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INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

April 23, 2008

Honorable Calvin B. Johnson, M.D., M.P.H., Secretary
Department of Health
802 Health and Welfare Building
Harrisburg, PA 17108

Re: Regulation #10-181 (IRRC #2672)
Department of Health
School Immunizations; Communicable and Noncommunicable Diseases

Dear Secretary Johnson:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact me.

Sincerely,

Kim Kaufman
Executive Director

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Enclosure

cc: Honorable Ted B. Erickson, Chairman, Senate Public Health and Welfare Committee
Honorable Vincent J. Hughes, Minority Chairman, Senate Public Health and Welfare Committee
Honorable Frank L. Oliver, Majority Chairman, House Health and Human Services Committee
Honorable George T. Kenney, Jr., Minority Chairman, House Health and Human Services Committee

Comments of the Independent Regulatory Review Commission

on

Department of Health Regulation #10-181 (IRRC #2672)

School Immunizations; Communicable and Noncommunicable Diseases

April 23, 2008

We submit for your consideration the following comments on the proposed rulemaking published in the February 9, 2008 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the Department of Health (Department) to respond to all comments received from us or any other source.

1. General Issues - Economic impact; Protection of the public health safety and welfare; Reasonableness.

Combination vaccines

The Pennsylvania Medical Society (Medical Society) suggests that the Department use combination vaccines for several immunizations. The Medical Society states that combination vaccines are recommended by the Centers for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics and the American Academy of Family Physicians. The Medical Society further cites a CDC report which states that combination vaccines reduce costs by permitting fewer medical visits, and by lowering costs for stocking and storing vaccines. The Medical Society also states combination vaccines reduce the stress of putting a child through multiple injections in a single visit. The Medical Society's comments identify several vaccinations that could be combined.

The Medical Society provided a compelling case for combination vaccines. The Preamble states that the Department developed the proposed amendments to the regulation following review of the recommendations of the ACIP. However, combination vaccines were not included in this rulemaking. The Department should explain why it did not include combination vaccines in its proposed amendments.

ACIP Guidelines

The Medical Society recommends that the Department adopt the ACIP guidelines by reference. This would eliminate the need to update the Department's regulations every time the recommendations change. The Medical Society's comments include several recommendations for changes in accordance with ACIP guidelines, including combination vaccines, ages for vaccination or boosters, injectible polio vaccine, MMR, varicella and additional vaccinations. The Department should explain why it did not adopt the ACIP guidelines by reference. If the Department believes the ACIP guidelines should not be adopted by reference, we recommend

that the Department carefully consider the individual comments and suggestions included in the Medical Society's comments. We will review the Department's responses as part of our consideration of whether the final-form regulation meets the criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b).

Additional vaccines

The Medical Society also asks the Department to consider adding vaccination requirements for hepatitis A, rotavirus, haemophilus influenzae type b and human papillomavirus. Should these be required by regulation?

2. Section 23.83 - Immunization requirements. - Protection of Public Health, Safety and Welfare; Reasonableness; Implementation procedures; Clarity.

Public, private, parochial or nonpublic school in this Commonwealth

Subsection (a) provides a listing of who is responsible for ascertaining whether a child has been immunized prior to admission to school. The regulation states that it is the duty of: "[e]ach school director, superintendent, principal or other person in charge of a public, private, parochial or nonpublic school in this Commonwealth, **including vocational schools, intermediate units, and special education and home education programs....**" (Emphasis added.) However, the regulation does not specifically address charter and cyber charter schools. For clarity, the final-form regulation should specifically include school personnel from charter and cyber charter schools. The same concern applies to the language in Subsection (c) and Section 23.86(a).

Ascertain that a child has been immunized

Subsection (a) requires various school personnel to ascertain that a child has been immunized, but does not specify the acceptable means for making this determination. We note that Subparagraph 27.77(a)(1)(i) of the Department's regulations requires "written verification from a physician, the Department or a local health department" of immunizations. We recommend either including similar language in Subsection (a) so that school personnel know how to comply with the regulation, or including language for all of the immunizations listed in Subsection (b), as is included in Subparagraph (b)(8)(ii) for Chickenpox (varicella).

Penalties and exemptions

We recommend adding a cross-reference in Subsection (a) to 24 P.S. §13-1303a (*Immunization required; penalty*). This will clarify the statutory exemptions from the immunization requirements and the penalties for noncompliance with this provision.

Properly-spaced doses

The paragraphs under Subsection (b) repeatedly use the phrase "properly-spaced doses," but does not identify where the standard of properly-spaced doses can be found. Is the standard found in the ACIP guidelines? We recommend that the final-form regulation include the standard that is to be used to determine "properly-spaced doses."

Phase-in year of 2010/2011

Under Subparagraph (b)(8)(i), Chickenpox (varicella) requirements will change to two doses for entry to kindergarten and for children 13 years of age or older. The regulation also allows a phase-in of the two doses for the 2010/2011 school year. How did the Department determine that school year 2010/2011 allows a reasonable amount of time to acquire these immunizations?

Additionally, the existing regulation requires a Chickenpox (varicella) vaccine dose at age 12 months *or older*. However, proposed Clause (8)(i)(A) does not include the phrase “or older.” We recommend adding the phrase “or older” to Clause (8)(i)(A).

To improve clarity, the Department should also explain the difference between the vaccine requirements in Subsections (b)(8)(i)(B) and (b)(8)(i)(C).

Laboratory testing

In Subsections (b)(4) and (5), the Department is deleting the specific requirement for serological evidence and replacing it with the requirement for “laboratory testing.” We recognize that in the Preamble, the Department explains technology is changing and it is reluctant to require a specific test. However, the requirement to prove immunity by “laboratory testing” is broad. What type of laboratory testing will the Department accept? Would the testing procedure and the laboratory have to be approved or accredited by an appropriate medical authority?

4-day grace period

Subsection (f) refers to a “4-day grace period” for the deadline for the administration of required vaccines. The final-form regulation should explain who will monitor this grace period, and what the consequences would be for exceeding it.

Facsimile Cover Sheet



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

To: Yvette Kostelac
Regulatory Coordinator
Agency: Department of Health
Phone: 3-2500
Fax: 5-6042, 3-3794 or 2-6959
Date: April 23, 2008
Pages: 5

Comments: We are submitting the Independent Regulatory Review Commission's comments on the Health Department's regulation #10-181 (IRRC #2672). Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

Accepted by: Jalene Koller **Date:** 4-23-08