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Minnesota Department of Health

717 Delaware Street Southeast
P.O. Box 9441
Minneapolis, MN 55440-9441
(612) 623-5000

January 13, 1995

Ms. Maryanne V. Hruby, Executive Director
Legislative Commission to Review Administrative Rules
55 State Office Building
100 Constitution Avenue
St. Paul, Minnesota 55155

Re: In the Matter of Proposed Rules of the State Department of Health Governing the Special Supplemental Nutrition Program for Women, Infants and Children (WIC Program)

Dear Ms. Hruby:

The Minnesota Department of Health intends to adopt rules relating to the WIC Program. We plan to publish a Notice Of Intent To Adopt Rules in the January 30, 1995 State Register.

As required by Minnesota Statutes, sections 14.131 and 14.23, the Department has prepared a Statement of Need and Reasonableness which is now available to the public. Also as required, a copy of this Statement is enclosed with this letter.

For your information, we are also enclosing a copy of the proposed Rules and a copy of the Notice Of Intent To Adopt Rules in this matter.

If you have any questions about these rules, please contact me at 623-5747.

Yours very truly,

Rick Chiat
WIC Vendor Supervisor

Enclosures: Statement of Need and Reasonableness
Rules
Notice Of Intent To Adopt Rules

State Of Minnesota

Department of Health

Proposed Permanent Rules Governing The Special Supplemental Nutrition Program For Women, Infants And Children (WIC Program)

Notice Of Intent To Adopt Rules Without A Public Hearing

Introduction. The Minnesota Department of Health intends to adopt, amend, and repeal permanent rules without a public hearing following the procedures set forth in the Administrative Procedure Act, Minnesota Statutes, sections 14.22 to 14.28. This proposed adoption, amendment and repeal shall be referred to in this Notice as the "proposed rule amendments." You have 30 days to submit written comments on the proposed rule amendments and may also submit a written request that a hearing be held on the proposed rule amendments.

Agency Contact Person. Questions or written comments on the proposed rule amendments and written requests for a public hearing on the proposed rule amendments must be submitted to: Rick Chiat, WIC Program Supervisor, Minnesota Department of Health, 717 Southeast Delaware Street, PO Box 9441, Minneapolis, MN 55440, telephone: 612/623-5747, fax: 612/623-5442. TDD users with questions about the proposed rule amendments may call the Minnesota Department of Health at 612/623-5522.

Subject Of Rules And Statutory Authority. The proposed rule amendments concern: the process by which the Minnesota Department of Health approves foods for purchase using WIC vouchers; the nutrition education plans and individual nutrition care plans developed by WIC local agencies; the WIC local agencies' contracts with the Commissioner of the Minnesota Department of Health; the substitution of the term "community health board" for "community health service agency"; and the definitions which apply to the WIC Program rules. The statutory authority for the proposed rule amendments is Minnesota Statutes, sections 144.11 and 145.894(k). The Minnesota Department of Health is proposing to repeal Minnesota Rules, parts 4617.0002, subpart 11; 4617.0046; 4617.0047; 4617.0170; 4617.0175; and 4617.0180. A copy of the proposed rule amendments is published in the State Register and attached to this Notice as mailed.

Comments. You have until 4:30 PM, Wednesday, March 1, 1995, to submit written comment in support of or in opposition to the proposed rule amendments or any part or subpart of the proposed rule amendments. Your comment must be in writing and received by Rick Chiat at the address listed above by the due date. Comment is encouraged. Your comment should identify the portion of the proposed rule amendments addressed, the reason for the comment, and any change proposed.

Request For A Hearing. In addition to submitting comments, you may also request that a hearing be held on the proposed rule amendments. Your request for a public hearing must be in writing and must be received by Rick Chiat at the address listed above by 4:30 PM on

March 1, 1995. Your written request for a public hearing must include your name and address. You are encouraged to identify the portion of the proposed rule amendments which caused your request, the reason for the request, and any changes you are proposing. If 25 or more persons submit a written request for a hearing, a public hearing will be held unless a sufficient number withdraw their requests in writing. If a public hearing is required, the Department will follow the procedures in Minnesota Statutes, sections 14.131 to 14.20.

Modifications. The proposed rule amendments may be modified as a result of public comment. The modifications must be supported by data and views submitted to the Department and may not result in a substantial change in the proposed rule amendments as attached and printed in the State Register. If the proposed rule amendments affect you in any way, you are encouraged to participate in the rulemaking process.

Statement Of Need And Reasonableness. A Statement Of Need And Reasonableness is now available. This Statement describes the need for and reasonableness of each provision of the proposed rule amendments and identifies the data and information relied upon to support the proposed rule amendments. A free copy of the Statement may be obtained from Rick Chiat at the address or telephone number listed above.

Small Business Considerations. In preparing these proposed rule amendments, the Department has considered the requirements of Minnesota Statutes, section 14.115, in regard to the impact of the proposed rule amendments on small businesses. The adoption of the proposed rule amendments will not directly affect small businesses.

Expenditure Of Public Money By Local Public Bodies. Minnesota Statutes, section 14.11, subdivision 1, does not apply because adoption of these proposed rule amendments will not result in additional spending by local public bodies in excess of \$100,000 per year for the first two years following adoption of the proposed rule amendments.

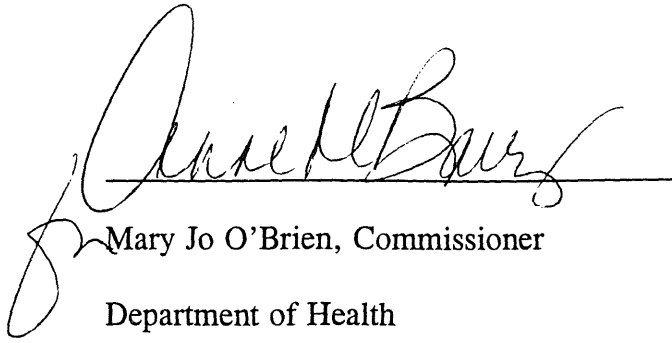
Impact On Agriculture Lands. Minnesota Statutes, section 14.11, subdivision 2, does not apply because adoption of these proposed rule amendments will not have an impact on agricultural land.

Departmental Charges. Minnesota Statutes, section 16A.1285, subdivisions 4 and 5, do not apply because the proposed rule amendments do not establish or adjust departmental charges.

Adoption And Review Of Rules. If no hearing is required, after the end of the comment period the Department may adopt the proposed rule amendments. The proposed rule amendments and supporting documents will then be submitted to the Attorney General for review as to legality and form to the extent form relates to legality. You may request to be notified of the date the proposed rule amendments are submitted to the Attorney General or be notified of the Attorney General's decision on the proposed rule amendments. If you wish to be so notified, or you wish to receive a copy of the adopted rule amendments, submit your request in writing to Rick Chiat at the address listed above.

1/13/35

Date


Mary Jo O'Brien, Commissioner
Department of Health

wic:ag4

STATE OF MINNESOTA

MINNESOTA DEPARTMENT OF HEALTH

**THE MATTER OF PROPOSED
MINNESOTA RULES RELATING
TO WIC**

**STATEMENT OF NEED
AND
REASONABLENESS**

PARTS 4617.0002, 4617.0020, 4617.0025, 4617.0030, 4617.0043, 4617.0044, 4617.0045, 4617.0046, 4617.0047, 4617.0049, 4617.0050, 4617.0056, 4617.0058, 4617.0170, 4617.0171, 4617.0172, 4617.0173, 4617.0174, 4617.0175, 4617.0180.

Amendments to Minnesota Rules, parts 4617.0002, 4617.0020, 4617.0025, 4617.0030, 4617.0043, 4617.0044, 4617.0045, 4617.0049, 4617.0050, 4617.56 and 4617.0058 are proposed. Repeal of Minnesota Rules, parts 4617.0046, 4617.0047, 4617.0170, 4617.0175 and 4617.0180 is proposed. The addition of Minnesota Rules, parts 4617.0171, 4617.0172, 4617.0173 and 4617.0174 is proposed.

GENERAL STATEMENT

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC Program, Section 17 of the Child Nutrition Act of 1966) is a food and nutrition program for pregnant, postpartum and breastfeeding women, infants and children under five years of age who meet established income guidelines and are at risk of nutritional deficiency.

The Child Nutrition Act was predicated on the finding that substantial numbers of pregnant, postpartum and breastfeeding women, infants and young children from families with inadequate income are at special risk with respect to their physical and mental health by reason of inadequate nutrition or health care, or both. The purpose of the program is to provide supplemental foods and nutrition education to individuals who meet the income and nutritional risk criteria for participation. The United States Department of Agriculture administers the program at the national level and funds the program through an administrative and food grant to each state. Individual states subcontract with local agencies to determine eligibility, provide

appropriate nutrition education, refer participants to necessary health and social services, and provide WIC vouchers to participants. See 7 C.F.R. § 246.1 (1994).

Food is provided to participants by means of a retail distribution system. Local WIC agencies distribute vouchers to participants for the types and amounts of foods that are consistent with the participant's nutritional needs. Participants redeem these vouchers at authorized retail food vendors or pharmacies.

The WIC Program is administered by the United States Department of Agriculture under United States Code, title 42, section 1786, and the Code of Federal Regulations, title 7, part 246. Within the United States Department of Agriculture, the Food and Nutrition Service [FNS] administers the program; within the FNS, the Supplemental Food Program Division and the Regional Offices are actually responsible for the program's administration. 7 C.F.R. § 246.3(a) (1994). The State agency is responsible for the effective and efficient administration of the program in accordance with 7 C.F.R. § 246.3(b) (1994) and any other relevant rules and regulations. The USDA provides the Minnesota Department of Health with most of the funds needed to operate the program at the state level. Funds are distributed by the Minnesota Department of Health to local agencies which implement the program's benefits to WIC participants.

Part 4617.0002 proposes changes to selected Definitions in order to maintain equivalency with the Code of Federal Regulations, title 7, part 246. Changes are also proposed to clarify existing Rules and to define terms in proposed Rules.

Part 4617.0020 substitutes the term "community health board" for "community health service agency" to reflect currently accepted terminology and to avoid confusion by use of a term which has different meanings elsewhere in this federal program.

Part 4617.0030 adds all current nondiscrimination laws, and their corresponding regulations, to which agency contracts must conform. This part also adds statements to be included in each local agency's contract with the commissioner.

Parts 4617.0044, 4617.0045 and 4617.0049 are amended, and parts 4617.0046 and 4617.0047 are repealed, to require an annual nutrition education plan in accordance with federal requirements, and to specify the plan requirements in the local agency's contract with the commissioner rather than in rule. Parts 4617.0050, 4617.0056 and 4617.0058 are amended to clarify the purpose of the individual care plan, which is a plan to provide nutrition care to individual WIC participants, and to reflect the repeal of part 4617.0046.

Parts 4617.0171 through 4617.0174 replace the existing procedure for approving the specific foods available for purchase with WIC vouchers. This new procedure is an annual procedure, reflects the federal bidding system used to select infant formula, defines competitive and noncompetitive food products, and allows the Commissioner to restrict the number of brands of competitive food products to approve for purchase using WIC vouchers. This will allow greater administrative efficiency. The existing rules regarding the food approval process (parts 4617.0170, 4617.0175 and 4617.0180) are repealed. Parts 4617.0025 and 4617.0043 are amended to reflect the new numbering of the food approval process rules.

To prepare the proposed rules, the Minnesota Department of Health followed the procedures mandated by the Minnesota Administrative Procedures Act. A notice to solicit outside opinion concerning the proposed rules was published in the State Register on Tuesday, December 27, 1994. Notice was given of the Department's intent to amend the rules now proposed for amendment.

STATUTORY AUTHORITY TO ADOPT RULES

Minnesota Statutes, section 14.05 (1992) grants general rulemaking authority to each agency pursuant to its authority established by law and in compliance with its duties and obligations. Minnesota Statutes, section 144.07 (1992) grants the Commissioner of the Department of Health authority to make, alter, amend or repeal all rules necessary to carry into effect its duty to develop and maintain an organized system of programs and services for protecting, maintaining and improving the health of the citizens. Minnesota Statutes, section 144.05(f) authorizes the Commissioner to coordinate and integrate local, state and

federal programs and services. Minnesota Statutes, sections 145.891 to 145.897 authorize the Commissioner of Health to develop and implement, with all necessary rules, a comprehensive state plan for the delivery of nutritional supplements to pregnant and lactating women, infants and children.

SMALL BUSINESS CONSIDERATIONS

Minnesota Statutes, section 14.115, requires the Department of Health to consider the effect on small businesses when it adopts rules. For purposes of this section, "small business" means a business entity, including farming and other agricultural operations and its affiliates, that (a) is independently owned and operated; (b) is not dominant in its field; and (c) employs fewer than 50 full-time employees or has gross annual sales of less than \$4,000,000. For purposes of a specific rule, an agency may define small business to include more employees if necessary to adapt the rule to the needs and problems of small business.

The rules proposed, amended and repealed will have no material effect on small businesses. The proposed change to the approval process for foods to be purchased with WIC vouchers will affect food manufacturers of potential WIC-approved foods. The Department is not aware of any "small business" food manufacturer which has previously applied for any of its products to be WIC-approved foods; therefore, the Department does not anticipate that the proposed amendments will affect any "small business" food manufacturers. Although the proposed amendments will have some affect on local agencies, the Department is not aware of any local WIC agency which qualifies as a "small business."

DEPARTMENTAL CHARGES IMPOSED BY THE RULES

Minnesota Statutes, section 16A.1285, subdivision 5, states: "The commissioner of finance shall review and comment on all departmental charges submitted for approval under chapter 14. The commissioner's comments and recommendations must be included in the statement of need and reasonableness and must address any fiscal and policy concerns raised during the review process."

Minnesota Statutes, section 16A.1285, subdivision 4, paragraph (c), states: "Any departmental earnings changes or adjustments authorized by the commissioner of finance must be reported to the chairs of the senate committee on finance and the house ways and means committee before August 1 of each year."

Minnesota Statutes, section 16A.1285, does not apply because the rules do not establish or adjust charges for goods and services, licenses, or regulation.

FISCAL IMPACT ON LOCAL PUBLIC BODIES

Minnesota Statutes, section 14.11, subdivision 1, requires that the Notice of Intent to Adopt Rules contain an estimate of the cost of implementing rules to local public bodies if the cost exceeds \$100,000 in either of the two years following adoption. As a practical matter, the Notice may contain the estimate of total costs, but may request that the reader refer to the SNR if the explanation of the cost estimate is lengthy.

Minnesota Statutes, section 14.11, subdivision 1, does not apply because adoption of these rules will not result in additional spending by local public bodies in excess of \$100,000 per year for the first two years following adoption of the rules. The Department does not anticipate that these amendments will require any additional spending by local public bodies because the changes which affect local WIC agencies are not substantial and because any additional costs which may result from these changes will be supported by the Minnesota WIC Program.

AGRICULTURAL LAND IMPACT

Minnesota Statutes, section 14.11, subdivision 2, and sections 17.80 to 17.84 govern the procedure to be followed if the proposed rules and amendments have an impact on agricultural land.

Minnesota Statutes, section 14.11, subdivision 2, does not apply because adoption of these rules will not have an impact on agricultural land.

OTHER STATUTORY REQUIREMENTS

Minnesota Statutes, sections 115.43, subdivision 1, and 116.07, subdivision 6, regarding pollution control and Minnesota Statutes, section 144A.29, subdivision 4, regarding nursing homes are not applicable to these rules.

DEFINITIONS

4617.0002

Subp. 2. **Agency.** The addition of "a community health board established pursuant to Minnesota Statutes, chapter 145A" (item B) is reasonable and necessary because many community health boards are local WIC agencies. The addition of items C and D are reasonable and necessary because these are defined as local agencies in Code of Federal Regulations, title 7, § 246.2 (1994).

Subp. 2A. **Bran cereal.** This definition is necessary because the proposed rule 4617.0173, subp. 4, item G, subitem 4, refers to bran cereal. The definition is reasonable because bran will generally not appear as the first ingredient of any cereal, since bran is a component of other grains. It is therefore reasonable to define a bran cereal as one in which the first ingredient is wheat bran, oat bran, or corn bran.

Subp. 2B. **Brand.** This definition is necessary because the term is used in the proposed parts 4617.0171-4617.0174. The definition is reasonable because each specific food product manufactured by a particular manufacturer will have a different name, and the proposed definition will therefore allow the Department to distinguish between food products.

Subp. 2C. **Breast-feeding.** This definition is reasonable and necessary to maintain equivalency with the Code of Federal Regulations, title 7, § 246.2, as amended, Federal Register, vol. 59, no. 48 (March 11, 1994) p. 11498.

Subp. 7. **Child.** The substitution of "individual" for "person" is reasonable and necessary because the definition of "person," as currently defined in the Minnesota WIC Rules, includes business entities as well as individuals. It is reasonable to substitute the words "who is at least one year old" because this language is easier to understand than the existing language which refers to "certification."

Subp. 11. **Community health service agency.** This definition is deleted because it is unnecessary. "Community health service agency" has been replaced in these proposed rules by the more accurate and commonly used term "community health board," a term which is

already defined in the current WIC Rules, part 4617.0002, subp. 10. A community health board is the legally responsible entity. For a complete discussion of the need for replacing "community health service agency" with "community health board," see the discussion of the proposed amendment of part 4617.0020.

Subp. 11A. **Corn cereal.** This definition is necessary because the term is used in proposed part 4617.0173, subpart 4, item G, subitem 4. The definition is reasonable because the first ingredient on the product label is the primary ingredient.

Subp. 16A. **Hot cereal.** This definition is necessary because the term is used in proposed part 4617.0173, subpart 4, item G, subitem 4. The definition is reasonable because the product is ordinarily heated before consumption.

Subp. 17A. **IHS.** This definition is necessary to provide an explanation of a term used in the definition of "agency," subp. 2 above. This definition of "IHS" is reasonable because it appears in the Code of Federal Regulations, title 7, § 246.2 (1994).

Subp. 18. **Individual nutrition care plan.** This amendment adds the word "nutrition" to clarify the purpose of the individual care plan. This amendment also corrects an incorrect citation in the current rule; the current citation (to part 4617.0062, subpart 3) is unrelated to care plans. The correct citation is to part 4617.0058.

Subp. 19. **Infant.** The substitution of "individual" for "person" is reasonable and necessary because the definition of "person," as currently defined in the Minnesota WIC Rules, includes business entities as well as individuals.

Subp. 20. **Licensed practical nurse.** The substitution of "individual" for "person" is reasonable and necessary because the definition of "person," as currently defined in the Minnesota WIC Rules, includes business entities as well as individuals. The proposed amendment also clarifies the definition of "licensed practical nurse" to provide that such an individual must be licensed by the Minnesota Board of Nursing. The change in reference to Minnesota Statutes is necessary because of the 1989 repeal of sections 148.29 to 148.297 and their replacement with sections 148.171 to 148.285. It is necessary to specify that the license

is to practice practical nursing because the Minnesota Board of Nursing also licenses registered nurses under the cited statutes.

Subp. 24. **Migrant service agency.** The addition of part 4617.0037, subpart 1, is reasonable because this section of the Rules describes the participation requirements of a migrant service agency.

Subp. 24A. **Noncitrus juice.** This definition is necessary because the term is used in part 4617.0173, subparts 1 and 4. This definition is reasonable because it includes all juice products other than juice products which are 100% citrus juice. The only citrus juices are fruit juices; it is therefore reasonable to include all vegetable juices in the definition of noncitrus juice. Fruit juice products which are 100% citrus juice are included in the definition of noncompetitive food products. See part 4617.0172, subpart 1, item E.

Subp. 26A. **Oat cereal.** This definition is necessary because the term is used in proposed part 4617.0173, subpart 4, item G, subitem 4. The definition is reasonable because the first ingredient on the product label is the primary ingredient.

Subp. 28A. **Participant.** This definition is necessary to define clearly the use of the term in the WIC rules, previously not defined. It is based on the definition of "participants" in the Code of Federal Regulations, title 7, section 246.2 (1994).

Subp. 33. **Physician's assistant.** The substitution of "individual" for "person" is reasonable and necessary because the definition of "person," as currently defined in the Minnesota WIC Rules, includes business entities as well as individuals.

Subp. 35. **Pregnant woman.** This minor amendment brings the definition into conformity with the definition of "pregnant women" in the Code of Federal Regulations, title 7, section 246.2 (1994).

Subp. 36. **Private physician.** This proposed change clarifies that the obstetric care provided by a private physician must meet the definition of ongoing routine obstetric care. This proposed change also clarifies that a private physician could, but need not, provide both pediatric care and obstetric care.

Subp. 37. **Proxy.** This clarification is reasonable because it reflects actual practice that a proxy includes both the legal guardian of an infant or child, who lacks the legal capacity to designate a proxy, as well as other individuals who can be designated by WIC participants or their legal guardians as their "proxy" to obtain and redeem vouchers. This amendment also clarifies that a proxy does not "buy" food, but instead redeems vouchers for food.

Subp. 38. **Registered nurse.** The substitution of "individual" for "person" is reasonable and necessary because the definition of "person," as currently defined in the Minnesota WIC Rules, includes business entities as well as individuals. It is reasonable to specify that a registered nurse is someone licensed by the Minnesota Board of Nursing, pursuant to Minnesota Statutes sections 148.171 - 148.285. It is necessary to specify that the license is to practice professional nursing because the Minnesota Board of Nursing also licenses practical nurses under the cited statutes.

Subp. 40A. **Rice cereal.** This definition is necessary because the term is used in proposed part 4617.0173, subpart 4, item G, subitem 4. The definition is reasonable because the first ingredient on the product label is the primary ingredient.

Subp. 44. **Voucher.** This proposed amendment deletes the reference to what is printed on vouchers, and instead clarifies that WIC customers exchange vouchers exclusively for WIC-approved foods. This change is necessary so that the commissioner does not need to specify all approved brands on the voucher. This proposed amendment also states that WIC vendors may deposit the vouchers at an established financial institution. It is necessary to amend this definition because the current definition inaccurately states that WIC vouchers could be exchanged for cash. That has never been the practice, and in fact would violate part 4617.0085, subpart 2(c)(5).

Subp. 44A. **Wheat cereal.** This definition is necessary because the term is used in proposed part 4617.0173, subpart 4, item G, subitem 4. The definition is reasonable because the first ingredient on the product label is the primary ingredient.

Subp. 44B. **WIC-approved foods.** This definition is reasonable and necessary as a short hand way of referring to all foods currently approved by the commissioner for purchase using WIC vouchers. The term is used in the proposed new definition of "participant" and the proposed amended definition of "voucher." It is necessary to refer to chapter 4617 as a whole because new parts 4617.0171 through 4617.0174 are being proposed to replace parts 4617.0170, 4617.0175 and 4617.0180; the first approvals under the newly proposed parts, however, would not be effective until the beginning of the next federal fiscal year.

Subp. 44C. **WIC customer.** This new definition is necessary because "WIC customer" is a term used in the proposed amendment to the definition of "voucher." "WIC customer" is an inclusive term which recognizes the authorized use of WIC vouchers by participants, their proxies and authorized representatives of the commissioner.

AGENCY APPLICATION REVIEW AND APPROVAL**4617.0020**

This amendment is proposed to clarify the existing rule by replacing a term of variable meaning with the commonly used and understood terminology.

Subp. 6. **Priority system. Item A, subitem 1.** The term "community health service agency" is replaced with "community health board." The use of the term "community health service agency" creates the possibility of confusion among applicants for authorization to administer WIC Programs. The commissioner has adopted the general practice of establishing agreements with the community health board, or board of health, rather than with any agency administering local health programs. Community health boards use a variety of administrative arrangements; they do not always establish "community health service" agencies. Even when they do, the community health board is the legally responsible entity. The use of the single term "agency" incorrectly suggests uniformity, or even the possibility of one overriding administrative agency to denote a multiplicity of administrative arrangements. Moreover, "community health services" is used elsewhere in the country to signify different types of organizations. Given the federal nature of the WIC Program, it is reasonable to avoid the use of terms which might be confused with other federal terms. Consistent terminology within the WIC rules promotes clarity in their understanding and interpretation. It is also reasonable and necessary to include the reference to the Minnesota Statutes to clarify that the rule is referring to community health boards established by the cited chapter.

DISQUALIFICATION

4617.0025

It is necessary to amend this part because part 4617.0180 is proposed for repeal. The citation to part 4617.0180 must therefore be changed to part 4617.0174.

LOCAL AGENCY CONTRACTS AND AGREEMENTS

4617.0030

This part is proposed for amendment to clarify existing requirements, including a change in the Minnesota Statutes, and to require additional statements to be included in the contracts between the local agencies and the commissioner.

Subp. 1. **State contracts.** (A) The proposed deletion of the reference to Minnesota Statutes, section 16.098, is necessary because of the repeal, in 1984, of section 16.098 [Contract Management and Review]. No change in the procedure for contract review and management is otherwise proposed. The proposed amendment to require only one legal representative of the local agency to sign the contract is reasonable for ease of administration and because only one signature of an authorized local agency representative is necessary in order for the contract to be legally binding on the local agency.

Subp. 1 (C). This proposed change is reasonable and necessary to clarify that no term of the local agency contract could be contrary to part 246 of Code of Federal Regulations, title 7, which governs the WIC Program.

Subp. 1 (D). This proposed change is necessary in order to ensure that local agencies are in full compliance with the nondiscrimination laws. It is reasonable that the Age Discrimination Act of 1975, and its corresponding regulations, and the Americans With Disabilities Act of 1990, and its corresponding regulations, be specifically included in the nondiscrimination clause requirement of local agencies dealing with WIC participants. It is reasonable to add specific citations to the United States Code for the various nondiscrimination statutes, for ease of reference. It is reasonable to delete the specific reference to the Code of Federal Regulations, title 7, part 15, which applies only to Title VI of the Civil Rights Act of 1964 (part 15), Title IX of the Education Amendments of 1972 (part 15a), and section 504 of the Rehabilitation Act of 1973 (part 15b), since the reference to these specific sections of the Code of Federal Regulations is replaced by the more inclusive reference to the regulations promulgated for all of the listed statutes.

Subp. 1 (H)(1). The proposed addition of this item and the proposed repeal of part 4617.0046 are reasonable and necessary in order to allow the commissioner greater flexibility. The cited federal regulation requires the nutrition education plan to be consistent with "the State's nutrition education component of Program operations and in accordance with this part and FNS [Food and Nutrition Service] guidelines." 7 C.F.R. § 246.11(d)(2) (1994). In Minnesota, the state's nutrition education component of Program operations is set out in the Minnesota WIC Program Operations Manual. By establishing the nutrition education plan requirements in the operations manual rather than in rule, the commissioner will have more flexibility to adapt to changes in federal law, in participant needs, in participant characteristics, and in professional nutrition recommendations.

Subp. 1 (H)(2). In light of the proposed repeal of part 4617.0046, it is necessary to specify that the nutrition education plan will include a description of the criteria used to select participants for high-risk nutrition education. This must be in the plan because of part 4617.0056, subpart 3, regarding high-risk criteria. This proposed change is consistent with the proposed amendment to part 4617.0056.

Subp. 1 (H)(3). This change is reasonable and necessary because of the repeal of part 4617.0046 and in order to give effect to part 4617.0058, which requires individual nutrition care plans for participants who meet individual nutrition care plan criteria. This proposed amendment is consistent with the proposed amendment of part 4617.0058.

EVALUATIONS AND MONITORING

4617.0043

Subp. 1. It is necessary to amend this part because part 4617.0180 is proposed for repeal. The citation to part 4617.0180 must therefore be changed to part 4617.0174.

NUTRITION EDUCATION PLAN REQUIREMENT**4617.0044**

This change is necessary because the Code of Federal Regulations, title 7, section 246.11(d)(2), requires local agencies to develop an annual nutrition education plan which is consistent with the Code of Federal Regulations, title 7, part 246, and the State's nutrition education component of program operations. (The regulation also requires the plan to be consistent with the guidelines established by the Food and Nutrition Service (FNS) of the U.S. Department of Agriculture.) It is reasonable to refer to the local agency's written contract with the commissioner rather than the state's nutrition education component of program operations because, under the proposed amendment of part 4617.0030, subp. 1 (H)(1), the local agency's contract with the commissioner will require adherence to Code of Federal Regulations, title 7, section 246.11(d)(2). The change in reference from 4617.0055 to 4617.0045 is necessary to correct an error in the previous internal reference. The deletion of the words "the requirements of" is reasonable because these words are unnecessary for the sentence to convey its intended meaning.

No impact is expected to result for local agencies by this proposed amendment. There is little or no change from existing practice, which is that the WIC Program asks local agencies to submit an annual update to the nutrition education plan.

NUTRITION EDUCATION PLAN SUBMISSION DEADLINES

4617.0045

This minor change in language is necessary because the proposed amendment of part 4617.0044 requires an annual plan.

CONTENTS OF A NUTRITION EDUCATION PLAN

4617.0046

AND

EVALUATION AND REVISION OF NUTRITION EDUCATION PLAN

4617.0047

The repeal of part 4617.0046, which specifies the contents of the nutrition education plan, and part 4617.0047, which specifies the evaluation and revision of the nutrition education plan, is reasonable because none of these requirements are found in the Code of Federal Regulations. The commissioner is instead proposing that the local agency, in its contract with the commissioner, agrees to develop a nutrition education plan which is consistent with Code of Federal Regulations, title 7, section 246.11, paragraph (d)(2). See the discussion of the amendment to rule 4617.0030, subp. 1 (H)(1).

APPROVAL OF NUTRITION EDUCATION PLAN

4617.0049

This proposed change is necessary because of the proposed repeal of part 4617.0047. It is reasonable for the commissioner to approve or disapprove a nutrition education plan based on whether the plan complies with the plan requirements set forth in the local agency's contract with the commissioner. Since a local agency has agreed to include in its plan the requirements set forth in the contract, a local agency's plan should not be approved unless it in fact includes what the local agency has agreed to include.

It is reasonable and necessary to delete references to a written report because of the proposed repeal of part 4617.0047. Part 4617.0047, subpart 3, currently requires local agencies to submit a written report in addition to the nutrition education plan. The proposed rule amendments do not require any such written report.

ROLE OF NUTRITION EDUCATION COORDINATOR

4617.0050

The cross-references to parts 4617.0044 and 4617.0058 are reasonable and necessary for ease of reference. The addition of the word "each" is reasonable and necessary to clarify that every individual nutrition care plan must be approved. The addition of the word "nutrition" is reasonable to clarify the nature and function of the individual care plan.

CONTENTS OF NUTRITION EDUCATION SESSIONS

4617.0056

Subp. 3. **Contents of high-risk nutrition education.** It is reasonable to delete the reference to part 4617.0046, item F, which is proposed for repeal. In light of the proposed repeal, it is necessary to designate where the high-risk criteria can be found. Pursuant to proposed part 4617.0030, subpart 1 (H)(2), the high-risk criteria must be contained in the local agency's nutrition education plan. It is reasonable to clarify, by the addition of "nutrition," the nature and function of the individual care plan.

INDIVIDUAL NUTRITION CARE PLAN**4617.0058**

It is reasonable to delete reference to the repealed part 4617.0046. In light of the proposed repeal of part 4617.0046, it is necessary to designate where the individual nutrition care plan criteria can be found. Pursuant to proposed part 4617.0030, subpart 1 (H)(3), the individual nutrition care plan criteria must be contained in the local agency's nutrition education plan.

The addition of "nutrition" to the term "individual care plan" is reasonable and necessary to clarify the purpose of the individual care plan. In order to use consistent terminology, it is reasonable to consistently use "individual nutrition care plan," and delete the reference to "a written plan to meet the nutrition needs." The deletion of the words "serving the participant" is reasonable because the local agency will be defining the individual care plan criteria in its nutrition education plan. It is reasonable to add the words "for each" to clarify that the local agency must prepare a nutrition care plan for every participant who meets the criteria specified in the local agency nutrition education plan, for every participant who requests a plan and for every participant for whom a competent professional authority has determined that an individual nutrition care plan is needed.

WIC - APPROVED FOODS

Repeal of pts. 4617.0170, 4617.0175 and 4617.0180

Concurrent with the proposed repeal of these parts, the Department is proposing new rules, parts 4617.0171 through 4617.0174. The rationale for each proposed new part is discussed below. It is reasonable and necessary to repeal the existing parts, rather than amend them, because of the extensive amendments which would be required. The repeal of the existing parts and adoption of new parts makes the rule changes more comprehensible than extensive amendments to the existing parts.

INFANT FORMULA APPROVAL PROCESS**4617.0171**

It is necessary and reasonable to differentiate the WIC food approval process for infant formula from the process which the commissioner will follow for the other foods available for purchase with WIC vouchers because the approval process for infant formula is governed by the infant formula procurement procedures contained in 7 C.F.R. § 246.16(m). It is consistent with 7 C.F.R. § 246.16(m) for the commissioner to approve both milk-based iron fortified infant formula and soy-based iron fortified infant formula. It is reasonable and necessary that each approved brand of infant formula meet the nutritional content, packaging and size requirements of 7 C.F.R. § 246.10(c) because only foods which meet these requirements may, under the federal regulation, be provided to participants in the WIC Program.

NONCOMPETITIVE FOOD APPROVAL PROCESS

4617.0172

Subp. 1. **Definition of noncompetitive food product.** This subpart is necessary because the state agency is required to "identify foods which are acceptable for use under the Program" in accordance with 7 C.F.R. § 246.10(b) and because there is a need to differentiate a noncompetitive food product from a competitive food product. This subpart lists as noncompetitive food products only food products for which, based on current information available to the commissioner, all brands of the food product are nutritionally acceptable according to 7 C.F.R. § 246.10(c). It is reasonable to distinguish such food products from the competitive food products defined in proposed part 4617.0173; since all brands of noncompetitive food products are anticipated to meet the federal requirements, it would be a waste of administrative resources to require manufacturers of noncompetitive food products to submit applications pursuant to the process set forth in proposed part 4617.0173.

It is necessary for the list of noncompetitive food products to prohibit specific food additives (i.e. artificial sweeteners, flavored milk, fruit or formula in infant cereal, and additional food products added to legumes, peanut butter, or carrots) because such additives increase the expense of the food product without improving its nutritional value. Such additives may in fact diminish the nutritional value of the food product. It is reasonable and necessary to place some restrictions on container size for the products listed in items A through C and E through I because these size restrictions do not exceed the maximum quantity of the food product per month permitted under 7 C.F.R. § 246.10(c), and because the proposed range of container sizes reflects industry standards in food packaging.

Subp. 2. **Approval of noncompetitive food products.** This subpart is necessary to differentiate the approval process for noncompetitive food products from the approval process for competitive food products under proposed pt. 4617.0173. It is reasonable that noncompetitive food products be automatically authorized for the WIC Program without an application because such food products are consistent in nutrition content across brands and

this nutrition content does not change appreciably over time. It is reasonable for the approval to remain in effect until the food product no longer meets the definition of a noncompetitive food product because, as long as the product meets the definition of a noncompetitive food product, it will be nutritionally acceptable under 7 C.F.R. § 246.10(c).

COMPETITIVE FOOD APPROVAL PROCESS

4617.0173

Subp. 1. **Definition of competitive food product.** This subpart is necessary because the state agency is required to "identify foods which are acceptable for use under the Program" in accordance with 7 C.F.R. § 246.10(b) and because there is a need to differentiate a noncompetitive food product from a competitive food product, as previously discussed with respect to part 4617.0172, subp. 1. This subpart lists as competitive food products the food products authorized by 7 C.F.R. § 246.10(c) for which not all brands meet the nutritional requirements set forth in that federal regulation. For example, adult cereals vary in the amount of sugar and iron which they contain. Noncitrus juices vary in the amount of vitamin C which they contain. These variations require the commissioner to check the individual food brands for compliance with the nutritional standards contained in 7 C.F.R. § 246.10(c) on an ongoing basis. Item C is necessary in order to accommodate additional food products which could be added to 7 C.F.R. § 246.10(c) and which meet the definition of a competitive food product. Item C will allow the commissioner to react quickly to approve new food products when such authorization is permitted under 7 C.F.R. § 246.10(c).

Subp. 2. **Duration of approval.** This subpart is necessary in order to set forth the maximum period of time for which a competitive food product may be approved. The one year period coinciding with the federal fiscal year is reasonable because of the frequency with which the formulation and nutritional composition of these food products can vary and because of the ever increasing number of new brands coming into the market. Using the federal fiscal year is reasonable because the WIC Program is a federally funded program and the management of the program is tied to the funding level received by the Department of Health each federal fiscal year. It is reasonable and necessary that the approval of a competitive food product end immediately if the food product stops meeting the approval criteria in subpart 4, because otherwise a food manufacturer could change, for example, the nutritional content of the food product and maintain approval of the food product for the duration of the one year

approval period. This may be contrary to the federal regulation which prescribes the nutritional requirements (7 C.F.R. § 246.10(c)).

Subp. 3. **Approval process.** This subpart is reasonable and necessary to establish the process by which the commissioner will solicit applications from food manufacturers for competitive food products and to set forth the method by which the commissioner will evaluate the submitted applications for completeness and for consistency with the approval criteria contained in subpart 4. The request for food product applications contained in item A is necessary to ensure that there are sufficient applications so that the commissioner can approve an adequate number and variety of brands of competitive food products to meet the nutritional needs and preferences of WIC customers. Item A, subitem 1 is reasonable and necessary so that the food manufacturer is informed of the reason for the request for application, and of the procedure the commissioner will use to approve a competitive food product. Item A, subitems 2, 4, and 5 are reasonable and necessary so that the food manufacturer receives notice of the approval criteria to be used by the commissioner, the deadline for submitting an application, and the expected time frame for the commissioner's review of the application. Item A, subitem 3, is reasonable and necessary so that the food manufacturer receives notice of the information that must be submitted as part of the application for competitive food approval. It is reasonable and necessary that the information be listed in the request rather than in rule so that the commissioner will have the flexibility to change the contents of an application form from year to year, as long as the required information falls within the parameters of information needed to identify the applicant and information needed for the commissioner to apply the approval criteria. If, for example, the federal regulation regarding the nutritional requirements of adult cereals is modified to require some nutrient in addition to iron, the application form could be changed to require the food manufacturer to submit information about the presence of that nutrient in the cereal, without amending this subpart. A written application from a food manufacturer is reasonable to avoid any misunderstanding of oral information, and because the commissioner must have enough documentation to determine

if the brand(s) of the competitive food product for which the food manufacturer is making application meets the approval criteria described in subpart 4.

Item B is necessary in order to clarify the circumstances under which the commissioner will not consider an application from a food manufacturer. This item is reasonable because the commissioner must use the information contained in item A, subitem (3) to determine if the brand of food product meets the approval criteria in subpart 4. It is reasonable and necessary that the commissioner consider only applications which are submitted by the deadline set forth in Item A, subitem 4, because the commissioner may not have time to perform the necessary review of late applications and still meet the October 1st notification deadline set forth in subpart 5.

Subp. 4. Approval criteria. This subpart is necessary to identify the specific criteria which the commissioner will use to evaluate an individual brand of a competitive food product for approval for the program.

Item A is both reasonable and necessary because no food may be approved for purchase using WIC vouchers unless it meets the nutritional requirements set forth in 7 C.F.R. § 246.10(c). (See 7 C.F.R. § 246.10(b).) It is therefore reasonable and necessary that the first sentence of subpart 4, item A, require a competitive food product to meet the nutritional requirements of the cited federal regulation. The balance of subpart 4, item A, is reasonable and necessary because these nutritional requirements are consistent with the current federal nutritional requirements.

Item B is reasonable and necessary because it enables WIC customers to purchase adult cereal and noncitrus juice in convenient container sizes and allows them the opportunity to receive the full number of ounces of these foods listed on their WIC vouchers. This should help to maximize the nutritional benefits of the program. The maximum sizes listed for frozen concentrate juice and single strength juice are also within the maximum quantities set forth in 7 C.F.R. § 246.10(c). The minimum size of 9 ounces for adult cereals is reasonable and necessary because this is the smallest box size commonly used by the cereal industry.

Item C is necessary in order to ensure that a particular brand of a competitive food product is widely available for purchase with WIC vouchers. Item C is reasonable because it is not administratively efficient for the commissioner to approve every brand of competitive food product which meets the nutritional and packaging requirements as described in items A and B. The minimum availability requirement of 5 percent is reasonable because unless a brand of food product is available at 5 percent or more of the vendors, it is extremely unlikely that the brand would be purchased by a significant number of WIC customers. The availability requirement in the current rule (part 4617.0180, subpart 5) of availability in three vendors did not require the product to be widely available. Under the proposed rules, the product must be widely available because the number of approved brands may be reduced. See explanation of item G below.

Item D is necessary because the cost of the foods approved for the program will directly impact the number of WIC customers which the program can serve. It is reasonable to have some maximum price parameters because the WIC Program is not an entitlement program. The program can only serve as many customers as the food dollars will allow. The 130 percent amount is reasonable because it defines a standard for comparison which is consistent over time (rather than the standard deviation currently in part 4617.0180, subpart 4), which accurately reflects the variations in pricing across the state, and which is more easily understood than the standard deviation in the current rule. It is reasonable to subtract any rebate received from the price of the food product, since the resulting amount is the net price paid by the WIC Program, and since the purpose of this item relates to actual dollars spent by the program.

Item E is reasonable and necessary because the WIC Program needs feedback from WIC customers regarding which brands of the competitive food products they prefer to purchase. The results of this survey may be used by the commissioner, depending on the number of applications received for competitive food product brands, according to Item G, subitem 1.

Item F is necessary to ensure that there is a sufficient choice of brands and varieties of competitive food products from which WIC customers can select and from which the vendors can satisfy their minimum stock requirements set forth in part 4617.0065, subpart 2. The minimum number of brands specified in this item is reasonable because it will allow for a sufficient choice of the varieties of the competitive food products (i.e. corn, wheat, rice, oat, bran and hot varieties of cereal; grape, pineapple, apple, vegetable and combination noncitrus fruit or vegetable juices).

Item G is necessary to ensure that WIC customers, local agencies and vendors can easily understand which brands of competitive food products are approved for purchase, and to ensure that the number of approved brands is administratively feasible to manage. Under the current rules, the commissioner is required to approve every brand of competitive food product which meets the basic requirements for approval in part 4617.0180 (i.e. nutritional acceptability, packaging, cost availability and distinction). The commissioner has been required to approve an ever increasing number of brands of adult cereals and noncitrus juices for purchase with WIC vouchers. For example, 57 brands of adult cereal are currently approved for the program. Although on the surface it may appear as if this vast array of brands would be an advantage, having this many brands leads to confusion on the part of WIC customers, local agencies and vendors regarding which cereals are actually approved for the program. From an administrative standpoint, the number of brands of competitive food products approved for the program makes it difficult to develop materials which can accommodate all of the choices available, such as the participant's WIC authorization card or WIC-approved foods lists. This, in turn, makes it difficult to educate WIC customers and vendors regarding which brands are approved for the program. This item is reasonable because it will provide the commissioner with the flexibility to limit the number of brands of competitive food products approved for the program on the basis of four relevant factors. The four factors are the results of the WIC customer food preference survey, cost, availability and variety. Including the food preference survey results as a factor will ensure that the

commissioner considers for approval those brands of food products which are preferred and most likely to be consumed by WIC customers. If the commissioner only approved brands of competitive food products which WIC customers did not really desire to consume, the nutritional integrity of the program could be jeopardized. The cost of the competing brands must be evaluated in order to ensure that the approval of the brands of food products will not adversely affect the number of WIC customers who could be served by the program. The availability of the brands of food products will be considered in order to evaluate which food products are most widely available across the state. The brands with the widest availability will be most accessible to WIC customers. The variety of the competitive food products will be examined in order to ensure that the brands of foods approved for the program are sufficiently diverse (i.e., corn, wheat, rice, oat, bran and hot varieties of cereal; grape, pineapple, apple, vegetable and combination fruit or vegetable juices) to meet the unique nutritional requirements of WIC customers. The listed types of adult cereals were selected because all adult cereals currently approved would fall into one of these six categories. The noncitrus juice brands selected were selected because the most widely available noncitrus juices are apple, grape, pineapple, vegetable, and combination juices.

Subp. 5. Notification of approval. This subpart is necessary to clarify the process the commissioner will follow to notify applicant food manufacturers, vendors and local agencies of the brands of competitive food products which are approved for purchase with WIC vouchers. It is reasonable to notify food manufacturers of the results of the application process because this is a standard part of this process and a standard practice of the commissioner. It is reasonable to notify local agencies of the competitive brands of foods approved for the program so they can educate WIC customers about these foods. It is reasonable to notify vendors of the brands of competitive foods approved for the program so they can meet the minimum stock requirements for the WIC Program (in part 4617.0065, subpart 2), and so they can ensure that their WIC customers only purchase these approved brands. It is reasonable that the notification of vendors and local agencies be made by October 1 since, pursuant to

proposed part 4617.0173, subpart 2, the approval of the competitive food product is effective on the first day of the federal fiscal year (which is October 1).

Subp. 6. **Revocation of approval.** This subpart is necessary in order to ensure the nutritional and fiscal integrity of the WIC Program. It is reasonable because the approval of a particular brand of a competitive food product is predicated on that brand's ability to meet the four basic approval criteria of nutritional content, packaging size, availability and cost. If one of these essential components of the approval process changes and the brand no longer meets these approval criteria, it must be removed from the list of authorized WIC foods as soon as it is administratively feasible to do so. In such cases, it is a standard practice of the commissioner to notify the food manufacturer in writing of the revocation action which has been taken.

GENERAL PROVISIONS

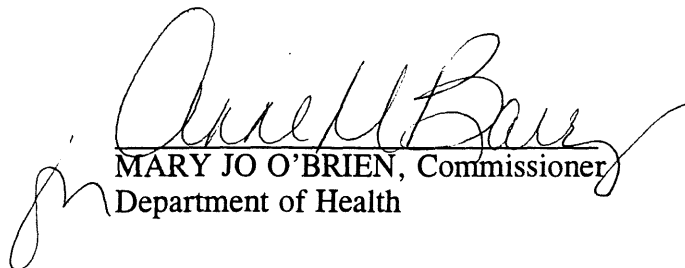
4617.0174

Subp. 1. **Expiration of prior approvals.** This subpart is necessary to clarify that the noncompetitive food products and the competitive brands of food products approved for the WIC Program on October 1, 1994, will continue to be the foods approved for the WIC Program through the duration of the federal fiscal year ending at 12:01 a.m. on October 1, 1995. Since this is the first day of the federal fiscal year following adoption of these proposed rules, it is on this date when the approvals pursuant to these proposed rules would first be effective, according to part 4617.0173, subd. 2. Also, this subpart is consistent with the notifications of approval which the commissioner has sent to the successful food manufacturer applicants under the current rules.

Subp. 2. **Cultural preference.** Subpart 2 is necessary in order to ensure that the food products approved for purchase with WIC vouchers accommodate the nutritional needs and/or preferences of the ethnically diverse WIC population in Minnesota, within the scope of what is permitted under 7 C.F.R. § 246.10(c). There is currently much debate at the national level over the possibility of expanding the list of foods eligible for the WIC Program in order to better reflect the food preferences of the diverse ethnic groups which comprise the WIC population. The United States Department of Agriculture recently issued a notice of solicitation inviting interested parties to comment on how the WIC food package could be changed to be more accommodating to the special nutritional needs of the various ethnic communities. This subpart is reasonable because once a new food product is added to 7 C.F.R. § 246.10(b) which would be of nutritional benefit to one or more cultural or ethnic groups, the commissioner should have the ability to approve the food product immediately without having to go through the approval process contained in proposed part 4617.0173. If the commissioner were required to follow the approval process, the approval of the food product would be delayed until the next federal fiscal year. Also, it is possible that no brand of the food product would meet all of the criteria contained in proposed part 4617.0173,

subpart 4. It is reasonable and necessary to notify local agencies of any foods approved under part 4617.0174, subpart 2, so that the local agencies can educate participants about these foods. It is reasonable and necessary to notify vendors of any foods approved under this subpart so that they can stock these foods, and so that they can ensure that their WIC customers only purchase authorized WIC foods.

Dated: January 13, 1995


MARY JO O'BRIEN, Commissioner
Department of Health

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