participant, or proxy.

(6) *Any authorized vendor.* Each State agency shall allow participants to receive supplemental foods from any vendor authorized by the State agency under retail delivery systems.

(s) *Payment to vendors, farmers and home food delivery contractors.* The State agency must ensure that vendors, farmers and home food delivery contractors are paid promptly. Payment must be made within 60 days after valid food instruments or cash-value vouchers are submitted for redemption. Actual payment to vendors, farmers and home food delivery contractors may be made by local agencies.

(t) *Conflict of interest.* The State agency must ensure that no conflict of interest exists, as defined by applicable State laws, regulations, and policies, between the State agency and any vendor, farmer or home food delivery contractor, or between any local agency and any vendor, farmer or home food delivery contractor under its jurisdiction.

(u) *Participant violations and sanctions—(1) General requirements.* The State agency must establish procedures designed to control participant violations. The State agency also must

establish sanctions for participant violations. Participant sanctions may include disqualification from the Program for a period of up to one year.

(2) *Mandatory disqualification.* (i) *General.* Except as provided in paragraphs (u)(2)(ii) and (u)(2)(iii) of this section, whenever the State agency assesses a claim of \$100 or more, assesses a claim for dual participation, or assess a second or subsequent claim of any amount, the State agency must disqualify the participant for one year.

(ii) *Exceptions to mandatory disqualification.* The State agency may decide not to impose a mandatory disqualification if, within 30 days of receipt of the letter demanding repayment, full restitution is made or a repayment schedule is agreed on, or, in the case of a participant who is an infant, child, or under age 18, the State or local agency approves the designation of a proxy.

(iii) *Terminating a mandatory disqualification.* The State agency may permit a participant to reapply for the Program before the end of a mandatory disqualification period if full restitution is made or a repayment schedule is agreed upon or, in the case of a participant who is an infant, child, or under age 18, the State or local agency approves the designation of a proxy.

(3) *Warnings before sanctions.* The State agency may provide warnings before imposing participant sanctions.

(4) *Fair hearings.* At the time the State agency notifies a participant of a disqualification, the State agency must advise the participant of the procedures to follow to obtain a fair hearing pursuant to § 246.9.

(5) *Referral to law enforcement authorities.* When appropriate, the State agency must refer vendors, home food delivery contractors, and participants who violate program requirements to Federal, State, or local authorities for prosecution under applicable statutes.

(v) *Farmers.* The State agency may authorize farmers at farmers markets (or roadside stands) to accept the cash-value voucher for eligible fruits and vegetables. The State agency must enter into written agreements with all authorized farmers. The agreement must be signed by a representative who has legal authority to obligate the farmer and a representative of the

State agency. The agreement must be for a period not to exceed three years. Only farmers authorized by the State agency may redeem the fruit and vegetable cash-value voucher. The State agency must require farmers to reapply at the expiration of their agreements and must provide farmers with not less than 15 days advance written notice of the expiration of the agreement.

(1) The agreement must include the following provisions, although the State agency may determine the exact wording. The farmer must:

(i) Assure that the cash-value voucher is redeemed only for eligible fruits and vegetables as defined by the State agency;

(ii) Provide eligible fruits and vegetables at the current price or less than the current price charged to other customers;

(iii) Accept the cash-value voucher within the dates of their validity and submit such vouchers for payment within the allowable time period established by the State agency;

(iv) Redeem the cash-value voucher in accordance with a procedure established by the State agency.

(v) Accept training on cash-value voucher procedures and provide training to any employees with cash-value voucher responsibilities on such procedures;

(vi) Agree to be monitored for compliance with program requirements, including both overt and covert monitoring;

(vii) Be accountable for actions of employees in the provision of authorized foods and related activities;

(viii) Pay the State agency for any cash-value vouchers transacted in violation of this agreement;

(ix) Offer WIC participants, parent or caretakers of child participants or proxies the same courtesies as other customers;

(x) Comply with the nondiscrimination provisions of USDA regulations as provided in § 248.7; and

(xi) Notify the State agency if any farmers' market ceases operation prior to the end of the authorization period.

(2) The farmer must not:

(i) Collect sales tax on cash-value voucher purchases;

(ii) Seek restitution from WIC participants, parent or caretakers of child participants or proxies for cash-value vouchers not paid or partially paid by the State agency;

(iii) Issue cash change for purchases that are in an amount less than the value of the cash-value voucher;

(3) Neither the State agency nor the farmer has an obligation to renew the agreement. Either the State agency or the farmer may terminate the agreement for cause after providing advance written notification.

(4) The State agency may deny payment to the farmer for improperly redeemed cash-value vouchers and may demand refunds for payments already made on improperly redeemed vouchers.

(5) The State agency may disqualify a farmer for WIC Program abuse. The farmer has the right to appeal a denial of an application to participate, a disqualification, or a program sanction by the State agency. Expiration of an agreement with a farmer and claims actions under § 246.23, are not appealable.

(6) A farmer which commits fraud or engages in other illegal activity is liable to prosecution under applicable Federal, State or local laws.

[65 FR 83278, Dec. 29, 2000, as amended at 70 FR 29579, May 24, 2005; 70 FR 71722, Nov. 29, 2005; 71 FR 56731, Sept. 27, 2006; 73 FR 68995, Dec. 6, 2007; 73 FR 11312, Mar. 3, 2008; 74 FR 555, Jan. 6, 2009; 74 FR 51758, Oct. 8, 2009]

EDITORIAL NOTE: At 74 FR 51758, Oct. 8, 2009, § 246.12 was amended by adding two sentences to paragraph (g)(4)(i)(D); however, the amendment could not be incorporated because they were not printed in the FEDERAL REGISTER.

§ 246.13 Financial management system.

(a) *Disclosure of expenditures.* The State agency shall maintain a financial management system which provides accurate, current and complete disclosure of the financial status of the Program. This shall include an accounting for all property and other assets and all Program funds received and expended each fiscal year.

(b) *Internal control.* The State agency shall maintain effective control over and accountability for all Program grants and funds. The State agency

must have effective internal controls to ensure that expenditures financed with Program funds are authorized and properly chargeable to the Program.

(c) *Record of expenditures.* The State agency shall maintain records which adequately identify the source and use of funds expended for Program activities. These records shall contain, but are not limited to, information pertaining to authorization, receipt of funds, obligations, unobligated balances, assets, liabilities, outlays, and income.

(d) *Payment of costs.* The State shall implement procedures which ensure prompt and accurate payment of allowable costs, and ensure the allowability and allocability of costs in accordance with the cost principles and standard provisions of this part, 7 CFR part 3016, and FNS guidelines and instructions.

(e) *Identification of obligated funds.* The State agency shall implement procedures which accurately identify obligated Program funds at the time the obligations are made.

(f) *Resolution of audit findings.* The State agency shall implement procedures which ensure timely and appropriate resolution of claims and other matters resulting from audit findings and recommendations.

(g) *Use of minority- and women-owned banks.* Consistent with the national goals of expanding opportunities for minority business enterprises, State and local agencies are encouraged to use minority- and women-owned banks.

(h) *Adjustment of expenditures.* The State agency must adjust projected expenditures to account for redeemed food instruments and for other changes as appropriate.

(i) *Transfer of cash.* The State agency shall have controls to minimize the time elapsing between receipt of Federal funds from the U.S. Department of Treasury and the disbursements of these funds for Program costs. In the Letter of Credit system, the State agency shall make drawdowns from the U.S. Department of Treasury's Regional Disbursing Office as close as possible to the actual date that disbursement of funds is made. Advances made by the State agency to local agencies shall also conform to these same standards.

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(j) *Local agency financial management.* The State agency shall ensure that all local agencies develop and implement a financial management system consistent with requirements prescribed by FNS and the State agency pursuant to the requirements of this section.

[50 FR 6121, Feb. 13, 1985; 50 FR 8098, Feb. 28, 1985, as amended at 65 FR 83286, Dec. 29, 2000]

§ 246.14 Program costs.

(a) *General.* (1) The two kinds of allowable costs under the Program are “food costs” and “nutrition services and administration costs.” In general, costs necessary to the fulfillment of Program objectives are to be considered allowable costs. The two types of nutrition services and administration costs are:

(i) *Direct costs.* Those direct costs that are allowable under 7 CFR part 3016.

(ii) *Indirect costs.* Those indirect costs that are allowable under 7 CFR part 3016. When computing indirect costs, food costs may not be used in the base to which the indirect cost rate is applied. In accordance with the provisions of 7 CFR part 3016, a claim for indirect costs shall be supported by an approved allocation plan for the determination of allowable indirect costs.

(2) Program funds may not be used to pay for retroactive benefits. Except as provided in paragraph (e) of this section and §§ 246.16(g) and 246.16(h) of this part, funds allocated by FNS for food purchases may not be used to pay nutrition services and administration costs. However, nutrition services and administration funds may be used to pay for food costs.

(b) *What costs may I charge to the food grant?* (1) The State agency may use food funds for costs of:

(i) Acquiring supplemental foods provided to State or local agencies or participants, whichever receives the supplemental food first;

(ii) Warehousing supplemental foods; and

(iii) Purchasing and renting breast pumps.

(2) For costs to be allowable, the State agency must ensure that food costs do not exceed the customary sales price charged by the vendor, home food delivery contractor, or sup-

plier in a direct distribution food delivery system. In addition, food costs may not exceed the price limitations applicable to the vendor.

(c) *Specified allowable nutrition services and administration costs.* Allowable nutrition services and administration (NSA) costs include the following:

(1) The cost of nutrition education and breastfeeding promotion and support which meets the requirements of § 246.11. During each fiscal year, each State agency shall expend, for nutrition education activities and breastfeeding promotion and support activities, an aggregate amount that is not less than the sum of one-sixth of the amount expended by the State agency for costs of NSA and an amount equal to its proportionate share of the national minimum expenditure for breastfeeding promotion and support activities. The amount to be spent on nutrition education shall be computed by taking one-sixth of the total fiscal year NSA expenditures. The amount to be spent by a State agency on breastfeeding promotion and support activities shall be an amount that is equal to at least its proportionate share of the national minimum breastfeeding promotion expenditure as specified in paragraph (c)(1) of this section. The national minimum expenditure for breastfeeding promotion and support activities shall be equal to \$21 multiplied by the number of pregnant and breastfeeding women in the Program, based on the average of the last three months for which the Department has final data. On October 1, 1996 and each October 1 thereafter, the \$21 will be adjusted annually using the same inflation percentage used to determine the national administrative grant per person. If the State agency's total reported nutrition education and breastfeeding promotion and support expenditures are less than the required amount of expenditures, FNS will issue a claim for the difference. The State agency may request prior written permission from FNS to spend less than the required portions of its NSA grant for either nutrition education or for breastfeeding promotion and support

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activities. FNS will grant such permission if the State agency has sufficiently documented that other resources, including in-kind resources, will be used to conduct these activities at a level commensurate with the requirements of this paragraph (c)(1). However, food costs used to purchase or rent breast pumps may not be used for this purpose. Nutrition education costs are limited to activities which are distinct and separate efforts to help participants understand the importance of nutrition to health. The cost of dietary assessments for the purpose of certification, the cost of prescribing and issuing supplemental foods, the cost of screening for drug and other harmful substance use and making referrals to drug and other harmful substance abuse services, and the cost of other health-related screening shall not be applied to the expenditure requirement for nutrition education and breastfeeding promotion and support activities. The Department shall advise State agencies regarding methods for minimizing documentation of the nutrition education and breastfeeding promotion and support expenditure requirement. Costs to be applied to the one-sixth minimum amount required to be spent on nutrition education and the target share of funds required to be spent on breastfeeding promotion and support include, but need not be limited to—

- (i) Salary and other costs for time spent on nutrition education and breastfeeding promotion and support consultations whether with an individual or group;
- (ii) The cost of procuring and producing nutrition education and breastfeeding promotion and support materials including handouts, flip charts, filmstrips, projectors, food models or other teaching aids, and the cost of mailing nutrition education or breastfeeding promotion and support materials to participants;
- (iii) The cost of training nutrition or breastfeeding promotion and support educators, including costs related to conducting training sessions and purchasing and producing training materials;
- (iv) The cost of conducting evaluations of nutrition education or

breastfeeding promotion and support activities, including evaluations conducted by contractors;

(v) Salary and other costs incurred in developing the nutrition education and breastfeeding promotion and support portion of the State Plan and local agency nutrition education and breastfeeding promotion and support plans; and

(vi) The cost of monitoring nutrition education and breastfeeding promotion and support activities.

(2) The cost of Program certification, nutrition assessment and procedures and equipment used to determine nutritional risk, including the following:

(i) Laboratory fees incurred for up to two hematological tests for anemia per individual per certification period. The first test shall be to determine anemia status. The second test may be performed only in follow up to a finding of anemia when deemed necessary for health monitoring as determined by the WIC State agency;

(ii) Expendable medical supplies;

(iii) Medical equipment used for taking anthropometric measurements, such as scales, measuring boards, and skin fold calipers; and for blood analysis to detect anemia, such as spectrophotometers, hematofluorometers and centrifuges; and

(iv) Salary and other costs for time spent on nutrition assessment and certification.

(3) The cost of outreach services.

(4) The cost of administering the food delivery system, including the cost of transporting food.

(5) The cost of translators for materials and interpreters.

(6) The cost of fair hearings, including the cost of an independent medical assessment of the appellant, if necessary.

(7) The cost of transporting participants to clinics when prior approval for using Program funds to provide transportation has been granted by the State agency and documentation that such service is considered essential to assure Program access has been filed at the State agency. Direct reimbursement to participants for transportation cost is not an allowable cost.

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(8) The cost of monitoring and reviewing Program operations.

(9) The cost, exclusive of laboratory tests, of screening for drug and other harmful substance use and making referrals for counseling and treatment services.

(10) The cost of breastfeeding aids which directly support the initiation and continuation of breastfeeding.

(d) *Costs allowable with approval.* The costs of capital expenditures exceeding the dollar threshold established in Agency policy and guidance are allowable only with the approval of FNS prior to the capital investment. These expenditures include the costs of facilities, equipment (including medical equipment), automated data processing (ADP) projects, other capital assets, and any repairs that materially increase the value or useful life of such assets.

(e) *Use of funds recovered from vendors, participants, or local agencies.* (1) The State agency may keep funds collected through the recovery of claims assessed against vendors, participants, or local agencies. Recovered funds include those withheld from a vendor as a result of reviews of food instruments prior to payment. Recovered funds may be used for either food or NSA costs.

(2) These recovered funds may be used in the fiscal year:

(i) In which the initial obligation was made;

(ii) In which the claim arose;

(iii) In which the funds are collected; or

(iv) after the funds are collected.

(3) The State agency may not credit any recoveries until:

(i) In the case of a vendor claim, the vendor has had the opportunity to correct or justify the error or apparent overcharge in accordance with § 246.12(k)(3);

(ii) In the case of a participant, any administrative hearing requested in accordance with § 246.9 has been completed; or

(iii) In the case of a local agency claim, any administrative review requested in accordance with the local agency agreement has been completed.

(4) The State agency must report vendor, participant, and local agency

recoveries to FNS through the normal reporting process;

(5) The State agency must keep documentation supporting the amount and use of these vendor, participant, and local agency recoveries.

[50 FR 6121, Feb. 13, 1987, as amended at 52 FR 21237, June 4, 1987; 53 FR 25314, July 6, 1988; 54 FR 18091, Apr. 27, 1989; 58 FR 11507, Feb. 26, 1993; 59 FR 11503, Mar. 11, 1994; 63 FR 63974, Nov. 18, 1998; 64 FR 67999, Dec. 6, 1999; 64 FR 70178, Dec. 16, 1999; 65 FR 83286, Dec. 29, 2000; 71 FR 56731, Sept. 27, 2006; 73 FR 11312, Mar. 3, 2008]

§ 246.15 Program income other than grants.

(a) *Interest earned on advances.* Interest earned on advances of Program funds at the State and local levels shall be treated in accordance with the provisions of 31 CFR part 205, which implement the requirements of the Cash Management Improvement Act of 1990. However, State agencies will not incur an interest liability to the Federal government on rebate funds for infant formula or other foods, *provided* that all interest earned on such funds is used for program purposes.

(b) *Other Program income.* The State agency may use current program income (applied in accordance with the addition method described in § 3016.25(g)(2) of this title) for costs incurred in the current fiscal year and, with the approval of FNS, for costs incurred in previous years or subsequent fiscal years. Provided that the costs supported by the income further the broad objectives of the Program, they need not be a kind that would be permissible as charges to Federal funds. Money received by the State agency as a result of civil money penalties or fines assessed against a vendor and any interest charged in the collection of these penalties and fines shall be considered as program income.

[50 FR 6121, Feb. 13, 1985, as amended at 63 FR 63974, Nov. 18, 1998; 64 FR 13324, Mar. 18, 1999; 71 FR 56731, Sept. 27, 2006]

§ 246.16 Distribution of funds.

(a) *General.* This paragraph describes the timeframes for distribution of appropriated funds by the Department to participating State agencies and the

authority for the Secretary to use appropriated funds for evaluation studies and demonstration projects.

(1) Authorized appropriations to carry out the provisions of this section may be made not more than 1 year in advance of the beginning of the fiscal year in which the funds shall become available for disbursement to the State agencies. The funds shall remain available for the purposes for which appropriated until expended.

(2) In the case of appropriations legislation providing funds through the end of a fiscal year, the Secretary shall issue to State agencies an initial allocation of funds provided under such legislation not later than the expiration of the 15-day period beginning on the date of the enactment and subsequent allocation of funds shall be issued not later than the beginning of each of the second, third and fourth quarters of the fiscal year.

(3) Allocations of funds pursuant to paragraph (a)(2) of this section shall be made as follows: The initial allocation of funds to State agencies shall include not less than $\frac{1}{3}$ of the appropriated amounts for the fiscal year. The allocation of funds to be made not later than the beginning of the second and third quarters shall each include not less than $\frac{1}{4}$ of the appropriated amounts for the fiscal year.

(4) In the case of legislation providing funds for a period that ends prior to the end of a fiscal year, the Secretary shall issue to State agencies an initial allocation of funds not later than the expiration of the 10-day period beginning on the date of enactment. In the case of legislation providing appropriations for a period of not more than 4 months, all funds must be allocated to State agencies except those reserved by the Secretary to carry out paragraph (a)(6) of this section.

(5) In any fiscal year unused amounts from a prior fiscal year that are identified by the end of the first quarter of the fiscal year shall be recovered and reallocated not later than the beginning of the second quarter of the fiscal year. Unused amounts from a prior fiscal year that are identified after the end of the first quarter of the fiscal year shall be recovered and reallocated on a timely basis.

(6) Up to one-half of one percent of the sums appropriated for each fiscal year, not to exceed \$5,000,000, shall be available to the Secretary for the purpose of evaluating Program performance, evaluating health benefits, providing technical assistance to improve State agency administrative systems, preparing reports on program participant characteristics, and administering pilot projects, including projects designed to meet the special needs of migrants, Indians, rural populations, and to carry out technical assistance and research evaluation projects for the WIC Farmers' Market Nutrition Program.

(b) *Distribution and application of grant funds to State agencies.* Notwithstanding any other provision of law, funds made available to the State agencies for the Program in any fiscal year will be managed and distributed as follows:

(1) The State agency shall ensure that all Program funds are used only for Program purposes. As a prerequisite to the receipt of funds, the State agency shall have executed an agreement with the Department and shall have received approval of its State Plan.

(2) Notwithstanding any other provision of law, all funds not made available to the Secretary in accordance with paragraph (a)(6) of this section shall be distributed to State agencies on the basis of funding formulas which allocate funds to all State agencies for food costs and NSA costs incurred during the fiscal year for which the funds had been made available to the Department. Final State agency grant levels as determined by the funding formula and State agency breastfeeding promotion and support expenditure targets will be issued in a timely manner.

(3) *When may I transfer funds from one fiscal year to another?—(i) Back spend authority.* The State agency may back spend into the prior fiscal year up to an amount equal to one percent of its current year food grant and one percent of its current year NSA grant. Food funds spent back may be used only for food costs incurred during the prior fiscal year. NSA funds spent back may be used for either food or NSA costs incurred during the prior fiscal

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year. With prior FNS approval, the State agency may also back spend food funds up to an amount equal to three percent of its current year food grant in a fiscal year for food costs incurred in the prior fiscal year. FNS will approve such a request only if FNS determines there has been a significant reduction in infant formula cost containment savings that affected the State agency's ability to maintain its participation level.

(ii) *Spend forward authority.* (A) The State agency may spend forward NSA funds up to an amount equal to three (3) percent of its total grant (NSA plus food grants) in any fiscal year. These NSA funds spent forward may be used only for NSA costs incurred in the next fiscal year. Any food funds that the State agency converts to NSA funds pursuant to paragraph (f) of this section (based on projected or actual participation increases during a fiscal year) may not be spent forward into the next fiscal year. With prior FNS approval, the State agency may spend forward additional NSA funds up to an amount equal to one-half of one percent of its total grant. These funds are to be used in the next fiscal year for the development of a management information system, including an electronic benefit transfer system.

(B) Funds spent forward will not affect the amount of funds allocated to the State agency for any fiscal year. Funds spent forward must be the first funds expended by the State agency for costs incurred in the next fiscal year.

(iii) *Reporting requirements.* In addition to obtaining prior FNS approval for certain spend forward/back spending options, the State agency must report to FNS the amount of all funds it already has or intends to back spend and spend forward. The spending options must be reported at closeout.

(c) *Allocation formula.* State agencies shall receive grant allocations according to the formulas described in this paragraph. To accomplish the distribution of funds under the allocation formulas, State agencies shall furnish the Department with any necessary financial and Program data.

(1) *Use of participation data in the formula.* Wherever the formula set forth in paragraphs (c)(2) and (c)(3) of this sec-

tion require the use of participation data, the Department shall use participation data reported by State agencies according to § 246.25(b).

(2) *How is the amount of NSA funds determined?* The funds available for allocation to State agencies for NSA for each fiscal year must be sufficient to guarantee a national average per participant NSA grant, adjusted for inflation. The amount of the national average per participant grant for NSA for any fiscal year will be an amount equal to the national average per participant grant for NSA issued for the preceding fiscal year, adjusted for inflation. The inflation adjustment will be equal to the percentage change between two values. The first is the value of the index for State and local government purchases, as published by the Bureau of Economic Analysis of the Department of Commerce, for the 12-month period ending June 30 of the second preceding fiscal year. The second is the best estimate that is available at the start of the fiscal year of the value of such index for the 12-month period ending June 30 of the previous fiscal year. Funds for NSA costs will be allocated according to the following procedure:

(i) *Fair share target funding level determination.* For each State agency, FNS will establish, using all available NSA funds, an NSA fair share target funding level which is based on each State agency's average monthly participation level for the fiscal year for which grants are being calculated, as projected by FNS. Each State agency receives an adjustment to account for the higher per participant costs associated with small participation levels and differential salary levels relative to a national average salary level. The formula shall be adjusted to account for these cost factors in the following manner: 90 percent of available funds shall provide compensation based on rates which are proportionately higher for the first 15,000 or fewer participants, as projected by FNS, and 10 percent of available funds shall provide compensation based on differential salary levels, as determined by FNS.

(ii) *Base funding level.* To the extent funds are available and subject to the provisions of paragraph (c)(2)(iv) of this

section, each State agency shall receive an amount equal to 100 percent of the final formula-calculated NSA grant of the preceding fiscal year, prior to any operational adjustment funding allocations made under paragraph (c)(2)(iv) of this section. If funds are not available to provide all State agencies with their base funding level, all State agencies shall have their base funding level reduced by a pro-rata share as required by the shortfall of available funds.

(iii) *Fair share allocation.* Any funds remaining available for allocation for NSA after the base funding level required by paragraph (c)(2)(ii) of this section has been completed and subject to the provisions of paragraph (c)(2)(iv) of this section shall be allocated to bring each State agency closer to its NSA fair share target funding level. FNS shall make fair share allocation funds available to each State agency based on the difference between the NSA fair share target funding level and the base funding level, which are determined in accordance with paragraphs (c)(2)(i) and (c)(2)(ii) of this section, respectively. Each State agency's difference shall be divided by the sum of the differences for all State agencies, to determine the percent share of the available fair share allocation funds each State agency shall receive.

(iv) *Operational adjustment funds.* Each State agency's final NSA grant shall be reduced by up to 10 percent, and these funds shall be aggregated for all State agencies within each FNS region to form an operational adjustment fund. The Regions shall allocate these funds to State agencies according to national guidelines and shall consider the varying needs of State agencies within the region.

(v) *Operational level.* The sum of each State agency's stability, residual and operational adjustment funds shall constitute the State agency's operational level. This operational level shall remain unchanged for such year even if the number of Federally-supported participants in the program at such State agency is lower than the Federally-projected participation level. However, if the provisions of paragraph (e)(2)(ii) of this section are applicable, a State agency will have its oper-

ational level for NSA reduced in the immediately succeeding fiscal year.

(3) *Allocation of food benefit funds.* In any fiscal year, any amounts remaining from amounts appropriated for such fiscal year and amounts appropriated from the preceding fiscal year after making allocations under paragraph (a)(6) of this section and allocations for nutrition services and administration (NSA) as required by paragraph (c)(2) of this section shall be made available for food costs. Allocations to State agencies for food costs will be determined according to the following procedure:

(i) *Fair share target funding level determination.* (A) For each State agency, FNS will establish a fair share target funding level which shall be an amount of funds proportionate to the State agency's share of the national aggregate population of persons who are income eligible to participate in the Program based on the 185 percent of poverty criterion. The Department will determine each State agency's population of persons categorically eligible for WIC which are at or below 185% of poverty, through the best available, nationally uniform, indicators as determined by the Department. If the Commodity Supplemental Food Program (CSFP) also operates in the area served by the WIC State agency, the number of participants in such area participating in the CSFP but otherwise eligible to participate in the WIC Program, as determined by FNS, shall be deducted from the WIC State agency's population of income eligible persons. If the State agency chooses to exercise the option in §246.7(c)(2) to limit program participation to U.S. citizens, nationals, and qualified aliens, FNS will reduce the State agency's population of income eligible persons to reflect the number of aliens the State agency declares no longer eligible.

(B) The Department may adjust the respective amounts of food funds that would be allocated to a State agency which is outside the 48 contiguous states and the District of Columbia when the State agency can document that economic conditions result in higher food costs for the State agency. Prior to any such adjustment, the State agency must demonstrate that it

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has successfully implemented voluntary cost containment measures, such as improved vendor management practices, participation in multi-state agency infant formula rebate contracts or other cost containment efforts. The Department may use the Thrifty Food Plan amounts used in the Food Stamp Program, or other available data, to formulate adjustment factors for such State agencies.

(ii) *Prior year grant level allocation.* To the extent funds are available, each State agency shall receive a prior year grant allocation equal to its final authorized grant level as of September 30 of the prior fiscal year. If funds are not available to provide all State agencies with their full prior year grant level allocation, all State agencies shall have their full prior year grant level allocation reduced by a pro-rata share as required by the shortfall of available funds.

(iii) *Inflation/fair share allocation.* (A) If funds remain available after the allocation of funds under paragraph (c)(3)(ii) of this section, the funds shall be allocated as provided in this paragraph (c)(3)(iii). First, FNS will calculate a target inflation allowance by applying the anticipated rate of food cost inflation, as determined by the Department, to the prior year grant funding level. Second, FNS will allocate 80 percent of the available funds to all State agencies in proportionate shares to meet the target inflation allowance. Third, FNS will allocate 20 percent of the available funds to each State agency which has a prior year grant level allocation, as determined in paragraph (c)(3)(ii) of this section and adjusted for inflation as determined in this paragraph (c)(3)(iii), which is still less than its fair share target funding level. The amount of funds allocated to each State agency shall be based on the difference between its prior year grant level allocation plus target inflation funds and the fair share funding target level. Each State agency's difference shall be divided by the sum of the differences for all such State agencies, to determine the percentage share of the 20 percent of available funds each State agency shall receive. In the event a State agency declines any of its allocation under either this paragraph

(c)(3)(iii) or paragraph (c)(3)(ii) of this section, the declined funds shall be reallocated in the percentages and manner described in this paragraph (c)(3)(iii). Once all State agencies receive allocations equal to their full target inflation allowance, any remaining funds shall be allocated or reallocated, in the manner described in this paragraph (c)(3)(iii), to those State agencies still under their fair share target funding level.

(B) In the event funds still remain after completing the distribution in paragraph (c)(3)(iii)(A) of this section, these funds shall be allocated to all State agencies including those with a stability allocation at, or greater than, their fair share allocation. Each State agency which can document the need for additional funds shall receive additional funds based on the difference between its prior year grant level and its fair share allocation. State agencies closest to their fair share allocation shall receive first consideration.

(iv) *Migrant services.* At least 1/10 of one percent of appropriated funds for each fiscal year shall be available first to assure service to eligible members of migrant populations. For those State agencies serving migrants, a portion of the grant shall be designated to each State agency for service to members of migrant populations based on that State agency's prior year reported migrant participation. The national aggregate amount made available first for this purpose shall equal 1/10 of one percent of all funds appropriated each year for the Program.

(v) *Special provisions for Indian State agencies.* The Department may choose to adjust the allocations and/or eligibles data among Indian State agencies, or among Indian State agencies and the geographic State agencies in which they are located when eligibles data for the State agencies' population is determined to not fairly represent the population to be served. Such allocations may be redistributed from one State agency to another, based on negotiated agreements among the affected State agencies approved by FNS.

(4) *Adjustment for new State agencies.* Whenever a State agency that had not previously administered the program

enters into an agreement with the Department to do so during a fiscal year, the Department shall make any adjustments to the requirements of this section that are deemed necessary to establish an appropriate initial funding level for such State agency.

(d) *Distribution of funds to local agencies.* The State agency shall provide to local agencies all funds made available by the Department, except those funds necessary for allowable State agency NSA costs and food costs paid directly by the State agency. The State agency shall distribute the funds based on claims submitted at least quarterly by the local agency. Where the State agency advances funds to local agencies, the State agency shall ensure that each local agency has funds to cover immediate disbursement needs, and the State agency shall offset the advances made against incoming claims as they are submitted to ensure that funding levels reflect the actual expenditures reported by the local agency. Upon receipt of Program funds from the Department, the State agency shall take the following actions:

(1) Distribute funds to cover expected food cost expenditures and/or distribute caseload targets to each local agency which are used to project food cost expenditures.

(2) Allocate funds to cover expected local agency NSA costs in a manner which takes into consideration each local agency's needs. For the allocation of NSA funds, the State agency shall develop an NSA funding procedure, in cooperation with representative local agencies, which takes into account the varying needs of the local agencies. The State agency shall consider the views of local agencies, but the final decision as to the funding procedure remains with the State agency. The State agency shall take into account factors it deems appropriate to further proper, efficient and effective administration of the program, such as local agency staffing needs, density of population, number of persons served, and availability of administrative support from other sources.

(3) The State agency may provide in advance to any local agency any amount of funds for NSA deemed necessary for the successful commence-

ment or significant expansion of program operations during a reasonable period following approval of a new local agency, a new cost containment measure, or a significant change in an existing cost containment measure.

(e) *Recovery and reallocation of funds.*

(1) Funds may be recovered from a State agency at any time the Department determines, based on State agency reports of expenditures and operations, that the State agency is not expending funds at a rate commensurate with the amount of funds distributed or provided for expenditures under the Program. Recovery of funds may be either voluntary or involuntary in nature. Such funds shall be reallocated by the Department through application of appropriate formulas set forth in paragraph (c) of this section.

(2) *Performance standards.* The following standards shall govern expenditure performance.

(i) The amount allocated to any State agency for food benefits in the current fiscal year shall be reduced if such State agency's food expenditures for the preceding fiscal year do not equal or exceed 97 percent of the amount allocated to the State agency for such costs. Such reduction shall equal the difference between the State agency's preceding year food expenditures and the performance expenditure standard amount. For purposes of determining the amount of such reduction, the amount allocated to the State agency for food benefits for the preceding fiscal year shall not include food funds expended for food costs incurred under the spendback provision in paragraph (b)(3)(i) of this section or conversion authority in paragraph (g) of this section. Temporary waivers of the performance standard may be granted at the discretion of the Department.

(ii) *Reduction of NSA grant.* FNS will reduce the State agency's NSA grant for the next fiscal year if the State agency's current fiscal year per participant NSA expenditure is more than 10 percent higher than its per participant NSA grant. To avoid a reduction to its NSA grant level, the State agency may submit a "good cause" justification explaining why it exceeded the applicable limit on excess NSA expenditures. This

justification must be submitted at the same time as the close-out report for the applicable fiscal year. Good cause may include dramatic and unforeseen increases in food costs, which would prevent a State agency from meeting its projected participation level.

(iii) *Spend forward funds.* If any State agency notifies the Department of its intent to spend forward a specific amount of funds for expenditure in the subsequent fiscal year, in accordance with paragraph (b)(3)(ii) of this section, such funds shall not be subject to recovery by the Department.

(f) *How do I qualify to convert food funds to NSA funds based on increased participation?*—(1) *Requirements.* The State agency qualifies to convert food funds to NSA funds based on increased participation in any fiscal year in two ways:

(i) *Approved plan.* A State agency may submit a plan to FNS to reduce average food costs per participant and to increase participation above the FNS-projected level for the State agency. If approved, the State agency may use funds allocated for food costs to pay NSA costs.

(ii) *Participation increases achieved.* The State agency may also convert food funds to NSA funds in any fiscal year if it achieves, through acceptable measures, increases in participation in excess of the FNS-projected level for the State agency. Acceptable measures include use of cost containment measures, curtailment of vendor abuse, and breastfeeding promotional activities. FNS will disallow the State agency's conversion of food funds to NSA funds in accordance with paragraph (h) of this section if:

(A) The State agency increases its participation level through measures that are not in the nutritional interests of participants; or

(B) It is not otherwise allowable under program regulations.

(2) *Limitation.* The State agency may convert food funds only to the extent that the conversion is necessary—

(i) To cover NSA expenditures in the current fiscal year that exceed the State agency's NSA grant for the current fiscal year and any NSA funds which the State agency has spent forward into the current fiscal year; and

(ii) To ensure that the State agency maintains the level established for the per participant NSA grant for the current fiscal year.

(3) *Maximum amount.* The maximum amount the State agency may convert equals the State agency's conversion rate times the projected or actual participation increase, as applicable. The conversion rate is the same as the per participant NSA grant and is determined by dividing the State agency's NSA grant by the FNS-projected participation level. The NSA grant used in the calculation equals the initial allocation of current year funds plus the operational adjustment funding allocated to the State agency for that fiscal year.

(g) *How do I qualify to convert food funds to NSA funds for service to remote Indian or Native villages?*—(1) *Eligible State agencies.* Only State agencies located in noncontiguous States containing a significant number of remote Indian or Native villages qualify to convert food funds to NSA funds under this paragraph (g) in any fiscal year.

(2) *Limitation.* In the current fiscal year, food funds may be converted only to the extent necessary to cover expenditures incurred:

(i) In providing services (including the full cost of air transportation and other transportation) to remote Indian or Native villages; and

(ii) To provide breastfeeding support in those areas that exceed the State agency's NSA grant for the current fiscal year and any NSA funds which the State agency has spent forward into the current fiscal year.

(h) *What happens at the end of the fiscal year in which food funds are converted?* At the end of the fiscal year, the Department will determine the amount of food funds which the State agency was entitled to convert to NSA funds under paragraphs (f) and (g) of this section. In the event that the State agency has converted more than the permitted amount of funds, the Department will disallow the amount of excess conversion.

(i) *How do converted funds affect the calculation of my prior year food grant and base NSA grant?* For purposes of establishing a State agency's prior year food grant and base NSA grant under

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paragraphs (c)(2)(i) and (c)(3)(i) of this section, respectively, amounts converted from food funds to NSA funds under paragraphs (f) and (g) of this section and § 246.14(e) during the preceding fiscal year will be treated as though no conversion had taken place.

(j) *Inflation adjustment of the fruit and vegetable voucher.* The monthly cash value of the fruit and vegetable voucher shall be adjusted annually for inflation. Adjustments are effective the first day of each fiscal year beginning on or after October 1, 2008. The inflation-adjusted value of the voucher shall be equal to a base value increased by a factor based on the Consumer Price Index for fresh fruits and vegetables, as provided in this section.

(1) *Adjustment year.* The adjustment year is the fiscal year that begins October 1 of the current calendar year.

(2) *Base value of the fruit and vegetable voucher.* The base value of the fruit and vegetable voucher is the monthly cash value of the voucher for fiscal year 2008. The base value equals:

- (i) \$6 for children;
- (ii) \$10 for pregnant and postpartum women; and
- (iii) \$10 for breastfeeding women.

(3) *Adjusted value of the fruit and vegetable voucher.* The adjusted value of the fruit and vegetable voucher is the cash value of the voucher for adjustment years beginning on or after October 1, 2008. The adjusted value is the base value increased by an amount equal to the base value of the fruit and vegetable voucher:

- (i) Multiplied by the inflation adjustment described in paragraph (j)(4) of this section; and
- (ii) Subject to rounding as described in paragraph (j)(5) of this section.

(4) *Inflation adjustment.* The inflation adjustment of the fruit and vegetable voucher shall equal the percentage (if any) by which the annual average value of the Consumer Price Index for fresh fruits and vegetables, computed from monthly values published by the Bureau of Labor Statistics, for the twelve months ending on March 31 of the fiscal year immediately prior to the adjustment year, exceeds the average of the monthly values of that index for the twelve months ending on March 31, 2007.

(5) *Rounding.* If any increase in the cash value of the voucher determined under paragraph (j)(3) of this section is not a multiple of \$1, such increase shall be rounded to the next lowest multiple of \$1. However, if the adjusted value of the voucher for the adjustment year, as determined under paragraph (j)(3) of this section, is lower than the adjusted value for the fiscal year immediately prior to the adjustment year, then the adjusted value of the voucher will remain unchanged from that immediate prior fiscal year.

[50 FR 6121, Feb. 13, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 246.16, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 246.16a Infant formula cost containment.

(a) *Who must use cost containment procedures for infant formula?* All State agencies must continuously operate a cost containment system for infant formula that is implemented in accordance with this section except:

(1) State agencies with home delivery or direct distribution food delivery systems;

(2) Indian State agencies with 1,000 or fewer participants in April of any fiscal year, which are exempt for the following fiscal year;

(3) State agencies granted a waiver under paragraph (e) of this section; and

(4) State agencies granted a postponement under paragraph (f) of this section.

(b) *What cost containment procedures must be used?* State agencies must use either a single-supplier competitive system as outlined in paragraph (c) of this section, or an alternative cost containment system as outlined in paragraph (d) of this section.

(c) *What is the single-supplier competitive system?* Under the single-supplier competitive system, a State agency solicits sealed bids from infant formula manufacturers to supply and provide a rebate for infant formulas. The State agency must conduct the procurement in a manner that maximizes full and open competition consistent with the requirements of this section.

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(1) *How must a State agency structure the bid solicitation?* (i) *Single solicitation.* Under the single solicitation system, the State agency's bid solicitation must require the winning bidder to supply and provide a rebate on all infant formulas it produces that the State agency chooses to issue, except exempt infant formulas. Rebates must also be paid on any new infant formulas that are introduced after the contract is awarded. The solicitation must require bidders that do not produce a soy-based infant formula to subcontract with another manufacturer to supply a soy-based infant formula under the contract. In this case, the bid solicitation must require that the winning bidder pay the State agency a rebate on the soy-based infant formula supplied by the subcontractor that is issued by the State agency. The bid solicitation must require all rebates (including those for soy-based infant formula supplied by a subcontractor) to be calculated in accordance with paragraph (c)(6) of this section. All of these infant formulas are called contract brand infant formulas.

(ii) *Separate solicitations.* Under the separate solicitation system, a State agency issues two bid solicitations. Any State agency or alliance that served a monthly average of more than 100,000 infants during the preceding 12-month period shall issue separate bid solicitations for milk-based and soy-based infant formula. The first solicitation must require the winning bidder to supply and provide a rebate on all milk-based infant formulas it produces that the State agency chooses to issue, except exempt infant formulas. Rebates must also be paid on any new milk-based infant formulas that are introduced by the manufacturer after the contract is awarded. These infant formulas are considered to be contract

brand infant formulas. The second bid solicitation must require the winning bidder to supply and provide a rebate on all soy-based infant formulas it produces that the State agency chooses to issue. Rebates must also be paid on any new soy-based infant formulas that are introduced by the manufacturer after the contract is awarded. These infant formulas are also considered to be contract brand infant formulas.

(2) *What is the size limitation for a State alliance?* A State alliance may exist among State agencies if the total number of infants served by States participating in the alliance as of October 1, 2003, or such subsequent date determined by the Secretary for which data is available, does not exceed 100,000. However, a State alliance that existed as of July 1, 2004, and serves over 100,000 infants may exceed this limit to include any State agency that served less than 5,000 infants as of October 1, 2003, or such subsequent date determined by the Secretary for which data is available, and/or any Indian State agency. The Secretary may waive these requirements not earlier than 30 days after submitting to the Committee on Education and the Workforce of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a written report that describes the cost-containment and competitive benefits of the proposed waiver.

(3) *On what types and physical forms of infant formula must bids be solicited?* The bid solicitation must require bidders to specify a rebate for each of the types and physical forms of infant formulas specified in the following chart. These rebates apply proportionally to other infant formulas produced by the winning bidder(s) (see paragraph (c)(6) of this section).

Type of infant formula	Physical forms of infant formula	Infant formula requirements
(i) For a single solicitation, the solicitation must require bidders to specify a rebate amount for the following:		
A single milk-based infant formula (primary contract infant formula); bidders must specify the brand name of the milk-based infant formula for which the rebate is being specified.	Concentrated liquid, powdered, and ready-to-feed.	Meets requirements under §246.10(e)(1)(iii) and §246.10(e)(2)(iii) and suitable for routine issuance to the majority of generally healthy, full-term infants.

Type of infant formula	Physical forms of infant formula	Infant formula requirements
(ii) For separate solicitations, the solicitation must require bidders to specify a rebate amount for the following:		
(A) A single milk-based infant formula (primary milk-based contract brand infant formula); bidders must specify the brand name of the milk-based infant formula for which the rebate is being specified.	Concentrated liquid, powdered, and ready-to-feed.	Meets requirements under § 246.10(e)(1)(iii) and § 246.10(e)(2)(iii) and suitable for routine issuance to the majority of generally healthy, full-term infants.
(B) A single soy-based infant formula (primary soy-based contract brand infant formula); bidders must specify the brand name of the soy-based infant formula for which the rebate is being specified.	Concentrated liquid, powdered, and ready-to-feed.	Meets requirements under § 246.10(e)(1)(iii) and § 246.10(e)(2)(iii).

(4) *How are contracts awarded?* A State agency must award the contract(s) to the responsive and responsible bidder(s) offering the lowest total monthly net price for infant formula or the highest monthly rebate (subject to paragraph (c)(4)(ii) of this section) for a standardized number of units of infant formula. The State agency must calculate the lowest net price using the lowest national wholesale cost per unit for a full truckload of the infant formula on the date of the bid opening.

(i) *Calculating the standardized number of units of infant formula.* The State agency must specify a standardized number of units (e.g., cans) of infant formula by physical form (e.g., concentrated liquid, powdered, and ready-to-feed) to be bid upon. The standardized number of units must contain the equivalent of the total number of ounces by physical form needed to give the maximum allowance to the average monthly number of infants using each form. The number of infants does not include infant participants who are exclusively breastfed and those who are issued exempt infant formula. The average monthly number of infant using each physical form must be based on at least 6 months of the most recent participation and issuance data. In order to calculate the standardized number of units of infant formula by form to be bid upon, the average monthly number of infants using each physical form is multiplied by the maximum monthly allowable number of ounces for each form (as allowed under § 246.10(e)(9)(Table1)), and divided by the corresponding unit size (i.e., number of ounces per unit being bid). In order to compare bids, total cost is cal-

culated by multiplying this standardized number of units by the net price for each physical form. Alternative calculations that arrive at a mathematically equivalent result are acceptable.

(ii) *Determining the lowest total monthly net price or highest rebate.* To determine the lowest total monthly net price a State agency must multiply the net price per unit by the established standardized amount of infant formula to be bid upon as calculated in paragraph (c)(4)(i) of this section. If the bid evaluation is based on highest rebate offered, the State agency must multiply the rebate offered by the established amount of infant formula to be bid upon as calculated in paragraph (c)(4)(i) of this section.

(iii) *Highest rebate limitation.* Before issuing the bid solicitation, a State agency that elects to evaluate bids by highest rebate must demonstrate to FNS' satisfaction that the weighted average retail prices for different brands of infant formula in the State vary by 5 percent or less. The weighted average retail price must take into account the prices charged for each type and physical form of infant formula by authorized vendors or, if a State agency elects, it may include stores that do not participate in the WIC program in the State. The State agency must also base calculations on the proportion of each type and physical form of infant formula the State agency issues based on the data provided to bidders pursuant to paragraph (c)(5) of this section.

(5) *What data must be provided to bidders?* The State agency must provide as part of the bid solicitation the participation and infant formula usage data and the standardized number of ounces

by physical form of infant formula to be used in evaluating bids as described in paragraph (c)(4) of this section. The State agency must notify bidders that the participation and infant formula usage data does not necessarily reflect the actual issuance and redemption that will occur under the contract.

(6) *How is the rebate to be calculated on all other contract brand infant formulas?* All bids must specify the rebates offered by each bidder for the primary contract infant formula(s). After the contract is awarded, the State agency must calculate the percentage discount for all other contract brand infant formulas (i.e., all other infant formulas produced by the bidder other than exempt infant formulas) approved for issuance by the State agency. The State agency must use the following method in calculating the rebates:

(i) *Calculation of percentage discounts.* Rebates for contract brand infant formulas, other than the primary contract infant formula(s) for which bids were received, must be calculated by first determining the percentage discount for each physical form (e.g., concentrated liquid, powdered, and ready-to-feed) of the primary contract infant formula(s). The percentage discount must be calculated by dividing the rebate for the primary contract infant formula by the manufacturer's lowest national wholesale price per unit, as of the date of the bid opening, for a full truckload of the primary contract infant formula. The percentage discounts must be used to determine the rebate for all other contract brand infant formulas approved for issuance by the State agency.

(ii) *Calculation of rebate amount.* The rebate for each type and form of all other contract brand infant formulas must be calculated by multiplying the percentage discount by the manufacturer's lowest national wholesale price per unit, as of the date of the bid opening, for a full truckload of the other contract brand infant formula. The percentage discount used for each of the other contract brand infant formulas depends on the physical form of the infant formula. For example, if the percentage discount provided for the primary contract brand powdered infant formula is 80 percent of its whole-

sale price, the same percentage discount must be applied to all other contract brand powdered infant formulas. The rebate for any types or forms of contract brand infant formulas that are introduced during the contract period must be calculated using the wholesale prices of these new contract brand infant formulas at the time the infant formulas are approved for issuance by the State agency.

(iii) *Calculation of rebates during contract term.* The rebates resulting from the application of the percentage discount must remain the same throughout the contract period except for the cent-for-cent rebate adjustments required in paragraph (c)(6)(iv) of this section.

(iv) *Cent-for-cent rebate adjustments.* Bid solicitations must require the manufacturer to adjust rebates for price changes subsequent to the bid opening. Price adjustments must reflect any increase and decrease, on a cent-for-cent basis, in the manufacturer's lowest national wholesale prices for a full truckload of infant formula.

(7) *What is the first choice of issuance for infant formula?* The State agency must use the primary contract infant formula(s) as the first choice of issuance (by physical form), with all other infant formulas issued as an alternative (see § 246.10(e)(1)(iii)).

(8) *Under what circumstances may the State agency issue other contract brand formulas?* Except as required in paragraph (c)(7) of this section, the State agency may choose to approve for issuance some, none, or all of the winning bidder's other infant formula(s). In addition, the State agency may require medical documentation before issuing any contract brand infant formula, except as provided in paragraph (c)(7) of this section (see § 246.10(c)(1)(i)) and must require medical documentation before issuing any WIC formula covered by § 246.10(c)(1)(iii).

(d) *What is an alternative cost containment system?* Under an alternative cost containment system, a State agency elects to implement an infant formula cost containment system of its choice. The State agency may only implement an alternative system if such a system provides a savings equal to or greater

than a single-supplier competitive system. A State agency must conduct a cost comparison demonstrating such savings as described in paragraphs (d)(1) and (d)(2) of this section.

(1) *How must the State agency structure the bid solicitation?* The State agency must solicit bids simultaneously using the single-supplier competitive system described in paragraph (c) of this section and the alternative cost containment system(s) the State agency has selected. The State agency may prescribe standards of its choice for the alternative cost containment system(s), provided that conditions established for each system addressed in the bid solicitation include identical bid specifications for the contract period length and the types and forms of infant formula(s) to be included in the systems. In addition, the alternative cost containment system must cover the types and forms of infant formulas routinely issued to the majority of generally healthy, full-term infants. The State agency must use the procedure outlined in paragraph (d)(2) of this section in conducting a cost comparison to determine which system offers the greatest savings over the entire contract period specified in the bid solicitation.

(2) *How does the State agency conduct the cost comparison?* (i) *Establishing infant formula cost containment savings.* (A) *Savings under the single-supplier competitive system.* The State agency must project food cost savings in the single-supplier competitive system based on the lowest monthly net price or highest monthly rebate, as described in paragraph (c)(4) of this section.

(B) *Savings under an alternative cost containment system.* The State agency must project food cost savings under alternative cost containment systems based on the lowest monthly net cost or highest monthly rebate, as described in paragraph (c)(4) of this section. Food cost savings must be based on the standardized amount of infant formula expected to be issued as calculated for a single-supplier competitive system, prorated by the percentage of anticipated total infant formula purchases attributable to each manufacturer. The State agency must use the aggregate market share of the manufacturers

submitting bids in calculating its cost savings estimate.

(C) *General.* In establishing the potential food cost savings under each system, the State agency must take into consideration in its estimate of savings any inflation factors which would affect the amount of savings over the life of the contract. Further, the State agency must not subtract any loss of payments which would occur under the terms of a current contract as a result of any State agency action to be effective after expiration of the contract.

(ii) *Nutrition services and administration cost adjustment.* The State agency must deduct from the food cost savings projected for each system under this paragraph (d) the nutrition services and administration costs associated with developing and implementing—but not operating—each cost containment system. This includes any anticipated costs for modifying its automated data processing system or components of its food delivery system(s), and of training participants, local agencies, vendors, and licensed health care professionals on the purpose and procedures of the new system. For contracts of two years or less, such costs must be proportionately distributed over at least a two year period. The State agency must not deduct any costs associated with procurement. The State agency must itemize and justify all nutrition services and administration cost adjustments as necessary and reasonable for the development and implementation of each system.

(iii) *Final cost comparison.* The State agency must calculate the food costs savings and deduct the appropriate nutrition services and administration costs for each system for which bids were received. The State agency must implement the single-supplier competitive system, unless its comparative cost analysis shows that, over the length of the contract stipulated in the bid solicitation, an alternative cost containment system offers savings at least equal to, or greater than, those under the competitive single-supplier system. If the comparative cost analysis permits selection of the alternative cost containment system and the State agency wishes to implement that system, it must first submit a

State Plan amendment with the calculations and supporting documentation for this cost analysis to FNS for approval. Only after the calculations are approved by FNS may the State agency award the contract or contracts under the alternative cost containment system.

(e) *How does a State agency request a waiver of the requirement for a single-supplier competitive system?* A State agency which, after completing the cost comparison in paragraphs (d)(2)(i) through (d)(2)(iii) of this section, is required to implement the single-supplier competitive cost containment system for infant formula procurement, may request a waiver from FNS to permit it to implement an alternative system. State agencies must support all waiver requests with documentation in the form of a State Plan amendment as required under § 246.4(a)(14)(x) and may submit such requests only in either of the following circumstances:

(1) The difference between the single-supplier competitive system and the alternative cost containment system is less than 3 percent of the savings anticipated under the latter system and not more than \$100,000 per annum.

(2) The single-supplier competitive system would be inconsistent with the efficient or effective operation of the program. Examples of justifications FNS will not accept for a waiver, include, but are not limited to: preservation of participant preference for otherwise nutritionally equivalent infant formulas; maintenance of health care professionals' prerogatives to prescribe otherwise nutritionally equivalent infant formulas for non-medical reasons; potential loss of free or otherwise discounted materials to WIC clinics and other health care facilities; potential inability of a manufacturer selected in accordance with applicable State procurement procedures to supply contractually-specified amounts of infant formula; and the possibility of interrupted infant formula supplies to retail outlets as a consequence of entering into a contract with a single manufacturer.

(f) *How does a State agency request a postponement of the requirement for a continuously operated cost containment*

system for infant formula? A State agency may request a postponement of the requirement to continuously operate a cost containment system for infant formula that has been implemented in accordance with this section. However, a State agency may only request a postponement when it has taken timely and responsible action to implement a cost containment system before its current system expires but has been unable to do so due to procurement delays, disputes with FNS concerning cost containment issues during the State Plan approval process or other circumstances beyond its control. The written postponement request must be submitted to FNS before the expiration of the current system. The postponement period may be no longer than 120 days. If a postponement is granted, the State agency may extend, renew or otherwise continue an existing system during the period of the postponement.

(g) *May a State agency implement cost containment systems for other supplemental foods?* Yes, when a State agency finds that it is practicable and feasible to implement a cost containment system for any WIC food other than infant formula, the State agency must fully implement that system in accordance with the time frames established by the State agency and notification must be given to FNS by means of the State agency's State Plan.

(h) *What are the implementation time frames for Indian State agencies that lose their exemption from the infant formula cost containment requirement?* If an Indian State agency operating a retail food delivery system expands its program participation above 1000 and thereby loses its exemption from the requirements of paragraph (a) of this section regarding the method of cost containment for infant formula, then the Indian State agency must begin compliance with paragraph (a) of this section in accordance with time frames established by FNS.

(i) *What are the penalties for failure to comply with the cost containment requirements?* Any State agency that FNS determines to be out of compliance with the cost containment requirements of this part must not draw down on or obligate any Program grant funds, nor will FNS make any further Program

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funds available to such State agency, until it is in compliance with these requirements.

(j) *What provisions are prohibited to be included in cost containment contracts?* A State agency may not issue bid solicitations or enter into contracts which:

(1) Prescribe conditions that would void, reduce the savings under or otherwise limit the original contract if the State agency solicited or secured bids for, or entered into, a subsequent cost containment contract to take effect after the expiration of the original contract;

(2) Does not include the registration and certification requirements in § 246.10(g);

(3) Require infant formula manufacturers to submit bids on more than one of the systems specified in the invitation for bids; or

(4) Require infant formula manufacturers to provide gratis infant formula or other items.

(k) *What are the requirements for infant formula rebate invoices?* A State agency must have a system in place that ensures infant formula rebate invoices, under competitive bidding, provide a reasonable estimate or an actual count of the number of units purchased by participants in the program.

(l) *What are the requirements for the national cost containment bid solicitation and selection for infant formula?* FNS will solicit and select bids for infant formula rebates on behalf of State agencies with retail food delivery systems based on the following guidelines:

(1) FNS will solicit bids and select the winning bidder(s) for infant formula cost containment contracts only if two or more State agencies with retail food delivery systems request FNS to conduct bid solicitation and selection on their behalf. FNS will conduct the bid solicitation and selection process only and will not award or enter into any infant formula cost containment contract on behalf of the individual State agencies. Each State agency will individually award and enter into infant formula cost containment contract(s) with the winning bidder(s). State agencies must obtain the rebates directly from the infant formula manufacturer(s). FNS will conduct the bid solicitation in accordance

with this paragraph (1) and the competitive bidding procurement procedures of the State agency with the highest infant participation in the bid group on whose behalf bids are being solicited. Any bid protests and contractual disputes are the responsibility of the individual State agencies to resolve.

(2) FNS will make a written offer to all State agencies to conduct bid solicitation and selection on their behalf at least once every 12 months. FNS will send State agencies a copy of the draft Request for Rebates when making the offer to State agencies. Only State agencies that provide the information required by this paragraph (1)(2) in writing, signed by a responsible State agency official, by certified mail, return receipt requested or by hand delivery with evidence of receipt within 15 days of receipt of the offer will be included in the national bid solicitation and selection process. Each interested State agency must provide:

(i) A statement that the State agency requests FNS to conduct bid solicitation and selection on its behalf;

(ii) A statement of the State agency's minimum procurement procedures applicable to competitive bidding (as defined in § 246.2) for infant formula cost containment contracts and supporting documentation;

(iii) A statement of any limitation on the duration of infant formula cost containment contracts and supporting documentation;

(iv) A statement of any contractual provisions required to be included in infant formula cost containment contracts by the State agency;

(v) The most recent available average monthly number of infant participants less those infant participants who are exclusively breastfed and those who are issued exempt infant formula. The average monthly participation level must be based on at least 6 months of participation data.

(vi) Infant formula usage rates by type (e.g., milk-based or soy-based), form (e.g., concentrated, powdered, ready-to-feed), container size, and supporting documentation;

(vii) A statement of the termination date of the State agency's current infant formula cost containment contract; and

(viii) Any other related information that FNS may request.

(3) If FNS determines that the number of State agencies making the request provided for in paragraph (1)(2) of this section does not comply with the requirements of paragraph (c)(2) of this section, FNS shall, in consultation with such State agencies, divide such State agencies into more than one group and solicit bids for each group. These groups of State agencies are referred to as "bid groups." In determining the size and composition of the bid groups, FNS will, to the extent practicable, take into account the need to maximize the number of potential bidders so as to increase competition among infant formula manufacturers and the similarities in the State agencies' procurement and contract requirements (as provided by the State agencies in accordance with paragraphs (1)(2)(ii), (1)(2)(iii), and (1)(2)(iv) of this section). FNS reserves the right to exclude a State agency from the national bid solicitation and selection process if FNS determines that the State agency's procurement requirements or contractual requirements are so dissimilar from those of the other State agencies in any bid group that the State agency's inclusion in the bid group could adversely affect the bids.

(4) For each bid group formed pursuant to paragraphs (1)(2) and (1)(3) of this section, FNS will use for soliciting bids the competitive bidding procurement procedures of the State agency in the group with the highest infant participation. To the extent not inconsistent with the requirements of this paragraph (1), FNS will use that set of procedures in soliciting the bids for that bid group of State agencies. FNS will notify each State agency in the bid group of the choice and provide them each a copy of the procurement procedures of the chosen State agency. Each State agency must provide FNS a written statement, signed by a responsible State agency official, by certified mail, return receipt requested or by hand delivery with evidence of receipt stating whether that State agency is legally

authorized to award an infant formula cost containment contract pursuant to that set of procedures within 10 days of the receipt of the notification. If the State agency determines it is not legally authorized to award an infant formula cost containment contract pursuant to those procedures, that State agency may not continue in that round of the national bid solicitation and selection.

(5) At a minimum, in soliciting bids FNS will address the following:

(i) Unless FNS determines that doing so would not be in the best interest of the Program, bids will be solicited for either:

(A) A single contract for each State agency under which the winning bidder will be required to supply and provide rebates on all infant formulas produced by that manufacturer (except exempt infant formulas) that are issued by the State agency. If that manufacturer does not produce a soy-based infant formula, the winning bidder will be required to subcontract with another manufacturer for a soy-based infant formula and the winning bidder will be required to pay a rebate on the soy-based infant formula; or

(B) Two separate contracts for each State agency. Under the first contract, the winning bidder will supply and provide a rebate on all the milk-based infant formulas the winning bidder produces (except exempt infant formulas) that are issued by the State agency and under the second contract the winning bidder will supply and provide a rebate on all the soy-based infant formulas the winning bidder produces (except exempt infant formulas) that are issued by the State agency.

(ii) The infant formula cost containment contract(s) to be entered into by the State agencies and infant formula manufacturers must provide for a constant net price for infant formula for the full term of the infant formula cost containment contract(s).

(iii) The duration of the infant formula cost containment contracts for each bid group will be determined by FNS in consultation with the State agencies. The term will be for a period of not less than 2 years, unless the law applicable to a State agency regarding the duration of infant formula cost

containment contracts is more restrictive than this paragraph (1)(5)(iii). In such cases, the term of the contract for only that State agency will be for one year, with the option provided to the State agency to extend the contract for a specified number of additional years (to be determined by FNS in consultation with the State agency). The date on which the individual State agencies' current infant formula cost containment contracts terminate may vary, so the infant formula cost containment contracts awarded by the State agencies within a bid group may begin on different dates.

(iv) FNS will not prescribe conditions that are prohibited under paragraph (j) of this section.

(v) FNS will solicit bids for rebates only from infant formula manufacturers. FNS may limit advertising to contacting in writing each infant formula manufacturer which has registered with the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(6) FNS will select the winning bidder(s). The winning bidder(s) will be the responsive and responsible bidder(s) meeting the specifications and all bid terms and conditions which offers the lowest net price weighted to take into account infant formula usage rates and infant participation. In all instances the winning bidder(s) will be those which singly or in combination yield the greatest aggregate savings based on the net price weighted to take into account the infant formula usage rates. To break a tie between 2 equally low bids, FNS will select the bidder to be awarded the infant formula cost containment contract by a drawing by lot limited to the bidders which submitted those bids.

(7) Once FNS has conducted bid selection, a State agency may decline to award the infant formula cost containment contract(s) only if the State agency determines that awarding the contract(s) would not be in the best interests of its Program, taking into account whether the national bid solicitation and selection would achieve a lower aggregate savings.

(8) As soon as practicable after selecting the winning bid(s), FNS will no-

tify the affected State agencies in writing of the bid results, including the name(s) of the winning bidder(s). If a State agency chooses to request approval to decline to award the infant formula cost containment contract(s) in accordance with paragraph (1)(7) of this section, it must notify FNS in writing, signed by a responsible State agency official, together with supporting documentation, by certified mail, return receipt requested or by hand delivery with evidence of receipt within 10 days of the State agency's receipt of this notification of bid results.

(9) If FNS approves any State agency's request to decline to award the infant formula cost containment contract(s) in accordance with paragraphs (1)(7) and (1)(8) of this section, FNS will notify the bidders of the decision. If two or more State agencies remain in the group, FNS will require the bidders to indicate in writing whether they wish to withdraw or modify their bids within 5 days of receipt of this notification. FNS will again permit State agencies to decline to award the infant formula cost containment contract(s) in accordance with paragraphs (1)(7) and (1)(8) of this section. If FNS approves these additional State agency requests to decline contract awards, FNS may conduct a resolicitation of bids in accordance with this paragraph (1).

(m) *What are the penalties for disclosing the amount of the bid or discount practices prior to the time bids are opened?* Any person, company, corporation, or other legal entity that submits a bid in response to a bid solicitation and discloses the amount of the bid, or the rebate or discount practices of such entities, in advance of the time the bids are opened by the Secretary or the State agency, shall be ineligible to submit bids to supply infant formula to the program for the bidding in progress for up to 2 years from the date the bids are opened. In addition, any person, company, corporation, or other legal entity shall be subject to a civil money penalty as specified in § 3.91(b)(3)(iv) of

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this title, as determined by the Secretary to provide restitution to the program for harm done to the program.

[65 FR 51224, Aug. 23, 2000, as amended at 73 FR 11313, Mar. 3, 2008; 73 FR 21811, Apr. 23, 2008]

§ 246.17 Closeout procedures.

(a) *General.* State agencies shall submit preliminary and final closeout reports for each fiscal year. All obligations shall be liquidated before closure of a fiscal year grant. Obligations shall be reported for the fiscal year in which they occur.

(b) *Fiscal year closeout reports.* State agencies—

(1) Shall submit to FNS, within 30 days after the end of the fiscal year, preliminary financial reports which show cumulative actual expenditures and obligations for the fiscal year, or part thereof, for which Program funds were made available;

(2) Shall submit to FNS, within 120 days after the end of the fiscal year, final fiscal year closeout reports;

(3) May submit revised closeout reports. FNS will reimburse State agencies for additional costs claimed in a revised closeout report up to the State's original grant level, if costs are properly justified and if funds are available for the fiscal year pertaining to the request. FNS will not be responsible for reimbursing State agencies for unreported expenditures later than one year after the end of the fiscal year in which they were incurred.

(c) *Grant closeout procedures.* When grants to State agencies are terminated, the following procedures shall be performed in accordance with 7 CFR part 3016.

(1) FNS may disqualify a State agency's participation under the Program, in whole or in part, or take such remedies as may be legal and appropriate, whenever FNS determines that the State agency failed to comply with the conditions prescribed in this part, in its Federal-State Agreement, or in FNS guidelines and instructions. FNS will promptly notify the State agency in writing of the disqualification together with the effective date. A State agency shall disqualify a local agency by written notice whenever it is determined by FNS or the State agency that

the local agency has failed to comply with the requirements of the Program.

(2) FNS or the State agency may disqualify the State agency or restrict its participation in the Program when both parties agree that continuation under the Program would not produce beneficial results commensurate with the further expenditure of funds. The State agency or the local agency may disqualify the local agency or restrict its participation in the Program under the same conditions. The two parties shall agree upon the conditions of disqualification, including the effective date thereof, and, in the case of partial disqualification, the portion to be disqualified.

(3) Upon termination of a grant, the affected agency shall not incur new obligations for the disqualified portion after the effective date, and shall cancel as many outstanding obligations as possible. FNS will allow full credit to the State agency for the Federal share of the noncancellable obligations properly incurred by the State agency prior to disqualification, and the State agency shall do the same for the local agency.

(4) A grant closeout shall not affect the retention period for, or Federal rights of access to, grant records as specified in §246.25. The closeout of a grant does not affect the State or local agency's responsibilities regarding property or with respect to any Program income for which the State or local agency is still accountable.

(5) A final audit is not a required part of the grant closeout and should not be needed unless there are problems with the grant that require attention. If FNS considers a final audit to be necessary, it shall so inform OIG. OIG will be responsible for ensuring that necessary final audits are performed and for any necessary coordination with other Federal cognizant audit agencies or the State or local auditors. Audits performed in accordance with §246.20 may serve as final audits providing such audits meet the needs of requesting agencies. If the grant is closed out without the audit, FNS reserves the right to disallow and recover an appropriate amount after fully considering

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any recommended disallowances resulting from an audit which may be conducted later.

[50 FR 6121, Feb. 13, 1985, as amended at 71 FR 56731, Sept. 27, 2006]

§ 246.18 Administrative review of State agency actions.

(a) *Adverse actions subject to administrative reviews—(1) Vendor appeals—(i) Adverse actions subject to full administrative reviews.* Except as provided elsewhere in paragraph (a)(1) of this section, the State agency must provide full administrative reviews to vendors that appeal the following adverse actions:

(A) Denial of authorization based on the application of the vendor selection criteria for minimum variety and quantity of authorized supplemental foods (§246.12(g)(3)(i)), or on a determination that the vendor is attempting to circumvent a sanction (§246.12(g)(6));

(B) Termination of an agreement for cause;

(C) Disqualification; and

(D) Imposition of a fine or a civil money penalty in lieu of disqualification.

(ii) *Adverse actions subject to abbreviated administrative reviews.* The State agency must provide abbreviated administrative reviews to vendors that appeal the following adverse actions, unless the State agency decides to provide full administrative reviews for any of these types of adverse actions:

(A) Denial of authorization based on the vendor selection criteria for business integrity or for a current Food Stamp Program disqualification or civil money penalty for hardship (§246.12(g)(3)(ii) and (g)(3)(iii));

(B) Denial of authorization based on the application of the vendor selection criteria for competitive price (§246.12(g)(4));

(C) The application of the State agency's vendor peer group criteria and the criteria used to identify vendors that are above-50-percent vendors or comparable to above-50-percent vendors;

(D) Denial of authorization based on a State agency-established vendor selection criterion if the basis of the denial is a WIC vendor sanction or a Food

Stamp Program withdrawal of authorization or disqualification;

(E) Denial of authorization based on the State agency's vendor limiting criteria (§246.12(g)(2));

(F) Denial of authorization because a vendor submitted its application outside the timeframes during which applications are being accepted and processed as established by the State agency under §246.12(g)(8);

(G) Termination of an agreement because of a change in ownership or location or cessation of operations (§246.12(h)(3)(xvii));

(H) Disqualification based on a trafficking conviction (§246.12(1)(1)(i));

(I) Disqualification based on the imposition of a Food Stamp Program civil money penalty for hardship (§246.12(1)(2)(ii)); and

(J) Disqualification or a civil money penalty imposed in lieu of disqualification based on a mandatory sanction imposed by another WIC State agency (§246.12(1)(2)(iii)).

(K) A civil money penalty imposed in lieu of disqualification based on a Food Stamp Program disqualification under §246.12(1)(1)(vii) and,

(L) Denial of an application based on a determination of whether an applicant vendor is currently authorized by the Food Stamp Program.

(iii) *Actions not subject to administrative reviews.* The State agency may not provide administrative reviews pursuant to this section to vendors that appeal the following actions:

(A) The validity or appropriateness of the State agency's vendor limiting criteria (§246.12(g)(2)) or vendor selection criteria for minimum variety and quantity of supplemental foods, business integrity, and current Supplemental Nutrition Assistance Program disqualification or civil money penalty for hardship (§246.12(g)(3));

(B) The validity or appropriateness of the State agency's selection criteria for competitive price (§246.12(g)(4)), including, but not limited to, vendor peer group criteria and the criteria used to identify vendors that are above-50-percent vendors or comparable to above-50-percent vendors;

(C) The validity or appropriateness of the State agency's participant access

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criteria and the State agency's participant access determinations;

(D) The State agency's determination to include or exclude an infant formula manufacturer, wholesaler, distributor, or retailer from the list required pursuant to § 246.12(g)(11);

(E) The validity or appropriateness of the State agency's prohibition of incentive items and the State agency's denial of an above-50-percent vendor's request to provide an incentive item to customers pursuant to § 246.12(h)(8);

(F) The State agency's determination whether to notify a vendor in writing when an investigation reveals an initial violation for which a pattern of violations must be established in order to impose a sanction, pursuant to § 246.12(l)(3);

(G) The State agency's determination whether a vendor had an effective policy and program in effect to prevent trafficking and that the ownership of the vendor was not aware of, did not approve of, and was not involved in the conduct of the violation (§ 246.12(l)(1)(i)(B));

(H) Denial of authorization if the State agency's vendor authorization is subject to the procurement procedures applicable to the State agency;

(I) The expiration of a vendor's agreement;

(J) Disputes regarding food instrument or cash-value voucher payments and vendor claims (other than the opportunity to justify or correct a vendor overcharge or other error, as permitted by § 246.12(k)(3); and

(K) Disqualification of a vendor as a result of disqualification from the Food Stamp Program (§ 246.12(l)(1)(vii)).

(2) *Effective date of adverse actions against vendors.* The State agency must make denials of authorization and disqualifications imposed under § 246.12(l)(1)(i) effective on the date of receipt of the notice of adverse action. The State agency must make all other adverse actions effective no earlier than 15 days after the date of the notice of the adverse action and no later than 90 days after the date of the notice of adverse action or, in the case of an adverse action that is subject to administrative review, no later than the date the vendor receives the review decision.

(3) *Local agency appeals—(i) Adverse actions subject to full administrative reviews.* Except as provided in paragraph (a)(3)(ii) of this section, the State agency must provide full administrative reviews to local agencies that appeal the following adverse actions:

(A) Denial of a local agency's application;

(B) Disqualification of a local agency; and

(C) Any other adverse action that affects a local agency's participation.

(ii) *Actions not subject to administrative reviews.* The State agency may not provide administrative reviews pursuant to this section to local agencies that appeal the following actions:

(A) Expiration of the local agency's agreement; and

(B) Denial of a local agency's application if the State agency's local agency selection is subject to the procurement procedures applicable to the State agency;

(iii) *Effective date of adverse actions against local agencies.* The State agency must make denials of local agency applications effective immediately. The State agency must make all other adverse actions effective no earlier than 60 days after the date of the notice of the adverse action and no later than 90 days after the date of the notice of adverse action or, in the case of an adverse action that is subject to administrative review, no later than the date the local agency receives the review decision.

(4) *Farmer appeals—(i) Adverse Actions.* The State agency shall provide a hearing procedure whereby farmers adversely affected by certain actions of the State agency may appeal those actions. A farmer may appeal an action of the State agency denying its application to participate, imposing a sanction, or disqualifying it from participation in the program. Expiration of an agreement is not subject to appeal.

(ii) *Effective date of adverse actions against farmers.* The State agency must make denials of authorization and disqualifications effective on the date of receipt of the notice of adverse action. The State agency must make all other adverse actions effective no earlier than 15 days after the date of the notice of the adverse action and no later

than 90 days after the date of the notice of adverse action or, in the case of an adverse action that is subject to administrative review, no later than the date the farmer receives the review decision.

(b) *Full administrative review procedures.* The State agency must develop procedures for a full administrative review of the adverse actions listed in paragraphs (a)(1)(i), (a)(3) and (a)(4) of this section. At a minimum, these procedures must provide the vendor, farmer or local agency with the following:

(1) Written notification of the adverse action, the procedures to follow to obtain a full administrative review and the cause(s) for and the effective date of the action. When a vendor is disqualified due in whole or in part to violations in § 246.12(1)(1), such notification must include the following statement: "This disqualification from WIC may result in disqualification as a retailer in the Food Stamp Program. Such disqualification is not subject to administrative or judicial review under the Food Stamp Program."

(2) The opportunity to appeal the adverse action within a time period specified by the State agency in its notification of adverse action.

(3) Adequate advance notice of the time and place of the administrative review to provide all parties involved sufficient time to prepare for the review.

(4) The opportunity to present its case and at least one opportunity to reschedule the administrative review date upon specific request. The State agency may set standards on how many review dates can be scheduled, provided that a minimum of two review dates is allowed.

(5) The opportunity to cross-examine adverse witnesses. When necessary to protect the identity of WIC Program investigators, such examination may be conducted behind a protective screen or other device (also referred to as an "in camera" examination).

(6) The opportunity to be represented by counsel.

(7) The opportunity to examine prior to the review the evidence upon which the State agency's action is based.

(8) An impartial decision-maker, whose determination is based solely on

whether the State agency has correctly applied Federal and State statutes, regulations, policies, and procedures governing the Program, according to the evidence presented at the review. The State agency may appoint a reviewing official, such as a chief hearing officer or judicial officer, to review appeal decisions to ensure that they conform to approved policies and procedures.

(9) Written notification of the review decision, including the basis for the decision, within 90 days from the date of receipt of a vendor's request for an administrative review, and within 60 days from the date of receipt of a local agency's request for an administrative review. These timeframes are only administrative requirements for the State agency and do not provide a basis for overturning the State agency's adverse action if a decision is not made within the specified timeframe.

(c) *Abbreviated administrative review procedures.* Except when the State agency decides to provide full administrative reviews for the adverse actions listed in paragraph (a)(1)(ii) of this section, the State agency must develop procedures for an abbreviated administrative review of the adverse actions listed in paragraph (a)(1)(ii) of this section. At a minimum, these procedures must provide the vendor with the following:

(1) Written notification of the adverse action, the procedures to follow to obtain an abbreviated administrative review, the cause(s) for and the effective date of the action, and an opportunity to provide a written response; and

(2) A decision-maker who is someone other than the person who rendered the initial decision on the action and whose determination is based solely on whether the State agency has correctly applied Federal and State statutes, regulations, policies, and procedures governing the Program, according to the information provided to the vendor concerning the cause(s) for the adverse action and the vendor's response; and

(3) Written notification of the review decision, including the basis for the decision, within 90 days of the date of receipt of the request for an administrative review. This timeframe is only an

administrative requirement for the State agency and does not provide a basis for overturning the State agency's adverse action if a decision is not made within the specified timeframe.

(d) *Continuing responsibilities.* Appealing an action does not relieve a local agency, farmer or vendor that is permitted to continue program operations while its appeal is in process from the responsibility of continued compliance with the terms of any written agreement with the State agency.

(e) *Finality and effective date of decisions.* The State agency procedures must provide that review decisions rendered under both the full and abbreviated review procedures are the final State agency action. If the adverse action under review has not already taken effect, the State agency must make the action effective on the date of receipt of the review decision by the vendor, farmer or local agency.

(f) *Judicial review.* If the review decision upholds the adverse action against the vendor, farmer or local agency, the State agency must inform the vendor, farmer or local agency that it may be able to pursue judicial review of the decision.

[65 FR 83266, Dec. 29, 2000, as amended at 70 FR 71724, Nov. 29, 2005; 73 FR 68998, Dec. 6, 2007; 73 FR 21811, Apr. 23, 2008; 74 FR 557, Jan. 6, 2009; 74 FR 51759, Oct. 8, 2009]

Subpart F—Monitoring and Review

§ 246.19 Management evaluation and monitoring reviews.

(a) *Management evaluations and reviews.* (1) FNS and each State agency shall establish a management evaluation system in order to assess the accomplishment of Program objectives as provided under this part, FNS guidelines, instructions, and the Federal-State agreement with the Department. FNS will provide assistance to States in discharging this responsibility, establish standards and procedures to determine how well the objectives of this part are being accomplished, and implement sanction procedures as warranted by State Program performance.

(2) The State agency must submit a corrective action plan, including implementation timeframes, within 60 days of receipt of an FNS management

evaluation report containing a finding that the State agency did not comply with program requirements. If FNS determines through a management evaluation or other means that during a fiscal year the State agency has failed, without good cause, to demonstrate efficient and effective administration of its program, or has failed to comply with its corrective action plan, or any other requirements contained in this part or the State Plan, FNS may withhold an amount up to 100 percent of the State agency's nutrition services and administration funds for that year.

(3) Sanctions imposed upon a State agency by FNS in accordance with this section (but not claims for repayment assessed against a State agency) may be appealed in accordance with the procedures established in § 246.22. Before carrying out any sanction against a State agency, the following procedures will be followed:

(i) FNS will notify the Chief State Health Officer or equivalent in writing of the deficiencies found and of FNS' intention to withhold nutrition services and administration funds unless an acceptable corrective action plan is submitted by the State agency to FNS within 60 days after mailing of notification.

(ii) The State agency shall develop a corrective action plan with a schedule according to which the State agency shall accomplish various actions to correct the deficiencies and prevent their future recurrence.

(iii) If the corrective action plan is acceptable, FNS will notify the Chief State Health Officer or equivalent in writing within 30 days of receipt of the plan. The letter approving the corrective action plan will describe the technical assistance that is available to the State agency to correct the deficiencies. The letter will also advise the Chief State Health Officer or equivalent of the sanctions to be imposed if the corrective action plan is not implemented according to the schedule set forth in the approved plan.

(iv) Upon notification from the State agency that corrective action has been taken, FNS will assess such action, and, if necessary, will perform a follow-up review to determine if the noted deficiencies have been corrected. FNS

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will then advise the State agency of whether the actions taken are in compliance with the corrective action plan, and whether the deficiency is resolved or further corrective action is needed.

(v) If an acceptable corrective action plan is not submitted within 60 days, or if corrective action is not completed according to the schedule established in the corrective action plan, FNS may withhold nutrition services and administration funds through a reduction of the State agency Letter of Credit or by assessing a claim against the State agency. FNS will notify the Chief State Health Officer or equivalent of this action.

(vi) If compliance is achieved before the end of the fiscal year in which the nutrition services and administration funds are withheld, the funds withheld shall be restored to the State agency's Letter of Credit. FNS is not required to restore funds withheld if compliance is not achieved until the subsequent fiscal year. If the 60-day warning period ends in the fourth quarter of a fiscal year, FNS may elect not to withhold funds until the next fiscal year.

(b) *State agency responsibilities.* (1) The State agency shall establish an ongoing management evaluation system which includes at least the monitoring of local agency operations, the review of local agency financial and participation reports, the development of corrective action plans to resolve Program deficiencies, the monitoring of the implementation of corrective action plans, and on-site visits. The results of such actions shall be documented.

(2) Monitoring of local agencies must encompass evaluation of management, certification, nutrition education, participant services, civil rights compliance, accountability, financial management systems, and food delivery systems. If the State agency delegates the signing of vendor agreements, vendor training, or vendor monitoring to a local agency, it must evaluate the local agency's effectiveness in carrying out these responsibilities.

(3) The State agency shall conduct monitoring reviews of each local agency at least once every two years. Such reviews shall include on-site reviews of a minimum of 20 percent of the clinics in each local agency or one clinic,

whichever is greater. The State agency may conduct such additional on-site reviews as the State agency determines to be necessary in the interest of the efficiency and effectiveness of the program.

(4) The State agency must promptly notify a local agency of any finding in a monitoring review that the local agency did not comply with program requirements. The State agency must require the local agency to submit a corrective action plan, including implementation timeframes, within 60 days of receipt of a State agency report of a monitoring review containing a finding of program noncompliance. The State agency must monitor local agency implementation of corrective action plans.

(5) As part of the regular monitoring reviews, FNS may require the State agency to conduct in-depth reviews of specified areas of local agency operations, to implement a standard form or protocol for such reviews, and to report the results to FNS. No more than two such areas will be stipulated by FNS for any fiscal year and the areas will not be added or changed more often than once every two fiscal years. These areas will be announced by FNS at least six months before the beginning of the fiscal year.

(6) The State agency shall require local agencies to establish management evaluation systems to review their operations and those of associated clinics or contractors.

[50 FR 6121, Feb. 13, 1985, as amended at 59 FR 11508, Mar. 11, 1994]

§ 246.20 Audits.

(a) *Federal audit responsibilities.* (1) OIG reserves the right to perform audits of State and local agencies and other organizations involved in the Program as determined by OIG to be necessary. In performing such audits, OIG will rely to the extent feasible on audit work performed by other Federal and non-Federal auditors.

(2) The State agency may take exception to particular audit findings and recommendations. The State agency shall submit a response or statement to FNS as to the action taken or a proposed corrective action plan regarding

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the findings. A proposed corrective action plan developed and submitted by the State agency shall include specific timeframes for its implementation and for completion of correction of deficiencies and their causes.

(3) FNS will determine whether Program deficiencies have been adequately corrected. If additional corrective action is necessary, FNS shall schedule a follow-up review, allowing a reasonable time for such corrective action to be taken.

(b) *State audit responsibilities.* (1) State agencies must obtain annual audits in accordance with part 3052 of this title. In addition, States must require local agencies under their jurisdiction to obtain audits in accordance with part 3052 of this title.

(2) Each State agency shall make all State or local agency sponsored audit reports of Program operations under its jurisdiction available for the Department's review upon request. The cost of these audits shall be considered a part of nutrition services and administration costs and may be funded from the State or local agency nutrition services and administration funds, as appropriate. For purposes of determining the Program's pro rata share of indirect costs associated with organization-wide audits, the cost of food shall not be considered in the total dollar amount of the Program.

[50 FR 6121, Feb. 13, 1985, as amended at 71 FR 56731, Sept. 27, 2006]

§ 246.21 Investigations.

(a) *Authority.* The Department may make an investigation of any allegation of noncompliance with this part and FNS guidelines and instructions. The investigation may include, where appropriate, a review of pertinent practices and policies of any State or local agency, the circumstances under which the possible noncompliance with this part occurred, and other factors relevant to a determination as to whether the State or local agency has failed to comply with the requirements of this part.

(b) *Confidentiality.* No State or local agency, participant, or other person shall intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any

right or privilege under this part because that person has made a complaint or formal allegation, or has testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this part. The identity of every complainant shall be kept confidential except to the extent necessary to carry out the purposes of this part, including the conducting of any investigation, hearing, or judicial proceeding.

Subpart G—Miscellaneous Provisions

§ 246.22 Administrative appeal of FNS decisions.

(a) *Right to appeal.* When FNS asserts a sanction against a State agency under the provisions of § 246.19, the State agency may appeal and must be afforded a hearing or review by an FNS Administrative Review Officer. The right of appeal shall not apply to claims for repayment assessed by FNS against the State agency under § 246.23(a). A State agency shall have the option of requesting a hearing to present its position or a review of pertinent documents and records including any additional written submission prepared by the State agency.

(1) FNS will send a written notice by Certified Mail-Return Receipt Requested to the state agency or otherwise ensure receipt of such notice by the agency when asserting a sanction against a State agency as specified in § 246.19(a).

(2) A State agency aggrieved by a sanction asserted against it may file a written request with the Director, Administrative Review Division, U.S. Department of Agriculture, Food and Nutrition Service, 3101 Park Center Drive, Alexandria, Va. 22302, for a hearing or a review of the record. Such request shall be sent by Certified Mail-Return Receipt Requested and postmarked within 30 days of the date of receipt of the sanction notice. The envelope containing the request shall be prominently marked "REQUEST FOR REVIEW OR HEARING." The request shall clearly identify the specific FNS sanction(s) being appealed and shall include a photocopy of the FNS notice of sanction. If the State agency does not

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request a review of hearing within 30 days of receipt of the notice, the administrative decision on the sanctions will be considered final.

(b) *Acknowledgment of request.* Within 15 days of receipt by the Director of the Administrative Review Division of a request for review or hearing, the Director will provide the State agency with a written acknowledgment of the request.

(1) The acknowledgment will include the name and address of the FNS Administrative Review Officer to review the sanction;

(2) The acknowledgment will also notify the State agency that within 30 days of the receipt of the acknowledgment, the State agency shall submit three sets of the following information to the Administrative Review Officer—

(i) A clear, concise identification of the issue(s) in dispute;

(ii) The State agency's position with respect to the issue(s) in dispute;

(iii) The pertinent facts and reasons in support of the State agency's position with respect to the issue(s) in dispute and a copy of the specific sanction notice provided by FNS;

(iv) All pertinent documents, correspondence and records which the State agency believes are relevant and helpful toward a more thorough understanding of the issue(s) in dispute;

(v) The relief sought by the State agency;

(vi) The identity of the person(s) presenting the State agency's position when a hearing is involved; and

(vii) A list of prospective State agency witnesses when a hearing is involved.

(c) *FNS action.* (1) When a hearing is requested pursuant to this section, the Administrative Review Officer will, within 60 days after receipt of the State agency's information, schedule and conduct the hearing. The State agency will be advised of the time, date and location of the hearing at least 10 days in advance.

(2) When a hearing is requested, the FNS Administrative Review Officer will make a final determination within 30 days after the hearing, and the final determination will take effect upon delivery of the written notice of this final decision to the State agency.

(3) When a review is requested, the FNS Administrative Review Officer will review information presented by a State agency and will make a final determination within 30 days after receipt of that information. The final determination will take effect upon delivery of the written notice of this final decision to the State agency.

§ 246.23 Claims and penalties.

(a) *Claims against State agencies.* (1) If FNS determines through a review of the State agency's reports, program or financial analysis, monitoring, audit, or otherwise, that any Program funds provided to a State agency for supplemental foods or nutrition services and administration purposes were, through State or local agency negligence or fraud, misused or otherwise diverted from Program purposes, a formal claim will be assessed by FNS against the State agency. The State agency shall pay promptly to FNS a sum equal to the amount of the nutrition services and administration funds or the value of supplemental foods or food instruments so misused or diverted.

(2) If FNS determines that any part of the Program funds received by a State agency; or supplemental foods, either purchased or donated commodities; or food instruments, were lost as a result of thefts, embezzlements, or unexplained causes, the State agency shall, on demand by FNS, pay to FNS a sum equal to the amount of the money or the value of the supplemental foods or food instruments so lost.

(3) The State agency shall have full opportunity to submit evidence, explanation or information concerning alleged instances of noncompliance or diversion before a final determination is made in such cases.

(4) FNS will establish a claim against any State agency that has not accounted for the disposition of all redeemed food instruments and cash-value vouchers and taken appropriate follow-up action on all redeemed food instruments and cash-value vouchers that cannot be matched against valid enrollment and issuance records, including cases that may involve fraud,

unless the State agency has demonstrated to the satisfaction of FNS that it has:

(i) Made every reasonable effort to comply with this requirement;

(ii) Identified the reasons for its inability to account for the disposition of each redeemed food instrument or cash-value voucher; and

(iii) Provided assurances that, to the extent considered necessary by FNS, it will take appropriate actions to improve its procedures.

(b) *Interest charge on claims against State agencies.* If an agreement cannot be reached with the State agency for payment of its debts or for offset of debts on its current Letter of Credit within 30 days from the date of the first demand letter from FNS, FNS will assess an interest (late) charge against the State agency. Interest accrual shall begin on the 31st day after the date of the first demand letter, bill or claim, and shall be computed monthly on any unpaid balance as long as the debt exists. From a source other than the Program, the State agency shall provide the funds necessary to maintain Program operations at the grant level authorized by FNS.

(c) *Claims—(1) Claims against participants.* (i) *Procedures.* If the State agency determines that program benefits have been obtained or disposed of improperly as the result of a participant violation, the State agency must establish a claim against the participant for the full value of such benefits. For all claims, the State agency must issue a letter demanding repayment. If full restitution is not made or a repayment schedule is not agreed on within 30 days of receipt of the letter, the State agency must take additional collection actions until restitution is made or a repayment schedule is agreed on, unless the State agency determines that further collection actions would not be cost-effective. The State agency must establish standards, based on a cost benefit analysis, for determining when collection actions are no longer cost-effective. At the time the State agency issues the demand letter, the State agency must advise the participant of the procedures to follow to obtain a fair hearing pursuant to §246.9 and that failure to pay the claim may result in

disqualification. In addition to establishing a claim, the State agency must determine whether disqualification is required by §246.12(u)(2).

(ii) *Types of restitution.* In lieu of financial restitution, the State agency may allow participants or parents or caretakers of infant or child participants for whom financial restitution would cause undue hardship to provide restitution by performing in-kind services determined by the State agency. Restitution may not include offsetting the claim against future program benefits, even if agreed to by the participant or the parent or caretaker of an infant or child participant.

(iii) *Disposition of claims.* The State agency must document the disposition of all participant claims.

(2) *Claims against the State agency.* FNS will assert a claim against the State agency for losses resulting from program funds improperly spent as a result of dual participation, if FNS determines that the State agency has not complied with the requirements in §246.7(1)(1).

(3) *Delegation of claims responsibility.* The State agency may delegate to its local agencies the responsibility for collecting participant claims.

(d) *Penalties.* In accordance with section 12(g) of the National School Lunch Act, whoever embezzles, willfully misapplies, steals or obtains by fraud any funds, assets or property provided under section 17 of the Child Nutrition Act of 1966, as amended, whether received directly or indirectly from USDA, or whoever receives, conceals or retains such funds, assets or property for his or her own interest, knowing such funds, assets or property have been embezzled, willfully misapplied, stolen, or obtained by fraud shall, if such funds, assets or property are of the value of \$100 or more, be fined not more than \$25,000 or imprisoned not more than five years, or both, or if such funds, assets or property are of a value of less than \$100, shall be fined not more than \$1,000 or imprisoned not more than one year, or both.

[50 FR 6121, Feb. 13, 1985, as amended at 52 FR 21238, June 4, 1987; 65 FR 83288, Dec. 29, 2000; 71 FR 56731, Sept. 27, 2006; 72 FR 68998, Dec. 6, 2007]

§ 246.24 Procurement and property management.

(a) *Requirements.* State and local agencies shall ensure that subgrantees comply with the requirements of 7 CFR part 3016, the nonprocurement debarment/suspension requirements of 7 CFR part 3017, and if applicable, the lobbying restrictions as required in 7 CFR part 3018 concerning the procurement and allowability of food in bulk lots, supplies, equipment and other services with Program funds. These requirements are adopted to ensure that such materials and services are obtained for the Program in an effective manner and in compliance with the provisions of applicable law and executive orders.

(b) *Contractual responsibilities.* The standards contained in A–130 and 7 CFR part 3016 do not relieve the State or local agency of the responsibilities arising under its contracts. The State agency is the responsible authority, without recourse to FNS, regarding the settlement and satisfaction of all contractual and administrative issues arising out of procurements entered into in connection with the Program. This includes, but is not limited to, disputes, claims, protests of award, source evaluation, or other matters of a contractual nature. Matters concerning violation of law are to be referred to such local, State or Federal authority as may have proper jurisdiction.

(c) *State regulations.* The State or local agency may use its own procurement regulations which reflect applicable State and local regulations, provided that procurements made with Program funds adhere to the standards set forth in A–130 and 7 CFR part 3016.

(d) *Property acquired with Program funds.* State and local agencies shall observe the standards prescribed in 7 CFR part 3016 in their utilization and disposition of real property and equipment, including automated data processing equipment, acquired in whole or in part with Program funds.

[50 FR 6121, Feb. 13, 1985, as amended at 59 FR 11508, Mar. 11, 1994]

§ 246.25 Records and reports.

(a) *Recordkeeping requirements.* Each State and local agency shall maintain full and complete records concerning

Program operations. Such records shall comply with 7 CFR part 3016 and the following requirements:

(1) Records shall include, but not be limited to, information pertaining to financial operations, food delivery systems, food instrument issuance and redemption, equipment purchases and inventory, certification, nutrition education, civil rights and fair hearing procedures.

(2) All records shall be retained for a minimum of three years following the date of submission of the final expenditure report for the period to which the report pertains. If any litigation, claim, negotiation, audit or other action involving the records has been started before the end of the three-year period, the records shall be kept until all issues are resolved, or until the end of the regular three-year period, whichever is later. If FNS deems any of the Program records to be of historical interest, it may require the State or local agency to forward such records to FNS whenever either agency is disposing of them.

(3) Records for nonexpendable property acquired in whole or in part with Program funds shall be retained for three years after its final disposition.

(4) All records shall be available during normal business hours for representatives of the Department and the Comptroller General of the United States to inspect, audit, and copy. Any reports or other documents resulting from the examination of such records that are publicly released may not include confidential applicant or participant information.

(b) *Financial and participation reports—(1) Monthly reports.* (i) State agencies must submit financial and program performance data on a monthly basis, as specified by FNS, to support program management and funding decisions. Such information must include, but may not be limited to:

(A) Actual and projected participation;

(B) Actual and projected food funds expenditures;

(C) A listing by source year of food and NSA funds available for expenditure; and,

(D) NSA expenditures and unliquidated obligations.

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(ii) State agencies must require local agencies to report such financial and participation information as is necessary for the efficient management of food and NSA funds expenditures.

(2) *Annual reports.* (i) Every year, State agencies must report to FNS the average number of migrant farmworker household members participating in the Program during a 12-month period of time specified by FNS.

(ii) State agencies must submit itemized NSA expenditure reports annually as an addendum to their WIC Program closeout reports, as required by § 246.17(b)(2).

(3) *Biennial reports.* (i) *Participant characteristics report.* State and local agencies must provide such information as may be required by FNS to provide a biennial participant characteristics report. This includes, at a minimum, information on income and nutritional risk characteristics of participants, information on breastfeeding incidence and duration, and participation in the Program by category (i.e., pregnant, breastfeeding and postpartum women, infants and children) within each priority level (as established in § 246.7(e)(4)) and by migrant farmworker households.

(ii) *Civil rights report.* Racial and ethnic participation data contained in the biennial participant characteristics report will also be used to fulfill civil rights reporting requirements.

(c) *Other reports.* State agencies must submit reports to reflect additions and deletions of local agencies administering the WIC Program and local agency address changes as these events occur.

(d) *Source documentation.* To be acceptable for audit purposes, all financial and Program performance reports shall be traceable to source documentation.

(e) *Certification of reports.* Financial and Program reports shall be certified as to their completeness and accuracy by the person given that responsibility by the State agency.

(f) *Use of reports.* FNS will use State agency reports to measure progress in achieving objectives set forth in the State Plan, and this part, or other State agency performance plans. If it is determined, through review of State

agency reports, Program or financial analysis, or an audit, that a State agency is not meeting the objectives set forth in its State Plan, FNS may request additional information including, but not limited to, reasons for failure to achieve its objectives.

(g) *Extension of reporting deadline.* FNS may extend the due date for any Financial and Participation Report upon receiving a justified request from the State agency. The State agency should not wait until the due date if an extension is to be requested, but should submit the request as soon as the need is known. Failure by a State agency to submit a report by its due date may result in appropriate enforcement actions by FNS in accordance with § 246.19(a)(2), including withholding of further grant payments, suspension or termination of the grant.

[50 FR 6121, Feb. 13, 1985, as amended at 52 FR 21238, June 4, 1987; 53 FR 15653, May 3, 1988; 59 FR 11508, Mar. 11, 1994; 65 FR 53528, Sept. 5, 2000; 71 FR 56731, Sept. 27, 2006; 72 FR 24183, May 2, 2007]

§ 246.26 Other provisions.

(a) *No aid reduction.* The value of benefits or assistance available under the Program shall not be considered as income or resources of participants or their families for any purpose under Federal, State, or local laws, including, but not limited to, laws relating to taxation, welfare and public assistance programs.

(b) *Statistical information.* FNS reserves the right to use information obtained under the Program in a summary, statistical or other form which does not identify particular individuals.

(c) *Medical information.* FNS may require the State or local agencies to supply medical data and other information collected under the Program in a form that does not identify particular individuals, to enable the Secretary or the State agencies to evaluate the effect of food intervention upon low-income individuals determined to be at nutritional risk.

(d) *Confidentiality of applicant and participant information—(1) WIC purposes.* (i) Confidential applicant and

participant information is any information about an applicant or participant, whether it is obtained from the applicant or participant, another source, or generated as a result of WIC application, certification, or participation, that individually identifies an applicant or participant and/or family member(s). Applicant or participant information is confidential, regardless of the original source and exclusive of previously applicable confidentiality provided in accordance with other Federal, State or local law.

(ii) Except as otherwise permitted by this section, the State agency must restrict the use and disclosure of confidential applicant and participant information to persons directly connected with the administration or enforcement of the WIC Program whom the State agency determine have a need to know the information for WIC Program purposes. These persons may include, but are not limited to: personnel from its local agencies and other WIC State or local agencies; persons under contract with the State agency to perform research regarding the WIC Program, and persons investigating or prosecuting WIC Program violations under Federal, State or local law.

(2) *Non-WIC purposes.* (i) *Use by WIC State and local agencies.* Any WIC State or local agency may use confidential applicant and participant information in the administration of its other programs that serve persons eligible for the WIC Program in accordance with paragraph (h) of this section.

(ii) *Disclosure to public organizations.* The State agency and its local agencies may disclose confidential applicant and participant information to public organizations for use in the administration of their programs that serve persons eligible for the WIC Program in accordance with paragraph (h) of this section.

(3) *Child abuse and neglect reporting.* Staff of the State agency and its local agencies who are required by State law to report known or suspected child abuse or neglect may disclose confidential applicant and participant information without the consent of the participant or applicant to the extent necessary to comply with such law.

(4) *Release forms.* Except in the case of subpoenas or search warrants (see paragraph (i) of this section), the State agency and its local agencies may disclose confidential applicant and participant information to individuals or entities not listed in this section only if the affected applicant or participant signs a release form authorizing the disclosure and specifying the parties to which the information may be disclosed. The State or local agency must permit applicants and participants to refuse to sign the release form and must notify the applicants and participants that signing the form is not a condition of eligibility and refusing to sign the form will not affect the applicant's or participant's application or participation in the WIC Program. Release forms authorizing disclosure to private physicians or other health care providers may be included as part of the WIC application or certification process. All other requests for applicants or participants to sign voluntary release forms must occur after the application and certification process is completed.

(5) *Access to information by applicants and participants.* The State or local agency must provide applicants and participants access to all information they have provided to the WIC Program. In the case of an applicant or participant who is an infant or child, the access may be provided to the parent or guardian of the infant or child, assuming that any issues regarding custody or guardianship have been settled. However, the State or local agency need not provide the applicant or participant (or the parent or guardian of an infant or child) access to any other information in the file or record such as documentation of income provided by third parties and staff assessments of the participant's condition or behavior, unless required by Federal, State, or local law or policy or unless the information supports a State or local agency decision being appealed pursuant to § 246.9.

(e) *Confidentiality of vendor information.* Confidential vendor information is any information about a vendor (whether it is obtained from the vendor or another source) that individually

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identifies the vendor, except for vendor's name, address, telephone number, Web site/e-mail address, store type, and authorization status. Except as otherwise permitted by this section, the State agency must restrict the use or disclosure of confidential vendor information to:

(1) Persons directly connected with the administration or enforcement of the WIC Program or the Food Stamp Program who the State agency determines have a need to know the information for purposes of these programs. These persons may include personnel from its local agencies and other WIC State and local agencies and persons investigating or prosecuting WIC or Food Stamp Program violations under Federal, State, or local law;

(2) Persons directly connected with the administration or enforcement of any Federal or State law or local law or ordinance. Prior to releasing the information to one of these parties (other than a Federal agency), the State agency must enter into a written agreement with the requesting party specifying that such information may not be used or redisclosed except for purposes directly connected to the administration or enforcement of a Federal, or State law; and

(3) A vendor that is subject to an adverse action, including a claim, to the extent that the confidential information concerns the vendor subject to the adverse action and is related to the adverse action.

(4) At the discretion of the State agency, all authorized vendors and vendor applicants regarding vendor sanctions which have been imposed, identifying only the vendor's name, address, length of the disqualification or amount of the civil money penalty, and a summary of the reason(s) for such sanction provided in the notice of adverse action. Such information may be disclosed only following the exhaustion of all administrative and judicial review, in which the State agency has prevailed, regarding the sanction imposed on the subject vendor, or the time period for requesting such review has expired.

(f) *Confidentiality of Food Stamp Program retailer information.* Except as otherwise provided in this section, the

State agency must restrict the use or disclosure of information about Food Stamp Program retailers obtained from the Food Stamp Program, including information provided pursuant to Section 9(c) of the Food Stamp Act of 1977 (7 U.S.C. 2018(c)) and § 278.1(q) of this chapter, to persons directly connected with the administration or enforcement of the WIC Program.

(g) *USDA and the Comptroller General.* The State agency must provide the Department and the Comptroller General of the United States access to all WIC Program records, including confidential vendor, applicant and participant information, pursuant to § 246.25(a)(4).

(h) *Requirements for use and disclosure of confidential applicant and participant information for non-WIC purposes.* The State or local agency must take the following steps before using or disclosing confidential applicant or participant information for non-WIC purposes pursuant to paragraph (d)(2) of this section.

(1) *Designation by chief State health officer.* The chief State health officer (or, in the case of an Indian State agency, the governing authority) must designate in writing the permitted non-WIC uses of the information and the names of the organizations to which such information may be disclosed.

(2) *Notice to applicants and participants.* The applicant or participant must be notified either at the time of application (in accordance with § 246.7(i)(11)) or through a subsequent notice that the chief State health officer (or, in the case of an Indian State agency, the governing authority) may authorize the use and disclosure of information about their participation in the WIC Program for non-WIC purposes. This statement must also indicate that such information will be used by State and local WIC agencies and public organizations only in the administration of their programs that serve persons eligible for the WIC Program.

(3) *Written agreement and State plan.* The State or local agency disclosing the information must enter into a written agreement with the other public organization or, in the case of a non-WIC use by a State or local WIC agency, the unit of the State or local agency that will be using the information.

The State agency must also include in its State plan, as specified in § 246.4(a)(24), a list of all organizations (including units of the State agency or local agencies) with which the State agency or its local agencies has executed or intends to execute a written agreement. The written agreement must:

(i) Specify that the receiving organization may use the confidential applicant and participant information only for:

(A) Establishing the eligibility of WIC applicants or participants for the programs that the organization administers;

(B) Conducting outreach to WIC applicants and participants for such programs;

(C) Enhancing the health, education, or well-being of WIC applicants or participants who are currently enrolled in such programs, including the reporting of known or suspected child abuse or neglect that is not otherwise required by State law;

(D) Streamlining administrative procedures in order to minimize burdens on staff, applicants, or participants in either the receiving program or the WIC Program; and/or

(E) Assessing and evaluating the responsiveness of a State's health system to participants' health care needs and health care outcomes; and

(ii) Contain the receiving organization's assurance that it will not use the information for any other purpose or disclose the information to a third party.

(i) *Subpoenas and search warrants.* The State agency may disclose confidential applicant, participant, or vendor information pursuant to a valid subpoena or search warrant in accordance with the following procedures:

(1) *Subpoena procedures.* In determining how to respond to a subpoena duces tecum (i.e., a subpoena for documents) or other subpoena for confidential information, the State or local agency must use the following procedures:

(i) Upon receiving the subpoena, immediately notify its State agency;

(ii) Consult with legal counsel for the State or local agency and determine whether the information requested is

in fact confidential and prohibited by this section from being used or disclosed as stated in the subpoena;

(iii) If the State or local agency determines that the information is confidential and prohibited from being used or disclosed as stated in the subpoena, attempt to quash the subpoena unless the State or local agency determines that disclosing the confidential information is in the best interest of the Program. The determination to disclose confidential information without attempting to quash the subpoena should be made only infrequently; and,

(iv) If the State or local agency seeks to quash the subpoena or decides that disclosing the confidential information is in the best interest of the Program, inform the court or the receiving party that this information is confidential and seek to limit the disclosure by:

(A) Providing only the specific information requested in the subpoena and no other information; and,

(B) Limiting to the greatest extent possible the public access to the confidential information disclosed.

(2) *Search warrant procedures.* In responding to a search warrant for confidential information, the State or local agency must use the following procedures:

(i) Upon receiving the search warrant, immediately notify its State agency;

(ii) Immediately notify legal counsel for the State or local agency;

(iii) Comply with the search warrant; and,

(iv) Inform the individual(s) serving the search warrant that the information being sought is confidential and seek to limit the disclosure by:

(A) Providing only the specific information requested in the search warrant and no other information; and

(B) Limiting to the greatest extent possible the public access to the confidential information disclosed.

(j) *Data collection related to local agencies.* (1) Each State agency must collect data related to local agencies that have an agreement with the State agency to participate in the program for each of Federal fiscal years 2006 through 2009, including those local agencies that participated only for part of the fiscal year. Such data shall include:

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- (i) The name of each local agency;
- (ii) The city in which each local agency was headquartered and the name of the state;
- (iii) The amount of funds provided to the participating organization, i.e., the amount of federal funds provided for nutrition services and administration to each participating local agency; and
- (iv) The type of participating organization, e.g., government agency, educational institution, non-profit organization/secular, non-profit organization/faith-based, and "other."

(2) On or before August 31, 2007, and each subsequent year through 2010, State agencies must report to FNS data as specified in paragraph (j)(1) of this section for the prior Federal fiscal year. State agencies must submit this data in a format designated by FNS.

[50 FR 6121, Feb. 13, 1985, as amended at 53 FR 35301, Sept. 13, 1988; 65 FR 83288, Dec. 29, 2000; 71 FR 56731, Sept. 27, 2006; 72 FR 24184, May 2, 2007; 73 FR 21811, Apr. 23, 2008]

§ 246.27 Program information.

Any person who wishes information, assistance, records or other public material shall request such information from the State agency, or from the FNS Regional Office serving the appropriate State as listed below:

(a) Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Vermont: U.S. Department of Agriculture, FNS, Northeast Region, 10 Causeway Street, room 501, Boston, Massachusetts 02222-1066.

(b) Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Puerto Rico, Virginia, Virgin Islands, West Virginia: U.S. Department of Agriculture, FNS, Mid-Atlantic Region, Mercer Corporate Park, 300 Corporate Boulevard, Robbinsville, New Jersey 08691-1598.

(c) Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee: U.S. Department of Agriculture, FNS, Southeast Region, 61 Forsyth Street, SW., room 8T36, Atlanta, Georgia 30303.

(d) Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin: U.S. Department of Agriculture, FNS, Midwest Region, 77 West Jackson Boulevard—20th Floor, Chicago, Illinois 60604-3507.

(e) Arkansas, Louisiana, New Mexico, Oklahoma, Texas: U.S. Department of Agriculture, FNS, Southwest Region, 1100 Commerce Street, room 5-C-30, Dallas, Texas 75242.

(f) Colorado, Iowa, Kansas, Missouri, Montana, Nebraska, North Dakota, South Dakota, Utah, Wyoming: U.S. Department of Agriculture, FNS, Mountain Plains Region, 1244 Speer Boulevard, suite 903, Denver, Colorado 80204.

(g) Alaska, American Samoa, Arizona, California, the Commonwealth of the Northern Mariana Islands, Guam, Hawaii, Idaho, Nevada, Oregon, Washington: U.S. Department of Agriculture, FNS, Western Region, 90 Seventh Street, Suite #10-100, San Francisco, California 94103.

[50 FR 6121, Feb. 13, 1985; 50 FR 8098, Feb. 28, 1985, as amended at 59 FR 11508, Mar. 11, 1994; 71 FR 56733, Sept. 27, 2006; 73 FR 11314, Mar. 3, 2008]

§ 246.28 OMB control numbers.

The following control numbers have been assigned to the information collection requirements in 7 CFR part 246 by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96-511.

7 CFR part 246 section where requirements are described	Current OMB control no.
.4(a) (8), (9), (11)	0584-0386
.5	0584-0043
.6	0584-0043
.7(a)	0584-0386
.7(e), (h), (j)	0584-0043
.7(n)	0584-0386
.7(i)	0584-A536
.10	0584-A536
.11(a)(3)	0584-0386
.11(d)	0584-0043
.12(f), (i), (i)(3), (j)	0584-0043
.14(d)(1)	0584-0043
.16(c)	0584-0043
.17(c)(1)	0584-0043
.19	0584-0043
.20(a)	0584-0043
.25(a), (b)	0584-0043, 0584-0347

[50 FR 6121, Feb. 13, 1985, as amended at 53 FR 15653, May 3, 1988; 54 FR 51295, Dec. 14, 1989; 58 FR 11507, Feb. 26, 1993]