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September 13, 2000

Honorable Robert Zimmerman, Jr.  
Secretary of Health  
Room 802 Health & Welfare Building  
Harrisburg, PA 17108

RE: Regulation #10-159 (IRRC#2134)  
Department of Health  
Drug and Alcohol Facilities and Services

Dear Secretary Zimmerman:

I submit the following comments in my capacity as Minority Chair of the Senate Public Health & Welfare Committee. Given the volume of public comments, and given the concerns that I have with these proposed regulations, I suggest that agency staff, IRRC staff and committee staff meet to discuss appropriate changes to your proposal.

Thank you for your time and consideration.

Sincerely yours,

A handwritten signature in cursive script that reads "Vincent Hughes".

Vincent Hughes  
Minority Chair  
Public Health & Welfare Committee

cc: John R. McGinley, Jr., Esq., Chair, Independent Regulatory Review Commission  
Senator Harold F. Mowery, Jr., Chair, Public Health & Welfare Committee

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**COMMENTS OF SENATOR VINCENT HUGHES  
ON DOH #10-159, DRUG AND ALCOHOL FACILITIES AND SERVICES**

**1. §701.1 - Definition of "Maintenance Treatment"**

The existing regulations, in the definition of the term "maintenance approach", includes the following sentence:

The ultimate goal of maintenance is to assist the client in permanently discontinuing the use of dependency producing substances.

The proposed regulations delete that sentence and add the following as the goal of "maintenance treatment":

to achieve stabilization or prevent withdrawal symptoms for treatment of an individual with an opiate dependency.

Why has the goal of the Commonwealth's methadone maintenance program changed? Please explain the expected benefits from changing the goal.

**2. §715.3(d) - Approval of Narcotic Treatment Programs**

The existing regulation, at 4 Pa. Code §263.3(e), states: "Inspections will occur without notice to the methadone project..." (emphasis added). The proposed regulation at §715.3(d) changes that to read: "The Department may inspect the narcotic treatment program without notice..." (emphasis added)

Why has the department removed the requirement of mandatory no-notice inspections? What standards will the department use to determine which narcotic treatment programs will be inspected without notice and which with notice?

**3. §715.3(g) - Approval of Narcotic Treatment Programs**

The existing regulation, at 4 Pa. Code §263.3(c), permits a narcotic treatment program to be granted conditional approval to operate only if the deficiencies cited can be corrected within 60 days. The proposed regulation, at §715.3(g), removes any time limit on the correction of deficiencies.

Why has the time limit been removed? Please explain the expected benefits from removing the time limit.

**4. §715.14 - Urine Testing**

The existing regulation, at §263.6, requires weekly urine testing for opiates and synthetic narcotics, and monthly testing for other controlled substances. The proposed regulation, §715.14(a) reduces the testing requirement to monthly for all tested substances.

Why has the frequency of testing for opiates and methadone been reduced from weekly to monthly? What are the expected benefits from this reduction?

**5. §715.14 - Urine Testing**

What is the consequence of failing a urine test? There is nothing included in this section to explain this.

**6. §715.21 - Termination**

The federal regulation, at 21 C.F.R. §291.505(d)(2)(ii), states:

The person responsible for a program shall ensure that test results are not used as a sole criterion to force a patient out of treatment but are used as a guide to change treatment approaches. The person responsible for a program shall also ensure that when test results are used, presumptive laboratory results are distinguished from results that are definitive.

Why is this statement not included in §715.21, and in §715.14, urine testing?