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Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Discretionary WIC Vendor Provisions in the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265; Final Rule

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 246

[FNS–2006–0035]

RIN 0584–AD47

Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Discretionary WIC Vendor Provisions in the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends regulations for the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) by adding three requirements mandated by the Child Nutrition and WIC Reauthorization Act of 2004 in amendments to the Child Nutrition Act of 1966 (CNA) concerning retail vendors authorized by WIC State agencies to provide supplemental food to WIC participants in exchange for WIC food instruments. The intent of these provisions is to enhance due process for vendors; prevent defective infant formula from being consumed by infant WIC participants; and ensure that the WIC Program does not pay the cost of incentive items provided by above-50-percent vendors in the form of high food prices. Finally, this rule also adjusts the vendor civil money penalty (CMP) levels to reflect inflation.

DATES: This rule is effective March 9, 2009.

FOR FURTHER INFORMATION CONTACT: Debra Whitford, Chief, Policy and Program Development Branch, Supplemental Food Programs Division, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 528, Alexandria, Virginia 22302, (703) 305–2746.

SUPPLEMENTARY INFORMATION:

I. Procedural Matters

Executive Order 12866

This rule has been determined to be significant and was reviewed by the Office of Management and Budget (OMB) in conformance with Executive Order 12866.

Regulatory Impact Analysis Summary

The following summarizes the conclusions of the regulatory impact analysis. A complete copy of the Impact Analysis appears in the appendix to this rule.

Need for Action

This rule amends the WIC regulations by adding three requirements mandated by the CNA concerning WIC-authorized retail vendors, as discussed below. This rule also establishes a process for the periodic adjustment (at least once every four years) of all vendor civil money penalty (CMP) levels to reflect inflation; under the current regulations, the CMP levels for some but not all vendor violations have been previously adjusted for inflation. Initially, this would have the effect of raising the maximum CMP level from $10,000 to $11,000 per violation, and raising the CMP level from $40,000 to $44,000 as the maximum amount for all violations occurring during a single investigation, for those WIC CMP levels which have not previously been adjusted for inflation.

Benefits

The notification of vendors of an initial incidence of a violation, one of the new requirements based on the 2004 reauthorization legislation, provides the vendor with an opportunity to correct a violation. Thus, State agencies may spend less time and resources on sanction cases and ultimately program operations would be improved and program costs would decrease. Requiring vendors to obtain infant formula only from suppliers registered with FDA or licensed under State law, another requirement based on the 2004 reauthorization legislation, will help to prevent the sale of adulterated stolen infant formula for use by infant WIC participants, thus safeguarding their health.

Requiring above-50-percent vendors to restrict the costs of their participant incentive items to nominal value, the last of the requirements based on the 2004 reauthorization legislation, would protect the WIC Program from paying excess money for WIC foods. Making the inflation adjustment consistent for all CMP levels would benefit WIC Program administration by making the CMP maximum amounts uniform for all violations.

Costs

Although this final rule has been designated as significant, the costs associated with implementing the changes are not expected to significantly add to current program costs.

Little time will be needed to issue a notice of violation to a vendor, which presumably will entail a standardized format with space for the vendor's name and address and for listing the violation. Likewise, little time will be needed to document in the vendor file the reason(s) such notice would compromise an investigation and thus would not be sent.

The State agency is required to provide the list of registered or licensed infant formula suppliers to vendors on an annual basis, which a State agency could satisfy by linking its Web site to the list of licensed suppliers on the Web site of the State's licensing agency, or by providing vendors with a telephone number or e-mail address to inquire about the license status of a supplier.

Based on Fiscal Year 2006 data, FNS currently estimates that only about 1,700 of the approximately 47,000 authorized retail vendors would potentially be subject to incentive items restrictions. Little time will be needed by the State agency to approve/disapprove incentive items, since this process only involves comparison of the vendor's price documentation with the less-than-$2 nominal value limit. Indeed, the State agency may provide above-50-percent vendors with a list of allowable incentive items, and the vendor would indicate on the list which of these incentive items it wishes to use and return the list to the State agency.

The final rule's process for the periodic adjustment of WIC vendor CMP amounts to reflect inflation would not increase administrative costs because the CMP calculation process would be the same for all vendor violations. Under the current regulations, the CMP levels for some but not all vendor violations have previously been adjusted for inflation. Under the final rule's process, all vendor CMP levels would be periodically adjusted for inflation. Initially, this would have the effect of raising the maximum CMP level from $10,000 to $11,000 per violation, and raising the CMP level from $40,000 to $44,000 as the maximum amount for all violations occurring during a single investigation, for those WIC CMP levels which have not previously been adjusted for inflation.

Regulatory Flexibility Act

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (RFA) of 1980, (5 U.S.C. 601–612). Pursuant to that review, Nancy Montanez Johner, Under Secretary, Food, Nutrition, and Consumer Services, has certified that this rule would not have a significant impact on a substantial number of small entities. Although not required by the RFA, FNS has prepared this Regulatory Flexibility Analysis describing the impact of the rule on small entities and State agencies.

In accordance with the CNA, as amended, the final rule would require that State agencies implement restrictions on the incentive items provided at no cost to program participants by above-50-percent vendors in order to prevent the cost of the incentive items from increasing the food prices charged to the WIC Program by these vendors. The final rule permits certain kinds of incentive items which cost the vendor less than $2, pursuant to USDA's authority in the CNA to establish a nominal monetary amount which would be acceptable for incentive items. FNS estimates that about 1,700 of the approximately 47,000 authorized vendors are above-50-percent vendors, including 1,066 which serve WIC participants exclusively, and an additional 634 which derive more revenue from WIC sales than from non-WIC sales but also have a substantial non-WIC customer base.

The annual receipts of 25 percent of all WIC-authorized vendors (11,600) surpass the maximum level of annual receipts used by the Small Business Administration (SBA) to define a ''small business concern'' in 13 CFR 121.201 ($25 million for grocery stores and $6.5 million for pharmacies), including 69 of the above-50-percent vendors. Also, the 634 above-50-percent vendors with a substantial non-WIC customer base have not been known to use the sort of incentive items which are prohibited by this rule. Thus the rule's incentive item restrictions mainly impact 997 of the 35,400 vendors which are small businesses according to SBA's regulations, 2.8 percent of the total (1,700 above-50-percent vendors − 69 large business = 1,631; 1,631 − 634 above-50-percent vendors with a substantial non-WIC customer base = 997).

It is unlikely that the incentive item restrictions of this final rule will have a significant impact on these 997 vendors which exclusively serve WIC participants. In 2005, the Food and Nutrition Service (FNS) published a regulation aimed at controlling the costs of higher-priced vendors (see, WIC Vendor Cost Containment Interim Rule, 70 FR 71708, November 29, 2005). The Vendor Cost Containment regulation requires that the average WIC redemptions per food instrument type for above-50-percent vendors (which includes those vendors that exclusively serve WIC participants) not exceed the regular vendor average WIC redemptions per food instrument type in each State. The requirements of the Vendor Cost Containment regulation have made it increasingly difficult to incorporate the cost of incentive items into the cost of supplemental foods. Thus, it is likely that the number of vendors providing incentive items has decreased significantly since the effective date of the Vendor Cost Containment regulation.

The Department considered nominal amounts slightly higher than $2. However, to avoid the possibility of the value of incentive items being incorporated into the costs of supplemental foods, the Department chose the $2 limit instead of higher amounts in order to preserve WIC funds for service to participants.

FNS also does not expect the other three provisions of the final rule to have a significant economic impact on small entities. One of these provisions requires State agencies to provide WIC retail vendors with a list of State-licensed infant formula wholesalers, distributors, retailers, and FDA-registered manufacturers; vendors may obtain infant formula for sale to WIC participants only from the suppliers on the list. These authorized sources of infant formula include thousands of wholesalers, distributors, and retailers nationwide, as well as six manufacturers. Thus it is exceedingly doubtful that this requirement will harm or inconvenience any vendors.

Also, State agencies are not included under the definition of ''small governmental jurisdictions'' in section 601(5) of the RFA, which only includes local governmental organizations. Thus the impacts of regulations on WIC State agencies, including the requirement for this list of infant formula sources, are not subject to RFA requirements. Even so, this final rule is sensitive to the administrative burden of State agencies, permitting State agencies to provide their lists of infant formula sources to vendors on web sites, to obtain the lists from other State agencies, and to limit the kinds of sources which will be included so that the lists would not be too large.

One of the other provisions requires the State agency to notify a vendor of a violation in writing before documenting a subsequent violation which could result in sanctions based on a pattern of violations, unless such notification would compromise an investigation. This provision will help vendors to comply with their responsibilities and thus prevent sanctions. FNS estimates that only 5 percent of WIC-authorized vendors would be impacted by this provision. Moreover, this impact would be economically beneficial for these vendors since such notification would help them to prevent the loss of business resulting from disqualification, or CMP payments imposed in lieu of disqualification, and related legal costs.

The remaining provision would periodically increase the CMP amounts to reflect inflation for those CMPs which had not previously been adjusted for inflation. FNS estimates that only 3 percent of WIC-authorized vendors would be impacted by this provision. Moreover, this provision would only increase maximum CMP amounts on a periodic basis to reflect inflation; the underlying formula for calculating CMP amounts, based on a percentage of a vendor's average redemptions and the number of violations as set forth in § 246.12(l)(1)(x), would not be altered by this provision.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Under Section 202 of the UMRA, the Department generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures by State, local or tribal governments, in the aggregate, or the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, Section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the most cost effective or least burdensome alternative that achieves the objectives of the rule.

This final rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local and tribal governments or the private sector of $100 million or more in any one year. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

The WIC Program is listed in the Catalog of Federal Domestic Assistance Programs under 10.557. For the reasons set forth in the final rule in 7 CFR part 3015, Subpart V, and related Notice (48 FR 29115, June 24, 1983), this program is included in the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials. (All references to regulatory sections in this preamble are references to Title 7 of the CFR unless otherwise indicated.)

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact

of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2)(B) of Executive Order 13121.

Prior Consultation With State Officials

Prior to drafting this final rule, FNS received input from State agencies regarding issues and concerns with implementation of the three legislative provisions contained in this rulemaking. FNS regional offices have formal and informal discussions with WIC State agency officials on an ongoing basis regarding program and policy issues. In December 2004 and April 2005, FNS issued policy guidance to WIC State agencies on the implementation of the legislative requirements addressed in this final rule. In response, FNS received a number of questions which resulted in informal discussions with State agency officials and other stakeholders on program implementation. Much of the discussion in the preamble of this rule reflects the substance of those consultations.

Nature of Concerns and the Need To Issue This Rule

State agencies are primarily concerned with the potential administrative burdens involved with implementing the new legislative requirements in this final rule.

Extent to Which Those Concerns Have Been Met

FNS has considered the impact of this final rule on WIC State and local agencies. Through the rulemaking process, FNS has attempted to balance the need for State agencies to meet the new requirements against the administrative challenges that State agencies are likely to encounter in meeting them. These challenges include the commitment of adequate resources to compile the list of acceptable entities from which infant formula must be purchased; determine when notification of violations would compromise an investigation; and, develop and enforce the incentive items provisions.

The final rule allows State agencies discretion to determine if providing notification of violations to vendors before documenting additional violations would compromise the investigation.

In addition, under the final rule, State agencies could use their Web sites as the primary means for providing their vendors with lists of infant formula manufacturers registered with the FDA and infant formula wholesalers, distributors, and retailers licensed under State law. Indeed, under the term ''other effective means,'' the final rule permits State agencies to provide vendors with a telephone number or e-mail address to inquire about the license status of a supplier, instead of providing vendors with a list. FNS will also provide the State agencies with the FDA list of manufacturers, and State licensing and tax authorities could provide the WIC State agencies with lists or Web site links on the other suppliers. Further, State legislation or rulemaking could be used to limit the kind of suppliers to be included on the lists provided to the vendors.

The final rule allows State agencies the discretion to determine what, if any, incentive items may be provided by above-50-percent vendors to participants. If a State agency decides not to permit such promotions at all, then there would be no administrative burden to the State agency to approve such items to ensure compliance with the statutory requirement.

Finally, State agencies would need to amend their schedules of sanctions to reflect the inflation adjustments for CMP levels in this final rule and to notify their vendors of this change. FNS does not expect this to involve a significant expenditure of resources.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full and timely implementation. This rule is not intended to have retroactive effect unless so specified in the **DATES** section of this rule. Prior to any judicial challenge to the provisions of the final rule, all applicable administrative procedures must be exhausted. This rule concerns WIC vendors. In the WIC Program, the administrative procedures which must be exhausted by WIC vendors are as follows. First, State agency hearing procedures pursuant to § 246.18(a)(1) must be exhausted for vendors concerning denial of authorization, termination of agreement, disqualification, civil money penalty or fine, or the State agency's determination of peer group or above-50-percent status. Second, the State agency process for providing the vendor an opportunity to justify or correct the food instrument pursuant to § 246.12(k)(3) must be exhausted for vendors concerning delaying payment for a food instrument or a claim. Third, administrative appeal to the extent required by § 3016.36 must be exhausted for vendors concerning procurement decisions of State agencies.

Civil Rights Impact Analysis

FNS has reviewed this final rule in accordance with the Department Regulation 4300–4, ''Civil Rights Impact Analysis,'' to identify and address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, FNS has determined that there is no way to soften the effect on any of the protected classes regarding those provisions of the rule concerning notice of violations and restrictions on incentive items. However, the rule explicitly forbids discrimination against a protected class recognized by the WIC Program (race, color, national origin, age, sex, or disability) regarding the inclusion of businesses on the list which State agencies must provide to vendors of infant formula manufacturers registered with the FDA, and State-licensed infant formula wholesalers, distributors, or retailers. All data available to FNS indicate that protected classes have the same opportunity to participate in the WIC Program as non-protected classes. FNS specifically prohibits the State and local government agencies that administer the WIC Program from engaging in actions that discriminate based on race, color, national origin, age, sex, or disability in accordance with § 246.8. Where State agencies have options and they choose to implement a certain provision, they must implement it in such a way that it complies with the § 246.8.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; *see* 5 CFR part 1320) requires that OMB approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This final rule contains information collections that are subject to review and approval by OMB; therefore, FNS has submitted an information collection under OMB#0584–0043 to OMB. This information collection contains changes in the burden based on comments on the proposed rule Discretionary WIC Vendor Provisions in the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265, 71 FR 43371, August 1, 2006 (proposed rule),

and information not available when the proposed rule was published.

As previously noted, October 1, 2004 was the effective date of Public Law 108–265. Thus in December 2004 and April 2005, FNS issued policy and guidance to WIC State agencies on implementation of its three requirements noted above. As a result, the comments on the information collection burden reflect actual experience. The following discussion describes the information collection burden of the proposed rule and responds to the comments received on the information collection burden:

1. Reporting

Section 246.4(a)(14)(iii)

Section 246.4(a)(14)(iii), as proposed, would require WIC State agencies to set forth policies and procedures in their WIC State Plans for notifying a retail vendor in writing when an investigation reveals an initial violation for which a pattern of violations must be imposed in order to impose a sanction, unless the State agency determines that the notice would compromise an investigation. Section 246.4(a)(14)(iii), as proposed, would also require WIC State agencies to set forth policies and procedures in their WIC State Plans for the approval of incentive items which above-50-percent vendors may provide to participants. FNS estimated that § 246.4(a)(14)(iii) would require one burden hour per State agency per year, resulting in 90 total annual burden hours. There were no comments on the information collection burden of this provision. Accordingly, 90 total annual burden hours is adopted for this provision.

Section 246.4(a)(14)(xvii)

Section 246.4(a)(14)(xvii), as proposed, would require WIC State agencies to set forth policies and procedures in their WIC State Plans for annually compiling and distributing to authorized WIC retail vendors a list of infant formula wholesalers, distributors, and retailers licensed under State law, and infant formula manufacturers registered with the Food and Drug Administration (FDA). FNS estimated that this would require one burden hour per State agency per year, resulting in 90 total annual burden hours. There were no comments on the information collection burden of this provision. Accordingly, 90 total annual burden hours is adopted for this provision.

Section 246.12(h)(8)

Section 246.12(h)(8), as proposed, would require WIC State agencies to establish a process for approval or disapproval of requests from above-50-percent vendors for permission to provide incentive items to WIC participants or other customers. The proposed rule did not include any burden hours for vendors for this provision. However, given the analysis of the recordkeeping information burden for State agencies regarding this provision, a reporting information burden for vendors also needs to be recognized. Both are discussed below regarding § 246.12(h)(8).

2. Recordkeeping

Section 246.12(g)(11)

Section 246.12(g)(10) of the proposed rule (which is designated as § 246.12(g)(11) in this final rule due to publication of an intervening rule) would require WIC State agencies to provide to authorized WIC retail vendors a list, on an annual basis, of infant formula wholesalers, distributors, and retailers licensed in the State in accordance with State law (including regulations), and infant formula manufacturers registered with FDA that provide infant formula. FNS has provided the State agencies with the list of the infant formula manufacturers registered with FDA. A State agency would contact the licensing agency in its State to obtain a list of the other suppliers. A State agency could satisfy this requirement by linking its Web site to the list of licensed suppliers on the web site of the State's licensing agency. FNS estimated that this would require one burden hour per State agency per year, resulting in 90 total annual burden hours.

Two WIC State agencies commented on the information collection burden concerning this requirement. One State agency commenter estimated that 500 hours would be required annually to maintain the list. Another State agency commenter estimated that 120 hours had been required for initial compilation and ongoing maintenance of the list. The experiences and views of these two State agencies may not be representative of the other State agencies. However, to ensure that the estimate provided to OMB for this final rule takes into account the varied experiences of all State agencies, the estimated burden hours per response for the list requirement has been increased from 1 hour to 50 hours for State agencies. Accordingly, the total annual burden hours for the list requirement has been increased from 90 to 4,500 (90 State agencies × 50 burden hours = 4,500 total annual burden hours).

FNS did not estimate any burden hours for vendors regarding this requirement. However, one commenter stated that this requirement would impose an undue burden on vendors because most vendors deal with dozens if not hundreds of suppliers of products within their stores, including numerous jobbers, sub-jobbers, and other sales persons; it would be impossible, this commenter stated, for the vendor to verify the validity of each source of every purchase or to contact the State agency to ascertain the status of the supplier.

The commenter's concerns are unjustified. The source which must be identified is only the source from whom the vendor purchased the infant formula, not the manufacturer or supplier from whom the vendor's source purchased the infant formula. Also, the infant formula list requirement only pertains to ''infant formula'' as defined in the WIC regulations, which does not include ''exempt infant formula'' (formulas requiring a medical prescription), ''WIC-eligible medical foods,'' or any other kind of food.

Further, as recognized by § 246.12(h)(3)(xv), vendors are already required to maintain inventory records used for Federal tax reporting purposes, which would include invoices for infant formula, and to make such records available to the State agency upon request. Thus the infant formula list requirement does not impose any new reporting or recordkeeping burden on vendors. Moreover, attaching a copy of an invoice to a vendor application form, or providing a copy to the State agency at some other time, would involve a negligible amount of time.

Section 246.12(h)(8)

Section 246.12(h)(8), as proposed, would require WIC State agencies to establish a process for approval or disapproval of requests from above-50-percent vendors for permission to provide incentive items to WIC participants or other customers. As previously mentioned, FNS currently estimates that about 1,700 of the approximately 47,000 authorized vendors would potentially be subject to incentive items restrictions. However, when the proposed rule was issued, FNS estimated that about 2,000 of approximately 50,000 authorized vendors would be subject to incentive items restrictions. A State agency could decide not to allow any incentive items at all, in which case an approval process would not be necessary. FNS had received inquiries from several WIC State agencies indicating an interest in not allowing such incentive items at all.

As a result, the estimate set forth in the preamble of the proposed rule assumed that half of the WIC State agencies would not allow any incentive items at all, and that half of the approximately 2,000 above-50-percent vendors nationwide reside in those States. The estimate also assumed that little time would be needed to approve/disapprove a request and record it, since this process only involves comparison of the vendor's price documentation with the less-than-$2 limit established for such items in the rule. Indeed, the State agency could have provided above-50-percent vendors with a list of allowable incentive items, valued below the less-than-$2 nominal value limit per item; the vendor would indicate on the list which of these incentive items it wishes to use and return the list to the State agency. Thus FNS estimated that State agencies would approve/disapprove incentive items for 1,000 above-50-percent vendors, and that each approval/disapproval would require 0.25 burden hours, resulting in 250 total annual burden hours.

One commenter addressed the burden of the incentive items restrictions. This commenter stated that the incentive items restrictions were burdensome, requiring complex internal policies and regulations, and resulting in additional monitoring and enforcement, as well as more training for vendors. The commenter did not address the number of burden hours.

Another commenter stated that it would be burdensome for State agencies to maintain invoices or similar documentation of the vendor's approved incentive items, showing that the cost of each item is either less than the $2 nominal value limit or obtained at no cost, as would be required by § 246.12(h)(8)(ii). As indicated in the proposed rule at 71 FR 43381, this documentation could include a list of items and the related invoices, submitted by the vendor to the State agency for approval, or this documentation could include a list of pre-approved items submitted by the State agency to the vendor for the vendor to return to the State agency indicating which of the pre-approved incentive items have been chosen by the vendor; this latter approach is acceptable as intended by the regulatory language that refers to ''similar documents.'' Thus, the State agency is required to maintain copies of invoices only if the State agency permits vendors to request approval for incentive items not included on a list of acceptable incentive items provided by the State agency.

The Department does not view the pre-approved list as involving an appreciable information collection burden. If the pre-approved list is returned by the vendor at the same time the vendor returns the signed vendor agreement during the authorization process, the proposed requirement of § 246.12(h)(8)(ii) amounts to little more than maintaining the copy of the vendor agreement signed by the vendor, which the State agency is already required to do. However, some State agencies may not use this approach, preferring instead that vendors request approval for incentive items outside of the vendor agreement process.

This commenter also did not state the number of burden hours needed to comply with this requirement. However, to ensure that the estimate provided to OMB for this final rule takes into account the concerns of these two commenters, the estimated burden hours per response for § 246.12(h)(8) has been increased from 0.25 hours to 1 hour per response for State agencies which require approval for incentive items outside of the vendor agreement process.

As pointed out in the section of this preamble concerning the RFA, it is likely that the number of vendors providing incentive items has decreased significantly since the effective date of the Vendor Cost Containment regulation. It is also likely that a significant portion of the above-50-percent vendors reside in States where either incentive items are not allowed, or, if incentive items are allowed, the agreement process is used. Based on data not available when the proposed rule was published, FNS now knows that 32 State agencies authorized above-50-percent vendors during Fiscal Year 2006. Thus FNS estimates that half of the approximately 1,700 above-50-percent vendors (850) would have an appreciable reporting information collection burden due to the restrictions on incentive items. Accordingly, the estimate has been revised to 850 total annual burden hours for the incentive items restrictions in this final rule (850 above-50-percent vendors ÷ 16 State agencies = 53.125 above-50-percent vendors per State agency; $16 \times 53.125 \times 1$ hour per response = 850 total annual burden hours).

Section 246.12(l)(3)

Section 246.12(l)(3) of the proposed rule would require the State agency 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 before another such violation is documented, unless the State agency determines, in its discretion on a case-by-case basis, that notifying the vendor would compromise an investigation. Prior to imposing a sanction for a pattern of violations, the State agency would 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. Approximately 2,300 vendors investigated annually commit violations involving a pattern.

For the proposed rule, FNS assumed that little time would be needed to issue the notice, which presumably would entail a standardized format with space for the vendor's name and address and for listing the violations. FNS also assumed that little time would be needed to document in the vendor file the reason(s) such notice would compromise an investigation and thus would not be sent. Thus FNS estimated that State agencies would either issue such notices or make such entries in vendor files 2,300 times, and that issuing each notice or making such entries would require 15 minutes each, resulting in 575 total annual burden hours ($2{,}300 \div 90 = 25.55$; $25.55 \times 90 \times 0.25 = 575$).

There were three comments on the information collection burden of this provision. Two of these comments stated that the provision was inconsistent with the goal of paperwork reduction, but did not take issue with the number of burden hours estimated in the preamble of the proposed rule. The other commenter, a State agency, stated that it had used approximately 9,180 hours reviewing additional compliance buys and generating notice letters as a result of the notice requirement.

As previously noted, approximately 2,300 vendors investigated annually by all WIC State agencies are found to be committing types of violations subject to sanctions only if the investigation shows that a pattern of such violations had occurred. Thus, applying the commenter's estimate of 9,180 hours for one State agency to the 2,300 vendors for all State agencies, 4 hours would be required to either issue the notification of violation to the vendor or note in the vendor's file the reason(s) for not issuing the notification. Since a single State agency conducts far fewer than 2,300 such investigations annually, the number of hours needed for a single State agency to issue the notification or document the reason(s) for not doing so would be significantly greater than 4 hours based on the commenter's estimate of 9,180 hours.

However, the commenter's estimate indicates that the estimated burden hours in the preamble of the proposed rule may have been too low. Accordingly, the information collection burden submitted to OMB for this activity has been increased from 0.25 hours per response to 1 hour per response, for an annual total for all 90 State agencies of 2,350 burden hours (2,300 ÷ 90 = 25.55; 25.55 × 90 × 1 burden hour = 2,300 burden hours).

Adjustments Unrelated to the Final Rule

Adjustments have been made to the existing burden hours for the entire OMB# 0584–0043 information collection burden to reflect the adding of a new respondent category for applicants for program benefits, and for vendors concerning collections which existed prior to the final rule. For applicants for program benefits, 292,983 burden hours have been added, to take into account the information provided by these applicants during the certification process.

For vendors, 23,500 burden hours have been added to take into account the information provided by vendors during the vendor application and agreement processes. Further, there are now 47,000 vendors, an increase over the previous 45,000 recognized in the approved information burden, which impacts the burden hour calculations for the application and agreement processes as well as the collection of vendor shelf prices and food sales data. However, the number of vendors actually required to provide food sales data annually has been reduced from the previous number of 45,000 to 5,640 because FNS matching of WIC vendor redemptions with redemptions for the same vendors in the Supplemental Nutrition Assistance Program (SNAP), formerly known as the Food Stamp Program, has made it unnecessary to collect shelf price data from 88 percent of the vendors (12 percent of 47,000 vendors is 5,640).

Also, numerous categories of State agency information burdens were previously based on 89 State agencies. Since the previous approval of the OMB #0584–0043 collection burden, an additional State agency has been added, so that now there are a total of 90 State agencies. All of the aforementioned adjustments together account for 391,981 hours.

The following chart shows the estimated annual information burden for the final rule. Five of the six burden categories noted in the chart pertain to State agencies; the one which pertains to vendors is so noted. Decimals are not included in the figures.

ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN OMB #0584–0043

Section of regulations	Annual number of respondents	Annual frequency	Average burden hours per response	Annual burden hours
Reporting Burden				
§ 246.4(a)(14)(iii)	90	1	1.0	90
§ 246.4(a)(14)(xvii)	90	1	1.0	90
§ 246.12(h)(8)vendors	850	1	1.0	850
Total Reporting Burden in the Final Rule	180	2		1,030
Recordkeeping Burden				
§ 246.12(g)(11)	90	1	50	4,500
§ 246.12(h)(8)	16	53	1.0	850
§ 246.12(l)(3)	90	26	1.0	2,300
Total Recordkeeping Burden in the Final Rule.	196	80		7,650
Total Reporting and Recordkeeping Burden in the Final Rule.	376	82		8,680
Total Program Changes Burden Hours for the Final Rule.				8,680
Total Adjustments Burden Hours (including other sections of the regulations).				391,981
Total Program Changes and Adjustments Burden Hours.				400,661
Total Current WIC Reporting and Recordkeeping Burden Approved by OMB for Information Collection #0584–0043.	15,595,000 (over-count)			3,050,545
Grand Total WIC Reporting and Recordkeeping Burden.	1,990,457 (as adjusted)			3,451,206

E-Government Act Compliance

FNS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

II. Background

The proposed rule entitled Discretionary WIC Vendor Provisions in the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265, was published on August 1, 2006, at 71 FR 43371 (proposed rule). FNS received 17 letters or electronic mail messages commenting on the proposed rule, including 10 from WIC State agencies; 2 from WIC-authorized vendors; 2 from vendor advocacy organizations; 1 from a WIC local agency association; 1 from a social service advocacy organization; and 1 from a company which provides consulting services to government agencies.

As previously noted, this final rule amends the WIC Program regulations by adding three requirements mandated by the amended CNA concerning retail vendors authorized by WIC State agencies to provide supplemental food to WIC participants in exchange for WIC food instruments. This rulemaking reflects the statutory requirement that WIC State agencies notify WIC-authorized vendors of an initial violation in writing for violations requiring a pattern of violative incidences in order to impose a sanction before documenting a subsequent violation, unless notification would compromise an investigation. In addition, the State agency is required to maintain a list of State-licensed wholesalers, distributors, and retailers, and FDA-registered manufacturers, and WIC-authorized vendors are required to purchase infant formula only from sources on the list. Further, State agencies are prohibited from authorizing or making payments to WIC-authorized vendors that derive more than 50 percent of their annual food sales revenue from WIC food instruments (''above-50-percent vendors'') and which provide incentive items or other free merchandise, except food or merchandise of nominal value, to program participants or other customers unless the vendor provides the State agency with proof that the vendor obtained the incentive items or merchandise at no cost.

October 1, 2004 was the effective date of Public Law 108–265 for all of these requirements. In December 2004 and April 2005, FNS issued policy and guidance to WIC State agencies on implementation of these requirements. This final rule reflects the policy and guidance provided to State agencies.

Additionally, this final rule adds a process for periodically adjusting the WIC vendor CMP levels for inflation in a manner that is consistent for all WIC violations.

The Department's responses to the comments are set forth below, except for the comments on the administrative burden of the proposed provisions. The Department's response to the comments on the administrative burden of the proposed rule are set forth above in the sections of this preamble entitled ''Federalism Summary Impact Statement'' and ''Paperwork Reduction Act.''

1. Notice of Violation (§§ 246.4(a)(14)(iii), 246.12(h)(3)(xviii), 246.12(l)(3), and 246.18(a)(1)(iii)(F))

Section 203(c)(5) of Public Law 108–265 amended Section 17(f) of the CNA by adding a new paragraph (26) to require the State agency to notify the vendor in writing of the initial violation, for violations requiring a pattern of occurrences in order to impose a sanction, prior to documenting another violation, unless the State agency determines that notifying the vendor would compromise an investigation.

This requirement was effective for violations committed under investigations beginning on or after October 1, 2004, even though the current § 246.12(l)(3) provides that the State agency is not required to warn a vendor that violations had been detected before imposing a sanction. In December 2004, State agencies were advised that their vendor agreements and sanction schedules must be reviewed and amended as appropriate to reflect this new requirement.

Nine comments addressed the notification provisions of the proposed rule. One commenter stated unconditional support for the notification provisions. Five commenters stated conditional support for the proposed provision. Three commenters stated their opposition to the proposed provision.

The Extent of the State Agency's Discretion (§ 246.12(l)(3))

One commenter objected to the provision for State agency discretion in the determination on whether to provide notification in § 246.12(l)(3) of the proposed rule. The commenter also objected to the statement at 71 FR 43377 of the proposed rule that a State agency could decide not to use notification on the basis of the severity of the initial violation, the compliance history of the vendor, and whether the vendor has been determined to be high risk. The commenter viewed these examples as well beyond the scope of the statute.

According to the commenter, the State agency must provide the notification unless there is a substantial basis to believe that fraud is occurring and such fraud is actively under investigation. Further, this commenter stated that the State agency must determine that the notice would compromise an investigation, not ''may'' or ''might'' do so, in order to decide that notification should not be provided. The commenter also stated that the State agency should be required to make an affirmative determination that notification would compromise an ongoing investigation and document the results of the determination before conducting a subsequent inspection. However, another commenter stated that the State agency should be permitted to determine that the notice ''could,'' ''probably,'' or would ''likely'' compromise an investigation, not ''would'' compromise an investigation, which is definite and difficult to know. Another commenter stated that, in most instances, vendors are unaware of violations because it is not possible to monitor all of the WIC food instruments accepted by store staff, although notification would not be appropriate when the State agency has sound reason to believe that the vendor owner or manager is involved in fraud against WIC.

The Department continues to believe, as stated at 71 FR 43377 of the proposed rule, that the statute provides the State agency with the discretion to determine whether notifying the vendor will compromise an investigation and to use its judgment to determine whether a notice should be sent to the vendor. Accordingly, the provision for State agency discretion in § 246.12(l)(3) of the proposed rule remains in the final rule. Also, the Department disagrees with the commenter's objections to the examples of factors cited at 71 FR 43377 which the State agency has the discretion to consider in making its determination.

One of the commenters also interpreted a statement at 71 FR 43377 of the proposed rule to mean that a State agency could decide not to provide the notification on the basis that an investigation is covert. The commenter stated that this would be contrary to the intention of the legislative provision since the need for notification pertained only to covert investigations; this provision would be rendered meaningless if a State agency could decide not to provide notification on the basis that an investigation is covert. The commenter also pointed out that this would be inconsistent with the provision in the proposed rule which would require a case-by-case determination by the State agency on whether to provide notification to the vendor. The Department agrees with the commenter. The statement in the preamble of the proposed rule was only intended to point out that the notification requirement pertains only to covert investigations since notification would reveal the existence of an investigation which had been previously unknown to the vendor. Thus § 246.12(l)(3) of the final rule, unchanged from the proposed rule, does not permit the State agency to exclude an investigation from the notification requirement on the sole basis that the investigation is covert.

This commenter further stated that the preamble of the proposed rule at 71 FR 43377 should not have stated that a State agency could decide not to provide notification on the basis that an

investigation was being conducted on the same vendor by another agency, since the coincidental investigation by another agency does not necessarily have any bearing on the status of the vendor's compliance with WIC Program requirements. The Department does not agree with this comment. The statutory provision states that the State agency shall notify the vendor unless the State agency determines that notifying the vendor would compromise an investigation, not its investigation. Thus an investigation being conducted by another agency, such as FNS or the USDA Office of Inspector General, is relevant to the State agency's determination on whether to provide notification. Accordingly, unchanged from the proposed rule, § 246.12(l)(3) of the final rule refers to an investigation, not its investigation.

This commenter also requested clarification regarding a statement at 71 FR 43377 that notification would not be needed after a violation occurred in a compliance buy visit subsequent to a notification based on a different type of violation which had occurred during a previous visit. The commenter believes that this may mean that the State agency may consider the risk of compromising investigations with notification to increase if a violation is observed in subsequent visits.

Such subsequent violations would need to be violations of a different type than the previous violation because a second or subsequent notification is not required for a violation of the same type for which notification has already been provided. Also, the fact that notification was provided regarding a previous violation does not mean that the State agency must provide notification for all subsequent violations of different types. Thus § 246.12(l)(3) of the final rule, unchanged from the proposed rule, allows the State agency to determine that notification concerning subsequent violations would compromise an investigation even though this determination was not made regarding the previous violation, due to facts or circumstances not known or not considered at the time of the previous violation.

Two commenters stated that State agencies should not be required to determine whether to provide notification on a case-by-case basis, as would be required by § 246.12(l)(3) of the proposed rule, but instead should be permitted to make categorical determinations based on the nature and seriousness of the violations. These commenters stated that serious violations such as overcharging are not inadvertent and thus should be subject to categorical exclusions from the notice requirement as determined by the State agency. One of these commenters also pointed out that the proposed rule categorically excludes violations based on WIC redemptions exceeding inventory and violations resulting in sanctions based on single violations such as trafficking, implying that other categories could also be excluded.

The Department does not agree. Serious violations may be fraudulent, but sometimes are not; overcharging cannot be categorically assumed to be fraudulent. Sometimes, overcharging might be inadvertent. Thus one compliance buy showing overcharging could not, by that fact alone, be sufficient for determining that notification would compromise an investigation. However, the severity of that violative incidence might be sufficient, if, for example, the overcharge was considerably higher than the monetary threshold established by the State agency as the basis for establishing that overcharging had occurred. The proposed rule would have excluded violations established by a single incidence because the statutory provision requires notification following the initial incidence of a violation which is established by a pattern of violative incidences; trafficking (§ 246.12(l)(1)(ii)(A)), illegal sales (§ 246.12(l)(1)(ii)(B)), and exchange of alcohol or tobacco for food instruments (§ 246.12(l)(1)(iii)(A)) are violations established by one violative incidence. Also, the proposed rule would have excluded violations based on WIC redemptions exceeding inventory (§ 246.12(l)(1)(iii)(B)) since this violation is detected in a single inventory audit instead of a pattern of violative incidences, so that there is no initial incidence. Accordingly, § 246.12(l)(3) of this final rule requires the State agency to determine whether to provide notification of violations to vendors on a case-by-case basis, as in the proposed rule.

Finally, one commenter stated that the notification requirement would allow a dishonest vendor to commit a violation without consequence and continue to do so for an extended period. The Department does not agree. A State agency may initiate a claim pursuant to § 246.12(k) regarding the food instruments containing the violative incidences even though the number of violative incidences (i.e., the pattern) needed to impose a sanction has not been established. Moreover, claims may be initiated before or after the investigation is completed; § 246.12(k)(4) states that 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.

Compliance Investigation Consisting of One Violative Incidence (§ 246.12(l)(2)(i) and (l)(3)(v))

One commenter stated that the vendor would be defenseless if the State agency defines one compliance buy as an investigation, since the vendor owner or manager would only learn about an employee's error when the State agency imposes a sanction on the vendor; the rule should require that, upon the initial discovery of any violation, the vendor must be notified, and this initial discovery must not constitute an investigation.

One violative incidence would constitute a complete investigation under the current regulations for only the most serious types of vendor violations subject to mandatory sanctions. As set forth in § 246.12(l)(1)(ii) and (l)(1)(iii), one violative incidence of trafficking (buying or selling WIC food instruments for cash) or illegal sales (selling firearms, ammunition, explosives, or controlled substances in exchange for WIC food instruments) must result in a six-year disqualification, and one violative incidence of the sale of alcoholic beverages or tobacco products in exchange for WIC food instruments must result in a three-year disqualification.

A pattern of violative incidences must be established in order to impose any of the other mandatory vendor sanctions. This pertains to four violations subject to mandatory three-year disqualifications, including overcharging; receiving, transacting, or redeeming food instruments outside of authorized channels; charging for supplemental food not received by the participant; and providing credit or non-food items (other than alcoholic beverages, tobacco products, cash, firearms, ammunition, explosives, or controlled substances) in exchange for WIC food instruments. A pattern of violative incidences must also be established in order to impose a mandatory one-year disqualification based on providing unauthorized food items, including for supplemental foods provided in excess of those listed on the food instrument.

By contrast, the current § 246.12(l)(2)(i) does not require that a pattern of violative incidences must be established in order for a State agency to impose sanctions based on violations which are not subject to mandatory

sanctions, referred to as ''State agency vendor sanctions.'' The State agency has the discretion to define such violations and the resulting sanctions, including the number of violative incidents required. However, the resulting disqualifications may not exceed one year because the violations addressed by State agency vendor sanctions are less serious than those addressed by mandatory sanctions.

Thus a State agency vendor sanction may be based on only one instance of a violation even though the more serious mandatory sanctions require a pattern of violative incidences; only the most serious mandatory sanctions are imposed based on one violative incidence.

As such, the proposed notification requirement would not apply to mandatory or State agency vendor sanctions based on one incidence of a violation; for those sanctions, one compliance buy would constitute a complete investigation. As a result, a vendor may receive notification and an opportunity to correct more serious violations that require a pattern of violative incidences, but no such opportunity for less serious violations subject to State agency vendor sanctions.

We believe that this result is inconsistent. Thus the Department has concluded that the State agency discretion under the current regulations to require only one violative incidence in order to impose State agency vendor sanctions is incompatible with the new notification requirement.

Accordingly, § 246.12(l)(2)(i) is revised in this final rule to state that a State agency vendor sanction must be based on a pattern of violative incidences. Also, the final rule includes a conforming change by adding § 246.12(l)(3)(v) to state that a single violative incidence visit may only be used to establish a violation for trafficking, illegal sales, and exchange of alcohol or tobacco for WIC food instruments.

Administrative Review (§ 246.18(a)(1)(iii)(F))

One commenter stated that the State agency's determination against providing notification should be subject to administrative review so that the vendor could present evidence illustrating that a State agency's determination to withhold notification was based on factors that a reasonable person could not believe justified the withholding of notification. Another commenter stated that the State agency's determination should be subject to review because the circumstances under which a State agency may avail itself of an exception to the notification requirement are narrowly drawn by the statute.

The Department does not agree. As stated at 71 FR 43382 of the proposed rule, administrative review of the absence of such notification would be inconsistent with the discretion provided to the State agency by the statute. Further, the information used by the State agency to make its determination may not be appropriate for public disclosure, such as the high-risk determination process, knowledge of an investigation conducted by another agency, and evidence obtained from a confidential source. Accordingly, § 246.18(a)(1)(iii)(F) of the proposed rule remains unchanged in the final rule.

2. List of Infant Formula Manufacturers, Wholesalers, Distributors, and Retailers (§§ 246.4(a)(14)(xvii), 246.12(g)(3)(i), 246.12(g)(11), 246.12(h)(3)(ii), 246.12(i)(2), and 246.18(a)(1)(iii)(D))

Section 203(e)(8) of Public Law 108–265 amends Section 17(h)(8)(A) of the CNA by requiring that each State agency maintain 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 FDA that provide infant formula. This statute requires authorized vendors to only purchase infant formula from sources on the above-described list. In December 2004, State agencies were notified of the requirement and when to amend their State Plans, vendor agreements, vendor manuals, and vendor training plans and materials as appropriate to reflect this new requirement.

This provision is intended to prevent stolen infant formula from being purchased with WIC food instruments. Such formula may constitute a health hazard for a variety of reasons, including direct tampering with formula before it is sold to unsuspecting retailers, falsification of labeling to change expiration dates, counterfeiting, or improper storage.

The Department proposed to add a new § 246.12(g)(10) which would require the State agency to provide the above-noted list of infant formula sources to the vendors on at least an annual basis, and that list must include the addresses as well as the names of the businesses; this is intended to make it easier for vendors to locate a nearby business and also to avoid inadvertently contacting an unlicensed business with a similar name. In addition, in § 246.12(g)(10)(i), the Department proposed to require a State agency to notify vendors that they must purchase infant formula only from the sources set forth on the State agency's list, although the State agency may, at its option, permit vendors to obtain infant formula from sources on another State agency's list. (Section 246.12(g)(10) of the proposed rule has become § 246.12(g)(11) in the final rule.) Further, §§ 246.4(a)(14)(xvii) and 246.12(g)(3)(i) proposed to require the State agency to adopt a new vendor selection criterion requiring vendors to obtain infant formula from the listed sources as a condition of authorization.

Eleven comments addressed these provisions; two supported the provisions unconditionally, one supported the provisions conditionally, with comments, and eight opposed the provisions.

Several comments questioned the effectiveness of the legislative provision and recommended that this provision be amended. One commenter stated that the proposed rule will not consistently prevent vendors from obtaining formula from unlisted suppliers and thus will not prevent stolen or defective formula from reaching WIC participants. Another commenter stated that the purchase of infant formula for sale by retailers is not sufficiently regulated by most States to keep adulterated stolen infant formula off of the shelves of retail stores because State or local business or health licensing in most States does not involve the oversight needed to ensure that retail stores only obtain infant formula from legitimate sources. This commenter recommended that the legislative provision be amended to prohibit vendors from obtaining infant formula from retailers, or give the State agency the discretion to exclude retailers. As an alternative to the list requirement, two commenters recommended that State agencies be required to routinely verify that their vendors have purchased infant formula from legitimate sources, such as at authorization or during routine monitoring visits. One commenter stated that the burden should be on the vendor to show that it obtains infant formula from an acceptable source.

These comments recommend revision of the legislative provision and are thus beyond the scope of this rulemaking. However, regarding State discretion on the exclusion of retailers, § 246.12(g)(10)(iii)(A) of the proposed rule would permit the exclusion of a State-licensed entity when specifically required by State law or regulations. State agencies would need to consult with their legal counsel to determine the correct process for implementing any restrictions on its list of infant formula

sources. Section 246.12(g)(10)(iii)(A) of the proposed rule remains unchanged in content, and now appears at § 246.12(g)(11)(iii)(A) of the final rule. Also, in § 246.12(g)(10), the Department proposed to permit the State agency to provide the list to vendors in a hard copy format or by other effective means, e.g., providing vendors with a telephone number, e-mail address, or Web site to inquire about the license status of a source. Under the proposed rule, a method of communicating this information to vendors would be acceptable if it is effective. For example, some vendors may not have access to the Internet and will need a hard copy provided by the State agency, or some other means to determine if a business is licensed. Section 246.12(g)(10)(iii)(A) of the proposed rule remains unchanged in content, and now appears at § 246.12(g)(11)(iii)(A) of the final rule.

Two commenters stated that an annual list would not account for the licensing of entities following issuance of the list. If a vendor wants to obtain infant formula from an entity which is not listed, the vendor can contact the State agency for the most up-to-date information. The Department recommends that State agencies seek input from their vendors on the best method for obtaining the most up-to-date information. A vendor advisory council would be an excellent forum for this discussion. Section 246.12(g)(10) of the proposed rule remains unchanged in content, and now appears at § 246.12(g)(11) of the final rule.

Two comments stated that the list requirement will make it difficult for vendors to obtain infant formula from entities located out-of-state. One of the commenters stated that a standard method for reporting data elements is needed because otherwise a State agency will find it difficult to determine if an out-of-state entity is on another State agency's list, and this commenter also inquired as to whether each State agency would need to obtain the lists of other State agencies. Section 246.12(g)(3)(i) of the proposed rule would provide State agencies with the discretion to permit its vendors to obtain infant formula from out-of-state entities on the lists of other State agencies. Section 246.12(g)(3)(i) of the proposed rule remains unchanged in the final rule. Thus a vendor desiring to obtain infant formula from an out-of-State supplier needs to contact its State agency for further instructions on whether this is permitted, and, if so, the procedure for doing so.

One commenter requested guidance regarding the State agency's responsibilities for ensuring that vendors are only obtaining infant formula from the licensed suppliers on the list, such as collecting supplier data from the vendors. Section 246.12(g)(3)(i) of the proposed rule would not have permitted the State agency to authorize a vendor applicant unless it determines that the vendor applicant obtains infant formula only from entities included on the State agency's list described in § 246.12(g)(10). As pointed out in the proposed rule at 71 FR 43379, vendors would be required to maintain invoices or receipts showing the source of their infant formula purchases to enable the State agency to monitor vendor compliance. State agencies currently have the authority to require vendors to maintain such documentation under § 246.12(h)(3)(xv).

Further, State agencies also currently have the authority under § 246.12(g)(3) to 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. Finally, State agencies currently have the discretion under § 246.12(l)(2) to establish sanctions for vendors which have obtained infant formula from unlicensed entities. The State agency may use routine monitoring visits pursuant to § 246.12(j)(2) to review infant formula invoices or other similar documentation for the purpose of determining whether the vendor has continued to obtain infant formula from a licensed entity.

Finally, one commenter stated that § 246.12(h)(3)(ii)(A) in the proposed rule should use the term ''participant'' instead of ''customer.'' The Department agrees. Accordingly, ''participant'' is substituted for ''customer'' in the last sentence of § 246.12(h)(3)(ii)(A) in the final rule.

3. Incentive Items (§§ 246.12(g)(3)(iv), 246.12(h)(8), 246.12(i)(2), 246.12(l)(1)(iv)(B), and 246.18(a)(1)(iii)(E))

Section 203(e)(13) of Public Law 108–265 amends section 17(h)(14) of the CNA by prohibiting a State agency from authorizing or making payments to above-50-percent vendors which provide incentive items or other free merchandise to program participants, with only two exceptions. One exception includes food or merchandise of nominal value as determined by the Secretary; USDA advised State agencies in December 2004 that the nominal value is less than $2. The other exception includes incentive items or other merchandise for which the vendor provides proof to the State agency showing that the vendor had obtained the incentive items or other merchandise at no cost. Above-50-percent vendors are for-profit vendors that derive more than 50 percent of their annual food revenue from the transaction of WIC food instruments or for-profit vendor applicants expected to derive more than 50 percent of annual food revenue from the transaction of WIC food instruments. The above-50-percent vendor category includes vendors which have often been referred to as ''WIC-only stores.'' In December 2004, State agencies were advised to amend their vendor selection criteria and sanction schedules to reflect this new requirement.

The Department proposed to add a new vendor selection criterion to the WIC regulations which would make compliance with the State agency's incentive items policies a condition of vendor authorization for above-50-percent vendors. This proposed provision, § 246.12(g)(3)(iv), also described allowable and prohibited incentive items. Further, the Department proposed to include a requirement for a mandatory sanction for incentive items violations committed by above-50-percent vendors. The proposed rule would also require training for vendors on the policies and procedures concerning incentive items. Finally, the rule proposed to require the State agency to include in its vendor agreement with the above-50-percent vendor, or in another document provided to the above-50-percent vendor and cross-referenced in the vendor agreement, the policies and procedures regarding the provision of incentive items to customers.

Seven comments were submitted on the incentive items provisions of the proposed rule. Two of these comments supported the incentive items provisions unconditionally; three supported the provisions conditionally, requesting revisions; and, two comments opposed the provisions.

Services

Under the proposed rule, services which constitute a conflict of interest, or which have the appearance of such conflict, would be a prohibited incentive item. For example, assistance with applying for WIC benefits would be prohibited because the above-50-percent vendor would benefit financially if the applicant is certified. For-profit services for which the participant pays a fair market value, and which do not present a conflict of interest, would be allowable.

One commenter stated that for-profit services should not be permitted as an

incentive item, as would have been allowed by § 246.12(g)(3)(iv)(A)(*4*) of the proposed rule. This commenter stated that it would require extensive research by the State agency to determine the fair market value of a service; the State agency's determination would be open to interpretation; and, resources would be needed to monitor vendor compliance. The commenter stated that such other services are really other business enterprises, so that WIC requirements for such activity would infringe on property rights. In addition, the commenter stated that this provision implies that transportation service could be an acceptable incentive item, but which should be prohibited for the aforementioned reasons. Similarly, another commenter stated that § 246.12(g)(3)(iv)(B)(*7*) of the proposed rule should not have proposed to prohibit services of greater than nominal value if they are minimal customary courtesies of the retail food trade, are not for-profit, and do not involve an actual or apparent conflict of interest. One other commenter stated that State agencies should not be able to prohibit the minimal customary courtesies of the retail food trade or for-profit services offered at fair market value, as would have been permitted by § 246.12(g)(3)(iv)(B)(*2*) of the proposed rule. Section 246.12(g)(3)(iv)(A)(*5*) of the proposed rule described such courtesies as helping a customer to find an item, bagging food, and assisting with loading food into the customer's vehicle, but these are only examples; other legitimate minimal customary courtesies may exist.

The legislative provision was intended to restrict the use of WIC funds by above-50-percent vendors to provide incentive items. (See House Committee on Education and the Workforce, Report No. 108–445, March 23, 2004, page 59, and Senate Committee on Agriculture, Nutrition, and Forestry, Report No. 108–279, June 7, 2004, page 58.) The legislative provision was not intended to infringe on the property rights of vendors to engage in legitimate for-profit business enterprises except to the extent that WIC funds are involved. Thus above-50-percent vendors must be permitted to engage in for-profit business enterprises that offer goods and services at a fair market value to WIC participants, since such goods and services would not be subsidized with WIC funds. Accordingly, the subject of for-profit business enterprises is addressed in § 246.12(g)(3)(iv)(C) of the final rule instead of § 246.12(g)(3)(iv). Section 246.12(g)(3)(iv)(C) states that for-profit business enterprises that offer goods or services at a fair market value to WIC participants 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. Goods or services of a for-profit enterprise would include any kind of business enterprise, service or otherwise; for example, both the sale of diapers as well as a diaper service would be excluded from the restrictions on incentive items.

The State agency will need to determine whether a business enterprise offers its goods or services at a fair market value based on comparable for-profit businesses. However, § 246.12(h)(3)(xv) already provides the State agency with the authority to specify the records which must be maintained by the vendor and provided to the State agency upon request. Thus the State agency may require the vendor to show that the prices charged by its business enterprise are comparable to the prices charged by comparable for-profit business enterprises. Also, the State agency may require that the vendor provide more information.

The Department continues to believe that State agencies should have the discretion to permit or prohibit above-50-percent vendors from providing participants with the minimal customary courtesies of the retail food trade, as reflected in § 246.12(g)(3)(iv)(A) of the final rule.

Finally, the comment on § 246.12(g)(3)(iv)(B)(7) of the proposed rule was correct to point out that the legislative provision does not refer to services as an exception to the prohibition on incentive items; the only exceptions specified in the legislative provision are food or merchandise of nominal value. However, the commenter agreed with the proposed rule's exception for the minimal customary courtesies of the retail food trade even though the legislative provision does not specify an exception for such services. The Department concludes that, given the intent of the incentive items restrictions in the legislation, services should be treated the same as food or merchandise. As noted above, the point of these restrictions is to restrict the use of WIC funds by above-50-percent vendors to provide incentive items. Services also cost money, which, in the case of above-50-percent vendors, would be provided by WIC transactions. Thus incentive items in the form of services should be restricted to the same extent as incentive items in the form of food or merchandise. Accordingly, the term ''services'' has been added to § 246.12(g)(3)(iv)(A)(*1*) and (g)(3)(iv)(A)(*2*) of the final rule for the purpose of treating services in the same manner as food or merchandise.

Impact on Market-Competitive Above-50-Percent Vendors

In the proposed rule, the Department specifically solicited comments on whether there are circumstances in which a legitimately market-competitive above-50-percent vendor could be disadvantaged by the prohibition on providing incentives to non-WIC customers. Two commenters stated that the incentive items restrictions of the proposed rule would penalize non-WIC-only above-50-percent vendors, because these vendors are competing for the same customers with other non-WIC-only vendors which are not restricted in their use of incentive items. However, the legislative provision does not distinguish between WIC-only vendors and other above-50-percent vendors; the legislative provision treats all above-50-percent vendors the same. As previously noted, revision of legislative provisions is beyond the scope of this rule-making.

Miscellaneous Comments

One commenter stated that § 246.12(g)(3)(iv)(B)(2) of the proposed rule could be interpreted as ''all or nothing,'' instead of proposing to provide the State agency with the authority to allow some but not all kinds of allowable incentive items. The commenter recommended that this provision refer to any allowable incentive item, not all incentive items as a whole. The Department agrees. Accordingly, this provision has been deleted and replaced with language in § 246.12(g)(3)(iv)(A) of the final rule which clarifies that a State agency may approve any of the incentive items listed in paragraph (g)(3)(iv)(A) at its discretion.

One commenter stated that § 246.12(h)(8)(ii) of the proposed rule should have proposed that the vendor, not the State agency, be required to maintain the copies of the vendor invoices showing that each incentive item had been obtained at less than the $2 nominal value limit or at no cost. This commenter states that the nominal value limit should be enforced by State agency review or audit. For example, if a vendor is discovered to be providing incentive items to participants during a compliance buy investigation, the State agency could request copies of the invoices from the vendor. However, the statutory provision at 42 U.S.C. 1786(h)(14) requires that State agencies not authorize an above-50-percent vendor providing incentive items above

the nominal value limit. Consistent with this statutory provision, the proposed § 246.12(g)(3)(iv) would prohibit the authorization of above-50-percent vendors who provide prohibited incentive items. As previously noted, the State agency may provide the above-50-percent vendor with a list of pre-approved incentive items at authorization, in which case the State agency does not need to obtain vendor invoices. Otherwise, the need for such documentation arises initially at authorization. Accordingly, the proposed § 246.12(h)(8)(ii) has been revised in the final rule to state that the State agency must maintain this documentation unless the State agency provides the vendor with a list of pre-approved incentive items at authorization.

One commenter also requested clarification on whether advertising constitutes an actual or apparent conflict of interest by creating the impression that the WIC Program is the source of the advertisement, such as an advertisement providing a 1–888 telephone number for contacting the vendor about eligibility for a ''federal nutrition assistance program that helps pregnant women.'' Advertising is not subject to this final rulemaking because it was not addressed in the proposed rule. However, § 246.12(g)(3)(iv) of this final rule prohibits the authorization of an above-50-percent vendor which indicates an intention to provide prohibited incentive items to customers, and refers to advertising as evidence of such intent. Further, § 246.12(g)(3)(iv)(B)(*1*) of this final rule prohibits above-50-percent vendors from providing services which constitute conflicts of interest or appear to do so, such as assistance with applying for WIC benefits.

4. Adjusting Vendor Civil Money Penalty (CMP) Levels for Inflation (§ 246.12(l)(1)(x)(C) and (l)(2)(i))

The Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), Public Law 101–410, 28 U.S.C 2461, requires adjustment of civil money penalty (CMP) levels to reflect inflation at least once every four years. This only applies to CMPs set forth in statutes. The only WIC vendor-related CMPs established in the CNA pertain to convictions in court for trafficking and illegal sales (§ 246.12(l)(1)(i)). Thus the Department's final rule implementing FCPIAA, ''Department of Agriculture Civil Monetary Penalties Adjustment,'' 70 FR 29573, May 24, 2005, only affected the WIC CMPs based on convictions in court for trafficking and illegal sales. As a result, the WIC CMP levels for all other vendor violations were not adjusted for inflation. This includes all CMPs for vendor violations that are addressed administratively by the State agency instead of through the courts. The Department believes that the amount of all CMPs should be uniform for all vendor violations. Accordingly, the proposed rule included provisions which would change the amount of the CMPs for the remaining WIC vendor violations to be consistent with the CMP levels based on convictions.

Four comments were submitted concerning these provisions. Three comments supported these provisions unconditionally. One comment supported the provisions conditionally. This commenter stated that any adjustment to CMP levels should be prospective, not retroactive, so that the inflation adjustment should commence with the effective date of the final rule as opposed to an immediate increase in the amount of those penalties. The Department agrees. The new CMP levels take effect on the effective date of the final rule, which, as noted above under **DATES,** is 60 days following the publication of the final rule in the **Federal Register**. The new CMP levels may not be implemented prior to that time.

List of Subjects in 7 CFR Part 246

Food assistance programs, Food donations, Grant programs—Social programs, Indians, Infants and children, Maternal and child health, Nutrition education, Public assistance programs, WIC, Women.

■ For the reasons set forth in the preamble, 7 CFR part 246 is amended as follows:

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

■ 1. The authority citation for part 246 continues to read as follows:

Authority: 42 U.S.C. 1786.

■ 2. In § 246.4, revise the first sentence of paragraph (a)(14)(iii) and add a new paragraph (a)(14)(xvii) to read as follows:

§ 246.4 State plan.

(a) * * *

(14) * * *

(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 sanction schedule, the process for notification of violations, or policies on incentive items are in the State agency's regulations, through citations to the regulations. * * *

* * * * *

(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.

* * * * *

■ 3. In § 246.12:

■ a. Amend paragraph (g)(3)(i) by adding a sentence at the end of the paragraph.

■ b. Add new paragraphs (g)(3)(iv) and (g)(11).

■ c. Revise paragraph (h)(3)(ii).

■ d. Revise the third sentence of paragraph (h)(3)(xviii).

■ e. Add new paragraph (h)(8).

■ f. Revise paragraphs (i)(2) and (l)(1)(iv).

■ g. Amend the second sentence of paragraph (l)(1)(x)(C) by removing the word ''$10,000'' and adding in its place the words ''the maximum amount specified in § 3.91(b)(3)(v) of this title'';

■ h. Amend the third sentence of paragraph (l)(1)(x)(C) by removing the words ''$10,000, except for those violations listed in paragraph (l)(1)(i) of this section, where the civil money penalty shall be the maximum amount per violation specified in § 3.91(b)(3)(v) of this title for trafficking violations, or § 3.91(b)(3)(vi) of this title for selling firearms, ammunition, explosives, or controlled substances in exchange for food instruments.'' and adding in their place the words ''the maximum amount specified in § 3.91(b)(3)(v) of this title for each violation.'';

■ i. Amend the fifth sentence of paragraph (l)(1)(x)(C) by removing the words ''$40,000, except for those violations listed in paragraph (l)(1)(i) of this section, where the total amount of civil money penalties may not exceed the maximum amount for violations

occurring during a single investigation specified in § 3.91(b)(3)(v) of this title for trafficking violations, or § 3.91(b)(3)(vi) of this title for selling firearms, ammunition, explosives, or controlled substances in exchange for food instruments.'' and adding in their place the words ''the amount specified in § 3.91(b)(3)(v) of this title as the maximum penalty for violations occurring during a single investigation.'';

■ j. Amend paragraph (l)(2)(i) by removing the words ''$10,000 for each violation.'' in the fourth sentence, and adding in their place the words ''a maximum amount specified in § 3.91(b)(3)(v) of this title for each violation.'', by removing the word ''$40,000.'' in the fifth sentence, and adding in its place the words ''an amount specified in § 3.91(b)(3)(v) of this title as the maximum penalty for violations occurring during a single investigation.'';

■ k. Further amend paragraph (l)(2)(i) by adding a sentence at the end of the paragraph; and

■ l. Revise paragraph (l)(3).

The revisions and additions read as follows:

§ 246.12 Food delivery systems.

* * * * *

(g) * * *

(3) * * *

(i) * * * The State agency may not authorize a vendor applicant unless it determines that the vendor applicant obtains infant formula only from sources included on the State agency's list described in paragraph (g)(11) of this section.

* * * * *

(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;

(*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.

* * * * *

(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 formula. 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) * * *

(3) * * *

(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.

* * * * *

(xviii) * * * 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.

* * * * *

(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 documents 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) * * *

(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.

* * * * *

(l) * * *

(1) * * *

(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.

* * * * *

(2) * * *

(i) * * * A State agency vendor sanction must be based on a pattern of violative incidences.

* * * * *

(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 (l)(1)(iii)(C) through (l)(1)(iii)(F), (l)(1)(iv), and (l)(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 (l)(1)(ii)(A), (l)(1)(ii)(B), and (l)(1)(iii)(A) of this section.

* * * * *

■ 4. In § 246.18, redesignate paragraphs (a)(1)(iii)(D) through (a)(1)(iii)(H) as paragraphs (a)(1)(iii)(G) through (a)(1)(iii)(K) and add new paragraphs (a)(1)(iii)(D), (a)(1)(iii)(E), and (a)(1)(iii)(F), to read as follows:

§ 246.18 Administrative review of State agency actions.

(a) * * *

(1) * * *

(iii) * * *

(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);

* * * * *

Dated: December 23, 2008.

Nancy Montanez Johner,

Under Secretary, Food, Nutrition, and Consumer Services.

Note: This Appendix will not appear in the Code of Federal Regulations.

Title: Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Discretionary WIC Vendor Provisions in the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265.

Date: December 11, 2008.

Agency: USDA, Food and Nutrition Service.

Contact: Ed Harper.

Phone: (703) 305–2340.

Fax: (703) 305–2576.

E-mail: Edward.Harper@fns.usda.gov.

Action:

a. *Nature:* Final Rule.

b. *Need:* This rule amends regulations for the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) by adding three retail vendor provisions mandated by the Child Nutrition and WIC Reauthorization Act of 2004. The

amendments are intended to (1) Strengthen the due process accorded to vendors found to be in violation of program rules, (2) reduce the risk that mislabeled, improperly stored, expired, or stolen infant formula is distributed to WIC participants, and (3) ensure that program funds are not used to subsidize the distribution of incentive items by vendors who derive more than fifty percent of their food sales revenue from WIC.

The rule also restores uniformity to the WIC vendor civil money penalty (CMP) system by indexing all maximum CMP amounts for inflation. The Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA) requires periodic adjustment of CMP levels to reflect inflation. However, the Act applies only to CMPs identified by statute. The only WIC vendor-related CMPs that are covered by the FCPIAA are those imposed following a conviction for trafficking or illegal sales. As a result, the CMP caps for those violations are the only WIC vendor sanctions subject to an inflation adjustment; the maximum penalties for other vendor violations are not. This rule would restore uniformity to the WIC CMP system by making an initial upward adjustment to the maximum CMP amount for penalties not covered by the FCPIAA, and then subjecting all CMP maximums to the same future inflation adjustments.

c. *Affected Parties:* The parties affected by this regulation are the USDA's Food and Nutrition Service (FNS), State agencies that administer the WIC program, retail vendors that are authorized to accept WIC food instruments, and infant formula wholesalers, distributors, retailers, and manufacturers.

Action
Background
Summary of Key Provisions
Table 1: Regulatory Language and Effects of the Rule
Cost/Benefit Assessment of Economic and Other Effects
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Benefits
1. Incentive items
2. Vendor notification of initial program violations
3. Authorized infant formula suppliers
4. CMP inflation
Cost Benefit Summary
Alternatives
1. State agency discretion in giving notice to vendors of initial program violations
2. Requirement that State agencies determine whether to withhold or provide notice of initial vendor violations on a case by case basis

Background

This rule amends the regulations of the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) by adding three vendor-related requirements mandated by the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265. The rule also restores uniformity to the maximum CMP amounts imposed on vendors for violation of program rules. These changes are described in greater detail below.

Vendor Notification

Penalties for some WIC vendor violations are not imposed until a vendor is found to have engaged in a pattern of improper behavior. In an effort to discourage repeat violations of the same program rules, and to strengthen due process for vendors accused of violations, this rule requires WIC State agencies to provide WIC vendors with written notice of an initial violation. The rule provides an exception for cases where State agencies determine that notification would compromise an ongoing investigation.

Authorized Infant Formula Suppliers

The rule requires State agencies to maintain lists of State-licensed wholesalers, distributors, and retailers, and infant formula manufacturers registered with the Food and Drug Administration. These lists must be distributed by the State agencies to their authorized WIC vendors, and must be included, directly or by reference, in the State agencies' WIC State Plans. In order to prevent defective formula from reaching WIC participants, the rule requires WIC vendors to purchase infant formula only from sources on those lists.

Incentive Items

Retailers that serve WIC clients exclusively (''WIC-only'' stores) have traditionally offered incentive items or free services to their customers. These incentives are one way that WIC-only stores compete with other retailers; WIC-only stores do not attract WIC clients based on the price of their products. In order to prevent WIC program funds from subsidizing these incentives through federal reimbursement of inflated store prices, the rule prohibits the use of most incentives by WIC-only vendors and by the broader group of retailers that derive more than 50 percent of their food sales revenue from WIC food instruments. The rule would continue to allow WIC-authorized vendors to offer incentives of nominal value, and incentives acquired by vendors at no cost.

Civil Money Penalties

The rule subjects all maximum civil money penalty (CMP) levels to periodic inflation adjustments. CMPs are levied against WIC vendors for program violations. This provision restores consistency to the penalty system. Under current rules, the maximum CMP for most vendor violations is fixed; the only CMP maximum amounts that are subject to periodic inflation adjustments are those imposed for trafficking and illegal sales violations that result in convictions in court.[1] As a result, the maximum CMP varies by type of violation. To correct this, the rule makes an immediate adjustment to the maximum penalty amounts that had not previously been subject to inflation adjustments. On enactment of the rule, the maximum penalty for those violations will be raised to $11,000 from $10,000 per incident; the total maximum CMP for all violations committed during a single investigation will be raised to $44,000 from $40,000. In future years, the maximum penalty

[1] These violations are covered by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461).

amounts for all violations will be subject to the same inflation adjustment.

With the exception of the CMP inflation provision, the changes proposed by this rule were mandated by Congress. They were effective October 1, 2004. FNS issued policy and guidance to WIC State agencies to implement these mandatory provisions in December 2004 and April 2005. This rule reflects the earlier policy, guidance, and proposed rule issued by FNS.

Summary of Key Provisions

Table 1: Regulatory Language and Effects of the Rule

Current Provision	Proposed Rule	Final Rule	Rule's Effects
Authorized infant formula manufacturers, wholesalers, distributors, and retailers	**Authorized infant formula manufacturers, wholesalers, distributors, and retailers**	**Authorized infant formula manufacturers, wholesalers, distributors, and retailers**	**USDA / FNS:** Reduces the possibility that Federal dollars will be used to purchase stolen, expired, contaminated, or unauthorized infant formula. FNS supplies the list of FDA-registered manufacturers of infant formula to the State agencies.
§246.4(a)(14) – State plans No provision regarding State-licensed and FDA-registered infant formula suppliers.	**§ 246.4(a)(14)(xvii) – State plans** States must include in their State plans a set of policies and procedures for compiling and distributing to WIC vendors a list of FDA-registered infant formula manufacturers, and State-licensed wholesalers, retailers and distributors.	**§246.4(a)(14)(xvii) – State plans** States must include in their State plans a set of policies and procedures for compiling and distributing to WIC vendors a list of FDA-registered infant formula manufacturers, and State-licensed wholesalers, retailers and distributors.	**State WIC agencies:** Modest annual increase in administrative burden to compile and distribute the list of authorized infant formula suppliers to WIC vendors. State agencies must contact their State licensing agencies to obtain the list of licensed wholesalers, distributors, and retailers. (States are given the list of FDA-registered infant formula manufacturers by FNS). Minimal annual increase in administrative burden to update WIC State plans to include policies and procedures for compiling and distributing the lists to authorized vendors.
§ 246.12(g) – vendor authorization No provision regarding State-licensed and FDA-registered infant formula suppliers.	**§ 246.12(g)(3)(i) – vendor authorization, selection criteria, minimum variety and quantity of supplemental foods** The State agency may not authorize a vendor applicant unless it determines that the vendor applicant obtains infant formula only from sources included on the State agency's list.	**§ 246.12(g)(3)(i) – vendor authorization, selection criteria, minimum variety and quantity of supplemental foods** The State agency may not authorize a vendor applicant unless it determines that the vendor applicant obtains infant formula only from sources included on the State agency's list.	**Infant formula wholesalers, distributors, retailers, and manufacturers:** Reduces possible loss of business to unapproved wholesalers, distributors, retailers and manufacturers.
	§246.12(g)(10) §246.12(g)(10)(i), (ii), (iii) – vendor authorization, list of authorized formula suppliers	**§246.12(g)(11), §246.12(g)(11)(i), (ii), (iii) – vendor authorization, list of authorized formula suppliers**	**Authorized retail vendors:** Minimal cost to deal only with authorized formula suppliers and manufacturers. Compliance with the rule reduces the possibility that vendors will purchase stolen, expired, or contaminated formula.
			WIC participants: Helps guarantee the safety

	The state agency must provide the list, with addresses, to all authorized WIC vendors. The State agency must notify vendors that they must purchase infant formula from the sources on the State's list (or on another State's list, if the State agency chooses to allow that). The State agency may not exclude a State-licensed entity from the list unless permitted or required by State law.	The state agency must provide the list, with addresses, to all authorized WIC vendors. The State agency must notify vendors that they must purchase infant formula from the sources on the State's list (or on another State's list, if the State agency chooses to allow that). The State agency may not exclude a State-licensed entity from the list unless permitted or required by State law.	and quality of infant formula consumed.
§246.12(h)(3)(ii) – vendor agreements No provision regarding State-licensed and FDA-registered infant formula suppliers.	**§ 246.12(h)(3)(ii) – vendor agreements** The vendor agreement must contain language that restricts the vendor to providing its WIC customers only infant formula that the vendor obtained from sources on the State's authorized supplier and manufacturer list.	**§246.12(h)(3)(ii) – vendor agreements** The vendor agreement must contain language that restricts the vendor to providing its WIC customers only infant formula that the vendor obtained from sources on the State's authorized supplier and manufacturer list.	
§246.12(i)(2) – State vendor training No provision regarding State-licensed and FDA-registered infant formula suppliers.	**§246.12(i)(2) – State vendor training** Annual vendor training must cover the requirement that vendors obtain infant formula only from sources on the State agency list.	**§246.12(i)(2) – State vendor training** Annual vendor training must cover the requirement that vendors obtain infant formula only from sources on the State agency list.	
§246.18 - Administrative review of State agency actions: actions not subject to review by vendors No provision regarding State-licensed and FDA-registered infant formula suppliers.	**§246.18(a)(1)(iii)(D) - Administrative review of State agency actions: actions not subject to review by vendors** The State agency's decision to include or exclude an infant formula manufacturer, wholesaler,	**§246.18(a)(1)(iii)(D) - Administrative review of State agency actions: actions not subject to review by vendors** The State agency's decision to include or exclude an infant formula manufacturer, wholesaler,	

	distributor, or retailer from the State agency list is not subject to administrative review.	distributor, or retailer from the State agency list is not subject to administrative review.	
Incentive items – above-50-percent vendors	**Incentive items – above-50-percent vendors**	**Incentive items – above-50-percent vendors**	**USDA / FNS:** Protects WIC program from overpaying for WIC foods. Should lower program costs.
§246.4(a)(14)(iii) – State agency plan: vendor agreement, description of food delivery system No provision regarding incentive items.	**§ 246.4(a)(14)(iii) – State agency plan: vendor agreement, description of food delivery system** The sample vendor agreement that must be contained in the State agency plan's food delivery system description must make reference to the State agency's policies on incentive items.	**§246.4(a)(14)(iii) – State agency plan: vendor agreement, description of food delivery system** The sample vendor agreement that must be contained in the State agency plan's food delivery system description must make reference to the State agency's policies on incentive items.	**State WIC agencies:** Modest increase in administrative burden to establish a policy and process for approving or denying requests by above-50-percent vendors to offer incentive items. Modest increase in burden to include or refer to these policies in the agencies' State Plans and vendor agreements. Modest increase in burden associated with responding to individual vendor requests for incentive item approval, and for maintaining documentation of individual approvals. Reduces payments to above-50-percent vendors.
§ 246.12(g) – vendor authorization No provision regarding incentive items.	**§ 246.12(g)(3)(iv) – vendor authorization, selection criteria, provision of incentive items** State agencies may not authorize, continue to authorize, or make payments to above-50-percent vendors who distribute or intend to distribute prohibited incentive items to customers.	**§246.12(g)(3)(iv) – vendor authorization, selection criteria, provision of incentive items** State agencies may not authorize, continue to authorize, or make payments to above-50-percent vendors who distribute or intend to distribute prohibited incentive items to customers.	**Infant formula wholesalers, distributors, retailers, and manufacturers:** None **Authorized retail vendors:** Vendors that previously relied on incentive items to attract customers may lose revenue. Vendors that did not previously rely on incentive items may win new customers. Vendors that continue to offer unauthorized or disallowed incentives face program sanctions.
	§246.12(g)(3)(iv)(A) Permissible incentives are food or merchandise of nominal value (less than $2) or obtained at no cost by the retailer. Also allowed are food sales and specials which involve no cost or less than $2 in cost to the vendor.	**§246.12(g)(3)(iv)(A)** Permissible incentives are food, merchandise, or services of nominal value (less than $2) or obtained at no cost by the retailer. Also allowed are food sales and specials which involve no cost or less than $2 in cost to the vendor. Permissible incentives also include minimal	**WIC participants:** Participants may receive fewer incentives, but those incentives are not program benefits.

		customary courtesies of the retail trade (bagging, loading bags in customer's car, etc.)
	§246.12(g)(3)(iv)(B) Impermissible incentives include lottery tickets offered at no charge or below face value, cash of any value, services which create a conflict of interest (such as assistance applying for WIC benefits), complimentary gifts made available in a public area, food or merchandise offered below cost, and, at the discretion of the State agency, any incentive allowed under §246.12(g)(3)(iv)(A)	**§246.12(g)(3)(iv)(B)** Impermissible incentives include lottery tickets offered at no charge or below face value, cash of any value, services which create a conflict of interest (such as assistance applying for WIC benefits), complimentary gifts made available in a public area, food, merchandise, or services offered below cost, any item which violates Federal, State, or local law, and, at the discretion of the State agency, any incentive allowed under §246.12(g)(3)(iv)(A)
		§246.12(g)(3)(iv)(C) Items sold at fair market value are not incentive items subject to approval or prohibition. However, they must not constitute a conflict of interest or result in a liability for the WIC program.
§246.12(h) – vendor agreements No provision regarding incentive items.	**§ 246.12(h)(8) – vendor agreements, allowable and prohibited incentive items for above-50-percent vendors** Vendor agreements for above-50-percent vendors (or other documents referenced in the agreements) must include the State agency's policy on incentive items.	**§246.12(h)(8) – vendor agreements, allowable and prohibited incentive items for above-50-percent vendors** Vendor agreements for above-50-percent vendors (or other documents referenced in the agreements) must include the State agency's policy on incentive items.

	§246.12(h)(8)(i), (ii), (iii) The State agency must provide written approval or disapproval of requests by above-50-percent vendors to offer incentive items. The State agency must maintain documentation showing that the items are obtained at no cost or fall below the nominal value limit. The State agency must define disallowed incentive items.	**§246.12(h)(8)(i), (ii), (iii)** The State agency must provide written approval or disapproval of requests by above-50-percent vendors to offer incentive items. The State agency must maintain documentation showing that the items are obtained at no cost or fall below the nominal value limit. The State agency must define disallowed incentive items.
§246.12(i)(2) – State vendor training, content No provision regarding incentive item training.	**§246.12(i)(2) – State vendor training, content** Annual vendor training must cover the State agency's policies and procedures regarding the use of incentive items.	**§246.12(i)(2) – State vendor training, content** Annual vendor training must cover the State agency's policies and procedures regarding the use of incentive items.
§246.12(l)(1)(iv) – Retail food delivery systems, vendor sanctions – one year disqualification No provision regarding incentive items	**§ 246.12(l)(1)(iv) – Retail food delivery systems, vendor sanctions – one year disqualification** The State agency must disqualify an above-50-percent vendor for one year for a pattern of offering prohibited incentive items to its WIC customers.	**§246.12(l)(1)(iv) – Retail food delivery systems, vendor sanctions – one year disqualification** The State agency must disqualify an above-50-percent vendor for one year for a pattern of offering prohibited incentive items to its WIC customers.
§246.18 - Administrative review of State agency actions: actions not subject to review by vendors No provision regarding State agency decisions on permissible for impermissible incentive items	**§246.18(a)(1)(iii)(E) - Administrative review of State agency actions: actions not subject to review by vendors** The State agency's decisions on permissible for impermissible incentive items are not subject to administrative review.	**§246.18(a)(1)(iii)(E) - Administrative review of State agency actions: actions not subject to review by vendors** The State agency's decisions on permissible for impermissible incentive items are not subject to administrative review.

Notification of vendor violations - sanctions

§246.4(a)(14)(iii) – State agency plan: vendor agreement, description of food delivery system

No provision regarding notification of certain initial vendor violations.

§246.12(h)(3)(xviii) – vendor agreements, 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 does not have to provide the vendor with prior warning that violations were occurring before imposing such sanctions.

Notification of vendor violations - sanctions

§ 246.4(a)(14)(iii) – State agency plan: vendor agreement, description of food delivery system

The sample vendor agreement that must be contained in the State agency plan's food delivery system description must make reference to the State agency's process for notification of certain initial vendor violations.

§ 246.12(h)(3)(xviii) – vendor agreements, 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.

Notification of vendor violations - sanctions

§246.4(a)(14)(iii) – State agency plan: vendor agreement, description of food delivery system

The sample vendor agreement that must be contained in the State agency plan's food delivery system description must make reference to the State agency's process for notification of certain initial vendor violations.

§246.12(h)(3)(xviii) – vendor agreements, 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.

USDA / FNS: To the extent that notification of initial vendor violations forestalls subsequent violations, program performance measures should improve; this improvement might take the form of a reduction in over- and under-payments. FNS will realize additional savings to the extent that vendor and customer fraud is reduced..

State WIC agencies: Modest increase in administrative burden of issuing notice to vendors of initial violations or, alternatively, of documenting why giving notice would compromise an ongoing investigation. At the same time, States will realize a reduction in the cost of administering and enforcing sanctions. The States, like FNS, will benefit from improved program performance an[illegible] a reduction in improper payments a[illegible]ud.

Infant formula wh[illegible]rs, distributors, retailers, and ma[illegible]rers: None

Authorized [illegible] vendors: Notice given after an initial program violation gives vendors an opportunity to avoid costly sanctions.

WIC participants: No direct or immediate benefit. However, the sanction provisions should improve program integrity, to the long-term benefit of future participants.

§246.12(l)(2)(i) – State agency vendor sanctions

No provision regarding a pattern of violations uncovered during compliance buys before a State agency sanction can be imposed..

§246.12(l)(3) – Vendor sanctions – prior warning
The State agency does not have to warn a vendor that violations had been detected before imposing mandatory or State agency vendor sanctions.

§246.12(l)(2)(i) – State agency vendor sanctions

No provision regarding a pattern of violations uncovered during compliance buys before a State agency sanction can be imposed..

§ 246.12(l)(3) – Vendor sanctions – notification of violations
The State agency must provide written notice when a compliance buy investigation reveals a violation for which a pattern must be established in order to impose a sanction. An exception is permitted if the State determines that such notice would compromise an investigation. This applies to all violations in §§(l)(1)(iii)(C) through (l)(1)(iii)(F), (l)(1)(iv), and (l)(2)(i) (essentially all sanctions for overcharges, unauthorized sales, and State agency-determined violations; it excludes trafficking, fraud, and exchange of WIC instruments for firearms, controlled substances, alcohol, or tobacco).

§246.12(l)(3)(i), (ii), (iii), (iv)
Vendors must be given written notice of an initial violation before imposing a sanction for a pattern of violations unless documentation explaining why notice would

§246.12(l)(2)(i) – State agency vendor sanctions

A State agency vendor sanction must be based on a pattern of violations if identified during compliance buys.

§246.12(l)(3) – Vendor sanctions – notification of violations
The State agency must provide written notice when a compliance buy investigation reveals a violation for which a pattern must be established in order to impose a sanction. An exception is permitted if the State determines that such notice would compromise an investigation. This applies to all violations in §§(l)(1)(iii)(C) through (l)(1)(iii)(F), (l)(1)(iv), and (l)(2)(i) (essentially all sanctions for overcharges, unauthorized sales, and State agency-determined violations; it excludes trafficking, fraud, and exchange of WIC instruments for firearms, controlled substances, alcohol, or tobacco).

§246.12(l)(3)(i), (ii), (iii), (iv)
Vendors must be given written notice of an initial violation before imposing a sanction for a pattern of violations unless documentation explaining why notice would

	compromise an investigation is placed in the vendor file. The same method used to notify vendors of the time and place of an administrative review can be used to notify the vendor of an initial violation. The State may resume compliance buys once the vendor receives notice of the initial violation. All incidences of a violation uncovered in an initial compliance buy constitute a single instance for purposes of establishing a pattern of violations.	compromise an investigation is placed in the vendor file. The same method used to notify vendors of the time and place of an administrative review can be used to notify the vendor of an initial violation. The State may resume compliance buys once the vendor receives notice of the initial violation. All incidences of a violation uncovered in an initial compliance buy constitute a single instance for purposes of establishing a pattern of violations. **§246.12(l)(3)(v)** State agency-established vendor violations cannot be imposed after a single violation uncovered in a compliance buy. The only sanctions that can be imposed after a single compliance buy violation are those for trafficking, illegal sales, and exchange of alcohol or tobacco for WIC food instruments.
§246.18 - Administrative review of State agency actions: actions not subject to review by vendors No provision regarding a State agency's decision whether to notify a vendor in writing after certain initial program violations.	**§246.18(a)(1)(iii)(F) - Administrative review of State agency actions: actions not subject to review by vendors** The State agency's decision whether to notify a vendor in writing after certain initial program violations is not subject to administrative review.	**§246.18(a)(1)(iii)(F) - Administrative review of State agency actions: actions not subject to review by vendors** The State agency's decision whether to notify a vendor in writing after certain initial program violations is not subject to administrative review.

Inflation of Civil Money Penalty Maximums	**Inflation of Civil Money Penalty Maximums**	**Inflation of Civil Money Penalty Maximums**	**USDA / FNS:** Uniformity in maximum CMP amounts should simplify administration and ease enforcement.
§246.12(l)(1)(x)(C) – Mandatory vendor sanctions: civil money penalty formula The maximum CMP for violations that warrant permanent vendor disqualification (other than those involving benefit trafficking or the sale of firearms, ammunition, explosives, or controlled substances in exchange for food instruments) is $10,000 per violation or $40,000 per investigation.	**§246.12(l)(1)(x)(C) – Mandatory vendor sanctions: civil money penalty formula** The maximum CMP for violations that warrant permanent vendor disqualification are those specified in §3.91(b)(3)(v).	**§246.12(l)(1)(x)(C) – Mandatory vendor sanctions: civil money penalty formula** The maximum CMP for violations that warrant permanent vendor disqualification are those specified in §3.91(b)(3)(v).	**State WIC agencies:** no significant effect. Increase in maximum CMPs may have a slight effect on penalty income available to the State agencies for food or NSA costs.
			Infant formula wholesalers, distributors, retailers, and manufacturers: None
			Authorized retail vendors: increased maximum penalty amounts for some violations.
			WIC participants: None
§246.12(l)(2)(i) – State agency vendor sanctions State agency-assessed CMPs shall not exceed $10,000 per violation or $40,000 per investigation.	**§246.12(l)(2)(i) – State agency vendor sanctions** State agency-assessed CMP maximums are those specified in §3.91(b)(3)(v).	**§246.12(l)(2)(i) – State agency vendor sanctions** State agency-assessed CMP maximums are those specified in §3.91(b)(3)(v).	

Cost/Benefit Assessment of Economic and Other Effects

The provisions of this rule are expected to improve WIC program performance and integrity by reducing the incidence of program violations by WIC-authorized vendors, minimizing the expenditure of program funds on non-program vendor incentive items, and ensuring the quality of infant formula distributed to WIC participants. The rule also establishes a uniform system of adjusting the maximum WIC CMP amounts for inflation.

Costs

Several provisions of the rule are expected to increase slightly the administrative burden faced by State WIC agencies. The total expected increase in costs is $0.66 million over five years.

1. Reporting

State WIC agencies are required to develop a sample vendor agreement that details their policies and procedures concerning the rule's vendor notification and incentive item provisions. The sample vendor agreement must be included (by attachment or citation) in the agencies' WIC State Plans. FNS estimates that this provision (§ 246.4(a)(14)(iii)) will increase the administrative burden faced by each State agency by one hour per year.

State agencies must also develop a set of policies and procedures for compiling and distributing to WIC vendors a list of State-licensed infant formula wholesalers, distributors, and retailers, and FDA-registered manufacturers. These policies must also be included, directly or by citation, in the agencies' State Plans. FNS estimates that this provision (§ 246.4(a)(14)(xvii)) will also add one hour annually to the States' administrative burden.

The rule requires State agencies to establish a system to review requests by above-50-percent vendors who wish to offer incentive items to their WIC customers (§ 246.12(h)(8)). The cost to vendors of submitting requests for approval is a reporting cost. As of early 2008, thirty-two State WIC agencies authorized above-50-percent WIC vendors.[2] FNS estimates that roughly half of these States both permit their above-50-percent vendors to offer incentive items and require them to seek individual State agency approval for each proposed incentive. Given that there are 1,700 authorized above-50-percent WIC vendors nationwide, this suggests that 850 vendors will submit individual incentive items to State agencies for approval. FNS estimates that the administrative burden of these requests will average one hour per vendor per year.

2. Recordkeeping

State WIC agencies must develop, maintain, and distribute to WIC vendors a list of State-licensed infant formula wholesalers, distributors, and retailers, and FDA-registered manufacturers. FNS provides the State agencies with the list of FDA-registered manufacturers. State agencies are responsible for compiling their own lists of wholesalers, distributors, and retailers licensed in their States. State agencies are required to update and distribute these lists to their WIC vendors at least annually. FNS estimates that this task (§ 246.12(g)(11)) will require 50 hours of administrative work per State agency per year.

As noted in the discussion of reporting burdens, the rule requires State agencies to develop a set of procedures for approval or disapproval of requests by above-50-percent vendors to offer particular incentive items to their customers. The rule gives the States some flexibility in implementing this provision. State agencies may choose to issue written approval or disapproval in response to each vendor request to offer a particular incentive. This relatively labor-intensive option would require that the States maintain documentation of each vendor request. The documentation would include invoices or receipts that verify the cost to the vendor of the proposed incentive. Alternatively, State agencies could develop a pre-approved list of acceptable incentive items. Vendors would select vendor items from the approved list and submit those selections to the State agency along with its signed WIC vendor agreement. That process would relieve the State agency from having to respond to individual vendor requests for incentive item approval.

FNS assumes that half of the thirty-two State WIC agencies that authorize above-50-percent WIC vendors will spend one hour per year on each one of an estimated 850 vendor incentive item requests. This suggests an annual recordkeeping burden for this provision (§ 246.12(h)(8)) of roughly 850 hours.[3]

Finally, the rule requires State agencies to notify a vendor in writing of an initial program violation, for violations of the type that require a second offense before a sanction is imposed, unless notification would compromise an ongoing investigation. Approximately 2,300 of the vendors who are investigated annually commit violations that require a pattern before a sanction can be imposed. If each notice requirement consumes, on average, one hour to process, then the total administrative burden of this provision (§ 246.12(l)(3)) is about 2,300 hours.

The total administrative cost of this rule, in terms of hours spent in compliance, is summarized in Table 2[4]:

[2] FNS program data.

[3] This estimate assumes that the administrative burden faced by State agencies that make use of pre-approved incentive item lists is insignificant.

[4] The "annual frequency" figures in table 2 are just the estimated number of hours divided by the number of respondents. The annual frequencies are shown rounded to the nearest integer.

TABLE 2—ADMINISTRATIVE COST SUMMARY

[Burden hours]

Section of Regulations	Annual number of respond-ents	Annual frequency	Average burden hours per response	Annual burden hours
New Reporting Burden:				
§ 246.4(a)(14)(iii)	90	1	1	90
§ 246.4(a)(14)(xvii)	90	1	1	90
§ 246.12(h)(8) vendors	850	1	1	850
Total New Reporting Burden in the Final Rule	.....	.....	.....	1,030
New Recordkeeping Burden:				
§ 246.12(g)(11)	90	1	50	4,500
§ 246.12(h)(8)	16	53	1	850
§ 246.12(1)(3)	90	26	1	2,300
Total New Recordkeeping Burden in the Final Rule	.....	.....	.....	7,650
Reporting and Recordkeeping Burden				
Total New Reporting and Recordkeeping Burden in the Final Rule	.....	.....	.....	8,860

Table 3 applies an average hourly wage rate to the estimated increase in administrative burden hours to estimate the total administrative cost of the rule [5]:

TABLE 3—COST OF ADMINISTRATIVE BURDEN

FY	Hours	Wage rate	Total cost (millions)
2008	8,680	$16.09	$0.14
2009	8,680	16.69	0.14
2010	8,680	17.30	0.15
2011	8,680	17.94	0.16
2012	8,680	18.61	0.16
Total	.....	.....	$0.75

[5] Wages and salaries for state and local government office and administrative support occupations, first quarter, FY 2008. *Employer Costs for Employee Compensation,* U.S. Department of Labor, Bureau of Labor Statistics. (*http://www.bls.gov/data/home.htm*)

The wage rate is inflated by the projected increase in the State and Local Expenditure Index. Office of Management and Budget projections for the President's FY 2009 Budget.

Benefits

1. Incentive Items

FNS collects no data on the type or value of incentive items that were offered by above-50-percent vendors to their WIC customers prior to passage of the 2004 Child Nutrition and WIC Reauthorization Act. Nor does FNS know how frequently such incentives were distributed by the typical vendor. However, among WIC-only stores (a subset of the broader category of above-50-percent vendors), incentive items were routinely offered as part of a typical marketing strategy.[6] In 2004, approximately 2.5 percent of WIC vendors were WIC-only. That relatively small group, however, accounted for a disproportionate 12 percent of 2004 WIC redemptions.[7]

At least some of the incentives offered before the 2004 Reauthorization Act were worth far more than this rule's $2 nominal limit. Senate Report 108–279, which accompanied the 2004 Reauthorization Act, cites ''appliances, pots and pans, bicycles, food items such as tortillas, and cash'' among the incentives offered by WIC-only stores.

Although this information does not permit the development of a quality numeric estimate of the total value of incentive items offered to WIC customers prior to enactment of the 2004 Reauthorization Act, it does suggest that the value could have been substantial.[8] The computation shown below is not intended to estimate the value of this rule's incentive item reforms with any precision. Instead, it is intended to demonstrate that even with very conservative assumptions, the administrative costs of this rule are almost certainly outweighed by the program savings of this one reform.

[6] WIC-only vendors do not compete for WIC customers on the price of their products. Incentives (including merchandise, food, and services) were, and remain, one way that WIC-only stores try to differentiate themselves from their competition.

[7] Data on the number, location and redemptions of WIC-only stores is reported to FNS annually in The Integrity Profile (TIP).

[8] The rule's restriction on incentive items is intended to prevent vendors from covering their costs of acquiring incentives by raising the prices that they charge the program for WIC foods. The value of the incentives offered by vendors is therefore an indirect cost to the WIC program.

850	Assume that 850 above-50-percent vendors currently offer incentive items to their WIC customers.[9]
÷ 48,297	Total number of WIC-authorized vendors.[10]
1.8%	Assume that this 1.8% of vendors serve a number of WIC participants exactly proportionate to their share of all WIC authorized vendors.[11]
× 4,577,348	Estimated number of households served monthly by WIC, FY 2007[12] (Total Participation/1.81).[13]
80,559	Number of incentive item recipients.
× $5.00	Assume each WIC household received just one $5 incentive item per year before the 2004 Reauthorization Act.[14]
$402,794	Annual value of incentives that would have been distributed annually in the absence of the 2004 Reauthorization Act.
− $161,117	Value of incentives if capped at the $2 nominal value of this rule.[15]
$241,676	Estimated Annual Savings from this rule.

Even with assumptions that almost certainly understate the numbers at each step in this computation, the annual savings from this provision of the rule alone far exceed the estimated annual administrative costs developed earlier.[16]

2. Vendor Notification of Initial Program Violations

This provision of the rule is designed to encourage WIC-authorized vendors to correct behavior after being informed by State agencies of an initial program violation. In addition to enhancing the due process accorded to WIC vendors, the new rule is expected to increase vendor compliance with program rules. Improved compliance with program rules may have economic benefits; it also has the potential to improve the health outcomes of WIC participants.

The most serious program violations mandate the imposition of sanctions after an initial occurrence.[17] The rule does not change the way that these violations are handled. However, the rule should reduce repeat occurrences of vendor violations such as overcharging the program, claiming reimbursement for sales not supported by inventory records, exchanging WIC food instruments for non-WIC foods or merchandise, and transacting food instruments outside of proper channels. To the extent that the rule is effective at reducing repeat occurrences of overcharging, the program will realize direct dollar savings.[18] Reduction in the repeat occurrence of the other violations listed here will enhance program effectiveness. A direct dollar value cannot be placed on that benefit. However, if fewer WIC food instruments are redeemed for non-WIC foods or merchandise, then the ultimate health outcomes of WIC participants may be improved.

Although it is true that this provision of the rule, if effective, will reduce the number of CMPs imposed for repeat program violations, the consequent reduction in penalty income should not be counted as an economic loss to the program. To the extent that CMP income is viewed as vendor compensation for program violations, it simply offsets harm done to the program and WIC participants. The primary purpose of the CMP system, however, is to increase vendor compliance with program rules. The reduction in CMP assessments is just another way to measure the benefit of increased vendor compliance and improved program performance.

3. Authorized Infant Formula Suppliers

The benefit of this provision cannot be quantified. FNS does not believe that stolen, expired, improperly stored, or otherwise defective formula reaches WIC participants in significant quantities. Nevertheless, the rule establishes a system that further safeguards the supply of program formula. The administrative costs of this safeguard, as estimated above, are minimal. The benefits, in terms of public confidence in the program and a reduction in an already small health risk to WIC infants, are believed to outweigh these small administrative costs.

4. CMP Inflation

Civil Money Penalties collected from WIC vendors are recorded in WIC accounts as ''program income'' which can be used by the States for food or administrative expenses. FNS collects some data on sanctions imposed on WIC vendors for program violations. However, the data are not detailed or complete enough to estimate the effect of the rule's CMP inflation provision on WIC program income. The WIC program's TIP (''The Integrity Profile'') system tracks the number, but not the value, of sanctions imposed on WIC vendors for ''serious'' program violations. Serious violations are those for which sanctions may be imposed under WIC regulations. The TIP data do not track less serious State agency-established violations.

The rule's CMP inflation provision does not have any effect on sanctions

[9] This is taken from the discussion of costs on p. 5. This number is, of course, a very rough estimate of the number of above-50-percent vendors that offer incentive items today. The number who offered incentive items prior to the 2004 Reauthorization was likely higher than the number who offer them today.

[10] FNS estimate, 2006.

[11] The TIP data on WIC participants served by WIC-only vendors in 2004 suggests that this assumption understates the dollar estimate developed here.

[12] Annual WIC program participation, FY 2007. FNS program data.

[13] National Survey of WIC Participants, 2001. WIC Economic Unit Composition by Category, Mean WIC participants in unit = 1.81.

[14] The 2004 Senate report suggests that this too is a conservative estimate.

[15] 104,664 incentive item recipients × $2.00.

[16] Another factor that complicates an estimate of the value of this provision of the rule, is the effect of the Vendor Cost Containment rule. That rule was also mandated by the Child Nutrition and WIC Reauthorization Act of 2004. The rule requires State agencies to implement a vendor peer group system, competitive price criteria, and allowable reimbursement levels with the goal of ensuring that the WIC Program pays authorized vendors competitive prices for supplemental foods. It specifically requires State agencies to ensure that above-50-percent vendors do not charge the program more for WIC foods than other authorized vendors do. The Vendor Cost Containment rule's competitive price requirements indirectly limit the ability of above-50-percent vendors to pass the cost of incentive items on to the WIC program. The incremental economic benefit of the incentive item provisions of the WIC Discretionary Vendor rule is less than what it would have been in the absence of the Vendor Cost Containment rule.

[17] These include trafficking (exchanging WIC food instruments for cash), exchange of food instruments for firearms or other controlled substances, and exchange of food instruments for alcohol or tobacco. *See* § 246.12(l)(1).

[18] FNS has not attempted to measure the effect of the rule's vendor notification provision on the value of subsequent vendor overcharges. If effective, the rule will reduce the number of vendor overcharges following an initial occurrence identified by a State WIC agency (through a compliance buy or other means). Under prior rules, the State agency was not required to notify the vendor of that initial occurrence. However, the imposition of a CMP following a second occurrence (after a follow-up compliance buy) would presumably have been as effective at ending subsequent vendor violations as a written notice following an initial violation. A primary benefit of the notification rule, then, is that it should free State agency resources to allow compliance buys at more vendors in a given amount of time.

imposed for WIC food instrument trafficking, or exchange of food instruments for firearms, explosives, or other controlled substances. Those violations are covered by the FCPIAA, and the maximum penalties that may be imposed for those violations are already adjusted for inflation.

Note also that the rule has no effect on sanctions that fall short of WIC's $10,000 maximum CMP amount per violation. The rule does not change the way that sanctions are computed. CMP amounts imposed in lieu of disqualification are still computed as ten percent of the vendor's average monthly WIC redemptions multiplied by the number of months that the vendor could have been disqualified under program rules for the same violation.[19] The inflation adjustment provision of the rule only has effect on penalties, computed under the formula described here, that hit the current $10,000 ceiling per violation (or $40,000 ceiling per investigation).

The TIP system reports 956 serious vendor violations (other than trafficking or exchange of food instruments for controlled substances) for FY 2007.[20] The States imposed 94 CMPs for those violations. If, in the extreme, one assumes that all of these violations were imposed at the $10,000 maximum allowed under current rules, then the total value of penalties imposed would have been $940,000.[21] This rule would raise the maximum CMP from $10,000 to $11,000, and subject the new maximum to future inflation adjustments. Thus, the rule would have immediately raised the value of these penalties by $94,000. Future inflation adjustments would increase the value of penalties imposed by a much smaller amount.

The actual effect of the rule on the value of CMPs imposed cannot be estimated. The $94,000 figure developed above is probably a very high-end estimate of the first year effect of the rule's CMP provision.

Cost Benefit Summary:

The costs of the rule, summarized in table 3, are estimated with some confidence. Each of the administrative burden estimates contained in the proposed rule were subject to public comment. FNS refined several of its final administrative burden estimates in response to suggestions that the proposed rule's estimates were too low. Even with these revisions, the administrative cost of the rule remains very small. FNS estimates that the total costs of implementation and ongoing administration to State WIC agencies is just $750,000 over five years.

FNS has not developed a dollar benefit of the rule. Nevertheless, FNS is confident that the dollar benefit of the rule exceeds the rule's modest costs. A very conservative estimate of the benefit of the rule's incentive item provision alone exceeds the estimated cost of the entire rule. The vendor notification provision is expected to generate additional dollar savings by quickly correcting inadvertent vendor mistakes (including mistaken overcharges) once a first incident is identified by the States. The notification provision also offers honest WIC vendors the opportunity to amend their procedures and avoid costly sanctions. The rule also strengthens safeguards designed to prevent the distribution of stolen, expired, contaminated, or otherwise defective infant formula to WIC participants. The infant formula provisions of the rule benefit participants by reducing an already small health risk. Finally, the rule's CMP provisions restore uniformity to the maximum dollar penalties imposed for serious vendor violations. This will simplify program administration and restore fairness to the penalty structure.

Alternatives:

The basic parameters of the incentive item, vendor notification, and infant formula supplier provisions are mandated by statute. Significant alternatives to these provisions of the rule could not be considered. However, commenters on the proposed rule raised some issues that were considered by FNS as alternatives to the final rule. A few of the comments that proposed significant alternatives are discussed below.

1. *State agency discretion in giving notice to vendors of initial program violations.*

FNS received several comments on the proposed rule's provision to allow State agencies the discretion to withhold notification of an initial vendor violation. Some commenters objected to the rule's failure to specify criteria or standards to be followed by State agencies in determining whether an initial notification would compromise a broader investigation into vendor misconduct. FNS did not alter the final rule in response to these commenters' concerns. Instead, FNS believes that the provision, as proposed, follows the intent of Congress, as expressed by the House Committee on Education and the Workforce.[22] The Committee encouraged the USDA to draft regulations and guidance that gives State agencies the discretion to withhold notice of initial violations from vendors that would compromise a State investigation into suspected vendor fraud.

For similar reasons, FNS declined to change the proposed rule to require administrative review of State agency decisions to withhold notification of an initial vendor violation. Administrative review of all such State agency decisions would deny the States the discretion that Congress intended them to have. As noted above, the standard specified by the rule (and recommended by Congress) to justify a State decision to withhold notification is simply suspicion of fraud. State agency suspicion, even carefully considered suspicion, does not lend itself to administrative review.

2. *Requirement that State agencies determine whether to withhold or provide notice of initial vendor violations on a case by case basis.*

Some commenters urged FNS to allow States to establish categorical rules on vendor notification of initial program violations. The commenters suggested that some types of violations are sufficiently serious to justify a State rule against initial vendor notification. FNS considered this suggestion, but did not change the rule's requirement that States consider each violation individually. The proposed and final rules both require State agencies to suspect fraud before deciding to withhold notification. The purpose of withholding notification is to permit further investigation into the nature and extent of the fraudulent behavior. The seriousness of a vendor violation is not an indication of vendor intent. For that reason, States should not be permitted to establish categorical rules on notification based on the seriousness of a violation alone. Such rules might have the unintended consequence of preventing States from immediately notifying vendors who inadvertently commit a serious violation. No purpose is served by disallowing immediate notification of violations that do not merit further investigation.

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[19] § 246.12(l)(x).

[20] TIP report, ''Store Tracking and Redemption System—Sanctions Resulting From Serious Program Violations'', FY 2007 total, run date May 1, 2008. This is a count of vendor violations identified by State WIC agencies. Because some vendors committed more than one of these 956 violations, the total number of vendors that were found to have committed a violation is less than 956.

[21] This assumes that none of the less serious State agency-established penalties, which are not tracked by TIP, would have been imposed at the $10,000 CMP maximum.

[22] Report No. 108–445, March 23, 2004.