

PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 23]

School Immunizations

The Department of Health (Department), with the approval of the State Advisory Health Board (Board), proposes to amend Chapter 23, Subchapter C (relating to immunization) to read as set forth in Annex A.

A. Purpose of the Proposed Rulemaking

The proposed amendments to Chapter 23, Subchapter C take steps to ensure that children attending school in this Commonwealth are adequately protected against potential outbreaks of vaccine-preventable diseases. In some cases, the only way to ensure that children are adequately protected—particularly those children who are medically unable to obtain a vaccination and, therefore, vulnerable—is to require the immunization of all children attending school. The Department intends to achieve this goal by amending § 23.85 (relating to responsibilities of schools and school administrators) to allow for a child to be provisionally admitted to school even though the child does not have all the required immunizations for admission or continued attendance as set forth in § 23.83 (relating to immunization requirements).

Following the outbreak of measles occurring in California in early 2015, and the occurrence of a case of measles in this Commonwealth (although not epidemiologically connected to the California outbreak), the Department reviewed its vaccination rates in schools and school districts, and found those rates to be lower than is optimal for the health of this Commonwealth. Low vaccination rates can lead to a waning of “herd immunity,” that is, the protection for the community against certain communicable diseases that arises when a critical mass of persons are immunized against those diseases. Herd immunity is what protects persons who are unable to receive vaccination, including those who are too young to receive the vaccine, pregnant women and immunocompromised individuals. A waning of herd immunity may, in turn, lead to the re-emergence of vaccine-preventable diseases considered to have been almost eliminated.

The Department determined that it was imperative for the health of the citizens of this Commonwealth for the rate of vaccination among children attending school to be increased. In considering how to achieve this end, the Department, in conjunction with the Department of Education, implemented an educational campaign to increase rates. Reviewing vaccination rates among school children in this Commonwealth, the Department decided that this type of campaign would not be sufficient to raise rates of vaccination to the level that would prevent the spread of dangerous communicable diseases within this Commonwealth.

The Department determined from its reported school immunization data that the largest number of nonvaccinated children attending school was not due to the medical and religious exceptions from vaccination allowed by law. Those children attending school in a provisional status make up the largest number of nonvaccinated children reported to the Department. The number of children reported to the Department as attending school in a provisional status in kindergarten and 7th grade for

school year 2013-2014 was in excess of 53,000. These numbers led the Department to the conclusion that the high number of children provisionally admitted to and attending school might, at some future point, contribute to a lessening of herd immunity, and the occurrence of the outbreak of a serious communicable disease.

In addition, the Department noted that the rates of vaccination among children increased significantly when the date on which schools were required to report was extended at the Department’s request. When, in 2014, the Department asked schools to report 2014-2015 data to it by December 31, rather than October 15, as set forth § 23.86(a) (relating to school reporting), the vaccination rates among school children increased. The rate for completion of the measles, mumps, rubella (MMR) kindergarten grade level vaccine increased from 87.49 in 2013 to 91.72 in 2014. This, combined with the relatively low number of medical, philosophical and religious exemptions reported, led the Department to conclude that it was not a refusal to be vaccinated that was causing low vaccination rates among school children, rather the lack of urgency felt by families to have vaccination requirements completed by school entrance or the start of school. This lack of urgency may be a function of the successful vaccination campaigns of the past, and the near elimination of dangerous childhood diseases from a normal childhood. Parents believe that they no longer need fear, as they did in the past, that a child will be blinded, seriously disabled or killed by measles, polio, diphtheria, pertussis, tetanus, hepatitis B or chickenpox since, up to the present time, these diseases do not occur with the frequency that they did in the past.

The California outbreak gives the lie to this false sense of security. Diseases such as measles, mumps, rubella, polio, diphtheria, meningitis, pertussis and chickenpox have not been eradicated, and may, and do, return to an unvaccinated population. In recent years, there have been breakthrough outbreaks in this Commonwealth and in other states of pertussis and chickenpox. Based on this information, and determining that an educational campaign, while useful, may not be sufficient to raise vaccination rates above the necessary percentage to ensure the continuation of protection for this Commonwealth, the Department has determined that it is in the best interests of the public’s health to propose to limit the provisional period, protecting and strengthening existing herd immunity.

The Department also intends to use this proposed rulemaking to change the manner and time frames for schools to report immunization rates to the Department, to obtain the most accurate immunization data possible, to acknowledge that certain types of vaccine are no longer available in the United States and to add a requirement to immunize against pertussis, the incidence of which has gradually been increasing in the United States since the 1980s. The Department is also proposing to add a second dose of meningococcal vaccine before entry to 12th grade.

B. Requirements of the Proposed Rulemaking

§ 23.82. Definitions

Definitions of “full immunization” and “medical certificate” are proposed to be added. These definitions are necessary to define the proposed requirements for a revised provisional period. “Full immunization” would mean that a child has received all immunizations required under § 23.83. A “medical certificate” would be

used by a health care provider, or a public health official if the child receives vaccinations through the public health system, to set out what immunizations the child requires to be fully vaccinated, and by when the child must receive them. Failure to meet the terms of the certificate would then allow for the child's exclusion from school under proposed § 23.85(e).

§ 23.83. *Immunization requirements*

Subsection (b) is proposed to be amended to reflect the fact that several vaccines required for school attendance are no longer available in the United States in certain forms. For example, two pediatric acellular vaccines are available in the United States. However, the diphtheria, tetanus and pertussis vaccine is not available, and the use of the diphtheria and tetanus vaccine is very rare and limited to children for whom use of the pertussis antigen is contraindicated. Therefore, current paragraphs (1) and (2) are proposed to be deleted and combined into proposed paragraph (1) to require the vaccine in a combination form.

Pertussis is proposed to be added to subsection (b)(1). The tetanus and diphtheria toxoid and acellular pertussis vaccine (Tdap), which includes pertussis, is required in the 7th grade under the current regulations. Pertussis is proposed to be added to address the need to fight the resurgence of a vaccine-preventable disease. The incidence of pertussis has been increasing since the 1980s. From 2010 to 2013, 13 pediatric deaths were reported in the United States.

Because MMR is no longer made as separate antigens, the Department proposes to require the combination form in proposed subsection (b)(3) and delete current subsection (b)(4)—(6). Proposed paragraph (3) takes into consideration the fact that other countries still may use separate antigens. This allows schools to count as properly vaccinated those children arriving from other countries having been vaccinated with those types of vaccines.

Proposed subsection (b)(3) allows for immunity to be proven by a history of measles and rubella by laboratory testing, and a written statement of history of mumps disease from a physician, nurse practitioner or physician's assistant. This is to ensure that the diagnosis of disease is the basis for the determination of a history of immunity, and is intended to ensure that a child has, in fact, had the disease for which the statement of history is given.

Proposed amendments to proposed subsection (b)(5), current subsection (b)(8), change the heading to "Varicella (chickenpox)" and only accept a history from a physician, nurse practitioner or physician's assistant. 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. This proposed amendment, as with the other amendments in this propose rulemaking, is focused on ensuring that children are protected from disease, either by vaccination or, for those children unable to be vaccinated for medical reasons, by allowing attendance at

school only when the child shows a history of immunity, and is therefore unable to spread disease.

The heading of subsection (c) is proposed to be amended to "special requirements for tetanus and diphtheria toxoid and acellular pertussis vaccine and meningococcal vaccine" to take into account proposed paragraph (2). The Department, following recommendations from ACIP to ensure protection for students from meningitis into their post-secondary education, is proposing in proposed paragraph (2) to add a dose of meningococcal vaccine for entry into the 12th grade, or in an ungraded school in the school year the child turns 18 years of age. In accordance with ACIP recommendations for children attending college, if the child has had a previous dose on or after his 16th birthday, the requirement would not apply. See MMWR March 22, 2013; 62 (RRO2): 1-22; see also <http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>.

Subsection (c)(1) currently requires at least one dose of Tdap for entry into 7th grade if at least 5 years have elapsed since the last dose of a vaccine containing tetanus and diphtheria. Tdap may be administered regardless of the interval of time between the last dose of a vaccine containing a tetanus or diphtheria toxoid. One dose of Tdap in combination form is proposed to be required. ACIP recommends a single dose of Tdap for persons 11 through 18 years of age.

§ 23.85. *Responsibilities of schools and school administrators*

Subsection (e) currently sets out requirements allowing a child to be provisionally admitted to school for up to an 8-month period if the child has a plan for completion of the required immunizations in the child's school health record, or, in the case of a multiple dose vaccine, if the child has received one dose and there is a plan for completion of the remaining doses in the child's health record. Subsection (e)(3) further sets out requirements for the school administrator or a designee to review that plan every 60 days. Subsection (e)(3) requires that the school administrator not admit the child or allow continued attendance after the end of that 8-month period.

The Department is proposing to eliminate the 8-month provisional period and, instead, to set up requirements that would allow for exclusion of students under certain circumstances. The requirements would differ for single dose and multiple dose vaccines.

If a child did not have a single dose vaccine required under § 23.83(b), the child would be excluded from school.

With respect to multiple dose vaccinations, if the child does not have at least one dose of any of the multiple dose vaccinations, then the child may not attend school. The child could be provisionally admitted for a 5-school-day period if the child receives the final dose of a multiple dose vaccine within 5 school days of the child's first day of attendance. The child's parent or guardian would need to provide the certificate of immunization on or before the 5th day as proof of the immunization. If a child has the first dose of a multiple dose vaccine series, is scheduled to and does receive the next dose during the 5-school-day provisional period, and provides a medical certificate scheduling any remaining doses, the child may attend school so long as the child adheres to the medical certificate. Again, the child's parent or guardian shall provide the medical certificate on or before the 5th school day. If the next dose of a vaccine series is not medically appropriate for the within the 5-school-day period, and

the child has a medical certificate as defined by this proposed rulemaking showing when the child will receive the remaining doses, the child may be provisionally admitted to school, so long as the child adheres to that immunization schedule.

As with current regulation, it would be the responsibility of the school administrator to review that medical certificate and determine whether or not the child is following the schedule, and whether or not to exclude the child who fails to follow the schedule. The time frame for that review is proposed to be changed from 60 days to at least every 30 days to ensure more accountability. A child's parent or guardian may bring to the school administrator's attention the fact that he has become up-to-date with vaccination requirements at any time, without waiting for the administrator's review. Further, the Department is proposing to require a school to maintain the medical certificate until the child's official school immunization record is completed to ensure accurate records on immunizations. This is important in the event of an outbreak of a vaccine-preventable disease in the school.

The Department has reviewed the regulatory and statutory schemes of other states and found that the provisional period, allowing admission and attendance for an 8-month period before requiring all required immunizations be completed, is one of the two longest in the country, along with the State of West Virginia. West Virginia has high vaccination rates among school children because it, unlike the Commonwealth, does not allow religious or philosophical exceptions. The Department determined that a shorter provisional period for admission or attendance at school was necessary because a length of time as long as the current 8-month period, which allows children who could be vaccinated but are not to attend school, puts at risk those children and staff who cannot be vaccinated.

Proposed subsections (g) and (h) set out circumstances under which a child could be admitted to school even without the immunizations required under § 23.83. The Department, having proposed to limit the provisional period, is also proposing to include language allowing for a temporary waiver of those requirements.

Proposed subsection (g) recognizes that, under certain circumstances, a child who cannot prove his immunization status must be allowed access to school. The McKinney-Vento Homeless Education Assistance Improvements Act of 2001 (42 U.S.C.A. §§ 11431—11435) requires schools to permit homeless children to be admitted regardless of immunization requirements. Proposed subsection (g)(1) states that schools shall comply with this Federal law. Proposed subsection (g)(2) takes into account potential problems with providing information upon transfer into a school, and allows a 30-day period to obtain and provide either proof of immunizations or proof of the need for an exemption.

Proposed subsection (h) addresses situations in which a child, through no action of the child or the child's family, is prevented from obtaining a vaccination or from proving the child's immunization status. Proposed subsection (h)(1) would provide for a temporary waiver of requirements when vaccine is unavailable through a vaccine shortage. Shortages have occurred in the past due to problems at manufacturing plants or potentially because of a high demand for vaccine. Because the Department wishes to ensure that an actual vaccine shortage exists, and that it is one recognized by the vaccine experts,

proposed subsection (h)(1) requires that the shortage be recognized by the CDC before a waiver would be considered.

Proposed subsection (h)(2) addresses a situation like that following Hurricane Katrina, in which displaced children were sent to this Commonwealth to stay with friends and family in the wake of that disaster, and sought admittance to schools in this Commonwealth for an extended period of time. Those children did not have access to immunization records, either paper or electronic. To return those children to the classroom, and some semblance of a normal life, as quickly as possible, the immunization requirements were not enforced.

The Department is proposing that any waiver have limits and that those limits be publicized by notice in the *Pennsylvania Bulletin*. This would ensure that children can return to a classroom even though they are unable to access vaccination records, due to no fault of their own, and that the waiver would not continue indefinitely and that appropriate limits are set. For example, it is conceivable that a disaster could occur affecting one part of this Commonwealth, or even one school district. There would be no need to remove requirements in areas not affected. Further, one vaccination could be in short supply, but that would not require the lifting of requirements for other vaccinations. In addition, the waiver would be time limited because, at some point, the need for the waiver would be outweighed by the need for the protection of those with whom unvaccinated children have contact.

§ 23.86. School reporting

This section currently addresses requirements for schools reporting immunization data to the Department. The Department makes these requirements of schools for it to meet reporting requirements placed on the Department by the CDC. Subsection (a) is proposed to be amended to change the date by which schools are required to report to it from October 15 of each school year to December 31, and to require reporting electronically. This would allow for a more accurate report, and allow more time for schools to gather information to make the report. The CDC requests annual school immunization coverage reports from the Department as part of the Federal immunization grant process. In reviewing reporting data, the Department determined that by requesting the data by October 15, schools are reporting data too early in the school year, and the reporting does not accurately reflect the actual number of children receiving immunizations.

The Department recognizes that some schools that are required reporters will not be able to complete a report electronically. Proposed subsection (b) requires these schools to report on paper by December 15 of each year. This would provide the Department with sufficient time to compile and enter those reports before those schools reporting electronically begin to submit their reports.

The Department has renumbered the remainder of the section to take these changes into account.

Proposed subsection (f)(7), current subsection (e)(7), is proposed to be amended to require reporting of the number of children in kindergarten and 7th grade who were denied admission because of their inability to provide documentation of the required vaccinations.

C. Affected Persons

The proposed rulemaking would affect all children entering and attending school in this Commonwealth, particularly those who are not current with the required

vaccinations for school entry and continued attendance. These children would no longer be given an 8-month period to obtain required vaccinations, and could be excluded from school until they obtain the appropriate vaccinations and, if necessary, signed medical certificate, proof of immunity, or medical or philosophical exclusion.

The proposed rulemaking would also affect the parents or guardians of these students, since parents and guardians would have to ensure that the children receive the required vaccinations and, if necessary, medical certificate, have appropriate proof of immunity, or obtain exclusions to enter and to continue to attend school. Parents and guardians would no longer be able to provide a history of varicella to prove a child's immunity, and would be required to obtain a statement from a practitioner able to diagnose the disease. The same requirement would be added for measles and mumps. The proposed amendments to the provisional period could cause parents and guardians to have to find child care, or miss work, to keep the child at home while these requirements were being fulfilled.

The effects of time and funds spent should be outweighed by the benefits to children and their parents, however. Because requiring these immunizations or a more accurate proof of immunity would protect children from contracting measles, polio, diphtheria, pertussis, meningitis, chickenpox and mumps, and other childhood diseases, their parents or guardians would not have to miss work, worry or pay medical bills related to these diseases. Physicians and health care providers would not have to treat sick children. Department staff would not need to become involved in the prevention of outbreaks of vaccine-preventable diseases as they do now. Children and school staff members who are unable to be vaccinated would be protected as well.

Those children who suffer the adverse reactions to a required immunization and their parents or guardians would also be affected. The potential for a fairly rare reaction to these childhood vaccinations must be balanced against the benefits provided from requiring them. Children and adults who might otherwise have become ill, or perhaps died, from meningitis, pertussis, diphtheria, tetanus chickenpox or mumps, polio, measles and the other listed vaccine-preventable diseases are affected beneficially by this proposed rulemaking.

The proposed rulemaking would affect school districts and their employees, since school districts are required to ensure that children attending school have the appropriate vaccinations and the time periods in which the school administrator is to review immunization records is proposed to be shortened from 60 to 30 days. Adding or amending the immunization requirements adds to the work of these individuals. Adding a requirement for electronic reporting could add an additional time requirements, since additional training could be done to ensure schools are familiar with how to use the system, and how to accurately report. Training, offered by the Department, would take some employee staff time. This time should be offset once training is accomplished since reporting electronically should eliminate paperwork review and calculations. The overall impact of new reporting requirements should be slight in that school districts already have systems in place to document immunization status of students. It would eliminate one of the required fields for reporting, that of the number of children provisionally admitted. Further, many schools already report electronically using the Department's reporting system. In addition, providing additional time to report should be benefi-

cial to schools. The Department requested reports be sent at the later December date in the past school year with some success.

D. Cost and Paperwork Estimate

Cost

Commonwealth

The Commonwealth would incur some costs for the purchase of vaccine through the expenditure of Federal immunization grant funds. The Commonwealth would also incur costs through the Medical Assistance Program, which pays for administering the vaccines for eligible persons. The Department makes vaccines available at no cost to private providers enrolled in the Vaccines For Children (VFC) Program for children through 18 years of age who do not have insurance, who are Medicaid eligible, or who are Alaskan Native or American Indian. In addition, the VFC Program vaccine is also made available to other public clinic sites (Federally Qualified Health Centers and Rural Health Clinics) for the same population previously indicated but also for underinsured children through 18 years of age. The Commonwealth should realize savings, at the same time, based on the amount of funds that would not be needed to control the outbreak of a disease a vaccine prevents.

Local government

There would be no fiscal impact on local governments. Local governments could see a slight cost savings, since local governments do bear some of the cost of disease outbreak investigations and control measures. The potential impact of this proposed rulemaking on school districts, which may be considered to be local government, is addressed under the following heading.

Regulated community

Families with insurance coverage should not see out-of-pocket cost for the added vaccines. Families without coverage would need to seek other assistance to pay for the vaccines or pay out-of-pocket. The Department provides vaccines to providers for certain eligible children through the VFC Program.

In addition, parents and guardians would be required to obtain a history of immunity from a physician, physician's assistant or nurse practitioner, and could no longer prove their children's immunity by their own statements of history of disease. This could involve additional time and cost to the parent or guardian. Additional time and costs could also be created by the need to obtain a medical certificate signed by a practitioner in the event the child needs additional doses of a multiple dose vaccine. The savings in prevention of vaccine-preventable illnesses for both the child in question, and other children and adults with whom that child comes into contact, would outweigh the cost of the vaccine and the cost of the visit to obtain the medical history or certificate.

To the extent that physicians, nurse practitioners and physician's assistants may be requested by parents and guardians to provide vaccination histories or other proof of vaccination, these practitioners could also be affected tangentially. Practitioners would also be affected by the fact that a child missing doses of multiple dose vaccines would now need the practitioner to sign a medical certificate setting out the time frame for obtaining those vaccinations for the child to be allowed to enter school. Obtaining these documents may require an additional visit to the practitioner.

The proposed rulemaking would also affect school districts and their employees, since school districts are

required to ensure that children attending schools have the appropriate vaccinations. Vaccination requirements are already in place, and schools already have mechanisms in place to make these determinations. This proposed rulemaking does add a dose of meningitis in the 12th grade, or the school year in which the child turns 18 years of age, and pertussis to the list of diseases for which a child must be vaccinated to be in school. With respect to pertussis, the antigen is merely added to an existing vaccination requirement, that of diphtheria and pertussis, so that rather than counting another vaccine, schools would be required to account for a different version of the vaccine.

The savings in the prevention of an outbreak of a childhood illness in a school district should outweigh the minimal cost in staff time.

General public

The general public should not see an increase in cost. The general public should see a decrease in costs resulting from a reduction in medical treatment needed to treat the disease. The general public may see a benefit in the reduction of vaccine-preventable diseases, such as measles, pertussis, chickenpox, mumps and meningitis. Since the school environment is conducive to the contracting and transmission of diseases among children and adults with no immunity, failure to immunize properly not only puts children and adults at risk for contracting these debilitating diseases, it also places the public at risk since these diseases are then easily spread by staff and children outside the school setting and into the general public.

Paperwork Estimates

Commonwealth and the regulated community

This proposed rulemaking would give schools additional time to report. The Department would need to review and include those new reported numbers in its report to the CDC. Schools are currently required to report immunization coverage status for their students to the Department for the Department to satisfy CDC requirements regarding reporting of immunizations. The additional paperwork requirements for the Commonwealth, including both the Department and the Department of Education, and the regulated community would be minimal since school districts already complete this annual report regarding the number of immunizations and follow up on provisional enrollment. School nurses, who perform recordkeeping and reporting requirements in schools, currently maintain and report this information. They would have additional time to make reports, since the reporting date has been extended by 2 months. The Department would provide reporting forms to schools, as it currently does, and the reports would be sent to the same Department office as the current reports. The Department proposes that schools who cannot report electronically may still report on paper, although it has proposed that these reports be due to the Department 2 weeks earlier than the electronic reports to allow for processing time.

School administrators would also be required to review medical certificates to allow students to attend school. However, school administrators currently are required to review an immunization plan, which contains similar information to the proposed medical certificate, although the plan does not need to be signed by a health care practitioner. The proposed rulemaking requires that the medical certificate be reviewed every 30 days to keep the child in school, and the current regulations allow for the

child to remain in school for 8 months, so that heightened scrutiny by the school administrator would be required. A closer review of that documentation would raise the level of compliance with the vaccination requirements and would, in turn, act to ensure the presence of herd immunity to protect those who cannot be vaccinated, and the public in general.

Local government

There is not an additional paperwork requirement for local government. The Department included school districts, which may be considered to be local government, under the "regulated community" heading.

General public

There is no additional paperwork requirement for the general public.

E. Statutory Authority

The Department obtains its authority to promulgate regulations regarding immunizations in schools from several sources. Section 16(a) of the Disease Prevention and Control Law of 1955 (35 P.S. § 521.16(a)) provides the Board with the authority to issue rules and regulations on a variety of matters regarding communicable and noncommunicable 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. Section 16(b) of the Disease Prevention and Control Law of 1955 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.

Section 2102(g) of The Administrative Code of 1929 (71 P.S. § 532(g)) gives the Department general authority for the promulgation of its regulations. Section 2111(b) of The Administrative Code of 1929 (71 P.S. § 541(b)) provides the 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 this Commonwealth. This subsection further provides that the regulations of the Board shall become the regulations of the Department.

The Department's specific authority for promulgating regulations regarding school immunizations is in The Administrative Code of 1929 (71 P.S. §§ 51—732) and the Public School Code of 1949 (24 P.S. §§ 1-101—27-2702). Section 2111(c.1) of The Administrative Code of 1929 provides the 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. This subsection 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 1303 of the Public School Code of 1949 (24 P.S. § 13-1303a) provides that the Board will make and review a list of diseases against which children must be immunized, as the Secretary may direct, before being admitted to school for the first time. This section provides that the school directors, superintendents, principals or other persons in charge of any public, private, parochial or other schools including kindergarten shall 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.

F. Effectiveness and Sunset Dates

The proposed rulemaking will become effective upon final-form publication in the *Pennsylvania Bulletin*. A sunset date has not been established. The Department will continually review and monitor the effectiveness of the regulations.

G. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on March 29, 2016, the Department submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form 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. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria in section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b) which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Department, the General Assembly and the Governor of comments, recommendations or objections raised.

H. Contact Person

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Cynthia Findley, Director, Division of Immunization, Department of Health, 625 Forster Street, Health and Welfare Building, Room 1026, Harrisburg, PA 17120, (717) 787-5681 within 30 days after publication in the *Pennsylvania Bulletin*. Persons with a disability who wish to submit comments, suggestions or objections regarding this proposed rulemaking may do so by using the previous number or address. Speech and/or hearing impaired persons may use V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800) 654-5984 (TT). Persons who require an alternative format of this document may contact Cynthia Findley so that necessary arrangements may be made.

KAREN M. MURPHY, PhD, RN,
Secretary

(Editor's Note: See 46 Pa.B. 1806 (April 9, 2016) for a proposed rulemaking by the State Board of Education relating to this proposed rulemaking.)

Fiscal Note: 10-197. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY
PART III. PREVENTION OF DISEASES
CHAPTER 23. SCHOOL HEALTH
Subchapter C. IMMUNIZATION

§ 23.82. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

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Certificate of immunization—The official form furnished by the Department. The certificate is filled out by the parent or health care provider and signed by the health care provider, public health official or school nurse or a designee. The certificate is given to the school as proof of full immunization. The school maintains the certificate as the official school immunization record or stores the details of the record in a computer data base.

Department—The Department of Health of the Commonwealth.

Full immunization—The completion of the requisite number of dosages of the specific antigens at recommended time and age intervals as set forth in § 23.83 (relating to immunization requirements).

Immunization—The requisite number of dosages of the specific antigens at the recommended time intervals under this subchapter.

Medical certificate—The official form furnished by the Department setting out the immunization plan for a student who is not fully immunized, filled out and signed by a health care provider, or by a public health official when the immunization is provided by the Department or a local health department, and given to a school as proof that the student is scheduled to complete the required immunizations.

Record of immunization—A written document showing the date of immunization—that is, baby book, Health Passport, family Bible, other states' official immunization documents, International Health Certificate, immigration records, physician record, school health records and other similar documents or history.

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§ 23.83. Immunization requirements.

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

[(1) **Diphtheria.** Four or more properly-spaced doses of diphtheria toxoid, which may be administered as a single antigen vaccine or in a combination form. The fourth dose shall be administered on or after the 4th birthday.

(2) **Tetanus.** Four or more properly-spaced doses of tetanus toxoid, which may be administered as a single antigen vaccine or in a combination form. The fourth dose shall be administered on or after the 4th birthday.]

(1) **Diphtheria, tetanus and pertussis.** Four or more properly-spaced doses administered in a combination form (diphtheria, tetanus and acellular pertussis (DTaP) or diphtheria, tetanus and pertussis (DTP)). If a child has a contraindication to pertussis, the child should receive diphtheria and tetanus vaccine (DT) to complete the vaccination series. The fourth dose shall be administered on or after the 4th birthday.

[(3)] (2) **Poliomyelitis.** [Three or more] Four properly spaced doses of either oral polio vaccine or enhanced activated polio vaccine, which may be administered as a single antigen vaccine, or in a combination form. [If a child received any doses of inactivated polio vaccine administered prior to 1988, a fourth dose of inactivated polio vaccine is required.] The fourth

dose shall be administered on or after the 4th birthday and at least 6 months after the previous dose.

[(4) *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 laboratory testing by a laboratory with the appropriate certification. Each dose of measles vaccine may be administered as a single antigen vaccine or in a combination form.

(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 laboratory testing by a laboratory with the appropriate certification. Rubella vaccine may be administered as a single antigen vaccine or in a combination form.

(6) *Mumps*. Two properly-spaced doses 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 or in a combination form.]

(3) *Measles (rubeola), mumps and rubella (German measles)*. One of the following:

(i) *Multiple antigens*. Two properly-spaced doses of live attenuated measles, mumps, rubella combination vaccine, the first dose administered at 12 months of age or older.

(ii) *Single antigens*. In the event the antigens were given separately, and not in a combination vaccine, the dosage is as follows:

(A) Two properly-spaced doses of live attenuated measles vaccine, the first dose administered at 12 months of age or older.

(B) One dose of live attenuated rubella vaccine, administered at 12 months of age or older.

(C) Two properly-spaced doses of live attenuated mumps vaccine, administered at 12 months of age or older.

(iii) *Evidence of immunity*. Evidence of immunity may be shown by a history of measles and rubella immunity proved by laboratory testing by a laboratory with the appropriate certification and a written statement of a history of mumps disease from a physician, nurse practitioner or physician's assistant.

[(7)] (4) *Hepatitis B*. Three properly-spaced doses of hepatitis B vaccine, unless a child receives a vaccine as approved by the Food and Drug Administration for a two-dose regimen, or a history of hepatitis B immunity proved by laboratory testing. Hepatitis B vaccine may be administered as single antigen vaccine or in a combination form.

[(8) *Chickenpox (varicella)*.] (5) *Varicella (chickenpox)*. One of the following:

(i) *Varicella vaccine*. Two properly-spaced doses of varicella vaccine, the first dose administered at 12 months of age or older. Varicella vaccine may be administered as a single antigen vaccine or in a combination form.

(ii) *Evidence of immunity*. Evidence of immunity may be shown by one of the following:

(A) Laboratory evidence of immunity or laboratory confirmation of disease.

(B) A written statement of a history of chickenpox disease from a [**parent, guardian or**] physician, **nurse practitioner or physician's assistant**.

(c) *Special requirements for tetanus and diphtheria toxoid and acellular pertussis vaccine and meningococcal vaccine*.

(1) *Required for entry into 7th grade*. In addition to the immunizations listed in subsection (b), the following immunizations are required at any public, private, parochial or nonpublic school in this Commonwealth, including vocational schools, intermediate unit, special education and home education programs, and cyber and charter schools as a condition of entry for students entering the 7th grade; or, in an ungraded class, for students in the school year that the student is 12 years of age:

[(1)] (i) *Tetanus and diphtheria toxoid and acellular pertussis vaccine [(Tdap)] (Tdap)*. [**One dose if at least 5 years have elapsed since the last dose of a vaccine containing tetanus and diphtheria as required in subsection (b). Tdap may be administered as a single antigen vaccine or in a combination form.**] **One dose of Tdap in a combination form.**

[(2)] (ii) *Meningococcal Conjugate Vaccine (MCV)*. One dose of [**Meningococcal Conjugate Vaccine**] MCV. [**MCV may be administered as a single antigen vaccine or in a combination form.**]

(2) *Required for entry into 12th grade*. In addition to the immunizations listed in subsections (b) and (c), one dose of MCV is required for entry into 12th grade at any public, private, parochial or nonpublic school in this Commonwealth, including vocational schools, intermediate unit, special education and home education programs, and cyber and charter schools, or, in an ungraded class, for students in the school year that the student is 18 years of age, if the child has not received a previous dose on or after the child's 16th birthday.

(d) *Child care group setting*. Attendance at a child care group setting located in a public, private or vocational school, or in an intermediate unit is conditional upon the child's satisfaction of the immunization requirements in § 27.77 (relating to immunization requirements for children in child care group settings).

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§ 23.85. Responsibilities of schools and school administrators.

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(e) *Provisional admittance to school*.

(1) *Multiple dose vaccine series*. If a child has not received all the antigens for a multiple dose vaccine series described in § 23.83, the child may [**be provisionally admitted to school only if evidence of the administration of at least one dose of each antigen described in § 23.83 for multiple dose vaccine series is given to the school administrator or the administrator's designee and the parent or guardian's plan for completion of the required immunizations is made part of the child's health record.**] **not be**

admitted to school, unless the child has at least one dose of each multiple dose vaccine series required under § 23.83, and one of the following occurs:

(i) The child receives the final dose of each multiple dose vaccine series required under § 23.83 within 5 school days of the child's first day of attendance, and the child's parent or guardian provides a certificate of immunization on or before the 5th school day.

(ii) If the child needs additional doses of a multiple dose vaccine series to meet the requirements of § 23.83, the child receives the next scheduled dose during the 5 school days referenced in subparagraph (i), and the child's parent or guardian provides a medical certificate scheduling the additional required doses on or before the 5th school day.

(iii) If the child needs additional doses of a multiple dose vaccine series to meet the requirements of § 23.83, but the next dose is not medically appropriate during the 5 school days referenced in subparagraph (i), the child's parent or guardian provides a medical certificate scheduling those additional doses on or before the 5th school day.

(2) *Single dose vaccines.* If a child has not received a vaccine for which only a single dose is required, [the child may be provisionally admitted to school if the parent or guardian's plan for obtaining the required immunization is made a part of the child's health record] the child may not be admitted to school.

(3) *Completion of required immunizations.* The [plan for completion of the required immunizations shall be reviewed every 60] medical certificate shall be reviewed at least every 30 days by the school administrator or the school administrator's designee. Subsequent immunizations shall be entered on the certificate of immunization or entered in the school's computer database. Immunization requirements described in § 23.83 shall be completed [within 8 months of the date of provisional admission to school. If the requirements are not met, the school administrator may not admit the child to school or permit continued attendance after that 8 month provisional period.] in accordance with the requirements of the medical certificate. If, upon review, the requirements of the medical certificate are not met, the school administrator may exclude the child from school.

(4) *Medical certificate.* A school shall maintain the medical certificate until the official school immunization record is completed.

(f) *Certificate of immunization.* A school shall maintain on file a certificate of immunization for a child enrolled. An alternative to maintaining a certificate on file is to transfer the immunization information from the certificate to a computer database. The certificate of immunization or a facsimile thereof generated by computer shall be returned to the parent, guardian or emancipated child or the school shall transfer the certificate of immunization (or facsimile) with the child's record to the new school when a child withdraws, transfers, is promoted, graduates or otherwise leaves the school.

(g) *Applicability.* This section does not apply to a child if either of the following occur:

(1) The child has not been immunized or is unable to provide immunization records due to being

homeless. A school shall comply with Federal laws pertaining to the educational rights of homeless children, including the McKinney-Vento Homeless Education Assistance Improvements Act of 2001 (42 U.S.C.A. §§ 11431—11435).

(2) The child, when moving or transferring into a school within this Commonwealth, is unable to provide immunization records immediately upon enrollment into the school. The child's parent or guardian shall have 30 days to provide immunization records to the school to show proof of immunization as set forth in § 23.83, or to satisfy the requirements for an exemption as set forth in § 23.84.

(h) *Temporary waiver.* The Secretary may issue a temporary waiver of the immunization requirements in § 23.83. The details of the temporary waiver will be set out in a notice published in the *Pennsylvania Bulletin*. A temporary waiver may be issued under either of the following circumstances:

(1) The Centers for Disease Control and Prevention, United States Department of Health and Human Services, recognizes a Nationwide shortage of supply for a particular vaccine.

(2) In the event of a disaster impacting the ability of children transferring into a school to provide immunization records.

§ 23.86. School reporting.

(a) A public, private, parochial or nonpublic school in this Commonwealth, including vocational schools, intermediate units, special education and home education programs, and cyber and charter schools, shall report immunization data to the Department electronically by [October 15] December 31 of each year[,] using [forms] a format and system provided by the Department.

(b) In the event a public, private, parochial or nonpublic school cannot complete its report electronically, it shall report to the Department by December 15 of each year using a form provided by the Department.

[(b)] (c) The school administrator or the administrator's designee shall forward the reports to the Department as indicated on the reporting form provided by the Department.

[(c)] (d) Duplicate reports shall be submitted to the county health department if the school is located in a county with a full-time health department.

[(d)] (e) The school administrator or the administrator's designee shall ensure that the school's identification information, including the name of the school, school district, county and school address, is correct, and shall make any necessary corrections, prior to submitting the report.

[(e)] (f) Content of the reports must include the following information:

* * * * *

(7) [The number of students in each grade level who were denied admission because of the student's inability to qualify for provisional admission or, in an ungraded school, in each age group as indicated on the reporting form.] The number of students in kindergarten, 7th grade or in an un-

graded school, 12 years of age only, who were denied admission because of the student's inability to provide documentation of the required vaccine doses.

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[Pa.B. Doc. No. 16-594. Filed for public inspection April 8, 2016, 9:00 a.m.]

STATE BOARD OF EDUCATION

[22 PA. CODE CH. 11]
Nonimmunized Children

The State Board of Education (Board) proposes to amend Chapter 11 (relating to student attendance) to read as set forth in Annex A. The Board is acting under the authority of sections 2603-B and 2604-B of the Public School Code of 1949 (24 P.S. §§ 26-2603-B and 26-2604-B).

Purpose

Section 11.20 (relating to nonimmunized children) is proposed to be amended for clarity and for consistency with a proposed rulemaking of the Department of Health (Department) amending 28 Pa. Code Chapter 23, Subchapter C (relating to immunization). See 46 Pa.B. 1798 (April 9, 2016).

Background

Currently, a child in this Commonwealth may not be admitted or permitted to attend school unless the child has met the immunization requirements established by the Department, which also provide for medical or religious exemptions from immunizations. A child who has not received all doses of required immunizations may be provisionally admitted for up to 8 months. Provisional admission is contingent upon the child completing the remaining required immunization doses per a plan crafted for the child. Administrators at the child's school are responsible for reviewing the child's plan for receiving the necessary vaccinations every 60 days.

Summary of the Proposed Rulemaking

The proposed rulemaking makes clarifying amendments to § 11.20(a). The proposed amendments delete language that is duplicative to requirements established by the Department in 28 Pa. Code § 23.84 (relating to exemption from immunization) and maintain the requirement for students to comply with the immunization regulations established by the Department to be admitted or permitted to attend school. Further, the proposed amendments would allow a student who is unable to provide documentation of full immunization to attend a public, private, nonpublic, special education or vocational school under certain circumstances when the Secretary of Health issues a temporary waiver of the immunization requirements. The reference to a temporary waiver is proposed to be added for consistency with the Department's proposed rulemaking amending 28 Pa. Code Chapter 23, Subchapter C that would establish a temporary waiver to immunization requirements that could be issued by the Secretary of Health in the event of a Nationwide vaccine shortage or in the event of a disaster.

Existing § 11.20(b) is proposed to be deleted to eliminate duplication with requirements established by the

Department in 28 Pa. Code Chapter 23, Subchapter C, which is currently cross-referenced in § 11.20(a).

Affected Parties

The proposed rulemaking would affect public, private, parochial and nonpublic schools, including vocational schools, intermediate units, and special education and home education programs, cyber and charter schools, and their employees. The proposed rulemaking also would affect citizens of this Commonwealth with school-aged children and their children.

Cost and Paperwork Estimates

The proposed rulemaking makes amendments for clarity and for consistency with the proposed rulemaking by the Department. The Board's proposed rulemaking does not establish new requirements that carry an additional cost or create new paperwork requirements for the regulated community.

Effective Date

The proposed rulemaking will become effective upon final-form publication in the *Pennsylvania Bulletin*.

Sunset Date

The Board will review the effectiveness of § 11.20 every 4 years in accordance with the Board's policy and practice respecting its regulations. Therefore, a sunset date is not necessary.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on March 29, 2016, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Committees on Education. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria in section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b) which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

Public Comments and Contact Person

Interested persons and individuals affiliated with small businesses are invited to submit written comments, questions, suggestions, commendations, concerns or objections regarding this proposed rulemaking to Karen Molchanow, Executive Director, State Board of Education, 333 Market Street, Harrisburg, PA 17126, ra-stateboardofed@pa.gov. Comments shall be submitted to the Board within 30 days of publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

Persons with disabilities needing an alternative means of providing public comment may make arrangements by calling Karen Molchanow, (717) 787-3787 or TDD (717) 787-7367.

KAREN MOLCHANOW,
Executive Director

Fiscal Note: 6-336. No fiscal impact; (8) recommends adoption.

Annex A
 TITLE 22. EDUCATION
 PART I. STATE BOARD OF EDUCATION
 Subpart A. MISCELLANEOUS PROVISIONS
 CHAPTER 11. STUDENT ATTENDANCE
 ADMISSION TO PUBLIC SCHOOLS

§ 11.20. Nonimmunized children.

(a) A child may not be admitted to or permitted to attend a public, private, nonpublic, special education or vocational school [in a district] unless the immunization, exemption, temporary waiver or provisional admission requirements of the Department of Health, at 28 Pa. Code Chapter 23, Subchapter C (relating to immunization), have been met [or the child has received from the chief school administrator of the public, private, nonpublic, special education or vocational school a medical or religious exemption from immunization under 28 Pa. Code § 23.84 (relating to exemption from immunization)].

[(b) A child who has not received all doses of the required immunizations or who has not been ex-

empted from immunization, but who has received at least one dose of each of the required immunizations, may be provisionally admitted and attend public school for a period of up to 8 months. Provisional admission or continued attendance shall be conditioned upon the parent or guardian's submission to the superintendent of a plan for the student's completion of the required immunization doses. The plan shall be reviewed by the school district at least every 60 calendar days. If, after 8 months, the child has not received all doses of the required immunizations, the child thereafter may not be further admitted to or be permitted to attend the public schools until all doses have been received.

(c)] (b) A child who has been admitted to school or permitted attendance in violation of this section may not be counted toward receipt of Commonwealth reimbursement for the period of the admission or attendance.

[Pa.B. Doc. No. 16-595. Filed for public inspection April 8, 2016, 9:00 a.m.]