



MAY 19 1999

United States Department of Agriculture

Food and Consumer Service

Mid-Atlantic Region

Mercer Corporate Park 800 Corporate Boulevard Robbinsville, N.J. 08861-1000

Ms. Lori McLaughlin Chief Counsel Office of Legal Counsel Pennsylvania Department of Health PO Box 90 Harrisburg, PA 17108-0090

Dear Ms. McLaughlin:



We are writing in response to your May 17, 1999, letter requesting our Program interpretation of 7 CFR 246.12(k) regarding vendor sanctions. This regulatory provision states, in part, that in determining the type and level of vendor sanctions, State agencies may consider "whether prior warning and an opportunity for correction was provided to the vendor." Specifically, you asked if such prior warning and opportunity for correction applies only to violations noted during monitoring visits or whether it also applies to violations noted during certification/recertification visits.

It is our opinion that the opportunity to correct deficiencies, as provided for in §246.12(k)(1), was intended to permit vendors to respond to deficiencies detected during on-site monitoring visits conducted during the course of the certification period only. It was not intended to apply to violations noted during certification/recertification visits. Furthermore, this provision does not require prior warning, but merely states that if prior warning and opportunity for correction have been given, the State agency may consider that in sanctioning the vendor.

As you know, we do not believe that every vendor who meets basic authorization qualifications should necessarily be authorized to accept WIC food instruments. Authorization to accept WIC food instruments should be considered a privilege, not a right, and must be governed by the needs of participants and the State agency's ability to effectively manage the number of vendors authorized. The application of vendor selection criteria may legitimately restrict the ability of particular stores to secure or retain their WIC authorization.

OPTIONAL FORM NO. 10 (7-98)

FAX TRANSMITTAL

of pages = 2

To	LESA TRESSLER	From	R. Hodsdon
Dept/Agency	PA DOH	Phone #	609-259-5021
Fax #	717-783-3794	Fax #	

NSN 7540-01-417-7000

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GENERAL SERVICES ADMINISTRATION



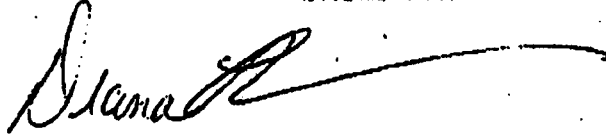
The Food and Consumer Service, formerly the Food and Nutrition Service

Ms. Lori McLaughlin

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Should you have any questions regarding this letter, please feel free to contact me.

Sincerely,



 PAT CUMISKEY-CZETO
Regional Director
Supplemental Food Programs

Commonwealth of Pennsylvania



DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

May 18, 1999

The Honorable Harold F. Mowery, Jr.
Majority Chairman
Senate Public Health and Welfare Committee
Room 169 Main Capitol
Harrisburg, Pennsylvania 17120

Dear Senator Mowery:

I am writing regarding the Women, Infant and Children ("WIC") regulations scheduled for review at a public hearing before the Independent Regulatory Review Commission on Thursday, May 20, 1999.

You may be interested in knowing that questions have been raised regarding USDA's interpretation of the federal regulations about a WIC store's opportunity to correct problems during the certification or recertification review. The Acting Regional Administrator for Supplemental Food Programs of the U.S. Department of Agriculture ("USDA") informed the Department's legal staff that the provision requiring a "warning and opportunity to correct" only applies to monitoring reviews and did not apply to certification or recertification reviews that the Department conducts to determine if a vendor meets qualifications established by the Department and should be authorized to participate in the WIC Program, in the first place.

The Department proceeded with the regulations as final with proposed rulemaking omitted in order to ensure that the Department is able to conduct the review of 1400 grocery stores prior to September 30, 1999 so that Federal funding for the WIC program would not be interrupted. The Department then intends to conduct a complete and immediate review of the WIC Program Regulations pursuant to the Governor's Executive Order 1996-1. In addition to the 1996-1 review, the Department will be required to revise its state regulations before May 17, 2000, in order to be compliant with the USDA final rule relating to WIC/Food Stamp Program Vendor Disqualification published in the Federal register on March 18, 1999.

Honorable Harold F. Mowery, Jr.

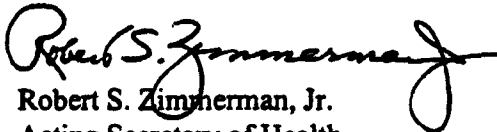
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May 18, 1999

During this regulatory review process, the Department will request that the USDA provide a legal opinion regarding the USDA's Regional Office's interpretation of the intent of the statute regarding a vendor's opportunity to correct a violation during the certification/recertification process.

I hope you find this information useful.

Sincerely,


Robert S. Zimmerman, Jr.
Acting Secretary of Health

bcc: Robert S. Zimmerman, Jr.
✓Lori McLaughlin
Gary L. Gurian
Legislative Office

Commonwealth of Pennsylvania



DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

May 18, 1999

The Honorable Dennis M. O'Brien
Majority Chairman
House Health & Human Services Committee
100 Main Capitol Building
Harrisburg, Pennsylvania 17120

Dear Senator O'Brien:

I am writing regarding the Women, Infant and Children ("WIC") regulations scheduled for review at a public hearing before the Independent Regulatory Review Commission on Thursday, May 20, 1999.

You may be interested in knowing that questions have been raised regarding USDA's interpretation of the federal regulations about a WIC store's opportunity to correct problems during the certification or recertification review. The Acting Regional Administrator for Supplemental Food Programs of the U.S. Department of Agriculture ("USDA") informed the Department's legal staff that the provision requiring a "warning and opportunity to correct" only applies to monitoring reviews and did not apply to certification or recertification reviews that the Department conducts to determine if a vendor meets qualifications established by the Department and should be authorized to participate in the WIC Program, in the first place.

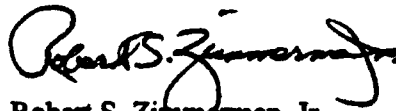
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May 18, 1999

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I hope you find this information useful.

Sincerely,



Robert S. Zimmerman, Jr.
Acting Secretary of Health

bcc: Robert S. Zimmerman, Jr.
Lori McLaughlin
Gary L. Gurian
Legislative Office



PFMA Officers

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Original: 2030

Mizner

cc: Tyrrell
Harris May 7, 1999
Sandusky
Legal
Nyce - Original

RECEIVED
99 MAY 10 AM 8:59
INDEPENDENT REGULATORY
REVIEW COMMISSION

John R. McGinley, Jr.
Chairman, Independent Regulatory
Review Commission
14th Floor, 333 Market Street
Harrisburg, PA 17101

Dear Commissioner McGinley:

The Pennsylvania Department of Health has sent you, or will shortly send you, a set of regulations implementing the Women, Infants, and Children (WIC) program. The Pennsylvania Food Merchants Association (PFMA) believes that the regulations are not only unwise but also unlawful. While the WIC regulations being proposed by the Department of Health presumably do not violate federal WIC requirements, they are inconsistent with Pennsylvania procedural law and Pennsylvania case law from a previous WIC dispute, and we believe that these regulations are unsound in terms of how the Department would continue to regulate the stores that serve WIC consumer-participants. We therefore urge you to disapprove the WIC regulations that the Department is sending to you for approval.

Regulatory Process

The Department of Health appears to acknowledge that the Regulatory Review Act, the Commonwealth Documents Law, and the Commonwealth Attorneys Act apply to the proposed regulations. However, the Department asserts that the "final-omitted" process under the Commonwealth Documents Law (CDL) (45 P.S. § 1204) allows the Department to skip the notice and comment requirements that are generally applicable to agency regulations. PFMA asserts, and asks you to conclude, that the final-omitted process is not available to the Department of Health with regard to these WIC regulations.

Section 1204 of the CDL lists three situations in which the "final-omitted" process would be lawful. Subsection 1204(1) allows the omission of ordinary procedures if a regulation relates to:

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(i) military affairs; (ii) agency organization, management or personnel; (iii) agency procedure or practice; (iv) Commonwealth property, loans, grants, benefits or contracts; or (v) the interpretation of a self-executing act of Assembly or administrative regulation.

None of these applies here. The Department of Health is making ordinary discretionary decisions in the WIC regulations that are coming before you.

Subsection 1204(2) allows agencies to bypass certain procedures when it provides individual notice to all affected persons. The Department of Health has not suggested that it will try to satisfy this subsection.

Subsection 1204(3) deals with emergencies. That is, it permits an agency to bypass the regular rule-making process for WIC programs when complying with the ordinary rule-making process would be impracticable, unnecessary, or contrary to the public interest. There is no emergency in this case. The federal rules for WIC programs require state plans, but not state regulations. The Department of Health apparently believes that it must issue regulations fairly soon because of the programmatic problems described in the Commonwealth Court decision in *Giant Food Stores, Inc v. Commonwealth, Dept. of Health*, 713 A.2d 177 (Pa. Cmwlth. 1998)]. We do not agree; the Commonwealth Court did not order the issuance of any regulations and did not establish any deadline. More important for present purposes, however, is the fact that the Commonwealth Court decision was issued on June 11, 1998. The passage of almost a year since then demonstrates that there is no emergency and defeats any suggestion that issuing proposed WIC regulations in the ordinary course of rule-making is impracticable. See *Automotive Service Councils v. Larson*, 82 Pa. Cmwlth. 47, 474 A.2d 404 (1984), where the court said that omitting proposed rule-making under section 204 of the Commonwealth Documents Law was improper in light of the time available to the agency.

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In short, the Department of Health's current "final-omitted" gambit violates the Commonwealth Documents Law and needlessly subjects everyone involved to the specter of litigation any time in the future that the regulations are invoked.

Recertification System and Penalties

A fundamental feature of the Department's traditional and proposed system is that WIC stores are certified or authorized for limited periods. Currently, there exists a system of penalties when inspections occur for recertification purposes that does not make sense in light of the system of penalties used when identical WIC inspections occur for other reasons. The grading of offenses in the proposed draft regulations may be a step in the right direction. But the fundamental problem remains. The federal WIC rules require periodic reviews and adjustments where necessary, but do not call for periodic automatic decertification and recertification nor do the federal rules prescribe the specific details of recertification. Thus, the fundamental problem with the recertification reviews is a creation of the Department of Health, not the federal government.

A decade ago, Commonwealth Court invalidated a Department of Health WIC action that removed a Giant Food Store from the program, because the Department of Health's action was based on the above mentioned artificial distinction between recertification inspections and other inspections. *Giant Food Stores, Inc. v. Commonwealth, Department of Health*, 123 Pa. Cmwlth. 418, 554 A.2d 174 (1989). The court correctly concluded that the Department's WIC recertification system was illogical and therefore invalid. In the 1989 case, Giant store #48 was to be expelled from the program for committing an offense in a recertification review which would have only brought a warning in a "monitoring" review. In that decision the court said:

The Department admits that the nature of the violation was such that in any period except a recertification one, the penalty would have been a warning. It is difficult to follow

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the Department's logic. The substantive effect of a one time shortage should make no qualitative difference depending on the time or type of inspection. As to whether a store is properly managed, there is no distinction to be made between a recertification inspection and any other type of inspection.

The finding [of violation made by the Department] is not based on substantial evidence. Substantial evidence is evidence that a reasonable mind would accept as adequate to support a conclusion. If a single product shortage is not sufficient to justify disqualification during a routine inspection, it is not sufficient to terminate store #48 from the WIC program on the basis of a one time shortage during a recertification inspection.

Giant, 123 Pa. Cmwlth. at 421-422, 554 A.2d at 176 (citations omitted). The Court therefore reversed the Department's decision to terminate the store. *Giant*, 123 Pa. Cmwlth. at 423, 554 A.2d at 176-177. After the 1989 court decision, the Department claimed that it could pursue its flawed approach to recertification once it wrote that approach down in a Handbook. We assume that the Department will feel all-the-more emboldened to pursue its judicially-invalidated approach once it publishes it as a regulation as it is currently attempting to do. Because the draft regulations are inconsistent with the Commonwealth Court decision, they are improper and should be rejected. The Department's approach, if allowed to go forward, will predictably lead to more needless litigation. The rancor and inefficiency of that process should be avoided by rejecting the regulation that is now being contemplated by the Department.

Other Substantive Issues

We have had initial discussions with the Department of Health regarding a different view of the program. In our view, for example, WIC store authorization should not be based on scarcity and monopolies, WIC

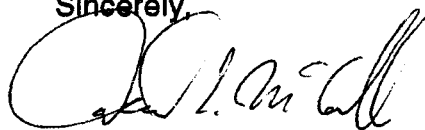
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Page Five

store authorization should not automatically "sunset" every few years, and the Department's means of comparing store prices is dysfunctional. The Department and the Governor's office have said that they are willing to rethink these issues over the longer term (and we acknowledge that this is a potentially good sign). However, the Department's proposal to promulgate the regulations through the "final omitted" process would push that process off further, and without good reason.

PFMA believes that this rethinking should happen now, with broad consultation with stake holders, through ordinary regulatory procedures. Thus, because of the procedural improprieties, the inconsistency with the case law regarding recertification inspections, and the program design flaws that are ripe for discussion, PFMA believes that the current "final-omitted" regulatory effort of the Department should be rejected.

We regret that we are at temporary loggerheads with the Department on this regulation, and we believe that your intervention now will spare us all needless conflict and put us on a road to achieving a consensus with which we all can live.

Sincerely,

A handwritten signature in black ink, appearing to read "D. L. McCorkle", written over a large, stylized circular flourish.

David L. McCorkle
President & CEO

DLM/mac



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INDEPENDENT REGULATORY
REVIEW COMMISSION

MAR -4 1999

United States
Department of
Agriculture

Food and Consumer
Service

Mid-Atlantic Region

Meyer Corporate Park
300 Corporate Boulevard
Robbinsville, N.J. 08861-1998

The Honorable Gary L. Gurlan
Acting Secretary of Health
Pennsylvania Department of Health
Health and Welfare Building, Room 802
PO Box 90
Harrisburg, PA 17108

FORTHCOMING

COPIES: Wyatt
Sandusky
Harris
Tyrrell
Gelnett ✓



Dear Acting Secretary Gurlan:

We are in receipt of your January 22, 1999 letter which provided proposed vendor regulations for the Pennsylvania WIC Program as well as testimony and comments on the regulations which were provided by the Pennsylvania Food Merchants Association. Our comments and questions are enclosed for your review.

We look forward to your response to this letter. Please feel free to contact our office should you have any questions.

Sincerely,

CHRISTOPHER J. MARTIN
Administrator
Mid-Atlantic Region

Enclosures



Rebuttal to Comments Made at September 24, 1998 Public Meeting by Mr. McCorkle

The Pennsylvania Food Merchants Association's (PFMA) objective is to develop revised regulations that "...better fit the very competitive nature of the food business in the Commonwealth today."

The WIC Program's role is to select vendors to service clients, not to set or ensure profit margins for participating vendors. Although vendors benefit from the considerable volume of food purchases made through WIC, as well as other foods purchased by the participants at the time of the WIC redemption, it is of the utmost importance to remember that participants, not vendors, are the Program's clients.

PFMA would like any retailer to be authorized as a WIC vendor as long as they meet the State health and food safety inspection standards and are willing to stock the full line of WIC allowable foods.

Although current Federal Regulations do not include specific selection criteria State agencies must use in selecting stores for WIC authorization, this will soon change. The WIC Reauthorization Act of 1998 requires the Secretary of Agriculture to promulgate final regulations not later than March 1, 2000 which include the following mandate: "... a State agency shall, in selecting a retail store for participation in the Program, take into consideration the prices that the store charges for food under the Program as compared to the prices that other stores charge for the foods."

In addition to the criteria required in the impending mandate and those suggested by PFMA, we believe the utilization of other selection criteria are critical for the State to be able to provide quality services to participants, reduce the possibility of vendor abuse, and maintain a manageable number of vendors.

PFMA implies that authorizing all retailers that meet the two above mentioned selection criteria will "...allow WIC participants an opportunity to select the store of their choice, not to limit them to a single store."

Since Pennsylvania WIC is vendor specific, participants are assigned a single store in which they must redeem their WIC checks. Revisions to the current selection criteria will not have an impact of participant flexibility.

PFMA indicates that its objectives are to find ways to administer the Program efficiently and without additional expenses to the Commonwealth.

If the State agency eliminated all but two of its current selection criteria, as is suggested by PFMA, the number of authorized vendors would likely increase dramatically. Since there are significant costs associated with each vendor that is authorized, the Commonwealth would experience significant additional expenses if PFMA's suggestions were implemented.

Rebuttal to Testimony on Draft Regulations Presented on September 24, 1998 by David McCorkle

Introduction

It is stated that, in Maryland, any retailer interested in serving as a WIC vendor is approved as long as adequate inventories of all WIC allowable items are maintained.

This is an incorrect statement. Maryland's vendor regulation 10.54.03.04 includes several other authorization requirements such as holding a current food service facility license; operate at a fixed location; maintain the store in a sanitary condition; and maintain its prices of authorized WIC foods at or below the prices submitted at the time of application until authorization.

It is stated that "there is no real opportunity for a fair and impartial review of the facts...by administrative appeal hearing officers." Furthermore, it is stated that the regulations must be amended to "provide for a fair and impartial review of all Department enforcement actions...."

The administrative appeal process currently followed by the Pennsylvania WIC Program strictly adheres to all requirements set forth in Federal Regulation 246.18 regarding the administrative appeal process which requires an impartial decision maker.

The testimony indicates that the regulations must be amended to provide for the establishment of a retail advisory committee to "assist the Department in administering the WIC Program...."

WIC Program regulations state that the State agency is responsible for the effective and efficient administration of the Program in accordance with regulatory requirements and is given grants to carry out this responsibility. As such, it would be inappropriate for the State agency to have a retail advisory committee assist them in administering the Program. We do, however, encourage State agencies to work with retail advisory committees to further the goals of the Program.

The testimony recommends that the Department "develop a vendor review process that insures full compliance with WIC guidelines."

The Pennsylvania WIC Program is currently fully compliant with all required policies, procedures, Federal Regulations, and FNS Instructions.

General Comments

PFMA states that WIC vendor contracts should be indefinite in length but subject to ongoing monitoring by the State.

We believe that fixed period agreements enable the State to manage its vendor population on a periodic basis more easily and allows it to be more responsive to changing Program conditions and needs than is the case with open-ended agreements. The majority of geographic State agencies contract with vendors for three years or less, making fixed-period contracts and agreements the norm nationwide.

It is stated that once a store is disqualified it "...will not be allowed to apply for a WIC vendors license if there are enough stores in the county for participants."

No disqualified store is prevented from applying for WIC authorization after their period of disqualification has ended. The previously disqualified store may not be authorized again if it is not needed in the area in which it is located. This is true for all retailers; those which are currently authorized, those that have completed a period of

disqualification, and those applying for authorization for the first time.

Issues of Concern

One of the issues of concern was "vendor to participant ratio." PFMA would like the current policy to be replaced by a "WIC participant freedom to shop policy." PFMA supports such a policy in order to allow any store interested in participating in the WIC Program to be approved as long as they maintain proper health standards and adequate WIC product inventory. It is further stated by PFMA, that participants should receive training to ensure that they receive the best value for the WIC benefit provided.

Even if the State agency removed its limitation criteria/vendor to participant ratio, WIC participants would still have to pick one of the approximately 1,300 authorized stores in which to do their WIC shopping since the State agency is vendor specific. It is important to understand that the establishment of vendor limitation criteria can be a critical element in providing quality services to participants and promoting efficient use of the State agency's food grant. Furthermore, if the State agency reduced its selection criteria to the two suggested by PFMA, all vendors meeting these criteria would be authorized regardless of the prices they charge. Since WIC is not an entitlement Program, such as the Food Stamp Program, with funding available to serve all eligible applicants, higher food costs result in a lower number of participants served. We do not believe this would result in the best value possible for the Program.

Another issue of concern is the WIC Pricing Criteria. PFMA feels that the current policy of comparing the most expensive brands of products available in one store against those available in another store is an unfair way of selecting stores and should be eliminated. Specifically, they feel that stores carrying more expensive brands will be at a disadvantage when price comparisons are made.

Another price criteria option would be to compare the lowest priced brands carried by one store against the lowest priced brands carried by another store. However, this too will result in some stores being excluded from the Program. Since the State agency will be mandated to select stores based on price, we support retaining their current methodology which is used by many other States throughout the region.

Another area of concern included PFMA's recommendation that the regulations should develop a process for the analysis of private label products and a procedure for approving such products.

WIC State agencies have the authority to determine which eligible products they wish to include on their WIC food lists. They are not obligated to authorize every product that meets minimum Federal requirements.

PFMA indicates that "Regulators must develop a distinction between willful violators and human error committed by well meaning employees."

It is our position that vendors should be held accountable for noncompliance and Program violations, whether they be deliberate attempts to abuse the Program or a chronic repetition of inadvertent errors, since both ultimately result in increased food costs and fewer participants being served. Not only is it extremely difficult for State agencies to ascertain the intent behind an action, whether inadvertent or deliberate such action has the same negative effect on the Program. Furthermore, we believe that the fact that errors were performed by non-management employees does not relieve the vendor of the responsibility for that employee's actions. Removing an abusive employee does not mitigate the effects of chronic vendor error and mismanagement on Program costs and does not lessen the vendor's responsibility to provide effective oversight and appropriate employee training.

Comments on PFMA's Testimony on Draft State Regulations (not addressed in our previous comments and using the regulation citations noted by PFMA)

General Comment: Throughout their testimony, PFMA reiterates its desire to have limitation criteria removed from the regulations. We fully support the State agency's decision to utilize limitation criteria as a means of ensuring the provision of quality services to participants; reducing the possibility of vendor fraud; and promoting efficient use of the State agency's food grant.

§1101.1, General Purpose and Scope, Section B and §1101.2, Definitions, "Appeal": PFMA suggests that the regulations be amended to state that appeals be conducted by an impartial mediator.

Federal Regulation 246.18 (b)(8) requires that State agencies hearing procedures include "an impartial decision maker." As such, PFMA's suggestions are already incorporated into Pennsylvania's appeal process and thus unnecessary to explicitly state in the regulations.

§1101.41 Recertification Reviews ("I"): PFMA's testimony implies that the Department has a plan to reduce the number of authorized stores by "arbitrarily" increasing the average number of WIC participants assigned per store.

The average number of participants per vendor has been extremely stable in Pennsylvania. The latest data available shows a ratio of 1:181 in Fiscal Year 1993; 1:188 in Fiscal Year 1994; 1:186 in Fiscal Year 1995; 1:185 in Fiscal Year 1996; and 1:183 in Fiscal Year 1997.

§1101.41 Recertification Reviews ("J"): PFMA would like the State to certify stores through a process similar to the Food Stamp Program. They further refer to Pennsylvania's moratorium on new applications as "arbitrary."

WIC is not an entitlement Program such as the Food Stamp Program with funding available to serve all eligible applicants. Higher costs which would result from authorizing greater numbers of retailers would result in lower numbers of participants being served.

Pennsylvania's moratorium on new applications was approved by our office as a State Plan amendment after serious concerns were raised regarding their ability to manage the certification/recertification of such a large number of currently authorized stores along with an unknown number of applicant vendors. After much discussion, it was decided that temporary moratoriums were appropriate and reasonable measures to implement.

§1101.43-Selection and Limitation Criteria-PFMA feels that the selection and limitation guidelines are arbitrary; unrelated to participant need, quality of stores, or their ability to serve WIC customers; and are anti-competitive.

Selection criteria are standards established by the State agency to ensure the systematic selection of the most qualified vendors for authorization. Although selection and limitation criteria may restrict the ability of particular stores to secure or retain WIC authorization, they are utilized to ensure participant access and are a critical element in providing quality services to participants.

§1101.56-Monitoring of WIC Authorized Stores-PFMA requested that all references to high-risk reviews be eliminated. PFMA recommended that the regulations be amended so that retailers have an opportunity to review identified problems before any sanction is implemented. Furthermore, PFMA indicates that the objective of the compliance investigation process is to "ensure that stores are provided the support necessary to fully implement all WIC guidelines and regulations."

High-risk reviews as described in Pennsylvania's regulations include compliance investigations and inventory audits. Such activities are required by Federal Regulation 246.12(f) and therefore may not be eliminated.

An interpretation of Federal Regulation 246.12(f) which we received from Supplemental Food Programs Division indicates that the opportunity to correct deficiencies was referring to deficiencies detected during on-site monitoring visits and not for more serious violations detected during covert compliance investigations or inventory audits.

Federal Regulation 246.12(f) clearly states that the purpose of conducting compliance investigations is "to collect evidence of improper vendor practices."

§1101.71-Administrative Appeals-Applicability of General Rules: PFMA's comment indicates that an appeal decision must be rendered within 45 days of the filing date of the request.

Federal Regulation 246.18(b)(9) provides State agencies with 60 days in which to provide written notification of the decision for appeals requested by vendors.

§1101.101-Local Agency and Store Appeals-Right to Appeal: PFMA expressed doubt that the appeal process could be equitable since the hearing examiner is selected by the Secretary of Health.

Federal Regulation 246.18(b)(8) requires State agencies to select an impartial decision maker. Should the State agency be found in violation of the Federal Regulations, appropriate action would be taken to correct the situation.

Comments on Pennsylvania's Proposed Vendor Regulations

General Comment

We strongly recommend that the regulations clearly indicate that they may be revised at any time due to policy, procedure, or regulatory changes which necessitate such a revision.

Chapter 1101-General Provisions

§1101.2-Definitions

The definition of "clinic" states that it is a facility where participants receive WIC Program benefits. Since participants receive the actual food benefit at WIC authorized stores, this definition may be confusing.

We suggest the definition of "compliance buys" indicate that they are covert.

We ask that the definition of "on-site review" also indicate that store visits may be made by federal government personnel. Furthermore, we suggest the definition indicate that these visits are overt.

In the definition of "training buy," please also indicate that such buys may be conducted by federal government personnel. Furthermore, you may want to indicate that these buys are initially covert and then become overt.

Chapter 1103-Authorization of Stores

§1103.1(a)-Certification and Recertification Reviews/Qualifying for Certification or Recertification

We suggest you clarify that the "on-site survey" is the same thing as the "on-site review" mentioned in the definitions section.

§1103.1(b)-Certification and Recertification Reviews/Certification or Recertification Review Process

In Item four, we suggest the following clarifications be added:

The disqualification referenced is from the WIC Program.

The period of disqualification must be completed before an application for recertification may be submitted.

§1103.2(a)-Probationary Certification/Criteria for Probationary Certification

Please explain why the State agency has chosen to delete the stale-dated food and formula waiver which had been allowed for probationary authorizations.

Please explain why the State agency will no longer be offering probationary certifications as a result of change of ownership or relocation of a currently authorized store, as is currently allowed.

§1103.4(b)-Selection and Limitation Criteria: Authorization Process/Limitation Criteria

Item two indicates that, in general, authorized stores can not be located within one mile of each other. We believe this to be fairly lenient limitation criteria. Please describe your rationale for selecting this mileage amount.

§1103.6(b)-Waiting List/Certification Review of Stores on Waiting List

Please refer to our comment on §1105.4(d).

§1103.7-Participant Hardship

We suggest the State agency include a participant hardship provision addressing situations in which a change of ownership occurs and the State agency receives no notice of the change prior to it occurring.

Chapter 1105-Requirements of WIC Authorized Stores

§1105.3(a)-Terms and Conditions of Participation/General Terms and Conditions

In Item 15, we recommend you require retailers to maintain price and inventory records for a specific period of time. If no time requirement is specified, information needed for activities such as inventory audits may not be available for the time frame being reviewed.

§1105.3(c)-Terms and Conditions of Participation/Terms and Conditions of Participation with Regard to WIC Check Processing and Redemption

Item five allows retailers to accept pre-signed checks as long as the signature on the check matches the signature on the WIC ID card. We suggest the provision be revised to clarify that the signature should be obtained at the time of purchase transaction and checks signed prior to the transaction may not be accepted.

§1105.4(c)-Change of Ownership of a WIC Authorized Store

The regulations state that a new owner which has applied for certification of a store operating at the same location which an authorized store had operated preceding a change of ownership may accept WIC checks for seven days subsequent to the change of ownership without having been certified. This provision would be prohibited by Federal Regulation 248.12(e) which states that only food vendors authorized by the State agency may redeem food instruments.

§1105.4(d)-Change of Ownership of a WIC Authorized Store

According to Federal Regulations, when there is a change of ownership, a vendor's contract/agreement is null and void. Discretion on this regulatory provision has been granted to States when the change of ownership is specifically defined as in Pennsylvania's current policy and procedure. However, unless these specific definitions are included in the regulation, we do not feel the change of ownership/waiting list exception explained here and also in §1103.6(b) is allowable. We would however, support the following revision to provision (§1105.4(d):

When a change of ownership occurs and the State has not received the required prior notice (i.e. participant hardship would result), the store under the new ownership may be put on probationary authorization for a period not to exceed six months if the State conducts an immediate, abbreviated on-site visit followed by a complete certification visit at the store. Until the immediate on-site visit is conducted, the new owner may not accept WIC checks. As soon as possible within the six month probationary period or during the next recertification process, whichever occurs first, the store under the new ownership must compete with all other interested stores for the store slot. If prior notice of the change in ownership was provided to the State agency (i.e. no participant hardship would result), the contract with the store must be considered null and void per Federal Regulation 246.12(f)(xix).

§1105.5(b)-Changes in Availability or Location of WIC Authorized Stores/Temporary Store Closings

As the regulations are currently written, there is no specific time limit on how long a store may be temporarily closed and remain authorized. Provision §1105.5(e) provides a means for participants assigned to the closed store to redeem their benefits. We understand that a specific time limit was not stated in order that temporary closings may be handled based on the specific circumstances of each situation. We believe that at some point it would be more appropriate to remove a store which has been closed for an extensive period of time and permanently authorize a new store in the area and permanently assign clients to that store.

§1105.5(c)-Changes in Availability or Location of WIC Authorized Stores/Store Closings

Item one states that a store which closes for more than 24 hours but less than three days for remodeling will not lose its WIC certification. This implies that a store which is closed for more than three days for remodeling will lose its certification. However, item 2 implies that such stores will not lose their WIC authorization so long as they secure permission from the State agency. We found this to be confusing.

§1105.6(a)-Monitoring of Stores/Purpose and Types of Monitoring of WIC Authorized Stores

We ask that you also indicate that Federal personnel may conduct announced and unannounced reviews of WIC authorized stores.

We ask that the State agency also retain the option of conducting compliance buys or inventory audits on non-high-risk stores.

We suggest you indicate that Federal Regulations require the State agency to monitor at least ten percent of its authorized vendors per year.

§1105.6(b)-Monitoring of Stores/High-Risk Reviews

Item b(1)(iii) indicates that written notification will be provided to retailers after compliance buys are conducted informing them of the results of the buys. We strongly discourage State agencies from sending warning/notification letters during the course of compliance investigations as we do not believe that giving such warnings during the course of compliance investigations was the intent of the Federal Regulations. However, if State



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 cc: Tyrrell
 Harris
 Sandusky



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 99 MAY 12 AM 9:08
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Mary Lou Harris
 IRRC
 14th Floor, 333 Market Street
 Harrisburg, PA 17101

Dear Mary Lou:

Thank you for taking time from you schedule this morning to help point us in the correct direction in sending correspondence to elected officials regarding the WIC Program.

As per your request I have enclosed a copy of the letter that we are sending out. If you have any questions please call me at 731.0600, ext: 5570.

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 Wilkes-Barre, PA

Thanks again for all of your help.

Yours truly,

Maria A. Christini
 Maria A. Christini
 Administrative Assistant to
 Randy St. John

/mac

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cc: Harris
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January 21, 1999

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Nyce ✓
 Sandusky ✓
 Tyrrell ✓
 Harris ✓
 Wyatt ✓
 Gelnett ✓

Jeffrey F. Champagne, Esquire
 McNeas Wallace & Nurick
 100 Pine Street
 Harrisburg, PA 17108

Re: Department of Health WIC Regulations

Dear Mr. Champagne:

I have reviewed your letters dated October 23, and November 3, 1998. You have agreed that your first letter to me was not delivered because you incorrectly addressed it. Your November 3, 1998 letter reflects some misunderstandings that I hope to clarify, herein.

First, I did not invite you to demonstrate why the "final-omitted" regulatory review process was not available to the Department of Health for the promulgation of WIC regulations. Rather, I invited you to consider the impact of a federal review and approval process on the Department's discretion with respect to promulgation of the regulations.

Second, on page two of your November 3, 1998 letter, without citation or reference to any federal rule, regulation or statute, you posit definitively that the most federal approval could mean is that the Pennsylvania Department of Health's approach is not inconsistent with federal law. Absent substance to support your allegations, I assume they are unsupported.

Third, I invited you to discuss whether or not your clients would have access to participation in the federal review process. You did not indicate whether or not you and your client even attempted to contact the Food and Drug Administration. Therefore, your argument appears to be without basis, though it is also possible that you have not shared details regarding contacts with the FDA. Your letters of November 3 and October 23, 1998 are devoid of any such discussion.

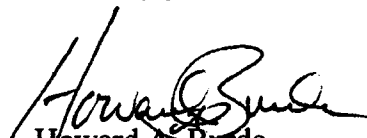
Jeffrey F. Champagne, Esquire
January 21, 1999
Page two

Fourth, I did not suggest that it was the federal government's job to ascertain whether the Pennsylvania Department of Health has complied with Pennsylvania rulemaking statutes.

Fifth, on page three of the November 3, letter you suggest that I do not need to know the ultimate particulars of the Department of Health's proposal in order to address the question. As I specifically stated in our most recent telephone conversation, I will not engage in hypothetical discussions on this matter with you or anyone else. I will draw my conclusions based upon specific proposals. Therefore, the particulars of the Department of Health's proposals are absolutely relevant to the discussion and I will draw no conclusions until after I have had the opportunity to review that work.

If you wish to pursue these matters further, please feel free to do so in writing.

Sincerely yours,


Howard A. Burde
Deputy General Counsel

cc: Mary Wyatte, Chief Counsel ✓
IRRC



98 OCT -8 AM 9:03 September 30, 1998

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**INDEPENDENT REGULATORY
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Ms. Mary Lou Harris, Sr. Regulatory Analyst
Independent Regulatory Review Commission
14th Harristown
2333 Market St.
Harrisburg, PA 17101

Forthcoming:

Nyce
Sandusky
Gelnett
Harris
TYRELL

Dear Mary Lou,

I have attached for your review a copy of a letter forwarded to Mr. Gerald Pappert at the Office of the Attorney General. I will keep you informed on responses from the Office of the Attorney General.

I hope that the Dept. of Health will initiate a stakeholders process to work through the administrative problems that led to the court case in this matter. Retailers in the Commonwealth support the objectives of the Women, Infants & Children's program. However, our members feel that administrative decisions made by the Dept. of Health have a significant impact on competition between stores. We feel that it is an appropriate time to review public policy on this topic and hope that the process can be initiated promptly.

I look forward to seeing you in the near future.

Sincerely,


Blackout
David L. McCorkle
President & CEO

DLM/sl
Enc.

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Pennsylvania Food Merchants Association



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PRESIDENT
David L. McCorkle

• Mr. Gerald J. Pappert
First Deputy Attorney General
Office of the Attorney General
Strawberry Sq.
Harrisburg, PA 17120

Dear Mr. Pappert:

Attached for your information is testimony provided to the PA Department of Health concerning the administration of the Women, Infants & Children's program in the Commonwealth. A copy of the hearing notice published in the PA Bulletin and other correspondence is provided for your review.

The members and directors of the PA Food Merchants Association have been advised that the office of the Attorney General will determine whether or not the "final omitted" process for promulgation of the Dept. of Health WIC regulations as drafted will be permitted. As noted in the letter from PFMA's attorney, Mr. Jeff Champagne, we do not believe that the "final omitted" procedure is appropriate for the promulgation of the state policy. We have asked the Dept. of Health to initiate a stakeholders process to develop workable guidelines for the WIC program. This process should be initiated immediately.

Your review of this matter and response would be appreciated.

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Sincerely,

David L. McCorkle
President & CEO

DLM/si
Enc. Testimony
Letter from Jeff Champagne

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Howard A. Burde
November 3, 1998
Page 2

Subsection 1204(1) allows the omission of ordinary procedures if a regulation relates to:

- (i) military affairs; (ii) agency organization, management or personnel;
- (iii) agency procedure or practice; (iv) Commonwealth property, loans, grants, benefits or contracts; or (v) the interpretation of a self-executing act of Assembly or administrative regulation.

The draft WIC regulations satisfy none of the clauses in subsection 1204(1). It is also virtually certain that no WIC regulation will satisfy any of the clauses in subsection 1204(1). This is because, among other things, there is no self-executing act of Assembly or administrative regulation that can be the basis for a WIC regulation. Thus, it is not premature to inform the Department of Health of the unavailability of omitting ordinary procedures under section 1204, and it is not premature to advise the Department of Health to proceed along a correct regulatory path.

With regard to the legal impact of the federal WIC approval, you might find the decision in *Elkin v. Commonwealth, Department of Public Welfare*, 53 Pa. Commw. 554, 419 A.2d 202 (1980), worth considering. The most that federal approval could mean is that the Pennsylvania Department of Health's approach is not inconsistent with federal law. If we were claiming that the Pennsylvania Department of Health's rules violate federal law, federal approval would be material. But this has not been our claim; federal approval is therefore immaterial. Our claims at this point are, in essence, that the Department of Health's rules are unwise and that they are subject to the Regulatory Review Act and other procedural statutes. This is of no import to the federal Executive Branch, because the federal government is not empowered to reject a state WIC plan based on either the state's lack of wisdom or its failure to follow state procedural law. I assume that your office would be among the first to object if the federal government rejected Pennsylvania's plan on the grounds that Pennsylvania's WIC rules are not as wise as New York's WIC rules or Montana's WIC rules.

Nor is it within the federal government's job to ascertain whether the Pennsylvania Department of Health has complied with Pennsylvania rule-making statutes. No one has asked the federal government to ensure that state rule-making law is followed and no one has empowered the federal government to reject a state proposal on the grounds of state procedural law. I assume that your office would be among the first to object if the federal Executive Branch took it upon itself to interpret and apply Pennsylvania procedural law to Pennsylvania's WIC plan. That responsibility and that power reside in Pennsylvania (and have been entrusted, in part, to your office). Your suggestion that the Pennsylvania Food Merchants Association should go running to Washington over this issue is, we believe, misguided. What is more, our ability to complain to the federal government about adherence to state procedures does not affect the analysis under 45 P.S. § 1204, which is central. **Thus, we are back at the key question: can the Department of Health omit some of the procedures that are generally**

Howard A. Burde
November 3, 1998
Page 3

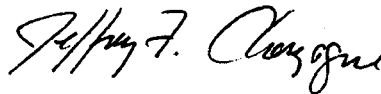
applicable under the Regulatory Review Act? We respectfully submit that the factors that you have preliminarily suggested do not satisfy the statutory standards for omitting any Regulatory Review Act procedure. Further, we suggest that you do not need to know the ultimate particulars of the Department of Health's proposal in order to address this question.

Thank you once again for taking the time to discuss the regulatory process. Please let me know if we can be helpful in moving the legal review process along. No legitimate interest is served by avoiding the legal issues that have been raised by the Department of Health's stated intent to omit some of the generally applicable procedures.

Sincerely,

McNEES, WALLACE & NURICK

By



Jeffrey F. Champagne

cc: David McCorkle
Mary Wyatte



COMMONWEALTH OF PENNSYLVANIA
 OFFICE OF GENERAL COUNSEL
 333 MARKET STREET, 17TH FLOOR
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cc: Harris
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January 21, 1999

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 Wyatt ✓
 Gelnett ✓

Jeffrey F. Champagne, Esquire
 McNeese Wallace & Nurick
 100 Pine Street
 Harrisburg, PA 17108

Re: Department of Health WIC Regulations

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Jeffrey F. Champagne, Esquire

January 21, 1999

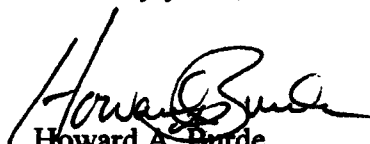
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If you wish to pursue these matters further, please feel free to do so in writing.

Sincerely yours,



Howard A. Burde

Deputy General Counsel

cc: Mary Wyatte, Chief Counsel ✓
IRRC

Commonwealth of Pennsylvania



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cc;

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Per MLH

DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

May 18, 1999

The Honorable Dennis M. O'Brien
Majority Chairman
House Health & Human Services Committee
100 Main Capitol Building
Harrisburg, Pennsylvania 17120

Dear Senator O'Brien:

I am writing regarding the Women, Infant and Children ("WIC") regulations scheduled for review at a public hearing before the Independent Regulatory Review Commission on Thursday, May 20, 1999.

You may be interested in knowing that questions have been raised regarding USDA's interpretation of the federal regulations about a WIC store's opportunity to correct problems during the certification or recertification review. The Acting Regional Administrator for Supplemental Food Programs of the U.S. Department of Agriculture ("USDA") informed the Department's legal staff that the provision requiring a "warning and opportunity to correct" only applies to monitoring reviews and did not apply to certification or recertification reviews that the Department conducts to determine if a vendor meets qualifications established by the Department and should be authorized to participate in the WIC Program, in the first place.

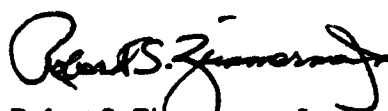
The Department proceeded with the regulations as final with proposed rulemaking omitted in order to ensure that the Department is able to conduct the review of 1400 grocery stores prior to September 30, 1999 so that Federal funding for the WIC program would not be interrupted. The Department then intends to conduct a complete and immediate review of the WIC Program Regulations pursuant to the Governor's Executive Order 1996-1. In addition to the 1996-1 review, the Department will be required to revise its state regulations before May 17, 2000, in order to be compliant with the USDA final rule relating to WIC/Food Stamp Program Vendor Disqualification published in the Federal register on March 18, 1999.

May 18, 1999

During this regulatory review process, the Department will request that the USDA provide a legal opinion regarding the USDA's Regional Office's interpretation of the intent of the statute regarding a vendor's opportunity to correct a violation during the certification/recertification process.

I hope you find this information useful.

Sincerely,



Robert S. Zimmerman, Jr.
Acting Secretary of Health

bcc: Robert S. Zimmerman, Jr.
✓Lori McLaughlin
Gary L. Gurian
Legislative Office

Commonwealth of Pennsylvania



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cc: Tyrrell
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**DEPARTMENT OF HEALTH
HARRISBURG**

THE SECRETARY

May 18, 1999

The Honorable Frank L. Oliver
Minority Chairman
House Health & Human Services Committee
34 Capitol, East Wing
Harrisburg, Pennsylvania 17120

Dear Senator Oliver:

I am writing regarding the Women, Infant and Children ("WIC") regulations scheduled for review at a public hearing before the Independent Regulatory Review Commission on Thursday, May 20, 1999.

You may be interested in knowing that questions have been raised regarding USDA's interpretation of the federal regulations about a WIC store's opportunity to correct problems during the certification or recertification review. The Acting Regional Administrator for Supplemental Food Programs of the U.S. Department of Agriculture ("USDA") informed the Department's legal staff that the provision requiring a "warning and opportunity to correct" only applies to monitoring reviews and did not apply to certification or recertification reviews that the Department conducts to determine if a vendor meets qualifications established by the Department and should be authorized to participate in the WIC Program, in the first place.

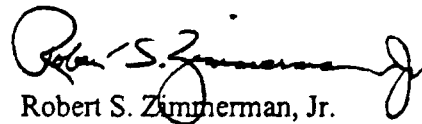
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May 18, 1999

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I hope you find this information useful.

Sincerely,



Robert S. Zimmerman, Jr.
Acting Secretary of Health

bcc: Robert S. Zimmerman, Jr.
Kori McLaughlin
Gary L. Gurian
Legislative Office

Commonwealth of Pennsylvania



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Mizner
cc: Tyrrell
Harris
Sandusky

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DEPARTMENT OF HEALTH
HARRISBURG

THE SECRETARY

May 18, 1999

The Honorable Vincent J. Hughes
Minority Chair
Senate Public Health and Welfare Committee
Room 543 Main Capitol
Harrisburg, Pennsylvania 17120

Dear Senator Hughes:

I am writing at the request of Niles Schore in response to certain questions he raised to Lori McLaughlin, Chief Counsel for the Department of Health, regarding the Women, Infant and Children ("WIC") regulations scheduled for review at a public hearing before the Independent Regulatory Review Commission on Thursday, May 20, 1999.

Ms. McLaughlin advised Mr. Schore that staff in her office spoke to Diana Torrice, Acting Regional Administrator for Supplemental Food Programs of the U.S. Department of Agriculture ("USDA"), regarding USDA's interpretation of the federal regulations about a WIC store's opportunity to correct problems during the certification or recertification review. Ms. Torrice informed the legal staff that the provision requiring a "warning and opportunity to correct" only applies to monitoring reviews and did not apply to certification or recertification reviews that the Department conducts to determine if a vendor meets qualifications established by the Department and should be authorized to participate in the WIC Program, in the first place.

As Ms. McLaughlin informed Mr. Schore, the Department proceeded with the regulations as final with proposed rulemaking omitted in order to ensure that the Department is able to conduct the review of 1400 grocery stores prior to September 30, 1999 so that Federal funding for the WIC program would not be interrupted. The Department then intends to conduct a complete and immediate review of the WIC Program Regulations pursuant to the Governor's Executive Order 1996-1. In addition to the 1996-1 review, the Department will be required to revise its state regulations before May 17, 2000, in order to be compliant with the USDA final rule relating to WIC/Food Stamp Program Vendor Disqualification published in the Federal register on March 18, 1999.

Honorable Vincent J. Hughes

2

May 18, 1999

During this regulatory review process, the Department will request that the USDA provide a legal opinion regarding the USDA's Regional Office's interpretation of the intent of the statute regarding a vendor's opportunity to correct a violation during the certification/recertification process.

I realize this is a complex chronology, and I trust I have explained the steps the Department of Health intends to follow to assure the continuation of Pennsylvania's nationally recognized WIC program.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert S. Zimmerman, Jr.", with a stylized flourish at the end.

Robert S. Zimmerman, Jr.
Acting Secretary of Health

Commonwealth of Pennsylvania

Original: 2030

Mizner

cc:

Tyrrell
Harris
Sandusky



DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

May 18, 1999

The Honorable Harold F. Mowery, Jr.
Majority Chairman
Senate Public Health and Welfare Committee
Room 169 Main Capitol
Harrisburg, Pennsylvania 17120

Dear Senator Mowery:

I am writing regarding the Women, Infant and Children ("WIC") regulations scheduled for review at a public hearing before the Independent Regulatory Review Commission on Thursday, May 20, 1999.

You may be interested in knowing that questions have been raised regarding USDA's interpretation of the federal regulations about a WIC store's opportunity to correct problems during the certification or recertification review. The Acting Regional Administrator for Supplemental Food Programs of the U.S. Department of Agriculture ("USDA") informed the Department's legal staff that the provision requiring a "warning and opportunity to correct" only applies to monitoring reviews and did not apply to certification or recertification reviews that the Department conducts to determine if a vendor meets qualifications established by the Department and should be authorized to participate in the WIC Program, in the first place.

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Honorable Harold F. Mowery, Jr.

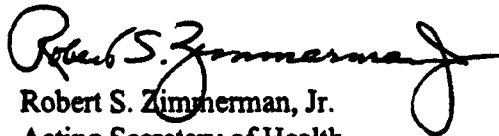
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May 18, 1999

During this regulatory review process, the Department will request that the USDA provide a legal opinion regarding the USDA's Regional Office's interpretation of the intent of the statute regarding a vendor's opportunity to correct a violation during the certification/recertification process.

I hope you find this information useful.

Sincerely,


Robert S. Zimmerman, Jr.
Acting Secretary of Health

bcc: Robert S. Zimmerman, Jr.
Lori McLaughlin
Gary L. Gurian
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September 30, 1998

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Independent Regulatory Review Commission
14th Harristown
2333 Market St.
Harrisburg, PA 17101

Forthcoming:
Nyce
Sandusky
Gelnett
Harris
TYRRELL

Dear Mary Lou,

I have attached for your review a copy of a letter forwarded to Mr. Gerald Pappert at the Office of the Attorney General. I will keep you informed on responses from the Office of the Attorney General.

I hope that the Dept. of Health will initiate a stakeholders process to work through the administrative problems that led to the court case in this matter. Retailers in the Commonwealth support the objectives of the Women, Infants & Children's program. However, our members feel that administrative decisions made by the Dept. of Health have a significant impact on competition between stores. We feel that it is an appropriate time to review public policy on this topic and hope that the process can be initiated promptly.

I look forward to seeing you in the near future.

Sincerely,

Blackout
David L. McCorkle
President & CEO

DLM/sl
Enc.



PFMA Officers

September 30, 1998

CHAIRMAN
William Bracey
Bill's Supermarket
Moscow, PA

VICE-CHAIRMAN
Murray Battelman
Richboro Shop N Bag
Richboro, PA

TREASURER
Joseph McNally
Toot & Scoot
Pittsburgh, PA

SECRETARY
David Genuardi
Genuardi's Family Markets
Norristown, PA

PRESIDENT
David L. McCorkle

• Mr. Gerald J. Pappert
First Deputy Attorney General
Office of the Attorney General
Strawberry Sq.
Harrisburg, PA 17120

Dear Mr. Pappert:

Attached for your information is testimony provided to the PA Department of Health concerning the administration of the Women, Infants & Children's program in the Commonwealth. A copy of the hearing notice published in the PA Bulletin and other correspondence is provided for your review.

The members and directors of the PA Food Merchants Association have been advised that the office of the Attorney General will determine whether or not the "final omitted" process for promulgation of the Dept. of Health WIC regulations as drafted will be permitted. As noted in the letter from PFMA's attorney, Mr. Jeff Champagne, we do not believe that the "final omitted" procedure is appropriate for the promulgation of the state policy. We have asked the Dept. of Health to initiate a stakeholders process to develop workable guidelines for the WIC program. This process should be initiated immediately.

Your review of this matter and response would be appreciated.

3C Officers

CHAIRMAN
Richard Guttman
Crossroads Food Marts
Belle Vernon, PA

VICE-CHAIRMAN
Scott Hartman
Rutter's Farm Stores
York, PA

SECRETARY/TREASURER
Joseph Donas
Co-Go's, Inc.
Pittsburgh, PA

Services for our Members:

- Legislative Representation
- Coupon Redemption
- Money Orders
- Insurance Programs
- Seminars
- Annual Conventions
- Publications

Sincerely,

David L. McCorkle
President & CEO

DLM/si
Enc. Testimony
Letter from Jeff Champagne

Original: 2030
Mizner
cc: Tyrrell
Harris
Sandusky

Testimony of Lori McLaughlin
Before the
Independent Regulatory Review Commission
May 20, 1999

Final Rulemaking with Proposed Rulemaking Omitted
Supplemental Food Program for Women, Infants
Regs. 10-158

Good morning. My name is Lori McLaughlin and I am Chief Counsel for the Pennsylvania Department of Health. I am accompanied today by Lesa Tressler, Assistant Counsel for the Department of Health, Frank Maisano, Director for the WIC Program and Greg Landis, Chief of the Grants and Retail Store Management Section of the WIC Program.

The Department requests your approval of this regulation package for the Supplemental Food Program for Women, Infants and Children. The regulations relate to the authorization and management of retail grocery stores wishing to participate in the WIC Program, as well as administrative appeals for the WIC Program. The regulations governing the authorization and management of retail grocery stores have been developed as a result of the Commonwealth Court decision issued in Giant Food Stores, Inc. v. The Commonwealth of Pennsylvania, Department of Health. In that decision, the Commonwealth Court found that the criteria the Department uses to select grocery stores to participate in the WIC Program was not valid because it was not published as a regulation. The Court did not address the propriety of the criteria; it found only that the criteria needed to be published as a regulation.

The purpose of the WIC Program is to provide certain nutritious foods to income eligible

pregnant, post-partum and breastfeeding women, infants up to the age of one and children up to the age of five who are at nutritional risk because of medical problems or poor diets. This program is funded entirely by Federal money. Currently, the Commonwealth is providing benefits to 260,000 participants in the WIC Program.

Because these regulations relate to the operation of the WIC Program, the Department was required to submit them to the United States Department of Agriculture for review and approval. Following revisions required by the USDA, these state regulations were approved by the USDA as compliant with Federal regulations, as well as approved for fiscal and administrative responsibility in the operation of the WIC Program.

The Department has determined that submission of these regulations with proposed rulemaking omitted is essential in order for the Department to continue operation of the WIC Program and to ensure compliance with Federal regulations governing the program. As required by Federal regulation, the Department is required to conduct a review of approximately 1400 grocery stores no later than September 30, 1999, the end of the Federal fiscal year. Failure to do so will result in audit exceptions and the possible loss of Federal funding. Loss of funding will have a devastating effect on the Commonwealth. Loss or even suspension of funding for a short period of time would render the WIC program inoperable because 100% of the funding is Federal, or would place a difficult, if not impossible financial burden upon the Commonwealth to fund the program which provides benefits to approximately 260,000 participants on a monthly basis. To put this in perspective, the current budget for the WIC Program is approximately \$170 million. WIC Program participants redeem, on an average, approximately \$500,000 worth of WIC checks per day at grocery stores authorized to participate in the WIC Program.

Notwithstanding the Department's omission of proposed rulemaking, the Department has committed to conduct a complete and immediate review of these regulations pursuant to the Governor's Executive Order 1996-1. In support of that promise, and in addition to the 1996-1 review, the Department will be required to revise its state regulations before May 17, 2000, in order to be compliant with the USDA-FNS final rule relating to WIC/Food Stamp Program Vendor Disqualifications published in the Federal Register on March 18, 1999.

On behalf of the Department of Health, I appreciate the opportunity to appear before you and will be happy to answer any questions from the Commission concerning these regulations.



Original: 2030
 Mizner
 cc; Tyrrell
 Harris
 Sandusky

MAY 19 1999

United States
 Department of
 Agriculture

Food and Consumer
 Service

Mid-Atlantic Region

Mercer Corporate Park
 800 Corporate Boulevard
 Robbinsville, N.J. 08601-1808

Ms. Lori McLaughlin
 Chief Counsel
 Office of Legal Counsel
 Pennsylvania Department of Health
 PO Box 90
 Harrisburg, PA 17108-0090

Dear Ms. McLaughlin:



We are writing in response to your May 17, 1999, letter requesting our Program interpretation of 7 CFR 246.12(k) regarding vendor sanctions. This regulatory provision states, in part, that in determining the type and level of vendor sanctions, State agencies may consider "whether prior warning and an opportunity for correction was provided to the vendor." Specifically, you asked if such prior warning and opportunity for correction applies only to violations noted during monitoring visits or whether it also applies to violations noted during certification/recertification visits.

It is our opinion that the opportunity to correct deficiencies, as provided for in §246.12(k)(1), was intended to permit vendors to respond to deficiencies detected during on-site monitoring visits conducted during the course of the certification period only. It was not intended to apply to violations noted during certification/recertification visits. Furthermore, this provision does not require prior warning, but merely states that if prior warning and opportunity for correction have been given, the State agency may consider that in sanctioning the vendor.

As you know, we do not believe that every vendor who meets basic authorization qualifications should necessarily be authorized to accept WIC food instruments. Authorization to accept WIC food instruments should be considered a privilege, not a right, and must be governed by the needs of participants and the State agency's ability to effectively manage the number of vendors authorized. The application of vendor selection criteria may legitimately restrict the ability of particular stores to secure or retain their WIC authorization.

OPTIONAL FORM NO. 10 (7-88)

FAX TRANSMITTAL

of pages = 2

To	LESA TRESSLER	From	R. Hodsdon
Dept./Agency	PA DOH	Phone #	609-259-5021
Fax #	717-783-3794	Fax #	

NOV 7540-01-517-7200

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GENERAL SERVICES ADMINISTRATION



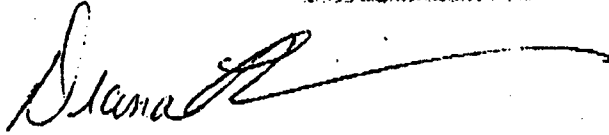
The Food and Consumer Service, formerly the Food and Nutrition Service

Ms. Lori McLaughlin

2

Should you have any questions regarding this letter, please feel free to contact me.

Sincerely,



 PAT CUMISKEY-CZETO
Regional Director
Supplemental Food Programs

Commonwealth of Pennsylvania

Original: 2030

Mizner

cc:

Tyrrell

Harris

Sandusky



DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

May 18, 1999

The Honorable Harold F. Mowery, Jr.
Majority Chairman
Senate Public Health and Welfare Committee
Room 169 Main Capitol
Harrisburg, Pennsylvania 17120

Dear Senator Mowery:

I am writing regarding the Women, Infant and Children ("WIC") regulations scheduled for review at a public hearing before the Independent Regulatory Review Commission on Thursday, May 20, 1999.

You may be interested in knowing that questions have been raised regarding USDA's interpretation of the federal regulations about a WIC store's opportunity to correct problems during the certification or recertification review. The Acting Regional Administrator for Supplemental Food Programs of the U.S. Department of Agriculture ("USDA") informed the Department's legal staff that the provision requiring a "warning and opportunity to correct" only applies to monitoring reviews and did not apply to certification or recertification reviews that the Department conducts to determine if a vendor meets qualifications established by the Department and should be authorized to participate in the WIC Program, in the first place.

The Department proceeded with the regulations as final with proposed rulemaking omitted in order to ensure that the Department is able to conduct the review of 1400 grocery stores prior to September 30, 1999 so that Federal funding for the WIC program would not be interrupted. The Department then intends to conduct a complete and immediate review of the WIC Program Regulations pursuant to the Governor's Executive Order 1996-1. In addition to the 1996-1 review, the Department will be required to revise its state regulations before May 17, 2000, in order to be compliant with the USDA final rule relating to WIC/Food Stamp Program Vendor Disqualification published in the Federal register on March 18, 1999.

Honorable Harold F. Mowery, Jr.

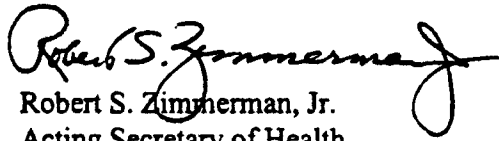
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May 18, 1999

During this regulatory review process, the Department will request that the USDA provide a legal opinion regarding the USDA's Regional Office's interpretation of the intent of the statute regarding a vendor's opportunity to correct a violation during the certification/recertification process.

I hope you find this information useful.

Sincerely,


Robert S. Zimmerman, Jr.
Acting Secretary of Health

bcc: Robert S. Zimmerman, Jr.
Lori McLaughlin
Gary L. Gurian
Legislative Office