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INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

June 28, 2001

Honorable Robert Zimmerman, Jr., Secretary
Department of Health
802 Health and Welfare Building
Harrisburg, PA 17108

Re: Regulation #10-137 (IRRC #2188)
Department of Health
Newborn Disease Screening and Follow-Up

Dear Secretary Zimmerman:

Enclosed are our Comments. They will soon be available on our website at www.irrc.state.pa.us.

Our Comments list objections and suggestions for consideration when you prepare the final version of this regulation. We have also specified the regulatory criteria which have not been met. These Comments are not a formal approval or disapproval of the proposed version of this regulation.

If you would like to discuss these Comments, please contact my office at 783-5417.

Sincerely,

Robert E. Nyce
Executive Director

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Enclosure

cc: Honorable Dennis M. O'Brien, Majority Chairman, House Health and Human Services Committee
Honorable Frank L. Oliver, Democratic Chairman, House Health and Human Services Committee
Honorable Harold F. Mowery, Jr., Chairman, Senate Public Health and Welfare Committee
Honorable Vincent J. Hughes, Minority Chairman, Senate Public Health and Welfare Committee
Nia Wilson, Legal Counsel, House Health & Human Services Committee
Stanley Mitchell, Chief Counsel, House Health & Human Services Committee

Comments of the Independent Regulatory Review Commission

on

Department of Health Regulation No. 10-137

Newborn Disease Screening and Follow-Up

June 28, 2001

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which have not been met. The Department of Health (Department) must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered by May 29, 2003, the regulation will be deemed withdrawn.

1. Section 28.1. Definitions. - Clarity.

Hemoglobin diseases

This definition includes a list of sickle cell diseases, including “SS, SC, SV, S *beta* Thalassemia, S O Arab.” A commentator stated that there is no hemoglobin named “SV.” We suggest the Department review the definition and consider replacing “V” with “+ other variant.”

2. Section 28.21. Responsibility for collecting and testing initial and repeat specimens. - Economic impact; Clarity

Subsection (c)

Subsection (c) requires a healthcare provider to designate a “newborn screening coordinator” to perform several duties. We have two concerns.

First, the regulation does not specify what qualifications the “newborn screening coordinator” must have. Included in the duties in Paragraph (1), the newborn screening coordinator must “ensure that a specimen collection form contains *correct* and complete information.” (Emphasis added.) What level of medical training does the newborn screening coordinator need to ensure information is “correct”?

Second, Paragraph (7) is vague. What is the intent of requiring the newborn screening coordinator to “assist the Department in followup of an abnormal or presumptive abnormal test result”?