Final Regulation #3147 Department of Health
#10-197: School Immunizations

Included here are these Documents:

1. RAF
2. Face Sheet
3. Annex
4. Letter from the Chairman
5. Transmittal Sheet

The following Documents can be found in the Related Documents Tab for this Regulation:

1. Preamble Part 1
2. Preamble Part 2
3. RAF Attachment 1
4. RAF Attachment 2
5. RAF Attachment 3
These amendments replace the 8-month provisional period with a new requirement. Previously, the regulations allowed a child to be provisionally admitted to school even though the child did not have all the required immunizations for entry or continued attendance as set out in § 23.83 (relating to immunization requirements) for 8 months before facing exclusion. These amendments require a child to have any single dose vaccine upon school entry, or risk exclusion. In the case of a multi-dose vaccine, the amendments require that the child have at least one dose of the vaccine upon school entry. If additional doses are required and are medically appropriate within the first five days of school, the child must have either the final dose during that five day period, or must have the next scheduled dose and must also provide a medical certificate setting out the schedule for the remaining doses. If the child has at least one dose, but needs additional doses, and those doses are not medically appropriate during the first five days of school, the child may provide a medical certificate on or before the 5th school day scheduling those doses. The medical certificate must be signed by a physician, certified registered nurse practitioner (CRNP), or physician assistant (PA). If the child receives the immunizations from the Department or a public health department, a public health official may sign the medical certificate. A child who fails to meet these requirements risks exclusion.

A child who meets these requirements may continue to attend school even if the child does not have all the required vaccinations, so long as the child complies with the vaccination schedule in the medical certificate. School administrators or their designees are required to review that medical certificate every 30 days to ensure that the child is in compliance.
The amendments also add a dose of meningococcal conjugate vaccine (MCV) for entry into the 12th grade, or, in an ungraded class, for entry into the school year where the child turns 18. This is in accordance with recommendations of the Advisory Committee on Immunization Practices (ACIP), an advisory committee of the Federal Centers for Disease Control and Prevention (CDC). The Department has also added pertussis to the list of diseases against which a child must be immunized before entering and attending school; this acknowledges the fact that certain vaccines, like single antigen diphtheria, single antigen tetanus and single antigen pertussis vaccine, are not available in the United States. Children being immunized against diphtheria and tetanus in the Commonwealth prior to these amendments were receiving DTaP, in accordance with ACIP recommendations (unless the child had a contraindication for the pertussis vaccine, or a religious/philosophical exemption) and so are already receiving a pertussis vaccination.

The amendments allow the Department to waive the immunization requirements in the case of a national vaccine shortage, or an emergency, and also provide a child transferring into school in the Commonwealth who is unable to provide vaccine records immediately to provide those records or an exemption within 30 days.

Finally the amendments change the manner and time frames for schools to report immunization rates to the Department, in order to ensure the most accurate immunization data possible from schools.

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

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

The Department also finds general authority for the promulgation of its regulations in the Administrative
Code of 1929 (71 P.S. § 51 et seq.) Section 2102(g) of the Administrative Code (71 P.S. § 532(g)) gives the Department this general authority. Section 2111(b) of the Administrative Code of 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 the Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department.

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

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

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

No, these amendments are not mandated by any federal or state law or court order, or federal regulations. There are no relevant state or federal court decisions relating to these amendments. The Department is aware of the federal Vaccine Court and the National Childhood Vaccine Injury Program, created by the National Childhood Vaccine Injury Act of 1986. (42 U.S.C. § 300aa-10 et seq.) The program allows children who are harmed by vaccines to obtain compensation for injuries suffered after receiving immunizations. In order to receive an award, a petitioner must make a number of factual demonstrations, including that the child received a vaccination covered by the statute, received it in the U.S., suffered a serious long lasting injury, and received no previous award or settlement on account of the injury. Cedillo v. Secretary of Health and Human Services, ___ Fed. Cl. ___ (No. 98-916V) (filed: February 12, 2009), slip op. at 2, affirmed, Cedillo v. Secretary of Health and Human Services, ___ F.3d ___ (No. 2010-5004). The petitioner must also establish a causal link between the vaccine and the injury. Id. If the petitioner is able to show that the vaccine recipient suffered an injury listed on the Vaccine Injury Table created through the statute, and corresponding to the vaccine in question, within an applicable time frame, then there is a presumption that the vaccine caused the injury, and the child is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by
some other factor. *Id.*

If the injury is not included in the table, the petitioner may still receive compensation if the petitioner is able to show causation in fact, and the petitioner must show by a preponderance of the evidence that the vaccine actually caused the injury in question. *Id.* at 3. The petitioner must show that the vaccination was at least a substantial factor in causing the condition, and must show proof of a logical sequence of cause and effect that the vaccine was the reason for the injury. The logical sequence must be supported by reputable medical or scientific explanation. *Id.* (Citations omitted).

The Department does not believe the decisions made by the Vaccine Court impact these regulations, as they involve individual petitioners bringing cases with circumstances unique to them. Nothing in those cases requires the Department to, or prohibits the Department from, amending its regulations.

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

These amendments are needed in order to decrease the threat of vaccine-preventable disease outbreaks in schools and in the general population. Many of these diseases are more prevalent among school age children, but can quickly spread to the adult population as well. Protection of the public from vaccine-preventable diseases can be accomplished by ensuring the continuance of “herd immunity” or “community immunity” among children in schools. Low vaccination rates can lead to a waning of herd immunity, which is defined as the protection for the community against certain communicable diseases that arises when a critical mass of persons are immunized against those diseases. Herd or community immunity is a means of protecting a whole community from disease by immunizing enough people so that no sustained chain of disease transmission can be established. By breaking the chain of a disease transmission, vaccination protects more than just the vaccinated person; it also protects people who have not been, or cannot be, vaccinated because they are too young or too sick. Willingham, E. and Helft, L, *What is Herd Immunity*, NOVA, posted September 5, 2014 citing Epidemiologic Reviews, 1993 (hereinafter referred to as “Willingham and Helft”), retrieved from [http://www.pbs.org/wgbh/nova/body/herd-immunity.html](http://www.pbs.org/wgbh/nova/body/herd-immunity.html) (accessed August 6, 2016); Salathe, M. *Herd immunity and measles: why we should aim for 100% vaccination coverage*, The Conversation, posted Feb. 2, 2015 (hereinafter referred to as “Herd immunity and measles”), retrieved from [http://theconversation.com/herd-immunity-and-measles-why-we-should-aim-for-100-vaccination-coverage-36868](http://theconversation.com/herd-immunity-and-measles-why-we-should-aim-for-100-vaccination-coverage-36868) (accessed August 6, 2016).

Although many commentators disagree with the concept of herd immunity, it does exist and is a driving
force behind much of vaccine policy. The more members of a community – including a school community – who are immune to a given disease, the better protected the whole community will be from an outbreak of disease, and the less likely the disease will spread from that community to other communities. When unvaccinated children, who intend to be vaccinated at some point, are allowed to continue in school for a long period of time, the “herd” is diluted during the time it takes them to become vaccinated. The longer the time frame in which children have to be vaccinated, the easier it is for any introduction of disease to put unvaccinated children at risk, those who are putting off vaccination, and those who, for medical or other reasons cannot be or are not vaccinated. The sooner more children are fully vaccinated, the sooner herd or community immunity is achieved to protect at-risk children and adults who cannot be vaccinated and all children without vaccinations, whether for medical or other reasons.

The level of immunization in a population required to achieve herd immunity does differ from disease to disease, and some diseases, for example, pertussis, seem unaffected by it. In order to determine thresholds of immunity, epidemiologists set a value, called a basic reproduction number (R0), in order to determine vaccination rates necessary to prevent spread of disease. Marshall, G., M.D., *The Vaccine Handbook: A Practical Guide for Clinicians*, (Professional Communications, Inc., 4th Ed. 2012), at 42-44. This is a complex calculation, and differs depending on the factors, assumptions, and methodologies various researchers use. *Id.* at 42.1

Measles, for example, is easily spread through droplets and through the air, is highly contagious, and has a relatively high threshold to protect a community. Thus, experts postulate that between 92% and 95% of the population must be vaccinated to prevent the disease from spreading. Bednarczyk, Orenstein and Omer, “Estimating the Number of Measles-Susceptible Children and Adolescents in the United States Using Data from the National Immunization Survey – Teen (NIS-Teen),” *Am. J. Epidemiol.* 2016, 184(2): 148-156 (November, 10, 2015), at 153. Polio, which is less contagious and spreads in a different way, has a lower threshold, at around 83%. For a variety of reasons, certain other diseases are not strongly affected by herd immunity. For example, a disease in which immunity from vaccine and from infection wane over time, and for which a human host could colonize the disease without becoming ill, would not be as impacted by herd immunity as other diseases. This may be an issue with certain meningitis vaccines, although there have been studies showing that vaccination for meningitis serogroup C in Britain did create herd immunity. “Prevention and Control of Meningococcal Disease,” *MMWR*, March 22, 2013, 62(RR02) (hereinafter referred to as “Prevention and Control (2013)”) at 10, retrieved

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1 An article in *Epidemiologic Reviews*, published by John Hopkins University School of Hygiene and Public Health, “Herd Immunity: History, Theory, Practice,” discusses the history and theory of herd immunity, the methodologies and theories different researchers use to determine disease transmission. Fine, P.E.M., “Herd Immunity: History, Theory, Practice,” *Epidemiologic Reviews*, (1993, The John Hopkins University School of Hygiene and Public Health), (15)(2). The article points out the difficulties of making precise estimates of herd immunity thresholds in any particular context based on differing assumptions (for example, maternal immunity, variation in age of vaccination, geographical heterogeneity.) *Id.* at 282. Table 5 of this article shows threshold rates from different studies for measles of from 55% to 96% to not specified, based on the methods of calculation and assumptions used by various authors, and raises issues with the assumptions used in several of those calculations. *Id.* at 284-287. The article did not offer an opinion as to the appropriate R0 value and threshold rates for measles. The article stated instead that “experience does suggest that most theoretically-derived estimates of vaccination uptake and herd immunity thresholds [for measles] have been optimistically low, because they do not cater for important heterogeneity within real populations.” *Id.* at 286. The Department has utilized a threshold rate of 92% to review its data, based on the articles it has reviewed, and the clear acknowledgement by those articles that measles is extremely infectious. Wallingham and Helft provided a threshold range of between 83% and 95% for measles, citing “Herd Immunity: History, Theory, Practice,” *supra*, while acknowledging that measles is so infectious that the threshold immunity required to protect a community is 95%. Wallingham and Helft, at 2.
The Department does not claim that herd immunity will protect students from every infectious disease. It will, however, protect students and adults in schools and in surrounding communities from highly contagious and serious diseases. In order to maintain levels of immunity to prevent the spread of potentially dangerous and highly infectious diseases, -- for example, measles, mumps, rubella, and polio -- vaccination rates need to be as follows: 75% to 86% for mumps, 83% to 85% for rubella, 93%-95% for measles, and 80-86% for polio. Wallingham and Hleft; Lecture, "Disease Control and (R0)," Johns Hopkins, Bloomberg School of Public Health, retrieved from http://ocw.jhsphs.edu/courses/publichealhbiology/PDFs/Lecture2.pdf (accessed August 6, 2016). When herd immunity wanes because of pockets of persons susceptible to disease or for other reasons, the remainder of the population is at risk. See Bednarczyk, at 153-154. "[W]ith approximately 8.7 million children aged 17 or younger who are susceptible to measles, there is a potential for large measles outbreaks, even in the context of generally high vaccination coverage." Id. at 153: "[A] substantial number of children and adolescents aged 17 years or younger in the United States are susceptible to measles, with some clustering raising concerns that endemic measles transmission should be reestablished despite the overall high level of immunity." Id. at 154.

Although the school district level data reviewed by the Department for school years 2014-2015, and now 2015-2016, show rates in most school districts near or above the 95% threshold for MMR vaccination levels, individual school level data shows a different picture in some schools. For purposes of herd immunity, the actual school a student attends is the student's particular community; it is here that the unvaccinated student would be most at risk (students do come into contact with the larger school district community, and with students from schools with potentially lower rates, although not on a daily basis). There are schools within the Commonwealth at which rates for MMR in kindergarten or in the 7th grade, for the portion of the school year at which the report was made, are below 92%. See School Information System, School Immunization Summary both Public and Private Schools, School Year: 2014-2015 (hereinafter referred to as "School Immunization Summary 2014-2015"), retrieved from http://www.health.pa.gov/My%20Health/Immunizations/schoolimmunizationrates/Documents/2014_15_SLR.pdf (accessed September 14, 2016) and School Information System, School Immunization Summary both Public and Private Schools, School Year: 2015-2016 (hereinafter referred to as "School Immunization Summary 2015-2016"), retrieved from http://www.health.pa.gov/My%20Health/Immunizations/schoolimmunizationrates/Documents/2015_16_SLR.pdf (accessed September 14, 2016). See Data from individual schools for kindergarten and for 7th grade, referred to as "school level data" for 2014 and 2015 are attached to this Regulatory Analysis Form (RAF) as Attachments 1 and 2, respectively. The Department provides county level data routinely. For purposes of this Final Rulemaking, the Department is providing school level data, but is redacting the names and addresses of the schools to protect the confidentiality of those schools. It is not the Department's intention to call attention to any one school, but to underscore the importance of vaccine rates.

In 2014-2015, when schools reported in December, approximately 26% of the kindergarten and 7th grade classes in non-cyber schools in the Commonwealth had vaccination rates below 92% for the MMR vaccine at some point in the school year. For some of those schools, the rates were below 85%. Rates in individual schools substantially improved in 2015-2016 (approximately 10% were below 92%) when school reporting was extended to March, but there still were schools significantly below the vaccine rates necessary for herd immunity. This means there is a period during the year in which not enough
children have been vaccinated to create herd immunity for diseases like measles, which was responsible for 481,530 cases nationwide in 1962, pre-vaccine, and 408 deaths of those children and adults.

Insufficient herd immunity also has the potential for school disruption, including closure, with concomitant loss of educational time, loss of work and pay for adults, need for daycare or other care for excluded children, administrative work to identify and exclude “susceptibles” (those who can prove neither immunity nor vaccination), disease surveillance and contact tracing in the community to contain the outbreak, costs to the health care system of both the ill and worried well, cost to parents and guardians of care for sick children, and cost to the public health care system of vaccine and prophylaxis. Although Pennsylvania has not been through a measles outbreak recently, the Department routinely conducts disease investigations and surveillance of the type that would be greatly expanded in the event of an outbreak of disease. The Department points to the costs to California because the actions taken in California would be the same as those required in the Commonwealth in the event of an outbreak. Although the actual monetary value of responding to an outbreak may differ from state to state, the types of costs and the extent of the costs are the same in any state. The longer children attending school with neither medical nor religious/philosophical reasons to avoid the vaccination, the greater the chance of an outbreak crisis like this occurring in the Commonwealth.

The California Department of Public Health estimated the public health costs of the measles outbreak in 2015 at $1.56 million dollars to $3.91 million dollars. Using a median cost per hospitalization from outbreaks from 2009-2013, California estimates total direct hospital costs at close to $500,000. California based its rough cost calculations on median costs per measles case on a CDC study of a 2011 measles outbreak published in the journal, Vaccine. Ortega-Sanchez, Vijayaraghavan, Barskey, Wallace, “The Economic Burden of Sixteen Measles Outbreaks on United States Public Health Departments in 2011,” Vaccine, 32 (2014) 1311-1317. The main findings from the study showed that the average outbreak duration was 22 days, the total identified contacts per outbreak ranged from 8,936 to 17,450, and the total cost burden ranged from $2.7 million dollars to $5.3 million dollars. Further information relating to costs or pertussis outbreaks in schools in other states and in health care settings in the Commonwealth and of MCV is included in Paragraph 22 of the RAF.

The Department has also added a dose of meningococcal vaccine for entry into the 12th grade, or, in an ungraded class, for entry into the school year where the child turns 18. This is in accordance with recommendations of the Advisory Committee on Immunization Practices (ACIP), an advisory committee of the Federal Centers for Disease Control and Prevention (CDC). The Department has also added pertussis to the list of diseases against which a child must be immunized before entering and attending school; this acknowledges the fact that certain vaccines, like single antigen diphtheria, single antigen tetanus and single antigen pertussis vaccine, are not available in the United States. Children being immunized against diphtheria and tetanus in the Commonwealth prior to these amendments were receiving DTaP, in accordance with ACIP recommendations (unless the child had a contraindication for the pertussis vaccine, or a religious/philosophical exemption) and so are already receiving a pertussis vaccination. The Department has added these requirements after reviewing ACIP recommendations, and to prevent the spread of dangerous and costly diseases among school children, adults working in those schools, and the wider community. Additional discussions of cost and effectiveness of these vaccines are included in Paragraph 15 of this RAF.
(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

There are no federal standards that relate to these amendments.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

Reviewing the available vaccination data from surrounding states shows that Pennsylvania's vaccination rates are lower than those states. The median length for provisional periods throughout the country is 30 days. The following chart shows the length of provisional periods for Pennsylvania and for surrounding states, along with the measles, mumps and rubella vaccination (MMR) rates for kindergarten (K) in those states for the year 2014. Although West Virginia has a provisional period as long as Pennsylvania, it has no religious/philosophical exception.

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<tr>
<th>Provisional period</th>
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<tr>
<td>In days</td>
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<td>Ohio</td>
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<td>W VA</td>
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<td>PA</td>
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(Email from the Centers for Disease Control and Prevention (CDC), Federal Department of Health and Human Services, October 2013 (First Column); and Morbidity and Mortality Weekly Report (MMWR))
Pennsylvania’s reduction of a provisional period for school admission should increase herd immunity in the Commonwealth, and, therefore, make the Commonwealth a safer place for children and adults. The fact that the Commonwealth is safer for its citizens does not necessarily have an impact, either positive or negative, on the Commonwealth’s ability to compete economically with other states.

With respect to the requirement that a dose of MCV be required for entry into the 12th grade, nine other states require this second dose, including Ohio, West Virginia, New York, Indiana, and Illinois. See http://www.immunize.org/laws/menin_sec.pdf

With respect to the pertussis dose at school entry, Pennsylvania is one of only two states that do not specifically require doses of DTaP. New York State does not require either tetanus or pertussis, however, New York City does required it. See http://www2a.cdc.gov/nip/schoollmmRgmtReport.asp?

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

The amendments do not affect other regulations of the Department, but they do affect regulations of the Pennsylvania Department of Education (PDE). PDE has a similar regulation at 22 Pa. Code § 11.20 (relating to nonimmunized children), allowing for an 8-month provisional period. Because PDE’s regulations reference the substantive provisions of the Department’s regulations relating to the list of diseases against which a child must be immunized to attend school, the Department and PDE have discussed this issue, and the Department is proceeding first with its regulatory package. Both agencies are moving to eliminate the 8-month provisional period from their respective regulations, but because the regulations were not jointly promulgated, the agencies are doing this in separate rulemakings. PDE will wait to promulgate final rulemaking until after the Department completes the promulgation of its regulations.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. (“Small business” is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)
The Department held the Advisory Health Board meeting on the proposed regulations on November 4, 2015. That meeting is a public meeting at which the Department presented the proposed regulations to the Board for its review and approval. The Department published notice of that meeting in the Pennsylvania Bulletin on October 24, 2015 (45 Pa.B. 6332 (October 2, 2015), in advance of the meeting, and in accordance with the requirements of the Sunshine Law. No members of the public or any stakeholder group appeared to provide comment regarding the proposed regulations. The Board approved the proposed regulations unanimously.

The Department also presented the regulations to the Health Policy Board on November 17, 2015, a board made up of representatives of health care providers, including facilities and practitioners, insurers, business, labor and consumers. Comments received at that meeting were favorable.

The Department has prepared and distributed to media outlets an FAQ document discussing the proposed regulations.

The Department reached out to representatives of the Pennsylvania School Nurses Association to discuss the proposed regulations, and provided the same information that was presented to the Advisory Health Board.

In November of 2015, the Department sent information to school nurses across the Commonwealth explaining changes to reporting procedures. The Department also sent out a survey to schools regarding the information intended to be included in the proposed regulation.

Further, in general, the Department issued a letter in June of 2015, to all physicians in the Commonwealth, urging them to participate in its “Don’t Wait. Vaccinate” campaign. The letter strongly urged all physicians to ensure that their patients were immunized before beginning school.

In addition to the communications initiated by the Department, the PDE, during its process of promulgating companion revisions proposed in regulation number 006-337, offered three opportunities for public comment on its draft proposed regulations at public meetings of the Board. PDE’s proposed regulations would reference the Department’s proposed requirements for immunizations, exemptions, temporary waivers and provisional admissions as set out in the Department’s proposed rulemaking. Opportunities for comment were provided during meetings of the Committee on Chapter 11 and the Council of Basic Education on January 13, 2016, and at the meeting of the State Board of Education (State Board) on January 14, 2016.

In addition, to garner input from small business owners, the State Board submitted a copy of the proposed regulation to the National Federation of Independent Business (NFIB) with a request that NFIB review and provide feedback relevant to the impact of the regulation on small business owners in the Commonwealth. The State Board has not been apprised of any concerns on behalf of the small business community.

The Department published proposed rulemaking in the Pennsylvania Bulletin on 46 Pa.B. 1798 (April 9, 2016), and provided a 30-day public comment period. The Department accepted comments until a week following the close of the public comment period, and has reviewed and accepted some of those comments, and prepared a preamble responding to all of them.
The Department again convened the Advisory Health Board to review the final rulemaking on September 6, 2016, and published prior notice of this meeting in the Pennsylvania Bulletin on August 27, 2016. 46 Pa.B. 5642 (August 27, 2016).

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

All citizens of the Commonwealth with school-aged children, who attend public, private, parochial or nonpublic school, as well as those children, would be affected by these proposed requirements. Parents and guardians are already required to ensure that their school-aged children are appropriately vaccinated before attending school; however, with the amendments to the regulations, school-aged children without the appropriate vaccinations or a medical certificate specifically stating when those vaccinations will be given, children may be excluded after five days. Children with medical certificates may continue to attend school without all the required vaccinations so long as they continue to meet the vaccine schedule included in that medical certificate. Children who fail to comply with their medical certificate may be excluded following the school administrator’s or his designee’s review at 30 day intervals.

With respect to vaccine costs, parents and guardians whose children’s vaccinations are covered by their insurance plans (public or private) pursuant to the ACA will not see any out-of-pocket cost for MCV or DTaP vaccines, although they may have additional copayments in order to obtain the vaccinations. Families whose insurance plans do not cover these vaccinations, or who do not have insurance, may obtain vaccines at a small administrative fee from the VFC Program through VFC providers, the Department’s state health centers and federally-qualified health centers. The Department is available to provide a list of providers if necessary. The Department also provides vaccines to schools through its Catch-Up program, although it is up to the school to request participation. The Department conducts outreach to schools regarding the Catch Up Program, and provides information to participating VFC providers regarding eligibility requirements. Those participating providers are able to inform their patients and appropriately screen them for eligibility.

In addition, parents and guardians whose children do not have up-to-date immunizations as of the first day of school will be required to obtain a medical certificate signed by a physician, CRNP or PA. That medical certificate must be submitted to the school within five days of the start of school in order to allow the student to remain in school while the immunization schedule is being followed. Parents and guardians will have to provide an updated certificate of immunization to the school as the child obtains his or her immunizations, or risk exclusion. A parent or guardian may provide the school with a medical or religious/philosophical exemption in lieu of the medical certificate to enable the child to remain in school without the required immunizations. These forms may require an additional visit to the practitioner, and either an additional co-payment, or a paperwork fee, or potentially both. A certificate of immunization has always been required; the medical certificate is a new document. A draft of the medical certificate is attached to this RAF as Attachment 3.
Trips to the practitioner’s office could result in loss of work time, however, similar and greater losses in work time could result from failure to immunize the child. In addition, the Department has made the effective date of the regulations coincide with the beginning of the 2017-2018 school year, but is publishing them as final by March of 2017, so that parents and guardians have nearly six months to plan for their 12th grade students to receive an MCV vaccine, as well as to ensure that their children who are not up-to-date with existing requirements receive the appropriate immunizations. This should be sufficient time to plan for necessary appointments and avoid loss of work time.

There may also be a loss in work time, and a health care cost for children who have adverse reactions to either MCV or DTaP. The recommendations of the ACIP indicate that costs related to the second dose of MCV is as follows:

A multivariable analysis was performed with a Monte Carlo simulation in which multiple parameters were varied simultaneously over specified probability distributions. These parameters included disease incidence (46%-120% of the 10 year average), case fatality ratio (34%-131% of the 10 year average), rates of long-term sequelae, acute meningococcal disease costs (i.e., inpatient care, parents’ work loss, public health response, and premature mortality costs), lifetime direct and indirect costs of meningococcal disease sequelae (i.e., long-term special education and reduced productivity), and cost of vaccine and vaccine administration (range: $64-$114). Vaccination coverage (37%-90%) and initial vaccine efficacy (39%-99%) also were varied for evaluation purposes. The vaccine was assumed to be 93% effective for the first year, and then waning immunity was modeled as a linear decline over the next 9 years unless a booster dose was administered. The vaccine effectiveness of a second dose was assumed to be higher with a slower rate of waning immunity. The results of the cost-effectiveness analysis indicate that a 2-dose series at age 11 years and 16 years has a similar cost effectiveness compared with the single dose at 11 years. However, the number of cases and deaths prevented is substantially higher with the 2-dose strategy.

“Prevention and Control (2013),” at 13. According to ACIP, the 2-dose strategy averted 184 cases (range 92-308), prevented 22 deaths (range 11-40), and saved 1442 quality-adjusted life years (range 610-2130), with a cost of $212,000 quality-adjusted life years saved (range 67,000-535,000). Based on this cost-effectiveness analysis, ACIP recommended the latter 2-dose strategy.

With respect to meningitis, the fatality rate is 10% to 15%, and 11% to 19% of survivors have long-term sequelae, including neurologic disabilities, limb or digit loss and hearing loss. “Prevention and Control (2013),” at 4. The fatality rate had been 50%, but antibiotics, intensive care units, and improved supportive measures have decreased the fatality rate. MCV is transmitted from human to human through direct contact, including respiratory droplets. These are the same types of cost to the state and families that the commentators contend arise from the vaccine (i.e., health care costs, potential deaths, loss of income for parents); however, the disease is preventable. All of these circumstances have costs, to the Commonwealth, to the parents of the affected child, to the health system, and to the school system. The Department notes that there is a choice regarding costs: a parent or guardian may choose to refuse the vaccination and obtain an exemption, and so risk contracting the disease. The Department also has the authority to weigh the risks and benefits and choose to add a disease to the list, and has done so with meningitis.

The Department has relied upon the recommendations made by ACIP regarding the meningococcal
conjugate vaccines. According to ACIP:

**MenACWY-D**

From licensure of MenACWY-D in January 14, 2005, through September 30, 2011, VAERS received 8,592 reports involving receipt of MenACWY-D in the United States; 89.0% reports involved persons aged 11 through 19 years. MenACWY-D was administered alone in 22.5% of case reports. The median time from vaccination to onset of an adverse event was 1 day. Males accounted for 40.6% of the reported events. The most frequently reported adverse events were fever 16.8%, headache 16.0%, injection site erythema 14.6%, and dizziness 13.4%. Syncope previously has been identified as an adverse event following any vaccination, with a higher proportion of syncope events reported to VAERS having occurred in adolescents compared with other age groups (89). Syncope was reported in 10.0% of reports involving MenACWY-D. Among all MenACWY-D reports, 563 (6.6%) were coded as serious (i.e., resulted in death, life-threatening illness, hospitalization, prolongation of hospitalization, or permanent disability).

Among those reports coded as serious, the most frequent adverse events reported included headache (37.5%), fever (32.5%), vomiting (23.6%), and nausea (22.2%). Cases of Guillain-Barré Syndrome (GBS) were recorded in 86 (15.3%) reports coded as serious, although the diagnosis has not been validated by medical records for all reports. A total of 24 (0.3%) deaths were reported, each of which was documented by autopsy report or other medical records and occurred in persons aged 10 through 23 years. Among the 24 reports of death, 11 (45.8%) indicated that the cause of death was meningococcal infection (nine with a serogroup included in the vaccine and two with a nonvaccine serogroup). Among the other 13 (54.2%) reports of death, which occurred from the day of vaccination to 127 days following vaccination, stated causes of death were cardiac (five), neurologic (two), infectious (two), behavioral (i.e., suicide) (two), rheumatologic (one), and unexplained (one). There was no pattern among these reports. Except for the finding of GBS, which was further evaluated and is discussed below, no signals were identified in VAERS after MenACWY-D vaccination.

**MenACWY-CRM**

During February 19, 2010—September 30, 2011, VAERS received 284 reports of adverse events following receipt of MenACWY-CRM in the United States. Approximately three fourths (78.9%) of the reported events concerned persons aged 11 through 19 years. Males were the subject of 44.0% of reports; 45.4% of reports involved other vaccines administered at the same time, and 4.2% of reports were coded as serious. One death was reported, with the cause of death stated as unexplained. The median time from vaccination to adverse event onset was 0 days (the day of vaccination). The most common adverse event reported was injection-site erythema (19.7%) followed by injection-site swelling (13.7%). Syncope was reported in 8.8% of reports. No cases of GBS were reported. Administration errors (e.g., wrong diluent used or subcutaneous injection) without adverse events were described in 15.5% of reports involving MenACWY-CRM.

"Prevention and Control (2013)," at 12. Based on this data, ACIP’s recommendation, which included a cost-benefit analysis, and the FDA’s licensure of the vaccine, which included a safety analysis, the Department has chosen to include a dose of MCV for entry into the 12th grade.
With respect to pertussis, data from a school-based pertussis outbreak in Omaha, Nebraska, in three months in 2008 found the cost per case to be $2171. That cost was attributable to the local health department, or, approximately 1% of the local health department’s annual budget, which would affect taxpayers. The study stated that “1) staff members reported 1,032 person-hours spent responding to the outbreak, and 2) the total cost of outbreak response, including overhead, labor, travel, and other costs, was $52,131 (measured in 2008 U.S. dollars). The majority of costs (59%) occurred during an intensive 10-day period, when most of the contact tracing and prophylaxis recommendations were made.” The outbreak took up a great deal of staff time according to the study, which found that each case of pertussis required nearly 42 regular person-hours and approximately 1 hour of overtime. The time spent investigating a pertussis case included tracing of all close contacts, and each pertussis case led to an average of 21 telephone calls and chemoprophylaxis recommendations for six close contacts. The health department did not pay for antibiotics or laboratory testing, which presumably was borne by the individuals through insurance or otherwise. According to the study, “[o]f the total cost, the largest components were investigations (37.2%) and decisions and implementation (22.9%). Resource use was most intensive during the outbreak period for all divisions [of the health department involved], Epidemiology (156% of budgeted hours), Administration (46%), and Media Relations (41%).”

In reviewing the findings, an editorial note stated that they were subject to at least three limitations. First, this report focused on the direct public cost incurred by a local health department in response to a pertussis outbreak. The report did not analyze the private costs of pertussis, including those costs borne by patients, persons recommended chemoprophylaxis, health-care providers, or institutions. However, private costs of pertussis are well studied elsewhere and can be substantial. Second, although this report measured the total delay in projects resulting from the outbreak, it did not measure the type or number of projects delayed. Future cost analyses also should measure the “opportunity cost” of outbreaks in more detail. Finally, although these data offer a picture of public health cost when responding to an outbreak, they only reflect the resource use of one health department and might differ for other health departments. For example, health departments that pay for laboratory testing and antibiotic courses for patients would incur additional costs. “Local Health Department Costs Associated with Response to a School-Based Pertussis Outbreak --- Omaha, Nebraska, September--November 2008,” MMWR, 60(01); 5-9 (January 14, 2011) (Footnotes omitted), retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a2.htm (accessed August 6, 2016). In short, the costs to the government, including taxpayers, and to the health system of any outbreak response can be significant.

Although the Department does not have data for a Commonwealth school outbreak of pertussis, the data for an outbreak in a health care facility in the Commonwealth showed that costs to the health care facility approximated $74,870, including laboratory tests, antibiotic treatment and prophylaxis, and incidental costs (labor and postage). There were also indirect costs to the health care facility of $11,200, including furloughs of workers. The health care workers themselves ended up with direct costs of $4,679 in outpatient visits, hospitalization and medications, and indirect costs of $1,730 in time lost from work.

Similar types of costs would attend an outbreak in school, although potentially it would be spread
throughout the affected community differently. Presumably a school would not pay for laboratory testing or treatment as the hospital did, but teachers and students would have copayments, and potentially treatment and prophylaxis costs if uninsured or underinsured. But the school, if required to exclude children and teachers would bear that cost, including loss of work, and potentially loss of educational time. The school would bear the cost of hiring substitute teachers to the extent teachers were impacted.

With respect to the cost of adverse events relating to vaccines, and the cost effectiveness of vaccines, at least one study suggests that childhood vaccination will prevent an estimated 322 million illnesses, 21 million hospitalizations, and 732,000 deaths over the lifetimes of children born between 1994 and 2013. “Benefits from Immunization during the Vaccines for Children Program Era – United States, 1994-2013” MMWR (April 25, 2014) Vol. 63(16) (hereinafter referred to as “Benefits from Immunization”), at 1, retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm (accessed August 6, 2016). The study concluded that vaccination would potentially avert $402 billion in direct costs, and $1.5 trillion in societal costs because of illnesses prevented in birth cohorts between 1994-2013. The study considered program costs, including cost of the vaccine, cost of administration, vaccine adverse events, and parent travel and work time lost. The cost analysis was conducted from both health care (direct) and societal (indirect and direct) perspectives. Direct costs included outbreak control and outpatient and inpatient visits. Indirect costs included the productivity losses from premature mortality, which was estimated using the human capital approach. Costs for work were determined by the number of days of missed work (for provision of care to sick children, for illness among cohort members, or for resulting disability) multiplied by the daily wage rate associated with the value of lost wage-earning work and the imputed value of housekeeping and home-care activities. The cost of vaccine administration from a private provider was estimated at $29.07. The cost of vaccine administration at a public clinic was estimated at $8.15. The study’s authors assumed that caregivers take two hours off from work to take the child for a vaccination, based on previous economic studies. The study’s authors then assumed that the average cost for these caregivers was $18.19 per hour, and that the cost for travel to a clinic was $23.45. See “Benefits from Immunization” and VFC Publications Supplement, “Appendix: Methods for the Cost Benefit Analysis Presented in ‘Benefits from Immunization During the Vaccines for Children Program Era — United States, 1994–2013’” (hereinafter referred to as “Supplement to Benefits” at 3-4, retrieved from http://www.cdc.gov/vaccines/programs/vfc/pubs/methods/ (accessed on August 6, 2016). The study found routine childhood vaccination to have created $107 billion in direct costs and $121 billion in societal costs. After accounting for these costs, the study found the net present values, or net savings from payers’ and societal perspectives, to be $295 billion and $1.38 trillion, respectively. While no one has undertaken a specific analysis of Pennsylvania data for such studies, Pennsylvania data figured into this research.

All school districts, public, private and parochial schools, including kindergartens, special education classes, home education programs, cyber schools, charter schools and vocational classes in the Commonwealth would be affected by these amendments. All school administrators and their designees for purposes of ensuring that children have the necessary and appropriate immunizations would be affected by the amendments. School districts and schools may see added cost from time spent by school administrators and their designees (most likely school nurses) reviewing immunization status of children for school entry and attendance. Although schools are already performing this responsibility, the time frame for the review has been reduced. Because the Department is aware of concerns of schools and school nurses in implementing these amendments within the time frame originally proposed, the
Department decided to extend the time for implementation. The Department expects Final Rulemaking to be published in time for kindergarten registration in March 2017 for the 2017-2018 school year to enable schools to provide information to parents and guardians regarding the changes to the regulation. This will provide schools and school nurses with the remaining months of the 2016-2017 school year to begin to prepare for implementing the changes. Schools and school nurses will be able to begin to review implementation status of students, to provide information to parents and guardians, and to determine which students may have issues in the fall of 2017-2018. Although not all issues relating to the time necessary to implement the changes will be resolved by this extended period prior to their effective date, the Department is hopeful that the five to six month period prior to their implementation will allow parents and guardians ample time to take steps to comply with the requirements, thus lessening time needed by schools to enforce the requirements at the start of the 2017 school year. The Department also acknowledges the need for education and outreach on these regulations, and particularly the 5-day requirement, and intends to do both with health care practitioners, schools and parents. The Department believes that sufficient outreach will significantly reduce the numbers of students in a provisional status at the beginning of the 2017-2018 school year. The Department is also hopeful, as other commentators in support of the 5-day provisional period have expressed, that those parents and guardians who lag behind with immunizing their children will be encouraged to take more prompt action by the Department’s stricter stance in this regard. This may ultimately decrease work for school nurses and school administrators as more children come into compliance. The Department believes shortening the time frame of the provisional period is necessary despite the potential increase in cost for time spent because the savings in the prevention of an outbreak of a childhood illness in a school district outweighs the cost in staff time. The Department has more fully discussed the potential costs involved in a school outbreak of a childhood disease above.

Although pertussis and MCV have been added to the list of required immunizations, neither of these requirements will impact school reporting, since pertussis is already included in the DTaP vaccine. DTaP is the vaccine that most children entering school were being given to meet the diphtheria and tetanus requirements, unless the child had a contraindication, and is already collected for reporting to the Department in kindergarten. MCV, required in the 12th grade, will not need to be counted for reporting to the Department. The paperwork caused by this requirement should be minimal, since school districts already complete an annual report regarding the number of immunizations. The Department will provide reporting forms to schools, as it currently does, and the reports will be sent to the same Department office as the current reports. Schools will be required to report electronically on the already existing system provided by the Department, but those schools who are unable to complete a report electronically will be able to report on paper, but within a slightly shorter time frame. Those paper forms will be provided by the Department, as they currently are.

School administrators and their designees will also be required to review immunization status of all children in all grades as they currently do, but the amendments require a child to have any single dose vaccine upon school entry, or risk exclusion. In the case of a multi-dose vaccine, the amendments require that the child have at least one dose of the vaccine upon school entry. If additional doses are required and are medically appropriate within the first five days of school, the child must have either the final dose during that five day period, or must have the next scheduled dose and must also provide a medical certificate setting out the schedule for the remaining doses. If the child has at least one dose, but needs additional doses, and those doses are not medically appropriate during the first five days of school, the child may provide a medical certificate on or before the 5th school day scheduling those doses. The medical certificate must be signed by a physician, certified registered nurse practitioner (CRNP), or
physician assistant (PA). If the child receives the immunizations from the Department or a public health department, a public health official may sign the medical certificate. A child who fails to meet these requirements risks exclusion. School administrators and their designees will be required to review those medical certificates every 30 days, rather than every 60 days. Follow-up regarding those medical certificates, and exclusion of students when necessary, will be the responsibility of the school administrator or the school administrator’s designee, as it currently is. School administrators and their designees already review immunization plans and make decisions regarding provisional enrollment. The Department will provide a medical certificate form to schools.

While requiring more frequent monitoring of students who are not fully immunized could impact a school’s administrative duties, the impact would vary depending on the number of children in a school who are not fully immunized. The impact also would depend on how a school elects to utilize the discretion granted to it per 28 Pa. Code § 23.85(e)(3) in designating staff responsible for fulfilling monitoring duties.

Further, although the Department is changing the dates on which immunizations must be reported, from October to December, the Department is not changing what schools are required to report. Prior to these amendments, schools were required to count the number of doses of required immunizations received by children in kindergarten and in the 7th grade, and report those numbers to the Department. Schools were providing the Department with counts of doses of DTaP before this amendment, since that is the vaccine providers are using for immunizations against diphtheria and tetanus, which were on the list of required immunizations prior to this amendment. No count of the second dose of MCV will be required, since the Department does not require reporting for 12th grade. This amendment, in fact, provides schools additional time to report; that change should be beneficial to schools. The Department had requested reports be sent in to the Department at the later December 31st date in the 2014-2015 school year.

To the extent that physicians or their designees are requested to provide a medical exemption for a student, these practitioners could also be affected tangentially. Physicians, CRNPs and PAs would also be affected by the fact that children missing doses of multiple dose vaccines would now need the practitioner to sign a medical certificate setting out the timeframe for obtaining those vaccinations in order for the child to be allowed to enter and attend school.

Most importantly, ensuring that children are vaccinated for preventable childhood diseases prior to entering and attending school will prevent the spread of dangerous diseases throughout the Commonwealth. It will ensure the development and maintenance of herd immunity so that persons unable to be vaccinated are protected from disease. It will prevent children from suffering illness, financial loss to parents and guardians, the potential loss of a child, and both financial loss and emotional turmoil to society connected with the spread of a dangerous illness throughout the community.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

All citizens of the Commonwealth with school-aged children and their children would be required to comply with the proposed rulemaking.
All public, private, parochial or nonpublic schools, including vocational schools, intermediate units, and special education and home education programs, cyber and charter schools would be affected by these amendments. The number of schools reporting immunizations would be the approximately 3908 schools reporting immunizations in 2015 – 2016.

All health care practitioners that provide immunizations to children as a part of their practice may be peripherally affected by the regulations, but they are not required to comply with them, since their scope of practice would not be affected by these amendments.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The financial, economic and social impact of these amendments on schools, school districts, school employees, parents, guardians, children and health care practitioners have been discussed in Section 15 above.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.
The benefits from: (1) savings in the prevention of an outbreak of a childhood illness in a school or school district, which could necessitate the issuance of letters to parents and guardians warning of the outbreak, (2) potential exclusions and readmissions of children and of staff with administrative costs related to checking for appropriate exclusion and readmission criteria, and, (3) in an extreme case, the potential shutdown of the school, with the attendant costs, should outweigh the minimal cost in staff time of ensuring that children have all the required vaccinations before entering or attending school. The Department has provided further details surrounding the cost of a pertussis outbreak in a school in Section 15.

The CDC also looked at the economic burden of 16 measles outbreaks on public health departments in 2011. In that study, the estimated number of contacts was 8936-17,450 persons. The estimated number of personnel hours ranged from 42,645 to 83,133. The estimated economic burden ranged from $2.7 million dollars to $5.3 million dollars.

The Department also did a literature review regarding the costs of measles outbreaks over the last 12 years and found the following:

- $142,452: 2004, Iowa
- $176,980: 2008, CA
- $24,569: 2010, Kentucky
- $130,000: 2011, Utah
- $200,000: 2015, Challem County, WA


Further, there are financial and emotional savings in preventing childhood illnesses. Other children coming into contact with sick children are spared sufferings from the illness. Adults susceptible to the illness through being immuno-compromised, or in situations where there is “breakthrough” disease, due to the wearing down of immunity (pertussis for instance), also may become ill, and lose time and productivity at work. Parents and guardians must take care of the sick child, which could also lead to loss of productivity, lost work time, and potentially a lost employment, depending upon the length and severity of the illness. Pregnant women coming into contact with certain childhood illnesses can suffer catastrophic effects to the baby. And, although there is now a tendency to downplay the seriousness of childhood illnesses, deaths still occur. In 2014, 18 deaths from chickenpox and pertussis occurred nationwide. The Department has more fully discussed costs related to MCV and the pertussis component to Tdap and DTaP in Section 15.

Aside from the emotional toll such illnesses and deaths take, and personal financial loss, society suffers
a loss from: (1) the loss of work time for parents and guardians taking care of sick children; and (2), the
cost associated with preventing and controlling outbreaks of disease, including expenditure of time and
funds by state and local governments in order to locate the index case, trace contacts, and ensure that all
persons are properly vaccinated or obtain proper treatment. In the worst case scenario, a state or local
government could find itself ordering and enforcing isolation or quarantine of more than one person,
which requires staff time and funding. The Department has more fully discussed these issues in Section
15.

Again, costs from adverse reactions to vaccines were taken into account in the study, Benefits from
Immunization During the Vaccines for Children Program Era – United States, 1994-2013, supra. That
study is more fully discussed in Section 15. The Department has also discussed the cost/benefit analysis
of the only two vaccine requirements being added by this Rulemaking, MCV and pertussis vaccine
component, in that section.

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

Parents and guardians whose children’s vaccinations are covered by their insurance plans (public or
private), pursuant to the federal Patient Protection and Affordable Care Act (ACA), (Pub.L. 11-148)
(March 23, 2010), will not see any out-of-pocket cost for a second dose of MCV, although they may
have additional copayments. The Department has also added pertussis to the list of diseases against
which a child must be immunized before entering and attending school; however, children are most
likely already receiving a vaccination with the pertussis component, DTaP, when they are receiving the
required immunization for diphtheria and tetanus. That vaccine should have no additional cost. Parents
and guardians whose insurance plans do not cover vaccinations, or who do not have insurance, may
obtain vaccines at a small administrative fee from the VFC Program through VFC providers, the
Department’s state health centers and federally-qualified health centers. Studies show that copayments
for families obtaining childhood vaccines from outside the public sector would be approximately $29.07
per child (in 2013 dollars). Supplement to Benefits, at 3-4. For public clinics, the Department noted that
the maximum regional charge in the Commonwealth was $23.14 per administration of the vaccine to a
child. The cost for completing paperwork can run from between $5.00 to $55.00, see
http://mgma.com/blog/shoul-your-medical-group-practice-charge-for-patient-forms (accessed August 10,
2016), although it appears that practices charging more than $21.00 are in the minority. See
Department has assumed a cost of approximately $20.00 per form, this appears to be roughly the most
common amount charged. Id. The Department and local health departments do not charge a paperwork
fee.

With respect to the cost of adverse events relating to vaccines, and the cost effectiveness of vaccines, at
least one study suggests that childhood vaccination will prevent an estimated 322 million illnesses, 21
million hospitalizations, and 732,000 deaths over the lifetimes of children born between 1994 and 2013.
“Benefits from Immunization,” at 1. The study concluded that vaccination would potentially avert $402
billion in direct costs, and $1.5 trillion in societal costs because of illnesses prevented in birth cohorts
from 1994-2013. The study considered program costs, including cost of the vaccine, cost of administration, vaccine adverse events, and parent travel and work time lost. The cost analysis was conducted from both health care (direct) and societal (indirect and direct) perspectives. Direct costs included outbreak control and outpatient and inpatient visits. Indirect costs included the productivity losses from premature mortality, which was estimated using the human capital approach. Costs for work were determined by the number of days of missed work (for provision of care to sick children, for illness among cohort members, or for resulting disability) multiplied by the daily wage rate associated with the value of lost wage-earning work and the imputed value of housekeeping and home-care activities. The cost of vaccine administration from a private provider was estimated at $29.07. The cost of vaccine administration at a public clinic was estimated at $8.15. The study’s authors assumed that caregivers take two hours off from work to take the child for a vaccination, based on previous economic studies. The study’s authors then assumed that the average cost for these caregivers was $18.19 per hour, and that the cost for travel to a clinic was $23.45. “Supplement to Benefits,” at 4.

The study found routine childhood vaccination to have created $107 billion in direct costs and $121 billion in societal costs. After accounting for these costs, the study found the net present values, or net savings from payers’ and societal perspectives, to be $295 billion and $1.38 trillion, respectively. While no one has undertaken a specific analysis of Pennsylvania data in this area, Pennsylvania data figured into this research, since the Commonwealth participates in the VFC Program. It should also be pointed out that this relates to the entire vaccine program; the costs associated with vaccine requirements are already in place in the Commonwealth, the Department is estimating an additional cost of MCV because, according to commentators, this will require an additional provider visit.

Other studies on pertussis outbreaks in schools have shown that unvaccinated children have at least an eightfold greater risk for pertussis than children fully vaccinated with DTaP. “Although vaccinated children can develop pertussis, they are less infectious, have milder symptoms and shorter illness duration, and are at reduced risk for severe outcomes, including hospitalization. . . . [V]accination continued to be the single most effective strategy to reduce morbidity and mortality caused by pertussis.” “Pertussis Epidemic – Washington, 2012,” MMWR, Vol. 61(28); 517-522 (July 20, 2012) (hereinafter referred to as “Pertussis Epidemic”) at 4, retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6128a1.htm (accessed August 6, 2016). In a study published in the Journal of the American Medical Association of the risk of vaccine preventable diseases among children aged 3-18 years in Colorado who have philosophical and religious exemptions, researchers determined that exemptions were 22.2 times more likely to acquire measles, and 5.9 times more likely to acquire pertussis. Feikin, D., M.D., MSPH, et al., “Individual and Community Risks of Measles and Pertussis Associated with Personal Exemptions to Immunizations,” JAMA 2000; 284(24) at 3145-3150, retrieved http://jama.jamanetwork.com/article.aspx?articleid=193407 (accessed August 6, 2016); see also Flanz, et al., Parental Refusal of Pertussis Vaccination is Associated with an Increased Risk of Pertussis Infection in Children, Pediatrics, Vol. 123(6) (June 2009).

The ACIP recommendations for MCV and DTaP take into consideration the cost-benefit analysis of recommending a vaccine and have been discussed in Section 15. Along with ACIP, the American Academy of Pediatrics, and the American Academy of Family Practitioners also recommend a second dose of MCV and DTaP for school entry. Based on these recommendations, the Department firmly believes that savings in prevention of childhood illness and death would outweigh the minimal cost of the MCV and DTaP vaccine, despite potential adverse events.
School districts and schools may see added cost from time spent by school administrators and their
designees (most likely school nurses) reviewing immunization status of children for school entry and
attendance. Although schools are already performing this responsibility, the amendments reduce the
time frame for the review. Discretion, however, still rests with the school administrator and his or her
designee regarding how the provisional period will be addressed in the school. The Department has also
extended the time to prepare for the implementation of the regulations in 2017-2018 by publishing this
Final Rulemaking by March of 2017, in time for kindergarten registration, and nearly 6 months prior to
the start of the 2017-2018 school year. The Department believes this shortened time frame is necessary
despite the potential increase in cost for time spent because the savings in the prevention of an outbreak
of a childhood illness in a school district outweighs the cost in staff time. The Department has more
fully discussed the potential costs involved in a school outbreak of a childhood disease in Section 15 and
above.

The Department has removed the proposed amendment which potentially added the greatest cost for
parents and guardians: that is, requiring a school to accept a history of immunity from varicella
(chickenpox disease) only from a physician, CRNP or PA.

To the extent that physicians or their designees will be requested to provide a medical exemption for a
student, these practitioners could also be affected tangentially. Physicians, CRNPs and PAs will be
affected by the fact that children missing doses of multiple dose vaccines need the physician, CRNP or
PA to sign a medical certificate setting out the time frame for obtaining those vaccinations in order for
the child to be allowed to enter and attend school.

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

There should be no fiscal impact on local governments, although they may see a cost savings, since local
governments with county or municipal health departments do bear some of the cost of disease outbreak
investigations and control measures. The Department has addressed the potential impact of these
amendments on schools and school districts, which may be considered to be local government, in those
sections relating to the “Regulated Community.”

(21) Provide a specific estimate of the costs and/or savings to the state government associated with the
implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

The Commonwealth will incur some costs for the purchase of meningococcal conjugate vaccines through the expenditure of federal immunization grant funds for the purposes of the VFC Program. The Commonwealth already expends federal grant funds for the purchase of DTaP. The Department does not expect an increase in costs for DTaP from this Rulemaking, since pertussis is already included in the DTaP vaccine, which is the vaccine that most children were being given to meet the diphtheria and tetanus requirements. The Department makes vaccines available at no cost to private providers enrolled in the Vaccines For Children (VFC) Program for children through 18 years of age who have no insurance, are Medicaid eligible, or are Alaskan Native or American Indian. In addition, VFC Program vaccine is also made available to other public clinic sites (Federally Qualified Health Centers and Rural Health Clinics) for the same population, and also for uninsured children through 18 years of age. Vaccines are made available to schools at no cost through the Department’s School Based Catch-Up Program for those students who have no medical home or are unable to seek the immunization through a public clinic site. The Commonwealth will realize savings, however, based on the amount of funds that will not be needed to control the outbreak of vaccine-preventable diseases. The Department has discussed potential costs related to vaccine preventable diseases in Sections 15 and 18.

The Commonwealth may incur minimal additional cost from printing and providing form medical certificates to Commonwealth schools.

The Department has provided information on costs to health departments for specified outbreaks in Section 15. In addition, a rough estimate of the measles outbreaks in California in 2014-2015, provided by the California Department of Public Health, puts the estimated public health cost in California in 2015 for the outbreak from $1.56 million dollars to $3.91 million dollars. Using a median cost per hospitalization from outbreaks from 2009-2013, California estimates total direct hospital costs at close to $500,000.

California provided information on the resource burden of controlling the outbreak as well:

- In Alameda County, there were six outbreak-related cases of measles and 700 measles contacts were identified.
- Orange County Health Care Agency required 1767 additional hours of work for measles outbreak control. This included surge staff assisting from other programs, volunteers, and overtime from nursing, epidemiology, and laboratory staff.
- In Orange County over 2000 community contacts required follow up, including contacts from 56 healthcare facility exposure events.
- In San Bernardino County over 180 suspected cases were investigated and over 600 measles contacts were identified. The estimated cost of staffing for the outbreak was $18,500.
- In Ventura County public health administered 94 MMR vaccine doses, 31 doses of IGIM; drew blood for 60 IgG tests and performed 355 immunization record reviews.
- At the Viral and Disease Rickettsial Disease Laboratory (VRDL), between 12/1/14 and 4/10/15, 1516 measles tests on 866 patients were performed. This included 950 laboratories polymerase chain reaction (PCR) tests, 469 serological tests (enzyme-linked immunosorbent assay (EIA) or indirect fluorescent antibody (IFA)), and 97 specimens that were genotyped.
- At local public health laboratories PCR testing was performed for 922 patients.
• Approximately 15 full time equivalent employees (FTE) from the Immunization Branch (IZB) and the VRDL worked on the measles response for 14 weeks (rough estimate since not all FTE tracked time).

California is basing its rough cost calculations on median costs per measles case arrived at in a CDC study on 2011 measles outbreaks, see Ortega-Sanchez, at 1311-1317. The main findings from the study showed that the average outbreak duration was 22 days, the total identified contacts per outbreak ranged from 8,936 to 17,450, and the total cost burden ranged from $2.7 million dollars to $5.3 million dollars.

Although the Department provided these costs previously, there were concerns that the data was not comparable to a situation in Pennsylvania, and therefore only Pennsylvania data should be reviewed. As the Department noted, there were three separate Pennsylvania outbreaks included in the CDC study, and Pennsylvania data for measles cases is included below. It should also be noted that the types of costs are the same in all states, although the cost amounts assigned to the type of cost may differ, depending on the year and the extent of the outbreak. The cost data for all 16 outbreaks is as follows:

**Public health costs of measles outbreaks (adapted by California from Ortega-Sanchez, 2014)**

<table>
<thead>
<tr>
<th>Outbreak name</th>
<th># cases</th>
<th>Total cost (min)</th>
<th>Total cost (max)</th>
<th>Cost per case (min)</th>
<th>Cost per case (max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MN1</td>
<td>22</td>
<td>918847</td>
<td>1640798</td>
<td>41765.77</td>
<td>74581.73</td>
</tr>
<tr>
<td>IN</td>
<td>14</td>
<td>584721</td>
<td>1044144</td>
<td>41765.79</td>
<td>74581.71</td>
</tr>
<tr>
<td>CA/MD/WI/N</td>
<td>9</td>
<td>421244</td>
<td>752221</td>
<td>46804.89</td>
<td>83580.11</td>
</tr>
<tr>
<td>KS</td>
<td>6</td>
<td>280829</td>
<td>501481</td>
<td>46804.83</td>
<td>83580.17</td>
</tr>
<tr>
<td>UT1</td>
<td>7</td>
<td>83532</td>
<td>208829</td>
<td>11933.14</td>
<td>29832.71</td>
</tr>
<tr>
<td>UT2</td>
<td>6</td>
<td>71598</td>
<td>178996</td>
<td>11933.00</td>
<td>29832.67</td>
</tr>
<tr>
<td>PA1</td>
<td>6</td>
<td>71598</td>
<td>178996</td>
<td>11933.00</td>
<td>29832.67</td>
</tr>
<tr>
<td>MI/MN/TX</td>
<td>6</td>
<td>71598</td>
<td>178996</td>
<td>11933.00</td>
<td>29832.67</td>
</tr>
<tr>
<td>NY</td>
<td>6</td>
<td>71598</td>
<td>178996</td>
<td>11933.00</td>
<td>29832.67</td>
</tr>
<tr>
<td>NY/MD</td>
<td>5</td>
<td>59665</td>
<td>149163</td>
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<td>29832.60</td>
</tr>
<tr>
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<td>47732</td>
<td>119331</td>
<td>11933.00</td>
<td>29832.75</td>
</tr>
<tr>
<td>PA3</td>
<td>4</td>
<td>47732</td>
<td>119331</td>
<td>11933.00</td>
<td>29832.75</td>
</tr>
<tr>
<td>CA</td>
<td>3</td>
<td>2685</td>
<td>22375</td>
<td>895.00</td>
<td>7458.33</td>
</tr>
<tr>
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<td>3</td>
<td>2685</td>
<td>22375</td>
<td>895.00</td>
<td>7458.33</td>
</tr>
<tr>
<td>MN2</td>
<td>3</td>
<td>2685</td>
<td>22375</td>
<td>895.00</td>
<td>7458.33</td>
</tr>
<tr>
<td>PA</td>
<td>3</td>
<td>2685</td>
<td>22375</td>
<td>895.00</td>
<td>7458.33</td>
</tr>
</tbody>
</table>

Clearly, ensuring children are appropriately vaccinated severely reduces the chances of these types of outbreaks, and significantly reduces costs to state (and local) government.
(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

I. Commonwealth and Schools/School Districts

The amendments would not change the vaccines required to be reporting in kindergarten and in 7th grade (DTaP is already reported, and MCV is required in 12th grade, so no report is required). The amendments will give schools additional time to report, however. The Department will review and include those new reported numbers in its report to the CDC. Schools are required to report immunization coverage status for their kindergarten and 7th grade students to the Department in order for the Department to satisfy CDC requirements relating to reporting of immunizations. The paperwork caused by this requirement is minimal, since school districts already complete an annual report regarding the number of immunizations. The Department will provide training on electronic reporting, as well as reporting forms as it currently does for schools unable to electronically report, and the reports would be sent to the same Department office as the current reports. Paper reports will be due to the Department two weeks earlier than the electronic reports, to allow for processing time.

School administrators and their designees, mainly school nurses, will be required to review immunization status of incoming children, as they are currently required to do, but within a much shorter time frame. Since pertussis is already included in the DTaP vaccine, which is already counted, this will not require additional review by the school; MCV is the only new immunization schools must ensure that students receive, and only among the students entering 12th grade. The Department has shortened the time frame for provisional admission from 240 days to five days because the Department has determined that this would be the most efficient, effective and practical means to prevent and control the spread of disease. See section 2102(a) of The Administrative Code of 1929 (71 P. S. § 532(a)). The Department has reviewed data relating to disruption and cost of outbreaks of vaccine-preventable diseases in schools and other settings, some of which is within its own experience, and some of which is the experience of other states. All of this experience is relevant, since disease surveillance and control methodologies may differ from disease to disease, but not from state to state. In the Department’s view, as the agency charged with protecting the health and safety of the citizens of this Commonwealth and with choosing the most efficient and effective way of doing so, the Department has to shorten the 8-month provisional period to five days.

The most important reason for the five-day period is to achieve “herd” or community immunity as quickly as possible. “Herd” or community immunity does exist, and is a driving force behind vaccine policy. “Herd” or community immunity refers to a means of protecting a whole community from disease by immunizing a critical mass of its populace. The more members of a community – including a school community – who are immune to a given disease, the better protected the whole community will be from an outbreak of disease. The longer the time frame during which children have to become vaccinated, the easier it is for any noncompliance to put unvaccinated children at risk. The sooner more children are fully vaccinated, the sooner “herd” or community immunity is established and achieved to protect at-risk children who cannot be vaccinated for medical or other reasons. When unvaccinated children are allowed into school, the “herd” is diluted for the time it takes children who can be vaccinated to become vaccinated and those unvaccinated children are at risk for a longer period of time.
Herd or community immunity protects a whole community from disease by immunizing enough people so that no sustained chain of disease transmission can be established. By breaking the chain of a disease transmission, vaccination protects more than just the vaccinated person; it also protects people who have not been, or cannot be, vaccinated because they are too young or too sick. See Wallingham and Helft; see also “Herd immunity and measles.”

The level of immunization in a population required to achieve herd immunity does differ from disease to disease, and some diseases, for example, pertussis, seem unaffected by it. In order to determine thresholds of immunity, epidemiologists set a value, called a basic reproduction number (R0), in order to determine vaccination rates necessary to prevent spread of disease. Marshall, G., M.D., The Vaccine Handbook: A Practical Guide for Clinicians, (Professional Communications, Inc., 4th Ed. 2012), at 42-44. This is a complex calculation, and differs depending on the factors, assumptions, and methodologies various researchers use. Id. at 42. These factors include how effective the vaccine is, how long-lasting immunity from both the vaccine and the infection is, and which populations form critical links in the spread of disease, since there may always exist pockets of susceptible individuals who are capable of spreading the disease. Id. at 44.

Measles, for example, is easily spread through droplets and through the air, is highly contagious, and has a relatively high threshold to protect a community. Thus, experts postulate that between 92% and 95% of the population must be vaccinated to prevent the disease from spreading. Bednarczyk, at 153. Polio, which is less contagious and spreads in a different way, has a lower threshold, at around 83%. For a variety of reasons, certain other diseases are not strongly affected by herd immunity. For example, a disease in which immunity from vaccine and from infection wane over time, and for which a human host could colonize the disease without becoming ill, would not be as impacted by herd immunity as other diseases. This may be an issue with certain meningitis vaccines, although there have been studies showing that vaccination for meningitis serogroup C in Britain did create herd immunity. “Prevention and Control (2013)” at 10.

The Department does not claim that herd immunity will protect students from every infectious disease. It will, however, protect students and adults in schools and in surrounding communities from highly contagious and serious diseases. In order to maintain levels of immunity to prevent the spread of potentially dangerous and highly infectious diseases, -- for example, measles, polio and chickenpox --

2 This does not mean that vaccination against pertussis has no benefit.

3 An article in Epidemiologic Reviews, published by John Hopkins University School of Hygiene and Public Health, “Herd Immunity: History, Theory, Practice,” discusses the history and theory of herd immunity, the methodologies and theories different researchers use to determine disease transmission. Fine, P.E.M., “Herd Immunity: History, Theory, Practice,” Epidemiologic Reviews, (1993, The John Hopkins University School of Hygiene and Public Health), 15:2. The article points out the difficulties of making precise estimates of herd immunity thresholds in any particular context based on differing assumptions (for example, maternal immunity, variation in age of vaccination, geographical heterogeneity.) Id. at 282. Table 5 of this article shows threshold rates from different studies for measles of from 55% to 96% to not specified, based on the methods of calculation and assumptions used by various authors, and raises issues with the assumptions used in several of those calculations. Id. at 284-287. The article did not offer an opinion as to the appropriate R0 value and threshold rates for measles. The article stated instead that “experience does suggest that most theoretically-derived estimates of vaccination uptake and herd immunity thresholds [for measles] have been optimistically low, because they do not cater for important heterogeneity within real populations.” Id. at 286. The Department has utilized a threshold rate of 92% to review its data, based on the articles it has reviewed, and the clear acknowledgement by those articles that measles is extremely infectious. Wallingham and Helft provided a threshold range of between 83% and 95% for measles, citing “Herd Immunity: History, Theory, Practice,” supra, while acknowledging that measles is so infectious that the threshold immunity required to protect a community is 95%. Wallingham and Helft, at 2.
approximate vaccination rates need to be as follows: 92% - 95% for measles, 83% for polio, and 89%-90% for chickenpox. Bednarczyk, at 153,; see also Lecture, “Disease Control and (R0),” Johns Hopkins, Bloomberg School of Public Health, at slide 24, retrieved from http://ocw.jhsph.edu/courses/publichealthbiology/PDFS/Lecture2.pdf (accessed August 6, 2016). When herd immunity wanes because of pockets of persons susceptible to disease or for other reasons, the remainder of the population is at risk. See Bednarczyk, at 153-154. “[W]ith approximately 8.7 million children aged 17 or younger who are susceptible to measles, there is a potential for large measles outbreaks, even in the context of generally high vaccination coverage.” Id. at 153. “[A] substantial number of children and adolescents aged 17 years or younger in the United States are susceptible to measles, with some clustering raising concerns that endemic measles transmission should be reestablished despite the overall high level of immunity.” Id. at 154.

Although the school district level data reviewed by the Department for school years 2014-2015, and now 2015-2016, show rates in most school districts near or above the 92% threshold for MMR vaccination levels, individual school level data reported for kindergarten and 7th grade shows a different picture in some schools. For purposes of herd immunity, the actual school a student attends is the student’s particular community; it is here that the unvaccinated student would be most at risk (students do come into contact with the larger school district community, and with students from schools with potentially lower rates, although not on a daily basis). There are schools within the Commonwealth at which rates for MMR in kindergarten and in the 7th grade, for the portion of the school year at which the report was made, are below 92%.

In 2014-2015, when schools reported in December, approximately 26% of the kindergarten and 7th grade classes in non-ster schools in the Commonwealth had vaccination rates below 92% for the MMR vaccine at some point in the school year. For some of those schools, the rates were below 85%. Rates in individual schools substantially improved in 2015-2016 (approximately 10% were below 92%) when school reporting was extended to March, but there still were schools significantly below the vaccine rates necessary for herd immunity. This means there is a period during the year in which not enough children have been vaccinated to create herd immunity for diseases like measles, which was responsible for 481,530 cases nationwide in 1962, pre-vaccine, and 408 deaths of those children and adults.

Insufficient herd immunity also has the potential for school disruption, including closure, with concomitant loss of educational time, loss of work and pay for adults, need for daycare or other care for excluded children, administrative work to identify and exclude “susceptibles” (those who can prove neither immunity nor vaccination), disease surveillance and contact tracing in the community to contain the outbreak, costs to the health care system of both the ill and the worried well, cost to parents and guardians of care for sick children, and cost to the public health care system of vaccine and prophylaxis. Although Pennsylvania has not been through a measles outbreak recently, the Department routinely conducts disease investigations and surveillance of the type that would be greatly expanded in the event of an outbreak of disease. The Department points to the costs to California, as discussed in Section 10, because the actions taken in California would be the same as those required in the Commonwealth in the event of an outbreak. Although the actual monetary value of responding to an outbreak may differ from state to state, the types of costs and the extent of the costs are the same in any state. The longer children attending school with neither medical nor religious/philosophical reasons to avoid the vaccination, the greater the chance of an outbreak crisis like the one in California occurring in the Commonwealth.

The Department notes that the regulations will be effective on August 1, 2017. The Department expects
to publish Final Rulemaking in the Pennsylvania Bulletin by March 2017, in time for kindergarten registration for the 2017-2018 school year. This will enable schools to provide information to parents and guardians regarding the changes to the regulation five to six months before the start of the 2017-2018 school year. The Department acknowledges the need for education and outreach on these regulations, and particularly the five-day requirement, and intends to do both with health care practitioners, schools, school nurses and parents and guardians.

School administrators and their designees will also be required to accept medical certificates, which will contain a formalized plan of immunization for those students who are not in compliance with the immunization requirements, and they will be required to review those medical certificates every 30 days, rather than every 60 days. Follow-up regarding those medical certificates, and exclusion of students when necessary will be at the discretion of the school, as it has always been. School administrators and their designees already review immunization plans and make decisions regarding provisional enrollment, although the amendments require that review to occur within the first five days of school, and then 30 days thereafter until the child completes his or her immunization plan. The Department will provide a medical certificate form to schools, and has attached a draft copy to this RAF as Attachment 3.

Further, the amendments do not require a child to obtain all vaccinations at the same time on the same date or even within the five-day provisional period. Presumably the number of children lacking all vaccines at school entry are minimal, and those children may have some type of medical/philosophical/moral exemption. These amendments require a child to have any single dose vaccine upon school entry, or risk exclusion. In the case of a multi-dose vaccine, the amendments require that the child have at least one dose of the vaccine upon entry into that school year, and then, if additional doses are required and are medically appropriate within the first five days of school, the child must have either the final dose during that five day period, or must have the next scheduled dose and must also provide a medical certificate setting out the schedule for the remaining doses. If the child has at least one dose, but needs additional doses, and those doses are not medically appropriate during the first five days of school, the child may provide a medical certificate on or before the 5th school day scheduling those doses. The medical certificate must be signed by a physician, certified registered nurse practitioner (CRNP), or physician assistant (PA). If the child receives the immunizations from the Department or a public health department, a public health official may sign the medical certificate. A child who fails to meet these requirements risks exclusion. If it takes longer than five days to obtain the number of immunizations required, the child may still continue to attend school, so long as the child continues to receive immunizations according to the schedule set out in the medical certificate and in accordance with the regulations.

The Department believes that sufficient outreach will significantly reduce the number of students in a provisional status at the beginning of the 2017-2018 school year. The Department is also hopeful, as other commentators in support of the five-day provisional period have expressed, that those parents and guardians who lag behind with immunizing their children will be encouraged by the Department’s stricter stance in this regard to take action more promptly. This may ultimately decrease work for school nurses and school administrators as more children come into compliance.

II. Local Government

There is no additional paperwork requirement for local government. (The Department has included
school districts, which may be considered to be local government, under Paragraph I, above.)

III. Parents and Guardians

Parents and guardians of children attending school in the Commonwealth, and those children, who are not up-to-date with immunizations required for school entry and attendance at the beginning of the 2017-2018 school year will be required to obtain a medical certificate from a physician, certified registered nurse practitioner (CRNP) or physician assistant (PA) setting out the schedule upon which immunizations will be given, and signed by that provider, obtain a medical exemption, or provide a religious/philosophical exemption. This documentation must be submitted to the school within five days of the start of school in order to allow the student to remain in school while the immunization schedule is being followed. Parents and guardians will have to provide an updated certificate of immunization to the school as the child obtains his or her immunizations in order to prove immunity, or risk exclusion. A parent or guardian may provide the school with a medical or religious/philosophical exemption in lieu of the medical certificate to enable the child to remain in school without the required immunizations. The Department is making these amendments effective for the 2017-2018 school year, but publishing the Final Rulemaking as early as possible prior to the March 2017 kindergarten registration dates, to allow parents and guardians sufficient time to obtain either the necessary immunizations, or the necessary exemptions. The Department notes that the immunizations required for school entry and attendance have not changed since 2011. As the Department has stated, the Department does not expect large numbers of children lacking all vaccines or even most at school entry, and those children may have some type of medical or religious/philosophical exemption. A child may still continue to attend school, even without all the required immunizations, so long as the child complies with the amendments and, if a medical certificate is necessary, complies with the immunization plan contained in that medical certificate.

The Department further notes that the change under this Rulemaking will be to add one dose of MCV in the 12th grade, and to add pertussis to the list of diseases for which a child must be immunized in order to enter and attend school. This acknowledges that most children, unless they have a medical contraindication, have already received a pertussis dose in receiving immunizations for diphtheria and tetanus -- the ACIP recommendation is for four DTaP doses. Therefore, most children should not have to receive multiple immunizations to be ready for the change in the regulations. Those children who are not up to date should have five to six months to obtain a medical exemption, a religious/philosophical exemption, or their immunizations, and, if necessary a medical certificate setting out their immunization plan, as the Department hopes to publish Final Rulemaking by March of 2017.

As the Department has stated, it intends to use outreach to significantly reduce the numbers of students in a provisional status at the beginning of the 2017-2018 school year. The Department is also hopeful that those parents and guardians who lag behind with immunizing their children will be encouraged by the Department's stricter stance in this regard to take action more promptly. This may ultimately decrease work for school nurses and school administrators as more children come into compliance.
(23) 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.

<table>
<thead>
<tr>
<th></th>
<th>Current FY Year</th>
<th>FY +1 Year</th>
<th>FY +2 Year</th>
<th>FY +3 Year</th>
<th>FY +4 Year</th>
<th>FY +5 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAVINGS:</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$ 0</td>
</tr>
</tbody>
</table>
Regarding issues of overall cost-effectiveness of vaccines, these are discussed in Paragraph 15 as well. Childhood vaccinations will prevent an estimated 322 million illnesses, 21 million hospitalizations, and 732,000 deaths over the lifetimes of children born between 1994 and 2013. “Benefits from Immunization,” at 1. The study concluded that vaccination would potentially avert $402 billion in direct costs, and $1.5 trillion in societal costs because of illnesses prevented in birth cohorts from 1994-2013. Id. at 2 This study specifically included the cost of adverse events caused by childhood vaccination. See generally “Supplement to Benefits,” supra.

The cost-effectiveness of a second MCV dose, including prevalence of adverse effects and efficacy of the vaccines is discussed in Paragraph 15. ACIP stated that the two-dose strategy averted 184 cases (range 92-308), prevented 22 deaths (range 11-40), and saved 1442 quality-adjusted life years (range 610-2130), with a cost of $212,000 quality-adjusted life years saved (range 67,000-535,000). Based on this cost-effectiveness analysis, ACIP recommended the latter 2-dose strategy.

The Department would expect to save approximately $2,171 per case of pertussis prevented. The cost of school-based pertussis outbreaks is included in Paragraph 15. The cost of measles outbreaks are included in Paragraphs 18 and 21, including Pennsylvania data. Similar types of costs would accompany any outbreak of a vaccine preventable disease, so that any disease outbreak prevented would save funds for the Department.

The overall savings information for childhood vaccinations has been included in footnote 5. Pennsylvania participates in the VFC Program, and its data would therefore have been included in the study. The impacts discussed in that study would therefore benefit the Commonwealth.

<table>
<thead>
<tr>
<th>Regulated Community</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Government</td>
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</tr>
<tr>
<td>State Government</td>
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<tr>
<td>Total Savings</td>
<td>0</td>
</tr>
<tr>
<td>COSTS:</td>
<td></td>
</tr>
</tbody>
</table>

---

4 Regarding issues of overall cost-effectiveness of vaccines, these are discussed in Paragraph 15 as well. Childhood vaccinations will prevent an estimated 322 million illnesses, 21 million hospitalizations, and 732,000 deaths over the lifetimes of children born between 1994 and 2013. “Benefits from Immunization,” at 1. The study concluded that vaccination would potentially avert $402 billion in direct costs, and $1.5 trillion in societal costs because of illnesses prevented in birth cohorts from 1994-2013. Id. at 2 This study specifically included the cost of adverse events caused by childhood vaccination. See generally “Supplement to Benefits,” supra.

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The overall savings information for childhood vaccinations has been included in footnote 5. Pennsylvania participates in the VFC Program, and its data would therefore have been included in the study. The impacts discussed in that study would therefore benefit the Commonwealth.
Provide the past three year expenditure history for programs affected by the regulation.

<table>
<thead>
<tr>
<th>Program</th>
<th>FY -3</th>
<th>FY -2</th>
<th>FY -1</th>
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<td>$11,571,000.00</td>
<td>$11,589,000.00</td>
<td>$11,899,000.00</td>
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</table>

6 The Department has estimated the cost of copayments, paperwork, and work time lost for getting an additional MCV dose to satisfy the 12th grade requirement to be approximately $120.00 from a private provider, and approximately $70.00 from a public provider. The public sector does not charge a paperwork fee for a medical certificate, which the Department has estimated at approximately $20.00. These numbers were arrived at using the estimates for cost given in the study “Benefits from Immunization,” supra, and in the Supplement to that study. See “Supplement to Benefits,” supra. The number of seniors enrolled in public and private schools in 2015-2016 was 146,320 students. Again, the cost of the vaccine itself is not included in the cost to the parents or guardians of seniors, since those costs are covered by insurance and are already calculated into any premium, and by the VFC Program. See Discussion related to insurance in Section 15 of this RAF. The cost of complying with the requirement for an immunization against pertussis could be the same, although the Department notes that children are already being vaccinated with DTaP for diphtheria and tetanus, which are already required immunizations, so the cost should be considered to be $0. Any child requiring a medical certificate will incur a paperwork cost in the private sector, and possibly will incur an additional copayment. The cost, therefore, for a medical certificate, including loss of time, co-payment and paper work fee will be the same as for getting a dose of MCV. The Department is unable to estimate the number of children requiring a medical certificate.

While school staff time may increase, the cost to the schools and school districts of an averted outbreak could be extensive, particularly if the school is required to close. Although the Department does not have data for a Commonwealth school outbreak of pertussis, the data for an outbreak in a health care facility in the Commonwealth showed that costs to the health care facility approximated $74,870, including laboratory tests, antibiotic treatment and prophylaxis, and incidental costs (labor and postage). There were also indirect costs to the health care facility of $11,200, including furloughs of workers. The health care workers themselves ended up with direct costs of $4679 in outpatient visits, hospitalization and medications, and indirect costs of $1,730 in time lost from work.

Similar types of costs would attend an outbreak in school, although potentially it would be spread throughout the affected community differently. Presumably a school would not pay for laboratory testing or treatment as the hospital did, but teachers and students would have copayments, and potentially treatment and prophylaxis costs if uninsured or underinsured. But the school, if required to exclude children and teachers would bear that cost, including loss of work, and potentially loss of educational time. The school would bear the cost of hiring substitute teachers to the extent teachers were impacted.

7 The Department would expect to utilize its grant and receive additional MCV vaccine through that grant. The Department would expect a minimal cost from the printing of a medical certificate. These costs would be assumed under the Department’s federal grant.
The expenditure figures in 23a are not cost-benefit data. They are the gross expenditures for the program excluding direct assistance from CDC for vaccines. The only additional costs the Immunization Program must incur because some of the proposed amendments are for the purchase of vaccine.

Some estimate of adding a dose of vaccine to the list could be extrapolated from considering the cost to adding a dose of meningococcal vaccine in the 12th grade.

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.
(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
(c) A statement of probable effect on impacted small businesses.
(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.
(a) See the response to Sections 15, 16, 17 and 19.

(b) See the response to Section 22.

(c) While practitioners (including physicians, PAs and CRNPs) are not affected by these amendments in the sense that their scope of practice is not being regulated in any way, they will be requested by the parents or guardians of children to provide a signed medical certificate in the event a child is missing certain doses of multiple dose vaccinations, in order for the child to be allowed to attend school.

Parents and guardians of school-aged children and those children, who are most closely affected by the proposed regulations, are not small businesses.

(d) No alternative method to achieving the purpose of the amendment was considered. There is no alternative method that would achieve the purpose of the amendment, which is to have children vaccinated as quickly as possible upon attending school, in order to achieve “herd” immunity in a timely fashion. This promotes the protection of the school community and the community at large.

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

The amendments include language that reflects federal requirements relating to the education of homeless children. Section 83.25(g)(1) is intended to exempt a child from exclusion from school if he or she is not immunized, or cannot provide immunization records due to homelessness. These children will qualify to receive VFC Program vaccines at no cost, and could potentially be served at a state health center, or any VFC Program provider.

The amendments include language that reflects federal requirements relating to children in foster care. Section 83.25(g)(3)

The Department has also included a provision in the regulations that allows for a temporary waiver of the regulations in the event that a child is transferring into a school because of a disaster and cannot locate his or her vaccination records. Section 83.25(h)(2).

The Department’s state health centers, Federally Qualified Health Centers, and the Department’s VFC Providers provide immunizations with a small administrative fee for children who do not have health insurance, or who do not have health insurance that covers vaccines.

In addition, although this is not a provision of the regulation, per se, the Department is publishing the regulation to provide as much time as possible prior to its effective date, in time for kindergarten registration and early enough in the school year so that schools and school nurses can most easily notify students and parents of new requirements for the succeeding year. This would assure successful implementation both for the school and for the Department.
Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

The Department had considered proposing to eliminate the provisional period entirely. After consideration, however, the Department has determined that a reduced provisional period, is the least burdensome, and the most effective way to improve immunization rates among school-aged children in the Commonwealth. The amendments require that a child have any single dose vaccine upon school entry, or risk exclusion. In the case of a multi-dose vaccine, the amendments require that the child have at least one dose of the vaccine upon entry into that school year, and then, if additional doses are required and are medically appropriate within the first five days of school, the child must have either the final dose during that five day period, or must have the next scheduled dose and must also provide a medical certificate setting out the schedule for the remaining doses. If the child has at least one dose, but needs additional doses, and those doses are not medically appropriate during the first five days of school, the child may provide a medical certificate on or before the 5th school day scheduling those doses. The medical certificate must be signed by a physician, certified registered nurse practitioner (CRNP), or physician assistant (PA). If the child receives the immunizations from the Department or a public health department, a public health official may sign the medical certificate. This allows the student to remain in school for 30-day intervals until the child either meets the requirements or fails to comply with his or her immunization schedule. Providing for this continuing review period, at least for multidose vaccines, meets the Department’s goals of ensuring the health and safety of the citizens of the Commonwealth, while allowing for the needs of schools to provide and children to obtain an education. The Department’s intention is to prevent a deleterious impact on herd immunity from a lackadaisical response to reporting requirements for school attendance. Failure to obtain the required vaccinations could be the cause of potential outbreaks of serious diseases, including measles, which could have devastating impacts on the community.
(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;
b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
c) The consolidation or simplification of compliance or reporting requirements for small businesses;
d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation; and
e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

The amendments do not carry an adverse impact for small businesses.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

After the California outbreak in 2014-2015, the Department reviewed its own school-based data and became concerned regarding the possibility of herd immunity waning in the Commonwealth based on its
review of its School Immunization Law Report (SILR) data from 2014-2015. The data from 2015-2016 confirmed the Department’s concerns. This data is comprised of reports from schools of immunization data for kindergarten and for the 7th grade. The data indicated to the Department that there was a possibility that, if immunizations were not increased, there could be problems in maintaining herd immunity. The Department, therefore, determined to take steps to reduce the provisional admittance to school period, thus increasing the number of children appropriately vaccinated, and protecting herd immunity for those vaccine preventable diseases. The data in question is stored in a SQL Server 2012 database, which allows the Department to replicate and test it as along as it exists in that database. The Department requires that the SILR forms used by school nurses to collect individual data are signed by a doctor and based on each student’s medical records. Nurses should then follow-up with parents as necessary, interpret, and compile the data for aggregate data input, which the Department will test for validity and completeness with the web application. The Department added validations for 2015.

Immunization program staff follow-up with school nurses by phone calls as they review the paper and the electronically submitted forms. The Department has created reports to review and compare data both for a single year and from year to year as an additional validation measure and have contacted the school-based submitter to verify and correct the data as necessary.

The Department has attached school-level data derived from its SILR reports for kindergarten and for the 7th grade from schools reporting for school year 2014-2015 and for school year 2015-2016 to this RAF as Attachments 1 and 2, respectively. The Department has redacted the names and addresses of individual schools to protect the confidentiality of those schools. It is not the Department’s intention to call attention to vaccination rates in any one school, but to underscore the importance of vaccine rates.


The Department has provided hyperlinks to various articles cited in its Preamble, and in this RAF. The Department has cited to five articles that are not available via the internet at no cost:


• Shephard, Ortega-Sanchez, Scott, Rosenstein, "Cost-Effectiveness of Conjugate Meningococcal Vaccination Strategies in the United States," *Pediatrics, Vol. 115*(5): 1220-1232 (May, 2005);

These articles indicate that they are copyright protected, therefore the Department has not attached these articles. The Department has provided citations to those articles both above, and in the Preamble to Final Rulemaking.

Finally, the Department is attaching a copy of the draft medical certificate as Attachment 3 to this RAF.

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

A. The date by which the agency must receive public comments:
B. The date or dates on which public meetings or hearings will be held:
C. The expected date of promulgation of the proposed regulation as a final-form regulation:
D. The expected effective date of the final-form regulation:
E. The date by which compliance with the final-form regulation will be required:
F. The date by which required permits, licenses or other approvals must be obtained:

A. The agency accepted public comment for 30 days after publication of the proposed rulemaking in the *Pennsylvania Bulletin* on April 9, 2016. The Department continued to accept public comment for 1 week after the close of the public comment period.

B. The Advisory Health Board public meeting was held on November 4, 2015, and the proposed regulations were discussed and approved by that body. The Advisory Health Board met again on September 6, 2016, to review the Final Rulemaking, and discussed and approved that Final Rulemaking.

C. The Department expects to publish Final Rulemaking on or before March 30, 2017.

D. The effective date of the Final Form Rulemaking will be August 1, 2017.

E. Compliance is required on the first day of attendance of the 2017-2018 school year.

F. Permits, licenses or other approvals would not be required by the Final Rulemaking.
Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Department continually reviews the validity and efficacy of its regulations.
NOTICE OF FINAL RULEMAKING

DEPARTMENT OF HEALTH

TITLE 28. HEALTH AND SAFETY

28 PA. CODE CHAPTER 23

SCHOOL HEALTH

Subchapter C. Immunization

Sections 23.82, 23.83, 23.85, 23.86. Definitions; Immunization Requirements; Responsibilities of Schools and School Administrators; School Reporting
Section 23.82. Definitions.

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

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

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

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

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

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Section 23.83. Immunization Requirements.

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

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

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

[(3)] (2) Poliomyelitis. [Three or more] Four properly spaced doses of either oral polio vaccine or enhanced activated INACTIVATED polio vaccine, which may be administered as a single antigen vaccine, or in a combination form. [If a child received any doses of inactivated polio vaccine administered prior to 1988, a fourth dose of inactivated polio vaccine is required.] The fourth dose shall be administered on or after
the 4th birthday and at least 6 months after the previous dose.

[(4) **Measles (rubeola).** Two properly-spaced doses of live attenuated measles vaccine, the first dose administered at 12 months of age or older, or a history of measles immunity proved by laboratory testing by a laboratory with the appropriate certification. Each dose of measles vaccine may be administered as a single antigen vaccine or in a combination form.

(5) **German measles (rubella).** One dose of live attenuated rubella vaccine, administered at 12 months of age or older or a history of rubella immunity proved by laboratory testing by a laboratory with the appropriate certification. Rubella vaccine may be administered as a single antigen vaccine or in a combination form.

(6) **Mumps.** Two properly-spaced doses of live attenuated mumps vaccine, administered at 12 months of age or older or a physician diagnosis of mumps disease indicated by a written record signed by the physician or the physician’s designee. Mumps vaccine may be administered as a single antigen vaccine or in a combination form.]
Measles (rubeola), mumps and rubella (German measles). One of the following:

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

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

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

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

(C) Two properly-spaced doses of live attenuated mumps vaccine, administered at 12 months of age or older.
(iii) **Evidence of immunity.** Evidence of immunity may be shown by

a history of measles and rubella immunity proved by

laboratory testing by a laboratory with the appropriate
certification and a written statement of a history of mumps
disease from a physician, nurse-practitioner CERTIFIED
REGISTERED NURSE PRACTITIONER, or physician's
assistant- PHYSICIAN ASSISTANT.

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

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

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

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

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

CERTIFIED REGISTERED NURSE

**PRACTITIONER,** or physician’s assistant

**PHYSICIAN ASSISTANT.**

(c) **Special requirements for tetanus and diphtheria toxoids and acellular pertussis vaccine and meningococcal CONJUGATE vaccine (MCV).**

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

[(1)](i) *Tetanus and diphtheria toxoidS and acellular pertussis vaccine*

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

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

(III) A CHILD WHO DOES NOT HAVE AN EXEMPTION AS PERMITTED BY § 23.84 AND WHO DOES NOT RECEIVE THE IMMUNIZATIONS AS REQUIRED IN SUBPARAGRAPHS (I) AND (II) MAY BE EXCLUDED IN THAT SCHOOL YEAR AND EACH SUCCEEDING SCHOOL YEAR THAT THE CHILD FAILS TO OBTAIN THE REQUIRED IMMUNIZATION.
(2) **Required for entry into 12th grade.** In addition to the immunizations listed in subsections (b) and (c), one dose of MCV is required for entry into 12th grade at any public, private, parochial or nonpublic school in this Commonwealth, including vocational schools, intermediate unit, special education and home education programs, and cyber and charter schools, or, in an ungraded class, for students in the school year that the student is 18 years of age, if the child has not received a previous dose on or after the child's 16th birthday. A DOSE OF MCV RECEIVED AT THE AGE OF 16 YEARS OR OLDER SHALL COUNT AS THE 12TH GRADE DOSE.

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

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**23.85. Responsibilities of schools and school administrators.**
(e) Provisional admittance to school.

(1) *Multiple dose vaccine series.* If a child has not received all of the antigens for a multiple dose vaccine series described in § 23.83 ON THE CHILD’S FIRST DAY OF ATTENDANCE FOR THAT SCHOOL YEAR, THE SCHOOL ADMINISTRATOR OR THE ADMINISTRATOR’S DESIGNEE the child may *be provisionally admitted to school only if evidence of the administration of at least one dose of each antigen described in § 23.83 for multiple dose vaccine series is given to the school administrator or the administrator’s designee and the parent or guardian’s plan for completion of the required immunizations is made part of the child’s health record.*] **not be admitted** PROVISIONALLY ADMIT THE CHILD **to school, unless the child has at least one dose of each multiple dose vaccine series required by § 23.83, and one of the following occurs:**

(i) *The child receives the final dose of each multiple dose vaccine series required by § 23.83 within 5 school days of the child’s first day of attendance, and the child’s parent or guardian provides a certificate of immunization on or before the 5th school day.*
(ii) If the child needs additional doses of a multiple dose vaccine series in order to meet the requirements of § 23.83, the child receives the next scheduled dose during the 5 school days referenced in subparagraph (i), and the child's parent or guardian provides a medical certificate ON OR BEFORE THE 5TH SCHOOL DAY scheduling the additional required doses on or before the 5th school day.

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

(2) *Single dose vaccines.* If a child has not received a vaccine for which only a single dose is required ON THE CHILD'S FIRST DAY OF ATTENDANCE FOR THAT SCHOOL YEAR, [the child may be provisionally admitted to
school if the parent or guardian’s plan for obtaining the required
immunization is made a part of the child’s health record, the child may not
be admitted to school.

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

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

(g) Applicability. The provisions of this section shall not apply to a child if either ONE of the following occurS:

(1) The child has not been immunized or is unable to provide immunization records due to being homeless. A school shall comply with any and all federal laws pertaining to the educational rights of homeless children, including the McKinney-Vento Homeless Education Assistance Improvements Act of 2001, 42 U.S.C. § 11431 et seq.
(2) The child, when moving or transferring into a school within this Commonwealth, is unable to provide immunization records immediately upon enrollment into the school. The child’s parent or guardian shall have 30 days to provide immunization records to the school to show proof of immunization as set out in §23.83. A MEDICAL CERTIFICATE AS SET OUT IN §23.83(E), or to satisfy the requirements for an exemption as set forth in §23.84. A CHILD WHO IS UNABLE TO PROVIDE THE NECESSARY RECORDS, MEDICAL CERTIFICATE OR EXEMPTION MAY BE EXCLUDED AT THE END OF THE 30-DAY PERIOD AND IN SUBSEQUENT SCHOOL YEARS UNTIL THE REQUIREMENTS OF THIS SUBCHAPTER ARE MET.

(3) THE CHILD HAS NOT BEEN IMMUNIZED OR IS UNABLE TO PROVIDE IMMUNIZATION RECORDS ON THE FIRST DAY OF ATTENDANCE FOR THE SCHOOL YEAR DUE TO BEING IN FOSTER CARE. A SCHOOL SHALL COMPLY WITH ANY AND ALL FEDERAL LAWS PERTAINING TO THE EDUCATIONAL RIGHTS OF CHILDREN IN FOSTER CARE, INCLUDING THE FOSTERING CONNECTIONS TO SUCCESS AND INCREASING
ADOPTIONS ACT, 42 U.S.C. § 675. THE CHILD’S FOSTER PARENT SHALL HAVE 30 DAYS TO PROVIDE IMMUNIZATION RECORDS TO THE SCHOOL TO SHOW PROOF OF IMMUNIZATION AS SET OUT IN § 23.83, A MEDICAL CERTIFICATE AS SET OUT IN § 23.85(E), OR TO SATISFY THE REQUIREMENTS FOR AN EXEMPTION AS SET FORTH IN § 23.84. A CHILD WHO IS UNABLE TO PROVIDE THE NECESSARY RECORDS, MEDICAL CERTIFICATE OR EXEMPTION MAY BE EXCLUDED AT THE END OF THE 30-DAY PERIOD AND IN SUBSEQUENT SCHOOL YEARS UNTIL THE REQUIREMENTS OF THIS SUBCHAPTER ARE MET.

(4) THE CHILD OBTAINS AN EXEMPTION UNDER SECTION 23.84 (RELATING TO EXEMPTION FROM IMMUNIZATION).

(h) *Temporary waiver.* The Secretary may issue a temporary waiver of the immunization requirements referenced in § 23.83. The details of the temporary waiver will be set out in a notice published in the Pennsylvania Bulletin. A temporary waiver may be issued under either of the following circumstances:
(1) The Centers for Disease Control and Prevention, United States Department of Health and Human Services, recognizes a Nationwide shortage of supply for a particular vaccine.

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

§23.86. School reporting.

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

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

[(b)](c) The school administrator or the administrator’s designee shall forward the reports to the Department as indicated on the reporting form provided by the Department.
[(c)] Duplicate reports shall be submitted to the county health department if the school is located in a county with a full-time health administrator.

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

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

* * *

(7) [The number of students in each grade level who were denied admission because of the student's inability to qualify for provision admission or, in an ungraded school, in each age group as indicated on the reporting form.] The number of students in kindergarten, 7th grade [level], or in an un-graded school, age 12 only, who were denied admission because of the student's inability to provide documentation of the required vaccine doses.
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Rachel Mayer
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Jeffrey H. Mayer
5914-B Wayne Avenue
Philadelphia, PA 19144
Re: Department of Health – Final Regulation No. 10-197
School Immunization
28 Pa. Code §§ 23.82, 23.83, 23.85, 23.86

Dear Mr. Sumner:

Enclosed is a copy of the above-referenced final-form regulations for review by the Commission pursuant to the Regulatory Review Act (Act) (71 P.S. §§745.1-745.15). These final-form regulations require a child to have any single dose vaccine upon school entry, or risk exclusion. In the case of a multi-dose vaccine, the final-form regulations require that the child have at least one dose of the vaccine upon entry into that school year, and then, if additional doses are required and are medically appropriate within the first five days of school, the child must have either the final dose during that five day period, or must have the next scheduled dose and must also provide a medical certificate setting out the schedule for the remaining doses. If the child has at least one dose, but needs additional doses, and those doses are not medically appropriate during the first five days of school, the child may provide a medical certificate on or before the 5th school day scheduling those doses. The medical certificate must be signed by a physician, certified registered nurse practitioner, or physician assistant. If the child receives the immunizations from the Department or a public health department, a public health official may sign the medical certificate. A child who fails to meet these requirements risks exclusion. The possibility of exclusion also occurs at the end of every 30 day review period; the final form regulation requires that a school administrator or his or her designee review the medical certificate every 30 days.

The final-form regulations also provide for certain waivers of the regulation under specified conditions – if the child is homeless, for example, or if the child is unable to locate his or her records due to a disaster.

The final-form regulations also add a dose of meningococcal conjugate vaccine (MCV) for entry into the 12th grade, or, in an ungraded class, for entry into the school year where the child turns 18. This is in accordance with ACIP’s recommendations. The Department has also added pertussis to the list of diseases against which a child must be immunized before entering and attending school; this acknowledges the fact that certain vaccines, like single antigen diphtheria, single antigen tetanus and single antigen pertussis vaccine, are not available in the United States.
Finally, the final-form regulation amends the manner and time frames for schools to report immunization rates to the Department, in order to obtain the most accurate immunization data possible from schools.

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. See 71 P.S. §§745.5a(a).

Fifty-five commentators have requested additional information relating to the final-form regulations. A list of the names and addresses of these commentators is enclosed. The Department received approximately 290 comments to the proposed rulemaking. These comments, which discussed a number of provisions contained in the proposed regulations, were forwarded to the Commission upon receipt by the Department.

The Act also provides that IRRC may have until its next scheduled meeting which occurs no less than 30 days after receipt of the final-form regulation to approve or disapprove the final-form regulation. 71 P.S § 745.5a(e).

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact Neil Malady, Director, Office of Legislative Affairs, at (717) 783-3985.

Sincerely,

[Signature]
Karen M. Murphy, Ph.D., R.N.
Secretary of Health

Enclosures
TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT

<table>
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<th>I.D. NUMBER:</th>
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<td>SUBJECT:</td>
<td>SCHOOL IMMUNIZATION</td>
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<td>DEPARTMENT OF HEALTH</td>
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**TYPE OF REGULATION**

- Proposed Regulation
- Final Regulation
  - Final Regulation with Notice of Proposed Rulemaking Omitted
  - 120-day Emergency Certification of the Attorney General
  - 120-day Emergency Certification of the Governor
  - Delivery of Tolled Regulation
    - a. With Revisions
    - b. Without Revisions

**FILING OF REGULATION**

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<td>HOUSE COMMITTEE ON HEALTH</td>
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<td>MAJORITY CHAIR Matthew E. Baker</td>
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<td>MINORITY CHAIR Florindo J. Febria</td>
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<td>SENATE COMMITTEE ON PUBLIC HEALTH &amp; WELFARE</td>
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<td>MINORITY CHAIR Shirley M. Kazar</td>
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<td>9/14/16</td>
<td>K. Cooper</td>
<td>INDEPENDENT REGULATORY REVIEW COMMISSION</td>
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<td>ATTORNEY GENERAL (for Final Omitted only)</td>
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September 16, 2016