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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:

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.

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.

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 supplemental 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), dieticians, 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.

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

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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.

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.

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).

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.

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

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:

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(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.

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 or group education sessions and the provision of information and educational materials designed to improve health status, achieve positive change in dietary habits, and emphasize relationships between nutrition and health, all in keeping with the individual's personal, cultural, and socioeconomic preferences.

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.

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.

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

Participation means the sum of the number of persons who have received supplemental foods or food instruments during the reporting period and the number of infants breastfed by participant breastfeeding women (and receiving no supplemental foods or food instruments) during the reporting 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.

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.

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.

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.

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) and Governmentwide Requirements for Drug-Free Workplace. Part 3017 implements the requirements established by Executive Order 12549 (February 18, 1986) and sections 5151-5160 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690).

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).

State means any of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Marianas Islands, and the Trust Territory of the Pacific Islands.

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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 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 to be beneficial for pregnant, breastfeeding, and postpartum women, infants and children, as prescribed by the Secretary in §246.10.

WIC-eligible medical foods means certain enteral products that are specifically formulated to provide nutritional support for individuals with a diagnosed medical condition, when the use of conventional foods is precluded, restricted, or inadequate. Such WIC-eligible medical foods may be nutritionally complete or incomplete, but they must serve the purpose of a food, provide a source of calories and one or more nutrients, and be designed for enteral digestion via an oral or tube feeding. 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, as amended at 52 FR 25189, July 2, 1987; 54 FR 51294, Dec. 14, 1989; 55 FR 9717, Mar. 15, 1990; 58 FR 11506, Feb. 26, 1993; 58 FR 47022, Sept. 7, 1993; 59 FR 11498, Mar. 11, 1994; 63 FR 63973, Nov. 18, 1998; 64 FR 13322, Mar. 18, 1999; 64 FR 56674, Oct. 21, 1999; 65 FR 3378, Jan. 21, 2000; 65 FR 53527, Sept. 5, 2000; 65 FR 51222, Aug. 23, 2000]

EFFECTIVE DATE NOTE 1: At 65 FR 77249, Dec. 11, 2000, §246.2 was amended by adding the definition of Remote Indian or Native village, effective January 10, 2001. For the convenience of the user the added text is set forth as follows:

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* * * * *

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).

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EFFECTIVE DATE NOTE 2: At 65 FR 83277, Dec. 29, 2000, §246.2 was amended by adding the definitions of Authorized supplemental foods, Compliance buy, High-risk vendor, Home food delivery contractor, Inventory audit, Participant violation, Price adjustment, Proxy, Routine monitoring, Vendor, Vendor authorization, Vendor limiting criteria, Vendor overcharge, Vendor selection criteria, Vendor violation, and WIC, effective February 27, 2001. For the convenience of the user, the added text is set forth as follows:

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* * * * *

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

* * * * *

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, and does not reveal during the visit that he or she is a program representative.

* * * * *

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.

* * * * *

Inventory audit means the examination of food invoices or other proofs of purchase to determine whether a vendor has purchased

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sufficient quantities of supplemental foods to provide participants the quantities specified on food instruments redeemed by the vendor during a given period of time.

* * * * *

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

* * * * *

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.

* * * * *

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 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.

* * * * *

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

* * * * *

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 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).

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.

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§ 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 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