

RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 23]

School Immunization

The Department of Health (Department), with the approval of the State Advisory Health Board (Board), amends § 23.83 (relating to immunization requirements) to read as set forth in Annex A.

I. Purpose and Background

This rulemaking promulgates immunization requirements that children seeking to enter and attend school in this Commonwealth shall 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 § 23.83, adds new requirements for chickenpox (varicella) immunity, and expands requirements for hepatitis B immunization.

This rulemaking 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 the child is permitted to attend a school in this Commonwealth, protects that child before the child 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 at 30 Pa.B. 4591 (September 2, 2000), and provided a 30-day public comment period. 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 rulemaking. 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 measles, mumps and rubella (MMR) 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 viewpoints 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 this Common-

wealth, and with choosing the most efficient and effective way of doing so. See section 2102(a) of The Administrative Code of 1929 (71 P. S. § 532(a)). After reviewing all the comments and its proposed rulemaking, 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 the proposal. Specific comments follow.

General Comments on Vaccination.

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

The rulemaking 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 these 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 these 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 § 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. The Independent Regulatory Review Commission (IRRC) also raised this issue.

The Department has taken the exemption language included in § 23.84 (relating to exemption from immunization) from the statute. The Public School Code of 1949 (code) (24 P. S. §§ 1-101—27-2702) provides for exceptions in two instances: (1) when the parent or guardian of the child objects to the immunization in writing on religious grounds, under section 1303a(d) of the code (24 P. S. § 13-1303a(d)); and (2) when a child is deemed to have a medical contraindication which may contraindicate immunization and a physician certifies to that fact. *Id.* at subsection (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 1303a(c) of the code. The certification should be unnecessary, however, since none of the vaccinations required by § 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 this Commonwealth. The Department's authority is to create a list of diseases for which a child must be immunized before attending school. See section 1303a(a) of the code. The assumption is that the practitioner will carry out his legal and ethical responsibilities to his 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.A. § 300aa-26(d). The vaccines included in § 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 subsection (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 subsection (c). The statute also requires that the materials be supplemented with visual presentations or oral explanations, as appropriate. *Id.* at subsection (d). If a parent or guardian has 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 noted 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 General Assembly, the General Assembly has also recognized the Department and the Board as authoritative on the issue of immunizations. In the Disease Prevention and Control Law of 1955 (see section 16(a)(6) (35 P. S. § 521.16(a)(6)), The Administrative Code of 1929 (see section 2111(c.1) (71 P. S. § 541(c.1)) and the code (see section 1303a (24 P. S. § 13-1303a(a)), the General Assembly 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, neither 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 rulemaking 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 State-wide 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 this Commonwealth 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 the child 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 this Commonwealth. See section 2101(a) of The Administrative Code 1929. The General Assembly 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. See section 1303a(a) of the Code; and

section 2111(c.1) of The Administrative Code of 1929 (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 Committee 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, preschools 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 AMA 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 this 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 previously mentioned. 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 (United States data). The vaccine has been licensed in the United States 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 (such as, measles, rubella) has shown that, postvaccination, 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 previously discussed 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 properties 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 rulemaking 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). 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 previously discussed.

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 to care for a child, nor does the regulation set a standard. The Department is required, by law, to assess the costs and benefits of the proposed rulemaking to the regulated community, to State and local government, to the private sector and to the public. See section 5(a)(4) of the Regulatory Review Act (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 final-form rulemaking affects those children entering school for the first time in kindergarten or first grade in this Commonwealth, and those entering the seventh grade, who have not yet been vaccinated for hepatitis B or chickenpox (varicella). This rulemaking also affects their parents or guardians.

The final-form rulemaking 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) under State law should not see any out-of-pocket cost for the vaccinations. Families whose insurance plans do not cover these vacci-

nations, 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 final-form rulemaking 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 are 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 final-form 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 final-form 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 this 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—521.21) (act) provides the Board with the authority to issue rules and regulations on a variety of issues relating to communicable and noncommunicable diseases, including what control measures are to be taken with respect to which diseases, provisions for the enforcement of control measures, requirements concerning immunization and vaccination of persons and animals, and requirements for the prevention and control of disease in public and private

schools. Section 16(b) of the 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.

Section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)), gives the Department this general authority. Section 2111(b) of The Administrative Code of 1929 (71 P. S. § 541(b)) provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of this Commonwealth. 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 of 1929 and in the code. Section 2111(c.1) of The Administrative Code of 1929 provides the Board with the authority to make and revise a list of communicable diseases against which children are required to be immunized as a condition of attendance at any public, private or parochial school, including kindergarten. 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 code 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, shall 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. See section 2 of the Hepatitis Prevention Act (35 P. S. § 630.2).

F. *Effectiveness/Sunset Dates*

The final-form 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 (71 P. S. § 745.5(a)), on August 23, 2000, the Department submitted a copy of the notice of proposed rulemaking published at 30 Pa. B. 4591 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 Regulatory Review 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 Regulatory Review Act (71 P. S. § 745.5a(a)), the Department submitted a copy of the final-form rulemaking 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.

This final-form rulemaking was deemed approved by the House Health and Human Services Committee and the Senate Public Health and Welfare Committee on April 30, 2001. IRRC met on May 3, 2001, and approved the regulation in accordance with section 5.1(e) of the Regulatory Review Act. The Attorney General approved the final-form rulemaking on May 16, 2001.

H. Contact Person

Questions regarding this final-form rulemaking may be submitted to: Alice Gray, Director, Division of Immunization, 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 Alice Gray at the previously mentioned address or telephone numbers so that necessary arrangements may be made.

I. Findings

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

(1) Public notice of the intention to adopt the amendment 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 final-form rulemaking 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 Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 28 Pa. Code Chapter 23, are amended by amending § 23.83 to read 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 and Annex A 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 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*.

ROBERT S. ZIMMERMAN, Jr.,
Secretary

Fiscal Note: Fiscal Note 10-162 remains valid for the final adoption of the subject regulation.

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 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 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 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 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. 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 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 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 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.

[Pa.B. Doc. No. 01-1797. Filed for public inspection September 28, 2001. 9:00 a.m.]

