

## **SUMMARY OF EXPRESS TERMS**

The proposed rulemaking would amend 10 NYCRR Subpart 60-1 to account for the WIC Program's transition to electronic benefits payments and to implement compliance measures for entities that provide infant formula to WIC vendors, as follows:

The title of Subpart 60-1 is amended to include food suppliers, including infant formula suppliers, as regulated entities.

Section 60-1.1, which defines terms relevant to the WIC program, is updated to reflect the transition to eWIC transactions. The definition of "food instrument" is amended to include eWIC cards, and definitions are added for "primary account number (PAN)," "personal identification number (PIN)," and "eWIC stand-beside terminal." Several definitions are added or expanded to encompass key stakeholders in the New York State (NYS) WIC program. "Vendor management agency (VMA)" refers to a local agency that contracts with NYS to provide vendor management services. "Vendor applicant" distinguishes prospective WIC vendors (i.e., vendors that are applying or reapplying for WIC authorization) from applicants for WIC benefits. "Food vendor" is replaced with "vendor," to include approximately 600 pharmacies authorized to redeem WIC benefits in NYS. "Food Supplier" refers to any wholesale distributor of food products approved by the WIC Program to authorized vendors. New definitions of "infant formula" and "infant formula supplier" have also been added. Finally, the definition of "participant" is updated to include a program beneficiary's authorized representative, a role specific to cyclical eWIC benefit issuance.

Section 60-1.4 is amended to remove language pertaining to the former paper-based benefit system and substitute appropriate language pertaining to the current electronic benefit system.

Sections 60-1.7 and 60-1.8 are amended to eliminate language pertaining to participant and vendor violations that are now obsolete with the introduction of electronic benefits administration.

Section 60-1.7 is further amended to make it a violation of the WIC program to fail to notify local agencies of changes to their income or household composition.

Section 60-1.8 is further amended to align the provision concerning disqualification and civil resolution with the requirements of Title 7 Code of Federal Regulations (CFR) Part 246. Section 60-1.9, which concerns program violations and penalties for local agencies, is repealed, as all provisions are enforceable via the local agency contract. Additionally, all references to local agency hearings and local agency disqualification are removed from Subpart 60-1, as a local agency which is denied a WIC contract is only entitled to receive a briefing pursuant to State Finance Law § 163.

Section 60-1.10 is renumbered section 60-1.9 and addresses language discrepancies pertaining to whom the Program entrusts vendor management responsibilities.

Sections 60-1.11 and 60-1.12 are renumbered sections 60-1.10 and 60-1.11 and reorganized such that newly renumbered section 60-1.10 addresses vendor hearings concerning disqualification or imposition of an administrative fine or civil money penalty, and newly renumbered section 60-1.11 addresses vendor hearings concerning denial of an application or termination of a contract, to better reflect current NYS administrative procedures.

Section 60-1.12 is further amended to incorporate all federal vendor authorization criteria by reference to Title 7 CFR Part 246, and all existing rules pertaining to individual federal criteria are deleted. Vendor limiting criteria, which define the maximum number of vendors the State can monitor given available resources are also deleted. Newly renumbered section 60-1.12 is further amended to accommodate the streamlined vendor application process; the standard vendor contract term is no longer limited to one year, and the Commissioner is granted authority to determine “open application” time periods during which vendors may apply or reapply for WIC authorization. Additional provisions permit a vendor to apply at any time, regardless of whether an “open

application” period is in effect, under any of the following circumstances: the vendor is located in an area identified as having inadequate participant access; the vendor seeks to apply within sixty days of acquiring a store that was authorized to redeem WIC benefits under previous ownership; all of the vendor’s stores had aggregate sales of at least \$5 million during the previous tax year and demonstrate eWIC readiness; or the Department determines that the vendor will serve at least twenty-five WIC participants who cannot be adequately served by another authorized vendor located within a one-mile radius due to a barrier stemming from language, ethnicity, nationality, or religious belief.

Section 60-1.13 is added to expressly adopt regulatory oversight authority over infant formula suppliers, which Title 7 CFR § 246.12 specifically leaves to state agencies and is necessary for the Department to ensure the health and safety of New York State’s infant population. Eligibility and compliance requirements are clearly defined, as are suppliers’ hearing rights.

Finally, Section 60-1.14 is added to satisfy the “incorporation by reference” requirements of New York State Executive Law § 102 which attach to several references to the United States Code and Code of Federal Regulations.

Pursuant to the authority vested in the Commissioner of Health by sections 700 and 2500 of the Public Health Law, 42 United States Code section 1771 et seq. and Part 246 of Title 7 of the Code of Federal Regulations, Subpart 60-1 of Title 10 of the Codes, Rules and Regulations of the State of New York (“NYCRR”) is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

The title of Subpart 60-1 is amended to read as follows:

Subpart 60-1 - WIC Program - Violations and Hearings Involving Applicants, Participants, Food Vendors, Food Suppliers and Local Agencies

Section 60-1.1 is amended to read as follows:

As used in this Subpart, the following terms shall have the following meanings:

(a) Administrative fine means a civil penalty imposed by the department on a vendor for WIC program violations under the authority of section 12 of the Public Health Law.

[(a)] (b) Administrative law judge means a person designated by the Commissioner of Health to conduct hearings under sections 60-1.6, 60-1.10 and 60-1.11 [and 60-1.12] of this Subpart. The commissioner may delegate to the Administrative Law Judge the power to render final decisions in these matters.

[(b)] (c) Adverse action shall mean the imposition of [monetary penalties,] administrative fines or civil money penalties; suspension or disqualification from[, ] authorization to redeem WIC benefits; or [the] denial of [participation in the WIC program] authorization to redeem WIC benefits. It shall

not mean nonrenewal of a contract, the term of which has expired [, nor notification to a vendor to cease and desist from depositing WIC checks in the vendor's bank account].

[(c)] (d) *Applicant* means a person who submits an application to a local agency for its determination of [his/her] their eligibility to receive supplemental foods under the WIC program.

[(d)] (e) *Categorically ineligible* means not meeting the definition of a pregnant [women] woman, breastfeeding [women] woman, postpartum [women] woman, or infant or child as set forth in subdivision [(m)] (r) of this section.

(f) *Civil money penalty (or CMP)* means a fine imposed by the department on a vendor for WIC program violations under the authority of part 246 of title 7 Code of Federal Regulations in lieu of disqualification from the WIC program.

[(e)] (g) *Commissioner* means the Commissioner of Health of the State of New York.

[(f)] (h) Conference means a meeting prior to a request for a fair hearing, between a representative of the department, a local agency or a vendor management agency and an applicant [or], participant, vendor applicant, or vendor who is aggrieved by the determination or action of such agency, to discuss such determination or action.

[(g)] (i) *Department or State Agency* shall mean the New York State Department of Health.

(j) *Disqualification* means:

(1) for purposes of the participant, the act of ending a participant's WIC program participation; or

(2) for purposes of the vendor, the act of ending or precluding a vendor's authorization to redeem WIC benefits for disciplinary reasons; or

(3) for the purposes of an Infant Formula Supplier, the act of revoking approval to supply infant formula to WIC Vendors and/or its removal from the WIC authorized Infant Formula Supplier list.

(k) eWIC means the Electronic Benefits Transfer (EBT) system used to issue and redeem WIC benefits in New York State.

(l) eWIC card means the card used to redeem WIC benefits at an authorized vendor.

(m) eWIC stand-beside terminal means point-of-sale equipment including, but not limited to, a barcode scanner, eWIC card reader, PIN pad, and printer provided to a WIC vendor solely for processing eWIC transactions.

[(h)](n) Fair hearing means the procedure under sections 60-1.6, 60-1.10 and 60-1.11 [60-1.12] of this Subpart by which applicants, participants, vendor applicants and [food] vendors [and local agencies] may appeal certain determinations or actions of a local agency, [or of] the State agency or a vendor management agency.

[(i) FNS means the Food and Nutrition Service of the United State Department of Agriculture.]

[(j)] (o) *Food instrument* means [a WIC check, drawn on the account of the State Department of Health exchangeable for WIC-approved products] an eWIC card, voucher, coupon, or other document which is used to obtain supplemental foods under the WIC program.

(p) *Food supplier* means any wholesale distributor of food products approved by the WIC program to sell food items to authorized WIC vendors.

[(k) *Food vendor* means any establishment which accepts WIC food instruments whether contracted to do so or not.]

(q) *Infant formula* means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk, as defined in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and that meets the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) and the regulations at 21 CFR parts 106 and 107.

(r) *Infant formula supplier* means any authorized wholesaler who provides infant formula to authorized WIC Vendors.

[(l)] (s) *Local agency* means an agency which has contracted with New York State to provide WIC benefits to participants.

[(m)](t) *Participant* means a [person who is a] pregnant woman, a breastfeeding woman for up to one year postpartum, a postpartum [women] woman up to six months following delivery, an infant under one year of age, or a child between one and five years of age, or their authorized representative, who is receiving supplemental foods, [or] food instruments or cash-value vouchers under the WIC Program.

[(n)] (u) *Persons with a special nutritional risk condition* means pregnant women [at nutritional risk as demonstrated by hematological or anthropometric measurements, or other documented nutritionally related medical conditions which demonstrate the need for supplemental foods], infants under six months of age, [and members of] migrant farm workers and their family members, [households who plan to leave the jurisdiction of the local agency] applicants with emergency referrals and homeless persons.

(v) *Personal identification number or PIN* means a numeric code used in conjunction with an eWIC card to authenticate a participant's identity during an eWIC transaction.

[(o)] (w) *Petitioner* means an applicant, participant or [his/her parent or guardian] their authorized representative, [food] vendor applicant, vendor, or food supplier [or local agency] who requests a fair hearing from the department.

(x) *Primary account number or PAN* means the 16-digit number on the front of an eWIC card.

[(p)] (y) *Respondent* means a [food] vendor or food supplier [or local agency] from whom the department seeks [a monetary] an administrative fine or civil money penalty under the provisions of section 60-1.10 [60-1.11] of this Subpart.

(z) Termination means the act of discontinuing a WIC vendor's contract with a vendor management agency for the remainder of the contract period, whether for administrative reasons or for violation of the terms of the contract.

(aa) Vendor means any establishment which accepts WIC food instruments, including eWIC transactions, whether contracted to do so or not.

(ab) Vendor applicant means any establishment that applies or reapplies to be a WIC vendor.

(ac) Vendor management agency or VMA means a local agency that is contracted with the department to perform WIC vendor management activities within a defined geographic area.

[(q)] (ad) *WIC [food] vendor* means [a food vendor] any retail food store or pharmacy which has a contract in effect with a [local] vendor management agency to supply [supplemental] WIC approved foods and/or infant formula to persons receiving benefits under the WIC program.

[(r)] (ae) *WIC program* means the Special Supplemental [Food] Nutrition Program for Women, Infants, and Children authorized by the Federal Child Nutrition Act of 1966, as amended.

Section 60-1.4 is amended to read as follows:

60-1.4 Circumstances entitling applicants and participants to a fair hearing.

(a) The following persons shall, upon request, be entitled to a fair hearing:

\* \* \*

(4) persons with a special nutritional risk condition who have not been determined eligible for WIC program benefits and who have not received [food instruments] such benefits within 10 days of application, and all other persons determined eligible who have not received [food instruments] benefits within 20 days of application; and

\* \* \*

Subdivision (a) of section 60-1.7 is amended to read as follows:

(a) A person who applies for or is receiving WIC benefits shall be considered in violation of the WIC program if that person or any individual acting on [his or her] their behalf:

\* \* \*

(3) receives from [food] vendors unauthorized food, cash or credit towards purchase of unauthorized food or other items of value in lieu of WIC authorized [supplemental] foods;

(4) physically or verbally abuses or threatens physical abuse of State agency, local agency, [food] vendor staff or other participants;

[(5) uses WIC food instruments outside of valid dates;]

[(6)] (5) [participates in the WIC program with] concurrently obtains benefits from more than one local agency or agencies;

[(7) alters the food package quantity or period of issue on the check;]

[(8)] (6) falsely reports food instruments lost or stolen;

[(9)] (7) steals WIC food instruments;

[(10)] (8) redeems WIC [food instruments] benefits at non-WIC [food] vendors; [or]

(9) fails to notify a local agency of income and/or household composition changes; or

(10) fails to provide necessary information related to an investigation involving their participation in the WIC program conducted by any Federal, State or local agencies, or other government or law enforcement entity.

[(11) countersigns the check before the food price is entered on the check.]

Section 60-1.8 is amended to read as follows:

Section 60-1.8 [Food vendor] WIC Vendor violations of the WIC program.

(a) Any [food] WIC vendor, who, in the course of a WIC transaction involving a food instrument [(WIC check)] commits any of the following acts shall be liable for disqualification from the WIC program [for a period of up to three years] in addition to being liable for [civil penalties of up to \$1,000 per violation] administrative fines [under the authority of section 12 of the Public Health Law] or civil money penalties:

(1) the WIC vendor charges the State [or local] agency for foods not received by the participant;

(2) the WIC vendor charges the State [or local] agency prices in excess of those charged to other customers;

(3) the WIC vendor provides cash or unauthorized items in exchange for WIC [checks] benefits;

(4) the WIC vendor provides cash for the return of items purchased with a WIC [check] food instrument;

[(5) the vendor fails to verify the signature on the customer's WIC identification card against the required signature on the customer's WIC check for all foods delivered or sold to the customer;]

[(6)] (5) the WIC vendor provides unwholesome items in exchange for [a] WIC benefits [check], such as but not limited to[,] food items provided past their expiration date, [and/or] spoiled or adulterated food items, or food items whose packaging has been physically compromised so as to render them potentially unfit for human consumption [foods];

[(7)] (6) the WIC vendor provides unauthorized items and/or items not [specified on the face of the WIC check in exchange for a WIC check] on the participant's WIC benefit balance at the time of the WIC transaction;

[(8)] (7) the WIC vendor issues a document (rain check) to a person utilizing [a] WIC [check] benefits purporting to give that person the right to buy, at a later date, a particular WIC item which the vendor does not have in stock at the time the document is issued;

[(9)] (8) the WIC vendor [forges a customer's signature onto a WIC check] is found in possession of unauthorized food instruments, eWIC primary account numbers, or eWIC personal identification numbers;

[(10)] (9) the WIC vendor [stamps a WIC vendor number onto a WIC check] processes a WIC food instrument for benefits already redeemed [by any other vendor] at another location;

[(11)] (10) the vendor accepts WIC [checks] food instruments without being a WIC [food] vendor;

[(12)] (11) the WIC vendor discriminates against or harasses any person utilizing [a] WIC [check] benefits;

[(13)] (12) the WIC vendor fails to price or adequately post a price for any WIC food item or  
[ensure that the amount of purchase is written in the space provided on the WIC check] fails to  
conduct a requested WIC transaction in the [customer's] presence of the WIC participant or the  
participant's authorized representation at the time of purchase;

[(14)] the vendor accepts WIC checks before or after the dates indicated on the checks during which  
the checks are valid;]

[(15)] (13) the WIC vendor fails to maintain, for a minimum of three years, all invoices and  
purchase slips for WIC food items, for inspection by authorized Federal, State or [local] vendor  
management agencies;

[(16)] (14) the WIC vendor fails to allow unobstructed examination of all WIC transaction records,  
including wholesale purchase records, food instrument[s] records, invoices and purchase slips for  
WIC food items, or has submitted and/or exhibited records indicating inconsistent redemption  
practices;

[(17)] (15) the WIC vendor fails to [have] produce, on demand, invoices and purchase slips from a  
food supplier and/or an authorized Infant Formula Supplier for WIC food items equal to the type  
and volume of WIC food items sold;

[(18)] the vendor fails to surrender WIC stamps upon disqualification or suspension;]

[(19)] (16) the WIC vendor fails to maintain, on premises of the authorized location, [a State-issued WIC vendor authorization stamp; or] public notice of WIC authorization and all eWIC stand-beside terminals certified for use in conducting WIC transactions;

[(20) the vendor deposits WIC checks into a bank account different than the vendor's sole authorized bank account listed on the vendor's contract; or

(21) the vendor stamps a check that was accepted at a location other than the sole authorized location contained in the vendor's contract.]

(17) the WIC vendor processes WIC transactions by scanning UPC codes from a UPC Code Book or Reference Sheet or similar, rather than from the actual item(s) selected for purchase; or

(18) the WIC vendor fails to comply with an order of the department to immediately cease and desist from transacting for WIC approved foods with an unapproved or disqualified Infant Formula Supplier, pursuant to section 60-1.13(1) of this Subpart.

(b) A [food] vendor shall be liable for any violation of subdivision (a) of this section by [his/her] their employees.

(c) A [food] vendor who accepts WIC food instruments or redeems WIC [checks] benefits in violation of this section, in addition to being liable for any [civil penalties] administrative fines [assessed pursuant to section 12 of the Public Health Law] or any civil money penalties, may be required to reimburse the State agency for funds obtained as result of the transactions.

(d) The imposition of administrative fines or any civil money penalties [pursuant to this section,] does not preclude the imposition of any fines or other penalties prescribed by applicable State, Federal or local law.

Section 60-1.9 is repealed, and sections 60-1.10 through 60-1.13 are renumbered as sections 60-1.9 through 60-1.12.

Newly renumbered section 60-1.9 is amended to read as follows:

Section 60-1.9 [Section 60-1.10]Conferences for [food] vendors.

(a) If a [local agency] vendor management agency has reasonable grounds for believing that a [participating] WIC vendor has committed an abuse of the WIC program, it shall send written notice to the department advising it of its findings together with any documentation.

(b) Upon receipt of the notice of suspected abuse, or on its own initiative, the department shall investigate the matter. If the department determines that an abuse has been committed and that a conference is advisable, it shall send a written notice to the vendor of the following:

\* \* \*

(6) that if the vendor fails to appear at the conference or to respond in writing to the notice of conference within 15 days to arrange for an alternate date, the vendor will be disqualified from the program. A copy of the notice of conference shall be sent to the [local] vendor management agency together with a statement that a representative of such agency may participate in the conference.

\* \* \*

(d) If the matter is not resolved at the conference, the commissioner or his designee shall send a written notice of conference decision to the [food] vendor informing the vendor of the following:

\* \* \*

(2) that the vendor is disqualified from the WIC program, effective on a specific date for a specified time [not exceeding three years];

(3) that the vendor has a right to request a fair hearing by [contacting, orally or in writing, the Director, Investigative Services Unit, Bureau of Nutrition, New York State Department of Health, Tower Building, Governor Nelson A. Rockefeller Empire State Plaza, Albany, NY 12237, (518) 474-3343,] following the procedure indicated in the written notice of conference decision within 15 days of the date of the notice [of suspension]; and

\* \* \*

Newly renumbered section 60-1.10 is amended to read as follows:

[Section 60-1.11] Section 60-1.10 Fair [H]hearings involving [food] vendors [for violations of sections 60-1.8 of this Subpart and local agencies for violation of section 60-1.9 of Subpart where a monetary penalty is sought] due to disqualification or imposition of an administrative fine or civil money penalty.

(a) Any [food] vendor [or local agency] which the department seeks to fine or fine and disqualify from the WIC program for violations of section 60-1.8 [or section 60-1.9] of this Subpart shall be afforded a right to a fair hearing under the terms of this section. [A disqualification without a contemporaneous monetary penalty is governed by the provisions of section 60-1.12.]

(b) A written notice of hearing shall be sent by certified mail to the [applicant] vendor and other parties involved at least 15 days prior to the scheduled date of the hearing. Such notice shall:

(1) specify the date, time and place of the fair hearing;

(2) state briefly the issues which are to be the subject of the fair hearing;

(3) explain the manner in which the fair hearing will be conducted;

(4) apprise the respondent of its right to be represented by an attorney, to testify, present documentary evidence, produce witnesses, cross-examine adverse witnesses, and to examine the case record prior to the fair hearing; and

(5) state that failure to appear at the fair hearing shall constitute waiver of the respondent's right to a hearing and that a default order will be issued against the respondent [, fining the respondent up to a maximum of \$1,000 per violation and/or disqualifying the vendor from participating in the WIC program for up to three years and permanently terminating the local agency from participating in the WIC program] affirming the disqualification; and, where the department seeks the imposition of administrative fines or civil money penalties, a default order may be issued, based upon substantial evidence, imposing administrative fines or civil money penalties.

(c) The provisions of section 60-1.6(d) and (h) of this Subpart concerning hearings, administrative law judges, and [record] records of hearings shall apply to fair hearings for [food] vendors [and local agencies] under this section.

(d) A copy of the fair hearing decision shall be sent to the respondent, [his/her] their attorney, if any, and other parties involved within 60 days following the date on which the department issued a notice of hearing.

(e) Nothing in this section shall prevent the department from immediately disqualifying any vendor [or local agency] from [participating in] the WIC program, provided that written notice of disqualification is given to the vendor at least 15 days before the effective date of the disqualification [and to the local agency at least 60 days before the effective date of disqualification, respectively]. The disqualification may not be stayed during the pendency of the hearing by the administrative law judge without the consent of the department's representative at

the hearing. The disqualification shall remain in effect unless an order is issued at the conclusion of the hearing which reinstates the vendor [or local agency].

(f) The department has the burden of proof to establish a violation of section 60-1.8 [or section 60-1.9] of this Subpart by substantial evidence.

Newly renumbered Section 60-1.11 is amended to read as follows:

60-1.11 [60-1.12] Fair hearings involving [food] vendor applicants and vendors [and local agencies where no contemporaneous penalty is sought] due to application denial or contract termination.

(a) A [food] vendor applicant or vendor, upon request, shall be entitled to a fair hearing under this section if its application to supply supplemental foods to WIC program participants is denied, or if it is [disqualified] terminated during the contract period from the WIC program for violation of its contract with the [local] vendor management agency or for high prices or low volume as defined in the vendor's contract [and no contemporaneous monetary penalty under the authority of section 12 of the Public Health Law is sought against it]. A fair hearing shall not be required when a vendor contract has expired and has not been renewed. [Neither the local agency nor the department shall accept an application for WIC participation from a vendor whose contract has not been renewed, for one year from the date of the contract expiration.

(b) A local agency, upon request, shall be entitled to a fair hearing under this section if its application to serve as a local WIC agency is denied or if it is disqualified. A fair hearing shall not be required when a local agency's contract with the State agency has expired and has not been renewed.

(c) (b) If a [local agency or a food] vendor applicant or vendor is denied authorization to redeem WIC benefits by, or is [disqualified] terminated from[, participation in] the WIC program, such vendor applicant or vendor [or agency] shall be given written notice promptly of such action, the reasons therefore, the rules and regulations governing [food] vendor [or local agency participation in] authorization by the WIC program, and the right to a fair hearing, and that such hearing may be obtained by the [local agency or] vendor by [petitioning, orally or in writing, the Director, Investigative Services Unit, Bureau of Nutrition, New York State Department of Health, Tower Building, Governor Nelson A. Rockefeller Empire State Plaza, Albany, NY 12237, (518) 474-3343 within 15 days from the date] following the procedure indicated in the notice of agency action [is served] within 15 days from the date of the notice. Failure to request a hearing within the required 15-day period will result in a waiver of the [food] vendor applicant's or vendor's [or local agency's] right to a hearing.

[(d)] (c) Once a timely request for hearing is received, a [A]written notice of hearing shall be sent by certified mail to the [applicant] petitioner and other parties involved at least 10 days prior to the scheduled date of the hearing. Such notice shall:

\* \* \*

(5) state that failure to appear at the fair hearing shall constitute waiver of the petitioner's right to a hearing and that an order will be issued denying or [disqualifying] terminating the petitioner's authorization [from participation in the WIC program] to redeem WIC benefits.

[(e)] (d) The administrative law judge, in rendering a decision on the [food] vendor[']s applicant's application for [participation in] authorization by the WIC program to redeem WIC benefits shall be bound by section [60-1.13] 60-1.12 of this Subpart.

[(f)] (e) Under this section, the burden of proof to [participate] become or remain [in] authorized by the WIC program to redeem WIC benefits shall be borne by [on a local agency or] the petitioner [vendor denied participation or disqualified for violations of the vendor's contract with the local agency or of this Subpart].

[(g)] (f) The provisions of section 60-1.6(d) and (h) of this Subpart concerning hearings, hearing officers, and record of hearings shall apply to fair hearings for vendor applicants and [food] vendors [and local agencies] conducted pursuant to this section.

[(h)] (g) A copy of the fair hearing decision shall be sent to the petitioner, [his/her] their attorney, if any, and any other parties involved, within 60 days following the date on which the State agency received the request for a hearing.

[(i)] Following a hearing denying a vendor participation in the WIC program for lack of need, neither the local agency nor the department shall accept from a vendor, for at least one year from the date of the order denying participation, an application to participate in the WIC program. In cases of vendor abuse, neither the local agency nor the department shall accept an application for the period of disqualification up to a maximum of three years from the date of vendor's disqualification.]

[(j)] (h) Nothing in this section shall prevent the department from immediately [disqualifying] denying authorization to redeem WIC benefits to any vendor applicant or terminating any vendor [or local agency] from [participating in] the WIC program provided that, in the case of termination, written notice of [disqualification] termination is given to the vendor at least 15 days before the

effective date of the [disqualification and to the local agency at least 60 days before the effective date of disqualification, respectively.] termination. A denial of authorization shall take effect upon written notice of the vendor applicant. The [disqualification] denial of authorization or termination may not be stayed during the pendency of the hearing by the administrative law judge without the consent of the department's representative at the hearing. The [disqualification] denial of authorization or termination shall remain in effect unless an order is issued at the conclusion of the hearing which authorizes the vendor applicant or reinstates the vendor [or local agency].

[(k)] (i) This section shall not preclude the department from commencing a subsequent proceeding to assess [a] an administrative fine or civil money penalty against the vendor [or the local agency] pursuant to section [60-1.11] 60-1.10 of this Subpart.

[(l)] (j) This section shall not preclude the department from ordering a [WIC] vendor to immediately cease and desist from [depositing] conducting WIC transactions of any kind [checks in the bank]. If the department takes such action, it shall immediately notify the vendor. The vendor may request a hearing in the [matter] manner set forth in subdivision [(c)] (b) of this section. This section shall govern the conduct of such a hearing.

Newly renumbered Section 60-1.12 is amended to read as follows:

60-1.12 [60-1.13] Vendor applicant [Enrollment] authorization criteria.

(a) Any vendor applicant that is a food store (excluding pharmacies) [which applies for participation in the WIC program shall be enrolled] may be authorized via a [State Health Department] department approved [one-year] expirable contract if all [of the following criteria are

met. If all the criteria are not met, the vendor may not be enrolled.] Federal requirements set forth in part 246 of title 7 Code of Federal Regulations and all State requirements are met, including

[(1)] [C]current and valid [food stamp] Supplemental Nutrition Assistance Program (SNAP) authorization.

[(2)(i)] The vendor/participant ratio in the ZIP code area of the applicant vendor is more than 75 participants per vendor, or

(ii) There is a participating WIC vendor within a 10-block or 1/2 mile walking distance of the applicant vendor who redeems more than \$3,000 in WIC checks per month, or

(iii) The applicant vendor had annual total sales in the previous calendar year of more than three million dollars in New York State.

(3) If the applicant vendor has assumed ownership of a store that had been participating in the WIC program within 60 days from the date the application is made, the criteria set forth in paragraph (2) of this subdivision will not apply unless the store under the previous owner redeemed fewer than 25 checks per month.

(4) The applicant vendor shall stock WIC-acceptable foods, as determined by the New York State Department of Health, in the minimum quantities prescribed in the vendor application document at the time of enrollment.

(5) Applicant vendor's prices shall be reasonable as compared to other vendors contracted with the local agency. Reasonable shall be defined by calculating the applicant vendor's selling price of their most commonly prescribed formula check type for an infant and the two most commonly prescribed check types containing multiple foods for a woman or child. The prices that are used for

these calculations should reflect the vendor's average prices for each type of item. Calculations should not be made based solely on the highest priced item. The cost of the checks should be within 10 percent of the project average for these check types as identified on the last project summary by vendor report. The project summary by vendor report identifies the project average for each check type by calculating the cost of each check type redeemed during the reporting month by vendors contracted with the applicant's local agency.]

(b) Any vendor applicant that is a pharmacy [which applies for participation in the WIC program shall be enrolled if all the following criteria are met. Any vendor who meets these criteria should be enrolled] may be authorized via a [State Health Department] department approved [one-year] expirable contract[.], if all Federal requirements set forth in part 246 of title 7 Code of Federal Regulations and all State requirements are met, including but not limited to:

[(1) There are no other pharmacies participating in the WIC program within a 1/2 mile walking distance of applicant pharmacy.

(2) The applicant pharmacy shall stock formula in the minimum quantities prescribed in the vendor application document at the time of enrollment.

(3) The applicant agrees to order and stock special formulas as requested by the local agency.

(4) The applicant's prices for formula are reasonable. Reasonable shall be defined by calculating the applicant vendor's selling price of an ITA check (eight 13-ounce cans iron-fortified concentrated formula). The total cost should be within 10 percent of the project average for this check type.]

(1) The applicant pharmacy agrees to order and stock special formulas as requested by the vendor management agency.

(c) The [applicant] vendor applicant [or pharmacy] shall have reasonable hours of operation.

Reasonable is defined as operating six days per week, eight hours per day.

(d) [The local agency shall have the option of not contracting with any vendor who has been previously disqualified from the WIC program or who has abused the WIC program or any other government sponsored program.] Applicants for WIC program participation must demonstrate consistency of business integrity. In reaching a determination as to sufficiency of an applicant's business integrity, the department may rely solely on facts already known to it and representations made by the applicant on its application. Unless denying authorization of an applicant would result in inadequate participant access, the department may not authorize an applicant if during the last six years the applicant or any of the applicant's current owners, officers, or managers have been convicted of or had a civil judgment entered against them for any activity indicating a lack of business integrity. Such activities indicating a lack of business integrity include but are not limited to fraud, antitrust violations, embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, receiving stolen property, making false claims, and obstruction of justice.

(e) [If there are no other available participating vendors within three miles of the applicant vendor or there is a demonstrated, documented cultural need (e.g., Kosher), the local agency may, within its discretion, admit the applicant vendor into the program without first meeting the criteria set forth in paragraphs (a) (1), (2), (3) and (5) or subdivision (b) or (c) of this section.] If the vendor applicant is located in an area with inadequate participant access as defined by the commissioner and meets the minimum vendor authorization criteria established in section 246.12(g)(3) of title 7 Code of Federal Regulations, the vendor management agency shall authorize the vendor applicant to redeem WIC benefits.

(f) [A local agency does not have to consider a vendor's reapplication for participation in the WIC program if the vendor was denied within the past year.

(g) When requested by the State or local agency, the applicant vendor has attended pre-contract training.] (1) The commissioner may determine “open application” time periods during which any vendor applicant may apply or reapply for authorization to redeem WIC benefits, unless the vendor applicant is found to lack consistency of business integrity, pursuant to subdivision (d) of this section.

(2) At any time, a vendor applicant may apply for authorization to redeem WIC benefits by demonstrating to the commissioner’s satisfaction that:

(i) the vendor applicant will serve 25 or more WIC participants that cannot be properly served by another WIC vendor located within a one-mile radius due to a barrier stemming from language, ethnicity, nationality, or religious belief;

(ii) all the vendor applicant’s stores had at least \$5 million in aggregate food sales during the previous year and demonstrate eWIC readiness;

(iii) there exists inadequate participant access, as defined by the commissioner, in the vendor applicant’s area;

(iv) within 60 days prior to application, the vendor applicant acquired a store that was authorized to redeem WIC benefits under previous ownership; or

(v) an otherwise exceptional circumstance exists that warrants such authorization.

A new section 60-1.13 is added to read as follows:

Section 60-1.13 – Requirements for Participating Infant Formula Suppliers.

(a) The department shall have the authority to designate approved wholesale suppliers of WIC-approved infant formula, and to limit vendors offering infant formula to wholesale procurements only from approved infant formula suppliers. No wholesale supplier of WIC-approved infant formula products may supply infant formula to a vendor which is eligible for reimbursement from the WIC program unless said infant formula supplier is designated as an approved supplier by the department pursuant to this section. Such designations shall be promulgated on a master list made available on the department's website and in writing on request, to be updated at least semi-annually.

(b) Applicants for WIC program participation as infant formula suppliers must demonstrate consistency of business integrity. In reaching a determination as to sufficiency of an applicant's business integrity, the department may rely solely on facts already known to it and representations made by the applicant on its application. The department may not authorize an applicant pursuant to this section if during the last six years the applicant or any of the applicant's current owners, officers, or managers have been convicted of a crime or had a civil judgment entered against them for any activity indicating a lack of business integrity. Activities indicating a lack of business integrity include, but are not limited to, evidence of fraud, antitrust violations, embezzlement, theft, forgery, bribery, falsification or destruction of records, filing a false instrument, making false statements, receiving stolen property, making false claims, and obstruction of justice.

(c) Infant formula suppliers seeking to receive approval from the department to supply infant formula to WIC vendors shall comply with the following requirements:

- (1) complete and submit a WIC authorized infant formula supplier application as required by the department;
  - (2) maintain and be prepared to present to the department on demand proof of a valid food safety license issued by the New York State Department of Agriculture and Markets or a comparable license from another state;
  - (3) refrain from the sale of any expired food items including infant formula, and be prepared to verify that all infant formula items sold to WIC vendors are in their original manufacturer's packaging or containers with clearly legible original labeling;
  - (4) store all WIC-approved infant formula in accordance with manufacturer recommendations;
  - (5) purchase infant formula only from an infant formula manufacturer or another entity on the New York State approved infant formula supplier list;
  - (6) present to the department on demand all sales records, invoices and copies of receipts for each delivery of WIC-approved infant formula, including a unique sales identification or invoice number;
  - (7) whenever infant formula is sold to a vendor, the infant formula supplier shall present to the department on demand the name and address of its infant formula supplier(s), and the date of wholesale purchase from that supplier; name and address of the vendor purchasing the product; records of the month, day and four-digit year of delivery; the specific number of infant formula items purchased, including product name, size of container, stock number or uniform product code; total quantity per item and unit price; and type of payment received;
  - (8) retain purchase and sale records of all WIC-approved food items sold to WIC vendors for a minimum of three (3) years, and make such records fully available to the department on demand;
- and

(9) allow the department and its authorized agent(s) unrestricted access to storage facilities and delivery vehicles for inspection purposes during normal business hours. Any business records described in paragraphs (6), (7) and (8) of this subdivision shall be available without restriction to inspectors at such times.

(d) Failure to meet any requirement of this section may be grounds for immediate revocation of an infant formula supplier's approval to participate in the WIC program, and may be the sole basis for denial of any subsequent application to participate.

(e) An infant formula supplier who has been disqualified pursuant to subdivision (d) of this section shall be entitled to a fair hearing. The infant formula supplier shall be given timely written notice of such action, the reasons therefore, the rules and regulations governing infant formula supplier participation in the WIC program, the right to a fair hearing, and that such hearing may be obtained by the infant formula supplier by following the procedure indicated in the written notice within 15 days from the date the notice of agency action is served. Failure to request a hearing within the required 15-day period will result in a waiver of the infant formula supplier's right to a hearing.

(f) Written notice of hearing shall be sent by certified mail to the infant formula supplier and other parties involved at least 10 days prior to the scheduled date of the hearing. Such notice shall:

- (1) specify the date, time and place of the hearing;
- (2) state briefly the issues which are to be the subject of the hearing;
- (3) explain the manner in which the fair hearing will be conducted;

(4) apprise the petitioner of its right to be represented by an attorney, to testify, present documentary evidence, produce witnesses, cross-examine adverse witnesses, and to examine prior to and during the hearing the documents and records supporting the action under appeal; and

(5) state that failure to appear at the hearing shall constitute waiver of the petitioner's right to a hearing and that an order will be issued denying or disqualifying the petitioner from participation in the WIC program.

(g) The administrative law judge, in rendering a decision on the infant formula supplier's eligibility for participation in the WIC program, shall be bound by section 60-1.12 of this Subpart.

(h) The burden of proof of eligibility to participate in the WIC program shall be on the infant formula supplier disqualified for violations of this Subpart.

(i) The provisions of section 60-1.6(d) and (h) of this Subpart concerning hearings, hearing officers, and record of hearings shall apply to fair hearings for infant formula suppliers conducted pursuant to this section.

(j) A copy of the fair hearing decision shall be sent to the petitioner, their attorney, if any, and any other parties involved, within 60 days following the date on which the State agency received the request for a hearing.

(k) Nothing in this section shall prevent the department from immediately disqualifying any infant formula supplier from participating in the WIC program, provided that written notice of disqualification is given to the supplier at least 15 days before the effective date of the

disqualification. The disqualification may not be stayed during the pendency of the hearing by the administrative law judge without the consent of the department's representative at the hearing. Disqualification shall remain in effect unless an order is issued at the conclusion of the hearing which reinstates the supplier.

(l) Nothing in this section shall preclude the department from ordering a vendor to immediately cease and desist from transacting for WIC-approved infant formula of any kind with an unapproved or disqualified infant formula supplier. If the department takes such action, it shall immediately notify the vendor. Failure to comply with such an order shall be a violation of WIC program requirements.

A new section 60-1.14 is added to read as follows:

Section 60-1.14 Incorporation by reference

(a) The provisions of the Code of Federal Regulations which have been incorporated by reference in this Subpart have been filed in the office of the Secretary of State of the State of New York, the publication so filed being the document entitled: Code of Federal Regulations, title 7, part 246 (pages 366 – 479), revised as of January 1, 2018, published by the Office of the Federal Register, National Archives and Records Administration, as a special edition of the Federal Register. The regulations incorporated by reference may be examined at the Office of the Department of State, 99 Washington Avenue, Albany, NY 12231 and at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237. They may also be purchased from the US Superintendent of Documents, US Government Publishing Office, Washington, DC 20402.

(b) The provisions of the United State Code which have been incorporated by reference in this Subpart have been filed with the Office of the Secretary of State of the State of New York, the publication so filed being entitled: United States Code, Title 21, Section 321 as revised Dec. 29, 2022, and Section 350a as revised Dec. 29, 2022, published by the Office of the Law Revision Counsel of the U.S. House of Representatives. The statutes incorporated by reference may be examined at the Records Access Office, New York State Department of Health, ESP Corning Tower, Albany, New York, 12237 or can be directly obtained from the Superintendent of Documents, US Government Printing Office, Washington, D.C. 20402.

## REGULATORY IMPACT STATEMENT

### **Statutory Authority:**

The statutory authority for these amendments is provided in sections 700 and 2500 of the Public Health Law. Section 700 designates the Department of Health (Department) as the agency of the State to administer any act of Congress which relates to maternal and child health services, such as The Child Nutrition Act of 1966 (42 USC § 1771 et seq, which established the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Public Health Law (PHL) § 2500 authorizes the Commissioner of Health to act in an advisory and supervisory capacity in matters pertaining to maternal and child health for which funds are, or will be, available. WIC is a discretionary program overseen by the United States Department of Agriculture (USDA)'s Food and Nutrition Services Agency. Section 246.3(b) of Title 7 of the Code of Federal Regulations (CFR) delegates responsibility for “the effective and efficient administration of the program” to states. Federal regulations further specify that states must establish procedures to deter participant violations (7 CFR § 246.12(u)(1)); develop criteria for authorizing WIC vendors (7 CFR § 246.12(g)(3)); and define participant access criteria (7 CFR § 246.12(l)(8)).

### **Legislative Objectives:**

WIC provides breastfeeding support, nutrition counseling, health care referrals, and supplemental foods to eligible women, infants, and children. Although federal WIC grants must be used in accordance with 7 CFR Part 246, the State may tailor program operations to best serve its participants. Pursuant to PHL §§ 700 and 2500, the Commissioner of Health has authority over policy decisions related to the quality of maternal and child health services provided to approximately 400,000 WIC participants each month and the distribution of over \$325,000,000 in program funds each year. The proposed amendments are consistent with the legislative objective in

that they are designed to provide access to safe food items to participants, and to provide the Department with the authority to disqualify food suppliers that do not comply with requirements meant to verify such safety.

**Needs and Benefits:**

These regulatory amendments are needed to ensure the safety of infant formula distributed under the New York State WIC Program and to update regulatory language pertaining to WIC Program violations to account for the Program’s transition from paper checks to an electronic benefit system.

Over the past few years, the Department of Health’s Bureau of Special Investigations (BSI), whose focus is to investigate fraud in State and federal nutrition programs, has become aware of fraudulent activities perpetrated by authorized WIC infant formula suppliers which circumvent BSI’s policies and procedures intended to protect the integrity of the WIC Program. More importantly, these actions put the health and safety of New York State’s infant population at risk.

In May 2018, a *New York Times Magazine* article outlined a criminal enterprise dealing with stolen infant formula. The infant formula was stored in unsafe conditions, particularly in a non-climate-controlled storage unit in Florida and shipped across the country, including New York State.

Under the NYS WIC Program, which is governed by State and federal regulations, an infant formula supplier is approved to provide infant formula to contracted NYS WIC Vendors, once the entity is inspected and licensed by the NYS Department of Agriculture and Markets (AG&M) or approved by another state as an infant formula supplier.

With the WIC Program’s transition to electronic benefits, current regulations contain language that is no longer appropriate, particularly regarding specific WIC Program violations

which were only relevant to paper check transactions. By removing references to those activities and replacing them with references to fraudulent activities that may occur under electronic benefit systems, BSI will be able to better mitigate fraud and prevent unnecessary monies from leaving Program coffers.

The proposed regulations would allow the State to have confidence that the infant formula being provided to babies in New York State is safe for consumption, having been obtained from a reliable source and stored according to manufacturer requirements. USDA Food and Nutrition Services (FNS) has approved these additional enforcement measures, in concept, and other states already have similar measures in place. They would also replace outdated language pertaining to fraudulent activities while maintaining the spirit of the current regulations.

**Costs:**

**Costs for the Implementation of, and Continuing Compliance with the Regulation to the**

**Regulated Entities:** Costs for the implementation of and continuing compliance should be minimal to regulated entities, as they are already required to maintain business records to clearly document income and expenses, including all supporting documents for State and federal tax purposes. The only additional burden will be the need to accommodate the on-site inspection process.

**Costs to State and Local Governments:**

This regulation will not add costs to local or State government operations.

**Costs to the Department of Health:**

This regulation will result in negligible increased costs for the Department. The Division of Nutrition's Bureau of Special Investigations (BSI) is 100% supported by federal grant funds under the Special Supplemental Nutrition Program for Women, Infants and Children (WIC).

Implementation of the proposed regulatory changes is part of BSI's mission and charge. Division of Legal Affairs (DLA) staff may also be needed to support BSI's efforts to a small extent; however, it is expected that this work will be absorbed by current staff.

**Local Government Mandates:**

This regulation imposes no new mandates on local governments.

**Paperwork:**

The regulated entities will be required to complete a no cost application to apply to be a New York State authorized food supplier transacting infant formula for the NYS WIC Program. This information will be used to complete a background check and verify the applicant's business integrity.

**Duplication:**

These regulations do not duplicate any State or federal rules.

**Alternatives:**

The Department considered not updating the regulations. However, failing to implement the proposed regulations would risk negative health and nutritional impacts on infants associated with consuming unsafe infant formula. As such, this alternative was not considered viable.

**Federal Standards:**

Section 246.12(G)(10)(iii) of Title 7 Code of Federal Regulations (CFR) allows for the removal of a food supplier from the authorized supplier list when specifically required or authorized by State law or regulations, or when the food supplier does not sell infant formula; otherwise, the federal regulations are silent on matters involving the regulation of food suppliers transacting infant formula for the WIC Program. USDA FNS has approved these additional enforcement measures, in concept.

**Compliance Schedule:**

These revisions would become effective upon publication of a Notice of Adoption in the New York State Register.

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## **REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS**

### **Effect of Rule:**

There is no expected regulatory effect on local governments, as all inspection and enforcement tasks will be performed by the Department of Health. The Department does not have data to specifically identify which regulated entities qualify as small businesses under New York law, noting that approximately 266 of the expected 319 regulated entities are located in New York. The nature and purpose of these regulations is such that there can only be minimal flexibility with regulated entities without undermining the purpose of the amendments.

### **Compliance Requirements:**

A small business who wants to be a regulated entity must:

1. Possess a valid food safety license from NYS Department of Agriculture and Markets, or a comparable license issued by another state.
2. Complete and submit an initial application, at no cost, to the Department of Health's Bureau of Special Investigations (BSI) prior to becoming a regulated entity, and a re-application, at no cost, at least once every three (3) years.
3. Refrain from the sale of any expired food items including infant formula and be prepared to verify that all infant formula items sold to WIC vendors are in their original manufacturer's packaging or containers with clearly legible original labeling.
4. Store all WIC-approved infant formula in accordance with manufacturer recommendations.

5. Purchase infant formula only from an infant formula manufacturer or another entity on the New York State approved infant formula supplier list.
6. Present to the department, upon demand, all sales records, invoices and copies of receipts for each delivery of WIC approved infant formula, including a unique sales identification or invoice number.
7. Regulated entities must provide the department on demand the name and address of its infant formula supplier(s), and the date of wholesale purchase from that supplier; name and address of the vendor purchasing the product; records of the month, day and four-digit year of delivery; the specific number of infant formula items purchased, including product name, size of container, stock number or uniform product code; total quantity per item and unit price; and type of payment received.
8. Retain purchase and sale records of all WIC-approved food items sold to WIC vendors for a minimum of three (3) years, with such records fully available to the department on demand.
9. Allow the department and its authorized agent(s) unrestricted access to storage facilities and delivery vehicles for inspection purposes during normal business hours.

**Professional Services:**

No professional services are required by this regulation.

**Compliance Costs:**

Compliance costs associated with these amendments are negligible. The majority of compliance costs would be in record-keeping, and it is reasonably assumed that any regulated entity would already be keeping such records in compliance with current laws.

**Economic and Technological Feasibility:**

Given the existing compliance requirements for regulated entities, no additional technological or economic burden will be placed on small businesses.

**Minimizing Adverse Impact:**

The Department's Bureau of Special Investigations will make best efforts to minimize intrusion into regulatory business entities; however, it is the Department's position that the potential risk to the infant population of the State outweighs any regulated entity's interest in avoiding the additional compliance requirements described in these amendments.

**Small Business and Local Government Participation:**

The Department will notify the 319 impacted businesses by letter indicating that the proposed rule is being put forth, and where they can review and comment on it. The Department will put regulations into public comment for the standard 60-day period. Small Businesses and Local Governments will have the opportunity to submit comments or questions to the Department. The Department will then respond via the public comment process responding to any questions or feedback provided. The Department will engage in active discussions and dialogue with all interested parties, including industry associations directly impacted by this regulation, to discuss the changes in the regulations, inform them of their need to comply, and to answer questions and listen to comments they may have on this regulation.

**For Rules That Either Establish or Modify a Violation or Penalties Associated with a Violation:**

The Department believes that the penalties established in these regulations are necessary to ensure the health and safety of infants consuming formula provided by regulated entities.

Therefore, no cure periods are being included in this regulation.

**STATEMENT IN LIEU OF  
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

## **STATEMENT IN LIEU OF JOB IMPACT STATEMENT**

A Job Impact Statement for these regulations is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.