



July 30, 2004

**United States
Department of
Agriculture**

Food and
Nutrition
Service

3101 Park
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Alexandria, VA
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SUBJECT: WIC Policy Memorandum #2004-4
Implementation of the Infant Formula Cost Containment
Provisions of P.L. 108-265

TO: Regional Directors
Supplemental Food Programs
All Regions

BACKGROUND

This memorandum provides guidance on the implementation of the nondiscretionary infant formula cost containment provisions of Public Law 108-265, the Child Nutrition and WIC Reauthorization Act of 2004, (Reauthorization Act) enacted on June 30, 2004. This law reauthorizes the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) through September 30, 2009. The infant formula cost containment provisions addressed in this memorandum are nondiscretionary (i.e., they are to be implemented exactly as written in the law). Policy memoranda addressing other provisions in the Reauthorization Act will be issued separately.

STATE ALLIANCES

Legislative Change

Section 203(a)(3) of the Reauthorization Act amends Section 17(b) of the Child Nutrition Act of 1966, as amended, (CNA) by adding the following new definition:

“(23) STATE ALLIANCE.—The term ‘State alliance’ means 2 or more State agencies that join together for the purpose of procuring infant formula under the program by soliciting competitive bids for infant formula.”

Current Regulations

Although regulations at 7 CFR 246.2 do not include a definition of “State alliance,” State agencies have formed such alliances for the purpose of competitive bidding for many years.

Policy Change

Effective October 1, 2004, the term “State alliance” will be used in the WIC Program to refer to two or more State agencies that join together for the purpose of soliciting competitive bids for the procurement of infant formula.

The contents of this guidance document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

Guidance documents lack the force and effect of law, unless expressly authorized by statute or incorporated into a contract. USDA may not cite, use, or rely on any guidance that is not available through their guidance portal, except to establish historical facts.

Legislative Change

Section 203(e)(3) of the Reauthorization Act amends Section 17(h)(8)(A) of the CNA by adding the following:

“(iv) SIZE OF STATE ALLIANCES.—

“(I) IN GENERAL.—Except as provided in subclauses (II) through (IV), no State alliance may exist among States 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, would exceed 100,000.

“(II) ADDITION OF INFANT PARTICIPANTS.—In the case of a State alliance that exists on the date of enactment of this clause, the alliance may continue and may expand to serve more than 100,000 infants but, except as provided in subclause (III), may not expand to include any additional State agency.

“(III) ADDITION OF SMALL STATE AGENCIES AND INDIAN STATE AGENCIES.—Any State alliance may expand to include any State agency that served less than 5,000 infant participants as of October 1, 2003, or such subsequent date determined by the Secretary for which data is available, or any Indian State agency, if the State agency or Indian State agency requests to join the State alliance.

“(IV) SECRETARIAL WAIVER.—The Secretary may waive the requirements of this clause 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.”

Current Regulations

Regulations at 7 CFR 246.16a do not limit the size of a group of State agencies that join together for the purpose of soliciting competitive bids for the procurement infant formula.

Policy Change

Effective July 1, 2004, a State alliance, as defined in Section 203(a)(23) of the CNA, may not exceed 100,000 infants served by the participating State agencies as of October 1, 2003. A State alliance that existed on June 30, 2004, may continue and may expand to serve more than 100,000 infants but may not, except as provided above, expand to include any additional State agency, except that it may expand to include any State agency that served less than 5,000 infant participants as of October 1, 2003, or Indian State agency that requests to join the State alliance.

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PRIMARY CONTRACT INFANT FORMULA

Legislative Change

Section 203(a)(3) of the Reauthorization Act amends Section 17(b) of the CNA by adding the following new definition:

“(22) PRIMARY CONTRACT INFANT FORMULA.—The term ‘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 under this section and for which a contract is awarded by the State agency as a result of that bid.”

Current Regulations

Although regulations at 7 CFR 246.2 do not include a definition of “primary contract infant formula,” the term “primary contract brand infant formula” is used throughout 7 CFR 246.16a.

Policy Change

Effective October 1, 2004, the term “primary contract infant formula” will be used in the WIC Program to refer to the specific infant formula for which the State agency has awarded a rebate contract to a manufacturer in response to a bid solicitation.

Legislative Change

Section 203(e)(4) of the Reauthorization Act amends Section 17(h)(8)(A) of the CNA by striking “contract brand of” in clause (ii)(I) and inserting “primary contract,” by inserting “for a specific infant formula for which manufacturers submit a bid” in clause (iii) after “lowest net price,” and by adding the following:

“(v) FIRST CHOICE OF ISSUANCE.—The State agency shall use the primary contract infant formula as the first choice of issuance (by formula type), with all other infant formulas issued as an alternative to the primary contract infant formula.”

Current Regulations

Regulations at 7 CFR 246.16a(c)(6) provide the State agency with the discretion to approve for issuance, in addition to the primary contract infant formula(s), none, some, or all of the winning bidder’s other infant formulas. In addition, the State agency may require medical documentation before issuing any contract brand infant formula and must require medical documentation before issuing any non-contract brand infant formula, exempt infant formula, or WIC-eligible medical food.

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Policy Change

Effective for all bid solicitations issued on or after October 1, 2004, the State agency must issue the primary contract infant formula, as defined in Section 203(a)(22) of the CNA, as the formula of first choice. The State agency may continue to issue alternatives, if determined to be more appropriate.

ROUNDING UP TO THE NEXT WHOLE CAN

Legislative Change

Section 203(c)(4) of the Reauthorization Act amends Section 17(f) of the CNA to add the following:

“(25) INFANT FORMULA BENEFITS.—A State agency may round up to the next whole can of infant formula to allow all participants under the program to receive the full-authorized nutritional benefit specified by regulation.”

Current Regulations

Regulations at 7 CFR 246.10(c) permit the State agency to issue a maximum monthly allowance of 128 dry ounces of powder, 403 fluid ounces of liquid concentrate, or 806 fluid ounces of ready-to-feed infant formula. However, due to variation in package sizes, some participants do not receive the maximum monthly allowance of infant formula specified in program regulations.

Policy Change

Effective for infant formula contracts resulting from a bid solicitation issued on or after October 1, 2004, the State agency may round up to the next whole can of infant formula so that all participants receive the full authorized nutritional benefits specified in program regulations. This provision only applies to new infant formula contracts that allow manufacturers to take this change into account when developing their rebate bids.

UNCOUPLING OF MILK-BASED AND SOY-BASED BIDS

Legislative Change

Section 203(e)(6) of the Reauthorization Act amends Section 17(h)(8)(A) of the CNA by adding the following:

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“(vii) SEPARATE SOLICITATIONS.—In soliciting bids for infant formula under a competitive bidding system, any State agency, or State alliance, that served under the program a monthly average of more than 100,000 infants during the preceding 12-month period shall solicit bids from infant formula manufacturers under procedures that require that bids for rebates or discounts are solicited for milk-based and soy-based infant formula separately.”

Current Regulations

Regulations at 7 CFR 246.16a(c)(1) provide the State agency with the option to structure its bid solicitation either as a single solicitation or as separate solicitations for milk-based and soy-based infant formulas.

Policy Change

Effective for bid solicitations issued on or after October 1, 2004, a State agency or a State alliance that serves a monthly average of more than 100,000 infants during the preceding 12-month period must solicit separate bids for milk-based and soy-based infant formulas.

CENT-FOR-CENT ADJUSTMENTS

Legislative Change

Section 203(e)(7) of the Reauthorization Act amends Section 17(h)(8)(A) of the CNA by adding the following:

“(viii) CENT-FOR-CENT ADJUSTMENTS.—A bid solicitation for infant formula under the program shall require the manufacturer to adjust for price changes subsequent to the opening of the bidding process in a manner that requires—

“(I) a cent-for-cent increase in the rebate amounts if there is an increase in the lowest national wholesale price for a full truckload of the particular infant formula; and

“(II) a cent-for-cent decrease in the rebate amounts if there is a decrease in the lowest national wholesale price for a full truckload of the particular infant formula.”

Current Regulations

Regulations at 7 CFR 246.16a(c)(5)(iv) call for bid solicitations to require manufacturers to adjust for price changes subsequent to the bid opening. However, the regulations only provide for increases in rebate amounts as a result of inflation in the wholesale prices of infant formula and does not provide for corresponding adjustments for decreases in wholesale prices. As an alternative to a cent-for-cent increase, the regulations permit the State agency to use another equally effective cost adjustment mechanism for inflation.

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Policy Change

Effective for bid solicitations issued on or after October 1, 2004, a bid solicitation must require the manufacturer, subsequent to the opening of the bidding process, to make a cent-for-cent adjustment in its rebate amount for either an increase or a decrease in the lowest national wholesale price for a full truckload of the particular infant formula.

REBATE INVOICES

Legislative Change

Section 203(e)(5) of the Reauthorization Act amends Section 17(h)(8)(A) by adding the following:

“(vi) REBATE INVOICES.—Each State agency shall have a system to ensure that infant formula rebate invoices, under competitive bidding, provide a reasonable estimate or an actual count of the number of units sold to participants in the program under this section.”

Current Regulations

Regulations at 7 CFR 246.16a do not address infant formula rebate invoices.

Policy Change

Effective October 1, 2004, the State agency must have a system to ensure that infant formula rebate invoices, under competitive bidding, provide a reasonable estimate or an actual count of the number of units purchased by participants during WIC transactions. Additional guidance will be issued in the near future that outlines several methods currently used by State agencies to calculate reasonable estimates of the number of units of infant formula actually purchased.

EFFECTIVE DATE

This policy memorandum is effective upon issuance. The various effective dates for the provisions included in this policy memo are indicated in each provision’s “Policy Change” paragraph. As noted above, in some cases additional guidance will be issued at a later date to provide further clarification regarding particular provisions. The changes contained in this policy memo will be promulgated into program regulations in the coming year through a nondiscretionary final rule.

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For questions about implementing these provisions, State agencies should contact their FNS Regional Office.

/s/
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