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January 29, 2010

Debra Whitford Director, Supplemental Food Programs Division Food and Nutrition Service, USDA 3101 Park Center Drive, Room 528 Alexandria, Virginia 22302

Re: FNS-2006-0037-0003, Revision in the WIC Food Package, Interim Rule

Dear Ms. Whitford:

Thank you for the opportunity to provide comments on the Revisions in the WIC Food Packages, Interim Rule, dated December 6, 2007. The Pennsylvania WIC Program (PA WIC) was pleased to see that sweeping changes were made to the food packages. The changes provide participants with more food choices and healthier options that better align with the nutrition education messages we have been providing to clients for years.

The following is a summary of our comments, accumulated through 20 months of planning and working towards implementation and 5 months of experience with the new foods and rules.

Administrative Burdens:

- 1. As we began to plan for implementation of the new food package rules, our approach was to identify the scope of products that would have to be considered as part of our state's Authorized Product List (APL). For several months after the announcement of the rules, State Agency staff discovered that several categories of foods did not have products available in the appropriate package sizes. While it is true that some food manufacturers eventually responded to the demand for new package sizes, we continually struggle with this issue as manufacturers change package sizes and reformulate products.
- 2. In general, the food industry seemed to be caught off guard by the impact and ramifications of such changes to our food package. When we initially began to reach out to manufacturers, in particular within the whole grain bread and the soy industry (for soy beverages and tofu), our appeals for information on their products were met with little to no response. By the time some of those industries took notice of the WIC requests coming

in from a multitude of state agencies, we were far enough along in our implementation plan that we were not able to include their products for consideration the first year of implementation. Consequently, state agencies were put in a very difficult position to deal with political pressure to allow products after food lists were printed and trainings were already completed. It would have been most helpful to have the buy-in of the food manufacturers and processors at an earlier stage so that they were adequately prepared to respond to our requests.

- 3. Another area which pitted state agencies against each other in the eyes of manufacturers resulted from inconsistencies in interpreting the way the rule was applied and changes in interpretation of the rules at a very late date. This was particularly an issue for us when authorizing tofu. The ruling clearly states "calcium-set tofu prepared with only calcium salts." While we took the literal interpretation of 'only calcium salts' when authorizing tofu products for the PA WIC food list, USDA issued subsequent language that allowed tofu products set with magnesium salts. This resulted in much confusion among state agencies and manufacturers. States that are trying to implement the rule as it is written faced resistance from manufacturers who insisted their products be added to the state's list. It is suggested that USDA provide clearer guidance and language in the regulations and not alter the intent of the regulations at a late date.
- 4. The Frequently Asked Questions (FAQ's) document was a useful tool, and while we understand that the intent was to address questions at a national level, there were additional emails issued that contradicted or expanded on responses posted in the FAQ's. It made it very difficult to find answers when several venues were used to respond to questions posed by states. While we always were able to keep up on reading the information distributed by Regional Office staff, the difficulty was trying to remember where we had read about topics, and because the changes were so extensive, there were many instances where we had to search our minds, emails, interim rule document, or FAQs to remember where we could find the necessary documentation to back up our decisions. The frequency of changes in interpretation and contradictions impacted a state's ability to make decisions regarding changes to computer systems and diminished the state's credibility in the eyes of local agency staff when they were trained one way at one meeting and then told that the previous information provided was incorrect. It is suggested that the FAQ's be maintained and all clarifications be sent out via that document instead of through a variety of communication mechanisms.
- 5. The amount of system development to ensure that Fully Breastfeeding Mothers of Multiples gets 1.5 times the quantity of foods was administratively burdensome in comparison with the number of participants that actually fall into this category. A major stumbling block has been trying to find container sizes that would allow this woman to receive 216 ounces of juice. There is no packaging currently that would accommodate this package, so a state has no option but to alter quantities of juice containers every other month. The programming required to accommodate this functionality is not a simple task, especially since the mother's food packages are so highly dependent on the Infant(s)' food package. In addition to the impact on computer systems, this quantity of juice seems

excessive. It is suggested that the juice for fully breastfeeding women of multiples remain the same as it is for fully breastfeeding women at 144 ounces. The 2.4 ounce additional juice per day provides little nutritional benefit, especially since scientific evidence points to water as being the best liquid to be consumed on a regular basis versus juice consumption.

- 6. There is great difficulty in managing the data system to account for the rolling amounts of formula from three months to four months and again at six months for partially breastfeeding dyads. Infants can easily be over the maximum formula for partially breastfed in month three (3), stay at the same number of cans of formula in months four (4) and five (5) (which makes them a partially BF infant), and then at six (6) months again be over the maximum amount of formula allowed. Even though there is no change in the amount of formula being offered both mom and baby have to have new packages entered because of the change in participant type of mom (post partum, partially BF, post partum no package). Not only was this extremely difficult to manage within our computer system but it is causing delays in printing checks in very busy clinics, which is a disruption to both staff and participants. It is suggested that the amounts of formula allowed for partially BF infants be higher in the early months so that there is not a forced change at four (4) months of age.
- 7. There is much confusion among participants and retail store staff about whole grain products. We recommend that USDA require that this category of foods be brand specific in the final rule. In the limited time the new food packages have been active, the majority of complaints received at the state agency have been from vendors and participants not knowing or understanding what the different ingredients in products mean or whether they meet or do not meet the criteria set in the food list. By being brand specific there is less confusion at the point of sale and a more positive experience for WIC participants and vendor cashiers.

Foods for Children and Women

8. For the child 1-2 years of age, we recommend states be given the option to be able to tailor the food package as appropriate to lower fat milk. The American Academy of Pediatrics now recommends lower fat milk for children 1 to 2 years who are at higher-than-normal risk of becoming overweight, or have a family history of high cholesterol, obesity, or heart disease. The interim rule was released prior to the release of the AAP guidelines, and thus the current regulations do not allow us to support these recommendations. Several physicians in the state have expressed a concern to us and asked if there could be any latitude offered to allow us to support their recommendation while simultaneously enforcing regulations. A designated WIC health professional (WIC CPA) or Registered Dietitian (RD) should be able to tailor the food package with a lower fat option without medical documentation.

- 9. With regard to the additional documentation required for issuance of soy beverage, tofu. low-fat and high-fat milk and extra cheese, we understand the intent behind the interim rule to keep the participant's physician or medical home apprised of choices that are sometimes made based on participant preference, and to insure that there are no contraindications for those choices. The collection of documentation from a medical professional with prescriptive authority in our state (physician, CRNP, or Physician Assistant) is proving to be burdensome to local agency clinic staff, and causes delays in the issuance of food benefits to participants. We would request that USDA consider the option of driving the communication from WIC to the medical professional, and put the burden of denial on the prescriptive authority rather than on WIC staff. The option of securing the permission to provide milk alternatives by phone does not alleviate the burden on clinic staff because it is difficult to reach the appropriate medical professional. and the collection of the signed form is still required. As medical offices move towards electronic patient files, the participant must incur a cost for any paper forms that have to be completed, so they are now subjected to both a time and financial burden to comply with participation in our Program. Ideally, we would like to see the final rule allow the issuance of milk alternatives to be determined by a registered dietitian or WIC CPA rather than the participant's medical home. The WIC CPA or an RD is a trained nutrition professional who is able to do a complete assessment and provide appropriate education to a participant. Requiring medical documentation for all of these circumstances when medically necessary may be more reasonable, but in the majority of instances, issuance of these milk alternatives can be safely accomplished and would eliminate an unnecessary burden for participants, local agency staff and medical providers alike.
- 10. Women who are partially breastfeeding twins are expending the same amount of calories, if not more, than a woman fully breastfeeding one infant. The interim rule does not list any maximum formula amounts that would preclude the Partially Breastfeeding Mother of Multiples from getting Food Package VII as described in footnote 4 of Table 2 of the regulation. Yet, in January 2009 our State Agency received word via an e-mail from USDA that if one infant is over the maximum amount of formula and the other is not, this mother should get food package V until infants turn 6 months old and would not be entitled to receive any food after her infants reach 6 months of age. This mother is still nursing the one infant more than partial and the second infant some, which is the equivalent of nursing 1 infant full term. We feel that, based on nutrient needs, she should be entitled to Food Package VII. It is suggested that USDA enforce the rule as it is written, and not as it was interpreted at a later date.
- 11. Children and women receiving food package three receive anywhere from 1,518 to 1,822 ounces of liquid per month. That works out to 51 to 61 ounces per day. Translate those ounces into calories. Children get approximately 36,388 liquid calories per month or 1,213 liquid calories per day. Fully breastfeeding women get approximately 40,212 liquid calories per month or 1,340 liquid calories per day. Fully breastfeeding women of multiples get even higher amounts. Providing this quantity of liquid calories goes against several of the reasons for why the food packages were originally changed. Liquid calories do not increase the fiber content of one's diet; children should learn to eat their calories not drink them; and scientific studies have proven that excessive liquid calorie intake is

one of the factors leading to the increased rates of obesity in this country. Keep in mind that we have not included any of the calories from the solid food WIC is providing and that WIC is a supplemental program; therefore, we should not be providing all of or even more than the calories needed by a person in one day. It is suggested that the final ruling address this issue by either decreasing the amount of formula provided, removing the dairy products from these packages, or some combination of both of these suggestions.

We are grateful for the opportunity to provide input as this historical change to the WIC Program becomes finalized. While it has been a monumental task to implement these changes in the allotted timeframe, we support the intent wholeheartedly, and have heard positive feedback from our participants. Thank you for the opportunity to provide comments. We hope that some of our recommendations can be considered.

Sincerely,

Gregory P. Landis

Director

Division of Women, Infants and Children (WIC)