Regulatory Analysis Form

(Completed by Promulgating Agency)

IRRC

Independent Regulatory Review Commission

SECTION I: PROFILE

(1) Agency:

Department of Health

(2) Agency Number: 10

Identification Number: 181

IRRC Number: 2672

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INDEPENDENT REGULATORY REVIEW COMMISSION

(3) Short Title:

School Immunization Requirements

(4) PA Code Cite:
28 Pa. Code §§ 23.83 & 23.86; 28 Pa. Code § 27.77

(5) Agency Contacts (List Telephone Number, Address, Fax Number and Email Address):

Primary Contact: Heather Stafford, RN, BSN, Director,
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717-787-5681

Secondary Contact: Alexandra McFall, RN, BSN
Division of Immunizations
717-787-5681

(6) Primary Contact for Public Comments (List Telephone Number, Address, Fax Number and Email Address) – Complete if different from #5:

(All Comments will appear on IRRC'S website)

Regulatory Analysis Form

(7) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- √ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

(8) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The amendments set out the immunization requirements for children to attend school and enter the seventh grade in the Commonwealth. These amendments revise existing regulations relating to school immunization requirements and require that: (1) for attendance at school, all students must have been immunized with four doses of a tetanus and diphtheria vaccine, three doses of hepatitis B vaccine and have varicella immunity (these requirements were previously required for entry into kindergarten or first grade and/or required for entry into the seventh grade only); (2) a documented dose of TdaP vaccine for all students entering school at the seventh grade or at 12 years of age in an ungraded class if at least five years have elapsed since the last dose of a vaccine containing tetanus and diphtheria toxoid; (3) one dose of MCV for students in the seventh grade; or at 12 years of age in an ungraded class, and (4) a four-day grace period for vaccine administration. The amendments also institute ACIP recommendations regarding an additional dose requirement for mumps and for varicella vaccine.

Further, the amendments revise the school immunization reporting requirements to require schools to report student's immunization status by doses of individual antigens. All categories of schools, including private, parochial, public, nonpublic and vocational schools, and intermediate units and special education programs, home education programs and cyber and charter schools are required to comply with these amendments. The amendments do not affect existing provisional enrollment provisions or religious and medical exemptions that are currently included in law and regulation.

Finally, the amendments also clarify what immunization requirements apply to children attending child care group settings located in a school. In addition, the amendments clarify that children in a school district operated pre-Kindergarten program, Early Intervention program's early childhood special education classrooms, and in a private academic pre-school are required to obtain appropriate immunizations as a condition of attending those programs.

(9) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments: N/A

B. The date or dates on which public meetings or hearings will be held: October 20, 2005, May 23, 2007; December 8, 2009

C. The expected date of promulgation of the proposed regulation as a final-form regulation: July 2010

D. The expected effective date of the final-form regulation: August 1, 2011

E. The date by which compliance with the final-form regulation will be required: School year 2011/2012

F. The date by which required permits, licenses or other approvals must be obtained: N/A

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

The Department will review the amendments as well as the remainder of the regulations relating to school immunization requirements on a periodic basis.

(11) State the statutory authority for the regulation. Include specific statutory citation.

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 (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 non public 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.

(12) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

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

(13) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

These amendments are intended to prevent dangerous communicable diseases in school-aged children. The required three doses of hepatitis B vaccine and varicella immunity for all grades, previously a requirement for entry into kindergarten or first grade and a requirement for entry into the seventh grade, will ensure protection against these diseases for students who transfer into grades after school entry and

especially for students prior to graduation. The requirement for school entry in these grades was intended as a means to phase in these requirements rather than requiring immediate compliance in all grade levels. The requirement for four doses of a tetanus and diphtheria vaccine was first implemented in 1998 for entry into kindergarten or first grade. Ensuring that all students have four doses will help ensure continued immunity against these diseases with older school children who would be affected by waning immunity of their primary immunization series. In 1998, the four-dose tetanus and diphtheria toxoid and hepatitis B immunization requirement for entry into kindergarten or first grade was implemented; in 2002 the varicella immunity requirement for entry into kindergarten or first grade and for entry into seventh grade was implemented.

Children complete their routine series of tetanus and diphtheria toxoid and acellular pertussis (TdaP) vaccinations at four to six years of age. Data suggest that immunity to these diseases declines among children after six years from the initial series of vaccinations. Pertussis (whooping cough) is the most prevalent vaccine preventable disease among older children and adolescents and is easily transmitted to infants who are not immunized or are only partially immunized. A TdaP immunization at seventh grade or at age 12 years in an ungraded class would ensure continued immunity against these diseases in adolescents and help prevent infection in infants. The meningococcal conjugate vaccine is recommended by the Centers for Disease Control and Prevention (CDC) for adolescents (defined as persons 11-12 years old) since the meningococcal disease fatality rate is highest in adolescents. In addition, the second peak incidence of invasive meningococcal disease occurs in adolescents. A requirement for meningococcal conjugate vaccine at seventh grade or at 12 years of age in an ungraded class works to protect the adolescent population from serious disease injury or death from meningococcal disease.

The Department is also requiring that, in order to attend school, children must have 2 properly spaced doses of varicella vaccine administered at 12 months of age or older. (See paragraph (8)(i)(A)). At the present time, only children entering the 7th grade who are 13 years of age or older are required to have the second varicella dose. At the beginning of school year 2011/2012, all children will be required to have 2 properly spaced doses of varicella vaccine in order to attend school. The Department believes that delaying implementation of the regulation until school year 2011/2012 will be sufficient to allow schools and students to prepare for and be compliant with the new immunization requirements. For example, the varicella vaccine has been licensed since 1995, and a one dose requirement of the vaccine for school attendance has been in place since 2001. Most children, therefore, already have received one dose of the vaccine. Further, the recommendation for a second dose of varicella was issued by ACIP in 2007, and many doctors are already giving the second dose as a result of these recommendations. In addition to the extended delay before implementation, the school immunization regulations of both the Department and DOE provide that a child may attend school so long as he or she has one dose, and then receives subsequent doses within an 8 month provisional period, (See 28 Pa. Code § 23.83(e) (relating to immunization requirements); 22 Pa. Code § 11.20 (relating to nonimmunized children) and 22 Pa. Code § 51.13 (relating to immunizations)), the regulation will not cause hardship to children by causing their immediate exclusion from school. This applies in the case of the new requirements for MCV and TdAP as well as for the second varicella dose.

Further, the Department has added a second mumps dose for children in grades kindergarten through 12, in accordance with ACIP recommendations. Both of these requirements are intended to prevent breakthrough disease, a problem the Commonwealth encountered with recent mumps outbreaks in previously vaccinated children.

The amendments also include a grace period for the provision of immunizations. The 4-day grace period allows a vaccine dose administered 4 days before the minimum interval between doses or before the appropriate age is reached to be counted as a valid dose. There is no scientific basis that a vaccine must be given with a strict interval between doses or at an exact age or the vaccine is ineffective or unsafe. The CDC published recommendations in the February 8, 2002 Morbidity and Mortality Weekly Report (MMWR) to allow less than or equal to a 4 day minimal interval and age limit for a valid dose of vaccine administration. On March 9, 2002, the Department provided notice of its intention to revise the school immunization regulations to take into account this recommendation through a publication of notice in the *Pennsylvania Bulletin.* (32 Pa. B. 1305 (March 9, 2002)).

Further, the Department has clarified when the requirements relating to school immunization apply and when the requirements relating to childcare group settings apply. This clarification serves an important public health purpose in ensuring that children not yet attending Kindergarten or first grade but who are still surrounded by other children, both older and younger, are protected from potentially dangerous diseases, and that those with whom they come in contact outside a school setting are protected as well.

Lastly, the Department is amending its regulations to change the manner in which schools are required to report immunizations. This alteration in reporting procedures follows changes in the CDC's requirements for states regarding immunization reporting for school students. Currently, the CDC requires annual immunization reporting for school students. The CDC is now requiring this reporting to include the status of the number of doses of individual antigens. The amendments comply with these anticipated CDC school immunization-reporting requirements.

Those children and adolescents who, because of the amendments, will be immunized and will not contract these diseases and suffer discomfort, miss school, or succumb to death, benefit from these amendments. The parents of those children and adolescents who will not have to miss work, worry, pay medical bills, and tend to their sick children also benefit from these amendments. Studies have reported parents lose an average of six days of work to care for an ill child with pertussis and an average cost of $767 for loss of productivity. 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 benefit from these amendments. Taxpayers who will not have to support expensive disease intervention activities; and the health care system, that might have to absorb the cost of some of the direct and indirect effects of these diseases, also benefit.

(14) If scientific data, studies, references are used to justify this regulation, please submit material with the regulatory package. Please provide full citation and/or links to internet source.

The following is a link to CDC MMWRs on the Immunization home page:

http://www.cdc.gov/vaccines/pubs/ACIP-list.htm

(15) Describe who and how many will be adversely affected by the regulation. How are they affected?

Those parents or guardians whose health care plans do not cover immunizations, and for whom payment is a hardship are affected unless they obtain other assistance. This may be alleviated to some extent by the Department's provision of these vaccines at no charge or at a charge based on a sliding fee scale. School districts and staff who must verify whether a child's immunizations are up to date have additional immunizations to review, and may consider themselves as adversely affected by these amendments. Those children who suffer the rare adverse reaction to a required immunization and their parents or guardians may also be adversely affected.

(16) 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, those persons who would be required to comply with the amendments are parents and guardians whose adolescent children have not received a Td immunization for at least five years; those adolescents who never had the meningococcal conjugate vaccine; and those students who missed the school entry and seventh grade entry requirements for hepatitis B immunizations and varicella immunity. This could affect approximately 150,000 adolescents entering the seventh grade in the Commonwealth on an annual basis; and those students who need catch-up immunizations to have four doses of a tetanus and diphtheria toxoid vaccine, three doses of hepatitis B vaccine and varicella immunity.

School districts and their staff that who will have to enforce the additional seventh grade requirements and the additional all grades requirements will be required to comply with these amendments.

SECTION III: COST AND IMPACT ANALYSIS

(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 which may be required. Explain how the dollar estimates were derived.

To implement the all grades requirement for expansion of hepatitis B immunizations, varicella immunity and a tetanus and diphtheria vaccine, the estimated cost to the regulated community is approximately $40 million; while estimated savings for the regulated community amount to $209 million. Savings are based on 1997 CDC data, which concludes that $29.10 is saved for every dollar spent on Diphtheria/Tetanus/Pertussis (DTP) vaccine; $2.10 is saved for every dollar spent on hepatitis vaccine; and $5.40 is saved on every dollar spent on varicella vaccine. There are no studies available for savings realized from the MCV, however, if the vaccine serves to spare one adolescent from serious disease injury or death it well justifies this amendment.

(18) Provide a specific estimate of the costs and/or savings to **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

These regulations have no fiscal impact on local governments. Cost savings may 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 regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

The Commonwealth would incur some costs for the purchase of TdaP and meningococcal conjugate vaccines; as well as additional Td, hepatitis B and varicella vaccines. Though all vaccines are paid for through federal immunization grant funds, this is not a limitless funding stream. The Department of Public Welfare will 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 medical follow-up for exposed, susceptible individuals.

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(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.

SAVINGS:	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
Regulated Community	**$**	**$**	**$**	**$**	**$**	**$**
Local Government		188,042,562	188,042,562	188,042,562	188,042,562	188,042,562
State Government						
Total Savings						
COSTS:		188,042,562	188,042,562	188,042,562	188,042,562	188,042,562
Regulated Community						
Local Government		38,149,043	13,352,165	13,352,165	13,352,165	13,352,165
State Government	$0					
Total Costs		2,943,037	1,177,215	1,177,215	1,177,215	1,177,215
REVENUE LOSSES:		**41,092,080**	**14,529,380**	**14,529,380**	**14,529,380**	**14,529,380**
Regulated Community						
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
(20a) Provide the past three year expenditure history for programs affected by the regulation.	$ 0	0	0	0	0	0

Program				
Immunization	FY -3	FY -2	FY -1	Current FY
	$7,881,993	$8,039,909	$8,417,248	$11,571,000

(21) Explain how the benefits of the regulation outweigh any cost and adverse effects.

The expenditure history figures shown above in item 20 are not cost-benefit data. They are gross expenditures for the program excluding direct assistance received from the CDC for vaccines. The only additional costs the Immunization Program must incur because of the amendments are for the purchase of vaccine. The cost to the public, the regulated community and to state and local government, that would be prevented by the implementation of these amendments, and the lives of children and of adults in the Commonwealth that would be saved by the prevention of these vaccine preventable diseases outweighs any adverse effect and cost incurred.

In determining costs related to the implementation of these amendments, the Department considered cost to the regulated community to be realized by the number of children (90%) in an age cohort who would be required to pay out of pocket for these immunizations. The state government costs are realized by the number of children (10%) in an age cohort who would get the immunizations through the Department because they have no other source of obtaining the required immunizations. The Department currently purchases all vaccines with funding from the federal government. Children who already have the immunizations would not be a part of these percentages, nor would the children who received the vaccine within two years of entering seventh grade. Presumably they will 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 are approximately 150,000 children per grade cohort. Children who might need catch-up hepatitis B and varicella immunizations include those in 4^{th}, 5^{th}, 6^{th}, 7^{th}, 11^{th} and 12^{th} grades. A 1998/1999 school survey (a survey completed prior to the seventh grade requirement being implemented) reported that 80% of middle school students were not immunized with the hepatitis B vaccine. Therefore, assuming that 80% of all school children who missed the kindergarten and seventh grade requirement are still not immunized, approximately 480,000 children will need catch-up immunizations. An estimated 90% or 432,000 children would obtain their immunizations in the regulated community at a cost of $23.00 per

dose of vaccine. This amounts to a total cost of $9,936,000. An estimated 10% or 48,000 children would obtain their immunizations from the State at a cost of $9.00 per dose. This amounts to a total cost of $432,000. An assumption is made that 30% of all students who missed the kindergarten and seventh grade requirement are still not immunized or have varicella immunity. Therefore, approximately 270,000 school children would need varicella immunizations with 90% or 243,000 obtaining them from the regulated community at a cost of $66.81 per dose (a total of $16,234,830), and 10% obtaining them from the State at a cost of $52.25 per dose (a total of $1,410,750).

School children entering the seventh grade will need to be immunized with TdaP and MCV. Based on a 2007 school immunization report, for seventh grade students it was reported that 47% of those children were not immunized within the last five years with a Tetanus diphtheria (TD) containing vaccine. An estimated 70,500 seventh grade children would need immunizations with the TdaP vaccine with 90% of those children obtaining them from the regulated community at $35.25 per dose This amounts to a total of $2,236,613. An estimated 10% or 7,050 children would obtain them from the State at a cost of $28.75 per dose. This amounts to a total of $202,687. There are no available studies to determine how many seventh grade children are immunized with the MCV; however it is estimated that 88% or 132,000 seventh grade children are not immunized with MCV. Therefore, an estimated 90% or 118,800 children would obtain the MCV from the regulated community at $82.00 per dose (a total of $9,741,600), and 10% would obtain the MCV from the State at $68.00 per dose (a total of $897,600).

There should be no additional costs for continuing the four day grace period or for implementing the revised reporting requirements.

It should also be noted that the Immunization Program is 100% federally funded.

(22) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

The impetus for these school immunization regulatory revisions stems from the CDC's Advisory Committee on Immunization Practices (ACIP). On June 30, 2005, ACIP recommended the routine use of TdaP in adolescents aged 11-18 years of age. ACIP further recommended that the preferred age for the TdaP immunization, if at least two years have passed, is 11-12 years of age. In addition, the Healthy People 2010 Objectives, intended to increase vaccination coverage levels for adolescents ages 13-15, sets the goal that 90% of the adolescent population should be immunized with a Td vaccine in the age range. In 2005, ACIP recommended the routine vaccination with meningococcal conjugate vaccine of children 11-12 years old. In 2002, the ACIP also recommended allowing a dose of vaccine administered less than or equal to four days of the minimal interval between doses and age limit to be considered a valid dose of administered vaccine.

In preparation for drafting these amendments as proposed, the Department had two meetings with the School Services Unit, Office of Elementary and Secondary Education of the Department of Education, and a stakeholders meeting with key individuals from school and medical professional organizations to discuss proposed revisions to the school immunization regulations. The Department sought the advice

and input of Department of Education and the Office of Childhood Development and Early Learning on its final rulemaking. They are in agreement with these amendments.

A stakeholders meeting was held on October 20, 2005, to gain input from key individuals involved in the education and school systems, the public and private provider community and the managed care and insurance entities.

The Department convened a meeting with the Advisory Health Board to provide an overview of the proposed changes on May 23, 2007. The Advisory Health Board approved the proposed changes.

The Department published proposed rulemaking in the Pennsylvania Bulletin on February 9, 2008 and provided a 30-day public comment period. The title under which the amendments were published failed to include reference to school immunization and only mentioned communicable and noncommunicable diseases and this could have created confusion among potential commentators so the Department extended the public comment period an additional 2 weeks with correct title.

The Department received comments from two commentators as well as IRRC. The Department reviewed those comments, and provided responses in its Preamble to Final Rulemaking. The Department also requested review of the final amendments from the Department of Education, as it had for the proposed rulemaking. The Department of Education is in agreement with this final rulemaking.

On December 1, 2009, the Department held a second meeting of the Advisory Health Board to review the changes to the proposed regulations in light of the comments provided. The Advisory Health Board approved the final rulemaking at that meeting.

(23) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory provisions were considered. The Department is required by law to amend the list of diseases against which school children are required to be immunized through regulation. Vaccination programs that focus on infants and children have decreased the occurrence of childhood vaccine preventable diseases. However, many adolescents continue to be adversely affected by vaccine preventable diseases because vaccination programs have not focused on improving vaccination coverage among adolescents. 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. Tetanus and diphtheria, although rare, carry the risks of serious illness and even death. Pertussis is the most prevalent vaccine preventable disease among adolescents and adults. Meningococcal disease strikes up to 3,000 Americans, killing 300 people every year. Meningococcal disease is particularly dangerous because it progresses rapidly and can kill within hours. Since the school environment is conducive to the contracting and transmission of diseases among children with no immunity, failure to immunize properly puts children at risk for contracting these debilitating diseases, and 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. In promulgating these regulations, the Department has chosen the least burdensome acceptable alternative.

(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 regulations.

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? How will this affect Pennsylvania's ability to compete with other states?

According to the 2006-2007 State Immunization Requirements published by the CDC:

- 46 states have varicella requirements for elementary and/or middle school.
- 46 states have hepatitis B requirements for elementary and/or middle school.
- 27 states have tetanus and diphtheria requirements for middle school.
- To date, two states, Texas and Arizona have school requirements for MCV, and several states are in the process of implementing requirements similar to those being proposed by the Department in this proposed rulemaking.

Within the Commonwealth, 2 local health departments, which have the authority to promulgate reglations relating to immunizations so long as they are more stringent than the Department's regulations, have required MCV and TdaP for school students. Allegheny County Health Department requires the vaccine for students entering seventh through twelfth grade; as of the 2008/2009 school year, Philadelphia Department of Public Health requires students entering sixth grade to have the vaccines.

These regulations have no impact on the Commonwealth's ability to compete with other states.

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

These amendments do not adversely affect other existing regulations or amendments of the Department or other state agencies. The Department sought the advice and input of Department of Education and the Office of Childhood Development and Early Learning on its final rulemaking. They are in agreement with these amendments.

(27) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

Schools will be required to report in accordance with the new reporting requirements, and the Department will need to review and include those new reported numbers in its report to the CDC. The additional paperwork requirements for the Commonwealth, including both the Department and PDE, and the regulated community is minimal, since school districts already complete an annual report regarding the number of immunizations and follow up on provisional enrollment. Schools are currently required to report immunization rates to the Department in order for the Department to satisfy CDC requirements relating to reporting of immunizations. School nurses, who perform record keeping and reporting requirements in the schools, currently maintain and report this information. The CDC, however, changed these requirements. Currently, the CDC requires reporting to include the status of the number of doses of individual antigens that have been administered to students. The amendments are intended to comply with these CDC school immunization-reporting requirements. The Department provides reporting forms to schools, as it currently does, and the reports would be sent to the same Department area as the current reports.

(28) 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.

The vaccines are available from the Department and from the County and Municipal Health Department clinics located in each county of the state, at low or no cost to the parent. Vaccines are made available at no cost to private providers enrolled in the Vaccines For Children (VFC) Program for children through 18 years of age who have no insurance, who are Medicaid eligible or who are Alaskan Native or American Indian. In addition, VFC Program vaccine is also made available to other public clinic sites (Federally Qualified Health Centers and Rural Health Clinics) for the same population as indicated above but also for underinsured children through 18 years of age. Vaccines are made available to schools at no cost through the Department's School Based Catch Up Program for those students who have no medical home or are unable to seek the immunization through a public clinic site. Insurance plans subject to the Childhood Immunization Insurance Act (40 P.S. §§ 3501-3508) also provide coverage for ACIP-recommended vaccines.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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REVIEW COMMISSION

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or independent Agencies.
BY _____ DEPUTY ATTORNEY GENERAL	DEPARTMENT OF HEALTH (AGENCY)	BY Andrew C. Clark
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-181	MAR 19 2010 DATE OF APPROVAL
	DATE OF ADOPTION: _____	(Deputy General Counsel) ~~(Chief Counsel, Independent Agency)~~ ~~(Strike inapplicable title)~~
9 Check if applicable. Copy not approved. Objections attached.	BY: EVERETTE JAMES TITLE: SECRETARY OF HEALTH	9 Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING

TITLE 28. HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 23]

SCHOOL HEALTH

Subchapter C. Immunization

[28 PA. CODE CH. 27]

COMMUNICABLE AND NONCOMMUNICABLE DISEASES

Section 27.77. Immunization requirements for children in child care group settings

Notice is hereby given that the Department of Health (Department), with the approval of the State Advisory Health Board (Board), hereby adopts amendments to amend 28 Pa. Code Chapter 23, Subchapter C (relating to immunization) and 28 Pa. Code § 27.77 (relating to immunization requirements for children in child care group settings). The amendments are to read as set forth in Annex A.

I. PURPOSE AND BACKGROUND

The regulation amends immunization requirements that children seeking to enter and attend school in the Commonwealth must meet, and 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 regulation is intended to control the spread of diseases in schools, which are known to be ideal settings for the transmission of communicable 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. Further, 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. There is less chance of other persons contracting a highly infectious disease if children are vaccinated and less chance of outbreaks of contagious diseases occurring.

The amendments combine the immunization requirements in § 23.83 (relating to immunization requirements) for school entry into kindergarten or first grade with immunization requirements for school attendance in all grades; and add two new immunization requirements for entry into the seventh grade. The Department reviewed the recommendations of the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and determined that certain ACIP recommendations would serve to meet the needs of the Commonwealth with respect to requirements for school immunizations. The amendments require that students be immunized with the hepatitis B vaccine (previously required for entry into either kindergarten or first grade and entry into the seventh grade) before entering school; and that students entering the seventh grade be immunized with the tetanus, diphtheria and acellular pertussis (TdaP) vaccine, if at least 5 years has elapsed since their last tetanus and diphtheria-containing immunization. The amendments also require that children entering the seventh grade be immunized with the meningococcal conjugate vaccine (MCV).

The amendments also institute ACIP recommendations regarding an additional dose requirement for mumps vaccine and for varicella vaccine. The existing requirement for varicella immunity upon school entry and for entry into the seventh grade will now be an all-grades requirement. Further, the amendments also clarify what immunization requirements apply to children under the age of 5 years attending child care group settings located in a school. They also make it clear that children in a school district operated pre-kindergarten program, early intervention program operated by a contractor or subcontractor (this includes districts, intermediate units and private vendors), and in a private academic pre-school, are required to obtain age-appropriate immunizations as a condition of attending those programs.

Finally, the proposed amendments add a four-day grace period for vaccine administration, also in accordance with recommendations of ACIP, and revise the Department's requirements for school reporting of immunizations in § 23.86 (relating to school reporting).

The Department published proposed rulemaking in the Pennsylvania Bulletin on February 9, 2008 and provided a 30-day public comment period. (See 38 Pa.B. 750 (Feb. 9, 2008). Because the title under which the proposed regulations were published failed to include reference to school immunization and only mentioned communicable and noncommunicable diseases, and this could have created confusion among potential commentators, the Department extended the public comment period an additional 2 weeks. (See 38 Pa. B. 1150 (March 8, 2008)). The Department received comments from only two commentators and from IRRC. The comments and the Department's responses to them appear in the summary of this final rulemaking.

II. SUMMARY

General Comments

IRRC and one commentator raised the question of whether the Department could simply adopt ACIP's recommendations regarding vaccinations by reference, and avoid the need for the Department's updating of regulations every time ACIP makes a change to its recommendations. If the Department chose not to do so, IRRC recommended that the Department carefully consider the commentator's other recommendations, and warned that IRRC would review the Department's responses in determining whether or not the regulation met the criteria in section 5.2 of the Regulatory Review Act.

The Department has considered this particular comment with regard to ACIP's recommendations on several previous occasions, and after reviewing its previous responses, will not revise the regulations as the commentator has requested.

In determining what immunizations to require for school attendance, the Department reviews ACIP's guidelines and recommendations. The Department does not, however, typically or uniformly accept or adopt all of ACIP's recommendations, either for the immunizations the Department will require, or for the standards applicable to those immunizations. ACIP's recommendations are helpful and often definitive but may not take into consideration issues that may be important to the adopting state jurisdiction. Because ACIP's recommendations are based on the purely public health reason of protecting children from every possible disease, the group does not take into account the possibility of community reaction, nor should it. Practitioners, too, seeking to recommend the best health practices to their patients, are not constrained by the need to accept and review public comment regarding the efficacy and necessity of obtaining a particular vaccine. The Department, through these regulations, however, is in the position of mandating that a child obtain a particular disease vaccine or be denied access to the educational system for some period of time. To that end, the Department must allow for the public to review and present its concerns regarding such a mandate. To have adopted the ACIP recommendations without further review would have mandated the provision of HPV to all boys and girls attending school without allowing for public comment. Regardless of one's position with respect to the efficacy of and necessity for receiving this vaccine, it must be acknowledged that this particular vaccine has given rise to some controversy and concern in the public. In addition, there are groups of individuals who strongly disagree with any immunization of children. Regardless of one's view of this issue, in the context of a regulation that requires immunizations for school

attendance, rather than recommending them for personal health reasons, these persons, too, should have a meaningful opportunity to voice their concerns.

Adopting ACIP recommendations upon their issuance would raise other issues. Some immunizations for diseases that are not prevalent in the Commonwealth would involve unnecessary cost to patients. For example, with respect to the hepatitis A vaccine, although ACIP is careful to recommend vaccination against hepatitis A in states that are considered to be at high risk, a simple adoption of ACIP requirements would be insufficient to fully explain to the regulated community, that is, children, parents and guardians, and schools, whether the immunization is or is not required. These persons are unlikely to know that the state is, in fact, not considered to be a high risk state for this disease due to low prevalence of hepatitis A disease. This would necessitate additional guidance from the Department in some form. While the issuance of additional guidance does not, at first glance, appear to be overly burdensome, it is not the effect on the Department that raises the issue here. The Department attempts to make its school immunization regulations as simple as possible, to aid schools and school nurses in their responsibilities to make certain only children who are appropriately vaccinated are attending schools. To this end, the Department attempts to limit the number of communications with respect to existing requirements. ACIP issues recommendations 3 times a year, however, and adopting ACIP recommendations wholesale would require schools and school nurses to review children for the appropriate vaccine requirements at least 3 times each year to ensure compliance with recommended changes.

Adopting ACIP's recommendations, without being able to review and affirmatively accept each one, with whatever modifications deemed necessary, would inhibit the flexibility needed by the Department to apply its and the Board's expertise to the question of what immunizations are appropriate as a condition of school attendance. This requires a balancing of the importance of the immunization to Pennsylvania children in preventing morbidity and mortality, versus the burden the requirements would place upon schools, parents, and the community.

In fact, the legislature has recognized the Department and the Board as authoritative on the issue of immunizations. In the Disease Prevention and Control Law of 1955, (see section 16(a)(6) (35 P.S. 521.16(a)(6)), the Administrative Code of 1929, (see section 2111(c.1) (71 P.S. §541(c.1)), and the School Code of 1949, (see section 1303a (24 P.S. §13-1303a(a)), the legislature has authorized the Department, with the Board, without reference to ACIP, to create a list of diseases against which children must be immunized. To cede this authority to create a list of diseases to a federal advisory committee that has no rulemaking authority or responsibility, and whose recommendations are not subject to a rigorous rulemaking process prior to issuance, is not in accord with the General Assembly's direction to the Department. It is the Department's responsibility, with the approval of the Board and the necessary state regulatory review bodies, including the legislature, to determine when and how to add required immunizations to the list. The Department may review standards from groups with expertise in the matters the Department is seeking to regulate, and may consult with those groups as well. In fact, the Department has done, and continues to do, just that in many areas falling under its purview. When, however, the legislature has delegated a responsibility to the Department, the final execution of that responsibility rests with the Department under the law. Therefore, the Department may review

and approve standards recommended by independent entities, but cannot, however, adopt future unspecified and unknown standards and guidelines.

Then, too, there is a question as to whether it is beneficial to allow some time to pass before accepting an ACIP recommendation as a mandate for school attendance. There may be problems with a vaccine that ACIP has not anticipated. The Department notes that, although the vaccine against the rotavirus was not recommended by ACIP for the age group in question here, within four months of ACIP's recommendation relating to that immunization, problems arose, and children suffered severe injury and death from twisting of the bowel, attributable to the vaccine. If this were to occur following the adoption of an immunization mandate for school attendance, the public's trust in state government to properly protect them could be irreparably damaged.

The Department understands the concern that the regulatory process lags behind current thinking of the scientific community. The Department is willing, following the implementation of these regulations, to invoke a stakeholder process to consider alternatives that may expedite the regulatory process, while at the same time preserving the Department's and the Board's careful review of any proposed changes to immunization requirements for school attendance.

New vaccinations continue to be developed, and recommendations of knowledgeable bodies change from day to day. What remains a constant, however, is the Department's commitment to protect the health and safety of the children of the Commonwealth by ensuring that it exercises its discretion and expertise to review recommendations and only require the most appropriate immunizations for school attendance in this Commonwealth. The fact that this may take some

time only means that such vaccinations are not required for a child's attendance at school immediately upon their recommendation by ACIP. It does not prevent a physician from recommending and offering the vaccination to his or her patients when the recommendations are issued. The Department would rather be cautious in the exercise of its discretion than create additional burden to the citizens of the Commonwealth by abdicating its responsibilities to take the most efficient and practical means necessary to prevent and control the spread of disease.

CHAPTER 23. SCHOOL HEALTH.

§23.83. Immunization Requirements.

Subsection (a). Duties of a school director, superintendent, principal, or other person in charge of a public, private, parochial or nonpublic school.

IRRC noted that the proposed regulation did not specifically address whether the requirements of the regulation would apply to charter and cyber schools. The Public School Code of 1929, upon which the regulations are based in part, states that: "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. The statute is sufficiently broad enough to include cyber and charter schools, without the need for that statement appearing in the regulation. Since the regulation is being amended at this time, the Department, however, has no objection to adding language that would make it clear that persons in charge of cyber and charter schools should also ascertain whether a child is in compliance with the appropriate immunization requirements, and that the immunizations required in section 23.83(b) for school attendance are also required for children in cyber and charter schools. Children in these educational settings are exposed to other children and placed at risk for contracting or spreading

a vaccine-preventable disease. These children are able to participate in extra-curricular activities, just as children who attend "regular" schools do, and have regular contact with adults, who may be susceptible to contracting diseases like pertussis. The language in sections 23.82 (relating to definitions; definition of "attendance at school"), 23.83(a) and (c) (relating to duties of school directors, superintendents, principals, or other persons in charge of any public, private, parochial, or nonpublic school), and 23.86(a) (relating to school reporting) has been changed to include a reference to cyber and charter schools.

IRRC recommended that the Department add language to subsection (a) specifically telling persons required by law to ascertain whether a child was in compliance with the appropriate immunization requirements how to make that determination. The commentator suggested that the Department add the language included in section 27.77 (relating to immunization requirements for children in child care group settings) and require that parents provide a written verification from a physician, the Department or a local health department be provided to the school. In the alternative, the commentator recommended that the Department include the language that the Department used with respect to proof of varicella immunity with each of the immunizations required.

The Department has not revised the regulation as recommended. The language that appears in the Department's regulations relating to child care group settings was written because there was no requirement prior to the promulgation of those regulations in 2002 that a child care group setting require certain vaccinations, or how that entity should verify vaccinations. Schools, however, are governed by regulations promulgated both by the Department, and the Department

of Education. (See 22 Pa. Code § 11.20 (relating to nonimmunized children) and 22 Pa. Code § 51.13 (relating to immunizations)). The Department has a provision at section 23.85 (relating to responsibilities of schools and school administrators) that discusses how schools are to carry out these responsibilities. Section 23.85(a) requires a school administrator to obtain a certificate of immunization from the child's parents, or a history of the child's immunization, and requires that the information be stored in a database. In general, the information is kept in the child's medical record; schools are required to keep medical records of students, independently of the Department's regulations relating to school immunizations. See 24 P.S. § 14-1402 (relating to health services). While the need existed in the regulations relating to child care group settings to explain how vaccinations would be verified, that requirement is already in place relating to schools, and does not need to be reiterated in these amendments.

Further, with respect to the language included with the varicella vaccine relating to verification of varicella immunity, the language could not be adopted for each immunization listed in subsection (b), because of the nature of the disease and the response of the public to that disease. Chickenpox (varicella) is often considered by parents to be a "rite of passage" of childhood, a disease that is not dangerous and need not be treated like a more "serious" disease would be, for example, like measles. Children with varicella are often not taken to the doctor's office. In addition, at the time the varicella regulation was first promulgated the vaccine had been relatively newly licensed in the United States. The Department, taking all these circumstances into consideration, allowed for immunity to be verified in different ways, and not simply by the recording of the administration of the vaccine. One way, for example, is through a statement of the parent that the child has had the disease. This language would not be applicable, and the

same considerations would not hold true, for instance, in the case of a disease like tetanus or diphtheria.

IRRC suggested that the Department cross-reference section 1303a of the Public School Code of 1949 (24 P.S. § 13-1303a) (relating to immunizations required; penalty), in subsection (a) in order to clarify the statutory exemptions and penalties involved.

The Department has added a cross-reference as recommended. With respect to the statutory exemptions, however, it should be noted that those are already included in the Department's school immunizations regulations at section 23.84 (relating to exemption from immunization).

Subsection (b). Required for attendance.

IRRC and one other commentator raised the question of combination vaccines. The commentator suggested that the Department use combination vaccines for several of the immunizations required. IRRC states that the commentator makes a compelling argument for the use of combination vaccines. IRRC requests that the Department explain why the Department's proposed rulemaking did not include a requirement for combination vaccines.

The commentator strongly urged the Department to encourage the use of combination vaccines where available, and to encourage the use of the correct vaccine for diphtheria, tetanus and pertussis. According to the commentator, children under the age of 6 years should receive 5 doses of DTaP, and adolescents age 11 through 18 should get one booster dose of TdaP based on the CDC guidelines. This would eliminate confusion between the two different vaccines.

The Department supports the commentator's position that combination vaccines are preferable, because of the reduction in cost by eliminating multiple visits, stocking and storing multiple vaccines and stress on the child. The Department's existing regulations neither encourage nor discourage the use of combination vaccines; it should be noted that many vaccines are not available in the Commonwealth or United States as single antigen vaccines. The Department believes that health care professionals, if they have single antigen vaccines available to them, will take these issues into consideration in deciding which vaccine to use. Given the concern expressed by commentators, however, the Department has decided to revise its regulations to add language acknowledging that a combination vaccine is an acceptable vaccine for purposes of school attendance, as well as a single antigen vaccine. The Department has added this language even in situations where no combination vaccine currently exists, to anticipate the continuing development of such vaccines. The Department agrees with the commentators and strongly encourages the use of combination vaccines when appropriate and available.

The Department cannot, however, state that single antigen vaccines will not be considered acceptable for school attendance. In some instances, for example, in the case of the hepatitis B vaccine, no combination vaccine is presently available for school age children. [1] In addition, because single antigen vaccines are still given in many other countries, there are children coming to school in the Commonwealth with single antigen measles and mumps vaccines that should be counted as valid doses. Were the regulation to require that only combination vaccines be counted as valid doses, these children would have to be re-vaccinated unnecessarily at additional cost.

[1] There is a combination vaccine for hepatitis B available; it is, however, only licensed for children 18 years of age and older.

With respect to the comment regarding the differences between TdaP and DTaP, the level of specificity the commentator is recommending in regulation regarding TdaP and DTaP goes beyond what the Department feels is appropriate for regulation in this area, given the possible encroachment on professional judgment resulting from such regulation. The Department is not in a position to substitute its regulatory authority for the professional judgment and knowledge of a health care practitioner. The Department believes that health care practitioners following accepted standards of practice and exercising their professional judgment do not need to be instructed by the Department through regulation of which vaccine to administer and when.

One commentator stated that the commentator felt that it would be more beneficial for the Department to require TdaP and MCV (meningococcal vaccine) for entry into the 8th grade than the 7th grade. This would allow additional time for students to become vaccinated, and prevent exclusion of those students who fail to obtain the required vaccinations. The commentator based this recommendation on the fact that out of a class of 500 sixth graders in what the commentator classified as a middle class school district there were only 100 students who received MCV, and 176 who received TdaP. Further, as a school nurse, the commentator had sent letters to parents explaining the Department's proposed regulations which would require those vaccinations, and got no significant response.

The Department has considered this comment, and has made no change to the regulation. The Department is unable to draw any conclusion from the parents' lack of response to the commentator's letter. Further, the vaccinations in question were not required for entry into

seventh grade at the time the commentator informally surveyed the sixth grade class and sent a letter to parents.

In addition, in 2007, in preparation for the eventual implementation of this regulation, the Department itself conducted a survey of 160 schools in selected school districts, including Philadelphia and Allegheny Counties. That survey showed that 11% of 7th graders had, at that point, received MCV, while 16% received TdaP, without the existence of a requirement that children have these vaccines for entry into the 7th grade. In setting entry into the seventh grade as the time at which children are required to have MCV and TdaP, the Department is following the ACIP guidelines with respect to those vaccinations. Nothing in its study or the commentator's informal survey leads the Department to the determination that to implement the vaccination in accordance with ACIP requirements would be improper or would create hardship on students. It should also be noted that the health departments of Allegheny and of Philadelphia Counties, both local health departments with the authority to promulgate their own regulations, so long as those regulations are more stringent than those of the Department (35 P.S. § 521.16(c)), require meningococcal vaccine for school students. As of the 2009/2010 school year, Allegheny County Health Department requires the vaccine for students entering seventh through twelfth grade; as of the 2008/2009 school year, Philadelphia Department of Public Health requires students entering sixth grade to have the vaccine.

Questions were also raised concerning the cost of MCV to the families whose children will now be required to obtain this vaccine before entering the seventh grade. Certain insurance plans are required to cover provision of MCV, since it is a recommendation of ACIP, and was included in

a notice published by the Department in accordance with the Childhood Immunization Insurance Act, 40 P.S. §§ 3501-3508, and its accompanying regulations. (See 31 Pa. Code §§ 89.801-89.809), In addition, the vaccine is covered for vaccine-eligible children enrolled in the federal Vaccines for Children Program (42 U.S.C. § 1936s). Lastly, for those children not covered by either of these programs, the Department makes vaccine, which it obtains through a federal grant, available through "catch-up" programs at schools and through its state health centers. It has done so in the past with respect to hepatitis B vaccine and varicella vaccine, and will do so with respect to MCV, TdaP and the second dose of varicella.

In connection with cost concerns, an issue has also been raised regarding the College and University Student Vaccination Act (act). (35 P.S. §§ 633.1-633.3). This act requires students entering college and living in dormitories to have a one-time vaccination against meningitis. Concerns were raised that students required to receive MCV in seventh grade under the Department's regulations would then be forced to have a booster shot prior to entering college in order to comply with the act. Pursuant to ACIP recommendations, MCV is specifically recommended for age 11 or 12, and is only recommended for ages 13-18 if the child has not been previously vaccinated. (See MMWR, Vol. 58, No. 37, 1042-3 (9/25/2009)). Secondly, booster shots are only recommended for children who remain at increased risk after 5 years. The recommendations specifically state that persons whose only risk factor is living in on-campus housing are not recommended to receive an additional dose. (Id.) Therefore, under these recommendations, there would be no requirement for an additional vaccine at college entry if the child is vaccinated in the seventh grade. It should also be noted that, depending upon the child's insurance coverage and age at the entry to college, there is a greater possibility of the vaccine

being covered by private insurance or a government program for the child if it is received at entry into seventh grade, than at entry into college.

IRRC and one other commentator asked whether the Department had considered adding requirements for immunization for hepatitis A, rotavirus, haemophilus influenzae type b and human papillomavirus (HPV) to its list of diseases against which children must be immunized prior to school attendance or entry. The Department has not changed the regulation in response to this comment.

The Department did consider the addition of hepatitis A to the list, but determined against including that requirement, since Pennsylvania is not considered a high risk state for that disease.

The Department began consideration of what action to take with respect to vaccination for HPV when that vaccination became licensed several years ago. The Department has formed the Cervical Cancer Task Force to discuss and make recommendations regarding that particular vaccination. At this time, there has been no recommendation for the addition of HPV to the list.

The Department has not added haemophilus influenzae type b or rotavirus to the list, since the regulations that the Department is amending are regulations dealing with school attendance. Typically, children begin school at age 5 and rotavirus and HIB are vaccines licensed for children under the age of 5.

One commentator also requested that the Department give preference to the injectible inactivated polio vaccine, since the oral polio vaccine is no longer considered the standard of care.

The Department has not revised the regulation. Oral polio vaccine is no longer available in the United States. The Department must, however, continue to take into consideration the possibility that children coming from other countries may have had the oral vaccine. The regulation must allow for this to be counted as a dose. Further, the Department relies upon health care practitioners to follow the standard of care demanded by their professional judgment and licensure requirements.

IRRC raised the question that the Department continually uses the phrase "properly spaced dose" in subsection (b) without explaining where the definition of "properly spaced dose," is to be found. The commentator recommended that the Department include the standard in the final rulemaking.

The Department has not revised the regulation. This language is not new to the school immunization regulations, although it does appear in the new language relating to mumps, hepatitis b, and varicella. (See subsection (b)(6), (7) and (8)). Physicians or other health care practitioners who have worked with these regulations have never raised a question as to its meaning prior to this time. The term "properly-spaced dose," refers to the standard of practice followed by practitioners whose license permits them to administer vaccinations and is unique to each vaccine series. Practitioners determine appropriate dosing by reference to guidelines developed by their medical associations and other experts in the field of immunizations. The

Department does not have the authority to define the standard of practice for licensed practitioners.

Further, within the context of the regulation, the term, "properly-spaced dose" is intended to identify which doses may be counted by the Department for audit purposes and for record checking. From the Department's perspective, a dose which is not a "properly-spaced" dose under the CDC's guidelines means that the Department will not count that dose towards the number of children receiving vaccinations, which is required to be reported to the CDC. The information may also be used in the event of an outbreak of a vaccine reportable disease. In that case, a child not having received properly-spaced doses (given at too early of an age or at less than a minimum interval between doses for that vaccine) may need to be excluded from attendance by the school. These regulations, however, do not provide for any punitive action against either the school or the practitioner.

Paragraphs (1) and (2). Diphtheria; Tetanus.

One commentator recommended that the language for diphtheria and tetanus be changed from requiring one dose on or after the 4th birthday, to the final dose being administered at 4 years of age. This is intended to clarify that the initial 3 doses have already been given, and that the booster shot should be administered at 4 years of age.

The Department agrees that the language of the paragraph should be changed to reflect that the three initial doses should occur prior to the 4th birthday. The Department believes that the language suggested by the commentator, that the final dose be given "at 4 years of age" is too

restrictive, and could be read to mean that the dose must be given on the 4th birthday. Therefore, the Department has revised the paragraph to read "The fourth dose shall be administered on or after the 4th birthday." This takes into consideration the commentator's concern that the regulation lacks clarity regarding when the first 3 doses may be given, and requires that the fourth and final dose be given on or after the child turns 4 years of age.

Paragraphs (4) and (5). Measles (Rubeola); German Measles (Rubella).

IRRC questioned the Department's removal of the requirement in subsections (b)(4) and (5) that serological evidence showing antibodies to rubeola (subsection (b)(4)) or rubella (subsection (b)(5)) determined by the hemagglutination inhibition test or any comparable test be the specific type of testing used as an alternative to evidence of vaccination. The Department has changed that requirement to allow acceptance of "laboratory testing" as evidence of immunization. IRRC recognized that, as the Department had stated in its Preamble to Proposed Rulemaking, the Department's intention was to allow for changing technology to be recognized, but questioned whether the requirement had now become too broad. IRRC asked what type of laboratory testing the Department would accept, and whether the testing procedure and laboratory would be required to be approved or accredited by an appropriate medical authority.

It is the Department's intention to allow for the most current testing to be utilized, and the language that has been removed from the regulation would have prevented that from occurring. In considering this comment, the Division of Immunization sought the advice of the Department's Bureau of Laboratories (BOL). There are numerous tests on the market for detection of Rubella and Rubeola antibodies. The majority are ELISA (enzyme linked

immunoabsorbent assay) tests, although there are other methods available. These tests could all be considered "comparable" to the hemagglutination inhibition test. Use of any of these tests would require licensure for nonsyphilis serology under the state Clinical Laboratory Act, and certification for general immunology under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Under the CLIA requirements, a laboratory offering one or more of these tests would require a CLIA certificate of compliance (the agency inspecting the laboratory would be the CLIA state agency, which in the Commonwealth is BOL) or a certificate of accreditation (the agency inspecting the laboratory would be a federally approved accrediting agency. CLIA certified and state permitted laboratories are inspected at least every two years. In addition, laboratories must participate regularly and successfully in an external proficiency testing program (usually 3 times per year). The Department has changed the regulation to clarify that the laboratory performing the testing must have the appropriate certification. See paragraphs (4) and (5).

Once a laboratory has met these requirements, it may perform testing to determine immunity for rubella and rubeola without any additional approvals by the Department.

Paragraph (8). Chickenpox (Varicella).

IRRC asked the Department to clarify how it determined that the school year 2010/2011 allowed a reasonable amount of time for children to meet the requirement for the two dose varicella vaccine.

In choosing the time frames for varicella compliance in the proposed regulations, the Department drew on its experience in phasing in vaccine requirements. The Department did not wish to delay an unduly long period of time in creating an all grades requirement, since there is a need for a second dose to ensure that children are appropriately immunized, and not either contracting or spreading a serious disease. The varicella vaccine has been licensed since 1995, and a one dose requirement of the vaccine for school attendance has been in place since 2001. Most children, therefore, already have received one dose of the vaccine. Further, the recommendation for a second dose of varicella was issued by ACIP in 2007, and many doctors are already giving the second dose as a result of these recommendations. Because the school immunization regulations of both the Department and DOE provide that a child may attend school so long as he or she has one dose, and then receives subsequent doses within an 8 month provisional period, (See 28 Pa. Code § 23.83(e) (relating to immunization requirements); 22 Pa. Code § 11.20 (relating to nonimmunized children) and 22 Pa. Code § 51.13 (relating to immunizations)), the Department did not believe that the proposed regulation would cause hardship to children by causing their immediate exclusion from school.

After a request to allow additional time for school nurses and for children, parents and guardians to prepare to administer all the new vaccine requirements, however, and given that the regulations will most likely not be final until the very end of school year 2009-2010, making that preparation more difficult for schools, the Department has agreed to delay implementation of the regulations until school year 2011-2012. This will provide ample time for schools to make families aware of the new immunization requirements, and will provide ample time for families to obtain the required immunizations before the school year starts in the fall of 2011. Because

of this change in implementation date, the Department has removed the phase-in requirements for varicella from the final regulation.

IRRC also recommended adding the qualifier, "or older" to proposed paragraph 8(i)(A), which required the first dose of the vaccine to be administered at 12 months of age, since the existing regulation contained that language. The Department agrees, and has changed the regulation to include the recommended language.

IRRC requested that the Department explain the difference between section (b)(8)(i)(B) and (C).

The Department has revised the regulation to remove the phase-in requirement, and deleted both section (b)(8)(i)(B) and (C). All children attending school will be required to have 2 properly-spaced doses of varicella vaccine, the first dose administered at 12 months of age or older.

§23.83(e). Pre-kindergarten programs, Early Intervention programs' early childhood special education classrooms and private academic pre-schools.

The Department sought the expertise of the Departments of Public Welfare and Education with respect to the language included in this section. The Office of Childhood Development and Early Learning provided clarification regarding the types of programs and the age of the children that are intended to be covered by this section. The Department has revised the language and title of the section to reflect those clarifications.

§23.83(f). Grace period.

IRRC requested that the final form regulation explain who will monitor the 4-day grace period, and what the consequences are for exceeding it.

The implementation of a 4-day grace period for the provision of doses of vaccine was instituted by the Department through a notice published in the Pennsylvania Bulletin in March of 2002 (32 Pa. B. 1305 (March 9, 2002)). The grace period was intended to allow for the acceptance of vaccinations as valid that were given at a time less than or equal to 4 days prior to the minimal interval or age limit for a valid dose of vaccine administration. A vaccine given outside this grace period would result in that dose being considered an invalid dose, and could result in a child not having the necessary immunizations for the purpose of school attendance. A vaccine counted as an invalid dose could cause the child to be excluded from school if he or she did not meet the requirements for provisional admission. (See 28 Pa. Code § 23.85 (relating to responsibilities of schools and school administrators); 22 Pa. Code § 11.20 (relating to nonimmunized children) and 22 Pa. Code § 51.13 (relating to immunizations)).

With respect to monitoring, the Department does random school audits where it checks for compliance with dosage requirements. School nurses and administrators are also aware of these requirements and monitor the immunization status of children.

§ 23.85. Responsibilities of Schools and School Administrators.

The Department did receive comments on this section, although it proposed no substantive changes to this specific regulation. The regulation previously allowed provisional admittance if a

child had received one dose of each antigen of a vaccine. Since a vaccine like MCV only requires one dose to complete the vaccine, concerns were raised that it was possible that a child failing to receive either MCV or TdaP by school entry in school year 2010-2011 would be excluded immediately without a provisional period allowed.

In response to these concerns, the Department has added language to the regulation to clarify that a child may be provisionally admitted to school in a situation in which he or she needs a single dose vaccine (like MCV and TdaP) as well as when the child is missing a multiple vaccine series, even if the child fails to obtain the necessary dose of the single dose vaccine. The Department has also changed the effective date of the regulations to August 1, 2011, so that they will be implemented for school year 2011-2012, in the hopes that this will limit the number of children needing provisional admittance for failure to obtain these vaccines.

§ 23.86. School Reporting.

Although the Department received no comments on this section, in reviewing the proposed regulations, the Department determined that nonsubstantive changes were necessary to subsection (d)(6) and (7). The Department revised those sections to mirror the language in earlier paragraphs. The Department also made changes to subsection (e)(3) to clarify that the paragraph requires does not require reporting on antigens given to each individual child, but, rather, requires reporting on the number of doses of each individual antigen given in each grade level.

CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASES.

Section 27.77. Exemptions to immunization requirements for children in child care group settings

One commentator recommended that the fourth dose of necessary vaccines should be given between the ages of 4 and 6, since this reflects the recommendations of ACIP, the American Academy of Pediatrics, and the American Academy of Family Practitioners. The commentator noted that this would alter the language of 28 Pa. Code § 27.77(d)(1)(i) and (ii) (relating to immunization requirements for children in child care group settings.

The Department has not made changes to its amendments in response to this comment. This final rulemaking is not intended to set out general rules of medical practice for the provision of immunizations to children. The Department's authority in promulgating these regulations is to set out a list of diseases against which children must be immunized for entry to and attendance at school. Therefore, the regulations are written to set out requirements for school attendance.

Because the age of children attending a school-based setting is changing, and many children younger than the typical age for school entry at kindergarten (5 years of age), are found in school-based settings, the Department has found it necessary to clarify its regulations relating to immunizations for children. This could, potentially, create confusion with the Department's separate set of regulations promulgated under a different authority addressing the issue of children in child care group settings. See 28 Pa. Code § 27.77 (relating to immunization requirements for children in child care group settings). In order to ensure that confusion does not continue, the Department has also revised section 27.77(d) (relating to exemptions from the

regulations relating to child care group settings), to ensure that children attending kindergarten, elementary or higher school who are 5 years of age or older are not subject to those child care group setting requirements, and are required, even in a child care group setting, to receive the immunizations set out in Chapter 23.

D. COST AND PAPERWORK ESTIMATE

1. Cost

a. Commonwealth

The Commonwealth will incur some costs for the purchase of TdaP and meningococcal conjugate vaccines, as well as additional Td, hepatitis B and varicella vaccines; and the mumps containing vaccine (MMR), through the expenditure of federal immunization grant funds. The Commonwealth will 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 have no insurance, who are Medicaid eligible or who are Alaskan Native or American Indian. In addition, VFC Program vaccine is also made available to other public clinic sites (Federally Qualified Health Centers and Rural Health Clinics) for the same population , and also for underinsured children through 18 years of age. Vaccines are made available to schools at no cost through the Department's School Based Catch-Up Program for those students who have no medical home or are unable to seek the immunization through a public clinic site. The Commonwealth will realize savings, however, based on the amount of funds that will not be needed to control the outbreak of vaccine preventable diseases.

The inclusion of a grace period into the regulations adds no cost for the Commonwealth, including either the Department or PDE. The 4-day grace period is intended to allow a vaccine dose administered 4 days before the minimum interval between doses or before the appropriate age is reached to be counted as a valid dose. Since there is no scientific basis for taking a position that a vaccine must be given with a strict interval between doses or at an exact age or the vaccine is ineffective or unsafe, the grace period would merely allow schools to accept vaccines provided within this period for purposes of determining compliance with the Department's regulations relating to school attendance.

b. Local Government

There will be no fiscal impact on local governments. Local governments may see a slight cost savings, since local governments do bear some of the cost of disease outbreak investigations and control measures. (The Department addresses the potential impact of these proposed amendments on school districts, which may be considered to be local government, under the heading of "Regulated Community.")

c. Regulated Community

Families whose children's vaccinations are covered by their insurance plans (public or private) pursuant to State law will not see any out-of-pocket cost for the added vaccines. Families whose insurance plans do not cover these vaccinations, or who do not have insurance, will need to seek other assistance to pay for the vaccines, or pay out-of-pocket. In general, there is other assistance provided for vaccinations from the Department, if no third party payer is available. The Department, through its state health centers, provides vaccinations. The Department also

provides vaccines to providers for certain eligible children through the VFC Program, and to schools through its Catch-Up program. The savings in prevention of childhood illness would outweigh the minimal cost of the vaccine.

The inclusion of a grace period does not add cost for school districts. School districts currently decide which children are appropriately immunized, and which are not appropriately immunized and so are to be excluded from attendance. The inclusion of a 4-day grace period, which is intended to allow a vaccine dose administered 4 days before the minimum interval between doses or before the appropriate age is reached to be counted as a valid dose, will now be taken into consideration in making this determination. This amendment does not add significantly to the cost of determining whether children are appropriately immunized, since the recommendation for a waiver period has been in place since the Department published its notice in 2002.

The amendments do add two additional immunizations for school officials to review, two additional vaccine doses to account for (2 doses of varicella and 2 doses of mumps), and may increase the amount of follow-up needed to ensure that provisionally enrolled students in all grades receive the necessary doses in the series for all required immunizations prior to the expiration of the eight-month provisional enrollment deadline. Provisional enrollment allows for a child who has not had all the required vaccine doses described in section 23.83 to continue attendance at school if he or she has had at least one dose of each required vaccine and there is a plan for that child obtaining all required immunizations or, in the case of a multiple dose vaccine, that, although the child lacks any dose, there is a plan in place to receive the required dose. (28

Pa. Code § 23.85(e)). A child provisionally admitted to school must have completed the immunizations required by section 23.83 within an 8 month period from the date of his or her provisional admission, or the school administrator may neither admit the child to school, nor permit the child's continued admission. (Id.) Again, the savings in the prevention of an outbreak of a childhood illness in a school district outweighs the minimal cost in staff time to review two additional immunizations and to follow-up on provisional enrollments.

No additional cost will be added to the regulated community by the deletion of the requirements that the hemagglutination test or a comparable test be used to show a history of immunity to measles or German measles, and that a more current test be used. Even without any amendment to the regulations, there would be a cost associated with choosing this particular method of showing immunity -- the cost of the hemagglutination test. Since the amendment does not prohibit that particular test from being used in the future, no cost beyond that of the hemagglutination test would be incurred, and the cost of the regulations in this regard remains stable. Future tests may, in fact, decrease in price, which would provide a cost savings for affected persons. Further, use of this method of proving immunity is not required.

Lastly, no additional cost is added by the Department's clarification regarding children in child care group settings located in schools. The requirements for attendance at school and school reporting do not apply to those children. The regulations that apply are those immunization requirements that are already in place that deal with child care group settings at 28 Pa. Code § 27.77.

d. General public

The general public will not see an increase in cost. The general public will see a decrease in costs resulting from a reduction in medical treatment needed to treat the disease and a reduction in the loss of work in order to stay home with a sick child. The general public may see a benefit in the reduction of vaccine preventable diseases, such as pertussis, chickenpox, mumps and meningitis. Since the school environment is conducive to the contracting and transmission of diseases among children with no immunity, failure to immunize properly not only puts children 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.

2. Paperwork Estimates

a. Commonwealth and the Regulated Community

Schools will be required to report in accordance with the new reporting requirements, which require them to report the number of doses of individual antigens that have been administered to students. The Department will 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 in order for the Department to satisfy CDC requirements relating to reporting of immunizations. The additional paperwork requirements for the Commonwealth, including both the Department and PDE, and the regulated community would be minimal, however, since school districts already complete this annual report regarding the number of immunizations and follow up on provisional enrollment. School nurses, who perform record keeping and reporting requirements in the schools, currently maintain and report this

information. The CDC, however, is in the process of changing these requirements. The Department will provide reporting forms to schools, as it currently does, and the reports will be sent to the same Department office as the current reports. Schools also have the option of electronic reporting.

b. Local Government

There is no additional paperwork requirement for local government. (The Department has included school districts, which may be considered to be local government, under the heading of "Regulated Community.")

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 of 1955 (35 P.S. § 521.1 et seq.) (Act) provides the Advisory Health Board (Board) with the authority to issue rules and regulations on a variety of matters 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 of 1949 (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 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 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 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. 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.

F. EFFECTIVENESS/SUNSET DATES

The amendments are effective on August 1, 2011. This will allow parents, guardians and schools time to become familiar with the requirements, prepare for their implementation and obtain the required vaccinations prior to the effective dates. No sunset date has been established. The Department will continually review and monitor the effectiveness of these regulations.

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 a Notice of Proposed Rulemaking, published at 36 Pa.B. 6403 on October 21, 2006, 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 compliance with Section 5(c) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of all comments received during the formal comment period, as well as other documentation.

In compliance with Section 5.1(a) of the Regulatory Review Act, the Department submitted a copy of the final-form regulations to IRRC and the Committees on _____. In

addition, the Department provided IRRC and the Committees with information pertaining to commentators and a copy of a detailed 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.

In preparing this final-form regulation the Department has considered all comments received from IRRC, the Committees and the public.

This final-form regulation was (deemed) approved by the House Health and Human Services Committee on _____ and (deemed) approved by the Senate Public Health and Welfare Committee on _____. IRRC met on _____, and approved the regulation in accordance with Section 5.1(e) of the Regulatory Review Act

H. CONTACT PERSON

Questions regarding these regulations may be submitted to Heather Stafford, Director, Division of Immunization, Department of Health, 625 Forster St., 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 the above 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 Ms. Stafford so that necessary arrangements may be made.

I. FINDINGS

The Department finds that:

(1) Public notice of intention to adopt the regulations adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§1201 and 1202), and the regulations thereunder, 1 Pa. Code §§7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) The adoption of regulations in the manner provided by this order is necessary and appropriate for the administration of the authorizing statute.

J. ORDER

The Department, acting under the authorizing statute, orders that:

(1) The regulations of the Department at 28 Pa. Code Chapters 23 and 27, are amended by amending §§ 23.82-23.83, 23.86 and 27.77 as set forth in Annex A.

(2) The Secretary of Health shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(3) The Secretary of Health shall submit this Order, Annex A and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for their review and action as required by law.

(4) The Secretary of Health shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(5) This order shall take effect August 1, 2011.

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:

* * *

Attendance at school -- The attendance at a grade, or special classes, kindergarten through 12th grade, including public, private, parochial, vocational, intermediate unit and home education students **AND STUDENTS OF CYBER AND CHARTER SCHOOLS**. This definition does not cover the attendance of children at a child care group setting, defined by 28 Pa. Code § 27.1 (relating to definitions), located in a public, private, or vocational school, or in an intermediate unit.

§ 23.83. Immunization requirements.

(a) [*Required for entry*] *Duties of a school director, superintendent, principal, or other person in charge of a public, private, parochial or nonpublic school.* [The following immunizations are required for entry into school for the first time at the kindergarten or first grade level, at public, private or parochial schools 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 or 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 attenuate 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 a history of chickenpox disease from a parent, guardian or physician.]

Each school director, superintendent, principal, or other person in charge of a public, private, parochial or nonpublic school in this Commonwealth, including vocational schools, intermediate

units, and special education and home education programs, **CYBER AND CHARTER SCHOOLS**, shall ascertain that a child has been immunized in accordance with the requirements in subsections (b), (c) and (e) prior to admission to school for the first time, **PURSUANT TO 24 p.s. § 13-1303A (RELATING TO IMMUNIZATION REQUIRED; PENALTY)**.

(b) *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] 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 **A** combination ~~with tetanus toxoid and pertussis vaccine~~ **FORM**. ~~One~~**THE FOURTH** dose shall be administered on or after the 4th birthday.

(2) *Tetanus.* [Three] 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 **A** combination ~~with diphtheria toxoid and pertussis vaccine~~ **FORM**. ~~One~~ **THE FOURTH** dose shall be administered on or after the 4th birthday.

(3) *Poliomyelitis.* Three or more 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.

(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 [serological evidence showing antibody to measles as determined by the hemagglutination inhibition test or a comparable test]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 [serological evidence showing antibody to rubella determined by the hemagglutination inhibition test or any comparable test]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*. [One dose]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**.

(7) *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)*. One of the following:

(i) Varicella vaccine:

~~**(A) Required for school entry in kindergarten or the first grade until the school year 2010/2011,**~~ 2 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.

~~(B) Required for school attendance until the school year 2010/2011, 2 properly-spaced doses of varicella vaccine for children 13 years of age or older.~~

~~(C) Required for school attendance as of the school year 2010/2011, 2 properly-spaced doses of varicella vaccine.~~

(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.

(c) *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 [vocational]nonpublic school in this Commonwealth, including vocational schools, intermediate units ~~and~~, 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) [*Hepatitis B.* Three properly-spaced doses of hepatitis B vaccine, unless a child receives a vaccine approved by the FDA as a two-dose regimen.

(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 a parent, guardian or physician.]

*Tetanus and diphtheria toxoid and acellular pertussis vaccine (Tdap)(**TdaP**).* One dose if at least five 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 INA COMBINATION FORM.**

(2) *Meningococcal Conjugate Vaccine (MCV).* One dose of Meningococcal Conjugate Vaccine. **MCV MAY BE ADMINISTERED AS A SINGLE ANTIGEN VACCINE OR IN A COMBINATION FORM.**

(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 28 Pa. Code § 27.77 (relating to immunization requirements for children in child care group settings).

(e) *Pre-kindergarten programs, eEarly iIntervention programs' EARLY CHILDHOOD SPECIAL EDUCATION CLASSROOMS and private academic pre-schools.* Attendance at a pre-kindergarten program operated by a school district, an early intervention program operated by a contractor or subcontractor including intermediate units, school districts and private vendors, or at private academic pre-schools is conditional upon the child's satisfaction of the immunization requirements in 28 Pa. Code § 27.77 (relating to immunization requirements for children in child care group settings). ~~If a child is 5 years of age or older, the child's attendance shall be conditional upon the child's satisfaction of the immunization requirements set out in subsection (b).~~

(f) *Grace period.* A vaccine dose administered within the 4-day period prior to the minimum age for the vaccination or prior to the end of the minimum interval between doses shall

be considered to be a valid dose of the vaccine for purposes of this chapter. **A DOSE ADMINISTERED GREATER THAN 4 DAYS PRIOR TO MINIMUM AGE OR INTERVAL FOR A DOSE IS INVALID FOR PURPOSES OF THIS REGULATION AND SHALL BE REPEATED.**

* * *

23.85. Responsibilities of schools and school administrators.

* * *

(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.

(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.

(3) ***COMPLETION OF REQUIRED IMMUNIZATIONS.*** The plan for completion of the required immunizations shall be reviewed every 60 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 administration 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.**

* * *

§23.86. School reporting.

(a) A public, private, [or] parochial or nonpublic school in this Commonwealth, including vocational schools, intermediate units, ~~and~~ special education and home education programs, **AND CYBER AND CHARTER SCHOOLS,** shall report immunization data to the Department by October 15 of each year, using forms provided by the Department.

(b) The school administrator or the administrator's designee shall forward the reports

to the [Immunization Program, Bureau of Communicable Diseases, Post Office Box 90, Harrisburg, Pennsylvania 17108]Department as indicated on the reporting form provided by the Department.

(c) 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) 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.

[(d)](e) Content of the reports shall include the following information:

(1) [The identification of the school including the name of the school, the school district, the county, the intermediate unit and the type of school.

(2)] The month, day and year of the report.

[(3)](2) The number of students attending school [by]in each grade-level, or in an ungraded school in each age group, as indicated on the reporting form.

[(4) The number of students attending school by grade level who were completely immunized.]

(3) The ~~immunization status by~~ **NUMBER OF** doses of **EACH** individual antigens ~~of every enrolled student~~ **GIVEN** in each grade-level, or in an un-graded school, in each age group, as indicated on the reporting form.

[(5)](4) The number of students attending school [by grade-level] who were classed as medical exemptions in each grade-level, or in an un-graded school, in each age group, as indicated on the reporting form.

[(6)](5) The number of students attending school [by grade level] who were classed as religious exemptions in each grade level, or in an un-graded school, in each age group, as indicated on the reporting form.

[(7)](6) The number of students provisionally admitted ~~to any~~**IN EACH** grade **LEVEL** or, in an un-graded school, in any age group **AS INDICATED ON THE REPORTING FORM**.

[(8)](7) The number of [children]students in ~~any~~ **EACH** grade level who were denied admission because of [their] the student's inability to qualify for provisional admission or, in an un-graded school, in ~~any~~ **EACH** age group

AS INDICATED ON THE REPORTING FORM.

[(9)](8) Other information as required by the Department.

[(e) For purposes of reporting the immunization status of a school's students to the Department, the following grade-levels will be used: kindergarten, grades 1-6, 7-9, 10-12 and special education.]

* * *

CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASES

SUBCHAPTER C. QUARANTINE AND ISOLATION

COMMUNICABLE DISEASES IN CHILDREN AND STAFF ATTENDING SCHOOLS AND CHILD CARE GROUP SETTINGS

Section 27.77. Immunization requirements for children in child care group settings.

* * *

(d) *Exemptions.*

(1) This section does not apply to the following:

(i) Children attending [Kindergarten] kindergarten, elementary school or higher school who are 5 years of age or older. These caregivers shall comply with §§ 23.81—23.87 (relating to immunization)

~~(ii) Children who are known by the caregiver to be [6] 5 years of age or older or to attend a kindergarten, elementary school or higher school.~~

LISTING OF COMMENTATORS FOR FINAL REGULATION NO. 10-181 SCHOOL IMMUNIZATION REQUIREMENTS 28 PA. CODE CHAPTER 23

1. Pennsylvania Medical Society
   777 East Park Drive
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   Harrisburg, PA 17105
   Peter S. Lund MD, FACS
   President

2. M. Catherine Roth, RN, CRNP
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   Neff Sixth Grade
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COMMONWEALTH OF PENNSYLVANIA
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March 22, 2010

Mr. Kim Kaufman
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Department of Health – Final Regulations No. 10-181
School Immunization Requirements. 28 Pa. Code Chapter 23

Dear Mr. Kaufman:

Enclosed is a copy of final-form regulations for review by the Commission pursuant to the Regulatory Review Act (Act) (71 P.S. §§745.1-745.15). Section 5.1(a) of the Act provides that, upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to the Commission and the Standing Committees, a copy of the agency's response to the comments received, the names and addresses of 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 received two (2) comments to the proposed rulemaking. While only one commentator requested a copy of the final regulations, both have been provided copies of the regulations. A list of the names and addresses of these commentators is enclosed. These comments, which discussed a number of provisions contained in the proposed regulations, were forwarded to the Commission upon receipt by the Department.

Section 5.1(e) of the Act provides that within 10 days following the expiration of the Standing Committee review period, or at its next regularly scheduled meeting, the Commission shall approve or disapprove the final-form regulations.

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact Neil Malady, Director, Office of Legislative Affairs.

Sincerely,

Everette James
Secretary of Health

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 10-181

SUBJECT: School Immunization Requirements. 28 Pa. Code Chapter 23

AGENCY: Department of Health

TYPE OF REGULATION

RECEIVED
2010 MAR 23 AM 3:10
INDEPENDENT REGULATORY REVIEW COMMISSION

Proposed Regulation

X 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
3-22-10	Honorable Frank L. Oliver	House Committee on Health & Human Services **Majority**
3-22-10	Honorable Matthew E. Baker	House Committee on Health & Human Services **Minority**
3/22/10	Honorable Patricia H. Vance	Senate Committee on Public Health & Welfare **Majority**
3/22/10	Honorable Vincent J. Hughes	Senate Committee on Public Health & Welfare **Minority**
3/22/10	K Cooper	Independent Regulatory Review Commission
		Attorney General (for Final Omitted only)
		Legislative Reference Bureau (for Proposed only)