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TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Proposed Rule

LSA Document #05-19

DIGEST

Adds 410 IAC 3.6 to establish an authorization and reauthorization process for food vendors and to establish a system of civil penalties and other sanctions for a WIC vendor contract under the WIC program or federal regulations under 7 CFR 246. Effective 30 days after filing with the Secretary of State.

410 IAC 3.6

SECTION 1. 410 IAC 3.6 IS ADDED TO READ AS FOLLOWS:

ARTICLE 3.6. WOMEN, INFANTS, AND CHILDREN PROGRAM RULES, PENALTIES, AND SANCTIONS FOR WIC VENDORS

Rule 1. Definitions

410 IAC 3.6-1-1 Applicability Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 1. The definitions in this rule apply throughout this article. (Indiana State Department of Health; 410 IAC 3.6-1-1)

410 IAC 3.6-1-2 "Authorization" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 2. "Authorization" means the process by which the department:

(1) assesses;

(2) selects; and

(3) enters into;

agreements with stores that apply or subsequently reapply to be authorized as WIC vendors. (Indiana State Department of Health; 410 IAC 3.6-1-2)

410 IAC 3.6-1-3 "Commodity supplemental food program" or "CSFP" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 3. "Commodity supplemental food program" or "CSFP" means a program of the United States Department of Agriculture that works to improve the health of low-income:

(1) pregnant and breastfeeding women;

(2) new mothers up to one (1) year postpartum;

(3) infants;

(4) children up to six (6) years of age; and

(5) elderly people at least sixty (60) years of age;

by supplementing their diets with nutritious USDA commodity foods. The CSFP provides food and administrative funds to states to supplement the diets of these groups. (Indiana State Department of Health; 410 IAC 3.6-1-3)

410 IAC 3.6-1-4 "Conflict of interest" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 4. "Conflict of interest" means a situation in which a private financial interest of:

(1) an officer;

(2) an employee; or

(3) the spouse or unemancipated child;

of a vendor coincides with the private financial interest of a local agency or department employee. (Indiana State Department of Health; 410 IAC 3.6-1-4)

410 IAC 3.6-1-5 "Contract brand infant formula" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 5. "Contract brand infant formula" means all infant formulas (except exempt infant formulas) produced by the manufacturer awarded the infant formula cost containment contract. If under a single solicitation the manufacturer subcontracts for soy-based infant formula, then all soy-based infant formulas covered by the subcontract are also considered contract brand infant formulas (see 7 CFR 246.16a(c)(1)(i)). If a state agency elects to solicit separate bids for milk-based and soy-based infant formulas, all infant formulas issued under each contract are considered the contract brand infant formula (see 7 CFR 246.16a(c)(1)(i)). For example, the term includes the following:

(1) All of the milk-based infant formulas issued by a state agency that are produced by the manufacturer that was awarded the milk-based contract.

(2) All of the soy-based infant formulas issued by a state agency that are produced by the manufacturer that was awarded the soy-based contract.

The term also includes all infant formulas (except exempt infant formulas) introduced after the contract is awarded. (Indiana State Department of Health; 410 IAC 3.6-1-5)

410 IAC 3.6-1-6 "Controlled substances" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 6. "Controlled substances" means material of a particular kind that is regulated for limited distribution or use. (Indiana State Department of Health; 410 IAC 3.6-1-5)

410 IAC 3.6-1-7 "Department" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 7. "Department" means the Indiana state department of health. (Indiana State Department of Health; 410 IAC 3.6-1-7)

410 IAC 3.6-1-8 "Disqualification" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 8. "Disqualification" means the act of ending the WIC program participation of an authorized vendor. (Indiana State Department of Health; 410 IAC 3.6-1-8)

410 IAC 3.6-1-9 "Food instrument" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 9. "Food instrument" means: (1) a voucher; (2) a check; or (3) another document;

issued by a local agency that specifies the quantity, size, and type of authorized foods available to a WIC participant within a designated time frame to be used at a WIC vendor. (Indiana State Department of Health; 410 IAC 3.6-1-9)

410 IAC 3.6-1-10 "Local agency" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 10. "Local agency" means a:
(1) public or private;
(2) nonprofit; and
(3) health or human;
service agency that provides health services through a contract with the department in accordance with 7 CFR 246.5. (Indiana State Department of Health; 410 IAC 3.6-1-10)

410 IAC 3.6-1-11 "Overcharge" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 11. "Overcharge" means a charge of more than one dollar (\$1) over the shelf price at the time of the use of the food instrument in question. (Indiana State Department of Health; 410 IAC 3.6-1-11)

410 IAC 3.6-1-12 "Participant" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 12. "Participant" means: (1) a woman who is: (A) pregnant; (B) breastfeeding; or (C) postpartum; (2) an infant; or (3) a child; enrolled in the WIC program. (Indiana State Department of Health; 410 IAC 3.6-1-12)

410 IAC 3.6-1-13 "Price comparison analysis" or "PCA" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 13. "Price comparison analysis" or "PCA" means an analysis using the prices of a selection of WIC foods submitted by the store or vendor to determine the relative costs of the store or vendor for comparison purposes. (Indiana State Department of Health; 410 IAC 3.6-1-13)

410 IAC 3.6-1-14 "Proxy" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5-6

Sec. 14. "Proxy" means any person designated by a:

(1) woman participant; or

(2) parent or caretaker of an infant or child participant;

to obtain and transact food instruments or to obtain supplemental foods on behalf of a participant. (Indiana State Department of Health; 410 IAC 3.6-1-14)

410 IAC 3.6-1-15 "Supplemental foods" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6

Affected: IC 16-35-1.5

Sec. 15. "Supplemental foods" means those foods containing nutrients determined to be beneficial for:

(1) women who are:
(A) pregnant;
(B) breastfeeding; or

(C) postpartum;(2) infants; and

(3) children;

as prescribed by 7 CFR 246.10. (Indiana State Department of Health; 410 IAC 3.6-1-15)

410 IAC 3.6-1-16 "Vendor" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 16. "Vendor" means a sole proprietorship, partnership, cooperative association, corporation, or other business entity operating one (1) or more stores authorized by the state agency to provide authorized supplemental foods to participants under a retail food delivery system. Each store operated by a business entity:

(1) constitutes a separate vendor; and

(2) must:

(A) be authorized separately from other stores operated by the business entity; and

(B) have a single, fixed location, except when the authorization of mobile stores is necessary to meet the special needs described in the state agency's state plan in accordance with 7 CFR 246.4(a)(14)(xiv).

(Indiana State Department of Health; 410 IAC 3.6-1-16)

410 IAC 3.6-1-17 "Vendor agreement" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 17. "Vendor agreement" means a legally binding contract, complying with 7 CFR 246.12(h), between the following: (1) An authorized vendor.

(2) The WIC program.

The agreement describes the terms and conditions the two (2) parties must follow for the vendor to redeem WIC food instruments. (Indiana State Department of Health; 410 IAC 3.6-1-17)

410 IAC 3.6-1-18 "Vendor violation" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 18. "Vendor violation" means any intentional or unintentional action or omission of a vendor's current:

(1) owners;

(2) officers;

(3) managers;

(4) agents; or

(5) employees;

with or without the knowledge of management, that violates the federal or state statutes, rules, or regulations governing the WIC program. (Indiana State Department of Health; 410 IAC 3.6-1-18)

410 IAC 3.6-1-19 "WIC program" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 19. "WIC program" means the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) authorized by section 17 of the Child Nutrition Act of 1966. (Indiana State Department of Health; 410 IAC 3.6-1-19)

410 IAC 3.6-1-20 "WIC service area" defined Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 20. "WIC service area" means an area where local WIC participants could conveniently shop alternative vendors. The term may include a county or marketing area, whichever is determined more appropriate by the department after considering factors including, but not limited to, the following:

(1) Geographic, population, and demographic information.

(2) Information submitted by the store or vendor.

In counties with a population less than seventy-seven thousand (77,000), the service area would generally be the county. In counties with a population greater than seventy-seven thousand (77,000), the service area would generally be an area within five (5) miles of the applicant. (Indiana State Department of Health; 410 IAC 3.6-1-20)

Rule 2. General Provisions

410 IAC 3.6-2-1 Application of rules Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 1. This article shall apply to the following:

(1) All stores that apply for participation as vendors in the WIC program.

(2) All vendors contracting with the department or its designees.

(3) Any:

(A) individual;

(B) business entity; or

(C) commercial enterprise;

that accepts or receives food instruments or credit or payment for food instruments, or both.

Any authorization issued before the effective date of this article shall remain valid and shall be subject to this article. (Indiana State Department of Health; 410 IAC 3.6-2-1)

410 IAC 3.6-2-2 Vendor selection Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 2. The WIC program must authorize an appropriate number and distribution of vendors in order to ensure the following:

(1) Adequate participant access to supplemental foods.

(2) Effective WIC program:

(A) management;

(B) oversight; and

(C) review;

of its authorized vendors.

In order to accomplish this, vendors and store applicants shall be subject to the vendor selection criteria in 410 IAC 3.6-3-4 and 410 IAC 3.6-3-5. (Indiana State Department of Health; 410 IAC 3.6-2-2)

410 IAC 3.6-2-3 Vendor reassessment Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 3. Vendors may be reassessed at any time during the vendor's agreement period using the vendor selection criteria in effect at the time of the reassessment. The department shall terminate the vendor agreements of vendors that fail to meet the selection criteria. (Indiana State Department of Health; 410 IAC 3.6-2-3)

410 IAC 3.6-2-4 Vendor preauthorization visit Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 4. Vendor applicants who have failed a preauthorization visit shall not receive a subsequent preauthorization visit until after they have advised in writing that they can comply with the vendor selection criteria. (Indiana State Department of Health; 410 IAC 3.6-2-4)

410 IAC 3.6-2-5 Expiration of vendor agreement Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 5. If the vendor wishes to continue to be authorized beyond the period of its current vendor agreement, the vendor must apply for reauthorization. (Indiana State Department of Health; 410 IAC 3.6-2-5)

410 IAC 3.6-2-6 Vendor agreement Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 6. All stores authorized as a vendor by the department shall do the following:

(1) Sign a vendor agreement prescribed by the department in accordance with 7 CFR 246.12(h).

(2) Agree to comply with all applicable federal and state laws and rules, including, but not limited to, 42 U.S.C. 1786 and 7 CFR 246.

(Indiana State Department of Health; 410 IAC 3.6-2-6)

410 IAC 3.6-2-7 Assignment or transfer

Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 7. (a) A vendor shall not sell, assign, or transfer the following in any manner:

(1) Its authorization.

(2) The vendor:

(A) agreement;

(B) stamp; or

(C) number.

Any actual or attempted sale, assignment, or transfer of the authorization, vendor agreement, vendor stamp, or vendor number shall result in termination of the vendor agreement. Relocation of less than one (1) mile is not a violation of this section.

(b) At least fifteen (15) calendar days in advance, the vendor shall notify the department of the following:

(1) Any:

- (A) sale;
- (B) lease;
- (C) bankruptcy; or
- (D) cessation;

of the vendor's business entity.

(2) Any sale of a majority interest in the vendor's:

- (A) corporation;
- (B) partnership;
- (C) sole proprietorship; or

(D) business entity.

The notification shall be sent by certified mail and in writing to the director of the Indiana state WIC program, Indiana state department of health. (Indiana State Department of Health; 410 IAC 3.6-2-7)

410 IAC 3.6-2-8 Voluntary withdrawal from the WIC program Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 4-21.5; IC 16-35-1.5 Sec. 8. A vendor may voluntarily withdraw from participation in the WIC program. The department, however, shall not accept voluntary withdrawal as an alternative to an order of disqualification for which no appeal is pending under IC 4-21.5. If, at the time of the withdrawal, the vendor owes:

(1) a fine assessment; or

(2) any other monies resulting from a sanction;

the fine assessment and any other monies due shall be paid in full. (Indiana State Department of Health; 410 IAC 3.6-2-8)

Rule 3. Selection of Vendors

410 IAC 3.6-3-1 Authorization of vendors Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-19-3-5

Sec. 1. (a) A store becomes a vendor when authorized in accordance with this rule.

(b) Once every three (3) years, the department shall conduct an open authorization period to select vendors. The open authorization period shall:

(1) begin April 12; and

(2) end May 11.

The contract for vendors authorized during this open authorization period begins on October 1.

(c) The WIC program shall send an application for authorization to a store's representative who has contacted the department in writing to request an application for authorization. The store seeking authorization as a vendor shall do the following:

(1) Complete the application for authorization.

(2) Return it to the WIC program before the end of the open authorization period.

Current vendors will receive an application from the WIC program in order to apply for reauthorization. Incomplete applications will be returned to the store's representative and must be returned within fifteen (15) days from the end of the open enrollment period to be considered timely.

(d) A store wishing to become a vendor outside the open authorization period must meet the requirements of section 10 of this rule. (Indiana State Department of Health; 410 IAC 3.6-3-1)

410 IAC 3.6-3-2 Authorization process for stores not currently authorized Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-19-3-5

Sec. 2. (a) A store must submit a WIC food vendor application to be considered for authorization.

(b) Applications received during the open authorization period shall be reviewed using the selection criteria in section 3 of this rule. Applications that:

(1) meet all criteria in section 4 of this rule; and

(2) successfully pass the preauthorization visit;

will be offered a vendor agreement. (Indiana State Department of Health; 410 IAC 3.6-3-2)

410 IAC 3.6-3-3 Reauthorization process for currently authorized vendors Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-19-3-5

Sec. 3. (a) A vendor must submit a WIC food vendor application to be considered for reauthorization.

(b) Applications received during the open authorization period shall be reviewed using the selection criteria in sections 4 and 5 of this rule. Currently authorized vendors:

(1) that meet all criteria in sections 4 and 5 of this rule will be offered a vendor agreement; and

(2) shall not receive a preauthorization visit.

(Indiana State Department of Health; 410 IAC 3.6-3-3)

410 IAC 3.6-3-4 Selection criteria for initial authorization Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-19-3-5

Sec. 4. Only stores meeting all of the following criteria, and having a total number of points assigned, under section 6 of this rule, greater than or equal to the lowest point total of vendors applying in the same WIC service area, will be selected for a preauthorization visit:

(1) The store shall be as follows:

(A) Located:

(i) within this state; or

(ii) in a county contiguous to the Indiana border.

(B) Open for business and able to serve WIC participants at least eight (8) hours per day, six (6) days per week.

(C) Located in a permanent, fixed location where participants may purchase allowable foods with their food instruments. (2) The store may not be currently disqualified from either of the following:

(A) Participation in the food stamp program or have been assessed a civil money penalty in lieu of a disqualification from the food stamp program that, had it been imposed, would not yet have expired.

(B) The WIC program.

The disqualifications in this subdivision must be final with no appeal pending.

(3) None of the store's current owners, officers, or managers have been convicted of or had a civil judgment entered against them for the following conduct demonstrating a lack of business integrity:

(A) Fraud.

(B) Antitrust violations.

(C) Embezzlement.

(D) Theft.

(E) Forgery.

(F) Bribery.

(G) Falsification or destruction of records.

(H) Making false statements.

(I) Receiving stolen property.

(J) Making false claims.

(K) Obstruction of justice.

(4) The store shall:

(A) meet the minimum stock requirements of section 8 of this rule; and

(B) not have redeemed or attempted to redeem food instruments without being authorized as a WIC vendor.

(5) Pharmacies or vendors with a pharmacy must be able to provide any WIC prescribed formula within two (2) working days of the request by a WIC participant unless the failure to provide the WIC prescribed formula is the result of any of the following:

(A) A natural disaster.

(B) Actions or decrees of governmental bodies.

(C) A communication line failure.

(D) Extraordinary circumstances beyond the control of the vendor.

(6) The store must purchase WIC formula from a source on the:

(A) department's list; or

(B) list of another state WIC agency;

pursuant to Section 203(e)(8) of the Child Nutrition and WIC Reauthorization Act of 2004, P.L.108-265.

(7) No conflict of interest shall exist between:

(A) the store; and

(B) any local agency or department employee.

(8) The store:

(A) shall not have attempted to circumvent disqualification from the WIC program through ownership change; and (B) must:

(i) participate in the food stamp program; and

(ii) have a food stamp number;

unless the store is a pharmacy only. (Indiana State Department of Health; 410 IAC 3.6-3-4)

410 IAC 3.6-3-5 Selection criteria for reauthorization Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-19-3-5

Sec. 5. In addition to the criteria in section 4 of this rule, a vendor seeking reauthorization must also meet the following criteria and have been assigned at least two (2) points under section 6 of this rule:

(1) The vendor shall:

(A) redeem at least:

(i) forty (40) food instruments per month and a minimum of one percent (1%) of the food instruments in the county; or

(ii) one hundred fifty (150) food instruments per month for the immediately preceding six (6) months of food instrument redemption data;

(B) have implemented all required corrective actions resulting from monitoring by the department, including reimbursement of any overcharges or overpayments; and

(C) be in compliance with the applicable federal and state regulations.

(2) The store shall not have provided refunds, or permit exchanges for foods purchased with food instruments, except for exchanges of an identical authorized food item when the original food item:

(A) is defective;

(B) is spoiled; or

(C) has exceeded:

(i) its "sell by" date;

(ii) its "best if used by" date; or

(iii) another date;

limiting the sale or use of the item.

"Identical food item" means the exact brand and size of the original food item purchased. Participants may only exchange WIC items with a receipt.

(Indiana State Department of Health; 410 IAC 3.6-3-5)

410 IAC 3.6-3-6 Application points

Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-19-3-5

Sec. 6. The department will assign points for the categories listed in this section as part of the authorization process. Points will be assigned to applications as follows:

(1) Low price comparison average (PCA). A store that has a PCA that is one percent (1%) to ten percent (10%) below the average price of vendors in the same WIC service area is awarded one (1) point. Any store that has a PCA more than ten percent (10%) below the average is awarded two (2) points.

(2) A store with a pharmacy will be awarded one (1) point if the WIC service area is without a WIC authorized pharmacy.

(3) A store that has at least fifty percent (50%) sales from food sales will be awarded one (1) point.

(4) Current authorized vendors who have:

(A) not received a second education/warning letter; or

(B) been required to attend a conference;

under 410 IAC 3.6-5-2(c)(3) in the last two (2) years will be awarded one (1) point.

(5) A store that has not accumulated enough points to be authorized, but is needed to avoid inadequate participant access under section 9 of this rule, will be awarded one (1) point.

(Indiana State Department of Health; 410 IAC 3.6-3-6)

410 IAC 3.6-3-7 Preauthorization visit Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-19-3-5

Sec. 7. (a) If the store's application for authorization meets all criteria in section 4 of this rule, the local agency shall conduct

a preauthorization visit of the store to determine compliance with the following:

(1) All WIC food prices are marked on or near the foods.

(2) WIC food prices submitted on the application match the store's shelf prices.

(3) Minimum stocking requirements of section 8 of this rule are met.

(4) WIC foods on the shelves available for sale are within their fresh date.

(5) WIC foods are stored and refrigerated in compliance with 410 IAC 7-24.

(b) The local agency shall do the following:

(1) Conduct the preauthorization visit.

(2) Forward the results to the department to do the following:

(A) Complete the review.

(B) Render a decision on the store's application.

(Indiana State Department of Health; 410 IAC 3.6-3-7)

410 IAC 3.6-3-8 Minimum stock Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-19-3-5

Sec. 8. (a) In order to ensure adequate participant access to supplemental foods, the following minimum stock shall be available on the shelf or in stock:

(1) Contract brand infant formula as follows:

(A) Thirty-two (32) thirteen (13) ounce cans of each of the following:

(i) Enfamil LIPIL with iron concentrate.

(ii) Enfamil Prosobee LIPIL iron fortified concentrate.

(B) Twenty (20) twelve and nine-tenths (12.9) ounce cans of Enfamil LIPIL with iron powder.

(C) Ten (10) twelve and nine-tenths (12.9) ounce cans of Enfamil Prosobee LIPIL iron fortified powder.

(2) One hundred percent (100%) dairy milk: fifteen (15) gallons total of:

- (A) whole;
- (B) low fat; and
- (C) skim;

milk in gallons.

(3) Cheese:

- (A) three (3) kinds; and
- (B) five (5) pounds;

of domestic prepackaged blocks or sliced cheese.

(4) Eggs: five (5) dozen large white eggs in one (1) dozen containers.

(5) One hundred percent (100%) juice:

(A) thirty (30) forty-six (46) ounce containers, at least four (4) kinds; and

(B) thirty (30) cans of eleven and five-tenths (11.5) or twelve (12) ounce frozen juice or shelf stable concentrate, or both, at least two (2) kinds.

(6) Cereal:

(A) six (6) kinds of dry; and

(B) one (1) kind of cooked;

cereal, for a total of twenty (20) boxes.

(7) Peanut butter: five (5) eighteen (18) ounce jars.

(8) Dried beans, peas, and lentils: three (3) kinds for a total of five (5) pounds in one (1) pound bags.

(9) Infant cereal:

(A) fifteen (15) boxes; and

(B) three (3) kinds;

of eight (8) ounce dry infant cereal without fruit.

(10) One hundred percent (100%) infant juice: six (6), thirty-two (32) ounce bottles.

(b) Noncompliance with this section will not result in an enforcement action if the vendor can demonstrate that any failure to meet the requirements of subsection (a) was the result of any of the following:

(1) A natural disaster.

(2) Actions or decrees of governmental bodies.

(3) A communication line failure.

(4) Extraordinary circumstances beyond the control of the vendor.

(c) The department will provide at least one (1) month written notice of any change in the contract brand infant formula. *(Indiana State Department of Health; 410 IAC 3.6-3-8)*

410 IAC 3.6-3-9 Inadequate participant access Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-19-3-5

Sec. 9. (a) The department may consider whether there is inadequate participant access when considering whether to grant or deny authorization or reauthorization.

(b) The department shall also consider whether there is inadequate participant access when deciding whether to impose a civil money penalty in lieu of disqualification under 410 IAC 3.6-4.

(c) There is inadequate participant access if:

(1) a vendor:

(A) has closed, withdrawn, or relocated farther than one (1) mile from its authorized location; and

(B) was redeeming more than forty (40) food instruments per month and one percent (1%) of the county's food instruments or one hundred fifty (150) food instruments per month with no minimum percentage;

(2) a pharmacy vendor has closed, withdrawn, or relocated farther than one (1) mile from its authorized location;(3) a vendor:

(A) has been disqualified for at least one (1) year in the WIC service area; and

(B) was redeeming more than forty (40) food instruments per month and one percent (1%) of the county's food instruments or one hundred fifty (150) food instruments per month with no minimum percentage;

(4) the number of food instruments redeemed in the WIC service area has increased by ten percent (10%) in the preceding quarter; or

(5) there is a hardship for a significant WIC population in an area that is not served by an authorized vendor. (Indiana State Department of Health; 410 IAC 3.6-3-9)

410 IAC 3.6-3-10 Store application outside the open authorization period Authority: IC 16-19-3-5; IC 16-35-1.5-6

Affected: IC 16-19-3-5

Sec. 10. (a) A store must submit a WIC food vendor application to be considered for authorization.

(b) Applications received outside the open authorization period shall be reviewed to determine if there is inadequate participant access.

(c) If the department determines that there is not inadequate participant access:

(1) the store will be notified in writing of that determination; and

(2) the application will be denied.

(d) If the department determines that there is inadequate participant access, the following will occur:

(1) The application will be reviewed using the selection criteria in section 5 of this rule.

(2) If the application:

(A) meets all criteria in section 4 of this rule; and

(B) successfully passes the preauthorization visit;

the store will be offered a vendor agreement.

(Indiana State Department of Health; 410 IAC 3.6-3-10)

410 IAC 3.6-3-11 Denial of authorization Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 4-21.5; IC 16-19-3-5

Sec. 11. (a) The department shall deny the application of a store or vendor if the selection criteria in either section 4 or 5 of this rule, or both, are not met unless the department determines there is inadequate participant access. The department will do the following:

(1) Notify the vendor in writing of the denial.

(2) Inform them of their appeal rights under IC 4-21.5.

(b) The department shall deny reauthorization if the vendor is not meeting the minimum food instrument redemption criteria in section 6(1) of this rule unless the department determines there is inadequate participant access.

(c) The department shall deny the application of a store or vendor if it contains false information.

(d) The department shall deny authorization for either of the following reasons:

(1) If:

(A) the vendor has been disqualified from the WIC program; and

(B) no appeals are pending.

(2) If the department determines that the store:

(A) relocated; or

(B) effected a change of ownership;

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to avoid a disqualification.
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(Indiana State Department of Health; 410 IAC 3.6-3-11)

410 IAC 3.6-3-12 Termination of authorized WIC vendors Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-19-3-5

Sec. 12. The department shall terminate a WIC vendor's authorization if any of the following occur:

(1) The store has been disqualified under 410 IAC 3.6-4 or 410 IAC 3.6-5.

(2) The WIC vendor supplied false information in their application for authorization or reauthorization.

(3) The store is not redeeming at least forty (40) food instruments per month by the sixth month of their authorization or reauthorization, unless the department determines that termination of the WIC vendor would cause inadequate participant access as described in section 9 of this rule.

(4) Ownership of the store changes.

(5) The store:

(A) relocates in excess of one (1) mile of its current location; or

(B) closes for more than three (3) consecutive business days and does not notify the department, unless the department determines that termination of the WIC vendor would cause inadequate participant access as described in section 9 of this rule.

(Indiana State Department of Health; 410 IAC 3.6-3-12)

Rule 4. Federally-Mandated WIC Vendor Sanctions

410 IAC 3.6-4-1 Permanent disqualifications Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 1. (a) The department shall permanently disqualify a WIC vendor convicted of either of the following: (1) Trafficking in food instruments.

(2) Selling:

(A) firearms;

(B) ammunition;

(C) explosives; or

(D) controlled substances, as defined in Section 102 of the Controlled Substances Act (21 U.S.C. 802); in exchange for food instruments.

(b) A WIC vendor is not entitled to receive any compensation for revenues lost as a result of such violation.

(c) The department may impose a civil money penalty in lieu of a disqualification for this violation when the department determines that:

(1) disqualification of the WIC vendor would result in inadequate participant access; or

(2) the WIC vendor had, at the time of the violation, an effective policy and program in effect to prevent trafficking, and the ownership of the WIC vendor:

(A) was not aware of;

(B) did not approve of; and

(C) was not involved in;

the conduct of the violation.

(Indiana State Department of Health; 410 IAC 3.6-4-1)

410 IAC 3.6-4-2 Six-year disqualifications Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 2. The department shall disqualify a WIC vendor for six (6) years for one (1) incidence of either of the following: (1) Buying or selling food instruments for cash (trafficking).

(2) Selling:

(A) firearms;

(B) ammunition;

(C) explosives; or

(D) controlled substances, as defined in 21 U.S.C. 802;

in exchange for food instruments.

(Indiana State Department of Health; 410 IAC 3.6-4-2)

410 IAC 3.6-4-3 Three-year disqualifications

Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 3. The department shall disqualify a WIC vendor for three (3) years for any of the following reasons:

(1) One (1) incidence of the sale of:

(A) alcohol;

(B) alcoholic beverages; or

(C) tobacco products;

in exchange for food instruments.

(2) A pattern of any of the following:

(A) Two (2) or more claims for reimbursement for the sale of an amount of a specific supplemental food item that exceeds the store's documented inventory of that supplemental food item within a twenty-four (24) month period.

(B) Three (3) or more vendor overcharges within a twenty-four (24) month period.

(C) Two (2) or more instances of any combination of receiving, transacting, or redeeming food instruments outside of authorized channels, including the use of an unauthorized vendor or an unauthorized person, or both, within a twenty-four (24) month period.

(D) Three (3) or more charges for supplemental food not received by the participant within a twenty-four (24) month period.

(E) Two (2) or more instances of providing credit or nonfood items, other than:

(i) alcohol;

(ii) alcoholic beverages;

(iii) tobacco products;

(iv) cash;

(v) firearms;

(vi) ammunition;

(vii) explosives; or

(viii) controlled substances, as defined in 21 U.S.C. 802;

in exchange for food instruments within a twenty-four (24) month period. (Indiana State Department of Health; 410 IAC 3.6-4-3)

410 IAC 3.6-4-4 One-year disqualifications Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 4. The department shall disqualify a vendor for one (1) year for a pattern of two (2) or more instances, within a twentyfour (24) month period, of providing unauthorized food items in exchange for food instruments, including charging for supplemental foods provided in excess of those listed on the food instrument. (Indiana State Department of Health; 410 IAC 3.6-4-4)

410 IAC 3.6-4-5 Second mandatory sanctions Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 5. When a vendor, who previously has been assessed a sanction for a: (1) six-year;

(2) three-year; or

(3) one-year;

disqualification, receives another sanction for any of these violations, the department shall double the second sanction. Civil money penalties may only be doubled up to the limits allowed under 7 CFR 246.12(l)(2)(i). (Indiana State Department of Health; 410 IAC 3.6-4-5)

410 IAC 3.6-4-6 Third or subsequent mandatory sanction Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 6. When a WIC vendor, who previously has been assessed two (2) or more sanctions for a:

(1) six-year;

(2) three-year; or

(3) one-year;

disqualification, receives another sanction for any of these violations, the department shall double the third sanction and all subsequent sanctions. The department shall not impose civil money penalties in lieu of disqualification for third or subsequent sanctions for violations listed for a six-year disqualification, three-year disqualification, or one-year disqualification. (Indiana State Department of Health; 410 IAC 3.6-4-6)

410 IAC 3.6-4-7 Disqualification based on another food program disqualification Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 7. The department shall disqualify a WIC vendor who has been disqualified from the food stamp program. The disqualification:

(1) shall be for the same length of time as the food stamp program disqualification;

(2) may begin at a later date than the food stamp program disqualification; and

(3) shall not be subject to administrative or judicial review under the WIC program.

(Indiana State Department of Health; 410 IAC 3.6-4-7)

410 IAC 3.6-4-8 Inadequate participant access determinations for federally-mandated vendor disqualification Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 8. Before disqualifying a vendor for a food stamp program disqualification or for any of the violations listed for a federally-mandated six-year disqualification, three-year disqualification, or one-year disqualification, the department shall determine if disqualification of the WIC vendor would result in inadequate participant access. If the department determines

that disqualification of the WIC vendor would result in inadequate participant access, the department shall impose a civil money penalty in lieu of disqualification. However, the department shall not impose a civil money penalty in lieu of disqualification for third or subsequent sanctions for violations listed for a:

(1) six-year;
(2) three-year; or
(3) one-year;
disgualification. (Indiana State Department of Health; 410 IAC 3.6-4-8)

410 IAC 3.6-4-9 Civil money penalty formula Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 9. (a) For each violation subject to a federally-mandated sanction, the department shall take the following steps to calculate a civil money penalty imposed in lieu of disqualification:

(1) Determine the vendor's average monthly redemption of food instruments for the six (6) month period ending with the month immediately preceding the month during which the notice of adverse action is dated.

(2) Multiply the average monthly redemption amount determined in subdivision (1) by ten percent (10%).

(3) Multiply the product from subdivisions (1) and (2) by the number of months for which the vendor would have been disqualified. This is the amount of the civil money penalty, provided that the civil money penalty shall not exceed the limits set forth in 7 CFR 246.12(l)(2)(i). For a violation that warrants permanent disqualification, the amount of the civil money penalty shall not exceed the limits set forth in 7 CFR 246.12(l)(2)(i). For a violation that warrants permanent disqualification, the amount of the civil money penalty shall not exceed the limits set forth in 7 CFR 246.12(l)(2)(i). When during the course of an investigation the department determines a vendor has committed multiple violations, the department shall impose a civil money penalty for each violation.

(b) The total amount of civil money penalties imposed for violations investigated as part of a single investigation may not exceed the limits set in 7 CFR 246.12(l)(2)(i). (Indiana State Department of Health; 410 IAC 3.6-4-9)

410 IAC 3.6-4-10 Multiple violations during an investigation Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 10. When during the course of an investigation the department determines a vendor has committed multiple violations of this rule, the department shall disqualify the vendor for the period corresponding to the most serious violation of this rule. However, the department shall include all violations in the notice of adverse action. (Indiana State Department of Health; 410 IAC 3.6-4-10)

Rule 5. Department Sanctions

410 IAC 3.6-5-1 Compliance Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 1. The purpose of the WIC program is to provide the following:

(1) Supplemental foods containing nutrients determined beneficial for:

(A) pregnant, breastfeeding, and postpartum women;

(B) infants; and

(C) children;

who are at nutritional risk.

(2) Nutritional education to eligible persons.

The WIC vendor is an important part of the WIC program. The primary focus of the WIC program is not to sanction WIC vendors. The department will emphasize compliance with this rule while taking into account the circumstances of the noncompliance with this rule. Sanctions will be imposed when necessary to ensure compliance. (Indiana State Department of Health; 410 IAC 3.6-5-1)

410 IAC 3.6-5-2 Major and minor violations

Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 2. (a) Major violations are violations that could result in harm to WIC participants or the WIC program. The following are major violations:

(1) Claiming reimbursement for the sale of an amount of a specific supplemental food item that exceeds the vendor's documented inventory of that supplemental food item for a specific period of time.

(2) Submission of false information:

(A) on the retail vendor price survey; or

(B) during the course of inspections of the vendor site.

(3) Receiving, transacting, or redeeming food instruments outside of authorized channels, including the use of an unauthorized vendor or an unauthorized person, or both.

(4) Charging for a supplemental food not received by the participant.

(5) Providing credit or nonfood items, other than:

(A) alcohol;

- (B) alcoholic beverages;
- (C) tobacco products;
- (D) cash;
- (E) firearms;
- (F) ammunition;

(G) explosives; or

(H) controlled substances, as defined in 21 U.S.C. 802;

in exchange for food instruments.

(6) Failure to attend a required training.

(7) Failure to maintain:

(A) inventory records; or

(B) other records;

the department requires of the vendor.

(8) Providing change when redeeming a food instrument.

- (9) Failure to provide authorized WIC program personnel access to the following:
 - (A) The business premises.
 - (B) Any redeemed food instruments on hand.
 - (C) Any other records pertaining to vendor participation.
- (10) Alteration of a food instrument other than a legitimate price or "date used" correction.

(11) Home delivery of WIC purchases.

(12) Failure to accept a valid food instrument when accompanied by a valid WIC identification folder.

(13) Recovery or attempted recovery of funds or food from WIC participants.

(14) Failure of a vendor pharmacy to provide special formulas as required by 410 IAC 3.6-3-4(a)(9).

(15) Failure to compare the signature on the food instrument with the signature on the WIC program identification card.

(16) Not allowing WIC participants to participate in sales promotions or manufacturer's specials or refusal to accept coupons when allowed for other customers.

(17) Denial of the purchase of up to the full amount of WIC foods authorized on a food instrument if requested by a WIC participant.

(18) Selling expired infant formula to participants.

(19) Failure to reimburse the department, within thirty (30) days of written request, for amounts paid by the department to the vendor on improperly redeemed food instruments.

(20) Including sales tax or container deposits as part of the actual cost of the authorized food listed on the food instrument or requiring the participant to pay the sales tax or container deposit.

(21) Requiring cash purchases in order to redeem food instruments.

(22) Accepting the return of items purchased with a food instrument for cash or credit towards other purchases or exchanges, with the exception of exchanges of an identical authorized food item when the original food item:

(A) is defective;

(B) is spoiled; or

(C) has exceeded its:

(i) "sell by" date;

(ii) "best if used by" date; or

(iii) another date;

limiting the sale or use of the item.

(23) Threatening or verbally abusing WIC participants or authorized WIC program personnel.

(b) Minor violations are violations that may impose less harm to participants or the program. The following are minor violations:

(1) Failure to supply a timely retail vendor price survey to the department.

(2) Requiring WIC participants to show identification other than WIC identification folders, except in cases when the WIC identification folder is not signed.

(3) Issuing rain checks for specific WIC food types, brand, or quantities listed on the food instrument not available or not received by the participant at the time a food instrument is redeemed.

(4) Failure to maintain the minimum required:

(A) quantity;

(B) size;

(C) type; and

(D) variety;

of WIC-approved foods as set forth in 410 IAC 3.6-3-8.

(5) Requiring a participant to select a specific type or brand of WIC-approved foods when the food instrument or the food list, or both, does not require the purchase of that specific type or brand.

(6) The:

(A) possession;

(B) display on the shelf in the vendor site;

(C) attempted sale; or

(D) actual sale;

of food products that originated from the Commodity Supplemental Food Program.

(7) Acceptance of food instruments that are signed by a participant or a proxy before the vendor fills in the total actual cost.

(8) Failure to remove out-of-date WIC foods from customer areas.

(9) Failure of the WIC foods identification test by store personnel or scanner system.

(10) Failure to do any of the following:

(A) Maintain WIC food prices within fifteen percent (15%) of other authorized WIC vendors in the WIC service area.

(B) Accurately show the price of WIC foods on the food:

(i) package;

(ii) container;

(iii) shelf; or

(iv) sign.

(C) Offer WIC participants the same courtesies and services offered to the general public.

(11) Using a cash register without a current WIC-approved food list at the cash register.

(12) Failure to allow the purchase of a WIC authorized food.

(13) Accepting a food instrument:

(A) before the "first day to use"; or

(B) after the "last day to use".

(14) Accepting an altered food instrument, other than a legitimate price or "date used" correction.

(15) Failure to provide a WIC participant with a cash register receipt for foods purchased with a food instrument.

(16) Retaining WIC identification or any information that identifies a person as a WIC participant or proxy or disclosing information regarding a participant of the WIC program to any person without a valid court order, other than to the department, its designee, or a federal WIC program official.

(c) Sanctions will be imposed as follows:

(1) For each major violation, a vendor may be fined as follows:

(A) Up to the lesser of one thousand dollars (\$1,000) or ten percent (10%) of the vendor's monthly average redemptions for:

(i) the greater of the twelve (12) months preceding the date of the sanction notice; or

(ii) a lesser number of months the vendor has been authorized.

(B) Disqualification from the WIC program for up to one (1) year.

(2) For the first minor violation within a twenty-four (24) month period, the vendor shall receive a letter of education indicating the following:

(A) The violation.

(B) How to remedy the violation.

(3) For a vendor's second minor violation within a twenty-four (24) month period, a vendor shall either:

(A) receive a second education/warning letter; or

(B) be required to participate in a conference with the department and local agency about the violation, either in person or by telephone.

After the letter or conference, the vendor shall submit written documentation of the corrective action that will be taken. (4) For a vendor's third minor violation within a twenty-four (24) month period, a vendor may be fined up to the lesser of three hundred dollars (\$300) or three percent (3%) of the vendor's monthly average redemptions for the greater of the following:

(A) The twelve (12) months preceding the date of the imposition of the sanction.

(B) A lesser number of months the vendor has been authorized.

(5) For any subsequent minor violations within a twenty-four (24) month period, a vendor may be fined up to the lesser of five hundred dollars (\$500) or five percent (5%) of the vendor's monthly average redemptions for the greater of the following:

(A) The twelve (12) months preceding the date of the sanction notice.

(B) A lesser number of months the vendor has been authorized.

(6) Multiple violations found may result in a cumulative penalty assessment based upon (c)(2) above [sic.].

(7) The maximum fine and maximum disqualification term shall be not more than the limits set forth in 7 CFR 246.12(l)(2)(i).

(d) A vendor remaining in the program after an imposed sanction shall provide the following:

(1) Certification that the situation giving rise to the sanction has been corrected.

(2) Documentation regarding the correction as requested by the department.

(Indiana State Department of Health; 410 IAC 3.6-5-2)

410 IAC 3.6-5-3 Prior warning Authority: IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 3. The department does not have to provide the vendor with a prior warning that violations were occurring before imposing any of the sanctions in this article, with the exception of section 2(c) of this rule. (Indiana State Department of Health; 410 IAC 3.6-5-3)

410 IAC 3.6-5-4 General requirements Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 4. The total period of disqualification imposed for department sanctions investigated as part of a single investigation may not exceed one (1) year. A civil money penalty or fine may not exceed eleven thousand dollars (\$11,000) for each violation. The total amount of civil money penalties and administrative fines imposed for violations investigated as part of an investigation may not exceed the limits set forth in 7 CFR 246.12(l)(2)(i). (Indiana State Department of Health; 410 IAC 3.6-5-4)

410 IAC 3.6-5-5 Administrative reviews Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 4-21.5; IC 16-19-3; IC 16-35-1.5

Sec. 5. The department shall provide administrative review to the extent required by IC 4-21.5, except that administrative review will not be provided for certain department actions as indicated in 7 CFR 246.18(a)(1)(iii). (Indiana State Department of Health; 410 IAC 3.6-5-5)

410 IAC 3.6-5-6 Termination of agreement

Authority: IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 6. When the department disqualifies a vendor, the department shall also terminate the vendor agreement. (Indiana State Department of Health; 410 IAC 3.6-5-6)

Rule 6. Incorporation by Reference

410 IAC 3.6-6-1 Incorporation by reference Authority: IC 16-19-3-5; IC 16-35-1.5-6 Affected: IC 16-35-1.5

Sec. 1. (a) When used in this article, references to the following publications shall mean the version of that publication listed in this subsection. The following publications are hereby incorporated by reference:

(1) 7 CFR 246.12 (January 1, 2006).
 (2) 42 U.S.C. 1786.
 (3) 7 CFR 246.10 (January 1, 2006).
 (4) 7 CFR 246.18 (January 1, 2006).

(5) 21 U.S.C. 802.

(b) Federal rules that have been incorporated by reference do not include any later amendments than those specified in the incorporated citation. Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. (Indiana State Department of Health; 410 IAC 3.6-6-1)

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on December 22, 2005 at 10:00 a.m., at the Indiana State Department of Health, 2 North Meridian Street, Rice Auditorium, Indianapolis, Indiana the Indiana State Department of Health will hold a public hearing on a proposed new rule to establish an authorization and reauthorization process for food vendors and to establish a system of civil penalties and other sanctions for a WIC vendor contract under the WIC program or federal regulations under 7 CFR 246.

United States Department of Agriculture regulations require the Indiana State Department of Health to adopt criteria for the selection of WIC vendors. The Indiana State Department of Health has included the criteria and process for selection of vendors in this rule.

Copies of these rules are now on file at the Community and Family Health Services Commission at the Indiana State Department of Health, 2 North Meridian Street and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Sue Uhl Deputy State Health Commissioner Indiana State Department of Health