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| Regulatory Analysis Form | | This space for use by IRRC <div style="text-align: center;"> RECEIVED 2000 AUG 23 AM 11:07 IRRC Number: <u>2142</u> <small>REVIEW COMMISSION</small> </div> |
| (1) Agency Department of Health | | |
| (2) I.D. Number (Governor's Office Use) DOH Regulation No. 10-162 | | |
| (3) Short Title School Immunization Requirements | | |
| (4) Pa Code Cite 28 Pa Code §23.83 | (5) Agency Contacts & Telephone Numbers Primary Contact: Alice J. Gray, RN, Director, Division of Immunizations. 717-787-5681 Secondary Contact: Barbara A. Newhouse, MPH Division of Immunizations 717-787-5681 | |
| (6) Type of Rulemaking (Check One) <input checked="" type="checkbox"/> Proposed Rulemaking <input type="checkbox"/> Final Order Adopting Regulation <input type="checkbox"/> Final Order, Proposed Rulemaking Omitted | (7) Is a 120-Day Emergency Certification Attached? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes: By the Attorney General <input type="checkbox"/> Yes: By the Governor | |
| (8) Briefly explain the regulation in clear and non-technical language. <p>The proposed regulations provide the immunization requirements for children to enter and attend school in the Commonwealth. These proposed regulations add new requirements for varicella vaccine and expand existing requirements for hepatitis B. The proposed regulations would require a documented history of varicella disease or an age-appropriate dose of varicella vaccine for all students entering school at kindergarten or in the first grade and seventh grade. In addition, three doses of hepatitis B vaccine will be required for all students entering the seventh grade. All categories of school students, including private, parochial, public, and vocational school students and students in special education programs and home education programs must comply with the school immunization requirement. The proposed regulations would not affect existing provisional enrollment, religious, and medical exemptions.</p> | | |

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The Department obtains its authority to promulgate regulations relating to immunizations in schools from several sources. Generally, the Disease Prevention and Control Law (35 P.S. §521.1 et seq.) (Act) provides the Advisory Health Board with the authority to issue rules and regulations on a variety of issues relating to communicable and non-communicable diseases, including what control measures are to be taken with respect to which diseases, provisions for the enforcement of control measures, requirements concerning immunization and vaccination of persons and animals and requirements for the prevention and control of disease in public and private schools. (35 P.S. §521.16(a)). Section 16(b) of the Act (35 P.S. §521.16(b)), gives the Secretary of Health (Secretary) the authority to review existing regulations and make recommendations to the Board for changes the Secretary considers to be desirable.

The Department also finds general authority for the promulgation of its regulations in the Administrative Code of 1929 (71 P.S. §51 et seq.) Section 2102(g) of the Administrative Code (71 P.S. §532(g)), gives the Department this general authority. Section 2111(b) of the Administrative Code (71 P.S. §541(b)), provides the Advisory Health Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of the Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department.

The Department's specific authority for promulgating regulations relating to school immunizations is found in the Administrative Code and in the Public School Code of 1949 (24 P.S. §1-101 et seq.) Section 2111(c.1) of the Administrative Code (71 P.S. §541(c.1)), provides the Advisory Health Board with the authority to make and revise a list of communicable diseases against which children are required to be immunized as a condition of attendance at any public, private, or parochial school, including kindergarten. The section requires the Secretary to promulgate the list, along with any rules and regulations necessary to insure the immunizations are timely, effective, and properly verified.

Section 1303a of the Public School Code (24 P.S. §13-1303a), provides that the Advisory Health Board will make and review a list of diseases against which children must be immunized, as the Secretary of Health may direct, before being admitted to school for the first time. The section provides that the school directors, superintendents, principals, or other persons in charge of any public, private, parochial, or other school including kindergarten, must ascertain whether the immunization has occurred, and certificates of immunization will be issued in accordance with rules and regulations promulgated by the Secretary with the sanction and advice of the Board.

The Hepatitis Prevention Act (35 P.S. §§630.1-630.3) provides the Department with authority to implement a program for the prevention of hepatitis B through immunization of children consistent with ACIP's recommendations. (35 P.S. §630.2).

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No, the proposed regulations are not mandated by any federal or state law or court order, or federal regulation.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

These proposed regulations are intended to prevent dangerous communicable diseases in school-aged children. School-aged children are considered an at-risk population for the contracting and transmission of potentially dangerous diseases, including chickenpox (varicella) and hepatitis B.

Requiring immunizations prior to entering school protects children before they enter a high-risk disease transmission environment; and before they engage in high-risk behavior which exposes them to the risk of contracting and communicating diseases. The proposed regulations would also prevent the spread of these diseases to other at-risk populations.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

The school environment is known to be an ideal setting for the transmission of communicable diseases among students who are susceptible due to lack of immunity. Hepatitis B and chickenpox (varicella) carry the risks of serious morbidity, lifelong disability and mortality. Since the school environment is conducive to the contracting and transmission of diseases among children with no immunity, failure to immunize properly puts the public at risk of an outbreak of a potentially lifethreatening and certainly debilitating illness.

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(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Those children who, because of the proposed regulations, will be immunized, and will not contract the disease and suffer discomfort, miss school, or be left with permanent sequel will benefit from these proposed regulations. The parents of those children who will not have to miss work, worry, pay medical bills, and tend to their sick children will also benefit from these proposed regulations. Physicians and other health care providers, including Department staff, who will not have to treat sick children or take action to control a disease outbreak will benefit from these proposed regulations. Pregnant women and their unborn children who will not be threatened with a serious congenital abnormality due exposure to chickenpox (varicella) during pregnancy will benefit from these proposed regulations. Taxpayers who will not have to support expensive disease intervention activities and the health care system as a whole which might have to absorb the cost of some of the direct and indirect effects of these diseases will also benefit.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

Those parents or guardians whose health plans do not cover immunizations, and for whom payment is a hardship will be affected unless they obtain other assistance.

School districts and staff who must verify whether a child's immunizations are up to date will have additional immunizations to review.

Physicians called upon to provide immunization histories for patients may consider themselves to be adversely affected.

Those children who suffer the rare adverse reaction to a required immunization and their parents or guardians may also be adversely affected.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

Primarily, parents and guardians whose children are not immune prior to entering school for the first time or before reaching the seventh grade will have to receive the mandated vaccines. This is approximately 10 to 20 percent of 150,000 children born each year in the Commonwealth, or 15,000 to 30,000 children.

School districts and their staff will have to enforce the varicella immunity requirement and the enhanced hepatitis B immunity requirement for each student entering school for the first time and for students entering into the seventh grade.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

The Department has held meetings with stakeholders interested in the addition of varicella and hepatitis B to the list of required immunizations. The following groups were included in the meetings Pennsylvania Department of Health Staff from the Division of Immunizations, the Division of School Health, the Bureau of Epidemiology and the Bureau of Community Health Systems; the Office of General Counsel; the Pennsylvania Department of Education; the Pennsylvania Chapter of the American Academy of Pediatrics (PA AAP); the Pennsylvania Medical Society (PMS); the Pennsylvania State Nurses Association; the Pennsylvania Association of Pupil Services Administrators; the Keystone Christian Education Association; the Philadelphia Department of Public Health; the Pennsylvania Association of School Nurses and Practitioners; the Pennsylvania State Education Association, School Nurse Executive Board; Keystone Health Plan; Blue Shield Highmark Health Plan; Gateway Health Plan; Penn State Geisinger Health Plan; HealthAmerica Health Plan; UPMC Health Plan; and Merck & Co.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures that may be required.

It is estimated to cost the regulated community \$1.5 million, while saving over \$35 million. Savings are based on 1997 CDC data, which concludes that \$5.40 is saved for every dollar spent on varicella vaccine and \$2.00 is saved for every dollar spent on hepatitis B vaccine.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures that may be required.

These regulations would have no fiscal impact on local governments.

Cost savings might result from not having to investigate reports of disease occurrence and/or implement disease outbreak control interventions. Some outbreak control programs in the past have exceeded \$100,000 – \$200,000 or more, of which 25 percent might be borne by local government depending on the magnitude of the outbreak, the disease that is occurring and the population affected.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulations, including legal and accounting or consulting procedures that may be required.

The Commonwealth might incur some costs for the purchase of additional vaccines. Though all vaccines are paid for through federal grants, this is not a limitless funding stream. The Department of Public Welfare would also incur costs through the Medical Assistance Program for administering the vaccines. Medical Assistance is funded by the state with a federal match. Cost savings would result from not having to coordinate disease investigations, institute outbreak control measures, and provide vaccine for exposed, susceptible individuals. Staff time and vaccine cost could easily exceed \$20,000 - \$50,000 or more for each occurrence.

Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government and state government for the current year and five subsequent years.

| | CFY Year | FY +1 Year | FY +2 Year | FY +3 Year | FY +4 Year | FY +5 Year |
|------------------------|-------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| SAVINGS | \$ | | | | | |
| Regulated Community | \$0 | 35,281,440 | 35,281,440 | 35,281,440 | 28,981,440 | 28,981,440 |
| Local Government | \$ 0 | | | | | |
| State Government | \$ 0 | | | | | |
| TOTAL SAVINGS | \$0 | <i>35,281,440</i> | <i>35,281,440</i> | <i>35,281,440</i> | <i>28,981,440</i> | <i>28,981,440</i> |
| COSTS | | | | | | |
| Regulated Community | \$0 | 1,477,800 | 1,477,800 | 1,477,800 | 757,800 | 757,800 |
| Local Government | \$ 0 | | | | | |
| State Government * | \$0 | 7,435,800 | 7,435,800 | 7,435,800 | 5,005,800 | 5,005,800 |
| TOTAL COSTS | \$0 | <i>8,913,600</i> | <i>8,913,600</i> | <i>8,913,600</i> | <i>5,763,600</i> | <i>5,763,600</i> |
| REVENUE LOSSES: | | | | | | |
| Regulated Community | \$ 0 | 0 | 0 | 0 | 0 | 0 |
| Local Government | \$ 0 | 0 | 0 | 0 | 0 | 0 |
| State Government | \$0 | 0 | 0 | 0 | 0 | 0 |
| Total Revenue Losses | \$0 | 0 | 0 | 0 | 0 | 0 |

* The Immunization Program is currently federally funded.

REGULATORY ANALYSIS FORM

(20a) Explain how the cost estimates listed above were derived.

In determining costs related to the implementation of these proposed regulations, the Department would consider cost to the regulated community to be realized by the number of children (10%) in an age cohort who would be required to pay out of pocket for these immunizations. The state government costs would be realized by the number of children (90%) in an age cohort who would get the immunizations through the Department of Health because they would have no other source of obtaining the required immunizations. The Department currently purchases all vaccines, including varicella and hepatitis B vaccines, with funding from the federal government. Children who already have the immunizations would not be a part of these percentages. Presumably they would have obtained and paid for their immunizations through other mechanisms, for example, private insurance or the Children's Health Insurance Program.

There are approximately 150,000 children born annually in Pennsylvania, therefore there would be approximately 750,000 children who would need immunizations through the age of five years or when a child first enters school. According to the 1998 National Immunization Survey by the Centers for Disease Control and Prevention (CDC), 43% of those children, an estimated 322,500, might not be immunized against varicella at the time of school entry. Dividing 322,500 by five years would result in 64,500 children who would not be immunized each year for five years at the time of entrance into school. The regulated community would be comprised of 10% (6,450) of those children immunized for \$44.00 per dose of vaccine and the state government would immunize 90% (58,050) of those children at \$36.00 per dose.

There are approximately 150,000 seventh graders each year in public and private schools. The expected number of seventh graders not having varicella immunity is estimated to be 50%. Therefore, 50% (75,000) of the seventh grade cohort of 150,000 children would need to be immunized with varicella vaccine each year. The regulated community would be comprised of 10% (7,500) of those children immunized at \$44.00 per dose; and the state government would immunize 90% (67,500) of those children at \$36.00 per dose.

Additionally to comply with these revised school immunization requirements; all seventh graders would need to be immunized against hepatitis B disease with three doses of hepatitis B vaccine. A 1999 school immunization survey reported that 80% of Pennsylvania's school students were not immunized against hepatitis B disease. However, the hepatitis B vaccine became a school immunization requirement for new school enterers (kindergarten or first grade) in the 1997/1998 school year. Taking into account that children entering school for the first time in the 1997/1998 school year will reach the seventh grade in the school year 2004/2005, for the first three years (2001/2002, 2002/2003, 2003/2004) the proposed regulations would be effective, approximately 120,000 seventh graders would need be immunized with three doses of hepatitis B vaccine. For these three years, the regulated community would be comprised of 10% (12,000) of those students immunized with three doses of hepatitis B vaccine at \$24.00 per dose. The state government would immunize 90% (108,000) of those students with three doses of hepatitis B vaccine at \$9.00 per dose. For two years after the 2003/2004 school year, it is estimated that 20,000 students would need to be immunized each year using the same per cents and dosage amounts as were used for the first three years.

The savings estimate was calculated using a 1997 report from the CDC which concludes that for every dollar spent on varicella immunizations - \$5.40 is saved; and for every dollar spent on hepatitis B immunizations - \$2.00 is saved. These savings would be realized in a combination of savings from lack of medical expenses, work not being missed to care for sick children, and school not missed by the children. These savings would pertain to the community at large and are expressed under the regulated community.

(20b) Provide the past three-year expenditure history for programs affected by the regulation.

| Program | 96-97 FY - 3 | 97-98 FY - 2 | 98-99 FY - 1 | 99-00 Current FY |
|--------------|-----------------|-----------------|-----------------|---------------------|
| Immunization | \$7,146,603 | \$7,502,506 | \$8,165,929 | \$7,505,000 |

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

The expenditure history figures shown above in item 20b are not cost-benefit data. They are gross expenditures for the entire program including expenditures for vaccines. The only additional costs the program must incur as a result of the proposed regulations are for the purchase of vaccine.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

There are no non-regulatory alternatives.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No alternative regulatory schemes were considered.

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(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

No, there are no provisions in this regulation that are more stringent than federal standards.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

More than 15 states already have in place or are pending, varicella legislature that requires varicella immunity or proof of vaccine prior to entering school for the first time. In addition, 17 states currently have a 3-doses requirement for hepatitis B vaccine for school entry.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

These proposed regulations will not adversely affect other existing or proposed regulations of the Department or other state agencies. The Department is currently in the process of proposing regulations relating to the control and prevention of communicable and noncommunicable diseases. These proposed regulations are expected to be published in the Pennsylvania Bulletin by summer of 2000. The communicable disease regulations would require reporting of varicella by laboratories immediately, and by physicians within a three-year period of their final publication. The intent of the Department is to study the effect of the immunization requirement through the reporting requirement contained in the communicable disease regulations.

(27) Will any public hearings or information meetings be scheduled? Please provide the dates, times, and locations, if available.

The Department will provide a 30-day public comment period upon publication of the proposed regulations in the Pennsylvania Bulletin.

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(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports that will be required as a result of implementation, if available.

There would be no substantive change in current reporting requirements between schools and the Department. The proposed regulations would provide an option to parents and guardians permitting them to provide a history of immunization proved by laboratory testing or a history of disease. This may be considered an additional requirement, and may impose additional paperwork on physicians, although this is an option for the parent or guardian, not a requirement.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

All required vaccines are available from the Department or County/Municipal Health Department clinics located in each county of the state at low or no cost to the parent.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The proposed regulations will be come effective upon final publication in the Pennsylvania Bulletin.

(31) Provide the schedule for continual review of the regulation.

The Department will review the proposed regulation on a periodic basis.

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| <p>Copy below is hereby approved as to form and legality. Attorney General.</p> <p><i>Cristina S. Costello</i> BY _____ DEPUTY ATTORNEY GENERAL AUG 01 2000 DATE OF APPROVAL</p> <p><input type="checkbox"/> Check if applicable. Copy not approved. Objections attached.</p> | <p>Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:</p> <p>DEPARTMENT OF HEALTH (AGENCY)</p> <p>DOCUMENT/FISCAL NOTE NO. _____</p> <p>DATE OF ADOPTION: _____</p> <p>BY <i>Robert S. Zimmerman, Jr.</i> Robert S. Zimmerman, Jr.</p> <p>TITLE: <u>Secretary of Health</u></p> | <p>Copy below is hereby approved as to form and legality. Executive or Independent Agency.</p> <p><i>Howard S. Bink</i> BY _____</p> <p>5/24/00 DATE OF APPROVAL</p> <p>(Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title)</p> <p><input type="checkbox"/> Check if applicable. No Attorney General approval or objection within 30 days after submission.</p> |
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TITLE 28. HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 23]

School Immunization Requirements

**CONTINUATION SHEET
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Notice is hereby given that the Department of Health (Department), with the approval of the State Advisory Health Board (Board), proposes to amend 28 Pa. Code §23.83 (relating to immunization requirements). The proposed amendments are set forth in Annex A hereto.

A. PURPOSE OF THE REGULATION

The proposed regulation sets out immunization requirements that children seeking to enter and attend school in the Commonwealth must meet. The proposed regulation is based upon recommendations of the Advisory Committee on Immunization Practices (ACIP), an advisory committee of the federal Centers for Disease Control and Prevention (CDC). The proposed regulation would reverse the order of subsections and add explanatory language to the current regulation for the sake of clarity, add new requirements for chickenpox (varicella) immunity, and expand requirements for hepatitis B immunization. The Department is proposing these amendments to ensure that the school environment, known to be an ideal setting for the transmission of communicable diseases, particularly where children are susceptible due to lack of immunity, is made more safe. Hepatitis B and chickenpox, as well as the already listed diseases, carry the risk of serious morbidity, lifelong disability, and death.

Children attending schools are known to be a group at high risk for contracting communicable and potentially dangerous diseases. Requiring immunity before a child enters school in first grade or kindergarten, or before he or she is permitted to attend a school in the Commonwealth, protects that child before he or she enters an environment which readily lends itself to the transmission of disease.

Ensuring that children are appropriately immunized carries with it advantages for the public as a whole, including other high-risk populations, as well as for the child. Vaccinated children who will not contract these diseases will not miss school and suffer discomfort from contracting hepatitis B or chickenpox. In addition, their parents will not be required to take time off from their jobs to care for a sick child, or pay medical bills related to their illness. There is less chance of other persons contacting a highly infectious disease if children are vaccinated. If outbreaks of highly communicable diseases are prevented by immunizations before they occur, public health officials and physicians need not treat or contain an outbreak, and public funds need not be spent on disease intervention activities.

B. REQUIREMENTS OF THE REGULATION

**CHAPTER 23. SCHOOL HEALTH
SUBCHAPTER C. IMMUNIZATION**

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Section 23.83. Immunization requirements.

In conjunction with the substantive amendments to this section, the Department is proposing to make minor changes for the purposes of clarity. The Department proposes to reverse the current order of subsections (a) and (b) so that the list of immunizations now required for school entry would appear in subsection (a) and come before the list of immunizations currently required for school attendance, which would now appear in subsection (b). This would place the immunization requirements in appropriate chronological order.

The current regulation relating to religious exemptions remains in effect, and are not affected by these amendments.

Subsection (a). Required for entry.

This subsection is substantially the same as current subsection (b), with some changes. Subsection (a) would clarify that all the vaccinations required for children attending school in the Commonwealth are also required for children entering school for the first time. It would remain substantially the same, therefore, with three main additions. Subsection (a) would include the german measles (rubella) vaccination and the mumps vaccination as immunizations required for school entry. This is already the practice, but the Department believes it is necessary to specifically include german measles (rubella) and mumps in subsection (a).

Subsection (a) would also allow hepatitis B immunity to be proven by seriological evidence of antibody to hepatitis B. This requirement would acknowledge that some children may have developed immunity to hepatitis B. Allowing proof of immunity by laboratory testing will avoid unnecessary vaccination for those children.

Further, subsections (a) and (b) currently recommend the combined DTP immunization for the purposes of immunizing against diphtheria and pertussis, and the combined MMRII vaccine for the purposes of immunizing against measles, mumps, and german measles (rubella). The Department is proposing not to retain this language in subsection (a), as it is a recommendation, and not a regulatory standard. The Department does believe that the combined MMRII vaccine should be recommended for children under the age of 7 years. The Department would, however, recommend the combined DTaP vaccine in place of the combined DTP vaccine. DTaP is a newer and improved vaccine. Although the risk for side effects with either vaccine is minimal when weighed against the benefits of immunization, DTaP is associated with fewer side effects than DTP, and reduces the risk of convulsions and high fever.

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The Department is also proposing to add chickenpox (varicella) immunity to the list of requirements for entry in kindergarten or first grade. In lieu of this vaccination, subsection (a)(8) would permit a parent, guardian, or physician to provide a written statement of history of chickenpox immunity, or would permit the child's history of immunity to be proved by laboratory testing.

Chickenpox is a highly contagious disease that may result in discomfort, severe illness, and death to the child. The disease may cause absence from school, which could have a deleterious effect on the child's school career. A child's illness from chickenpox can result in a parent or guardian expending money to treat an otherwise preventable disease, as well as causing worry and absence from work to care for the child. There is also the possibility of an outbreak of the disease in a susceptible population, for example, non-immunized school-age children, multiplying the effect throughout the community. The May 28, 1999 *Morbidity and Mortality Weekly Report* (MMWR), a publication of the CDC, reported that chickenpox (varicella) incidence is highest among children aged 1-6 years. Therefore, implementing immunity requirements for school entry will have a great effect on reducing the incidence of disease. The CDC noted in a 1997 study that for every dollar spent for chickenpox (varicella) vaccine, \$5.40 is saved in indirect health benefit costs (work lost) and direct medical costs. Requiring chickenpox (varicella) immunity will therefore save money for both the Commonwealth and the public.

The Department, with the approval of the Advisory Health Board, has determined that it is more effective for the prevention and control of the spread of disease, and in the interests of the children of the Commonwealth, as well as other susceptible populations, to require immunization for this disease. Both the American Academy of Pediatrics and the ACIP recommend that this vaccination be given. The Department, with the approval of the Advisory Health Board, has chosen to follow that recommendation.

Subsection (b). Required for attendance.

This subsection is substantially the same as current subsection (a). The Department is proposing some changes to this subsection as well as repositioning it. Subsection (b) would make clear that a child in school in the Commonwealth who has not received immunizations as listed in subsection (a), for whatever reason, would be required to receive the immunizations listed in subsection (b) as a condition of continued attendance.

As in proposed subsection (a), the Department is proposing to add language permitting laboratory proof of hepatitis B in lieu of a vaccination. The Department is also proposing not to retain language recommending the use of the combined DTP vaccine and the combined MMRII vaccine.

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Subsection (c). Required for entry into the seventh grade.

This subsection would be new. The Department is proposing to delete the current text of subsection (c) as unnecessary. Subsection (c) currently requires that two doses of the measles (rubeola) immunization be an all-grades requirement beginning in the school year 2000-2001. The requirement for this immunization would be included in subsections (a) and (b).

Subsection (c), as amended, would require that 3 properly spaced doses of the hepatitis B vaccine be given upon entry into the seventh grade or, in a nongraded system, at the time a child is 12 years of age if the child did not previously receive the immunization. Hepatitis B is also a serious and highly contagious disease. Pennsylvania law requires vaccination for the disease at school entry (see 35 P.S. §620.3), however, that law also requires the Department to implement a program of hepatitis B prevention through immunization of children. (See 35 P.S. §620.2). The MMWR for November 22, 1996, reported that in the United States, most persons with hepatitis B contracted the virus as young adults or adolescents. In that November MMWR, ACIP recommended that adolescents at 11 and 12 years of age, who have not been previously vaccinated for the virus, should be vaccinated against hepatitis B. Based on this recommendation, the Department, with the approval of the Advisory Health Board, is proposing to expand its regulation to require the hepatitis B vaccination in the seventh grade, or, in an ungraded class, in the year in which the child is 12 years of age, as part of its hepatitis B prevention program.

Subsection (c) would also require that the chickenpox (varicella) vaccination be given to children in the seventh grade, or, in an ungraded class, in the year in which the child is 12 years of age, if the child has not already acquired immunity. This proposal is based upon ACIP recommendations, and has the approval of the Advisory Health Board. Subsection (c)(2)(i) and (ii) would set out proper dosages for different age groups. As in subsection (a)(8)(i), subsection (c)(2)(iii) would accept a history of chickenpox immunity proved by laboratory testing, or would allow a parent, guardian, or physician to provide a statement of history of chickenpox disease, in lieu of the immunization. Subsection (c)(2)(iii) would also permit an emancipated child to provide this statement.

C. AFFECTED PERSONS

These proposed regulation would affect children entering school for the first time in kindergarten or first grade in the Commonwealth, and those children attending school in the Commonwealth, who have not yet been vaccinated for hepatitis B or chickenpox (varicella). The proposed regulation would also affect their parents or guardians. The proposed regulation would also affect school districts and their employees, since school districts are

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required to ensure that children attending school have the appropriate vaccinations. To the extent that physicians would be requested by parents and guardians to provide vaccination histories or other proof of vaccination, physicians would also be affected tangentially.

D. COST AND PAPERWORK ESTIMATE

1. Cost

a. Commonwealth

The Commonwealth would incur some costs for the purchase and administration of the additional vaccines. The savings, however, in terms of the amount of funds that would not be needed to coordinate disease outbreak investigations and control measures, would outweigh the additional program and vaccine costs.

b. Local Government

There would be no additional cost to local governments. Local governments should see some cost savings from the prevention of disease outbreaks, since local governments do bear some of the cost of disease outbreak investigations and control measures.

c. Regulated Community

Families whose children's vaccinations are covered by their insurance plans (public or private) pursuant to State law should not see any out-of-pocket cost for the vaccinations. Families whose insurance plans do not cover these vaccinations, or who do not have insurance, will need to seek other assistance to pay for vaccinations, or pay out-of-pocket. In general, there is other assistance provided for vaccinations from the Department, if no third party payer available. The Department provides vaccinations either free of charge, or charges a fee based on a sliding fee scale according to the family's income. The savings in prevention of childhood illness would outweigh the minimal cost of the vaccine.

School districts already have mechanisms in place for determining whether or not children have been appropriately immunized, and taking action based on that determination. This proposed regulation would add two additional immunizations to review, which should not add to the current cost of ensuring immunizations are up to date. Again, the savings in prevention of an outbreak of a childhood illness in a school district should outweigh the minimal cost in staff time to review two additional immunizations.

d. General Public

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The general public should not see an increase in cost.

2. Paperwork Estimates

a. Commonwealth and the Regulated Community

There would be minimal additional paperwork requirements for the Commonwealth and the regulated community. The requirement that school districts report the number of immunizations is already in place. The proposed regulation would merely add two additional immunization requirements to the current list of required immunizations.

Although physicians could be requested by a parent or guardian to provide an immunization history for varicella, the Department would not be mandating that physicians provide an immunization history. The proposed regulation merely state that the Department would accept such a history in lieu of the actual vaccination requirement.

Parents and guardians would need to present information relating to varicella immunity when children enter school for the first time in the Commonwealth in kindergarten or the first grade. Parents, guardians, and emancipated children would need to present information relating to hepatitis B immunity when entering the seventh grade.

b. Local Government

There is no additional paperwork requirement for local government.

c. General Public

There is no additional paperwork requirement for the general public.

E. STATUTORY AUTHORITY

The Department obtains its authority to promulgate regulations relating to immunizations in schools from several sources. Generally, the Disease Prevention and Control Law (35 P.S. §521.1 et seq.) (Act) provides the Advisory Health Board with the authority to issue rules and regulations on a variety of issues relating to communicable and non-communicable diseases, including what control measures are to be taken with respect to which diseases, provisions for the enforcement of control measures, requirements concerning immunization and vaccination of persons and animals, and requirements for the prevention and control of

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disease in public and private schools. (35 P.S. §521.16(a)). Section 16(b) of the Act (35 P.S. §521.16(b)) gives the Secretary of Health (Secretary) the authority to review existing regulations and make recommendations to the Board for changes the Secretary considers to be desirable.

The Department also finds general authority for the promulgation of its regulations in the Administrative Code of 1929 (71 P.S. §51 et seq.) Section 2102(g) of the Administrative Code (71 P.S. §532(g)) gives the Department this general authority. Section 2111(b) of the Administrative Code (71 P.S. §541(b)) provides the Advisory Health Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of the Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department.

The Department's specific authority for promulgating regulations relating to school immunizations is found in the Administrative Code and in the Public School Code of 1949 (24 P.S. §1-101 et seq.) Section 2111(c.1) of the Administrative Code (71 P.S. §541(c.1)) provides the Advisory Health Board with the authority to make and revise a list of communicable diseases against which children are required to be immunized as a condition of attendance at any public, private, or parochial school, including kindergarten. The section requires the Secretary to promulgate the list, along with any rules and regulations necessary to insure the immunizations are timely, effective, and properly verified.

Section 1303a of the Public School Code (24 P.S. §13-1303a) provides that the Advisory Health Board will make and review a list of diseases against which children must be immunized, as the Secretary of Health may direct, before being admitted to school for the first time. The section provides that the school directors, superintendents, principals, or other persons in charge of any public, private, parochial, or other school including kindergarten, must ascertain whether the immunization has occurred, and certificates of immunization will be issued in accordance with rules and regulations promulgated by the Secretary with the sanction and advice of the Board.

The Hepatitis Prevention Act (35 P.S. §§630.1-630.3) provides the Department with authority to implement a program for the prevention of hepatitis B through immunization of children consistent with ACIP's recommendations. (35 P.S. §630.2).

F. EFFECTIVENESS/SUNSET DATES

The proposed regulation will become effective upon final publication in the Pennsylvania Bulletin. No sunset date has been established. The Department will continually review and monitor the effectiveness of these regulations.

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G. REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act (71 P.S. §§745.1-745.15), the Department submitted a copy of this proposed regulation on August 23, 2000, to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has any objections to any portion of the proposed amendments, it will notify the Department by November 2, 2000. The notifications shall specify the regulatory review criteria which have not been met by that portion. The Act specifies detailed procedures for review, prior to final publication of the regulation by the Department, the General Assembly and the Governor, of objections raised.

H. CONTACT PERSON

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulation to Alice Gray, Director, Division of Immunization, Department of Health, P.O. Box 90, Harrisburg, PA 17108, (717) 787-5681, **within 30 days** after publication of this notice in the Pennsylvania Bulletin. Persons with a disability who wish to submit comments, suggestions, or objections regarding the proposed regulation may do so by using V/TT (717) 783-6514 for speech and/or hearing impaired persons or the Pennsylvania AT&T Relay Service at (800-654-5984[TT]). Persons who require an alternative format of this document may contact Ms. Gray so that necessary arrangements may be made.

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ANNEX A

TITLE 28. HEALTH AND SAFETY

PART III. PREVENTION OF DISEASES

CHAPTER 23. SCHOOL HEALTH

Subchapter C. IMMUNIZATION

§23.83. Immunization requirements.

(a) [*Required for attendance.* The following immunizations are required as a condition of attendance at school in this Commonwealth.

(1) *Diphtheria.* Three or more properly spaced doses of diphtheria toxoid, which may be administered as a single antigen vaccine, in combination with tetanus toxoid or in combination with tetanus toxoid and pertussis vaccine. The Department recommends the combined DTP vaccine for children under 7 years of age.

(2) *Tetanus.* Three or more properly spaced doses of tetanus toxoid, which may be administered as a single antigen vaccine, in combination with diphtheria toxoid or in combination with diphtheria toxoid and pertussis vaccine. The Department recommends the combined DTP vaccine for children under 7 years of age.

(3) *Poliomyelitis.* Three or more properly spaced doses of either oral polio vaccine or enhanced inactivated polio vaccine, but if a child received any doses of inactivated polio vaccine prior to 1988, a fourth dose of inactivated polio vaccine is required.

(4) *Measles (rubeola).* One dose of live attenuated measles vaccine administered at 12 months of age or older or a history of measles immunity proved by serological evidence showing antibody to measles determined by the hemagglutination inhibition test or a comparable test. Measles vaccine may be administered as a single antigen vaccine. The Department recommends the combined MMRII vaccine.

(5) *German measles (rubella).* One dose of live attenuated rubella vaccine administered at 12 months of age or older or a history of rubella immunity proved by serological evidence showing antibody to rubella determined by the hemagglutination inhibition test or a comparable test. Rubella vaccine may be administered as a single antigen vaccine. The Department recommends the combined MMRII vaccine.

(6) *Mumps*. One dose of attenuated mumps vaccine administered at 12 months of age or older or a physician diagnosis of mumps disease indicated by a written record signed by the physician or the physician's designee. Mumps vaccine may be administered as a single antigen vaccine. The Department recommends the combined MMRII vaccine.] Required for entry. The following immunizations are required for entry into school for the first time at the kindergarten or first grade level, at any public, private, or parochial school, in this Commonwealth, including special education and home education programs.

(1) *Hepatitis B*. Three properly-spaced doses of hepatitis B vaccine or a history of hepatitis B immunity proved by laboratory testing.

(2) *Diphtheria*. Four or more properly-spaced doses of diphtheria toxoid, which may be administered as a single antigen vaccine, in combination with tetanus toxoid or in combination with tetanus toxoid and pertussis vaccine. One dose shall be administered on or after the 4th birthday.

(3) *Tetanus*. Four or more properly-spaced doses of tetanus toxoid, which may be administered as a single antigen vaccine, in combination with diphtheria toxoid or in combination with diphtheria toxoid and pertussis vaccine. One dose shall be administered on or after the 4th birthday.

(4) *Poliomyelitis*. Three or more properly-spaced doses of any combination of oral polio vaccine or enhanced inactivated polio vaccine.

(5) *Measles (rubeola)*. Two properly-spaced doses of live attenuated measles vaccine, the first dose administered at 12 months of age or older, or a history of measles immunity proved by serological evidence showing antibody to measles as determined by the hemagglutination inhibition test or a comparable test. Each dose of measles vaccine may be administered as a single antigen vaccine.

(6) *German measles (rubella)*. One dose of live attenuated rubella vaccine, administered at 12 months of age or older or a history of rubella immunity proved by serological evidence showing antibody to rubella determined by the hemagglutination inhibition test or any comparable test. Rubella vaccine may be administered as a single antigen vaccine.

(7) *Mumps*. One dose of live attenuated mumps vaccine, administered at 12 months of age or older or a physician diagnosis of mumps disease indicated by a written record signed by the physician or the physician's designee. Mumps vaccine may be administered as a single antigen vaccine.

(8) Chickenpox (varicella). One of the following:

(i) One dose of varicella vaccine, administered at 12 months of age or older.

(ii) A history of chickenpox immunity proved by laboratory testing or a written statement of history of chickenpox disease from a parent, guardian or physician.

(b) [*Required for entry.* The following immunizations are required for entry into school for the first time at the kindergarten or first grade level, at any public, private, or parochial school, including special education and home education programs.

(1) *Hepatitis B.* Three properly-spaced doses of hepatitis B vaccine.

(2) *Diphtheria.* Four or more properly-spaced doses of diphtheria toxoid, which may be administered as a single antigen vaccine, in combination with tetanus toxoid or in combination with tetanus toxoid and pertussis vaccine. The Department recommends the combined DTP vaccine. One dose shall be administered on or after the 4th birthday.

(3) *Tetanus.* Four or more properly-spaced doses of tetanus toxoid, which may be administered as a single antigen vaccine, in combination with diphtheria toxoid or in combination with diphtheria toxoid and pertussis vaccine. The Department recommends the combined DTP vaccine. One dose shall be administered on or after the 4th birthday.

(4) *Poliomyelitis.* Three or more properly-spaced doses of any combination of oral polio vaccine or enhanced inactivated polio vaccine.

(5) *Measles (rubeola).* Two properly-spaced doses of live attenuated measles vaccine, the first dose administered at 12 months of age or older, or a history of measles immunity proved by serological evidence showing antibody to measles as determined by the hemagglutination inhibition test or a comparable test. Each dose of measles vaccine may be administered as a single antigen vaccine. The Department recommends the combined MMRII vaccine.] *Required for attendance.* The following immunizations are required as a condition of attendance at school in this Commonwealth if the child has not received the immunizations required for school entry listed in subsection (a).

(1) *Diphtheria.* Three or more properly spaced doses of diphtheria toxoid, which may be administered as a single antigen vaccine, in combination with tetanus toxoid or in combination with tetanus toxoid and pertussis vaccine.

(2) Tetanus. Three or more properly spaced doses of tetanus toxoid, which may be administered as a single antigen vaccine, in combination with diphtheria toxoid or in combination with diphtheria toxoid and pertussis vaccine.

(3) Poliomyelitis. Three or more properly spaced doses of either oral polio vaccine or enhanced inactivated polio vaccine, but if a child received any doses of inactivated polio vaccine administered prior to 1988, a fourth dose of inactivated polio vaccine is required.

(4) Measles (rubeola). Two properly spaced doses of live attenuated measles vaccine, administered at 12 months of age or older or a history of measles immunity proved by serological evidence showing antibody to measles determined by the hemagglutination inhibition test or a comparable test. Each dose of measles vaccine may be administered as a single antigen vaccine.

(5) German measles (rubella). One dose of live attenuated rubella vaccine, administered at 12 months of age or older or a history of rubella immunity proved by serological evidence showing antibody to rubella determined by the hemagglutination inhibition test or any comparable test. Rubella vaccine may be administered as a single antigen vaccine.

(6) Mumps. One dose of live attenuated mumps vaccine, administered at 12 months of age or older or a physician diagnosis of mumps disease indicated by a written record signed by the physician or the physician's designee. Mumps vaccine may be administered as a single antigen vaccine.

(c) [Required for the school year 2000/2001. The following immunization shall be an all-grades requirement at the beginning of the 2000/2001 school year (August/September 2000) for attendance at school in this Commonwealth:

Measles (rubeola). Two properly-spaced doses of attenuated measles vaccine, the first dose administered at 12 months of age or older, or a history of measles immunity, proved by serological evidence showing antibody to measles as determined by the hemagglutination inhibition test or a comparable test. Each dose of measles vaccine may be administered as single antigen. The Department recommends the combined MMRII vaccine.] Required for entry into seventh grade. In addition to the immunizations listed in subsection (b), the following immunizations are required at any public, private, parochial or vocational school, in this Commonwealth, including special education and home education programs, as a condition of entry for students entering the seventh grade, or, in an ungraded class, for students in the school year that the student is 12 years of age:

(1) Hepatitis B. Three properly-spaced doses of hepatitis B vaccine or a history of hepatitis

B immunity proved by laboratory testing.

(2) Chickenpox (varicella). One of the following:

- (i) One dose of varicella vaccine, administered at 12 months of age or older.
- (ii) Two properly-spaced doses of varicella vaccine for children 13 years of age and older.
- (iii) A history of chickenpox immunity proved by laboratory testing, or a written statement of history of chickenpox disease from the parent, guardian, emancipated child or physician.

Commonwealth of Pennsylvania



DEPARTMENT OF HEALTH
HARRISBURG

ROBERT S. ZIMMERMAN, JR., MPH
SECRETARY OF HEALTH

August 23, 2000

Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Department of Health Proposed Regulation No. 10-162
School Immunization Requirements

Dear Mr. Nyce:

Attached is a proposed regulation for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§745.1-745.15). The proposed regulation amends the Department of Health's regulation relating to immunization requirements (28 Pa. Code §23.83). The proposed regulation is being promulgated under the Disease Prevention and Control Law of 1955 (35 P.S. §521.1 *et seq.*), Section 2111(c.1) of the Administrative Code (71 P.S. §541(c.1)), Section 1303a of the Public School Code of 1949 (24 P.S. §1303a), and the Hepatitis Prevention Act (35 P.S. §630.1, *et seq.*). As required by Executive Order 1996-1, the Department is attempting to revise and update its regulations relating to immunization to include additional immunization requirements which have recently been recommended by national advisory groups on these matters.

Section 5(g) of the Regulatory Review Act (71 P.S. §745.5(g)), provides that the Commission shall, within 10 days after expiration of the Standing Committee review period, notify the proposing agency of any objections to the proposed regulations. The regulations are expected to be published September 2, 2000. A 30-day comment period is provided.

Section 5.1(a) of the Regulatory Review Act (71 P.S. §745.5a(a)), provides that upon completion of the agency's review of comments, the agency shall submit to the Commission a copy of the agency's response to the comments received, the names and addresses of the commentators who have requested additional information relating to the Final-Form Regulations and the text of the Final-Form Regulations which the agency intends to adopt.

The Department will provide the Commission within 5 days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the Commission with any assistance it requires to facilitate a thorough review of the proposed

Robert E. Nyce

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August 23, 2000

regulations. If you have any questions, please contact Deborah Griffiths, Director, Office of Legislative Affairs at (717) 783-3985.

Sincerely,

A handwritten signature in black ink that reads "Robert S. Zimmerman, Jr." with a stylized flourish at the end.

Robert S. Zimmerman, Jr.
Secretary of Health

Attachments

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT**

RECEIVED

2000 AUG 23 AM 11:07

INDEPENDENT REGULATORY
REVIEW COMMISSION

I.D. NUMBER: 10-162
SUBJECT: School Immunization Requirements
AGENCY: Department of Health

TYPE OF REGULATION

- X Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
 - a. With Revisions
 - b. Without Revisions

FILING OF REGULATION

| DATE | SIGNATURE | DESIGNATION |
|----------|--------------------|---|
| 8-23-00 | <i>[Signature]</i> | HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES |
| 8-23-00 | <i>[Signature]</i> | |
| 8/23/00 | <i>[Signature]</i> | SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE |
| 8-23-00 | <i>[Signature]</i> | |
| 8-23-00 | <i>[Signature]</i> | INDEPENDENT REGULATORY REVIEW COMMISSION |
| | | ATTORNEY GENERAL |
| 08/23/00 | <i>[Signature]</i> | LEGISLATIVE REFERENCE BUREAU |

August 17, 2000