Regulatory Analysis Form	This space for use by IRRC
(1) Agency Department of Health	RECEIVED 2008 JAN 24 PM 12: 22 INDEPENDENT REGULATORY REVIEW COMMISSION
(2) I.D. Number (Governor's Office Use) DOH Reg. No. 10-181	IRRC Number: 2672

(3) Short Title

School Immunization Requirements

(4) Pa. Code Cite	(5) Agency Contacts & Telephone Numbers
28 Pa. Code §§ 23.82, 23.83, 23.86, 27.77	Primary Contact: Alice J. Gray, RN, Director, Division of Immunizations. 717-787-5681 Secondary Contact: Heather Stafford, RN Division of Immunizations 717-787-5681

(6) Type of Rulemaking (Check One)	(7) Is a 120-Day Emergency Certification Attached?
√ Proposed Rulemaking	√ No
Final Order Adopting Regulation	Yes: By the Attorney General
Final Order, Proposed Rulemaking Omitted	Yes: By the Governor

(8) Briefly explain the regulation in clear and non-technical language.

The proposed amendments would provide the immunization requirements for children to attend school and enter the seventh grade in the Commonwealth. These proposed amendments would revise existing regulations relating to school immunization requirements to 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 two 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 proposed amendments would also institute ACIP recommendations regarding an additional dose requirement for mumps and for varicella vaccine. The 2 dose requirement for varicella vaccine would be phased in so that it would become an all grades requirement beginning for the school year 2010/2011. Until that time, children entering

school for the first time in kindergarten or the first grade would be required to have 2 properly-spaced doses of varicella vaccine, and all children 13 years of age or older attending school would be required to have 2 properly-spaced doses.

Further, the proposed amendments would 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 and home education programs would be required to comply with these proposed amendments. The proposed amendments would not affect existing provisional enrollment provisions or religious and medical exemptions that are currently included in law and regulation.

Finally, the proposed amendments would also clarify what immunization requirements apply to children under the age of 5 years attending child care group settings located in a school. In addition, the proposed amendments are intended to clarify 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 appropriate immunizations as a condition of attending those programs.

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

The Department obtains its authority to promulgate regulations relating to immunizations in schools from several sources. Generally, the Disease Prevention and Control Law (35 P.S. §521.1 et seq.) (Act) provides the Advisory Health Board (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.

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

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

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

These proposed 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 would protect the adolescent population from serious disease injury or death from meningococcal disease.

The Department is also proposing that, in order to enter school in kindergarten or first grade

children must have 2 properly-spaced doses of varicella vaccine administered after 12 months of age. (See proposed paragraph (8)(i)(A)). In order to attend school, all children 13 years of age and older would also be required to have 2 properly-spaced doses. 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 2010/2011, all children would be required to have 2 properly-spaced doses of varicella vaccine in order to attend school. This is in accordance with ACIP recommendations. Further, the Department is proposing to add a second mumps dose for children in grades kindergarten through 12, in accordance with ACIP recommendations. Both of these requirements would be intended to prevent breakthrough disease, as the Commonwealth saw with recent mumps outbreaks in previously vaccinated children.

The proposed 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 proposed a section clarifying when the requirements relating to school immunization apply and when the requirements relating to childcare group settings apply. The Department is also proposing language to make it clear that children in pre-kindergarten programs, early intervention programs and private academic pre-schools are required to comply either with the immunization requirements for school attendance, or those required for attendance at child care group settings, depending upon the age of the child. 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 those with whom they come in contact outside a school setting are protected as well.

Lastly, the Department is proposing to amend existing regulations to change the manner in which schools are required to report immunizations. This alteration in reporting procedures is being proposed because of imminent 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 moving to require this reporting to include the status of the number of doses of individual antigens. The proposed amendments are intended to comply with these anticipated CDC school immunization-reporting requirements.

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

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

Those children and adolescents who, because of the proposed amendments, will be immunized and will not contract these diseases and suffer discomfort, miss school, or succumb to death, will benefit from these proposed 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 will also benefit from these proposed 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 will benefit from these proposed 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, will also benefit.

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

Those parents or guardians whose health care plans do not cover immunizations, and for whom payment is a hardship will be 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. Further, the Governor's initiative "Cover all Kids" will add to the number of children presently without insurance who are able to access insurance benefits for these vaccinations. School districts and staff who must verify whether a child's immunizations are up to date will have additional immunizations to review, and may consider themselves as adversely affected by these proposed amendments. Those children who suffer the rare adverse reaction to a required immunization and their parents or guardians may also be adversely affected.

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

Primarily, those persons who would be required to comply with the proposed amendments are parents and guardians whose adolescent children have not received a Td immunization for at least two 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 would have to enforce the additional seventh grade requirements and the additional all grades requirements would be required to comply with these proposed amendments.

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

The 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 4 days of the minimal interval between doses and age limit to be considered a valid dose of administered vaccine. In June 2006, the ACIP recommended a second dose of varicella vaccine since 15% to 20% of children who have received 1dose of the vaccine are not fully protected and could develop chickenpox after coming in contact with the varicella zoster virus. Additionally, 1 dose of the vaccine may not continue to provide protection into adulthood when chickenpox is more severe. A second dose of varicella vaccine provides increased protection against the disease. In response to the outbreak of mumps during 2006, the ACIP recommended that all school aged children received 2 doses of mumps given a MMR. Since 2000, all school aged children have been required to have 2 doses of measles vaccine; measles vaccine is almost always given as MMR; therefore all school age children would already have received 2 doses of mumps containing vaccine.

In preparation for proposing these amendments, the Department had 2 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 the proposed revisions to the school immunization regulations. The Department of Education (PDE) is in agreement with these proposed amendments.

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

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 1 adolescent from serious disease injury or death it well justifies this proposed 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 that may be required.

These proposed amendments would have no fiscal impact on local governments. Cost savings might result from not having to investigate reports of disease occurrence and/or implement disease outbreak control interventions. Some outbreak control programs in the past have exceeded $100,000 – $200,000 or more, of which 25 percent might be borne by local government depending on the magnitude of the outbreak, the disease that is occurring and the population affected.

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

The Commonwealth 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 would also incur costs through the Medical Assistance Program for administering the vaccines. Medical Assistance is funded by the state with a federal match.

Cost savings would result from not having to coordinate disease investigations, institute outbreak control measures, and provide medical follow-up for exposed, susceptible individuals.

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

	CFY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS						
Regulated Community		231,212,888	231,212,888	231,212,888	231,212,888	231,212,888
Local Government						
State Government						
TOTAL SAVINGS		231,212,888	231,212,888	231,212,888	231,212,888	231,212,888
*Doesn't include savings for meningococcal conjugate vaccine.						
COSTS						
Regulated Community		49,281.952	13,990,387	13,990,387	13,990,387	13,990,387
Local Government	$ 0					
State Government *		3,126,562	1,283,812	1,283,812	1,283,812	1,283,812
TOTAL COSTS		**53,706,314**	**15,274,199**	**15,274,199**	**15,274,199**	**15,274,199**
REVENUE LOSSES:						
Regulated Community	$ 0	0	0	0	0	0
Local Government	$ 0	0	0	0	0	0
State Government	$0	0	0	0	0	0
Total Revenue Losses	$0	0	0	0	0	0

The Immunization Program is currently federally funded.

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

In determining costs related to the implementation of these proposed amendments, the Department would consider cost to the regulated community to be realized by the number of children (90%) in an age cohort who would be required to obtain the immunizations through pay out of pocket or another private pay method such as private health insurance for these immunizations. The state government costs would be realized by the number of children (10%) in an age cohort who would get the immunizations through the Department because they would 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

There are approximately 150,000 children born annually in Pennsylvania, therefore there are approximately 150,000 children per grade cohort. Children who might need the hepatitis B series would include those in the 12th grade; and children who might need the first dose of varicella vaccine would include those in 5th , 6th , and 12th 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 the school children who missed the kindergarten and seventh grade requirement for the hepatitis B series are still not immunized, approximately 120,000 children will need hepatitis B immunizations. An estimated 90% or 108,000 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 $7,452,000. An estimated 10% or 12,000 children would obtain their immunizations from the State at a cost of $9.00 per dose. This amounts to a total cost of $324,000.

An assumption is made that 30% of the students who missed the kindergarten and seventh grade requirement for varicella immunity are neither immunized nor have other varicella immunity. Therefore, approximately 135,000 school children would need the first dose of varicella vaccine. An estimated 90% or 121,500 children obtaining them from the regulated community at a cost of $71.11 per dose for a total of $8,639,865, and 10% or 13,500 obtaining them from the State at a cost of $56.90 per dose for a total of $768,150. To meet the second dose varicella immunization requirement for new school enterers into kindergarten or first grade, an assumption is made that 50% or 75,000 of those children will need a second dose of vaccine. An estimated 90% or 67,500 would obtain their immunizations in the regulated community at a cost of $71.11 per dose. This amounts to a total cost of $4,799,925. An estimated 10% or 7,500 children would obtain their immunizations from the State at a cost of $56.90 per dose. This amounts to a total cost of $768,150.

Two doses of varicella have always been the ACIP recommendation for children 13 years of age and older; therefore when the all grades second dose varicella immunity requirement becomes affective for school year 2010, an assumption is made that 50% or 225,000 children in 5th, 6th, and 7th grades will need a second dose of vaccine. With an estimated 90% or 202,500 children obtaining the second dose vaccine from the regulated community, the cost of vaccine at $71.11 per dose would total $14,399,775. With an estimated 10% or 22,500 children obtaining their immunization from the State at a cost of $56.90 per dose, the total cost would be $1,280,250.

School children entering the seventh grade would need to be immunized with Tdap and MCV. A survey completed during the 2004 - 2005 school year for seventh grade students reported that 73% of those children were not immunized within the last five years with a Tetanus diphtheria (Td) containing vaccine. An estimated 109,500 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 $3,473,887. An estimated 10% or 10,950 children would obtain them from the State at a cost of $28.75 per dose. This amounts to a total of $314,812. There are no available studies to determine how many seventh grade children are immunized with the MCV; however it is estimated that 95% or 142,500 seventh grade children are not immunized with MCV. Therefore, an estimated 90% or 128,250 children would obtain the MCV from the regulated community at $82.00 per dose for a total of $10,516,500, and 10% would obtain the MCV from the State at $68.00 per dose for a total of $969,000.

There should be no additional costs for continuing the 4 day grace period or for implementing the revised reporting requirements.

The savings estimate was calculated using a 1997 report from the CDC which concludes that for every dollar spent on DTP immunizations – $29.10 is saved; for every dollar spent on hepatitis B immunizations - $2.10 is saved; and for every dollar spent varicella immunizations - $5.40 is saved. These savings would be realized in a combination of savings from lack of medical expenses, work not being missed to care for sick children, and school not missed by the children. These savings would pertain to the community at large and have been included in the numbers provided above for the regulated community.

No estimate is available for savings resulting from the MCV immunizations; however, if one adolescent life is spared by the MCV immunization, the cost is immeasurable.

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

Program	FY – 3 **2003**	FY – 3 **2004**	FY – 3 **2005**	Current FY **2006**
Immunization	$8,663,511	$7,611,364	$7,920,317	$11,477,000

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

The expenditure history figures shown above in item 20b are not cost-benefit data. They are gross expenditures for the program excluding direct assistance received from the CDC for vaccines. The only additional costs the Immunization Program would incur because of the proposed 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 proposed 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.

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

There are no non-regulatory alternatives.

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

No alternative regulatory schemes were considered.

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

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

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

According to the 2001-2002 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, no states have school requirements for MCV, but some states are in the process of implementing requirements similar to those being proposed by the Department in this proposed

rulemaking.

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

These proposed amendments would not adversely affect other existing or proposed amendments of the Department or other state agencies. The Department has discussed these requirements with the Department of Education, which is in agreement with the Department's proposed amendments.

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

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.

Further, the Department will provide a 30-day public comment period upon publication of the proposed amendments in the *Pennsylvania Bulletin.*

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

Schools would need to report in accordance with the new reporting requirements, and the Department would 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 would be minimal however, 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, is in the process of changing these requirements. Currently, the CDC requires annual immunization reporting for school students. The CDC is moving to require this reporting to include the status of the number of doses of individual antigens that have been administered to students. The proposed amendments are intended to comply with these anticipated CDC school immunization-reporting requirements. The Department would provide reporting forms to schools, as it currently does, and the reports would be sent to the same Department area as the current reports.

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

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.

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

The proposed amendments will become effective upon final publication in the Pennsylvania Bulletin.

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

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

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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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 NOV 20 2007 DATE OF APPROVAL	DEPARTMENT OF HEALTH (AGENCY) DOCUMENT/FISCAL NOTE NO. 10-181 DATE OF ADOPTION: _____ BY: CALVIN B. JOHNSON, M.D., M.P.H. TITLE: SECRETARY OF HEALTH	BY _____ Andrew C. Clark OCT 22 2007 DATE OF APPROVAL (Deputy General Counsel) (~~Chief Counsel, Independent Agency~~) (~~Strike inapplicable title~~)
9 Check if applicable. Copy not approved. Objections attached.		9 Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF PROPOSED 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), proposes 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 proposed amendments are set forth in Annex A hereto.

A. PURPOSE OF THE REGULATION

The proposed amendments would revise § 23.83 (relating to immunization requirements) to combine immunization requirements for school entry into kindergarten or first grade with immunization requirements for school attendance in all grades; and to add two new immunization requirements for entry into the seventh grade. The Department has developed these proposed amendments following review of the recommendations of the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP). The Department has determined that certain of ACIP's recommendations would serve to meet the needs of the Commonwealth with respect to requirements for school immunizations. The proposed amendments would require that students before entering school be immunized with the hepatitis B vaccine (previously required for entry into either kindergarten or first grade and entry into the seventh grade); and would require that students entering the seventh grade be immunized with the tetanus, diphtheria and accelular pertussis (Tdap) vaccine, if at least 2 years has elapsed since their last tetanus and diphtheria immunization, and be immunized with the meningococcal conjugate vaccine (MCV).

Finally, the proposed amendments would institute ACIP recommendations regarding an additional dose requirement for mumps vaccine and for varicella vaccine. The proposed amendments would change the existing requirement for varicella immunity upon school entry and for entry into the seventh grade into an all-grades requirement, but would phase in the 2-dose requirement. Children entering school in kindergarten or first grade would be required to have 2 properly-spaced doses of the vaccine. The Department's requirement that children who are 13 years of age or older have 2 properly-spaced doses for entry into the seventh grade would become a requirement for school attendance for those children. The Department would then require 2 properly-spaced doses of the varicella vaccine for all grades beginning school year 2010/2011. The proposed amendments would not alter the existing option that varicella immunity may be proven by either a written history from a parent, guardian or physician, or by laboratory confirmation of the disease.

Further, the proposed amendments are also intended to clarify what immunization requirements apply to children under the age of 5 years attending child care group settings located in a school. In addition, the proposed amendments are intended to clarify 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 appropriate immunizations as a condition of attending those programs.

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

B. REQUIREMENTS OF THE REGULATION

CHAPTER 23. SCHOOL HEALTH
SUBCHAPTER C. IMMUNIZATION

Section 23.82. Definitions.

The Department proposes to clarify the definition for "attendance at school." It proposes to add a sentence to that definition that clarifies that attendance at school does not include the attendance of children in child care group settings located in schools. The term "child care group setting," and the requirements for immunizations relating to those settings are included in the Department's regulations relating to communicable and noncommunicable diseases at 28 Pa. Code §§ 27.1 and 27.77 (relating to definition for "child care group settings;" immunization requirements for children in child care group settings). Section 27.77(d) states that children attending kindergarten, elementary school or higher school and children known to the care giver to be 5 years of age or to attend a kindergarten are to follow the requirements in section 28.83 (relating to immunization requirements). (28 Pa. Code § 27.77(d)(1)(i) and (ii)). The Department promulgated these exceptions to section 27.77 because some immunizations required in section 27.77 are not age-appropriate for these children. Immunization requirements should be applied based on age, not on the location of the child. The requirements in section 23.83 are

those that are appropriate for a child older than the age of 5 years, and are those recommended by ACIP for children in those age groups.

Although section 27.77 is clear on which immunizations are appropriate by age in a child care group setting, there is no comparable language in section 23.83. This has resulted in some confusion when a child care group setting is located in a school, or where a school has a K-4 class, that is, kindergartens that accept children at the age of 4 years. The Department is proposing to add a new subsection (d) to section 23.83 in order to clarify that children attending child care group settings located in schools are to follow the immunization requirements included in 28 Pa. Code § 27.77. These requirements are specifically geared towards children under the age of 5 years. It would be medically inappropriate and contrary to the recommendations of ACIP for these children to be required to have some doses of certain immunizations listed in section 23.83. If a child attending that child care group setting is older than 5 years of age, then the school immunization requirements would apply regardless of the child's location.

In order to take into account the attendance of children younger than 5 years of age in kindergarten classes, the Department is also proposing to make changes to section 27.77(d). Those revisions would reflect this change in the ages of children attending kindergartens, and ensure that the immunizations required to be given to children are age-appropriate, regardless of the setting in which the child is located.

Section 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.*

The Department proposes to combine subsection (a), which addresses immunizations required for entry into kindergarten or first grade, with subsection (b), which addresses immunizations required for attendance in all grades. Because there should be no difference between the list of immunizations required for school entry, and those required for school attendance, there is no need for two separate subsections addressing those immunization requirements. The Department proposes to create a new subsection (a), relating to duties of a school director, superintendent, principal, or other person in charge of a public, private, parochial or nonpublic school. New subsection (a) would include the statutory requirement that a school director, the superintendent, principal, or other person in charge of public, private, parochial or other nonpublic schools within the Commonwealth must ascertain whether children are immunized in accordance with the list of immunizations developed by the Department. That list is set out in proposed subsection (b).

These amendments would make no change to the regulation that permits provisional enrollment of students who have received at least one dose of the required immunization for a disease. A child may enter school with one dose of a vaccine series, but is then required to obtain all the necessary doses to continue in attendance. See 28 Pa. Code § 23.85 (relating to responsibilities of schools and school administrators).

Subsection (b).Required for attendance.

The Department proposes to revise subsection (b) of this section to add hepatitis B immunizations (see proposed paragraph (7)) and chickenpox (varicella) immunity (see proposed paragraph (8)), now required for entry into kindergarten or first grade, to those immunizations required for school attendance. The Department chose to phase in the requirements for hepatitis B immunizations and varicella immunity of all students attending school by requiring those immunizations first be obtained upon school entry into kindergarten or first grade and into the seventh grade, rather than requiring immediate compliance in all grade levels. This allowed schools to gradually require compliance of their student populations. In 1998, the hepatitis B immunization requirement and the 4th dose of tetanus/diphtheria immunization requirement were added to school entry into kindergarten or first grade. In 2002, the chickenpox (varicella) immunity requirement was added to school entry into kindergarten or first grade; and the hepatitis B immunization and varicella immunity requirements were added to entry into the seventh grade. Those children initially affected by the 1998 requirements are now in grade 8 and those children initially affected by the 2002 regulation are now in grades 4 and 11. Therefore, there are not many children that remain to "catch up" with one or both of these requirements.

In addition to making varicella immunity an all-grades requirement, the Department is proposing to revise the requirements for vaccination, in accordance with ACIP recommendations. ACIP recommends that children receive two doses of the varicella vaccine by the age of 13 years in order for them to be appropriately immunized. To meet this recommendation without placing undue burden on either parents and guardians, who

must obtain these vaccinations for their children, or on schools, which must determine whether children have met these requirements in order to attend school, the Department has elected to phase in the 2 varicella dose requirement. The Department proposes that until the school year 2010/2011, in order to enter school in kindergarten or first grade children must have 2 properly-spaced doses of varicella vaccine administered after 12 months of age. (See proposed paragraph (8)(i)(A)). Children 13 years of age or older would also be required to have two properly-spaced doses in order to attend school. This requirement had been in place solely for children entering the seventh grade; the proposed amendments would make it a requirement for school attendance for children 13 years of age or older. (See proposed paragraph (8)(i)(B)). At the beginning of school year 2010/2011, all children will be required to have 2 properly-spaced doses of varicella vaccine in order to attend school. (See proposed paragraph (8)(i)(C)).

Finally, the Department has not altered the provision allowing immunity to be proven by laboratory evidence or laboratory confirmation of the disease or by the statement from a physician, parent or guardian of a history of disease, rather than by evidence of a vaccination. (See proposed paragraph (8)(ii)).

The Department is also proposing to revise paragraphs (4) and (5) of subsection (b), which state what is required to show a history of immunity from measles (rubeola) and from German measles (rubella). In both those paragraphs, a history of immunity may be shown by "serological evidence showing antibody determined by the hemagglutination inhibition test or any comparable test." Because of changing technology, however, the

Department is reluctant to continue to require a specific test for this particular purpose. The Department, therefore, is proposing to replace the language in both paragraphs with the requirement that a history of immunity be shown by "laboratory testing." (See proposed subsection (b)(4) and (5)). This allows the most effective test for this purpose to be used, without dictating what test is being required.

Finally, the Department is also proposing to amend paragraphs (1), (2) and (6) of this section to add new dosage requirements relating to diphtheria/tetanus and mumps. Paragraphs (1) and (2) currently only require 3 doses of diphtheria/tetanus; the Department proposes to require a fourth dose after the child's fourth birthday. Paragraph (6) currently requires only one dose of live attenuated mumps vaccine for children at 12 months of age or older for attendance at school. (28 Pa. Code § 23.83(b)(6)). In response to recent outbreaks of mumps in school-age children who had been previously vaccinated, ACIP recently revised recommendations for mumps immunizations to recommend two doses of mumps vaccine instead of one dose for school-aged children, that is, children attending school in kindergarten through the 12th grade. Observation of the recent mumps outbreaks in schools suggests that one dose of the mumps vaccine or MMR (measles, mumps, rubella) vaccine is not sufficient to prevent mumps outbreaks in school-age children. The Department is proposing to adopt ACIP's recommendation, and proposing to add the requirement of an additional dose of live attenuated mumps vaccine in order to prevent future outbreaks of mumps in schools in the Commonwealth.

Subsection (c). *Required for entry into the 7th grade.*

The Department proposes to revise subsection (c) of this section, which lists those immunizations required for entry into the seventh grade, to delete the hepatitis B immunization and varicella immunity requirements and to include tetanus and diphtheria toxoid and acellular pertussis vaccine (Tdap) and meningococcal conjugate vaccine (MCV) immunizations. The proposed regulation would require one dose of Tdap vaccine, if at least 5 years have elapsed since the last dose of a vaccine containing tetanus and diphtheria toxoid, and one dose of MCV.

Pertussis is the most prevalent vaccine preventable disease among older children, adolescents and adults. The number of adolescents and adults diagnosed with pertussis has increased five-fold over the past 14 years. In 2003 in the United States, persons 11-18 years of age made up 36% of the total reported pertussis cases. In 2004, there were 342 cases of pertussis in Pennsylvania with 91 of those cases in the 10-14 year old age group. Children complete their routine series of tetanus/diphtheria/pertussis vaccine at 4 to 6 years of age; data suggest that immunity declines five to ten years after the last childhood vaccination.

Pertussis is easily transmitted and carries risks in older age groups, as well as for un-immunized or partially immunized infants. In older age groups, risks include prolonged coughing, vomiting and missed school or work. The clinical presentation of pertussis in adolescents ranges from mild cough illness to serious and prolonged coughing lasting for weeks to months. Pertussis outbreaks in schools with adolescents are disruptive and lead to significant public health control efforts. Studies have reported that parents lose an average of 6 days of work to care for an ill child with pertussis. This translates to an

average cost of $767 in lost productivity. Adolescents miss an average of 5.5 days of school with pertussis. When pertussis is transmitted to un-immunized or partially immunized infants, the complications can be serious.

The Federal Food and Drug Administration (FDA) licensed two Tdap vaccines in 2005 to provide protection against these diseases in adolescents and adults. On June 30, 2005, ACIP recommended the routine use of Tdap vaccine in adolescents 11-18 years of age. ACIP's preferred age for the Tdap immunization is 11-12 years of age. The Department is proposing to follow these recommendations by making the Tdap immunization required for entry into the 7th grade or at 12 years of age in an ungraded class if at least 5 years have elapsed since the last dose of a vaccine containing tetanus and diphtheria toxoid has been received.

The proposed amendments would also require one dose of MCV for entry into the 7th grade or at 12 years of age in an ungraded class. (See proposed subsection (c)(2)). This newly licensed meningococcal conjugate vaccine, licensed as of January 14, 2005, by the FDA for use in persons 11-55 years of age, offers longer protection against meningococcal disease than previous meningococcal vaccines.

Meningococcal disease strikes up to 3,000 Americans, killing approximately 300 people every year. Ten to 12% of people with meningococcal disease die and among survivors up to 15% may suffer long-term permanent disabilities including hearing loss, limb amputation or brain damage. Meningococcal disease is particularly dangerous because it

progresses rapidly and can kill within hours. Although the incidence of invasive meningococcal disease is highest in infants, the case fatality rate is highest in adolescents. The incidence of invasive meningococcal disease peaks in infants younger than 12 months, but a second peak occurs during adolescence.

The General Assembly of this Commonwealth has recognized the dangers of meningococcal disease. In response to these concerns, it passed the College and University Student Vaccination Act (35 P.S. §§ 633.1-633.3), which prohibits a student from residing in a college or university dormitory or housing unit unless the student has a one- time vaccination against meningococcal disease. (See 35 P.S. § 633.3 (relating to vaccination requirement)).

ACIP has recommended routine vaccination of adolescents (defined as persons 11-12 years of age) at a pre-adolescent health-care visit. For those adolescents who have not previously received MCV, ACIP recommends vaccination before high school entry (at approximately 15 years of age) and for college freshmen living in dormitories. The Department has reviewed ACIP's recommendations relating to MCV, and has determined that they are acceptable to meet the needs of the Commonwealth. Therefore, the Department is basing its proposed amendment on ACIP's recommendations.

Subsection (d). *Child Care Group Settings.*

This subsection would be new. It is intended to clarify questions raised because some child care group settings are located in schools, and some schools now have kindergarten

classes including children who are younger than 5 years of age. Because the ACIP recommendations for children younger than 5 years of age differ from those recommended for most children of the ages attending kindergarten, elementary school or higher school, only a child in a child care group setting who is 5 years of age or older should receive the immunizations included in section 23.83 (relating to school immunizations). Children younger than 5 years of age should still continue to receive the immunizations included in section 27.77 (relating to immunization requirements for children in child care group settings), regardless of where their child care group setting is located, or whether they are in a kindergarten class.

By proposing to add subsection (d), the Department is proposing to clarify that children younger than 5 years of age attending child care group settings located in schools are not to follow the immunization requirements for school attendance, but are to follow the requirements for immunizations in child care group settings included in the Department's regulations relating to communicable and noncommunicable diseases. (See 28 Pa. Code § 27.77). These regulations are specifically directed at children younger than the age of 5 years, and require immunizations appropriate to those younger age groups. The Department is also proposing changes to section 27.77(d) to reflect that children younger than 5 years of age are now attending kindergartens, and to ensure that age appropriate immunizations are provided to children regardless of the location of their setting.

Subsection (e). *Pre-kindergarten programs, early intervention programs and private academic pre-schools.*

This section would be new. It would make it clear that children in pre-kindergarten programs, early intervention programs and private academic pre-schools are required to comply either with the immunization requirements for school attendance, or those required for attendance at child care group settings, depending upon the age of the child. This clarification is important because children who are not yet attending kindergarten or first grade but who are still surrounded by other children, both older and younger, may contract disease as easily as those who are attending school in kindergarten or the first grade. It is important for the health of the child and the health of the Commonwealth that the spread of potentially dangerous and debilitating disease be prevented or at least contained through the use of immunization in educational settings.

It is equally important that the immunizations received by the child be age-appropriate, as mentioned above. Therefore, the Department is proposing that children younger than 5 years of age would be required to comply with the Department's regulations at 28 Pa. Code § 27.77 (relating to immunization requirements for children in child care group settings). Children 5 years of age or older would be required to comply with the requirements of subsection (b) of the proposed amendments.

Subsection (f). *Grace Period.*

This proposed subsection would be new. The Department is proposing to include a 4-day grace period for the administration of required vaccines in accordance with ACIP recommendations and with the notice of its intention to amend its regulations published by the Department in the Pennsylvania Bulletin on March 9, 2002 (32 Pa. B. 1305).

There is no scientific basis for concluding that if a vaccine is not given with a strict interval between doses or at an exact age, the vaccine is ineffective or unsafe. The CDC published recommendations in the February 8, 2002, Morbidity and Mortality Weekly Report (MMWR) which would allow vaccines to be given at a time less than or equal to 4 days prior to the recommended minimal interval between dosages and before the appropriate age for vaccine is reached and still be counted as a valid dose of vaccine. The Pennsylvania Chapter of the American Academy of Pediatrics supported ACIP's recommendations of allowing a 4 - day grace period for dose interval and age limit. The recommendation, however, conflicts with Pennsylvania's school immunization requirement in this section for measles, mumps, rubella, and varicella vaccines, which states that these vaccines must be administered on or after a child turns 12 months old in order for the vaccine to be accepted as a valid dose. With respect to varicella, the Department's regulations for entry into seventh grade require either one dose of vaccine at 12 months of age or older, or two doses of vaccine at 13 years of age or older. (See current subsection (c)(2)(i) and (ii)).

After consideration of ACIP's February 8, 2002 recommendation and review of the relevant information relating to that recommendation, the Department agreed with ACIP's determination that administering a vaccine dose 4 days earlier than the minimum interval or age limit would be unlikely to have a significant negative effect on the immune response to that dose. After discussion with and agreement from the Pennsylvania Department of Education (PDE), the Department published a notice to that

effect in the Pennsylvania Bulletin in March of 2002. That notice stated that the Department intended to amend its regulations to reflect this ACIP recommendation. (See 32 Pa. B. 1305 (March 9, 2002)). The Department now proposes to do so.

Section 23.86. School reporting.

The Department is proposing to revise this section to address requirements for reporting immunization data placed on the Department by the CDC. The CDC requests annual school immunization coverage reports from the Department as part of the Federal Immunization Grant process. In the last few years, the CDC has requested that the Department provide to the CDC information relating to individual vaccine dose coverages. In order to comply with this request, the Department has been estimating individual vaccine dose coverage by schools' self-reports and validation audits for up-to-date status for all required vaccines. The CDC may not accept Pennsylvania's estimated vaccine coverage rates in the future. The Department is proposing to amend this section to allow it to meet the CDC's reporting requirements and to ensure that the Department continues to receive grant funding for immunizations.

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.

The Department is proposing to amend subsection (d) of this section. Subsection (d) excludes children 5 years of age and older attending kindergarten, elementary school or higher school and children known to the care giver to attend a kindergarten from the immunization requirements of section 27.77, and requires them to follow the school immunization requirements in section 28.83. Because more children are now attending school based settings under the age of 5 years, this language will work to require children younger than 5 years of age that are in child care group settings located in schools to obtain immunizations appropriate for their age. The Department, therefore, is proposing to revise this subsection to ensure that those children younger than 5 years of age in school based settings such as pre-kindergarten, are required to obtain immunizations that are age appropriate.

C. AFFECTED PERSONS

The proposed amendments would affect children attending school in the Commonwealth and entering the seventh grade or at 12 years of age in an ungraded class who have not received tetanus and diphtheria toxoid immunizations within the last 5 years or who have not received the MCV immunization. The proposed amendments would also affect those students who missed the school entry requirement for hepatitis B vaccination, varicella immunity and the 4th dose of the tetanus and diphtheria vaccinations. In addition, the proposed amendments would affect those students who missed the seventh grade entry

requirements for hepatitis B vaccination and varicella immunity. Finally, the proposed amendments would affect those children who need to receive a second dose of varicella and mumps vaccines.

The proposed amendments would also affect the parents or guardians of these students, since they would have to ensure that the children receive these vaccinations, and may be required to pay out-of-pocket for them. However, because requiring these immunizations would protect children from contracting tetanus, diphtheria, pertussis and meningitis, chickenpox and mumps, their parents or guardians would not have to miss work, worry, or pay medical bills related to these diseases. Physicians and health care providers would not have to treat sick children. Department staff would not need to become involved in the prevention of outbreaks as they do now.

Those children who suffer the rare adverse reaction to a required immunization and their parents or guardians would also be affected. Conversely, children who might otherwise have become ill, or perhaps died, from meningitis, pertussis, diphtheria, tetanus, hepatitis B chickenpox or mumps, are also affected beneficially by these proposed amendments.

The proposed amendments would affect school districts and their employees, since school districts are required to ensure that children attending school have the appropriate vaccinations, and to report that information to the Department according to the Department's revised reporting requirements. The impact would be slight, however, in that school districts already have systems in place to document immunization status of

students, and because the recommendation by ACIP that a grace period be provided in determining the immunization status of students was initially made in 2002.

D. COST AND PAPERWORK ESTIMATE

1. Cost

a. Commonwealth

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; and the mumps containing vaccine (MMR), through the expenditure of federal immunization grant funds. The Commonwealth would also incur costs through the Medical Assistance Program, which pays for administering the vaccines for eligible persons. The Department makes vaccines available at no cost to private providers enrolled in the Vaccines For Children (VFC) Program for children through 18 years of age who 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. The Commonwealth should realize savings, at the same time, based on the amount of funds that would not be needed to control the outbreak of the disease the vaccine prevents.

The inclusion of a grace period into the regulations should add 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 would be no fiscal impact on local governments. Local governments could see a slight cost savings, since local governments do bear some of the cost of disease outbreak investigations and control measures. (The 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 should 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 should not add cost for school districts. School districts currently decide which children are appropriately immunized, and which are not appropriately immunized and so should 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, would now have to be taken into consideration in making this determination. This proposed amendment should not add significantly to the cost of determining whether children are appropriately immunized, since this recommendation has been in place since the Department published its notice in 2002.

These proposed amendments would 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 could 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. (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 should outweigh the minimal cost in staff time to review two additional immunizations and to follow-up on provisional enrollments.

No additional cost should be added to the regulated community by the Department's proposal to delete the requirements that the hemagglutination test or a comparable test be used to show a history of immunity to measles or German measles, and to replace that requirement with a more current test. 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 would 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 should remain stable. Future tests may, in fact, decrease in price, which could provide a cost savings for affected persons. Further, use of this method of proving immunity is not required.

Lastly, no additional cost should be 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 should not apply to those children. The regulations that would 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 should not see an increase in cost. The general public should see a decrease in costs resulting from a reduction in medical treatment needed to treat the disease 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 would need to report in accordance with the new reporting requirements, which would require them to report the number of doses of individual antigens that have been administered to students. The Department would need to review and include those new reported numbers in its report to the CDC. Schools are currently required to report immunization coverage status for their students to the Department 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 would provide reporting forms to schools, as it currently does, and the reports would be sent to the same Department office as the current reports. 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 proposed amendments would become effective upon their publication in the Pennsylvania Bulletin as final rulemaking. 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 this proposed regulation on January 24, 2008, to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare

Committee. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has any objections to any portion of the proposed amendments, it will notify the Department by April 9, 2008. The notifications shall specify the regulatory review criteria which have not been met by that portion. The Act specifies detailed procedures for review, prior to final publication of the regulation by the Department, the General Assembly and the Governor, of objections raised.

H. CONTACT PERSON

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulation to Heather Stafford, Acting Director, Division of Immunization, Department of Health, P.O. Box 90, Harrisburg, PA 17108, (717)787-5681, within 30 days after publication of this notice in the Pennsylvania Bulletin. Persons with a disability who wish to submit comments, suggestions, or objections regarding the proposed regulation may do so by using 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 Heather Stafford so that necessary arrangements may be made.

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. 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, 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.

(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 combination with tetanus toxoid and pertussis vaccine. One 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 combination with diphtheria toxoid and pertussis vaccine. One dose shall be administered on or after the 4th birthday.

* * *

(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. Each dose of measles vaccine may be administered as a single antigen vaccine.

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

(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.

(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.

(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.

(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, 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). 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).

(2) *Meningococcal Conjugate Vaccine (MCV).* One dose of Meningococcal Conjugate Vaccine.

(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), unless the child is 5 years of age or older. Attendance of a child who is 5 years of age or older at a child care group setting is conditional upon the child's satisfaction of the immunization requirements in this subchapter.

(e) *Pre-kindergarten programs, early intervention programs 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.

* * *

§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, 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 doses of individual antigens of every enrolled student 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 grade or, in an un-graded school, in any age group.

[(8)](7) The number of [children]students in any 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 age group.

[(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. Immunziation 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.

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

January 23, 2008

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

Re: Department of Health – Proposed Regulations No. 10-181
School Immunization Requirements

Dear Mr. Kaufman:

Enclosed are proposed regulations for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§ 745.1-745.15). These proposed amendments would make changes to existing regulations relating to school immunization requirements, including the addition of two new immunizations, the movement of two immunizations from the requirements for entry into the seventh grade or at the age of 12 years into those required for school attendance, the updating of dosage requirements, and the addition of a 4-day grace period for vaccine administration. In addition, the Department is proposing language to clarify what requirements relating to immunizations apply to children under the age of 5 years who are present in a school, and what requirements apply to children attending certain specified programs, for example, early intervention programs operated by contractors or subcontractors including intermediate units. Lastly, the proposed regulations would change school reporting requirements.

Section 5(g) of the Regulatory Review Act, 71 P.S. § 745.5(g), provides that the Commission may, within 30 days after the close of the public comment period, convey to the proposing agency and the Standing Committees any comments, recommendations and objections to the proposed regulations. The Department expects the regulations to be published on February 9, 2008. A 30-day comment period is provided.

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

POST OFFICE BOX 90, HARRISBURG, PA. 17108 717-787-6436

The Department will provide the Commission within 5 business days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the Commission with any assistance it requires to facilitate a thorough review of the proposed regulations. If you have any questions, please contact Brent Ennis, Director of the Office of Legislative Affairs, at (717) 783-3985.

Sincerely,

Calvin B. Johnson, M.D., M.P.H.
Secretary of Health

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

RECEIVED

2008 JAN 24 PM 12: 22

INDEPENDENT REGULATORY REVIEW COMMISSION

I.D. NUMBER:	10-181
SUBJECT:	School Immunization Requirements
AGENCY:	Department of Health

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
1/24/08	Lori Pucker	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
1/24/08	Kendra Lightner	MAJORITY CHAIRMAN Frank Louis Oliver
1/24/08	Lauren Cahen	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
1/24/08	Lindy Kaufman	MAJORITY CHAIRMAN Edwin B. Erickson
1/24/08	J. Gelwicks	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

November 21, 2007