

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 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) \$8 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.

(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
<b>(i) For a single solicitation, the solicitation must require bidders to specify a rebate amount for the following:</b>		
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.
<b>(ii) For separate solicitations, the solicitation must require bidders to specify a rebate amount for the following:</b>		
(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 calculated 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 wholesale 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 pro-

urement 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 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 (l) 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 (l)(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 proce-

dures 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 notify 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,

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company, corporation, or other legal entity shall be subject to a civil money penalty as specified in § 3.91(b)(3)(iv) of 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