Regulatory Analysis Form	This space for use by IRRC
(1) Agency Department of Health	RECEIVED 2001 APR -9 AM 10: 58 REVIEW COMMISSION IRRC Number: #2142
(2) I.D. Number (Governor=s Office Use) DOH Regulation No. 10-162	

(3) Short Title

School Immunization Requirements

(4) Pa Code Cite	(5) Agency Contacts & Telephone Numbers
28 Pa Code §23.83	Primary Contact: Alice J. Gray, RN, Director, Division of Immunizations. 717-787-5681 Secondary Contact: Barbara A. Newhouse, MPH Division of Immunizations 717-787-5681

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

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

The regulations provide the immunization requirements for children to enter and attend school in the Commonwealth. These regulations add new requirements for varicella vaccine and expand existing requirements for hepatitis B. The regulations require a documented history of varicella disease or an age-appropriate dose of varicella vaccine for all students entering school at kindergarten or in the first grade and seventh grade. In addition, three doses of hepatitis B vaccine are required for all students entering the seventh grade. All categories of school students, including private, parochial, public, and vocational school students and students in special education programs and home education programs must comply with the school immunization requirement. The regulations do not affect existing provisional enrollment, religious, and medical exemptions.

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

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

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

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

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

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

(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 regulations are not mandated by any federal or state law or court order, or federal regulation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

These regulations would have no fiscal impact on local governments.

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

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

The Commonwealth might incur some costs for the purchase of additional vaccines. Though all vaccines are paid for through federal grants, this is not a limitless funding stream. The Department of Public Welfare would also incur costs through the Medical Assistance Program for administering the vaccines. Medical Assistance is funded by the state with a federal match.

Cost savings would result from not having to coordinate disease investigations, institute outbreak control measures, and provide vaccine for exposed, susceptible individuals. Staff time and vaccine cost could easily exceed $20,000 - $50,000 or more for each occurrence.

Regulatory Analysis Form

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

	CFY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS	$					
Regulated Community	$0	35,281,440	35,281,440	35,281,440	28,981,440	28,981,440
Local Government	$ 0					
State Government	$ 0					
TOTAL SAVINGS	$0	***35,281,440***	***35,281,440***	***35,281,440***	***28,981,440***	***28,981,440***
COSTS						
Regulated Community	$0	1,477,800	1,477,800	1,477,800	757,800	757,800
Local Government	$ 0					
State Government *	$0	7,435,800	7,435,800	7,435,800	5,005,800	5,005,800
TOTAL COSTS	***$0***	***8,913,600***	***8,913,600***	***8,913,600***	***5,763,600***	***5,763,600***
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 regulations, the Department considers cost to the regulated community to be realized by the number of children (10%) in an age cohort who are required to pay out of pocket for these immunizations. The state government costs are realized by the number of children (90%) in an age cohort who would get the immunizations through the Department of Health because they have no other source of obtaining the required immunizations. The Department currently purchases all vaccines, including varicella and hepatitis B vaccines, with funding from the federal government. Children who already have the immunizations are not a part of these percentages. Presumably they will obtain and pay for their immunizations through other mechanisms, for example, private insurance or the Children's Health Insurance Program.

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

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

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

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

The savings estimate was calculated using a 1997 report from the CDC which concludes that for every dollar spent on varicella immunizations - $5.40 is saved; and for every dollar spent on hepatitis B immunizations - $2.00 is saved

These savings will 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 will pertain to the community at large and are expressed under the regulated community.

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

Program	FY – 3	FY – 2	FY – 1	Current FY
Immunization	$7,146,603	$7,502,506	$8,165,929	$7,505,000

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

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

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

There are no non-regulatory alternatives.

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

No alternative regulatory schemes were considered.

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

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

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

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

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

These regulations will not adversely affect other existing or regulations of the Department or other state agencies. The Department is currently in the process of proposing regulations relating to the control and prevention of communicable and noncommunicable diseases. These regulations are expected to be published as final rulemaking by April of 2001. The communicable disease regulations would require reporting of varicella by laboratories immediately, and by physicians within a three- year period of their final publication. The intent of the Department is to study the effect of the immunization requirement through the reporting requirement contained in the communicable disease regulations.

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

The Department published proposed rulemaking in the Pennsylvania Bulletin on September 2, 2000 (30 Pa. Bull. 4591), and provided a 30-day public comment period. IRRC and the Standing Committees may, if they choose, hold public hearings once the Department submits the final form regulations to them.

Regulatory Analysis Form
(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports that will be required as a result of implementation, if available. There would be no substantive change in current reporting requirements between schools and the Department. The regulations provide an option to parents and guardians permitting them to provide a history of immunization proved by laboratory testing or a history of disease. This may be considered an additional requirement, and may impose additional paperwork on physicians, although this is an option for the parent or guardian, not a requirement.
(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers. All required vaccines are available from the Department or County/Municipal Health Department clinics located in each county of the state at low or no cost to the parent.
(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained? The regulations will be effective upon final publication in the Pennsylvania Bulletin.
(31) Provide the schedule for continual review of the regulation. The Department will review the regulation on a periodic basis.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

2142

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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	DEPARTMENT OF HEALTH (AGENCY)	BY _____
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-162	3/29/01 DATE OF APPROVAL
	DATE OF ADOPTION: _____	(Deputy General Counsel) ~~(Chief Counsel, Independent Agency)~~ (Strike inapplicable title)
☐ Check if applicable. Copy not approved. Objections attached.	BY: ROBERT S. ZIMMERMAN, JR. TITLE: SECRETARY OF HEALTH	☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING

TITLE 28. HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 23]

School Immunization Requirements

Notice is hereby given that the Department of Health (Department), with the approval of the State Advisory Health Board (Board), hereby adopts amendments to 28 Pa. Code §23.83 (relating to immunization requirements) to read as set forth in Annex A.

I. PURPOSE AND BACKGROUND

The regulation promulgates immunization requirements that children seeking to enter and attend school in the Commonwealth must meet, and is based upon recommendations of the Advisory Committee on Immunization Practices (ACIP), an advisory committee of the federal Centers for Disease Control and Prevention (CDC). It also reverses the order of subsections in section 23.83, adds new requirements for chickenpox (varicella) immunity, and expands requirements for hepatitis B immunization.

The regulation is intended to control the spread of diseases in schools, which are known to be ideal settings for the transmission of communicable diseases. Requiring immunity before a child enters school in first grade or kindergarten, or before he or she is permitted to attend a school in the Commonwealth, protects that child before he or she enters an environment which readily lends itself to the transmission of disease. Further, ensuring that children are appropriately immunized carries with it advantages for the public as a whole, including other high-risk populations, as well as for the child. There is less chance of other persons contacting a highly infectious disease if children are vaccinated, and less chance of outbreaks of contagious diseases occurring.

The Department published proposed rulemaking in the Pennsylvania Bulletin on September 2, 2000, and provided a 30-day public comment period. (See 30 Pa. B. 4591 (Sept. 2, 2000)). The Department received several comments to the proposed rulemaking. The comments and the Department's responses to them appear in the summary of this final rulemaking.

II. SUMMARY

The Department received approximately 50 comments on its proposed regulation. Most of these comments were from individuals, parents and other concerned citizens, who feel strongly that the varicella vaccine should not be required. Some of these commentators oppose vaccination in general. Several blamed vaccination, specifically the MMR (measles, mumps, and rubella) vaccine, for causing conditions such as autism in their own children. Other commentators, however, wrote to support the varicella vaccine, and to relate personal tragedies resulting from the failure to have a child immunized for chicken pox. The Department respects the personal view points of all these commentators. The Department acknowledges, as several of these commentators noted, that there is no absolutely safe vaccine. The Department also understands that several commentators believe that the decision whether to vaccinate their children should be made by them alone, and that immunizations should not be mandated. The Department,

however, is charged with protecting the health and safety of the citizens of the Commonwealth, and with choosing the most efficient and effective way of doing so. (71 P.S. § 532(a)). After reviewing all the comments and its proposed regulation, the Department stands firm on its belief that the benefit of requiring varicella immunity outweighs the risks. Therefore, the Department has made no change to its regulation. Specific comments are addressed below.

General Comments on Vaccination.

Several commentators opposing vaccination in general stated that the Department's proposed rulemaking would make it illegal for parents to delay or not to give a vaccination at all, and that the regulation would put parents in the position of being criminals if they conscientiously object to the vaccine.

The regulation allows for exemptions from the required vaccines for medical or religious reasons. If a parent or guardian is objecting to a vaccine for these reasons, or believes that their objection rises to the level of a religious belief, they may attempt to obtain an exemption. It is not the Department's intention to hold a parent criminally liable for failing to ensure that a child has the required immunizations. The child would, however, be excluded from school until the immunization requirements can be met.

One commentator commented that scientists were concerned about long term effects of viral DNA from live virus vaccines being incorporated into human genes.

The Department is unaware of any scientific studies that state that DNA from a live virus will have a deleterious effect on human genes.

Another commentator raised a concern that healthy children are given so many vaccines that their immune systems are becoming severely compromised.

The Department disagrees with this comment. Children are exposed to many foreign antigens every day. Eating food introduces new bacteria into the body, and numerous bacteria live in the mouth and nose, exposing the immune system to still more antigens. An upper respiratory viral infection exposes a child to from 4 to 10 antigens, and a case of "strep throat" exposes a child to from 25 to 50 antigens. According to *Adverse Events Associated with Childhood Vaccines*, a 1994 report from the Institute of Medicine, "In the face of these normal events, it seems unlikely that the number of separate antigens contained in childhood vaccines . . . would represent an appreciable added burden on the immune system that would be immunosuppressive." Available scientific data show that simultaneous vaccination with multiple vaccines has no adverse effect on the normal childhood immune system.

A number of studies have been conducted to examine the effects of giving various combinations of vaccines simultaneously. In fact, neither ACIP nor the American Academy of Pediatrics (AAP) would recommend the simultaneous administration of any vaccines until such studies showed the combinations to be both safe and effective. These

studies have shown that the recommended vaccines are as effective in combination as they are individually, and that such combinations carry no greater risk for adverse side effects. Consequently, both the ACIP and AAP recommend simultaneous administration of all routine childhood vaccines when appropriate.

One commentator asked that the Department stop mandating unnecessary immunizations.

The Department disagrees that the required immunizations listed in section 23.83 are unnecessary. Vaccines have prevented millions of deaths each year from preventable infectious diseases. School settings are an ideal place for unprotected children to contract communicable and potentially dangerous diseases. Requiring immunity for school attendance protects that child and others from unnecessary illnesses.

One commentator asked that the Department create a medical exemption in the event a physician determines the immunization of a child may be detrimental to the health of a household contact. IRRC also raised this issue.

The Department has taken the exemption language included in section 23.84 (relating to exemption from immunization) from the statute. The Public School Code of 1949 provides for exceptions in two instances: (1) where the parent or guardian of the child objects to the immunization in writing on religious grounds (24 P.S. §13-1303a(d)); and (2) where a child is deemed to have a medical contraindication which may contraindicate immunization and a physician certifies to that fact. Id. at (c). It is the Department's opinion that if a physician believes the vaccination to be medically contraindicated for an individual in the child's household, that physician may certify an exemption under section 13-1303a(c). Such a certification should be unnecessary, however, since none of the vaccinations required by section 23.83 have contraindications for an immunocompromised person residing in the household of a vaccinated child.

Two commentators raised concerns that neither parents nor medical practitioners are adequately advised of the potential for adverse reaction to the currently mandatory vaccines. The commentators stated that in their experience, no doctor has ever discussed the risks associated with the vaccinations with the parent to help the parent determine the risks to the child of undergoing the vaccination.

The Department agrees that practitioners should, as a matter of prudent practice, discuss with parents and guardians the risks associated with the provision of a vaccine. The Department does not have the authority to set standards for health care practitioners in the Commonwealth. The Department's authority is to create a list of diseases for which a child must be immunized before attending school. 24 P.S. §13-1303a(a). The assumption is that the practitioner will carry out his or her legal and ethical responsibilities to his or her patient.

The Department does note, however, that the National Vaccine Program (42 U.S.C.A. §§300aa-1 – 300aa-34) requires all health care providers in the United States who administer vaccines covered in the Injury Compensation Table, prior to the

administration of each dose of the vaccine, to provide copies of the relevant Vaccine Information Statements (VIS). See 42 U.S.C. §300aa-26(d). The vaccines included in section 23.83 are all included on the Injury Compensation Table. The required materials are produced by the CDC, the Committee on Childhood Vaccines, the Food and Drug Administration, and various health care provider and parent groups. Id. at (b). The information to be included in the materials is set by statute, and includes the benefits and risks associated with the vaccine. Id. at (c). The statute also requires that the materials be supplemented with visual presentations or oral explanations, as appropriate. Id. at (d). Should a parent or guardian have a question concerning a vaccination, the Department's Division of Immunization is available to provide information. That Division may be contacted at (717) 787-5681.

IRRC also questioned whether it was the Department's intention to follow ACIP guidelines in establishing requirements for school immunization, and, if so, recommended that the Department consider incorporating ACIP guidelines by reference into the regulation. IRRC notes that ACIP is recognized as the authority in this area by Pennsylvania law, citing section 2 of the Hepatitis B Prevention Act (35 P.S. § 630.2) which requires the Department to establish a program for the prevention of hepatitis B through immunization of children consistent with the recommendations of ACIP. Another commentator also suggested that allowing for automatic approval of ACIP updates would eliminate lag time between the recommendation and the regulation.

With respect to IRRC's comment regarding ACIP as the authority recognized by the legislature, the legislature has also recognized the Department and the Advisory Health Board as authoritative on the issue of immunizations. In the Disease Prevention and Control Law of 1955, (see section 16(a)(6) (35 P.S. 521.16(a)(6)), the Administrative Code of 1929, (see section 2111(c.1) (71 P.S. §541(c.1)), and the School Code of 1949, (see section 1303a (24 P.S. §13-1303a(a)), the legislature has authorized the Department, with the Board, without reference to ACIP, to create a list of diseases against which children must be immunized.

The Department does consider ACIP guidelines and recommendations in determining what immunizations to require for attendance at school. The Department is not, however, required by any body to accept all ACIP recommendations, either for the immunizations the Department will require, nor for the standards applicable to those immunizations. It is up to the Department, with the approval of the Board, to determine when and how to add required immunizations to the list. In some cases, ACIP's recommendations may not be readily applicable to school age children. Dosages may differ depending on the age the child begins the vaccine regimen. The Department, with the Board's approval, includes in its regulations the minimum dosages necessary for protection. Adopting ACIP recommendations would, among other things, be confusing for schools and school nurses. Further, ACIP recommendations could change in the middle of a school year. This, too, would be difficult for schools to track. The Department does not wish to be tied to ACIP's recommendations, since it requires the flexibility to apply its and the Board's expertise to the question of what immunizations to require.

Section 23.83(a)(1) and (8) and (c)

The Department received comments both in support of, and against, its proposed regulation requiring varicella immunity for school entry (see subsection (a)(1) and (8)), and hepatitis B and varicella immunity for entry into the seventh grade (see subsection (c)(1) and (2)). Opposition came from individual commentators. Support came from individuals, providers' professional associations and public interest groups.

One commentator expressed his support, and requested that the Department consider and encourage the incorporation of evolving technologies into the immunization information gathering process.

The Department agrees that utilizing advancing technology would make tracking immunization levels statewide easier to accomplish. The Department is currently incorporating a statewide immunization information system into public clinic sites. This system will enable certain approved health care providers to easily access a child's immunization history, hopefully preventing unnecessary vaccinations, and facilitating updating a child's immunizations. The Department is intending to extend this system statewide in the private sector following implementation at all public sites.

IRRC questioned why the Department had included chickenpox and hepatitis B in subsection (a), which set out requirements for first-time entry into school at kindergarten and the first grade, but had not included them in subsection (b), which included requirements for attendance at school. IRRC asked what the impact would be if a child moved to Pennsylvania from another state and failed to have these two immunizations.

The Department has made the determination that hepatitis B and varicella immunization and immunity requirements should be phased into the school system. The Department has done so by requiring hepatitis B and varicella immunization or immunity at first-time entry into school at kindergarten and first grade, and then to include the requirement for entry into the seventh grade, or at the age of 12. See subsection (c). This is consonant with ACIP recommendations, and allows the school some flexibility in working out administrative arrangements to accomplish this requirement, as well as affords parents time to obtain the required vaccinations or provide the necessary history of immunity for an older child. Parents should be encouraged to have all children protected from these two diseases.

Because the Department is now requiring either immunization or immunity at school entry in the first grade or kindergarten, the number of children without immunity to these diseases should decrease over succeeding years. In the seventh year after the regulation's implementation, the number of children without these immunities should be close to zero. The entry of a child without immunity to hepatitis B and varicella into school after the first grade or kindergarten and prior to the seventh grade, will pose little problem since the chances of the child contracting the disease from a increasingly immunized student

body will be small, and the child's ability to cause an outbreak if he or she does succeed in contacting the disease will also be small.

Several individual commentators commented that varicella was a benign childhood disease that would give a child lifelong immunity. These commentators felt that it was unnecessary to force a vaccine on a healthy child for whom the disease would most likely be no more than an inconvenience, and that an adult could choose to be vaccinated if the adult chose. These commentators stated that varicella was not a public health threat. One commentator stated that the disease should not be labeled as severe since CDC statistics show that most cases are free from complication. In response to these comments, and others raising opposition to the vaccine, IRRC has asked that the Department provide additional explanation or documentation of the need to require varicella immunity as a prerequisite for school entry.

The Department is the State agency with the responsibility for preserving and protecting the health of the citizens of the Commonwealth. 71 P.S. §532(a). The legislature has recognized that the Department, in conjunction with the Board, has the expertise to determine what vaccinations and immunizations should be required to protect the public health. 24 P.S. §13-1303a(a); 71 P.S. §541(c.1). In the opinion of the Department and the Board, varicella is a public health threat. The Department and the Board base their decision on the recommendations of ACIP.

These recommendations are included in the following publications: CDC. Prevention of varicella. Recommendations of the Academy Committee on Immunization Practices. MMWR 1996;45(RR-11):1-36; CDC. Prevention of varicella. Recommendations of the Advisory Committed on Immunization Practices (ACIP). MMWR 1996;45(RR-11):1-36; CDC. Prevention of varicella. Updated recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999;48(RR-6):1-5; CDC. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1991;40(RR-13):1-25; CDC. Immunization of adolescents. Recommendations of the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Medical Association. MMWR 1996;45(RR-13):1-16; CDC. Update: recommendations to prevent hepatitis B virus transmission—United States. MMWR 1995;44:574-5.

Prior to the availability of varicella vaccine there were approximately 4 million cases of varicella a year in the United States. It is correct that most cases are free from complications. However, although varicella is frequently perceived as a disease that does not cause serious illness, especially among healthy children, 11,000 hospitalizations and 100 deaths from complications relating to varicella occurred every year in the United States before the varicella vaccine became available. The majority of deaths and complications occurred in previously healthy individuals.

Experience with vaccination programs, both in the United States and elsewhere, has consistently demonstrated that childhood vaccination programs are much more successful than those aimed at adolescents and adults. Finally, it is not possible to predict which child or adult will suffer serious complications from varicella. Now that a reasonably safe and effective vaccine is available, the benefits of that vaccination outweigh the risks.

The decision to vaccinate an individual child benefits both the individual and the wider community. Having school requirements for vaccination achieves high levels of protection in schools, pre-schools and child care centers, resulting in less illness and school time missed by healthy children (some of whom may have serious complications) and less danger of severe infection among children who cannot be vaccinated. Persons who are not able to receive chickenpox vaccine include children with leukemia and other cancers, persons taking high doses of steroid medications for a variety of medical conditions (including asthma), pregnant women and infants less than 1 year of age. These people have a higher risk of developing severe chickenpox with complications. The best way to protect them is to achieve high levels of vaccination among persons in the community so that they are less likely to come in contact with a person with chickenpox.

Two commentators mentioned that an American Medical Association publication recommended exposing children to varicella, and asked what had changed over the last 6 years to invalidate that recommendation. Another commentator also mentioned an article in the Journal of the American Medical Association claiming it stated primary care physicians were not recommending the vaccine.

The varicella vaccine was licensed in 1995 in the United States. Prior to the availability of that vaccine, it would have been safer for a child to contract chickenpox than for an adult to run the risk of contracting the disease. Several physicians' organizations have indicated their support for the vaccination, both nationally, and within the Commonwealth. The American Academy of Pediatrics has recommended the vaccine, along with ACIP, and the Pennsylvania Medical Society and the Pennsylvania Academy of Family Physicians have written the Department in support of the Department's proposed varicella immunity requirement.

Several commentators commented that there is insufficient data to show that the administration of the varicella vaccine with other vaccines is safe. Several commentators stated there was not sufficient data to show that administering the vaccine individually is safe. One commentator also raised the question of "break through" cases of varicella (cases of disease that occur in vaccinated persons are almost always less severe) and asked whether deaths from the vaccine were comparable to deaths from the disease nationwide.

The Department disagrees that the varicella vaccine is not sufficiently safe to be required. The CDC has recommended the use of the vaccine because, based on the testing done, the benefits of the vaccine outweigh the risks of its use. The Department has discussed the dangers of the disease above. Further, there are more deaths nationwide from the disease than can be attributed to the varicella vaccine.

Available scientific data show that simultaneous vaccination with multiple vaccines has no adverse effect on the normal childhood immune system. The study cited by two commentators in their comments was intended to detect potential hazards, including rare events associated with the varicella vaccine, and to assess case reports for clinical and epidemiological implications. Wise, Postlicensure Safety Surveillance for Varicella Vaccine, 284 JAMA 1271, 1271 (Sept. 13, 2000). In giving case backgrounds of case reports, the article made mention of other vaccinations provided the individual, but the study was not intended to review the effect of the combination of vaccinations, and reaches no conclusion on that matter. In conclusion, the article states the following:

> Chickenpox can be serious and even deadly, but varicella vaccine can now prevent serious varicella infections with a high degree of reliability. (Footnotes omitted). Safety surveillance through [the Vaccine Adverse Event Reporting System] confirms that most of the vaccine's adverse effects are minor. Although reports to VAERS provide either tentative or clear evidence for a variety of serious vaccine risks, all appear to be rare, and the majority, while plausible, lack confirmation of causation by [the vaccine given].

Id. at p. 1278.

A number of studies have been conducted to examine the effects of giving various combinations of vaccines simultaneously. These studies have shown that the recommended vaccines are as effective in combination as they are individually, and that such combinations carry no greater risk for adverse side effects. Consequently, both the ACIP and AAP recommend simultaneous administration of all routine childhood vaccines when appropriate.

Another commentator specifically raised the concern that vaccines include mercury.

The varicella vaccine does not contain mercury. Mercury has been eliminated from most of the routine childhood vaccines, and the CDC projects that totally mercury-free vaccines will be available within the next year.

One commentator commented that the manufacturer of the varicella vaccine has admitted that immunization is only temporary, and several other commentators questioned the long term effectiveness of the varicella vaccine. One commentator suggested that the vaccine could require continuous "booster shots" to create lifetime immunity. The commentator suggested that since the vaccine could fail in adults and the disease is more serious in adults, the vaccine should not be required, but children should be allowed to get the disease naturally.

The length of protection or immunity from any new vaccine is never known when it is first introduced. Available data from following up children vaccinated in prelicensure clinical trials indicate that protection from varicella vaccine lasts for at least 25 years (Japanese data) and 14 years (U.S. data). The vaccine has been licensed in the U.S. since

1995, and clinical trials were occurring prior to that time. The vaccine has been in use in Japan for a longer period of time. Experience with other live viral vaccines (e.g. measles, rubella) has shown that, post-vaccination, immunity remains high throughout life. For these vaccines, second doses are needed to cover the small percentage of people who fail to seroconvert (that is, whose systems fail to create antibodies as protection against the disease) after the first dose. This is known as primary vaccine failure. Follow-up studies continue to assess levels of immunity in persons who have been vaccinated as disease incidence declines. The CDC's advisory committee, ACIP, taking into account all the available information relating to the varicella vaccine, has made the determination that the vaccine is sufficiently effective to recommend its use.

Further, the Department believes that it is precisely because of the serious complications for adults that the vaccine should be given to children.

With respect to manufacturer's labels, manufacturers of products warn users of products of possible problems with products in part out of concern for liability. Because a manufacturer cannot prove that a vaccine is effective for a lifetime, it cannot say so without the possibility of legal difficulties. The studies discussed above show sufficient longevity for ACIP and the AAP to determine that the vaccine's benefits outweigh its risks. The Department has accepted, and the Board has approved, these recommendations.

Several commentators commented that there was evidence that the varicella vaccine, along with other vaccines, could be responsible for the increasing incidence of rare childhood conditions. A few commentators suggested that the vaccine could be a cause of infertility, behavioral problems, and increases in other rare childhood conditions.

The currently available scientific evidence does not support the hypothesis that vaccines cause autism, or any other syndrome, infertility, or behavioral problems. There is considerable parent interest in these issues, and research regarding these concerns is ongoing by national and private entities. The Department does not believe these scientifically unsupported suspicions outweigh the benefit to the child or the public from requiring varicella immunization.

Commentators also raised concerns about potentially carcinogenic materials in the varicella vaccine. Some also objected to the vaccine, stating that it contained formaldehyde and aluminum.

Millions of doses of vaccines are administered to children in this country each year. Ensuring that those vaccines are potent, sterile, and safe requires the addition of minute amounts of chemical additives. Chemicals are added to vaccines to inactivate a virus or bacteria and stabilize the vaccine, helping to preserve the vaccine and prevent it from losing its potency over time. The amount of chemical additives found in vaccines is very small. Again, the Department does not believe this concern necessitates the deletion of the regulation. The possibility that the small amount of additives may cause a serious allergic response is outweighed by the efficacy of the vaccine in preventing serious

disease and disease outbreaks. Formaldehyde is used to inactivate toxic proprieties in vaccines that contain toxins (for example, tetanus). It is also used to kill unwanted viruses and bacteria that might be found in cultures used to produce vaccines. Aluminum gels or salts of aluminum are added as adjuvants to help the vaccine stimulate production of antibodies to fight off diseases and aid other substances in their action. In vaccines, adjuvants may be added to help promote an earlier response, more potent response, or more persistent immune response to disease.

Several commentators objected to the varicella vaccine stating that it was manufactured from human fetal cells.

The Department has not changed the regulation in response to this comment. Fetal tissue is not currently used to produce vaccines; cell-lines generated from a single fetal tissue source are used. Vaccine manufacturers obtain human cell-lines from FDA-certified cell banks. Some vaccines, including varicella vaccine, are made from human cell-line cultures. No new fetal tissue will be needed to produce cell-lines to make these vaccines, now or in the future.

One commentator raised the concern that a "black and white" rule requiring the varicella vaccine for school entry in kindergarten or first grade and for entry into the seventh grade would mean that children who had had the disease would need an unnecessary injection or laboratory test to prove immunity.

The Department's regulation requires chickenpox immunity. This is demonstrated by proof of having received varicella vaccine (see subsections (a)(8)(i) and (c)(2)), or a history of chickenpox immunity proved by laboratory testing or a written statement of history from a parent, guardian or physician. See subsections (a)(8)(ii) and (c)(2)(iii) (emphasis added). Therefore, a child is neither required to undergo an unnecessary vaccination, or have blood drawn for a laboratory test unless the parent, guardian, or physician is unable to provide a history of immunity.

Several commentators focused on the Department's statement in the preamble to the proposed rulemaking that part of the cost associated with not requiring varicella immunity for children entering or attending school is the cost resulting from a parent or guardian taking time off from work to care for the child. The commentators stated that it was not the function of a health agency to determine how much work a parent was allowed to miss to care for children, and that children belong to the parent, and not the state. According to these commentators, this was solely a parental decision.

The commentators have misconstrued the Department's statement. The Department is required to address the fiscal impact of a regulation when it proposes or adopts the regulation. The Department's reason for requiring varicella immunity is not to have less work disruption due to illness. This is not the main reason for proposing this requirement. It is a statement of parental and societal economic impact. The major reason for vaccination with chickenpox vaccine is the reduction of serious complications from an otherwise preventable disease, or has been discussed above.

Further, the Department's statement in the preamble to proposed rulemaking was not intended to set a standard for how much work a parent may miss in order to care for a child, nor does the regulation set such a standard. The Department is required, by law, to assess the costs and benefits of the proposed regulation to the regulated community, to state and local government, to the private sector, and to the public (71 P.S. § 745.5(a)(4)). Part of the cost-savings of requiring varicella immunity is, in the Department's opinion, the reduction of lost time and productivity on the part of parents and guardians required to miss work to care for their children. This is not to say that parents and guardians may not or should not stay home from work to care for their sick children, it merely projects that the need of parents and guardians to do so will diminish as the requirements of the Department's regulation are implemented.

One commentator raised the issue of reimbursement, but noted the Department had no jurisdiction to resolve that issue. The Department has no need to address that comment.

C. AFFECTED PERSONS

This regulation affects those children entering school for the first time in kindergarten or first grade in the Commonwealth, and those entering the seventh grade, who have not yet been vaccinated for hepatitis B or chickenpox (varicella). The regulation also affects their parents or guardians.

The regulation also affects school districts and their employees, since school districts are required to ensure that children attending school have the appropriate vaccinations. To the extent that physicians may be requested by parents and guardians to provide vaccination histories or other proof of vaccination, physicians could also be affected tangentially.

D. COST AND PAPERWORK ESTIMATE

1. Cost

a. Commonwealth

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

b. Local Government

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

c. Regulated Community

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

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

d. General Public

The general public should not see an increase in cost.

2. Paperwork Estimates

a. Commonwealth and the Regulated Community

There is minimal additional paperwork requirements for the Commonwealth and the regulated community. There is a requirement that school districts report the number of children with up-to-date immunizations, the number of children in the process of obtaining the required immunizations and the number of children not meeting the immunization requirement. The regulation adds two additional immunization requirements to the current list of required immunizations.

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

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

b. Local Government

There is no additional paperwork requirement for local government.

c. General Public

There is no additional paperwork requirement for the general public.

E. STATUTORY AUTHORITY

The Department obtains its authority to promulgate regulations relating to immunizations in schools from several sources. Generally, the Disease Prevention and Control Law of 1955 (35 P.S. §521.1 et seq.) (Act) provides the Advisory Health Board with the authority to issue rules and regulations on a variety of issues relating to communicable and non-communicable diseases, including what control measures are to be taken with respect to which diseases, provisions for the enforcement of control measures, requirements concerning immunization and vaccination of persons and animals, and requirements for the prevention and control of disease in public and private schools. (35 P.S. §521.16(a)). Section 16(b) of the Act (35 P.S. §521.16(b)) gives the Secretary of Health (Secretary) the authority to review existing regulations and make recommendations to the Board for changes the Secretary considers to be desirable.

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

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

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. It further provides that certificates of immunization will be issued in accordance with rules and regulations promulgated by the Secretary with the sanction and advice of the Board.

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

F. EFFECTIVENESS/SUNSET DATES

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

G. REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act of June 30, 1989 (P.L. 73, No. 19) (71 P.S. §§745.1-745.14), on December 8, 1999, the Department submitted a copy of Notice of Proposed Rulemaking published at 30 Pa. B. 4591 (Sept. 2, 2000) to IRRC and the Chairpersons of the House health and Human Services Committee and the Senate Public Health and Welfare Committee for review and comment. In compliance with Section 5(c) of the Act, the Department also provided IRRC and the Committees with copies of all comments received, as well as other documentation.

In compliance with section 5.1(a) of the Act, the Department submitted a copy of the final-form regulation to IRRC and the Committees on April 9, 2001. In addition, the Department provided IRRC and the Committees with information pertaining to commentators and a copy of a detailed regulatory analysis form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

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

These final-form regulations were approved by the House Health and Human Services Committee on _____ and approved by the Senate Public Health and Human Services Committee on _____. IRRC met on _____ and approved the regulation in accordance with Section 5.1(e) of the Act. The Attorney General approved the regulation on _____.

H. CONTACT PERSON

Questions regarding these regulations may be submitted to: Alice Gray, Director, Division of Immunization, Pennsylvania Department of Health, P.O. Box 90, Harrisburg, Pa 17108-0090 (717) 787-5681. Persons with disabilities may submit questions in alternative formats such as audio tape, Braille or by using V/TT (717) 783-6514 for speech and/or hearing impaired persons or the Pennsylvania AT&T Relay Service at (800-654-5984[TT]). Persons who require an alternative format of this document may contact Ms. Gray at the above address or telephone numbers so that necessary arrangements may be made.

I. FINDINGS

The Department, with the approval of the Advisory Health Board, finds that:

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

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

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

J. ORDER

The Department, with the approval of the Advisory Health Board, acting under the authorizing statutes, orders that:

(a) The regulation of the Department, 28 Pa. Code §23.83 (relating to immunization requirements), is hereby amended as set forth in Annex A.

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

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

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

(e) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

ANNEX A

TITLE 28. HEALTH AND SAFETY

PART III. PREVENTION OF DISEASES

CHAPTER 23. SCHOOL HEALTH

Subchapter C. IMMUNIZATION

§23.83. Immunization requirements.

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

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

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

(3) *Poliomyelitis.* Three or more properly spaced doses of either oral polio

vaccine or enhanced inactivated polio vaccine, but if a child received any doses of inactivated polio vaccine prior to 1988, a fourth dose of inactivated polio vaccine is required.

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

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

(6) *Mumps.* One dose of attenuated mumps vaccine administered at 12 months of age or older or a physician diagnosis of mumps disease indicated by a written record signed by the physician or the physician's designee. Mumps vaccine may be administered as a single antigen vaccine. The Department recommends the combined MMRII vaccine.] *Required for entry.* The following immunizations are required for entry

into school for the first time at the kindergarten or first grade level, at public, private, or parochial school in this Commonwealth, including special education and home education programs.

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

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

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

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

(5) *Measles (rubeola).* Two properly-spaced doses of live attenuated measles

vaccine, the first dose administered at 12 months of age or older, or a history of measles immunity proved by serological evidence showing antibody to measles as determined by the hemagglutination inhibition test or a comparable test. Each dose of measles vaccine may be administered as a single antigen vaccine.

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

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

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

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

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

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

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

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

(3) *Tetanus.* Four or more properly-spaced doses of tetanus toxoid, which may be administered as a single antigen vaccine, in combination with diphtheria toxoid or in

combination with diphtheria toxoid and pertussis vaccine. The Department recommends the combined DTP vaccine. One dose shall be administered on or after the 4th birthday.

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

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

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

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

combination with diphtheria toxoid and pertussis vaccine.

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

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

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

(6) *Mumps.* One dose of live attenuated mumps vaccine, administered at 12 months of age or older or a physician diagnosis of mumps disease indicated by a written

record signed by the physician or the physician=s designee. Mumps vaccine may be administered as a single antigen vaccine.

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

Measles (rubeola). Two properly-spaced doses of attenuated measles vaccine, the first dose administered at 12 months of age or older, or a history of measles immunity, proved by serological evidence showing antibody to measles as determined by the hemagglutination inhibition test or a comparable test. Each dose of measles vaccine may be administered as single antigen. The Department recommends the combined MMRII vaccine.] *Required for entry into 7th grade.* In addition to the immunizations listed in subsection (b), the following immunizations are required at any public, private, parochial or vocational school in this Commonwealth, including special education and home education programs, as a condition of entry for students entering the seventh grade; or, in an ungraded class, for students in the school year that the student is 12 years of age:

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

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

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

(ii) Two properly-spaced doses of varicella vaccine for children 13 years of age and older.

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

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

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

April 9, 2001

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

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

Dear Mr. Nyce:

Enclosed is a copy of final-form regulations for review by the Commission pursuant to the Regulatory Review Act (Act) (71 P.S. §§745.1-745.15). Section 5.1(a) of the Act provides that, upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to the Commission and the Standing Committees, a copy of the agency's response to the comments received, the names and addresses of commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

A list of the names and addresses of the commentators who requested a copy of the final-form regulations is enclosed. Their comments, which discussed a number of provisions contained in the proposed regulations, were forwarded to the Commission upon receipt by the Department.

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

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

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

Sincerely,

Robert S. Zimmerman, Jr.
Secretary of Health

Enclosures

MAILING LIST FOR SCHOOL IMMUNIZATION
FINAL-FORM REGULATIONS
NO. 10-162

Ms. Joan M. Block, R.N.
President
Hepatitis B Foundation
700 East Butler Ave.
Doylestown, PA 18901-2697

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Dr. Richard L. Schaffnit, D.C.
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Dr. Kevin P. Shaffer, M.D.
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Pennsylvania Academy of Family Physicians
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TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

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

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

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

RECEIVED
2001 APR -9 AM 10:58
REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
4/9	Lila J. Burns	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
4/9		
4/9	Kristi Kreiser	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
4/9		
4/9		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

March 29, 2001