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Senate of Pennsylvania

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PA HIGHER EDUCATION ASSISTANCE
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PA LEGISLATIVE BLACK CAUCUS
PA MINORITY BUSINESS DEVELOPMENT AUTHORITY
PA TRAUMA SYSTEMS FOUNDATION

April 10, 2000

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

Re: Department of Health Regulation (No. 10-161), Women Infants and Children
(WIC) Program

Dear Chairman McGinley:

I have attached my comments to the Department of Health on the above-referenced proposed regulations. Unless substantial changes are made to the regulations before they are issued in final form, I will recommend disapproval of these regulations for the reasons stated in the attached letter to Secretary Zimmerman. Please let me know if you have any questions. Thank you.

Sincerely,

Vincent J. Hughes

cc: Senator Harold F. Mowery, Jr., Chair, Public Health and Welfare Committee

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April 3, 2000

The Honorable Robert S. Zimmerman
Secretary of Health
Pennsylvania Department of Health
Room 802 Health & Welfare Building
Harrisburg, PA 17108

Re: Department of Health Regulations #10-161

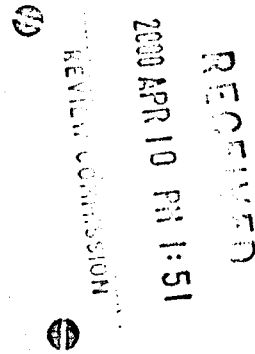
Women Infants and Children (WIC) Program

Dear Secretary Zimmerman:

I am writing to express my disapproval of the Department of Health's (the "Department") most recent WIC program regulations. These regulations fail to correct the deficiencies contained in the previous regulations, and do not address the Commonwealth Court's Decision in Giant Food Stores v. Dept. of Health, 554 A.2d 174 (Pa. Cmwlth. 1989). The Department continues to defy the Commonwealth Court's decision without a clear rationale, and the new regulations simply perpetuate the mistakes of the old regulations, rather than seeking to rectify a legal deficiency.

As you know, the Commonwealth Court held in Giant Food Stores that the Department's distinction between certification/recertification and other types of inspections was illogical and invalid as a matter of State law. The Court noted that "[i]f a single product shortage is not sufficient to justify disqualification during a routing 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." 123 Pa. Cmwlth at 421, 554 A.2d at 176.

The Department has not abided by this ruling. Your letter of May 18, 1999 indicated that the Department was foreclosed from following this decision by Federal Regulations promulgated by the United States Department of Agriculture ("USDA"). You also indicated that the Department intended to request a legal opinion from the USDA regarding that agency's



April 10, 2000

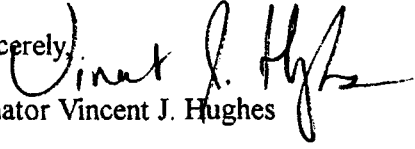
interpretation of the Federal Regulations concerning a vendor's opportunity to correct a violation during the certification/recertification process. To date, my office has not received a copy of this letter.

My review of the Federal Regulations shows that State agencies are not foreclosed from allowing food vendors to correct deficiencies found during certification or recertification review. The relevant regulatory materials are found at 7 C.F.R. 246.12, and relate to food delivery systems:

- ◆ Section (e)(1) mentions an "on-site visits prior to, or at the time of, initial authorization of a new vendor."
- ◆ Section (f)(2)(xi) states that "[t]he food vendor may be monitored for compliance with Program rules."
- ◆ Section (g) discusses "Periodic review of food vendor qualifications." This section provides that a State "shall conduct a periodic review of the qualifications of all authorized food vendors under its jurisdiction, at least once every two years. The State agency shall establish criteria used to assess the adequacy of all food vendor qualifications. Based on the results of such reviews the State agency shall make appropriate adjustments among the participating food vendors, such as termination of agreements."
- ◆ Section (i) establishes that "State agencies shall be responsible for the monitoring of food vendors within its jurisdiction." Section (i)(2) requires that the "State agency shall design and implement a system to conduct on-site monitoring visits to at least 10 percent of authorized food vendors per year, selected on a representative basis, in order to survey the types and levels of abuse and errors among participating food vendors and to take corrective action, if necessary."
- ◆ Section (k)(v)(2) provides that "[w]arnings may be given prior to the imposition of sanctions."

An exhaustive review of the relevant Federal Regulations has failed to indicate a mandate for distinguishing between periodic and certification/recertification inspections. The issue is not whether the State may, in theory, do so, but whether the Federal Government mandates that the State make this distinction. Unless the Federal Government mandates the bifurcated inspection process, this State's Courts were free to hold that the distinction is illegal. In holding that the State's bifurcated procedures for reviewing WIC providers were illogical and illegal, the Commonwealth Court imposed a burden on the State WIC program. Unless the Department can specifically point to Federal Regulations that conflict with this interpretation, the Department is in violation of the Commonwealth Court's opinion.

Sincerely,


Senator Vincent J. Hughes

Enclosure (1)

cc: Robert E. Nyce, Executive Director, Independent Regulatory Review Commission

Commonwealth of Pennsylvania

MAY 19 1999



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.

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.", written in a cursive style.

Robert S. Zimmerman, Jr.
Acting Secretary of Health

Gelnett, Wanda B.

From: Niles Schore [nschore@dem.pasen.gov] **Original:** 2097
Sent: Tuesday, March 21, 2000 4:07 PM **Mizner**
To: irrc@irrc.state.pa.us **cc:** Harris
Subject: DOH regulation 10-161; WIC Program **attn:John Nanorta** **Nanorta**
Smith
Sandusky, Legal

Dear IRRC: I have reviewed the above regulation on behalf of Sen. Hughes and have the following preliminary comments:

1. These regulations still fail to correct the problem cited by the Commonwealth Court in *Giant Food Stores v. Dep't. of Health*, 554 A.2d. 174 (1989). The regulatory scheme still has a bifurcated system of review. If a violation is found during a certification/recertification review, there is no opportunity to correct. Sec. 1103.1(f). If, however, the same exact violation is found during any other monitoring inspection there are at least two opportunities to correct. Sec. 1105.6.
2. My review of the federal regulations at 7 CFR 246.12(g) found no federal prohibition of a state agency granting opportunity to correct during a certification/recertification review. If the DOH believes there is such a prohibition, can they provide a citation for it.

Thank you,
Niles Schore