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

November 2, 2000

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

Re: Regulation #10-162 (IRRC #2142)
Department of Health
School Immunization

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
Alice Gray, R.N., Director, Division of Immunization, Department of Health
Barbara Newhouse, MPH, Division of Immunization, Department of Health

Comments of the Independent Regulatory Review Commission

on

Department of Health Regulation No. 10-162

School Immunization

November 2, 2000

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 If the final-form regulation is not delivered by October 2, 2002, the regulation will be deemed withdrawn.

1. Adoption by reference. - Protection of the public health and safety; Reasonableness; Clarity.

In the Preamble, the Department explains that the amendments are based on recommendations of the Advisory Committee on Immunization Practices (ACIP) under the federal Centers for Disease Control and Prevention. The ACIP is recognized as the authority in this area under Pennsylvania law. Section 2 of the Hepatitis B Prevention Act (35 P.S. § 630.2) requires the Department "to establish a program for the prevention of hepatitis B through immunization of children consistent with the recommendations of the Advisory Committee on Immunization Practices."

Is it the Department's intention to follow ACIP guidelines in establishing requirements for school immunization? If so, the Department should consider incorporating ACIP guidelines by reference in the regulation, pursuant to 45 Pa.C.S. § 727 and 1 Pa. Code § 3.41. A concern is that new vaccine availability could lag behind the ACIP guidelines. If this is the case, the regulation should provide a grace period for distribution of new vaccines.

2. Section 23.83. Immunization requirements. - Protection of the public health and safety; Reasonableness; Consistency; Need.

(a) Required for entry.

(b) Required for attendance.

Chickenpox and hepatitis B immunizations are included in the list of immunizations required for entry into kindergarten and first grade under Subsection (a). However, they are not included in the list of immunizations required for attendance under Subsection (b). Why? What is the impact of this requirement when a child moves to Pennsylvania and does not have these two immunizations?

Requirement for chickenpox immunization.

Sections 23.83(a)(8) and (c)(2) require chickenpox immunization as a requirement for entry “at a public, private, or parochial school in this Commonwealth, including special education and home education programs.” Public comment was submitted both in support of and in opposition to adding chickenpox immunity to the list of immunizations required for entry into school. The Department should provide additional explanation or documentation of the need to require chickenpox immunization as a prerequisite for school entry.

3. Section 23.84. Exemption from immunization. - Protection of the public health and safety; Need.

Existing Section 23.84 provides an exemption in the event a physician determines an immunization may be detrimental to the health of the child. One commentator stated that immunizations can be detrimental to other persons in the child’s household whose immune systems have been compromised by other diseases or treatments. Is this a possibility? If so, the Department should consider addressing this issue in a future rulemaking.