

# Comments of the Independent Regulatory Review Commission



## Department of Health Regulation #10-197 (IRRC #3147)

### School Immunizations

**June 8, 2016**

We submit for your consideration the following comments on the proposed rulemaking published in the April 9, 2016 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (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. Economic or fiscal impacts; Protection of the public health, safety and welfare; Clarity, feasibility and reasonableness of requirements; Need for the regulation; Reasonableness of requirements, implementation procedures and timetables for compliance; Compliance with the RRA; Acceptable data.**

Section 5.2 of the RRA (71 P.S. § 745.5b) directs this Commission to determine whether a regulation is in the public interest. When making this determination, the Commission considers criteria such as economic or fiscal impact and reasonableness. To make that determination, the Commission must analyze the text of the proposed rulemaking and the reasons for the new or amended language. The Commission also considers the information a promulgating agency is required to provide under Section 5(a) of the RRA (71 P.S. § 745.5(a)) in the Regulatory Analysis Form (RAF). Some of the information contained in the RAF submitted with this rulemaking is not sufficient to allow this Commission to determine if the regulation is in the public interest. Specifically, we ask the Department to provide the following information with the final-form regulation.

- In response to RAF #10 regarding need for the regulation, the Department states that it reviewed vaccination rates in schools and school districts, and found those rates to be “lower than is optimal” for the health of the Commonwealth. Commentators ask that the Department provide specific data to address vaccination rates. Further, the Department cites herd immunity claims, which many commentators argue are unsupported. In the Preamble and response to the RAF, the Department should provide specific data to support the need for the regulation related to vaccination rates and herd immunity.
- RAF #17 asks the Department to identify the financial impact of the regulation; RAF #19 asks for specific cost estimates for the regulated community; and RAF #22 asks for a statement of additional reporting, recordkeeping or other paperwork required of the regulated community. Commentators disagree with the Department’s responses to these

questions, stating that costs will run in the millions of dollars. One specific concern cited by the regulated community includes getting proof of immunity, which commentators say would be a substantial cost to parents. Additionally, many commentators question the applicability of insurance to vaccinations and note their possible expense. Commentators also state that the Department significantly understates the increased administrative and paperwork burden the proposed regulation places on school districts. The Department should address these concerns and provide specific cost estimates related to the financial impact of the final-form regulation on the regulated community.

- In response to RAF #29 regarding the expected effective date of the final-form regulation, the Department states, “Compliance would be required on the first day of the next school year following publication as final rulemaking in the Pennsylvania Bulletin.” It’s possible that the timing of final publication may make it difficult to be in compliance on the first day of the next school year. We ask the Department to consider this as it relates to the timing for full implementation of the regulations, and to ensure that the effective date provides sufficient time for school entities to plan, implement policies and communicate with parents/guardians about the new requirements.

## **2. Section 23.82. Definitions. – Clarity.**

### *Medical certificate*

This definition requires a form to be filled out and signed by a “health care provider.” It is not clear who specifically qualifies as a health care provider. Elsewhere in the regulation, such as in Section 23.83(b)(5)(ii)(B), a list is provided of “a physician, nurse practitioner or physician’s assistant.” We also recognize that immunizations can be administered by registered nurses (49 Pa. Code § 21.16) and pharmacists (63 P.S. § 390-9.2). Can a registered nurse or pharmacist also fill out and sign a medical certificate? The regulation should be clear regarding what specific professions can fill out and sign a medical certificate.

## **3. Section 23.83. Immunization requirements. – Economic or fiscal impacts; Protection of public health, safety and welfare; Need for the regulation; Reasonableness of requirements, implementation procedures and timetables for compliance.**

### *Subsection (b) Required for attendance.*

This subsection specifies the immunizations that are required for admittance to a Pennsylvania school. The Department should ensure that implementation of the new requirements is clear for the regulated community. Commentators raise questions regarding whether the requirements apply only to students who are entering Kindergarten and 7<sup>th</sup> and 12<sup>th</sup> grades, whether the requirements apply retroactively to all current students, and how the requirements apply to a student who moves into a new school district. Given that not meeting the immunization requirements can affect a child’s education, we ask the Department to provide clear explanations of how the requirements in the regulation will be implemented in the final-form regulation’s Preamble and in its responses to comments.

Also, commentators ask that the Department exempt homeschool and cyber students. Did the Department consider such exemptions? The Department should address its consideration of this concern in the final-form regulatory package.

*Paragraph (b)(1) Diphtheria, tetanus and pertussis.*

The Department explains in the Preamble that it is combining existing requirements into proposed Paragraph (b)(1) and adding pertussis because the incidence of pertussis has been increasing since the 1980s. The Department explains that some vaccines are being removed from the regulation because these forms of vaccines are no longer available in the United States. Some commentators are opposed to the doses being administered in a combined form. If vaccines are no longer available, the Department should state this clearly in the Preamble and final-form RAF to more clearly explain the need for this change.

*Subparagraph (b)(4)(ii) Evidence of immunity.*

The Department is proposing in Subparagraph (b)(4)(ii) to no longer allow a parent or guardian to provide a written statement as proof of chicken pox. The Department explains in the Preamble, in part:

Currently, evidence of varicella immunity may be shown either by laboratory confirmation, or a statement of history from a physician, parent or guardian. This is in keeping with the Centers for Disease Control and Prevention (CDC), United States Department of Health and Human Services, Advisory Council on Immunization Practices (ACIP) recommendations, and is intended to ensure that the child has actually had chickenpox . . . . Many types of viruses can cause rashes; the Department wishes to make certain that the persons providing evidence that the child has actually had the disease are those able to diagnose chickenpox disease, and familiar with the chickenpox rash.

Commentators argue that parents should be permitted to provide evidence since they assert chicken pox is a mild illness that does not require medical intervention and that contagious children should not be taken into medical facilities where other children are present. Commentators state that this change will impose a financial burden on families.

Do the CDC and ACIP guidelines allow parents or guardians to diagnose varicella? If so, the Department should provide further support for changing this practice. Also, if so, the Department should explain the reasonableness of imposing new financial burdens when the existing practice is acceptable to the CDC.

*Subparagraph (c)(1)(i) Tetanus and diphtheria toxoid and acellular pertussis vaccine (Tdap).*

Paragraph (b)(1) includes an exemption if a child has a contraindication to pertussis. The Department should consider adding a similar exemption to Subparagraph (c)(1)(i).

Additionally, commentators note that some doctors will not give this vaccine to children at the 6<sup>th</sup> grade physical if the children are not 12 years old at the time. The Department should ensure that implementation of this requirement is clear for the regulated community to comply.

*Paragraph (c)(2) Required for entry into 12<sup>th</sup> grade.*

The Department proposes to require an additional dose of Meningococcal Conjugate Vaccine (MCV) for entry into 12<sup>th</sup> grade. Commentators state that an additional dose of MCV is unnecessary and significantly raises costs. We ask the Department to further explain the need for the additional dose and how the benefits outweigh the costs.

Further, commentators raise questions about situations such as whether a third dose would be required for students who get a dose of MCV after 7<sup>th</sup> grade but before the 16<sup>th</sup> birthday or what happens when students come in from out of state without the first dose. The Department should ensure that the final-form regulation makes clear how the requirement is to be implemented.

**4. Section 23.85. Responsibilities of schools and school administrators. – Economic or fiscal impacts; Protection of public health, safety and welfare; Reasonableness of requirements, implementation procedures and timetables for compliance.**

*Subsection (e) Provisional admittance to school.*

The Preamble explains that under existing Subsection (e), a child could be provisionally admitted to school for up to an eight-month period. The Department is proposing to eliminate the eight-month period and set up requirements that allow for exclusion of students under certain circumstances. The requirements would differ for single dose and multiple dose vaccines. In certain circumstances a child could be provisionally admitted for a period of five school days.

Commentators generally support this proposal, but state that the length of time is not feasible for school nurses or parents, and it may put a child who needs multiple vaccines at risk. Other commentators oppose any provisional admittance. The Department should explain the reasonableness of the timeframe in the Preamble to the final-form regulation and how the timeframe adequately protects public health.

*Paragraph (e)(1) Multiple dose vaccine series.*

Clauses (e)(1)(ii) and (iii) both end with similar language which states that a child's parent or guardian will provide a medical certificate scheduling the additional required dose(s) on or before the fifth school day. It is unclear as to whether the additional dose(s) must be scheduled on or before the fifth school day, or whether the parent or guardian is to provide the medical certificate on or before the fifth school day. We ask the Department to clarify what is required by these provisions.

*Paragraph (e)(3) Completion of required immunizations.*

We have two concerns.

First, Paragraph (e)(3) shortens from 60 days to 30 days the timeframe for review of the medical certificate of provisionally admitted students. Commentators state that this change creates an administrative burden and request a middle-ground timeframe. The Department should explain the reasonableness of the timeframe in the final-form regulation and how the timeframe adequately protects public health.

Second, Paragraph (e)(3) also allows a school administrator to choose whether to exclude a child if the requirements of the medical certificate are not met upon review. Commentators ask that “may” be changed to “shall” in the final-form regulation. If the Department requires immunizations for attendance, why should a school administrator have this discretion? The Department should explain the reasonableness of providing flexibility in the final-form regulation and how allowing non-immunized children to attend school adequately protects public health.

*Paragraph (g)(2) Applicability.*

Paragraph (g)(2) allows 30 days for a parent or guardian of a child who moves or transfers into a Commonwealth school to provide immunization records. Commentators request additional time. The Department should explain the reasonableness of the timeframe in the Preamble to the final-form regulation and how the timeframe adequately protects public health.

*Paragraph (h)(1) Temporary waiver.*

Paragraph (h)(1) allows for a temporary waiver in the case of a nationwide shortage of supply for a particular vaccine. Is it possible that there could be a regional shortage and, if so, should that also trigger a temporary waiver?

**5. Section 23.86. School reporting. – Reasonableness of requirements, implementation procedures and timetables for compliance.**

Paragraph (f)(7) requires schools to report the number of students in kindergarten, 7<sup>th</sup> grade or in an ungraded school, age 12 only, who were denied admission because of the student’s inability to provide documentation of the required vaccine doses. Since Section 23.83(c)(2) adds a new requirement for one dose of MCV for entry into 12<sup>th</sup> grade, should schools also report the number of students in 12<sup>th</sup> grade who were denied admission because they could not provide documentation of the required vaccine dose?

**6. Clarity of terms.**

The terms “nurse practitioner” and “physician’s assistant” are used in Sections 23.83(b)(3)(iii) and (b)(5)(ii)(B). We have two concerns. First, in 49 Pa. Code Chapter 21, the State Board of Nursing regulates registered nurses, practical nurses and certified registered nurse practitioners. The Department’s regulation is not clear regarding which of the three categories of the nursing profession qualify as a “nurse practitioner.” Second, at 49 Pa. Code Chapter 18, Subchapter D, the State Board of Medicine regulates “physician assistants.” For clarity and consistency, we

recommend using the specific terms used by other agencies with regulatory authority over these professions to describe these medical professionals.