

One commentator quoted Tetyana Obukhanych, an immunologist, as stating that the introduction of the acellular pertussis vaccine in the late 1990s was followed by an unprecedented resurgence of whooping cough. She quotes her as further stating that an experiment with deliberate pertussis infection in primates revealed that the aP [acellular pertussis] vaccine is not capable of preventing colonization and transmission of *B. pertussis*, citing a study in 2015 for the finding that acellular pertussis vaccines protect against disease but fail to prevent infection and transmission in a nonhuman primate model. The FDA has issued a warning regarding this crucial finding. The commentator further cited the 2013 meeting of the Board of Scientific Counselors at the CDC as revealing additional alarming data that pertussis variants currently circulating in the USA acquired a selective advantage to infect those who are up to date for the DTaP boosters, meaning that people who are up to date are more likely to be infected, and thus contagious, than people who are not vaccinated. The commentator stated that it did not make sense for the Department to require more doses of a problematic vaccine. The commentator stated that this would place an undue burden on those who might react, with no benefit to them or anyone else.

Another commentator stated that there is much scrutiny with the pertussis vaccine, and that the first pertussis vaccine did not work, and the second one has mutated. The commentator stated that the outbreaks of pertussis are all persons vaccinated with the newer vaccine. The commentator stated that due to the mutation of the virus, it has become more virulent and people who get the disease are getting sicker than people in previous outbreaks. The commentator stated that the commentator believed it would be irresponsible to force another skeptical vaccine

on innocent children especially when it is another mixed vaccine like Tdap. The commentator stated parents and grandparents must insist on vaccines that are properly tested for longer periods of time by independent organizations, and that overloads of mixed vaccines are not forced on infants and children. The commentator stated that the testing is done by the vaccine manufacturers who are not liable or accountable for safety or efficacy.

The commentator went on to state that according to VAERS, there have been more than 21,014 reports of serious adverse reactions associated with pertussis-containing vaccines, with the vast majority, 15,535, in children under the age of three. According to the commentator, 93% of the 2628 deaths reported in association with pertussis-containing vaccines are also in children under the age of three . Requiring an additional dose for children entering kindergarten may result in an increase in deaths for that age group, and since the vaccine does not prevent the disease, there would be no benefit to balance such a risk.

The commentator stated that we should be aware that not every vaccine works as well as advertised, and that some can do irreparable harm. The commentator stated that more and more catastrophic reactions are being reported, and that there are increasing reports of vaccine failure, such as the recent outbreak of mumps, which was tied not to the failure of the herd to vaccinate, but to manufacturer fraud. The commentator stated that the knee-jerk response of requiring more and more vaccines, and tying the right to attend to school to more and more vaccines is not the answer.

One commentator stated that it has been proven that pertussis is often spread by persons that are recently vaccinated, and until more studies are done, and it can be determined how and why this is happening, or an alternative is developed that is safer, it should not be mandated. The commentator stated that parents should be able to choose between the Td shot and the Tdap.

The Department disagrees with the commentators, and has not made a change to the regulation based on those comments. As the Department has explained, many students are already being immunized against pertussis at school entry and for attendance due to the fact that single antigen diphtheria, tetanus and pertussis vaccines are not available in the United States. In addition, ACIP recommends vaccination of children with an acellular pertussis vaccine. “Pertussis Vaccination: Use of Acellular Pertussis Vaccines among Infants and Young Children,” *MMWR* 46(RR-7);1-25 (March 28, 1997) (hereinafter referred to as “Use of Acellular Pertussis Vaccines”). The American Academy of Pediatrics also recommends vaccination against diphtheria, tetanus and pertussis. See <https://www.healthychildren.org/English/safety-prevention/immunizations/Pages/diphtheria-Tetanus-Pertussis-Vaccines-What-You-Need-to-Know.aspx> (accessed September 6, 2016).

Children in the Commonwealth are being immunized with DTaP in order to attend school. The SILR data shows that this is occurring, because schools are providing the Department with information on the number of students being vaccinated with DTaP and Tdap in kindergarten and in the 7th grade. See School Level Data for 2014 and 2015, attached to the RAF of Final Rulemaking. The Department acknowledges that no vaccine is completely safe, and that adverse effects do occur. ACIP recommended the use of DTaP, however, and the FDA licensed it, taken safety issues into consideration. See, generally, “Use of Acellular Pertussis Vaccines.” The

Department, and the Advisory Health Board, are following ACIP's recommendations. If, however, the pertussis antigen is contraindicated for a child, as contraindications are described by ACIP, (Pink Book, at 274), or if a practitioner giving the vaccination believes there is a contraindication, the child has the option of receiving DT to complete the series (*see* subsection (b)(1)), or if the child would be receiving Tdap (*see* § 23.83(c)(1)(i)), a medical exemption.

In addition, the waning of pertussis immunity among vaccinated and unvaccinated individuals has been documented. However, ACIP and the American Academy of Pediatrics have recommended booster vaccines, not the elimination of the vaccine requirement. As with any vaccine, there are known adverse effects. A more effective vaccine, which contained whole cell pertussis vaccine, was disfavored because of potential health issues, and acellular pertussis vaccines were developed. "Use of Acellular Pertussis Vaccines," at 1. The Department is aware that not every vaccine is 100% effective, but, as studies have shown, vaccinated children have a less virulent form of the disease, and are less likely to contract it. *See* "Parental Refusal of Pertussis Vaccination," *supra*; *see also* "Pertussis Epidemic," at 4 ("Unvaccinated children have at least an eightfold greater risk for pertussis than children fully vaccinated with DTaP").

According to ACIP, in studies it considered in recommending the Tdap vaccination, pertussis disease has three phases, catarrhal, which is characterized by an intermittent cough and coryza, which lasts one to two weeks, a paroxysmal phase, characterized by spasmodic cough, posttussive vomiting and an inspiratory whoop, which lasts four to six weeks, and a convalescent phase, during which symptoms slowly improve, but which can last months. "Preventing Tetanus, diphtheria, and Pertussis among Adolescents: Use of Tetanus Toxoid, Reduced

Diphtheria Toxoid, and Acellular Pertussis Vaccines,” *MMWR* 55(RR03); 1-34 (March 24, 2006) (hereinafter referred to as “Preventing Tetanus, diphtheria, and Pertussis”) at 3, retrieved from <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5503a1.htm> (accessed August 6, 2016).

Complications during the illness include hypoxia, pneumonia, seizures, weight loss, encephalopathy, and death. *Id.* The Department and the Advisory Health Board, relying on ACIP’s and the AAP’s recommendations, and the FDA’s licensure of the vaccine, has determined to include pertussis in the list of diseases against which children must be immunized. The Department notes, again, that a parent or guardian has recourse to the medical and religious/philosophical exemptions if their child qualifies for those exemptions.

With respect to the comment that a parent should be able to choose between Tdap and Td, the Department notes that Tdap is already a required vaccination. Nothing in this Rulemaking changes that requirement. If a child has a contraindication for pertussis, the response for entry into the 7th grade would be to obtain a medical exemption, not to vaccinate the child with an additional diphtheria and tetanus combination. The Department added Tdap to the list of immunizations required for entry into the 7th grade in 2011 to account for the waning pertussis immunity being seen across the country. *See* 40 Pa.B. 2747 (May 29, 2010).

One commentator stated that the current outbreak of pertussis among fully vaccinated and up-to-date children suggests real challenges for vaccine manufacturers, particularly in regard to the efficacy of vaccines containing pertussis bacteria. The commentator suggested that the inefficacy of the vaccine merits a cessation of any new regulation, and respect for parents who wish to preemptively condition their child for pertussis immunity by homeoprophylaxis or

homeopathic “vaccination,” as studied and directed by Dr. Isaac Golden, Ph.D. (MA), D.Hom. N.D., B.Ec (Hon) of Australia.

The Department disagrees with the commentator. In promulgating this Final Rulemaking, the Department notes that it, with the approval of the Advisory Health Board, is following the recommendations of ACIP and in agreement with the recommendations of the AAP. The Department notes that a parent or guardian has recourse to the medical and religious/philosophical exemptions to if their child qualifies for those exemptions.

The PACIC stated that pertussis should not be included in a combination vaccination, because it is highly possible that the vaccine type or procedure used may be altered in the near future, and combining it with tetanus and diphtheria antigens in one paragraph will make future changes more difficult while creating no notable benefit now.

The Department has not changed the regulation. The Department notes that there is no single antigen pertussis vaccine available. “Preventing Tetanus, Diphtheria, and Pertussis,” *supra*, at 2. Pertussis vaccine is only available as part of DTaP or Tdap vaccines, and so cannot be listed separately. Any child with a possible contraindication to the pertussis vaccine can, as permitted by the regulation, finish the series with DT; in the case of the Tdap requirement, or, if the child’s physician or physician’s designee finds it to be appropriate, the child may obtain a medical exemption.

Paragraph (2). Poliomyelitis.

Multiple commentators recommended that the Department change the regulation from “enhanced activated polio vaccine” to “enhanced inactivated” polio vaccine. One commentator stated that the existing polio vaccine is being phased out, and there are numerous complications from polio vaccines, from causing polio to SV40 related cancers and mutations. Another commentator stated that problems with the polio vaccine have required a massive effort to destroy all vials of it. The commentators stated that this is a reason why caution should be exercised in adding new vaccines to the schedule.

The Department has replaced the language “enhanced activated polio vaccine” in this paragraph with “inactivated polio vaccine.” This accords with ACIP recommendations in July of 1999 that inactivated polio vaccine be used exclusively in the United States, beginning in 2000. Pink Book, at 304. Exclusive use of inactivated polio vaccine in the United States eliminated the shedding of live vaccine virus, which was responsible for vaccine-associated paralytic polio. *Id.* at 301-302. “Exclusive use of [inactivated polio vaccine] eliminated the shedding of live vaccine virus, and eliminated any indigenous VAPP.” *Id.* at 304. The Department notes that the near eradication of polio in the last century was one of the greatest achievements in public health.

One commentator stated that a 4th polio dose is unnecessary.

The Department disagrees with the commentator and has not revised the regulation. The Department notes that the existing regulation regarding polio states that three *or more* doses are required (*see* former § 23.83(b)(3) (relating to poliomyelitis)), and specifying four doses simply clarifies an existing regulation.

The PACIC stated that the Department had stated that polio had not been eradicated, but that while this was true globally, it has been eliminated in the United States.

The Department agrees that polio has been eliminated in the United States. The Department notes that this is attributable to the introduction of the polio vaccine in this country. Polio still exists in other countries like Afghanistan, Pakistan and Nigeria, where efforts to eradicate it have been stymied by the killing of persons trying to provide vaccines to the population. BBC News, “Pakistan polio: Seven killed in anti-vaccination attack” *BBC News* (April 20, 2016), retrieved from <http://www.bbc.com/news/world-asia-36090891> (accessed August 6, 2016); *see also* Scales, D., “At Least Nine Polio Workers Killed in Nigeria,” *The Disease Daily* (February 11, 2013), retrieved from <http://www.healthmap.org/site/diseasedaily/article/least-nine-polio-workers-killed-nigeria-21113> (accessed August 6, 2015). The possibility of a case coming to the United States cannot be discounted.

Paragraph (3)(iii). Evidence of immunity (for measles, mumps, rubella).

IRRC commented that the Department’s use of the terms, “nurse practitioner,” and “physician’s assistant,” were inaccurate, since the first was not sufficiently specific to detail what type of a practitioner was intended, and the second was an inaccurate use of the term. IRRC noted the appropriate term should be “physician assistants” not “physician’s assistant.”

The Department has revised the regulation to more specifically refer to a “certified registered nurse practitioner,” and to use the correct term, “physician assistant.”

Paragraph (5)(ii). Evidence of immunity for Varicella (chickenpox).

The Department received many comments opposing the change to the proof of immunization requirements for varicella.

Several commentators misunderstood the Department's intentions regarding the regulation. One commentator opposed the proposed change to immunize for chickenpox. The commentator stated that she thought this requirement was bogus, but that it should be her right to vaccinate her child as she sees fit. She stated that there is no data that having the varicella vaccine wards off having shingles in later years. She stated that there are more cases of flu than of chickenpox on a yearly basis, and that she is sure more people die from flu than chickenpox.

One commentator stated that while she is not opposed to other vaccinations, she is ethically opposed to the varicella vaccination.

The HSDLA and one other commentator stated that children who have had chickenpox should not be required to obtain the vaccine, because they have natural immunity.

The commentators are confused as to the proposed change in the regulation. Varicella immunization has been a required immunization since 2001. 31 Pa.B. 5525 (September 28, 2001). The Department did not intend to require children who have already had the disease to be re-vaccinated. The Department had proposed to amend the proof of immunity provision that had allowed a parent to provide a history of varicella disease as proof of immunity with language

that would only permit a history of disease from a physician, CRNP or PA. This is in accordance with ACIP recommendations. "Prevention of Varicella," *MMWR*, 56(RR04); 1-40 (June 22, 2007), retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5604a1.htm> (accessed August 12, 2016). The change was recommended because it is difficult to determine whether a rash is in fact chickenpox, and the Department is concerned that a child actually be immune, in part so that the child is not at risk in the event of an outbreak. After reviewing other comments, however, the Department has decided to keep the parental history requirement in place as discussed above. In originally proposing the change, the Department was following CDC recommendations through its advisory body, ACIP, and was merely concerned with ensuring that children with rashes have really had chickenpox, and are thus actually immune. It is difficult for a non-clinical person, even a parent, to definitively identify the etiology of any rash.

The PASA and two other commentators agreed with the Department's requirement that a history be provided by a physician, a certified registered nurse practitioner, or a physician assistant. One commentator stated that parents are not able to determine with any validity whether a particular combination of symptoms and rash is an actual case of varicella.

The Department thanks the commentators for their support, and agrees that it is difficult for a non-clinical person to definitively identify the etiology of any rash. The Department has, however, determined to eliminate this provision, and allow the submission of a parental history of disease to continue to stand as proof of immunity for varicella. The Department, in the proposed regulations, had decided to propose to adopt ACIP recommendations and change the existing regulation to require a history of disease from a doctor, PA or CRNP, rather than a

parent or guardian. The Department proposed this change because, particularly with diseases involving rashes, it is difficult for anyone to make a definitive identification of the disease, and because it is more likely that a doctor, CRNP or PA, for whom either diagnosis or examination is within the scope of practice, and with clinical experience, can more accurately identify a particular rash.

After reviewing comments relating to cost to parents and guardians and time constraints on them, however, the Department has rethought that requirement. The Department still believes that the most effective method of determining actual immunity, other than from history of the vaccination, is to require a history from a doctor, CRNP or PA. The Department, however, has decided not to make that change and only allow a history from those practitioners. The Department will adopt the change to the regulation expanding the type of practitioners allowed to provide a history in addition to a physician, but making the requested changes to the terms “nurse practitioner” and “physician’s assistant” as IRRC recommended. The Department will, however, keep the provision allowing, in the alternative, a history from the parent or guardian. (See subsection (b)(5)(ii)(B)).

The Department acknowledges that many parents and guardians may not take a child to be seen by a health care practitioner for a potential case of chickenpox, and that a health care practitioner may not wish to see the child in the office. If a physician, CRNP or PA refuses to see a child, however, or if a child has had the disease in the past and not seen a physician, CRNP or PA, the only way to satisfy this requirement would then be by a blood test. Such a test would involve the parent or guardian in additional costs that are potentially not covered by insurance. Because of

this, the Department has withdrawn this change to the regulation. Parents and guardians may still provide history of disease under § 23.83(b)(5)(ii)(B) (relating varicella (chickenpox)).

The Department notes, however, that in the event of an outbreak of disease in a school, the children who are listed as having immunity due to a history of disease, but are not actually immune, may create additional problems in containing the disease. They can catch the disease, and be ill and involve their parents and guardians in expenses attendant to that illness. They can also potentially continue to spread the disease unknowingly into a wider area until they become ill and are quarantined themselves. Because the universe of persons susceptible to disease cannot be known, the outbreak may be more difficult to contain.

IRRC noted that multiple commentators had stated that parents should be permitted to provide evidence since chickenpox is a mild disease that does not require medical intervention and that contagious children should not be taken into medical facilities where other children are present. IRRC noted these commentators also raised the financial burden on families. IRRC asked whether the ACIP and CDC guidelines allowed parents to diagnose varicella. If this is the case, IRRC stated that the Department should provide further support for changing this practice. IRRC stated that the Department should also explain the reasonableness of imposing new financial burdens when the existing practice is acceptable to the CDC.

Multiple commentators stated that changing the regulation would require the child to be seen in a health care practitioner's office. The commentators stated that many practitioners do not want a child who may have chickenpox coming to the office because it would expose others in the

waiting room. Multiple commentators stated that requiring the child to go to the doctor's office or to the emergency room would be a burden upon the ill child and put a financial burden on families. Several commentators, including PACIC, stated that it was irresponsible of the Department to force a child with a highly contagious disease to visit a medical facility where other children, including those who are medically fragile, will likely be present and therefore be at high risk to spread the disease. One commentator stated that normal advice was to avoid public places when a child was sick with chickenpox.

One commentator asked whether the Department was proposing that parents parade their "contagious children" into a medical office to receive confirmation of chickenpox. She stated that asking for proof of immunity for a non-dangerous virus was unnecessary. One commentator stated that normal advice to those with chickenpox is to avoid public places. One commentator noted that if one sibling spread chickenpox to another, the only documentation would be parental history.

One commentator asked where the big epidemic was that would make anyone think that parents don't know what is going on and sending their children to school to infect others. The commentator stated that the regulation would cause parents to carry the financial burden of paying for an unnecessary office visit to confirm what can be easily seen, and would increase the possibility of spreading disease.

Many commentators stated that it appeared as if the Department did not trust parents and guardians to be honest regarding whether or not their child had had chickenpox. One

commentator stated that chickenpox could be recognized by the fluid-filled itchy vesicles. Another commentator stated that her children had chickenpox when they lived outside the Commonwealth, and no responsible doctor would provide her with a verification of this since over a decade had passed. She stated that this would lead to the impression to students and parents that parents cannot be trusted, and damages the bigger picture issue.

Several commentators suggested that it was difficult for anyone to make a determination that a child had varicella. One commentator stated that she had recently cared for a child with chickenpox and strongly opposed requiring proof of natural immunity to be provided by a medical professional. The commentator stated that chickenpox misdiagnoses occur frequently and the symptoms are vague and similar to diseases such as the common flu. The commentator stated that chickenpox can be confused with other infectious diseases that cause a rash such as strep, measles, and roseola. The commentator stated that a diagnosis could be overlooked because a child has already been vaccinated. The commentator asks what the purpose of a diagnosis is when a test is required to determine the disease accurately. Another commentator noted that a friend traveled to Texas and his son came down with an extreme case of Hand, Foot and Mouth disease, which was diagnosed as chickenpox by an urgent care center in Texas. He was not able to travel home since they thought it was chickenpox.

Many commentators stated that chickenpox was not life-threatening and children, including them, recovered without going to the doctor. One commentator stated that since parents would not be taking the child to the office, the health care provider would simply be forwarding the parent's assessment of the infection anyway.

Several commentators stated that many parents choose not to take their child to the doctor when the child is infected by varicella, and should not be required to do so, since it is not usually the case that a child ill with chickenpox needs a physician's care. This would create an undue burden on the parent and on the doctor's office. Another commentator stated that requiring a physician, CRNP or PA to provide a history of immunity for chickenpox rather than a parent was unnecessary, and did not make allowances for a child who never went to a doctor when the child had chickenpox.

One commentator stated that parents and medical staff did not need to be burdened with more unnecessary medical paperwork; the commentator stated that there is now a two week time frame for processing and a charge for the completion of the paperwork at the commentator's provider. The commentator asked the Department to think how that would affect a family with two children in school, and with sports, camp and school activities. The commentator stated that it was a lot of running back and forth and costs add up.

One commentator stated that the Department's requirements were "unreasonable" and "ignorant." She stated that clearly none of the Department staff involved in drafting the regulations had children. She stated that if she called her child's pediatrician and asked for an appointment just because she needed documentation from a physician, they would refuse to see the child, and she would have hardships from taking time from work, and having to pay the office copay.

One commentator mentioned that chickenpox was a “right-of-passage” in the 1980s when she was a child. She stated that she was not aware of any children in her community, school or family seriously injured with chickenpox. She stated that children whose mothers have had chickenpox are unlikely to catch it before they are one year old, because of antibodies in the mother’s blood. She stated that before the vaccine, of four million children per year affected with the virus, only 100 deaths occurred annually. According to the commentator, unlike with the vaccine, life-long immunity is acquired through having the disease.

Two commentators stated that when they were children, their physicians instructed their parents to have all of the siblings sleep in the same room to contract it. Two commentators stated that the disease was no worse than hoof and mouth, and that their children had contacted hoof and mouth in daycare centers. Several commentators stated that a child should not be required to receive the vaccine if the child has natural immunity. These commentators stated that a written statement from the parents should be enough evidence to state a history of immunity and should be trusted. One commentator said that it was absurd to tell a parent they could not be trusted to be honest about their child’s history of chickenpox, and that it was also insulting and a financial burden to make an additional visit to the doctor’s office.

After reviewing all the comments relating to its proposed amendment, and giving consideration to the potential costs of this requirement, the Department has changed the regulation to eliminate the requirement that only physicians, CRNPs, and PAs may provide history of disease, as discussed above. The Department must make it clear in response to IRRC’s comment regarding whether parents may diagnose, however, that only certain health care practitioners are permitted,

within the scope of their practice, to diagnose. The issue here was not one of diagnosis, however, since neither the CDC nor ACIP can set rules on a practitioner's scope of practice. The issue was also not one of whether the parent or guardian is telling the truth relating to a child's history of disease. The issue was that it is extremely difficult for a lay person to see a rash and know that it is definitively one thing or another. Therefore, in outbreak cases, a child may be noted as having immunity when in fact the child does not.

The Department acknowledges that many parents and others believe chickenpox to be a mild illness that does not necessitate a visit to a health care practitioner, and in those cases where a child has not seen a physician, CRNP or PA for the disease, there is no physician, CRNP or PA who would be capable of providing a history of disease. Because this would then require a blood test that is expensive and not covered by insurance, the Department has withdrawn the proposed language. The Department must make it clear, however, that the Department does not and has never taken the position that chickenpox is simply a mild childhood disease. In its Preamble to Final Rulemaking adopting varicella immunity as required for school entry and entry into the 7th grade in 2001, the Department stated the following:

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

31 Pa.B. at 5527. One commentator has cited these figures to show that varicella is not a disease to give concern. The Department disagrees and has always disagreed. For that reason, the

Department added varicella immunity to the list of diseases against which immunity is required in 2001.

In response to commentators' concerns that to require a child to see a physician, CRNP or PA in the office for a case of chickenpox would place a potentially infectious child in a situation to spread the disease, the Department notes that there are ways of dealing with issues of spread of disease in doctor's offices that do not put either the child or the other patients at risk.

In addition, with respect to comments that it is insulting that the Department does not believe a parent can recognize chickenpox, or that it is easily identifiable, the Department disagrees. The Department's proposed change was prompted by the fact that obtaining a history of disease from a non-medical person, even if the non-medical person is a parent, is fraught with the possibility of mistake. It is difficult to determine whether or not a rash is chickenpox simply from clinical symptoms, although a health care practitioner who deals with rashes and fevers on a daily basis, and through education and experience, has a better opportunity of making that determination.

In response to IRRC's comment that the Department should explain the financial reasonableness of imposing a new requirement when the existing practice of accepting a parental history was acceptable to the CDC, the Department notes that ACIP, the Advisory Committee on Immunization Practices that advises the CDC regarding childhood immunizations, recommended that the criteria for evidence of varicella immunity should not include a self-reported vaccine dose or a history of vaccination provided by a parent, without more. ACIP recommended that evidence of immunity should be either a diagnosis of varicella by a health-care provider or a

health-care provider verification of a history of disease rather than parental or self-reporting. “Prevention of Varicella,” at 15. (“ACIP has approved criteria for evidence of immunity to varicella. Only doses of varicella vaccines for which written documentation of the date of administration is presented should be considered valid. Neither a self-reported dose nor a history of vaccination provided by a parent is, by itself, considered adequate evidence of immunity.”) The change the Department proposed, therefore, was recommended by an advisory group to the CDC, which does not believe that a parental history is sufficient to accurately identify those children who may be at risk for the disease.

One commentator stated that this amendment would remove the individual’s right to a health system of their own choosing. The commentator stated that agencies cannot constitutionally demand or define how or through what means or entity an individual must receive medical care.

The Department’s proposed amendment did not attempt to tell an individual how or where to receive health care. The amended regulation simply would have disallowed the use of a parental history of disease to prove that a child was immune to chickenpox. For other reasons, however, the Department has decided to remove this requirement from the regulation and leave the parental history of chickenpox in place as proof of immunity.

The PACIC asked that data be provided relating to proof of immunity. The PACIC asked whether there was data showing that parents stating that their children have chickenpox is untrue. The commentator stated that there be data showing that parents are no longer capable of identifying chickenpox. Another commentator stated that if the Department was making this

change to the regulation because the current system was being abused, then the Department should produce proof of the abuse. The commentator did not believe that there was any basis for this change. One commentator asked whether the Department had data showing that parents were no longer capable of identifying childhood diseases such as chickenpox.

The Department has changed the regulation, and so the request for data is moot. The Department notes, however, that the ACIP recommendation was based on the following:

Historically, self-reporting of varicella disease by adults or by parents for their children has been considered valid evidence of immunity. The predictive value of a self-reported positive disease history was extremely high in adults in the prevaccine era although data on positive predictive value are lacking in parental reports regarding their children. As disease incidence decreases and the proportion of vaccinated persons with varicella having mild cases increases, varicella will be less readily recognized clinically. A recent study demonstrated that only 75% of unvaccinated children aged 12 months--4 years who reported a positive history of varicella were in fact immune (confirmed by serological testing), compared with 89% of children aged 5--9 years and 10--14 years. To limit the number of false-positive reports and ensure immunity, ACIP recommends that evidence of immunity should be either a diagnosis of varicella by a health-care provider or a health-care provider verification of a history of disease rather than parental or self-reporting.

Id.

The Department did not, however, intend to suggest that parents and guardians were lying about the status of their children, or that this provision was being abused. The Department's proposed change was prompted by the fact that obtaining a history of disease from a non-medical person, even if the non-medical person is a parent, is fraught with the possibility of mistake. It is difficult to determine whether or not a rash is chickenpox simply from clinical symptoms, although a health care practitioner who deals with rashes and fevers on a daily basis has a better opportunity, through education and experience, of making that determination. The Department

understands the cost related issues, however, and has decided to maintain the requirement that parents be able to provide a history of disease for varicella.

One commentator noted that in an urban high school setting with a transient population, many children do not have insurance and titers are expensive.

The Department recognizes that titers are expensive, and, factoring that into other considerations, has decided against changing the regulation.

Multiple commentators, including PACIC, stated that not all families have existing relationships with the list of specified medical workers, and this provision could force a family to enter into a contractual relationship with unknown medical staff. These commentators stated that families would have the financial burden of copays, charges and laboratory fees. Two commentators stated that this would be around \$250.00 for two children. One commentator stated that making a trip to a medical professional and getting testing done to verify that the child has immunity is a huge cost for parents. Several commentators stated that even if the state paid for every child to be tested, taxpayers would still be paying for this requirement through their taxes. Lastly, these commentators stated that this could create an environment of distrust between the school staff and the parents if the parents' word appeared to be questioned.

The Department has changed the regulation after consideration of the potential costs of the requirement. In response to the commentators' concerns, however, although the Department is aware that there are families without primary care providers, that is, the list of medical staff

referenced by the commentator, the passage of the Affordable Care Act, which requires all persons to be insured, gives more families the opportunity to be connected to a medical home, since for most insurance plans, a primary care provider is required and can be assigned. For families who lack insurance coverage, and are uninsured or underinsured, the Department, through its VFC providers, can provide the vaccine, which may be necessary if there is no provider to sign the history of immunity. The Department suggests that if a child does not have a medical home, being “forced” to find one may not be catastrophic in terms of the child’s general health and wellbeing.

One commentator stated that her daughter had caught a mild case of chickenpox from the vaccine that was supposed to protect her. The commentator stated that she wanted to bring the child into the doctor’s office because she had a serious upper respiratory infection along with the mild case of pox on her body. The commentator stated that the doctor would not allow her to bring the child in because the child was contagious. The commentator noted that this was interesting, she could not bring the child in to get medical confirmation. The commentator stated that for the next ten years she had to fight every time someone wanted to make her child have a chickenpox booster, because a child does not need a booster if the child has had the disease, and she could not prove that the child had the disease. She stated that when it was time for college, she had to prove the child had the disease, and this was very expensive. The commentator stated that this remains a problem. According to the commentator, the child will be unable to obtain a proof of immunity from a medical professional, so the child will either have to be revaccinated, or pay for titer testing. The commentator asked that the Department not allow or encourage the pharmaceutical industry to push its agenda of money making vaccines on the general public by

forcing parents to expose their children to unnecessary and unsafe numbers of vaccines because parents or guardians cannot afford to have titers done.

The Department understands the commentator's frustration with her health care practitioner, but cannot comment on the reasons for which that practitioner may or may not have chosen to see her child. The Department has chosen against changing the regulation. With respect to the commentator's comments regarding the pharmaceutical industry, however, the Department has no control over that industry, and cannot either allow or encourage it to do anything.

The Department notes, further, that it cannot fix the commentator's problem of having to prove immunity of varicella for college entry or retake the vaccination. This will continue to occur in those colleges that choose not to accept a history of immunity from a parent or guardian. The Department has no control over what requirements a college or university might have, and although the possible expense of obtaining a history of varicella disease from a physician, CRNP or PA or obtaining a blood test to prove immunity will now be avoided in elementary or secondary school, since the Department is not changing the regulation, it is possible that, like the commentator, a parent or guardian may have to incur the expense of a blood test or a visit to the physician, CRNP or PA prior to admission to a college or university.

One commentator asked when the elimination of the ability to accept a parental history of varicella would go into effect.

This requirement will not go into effect, since the Department has changed the regulation to maintain the requirement that a parent may give a history of disease as proof of immunity for varicella.

PSEA recommended that the Department create an educational campaign for providers and parents regarding the requirement that a history of disease can only be obtained from a physician, CRNP or PA.

The Department has changed the regulation, so that no education on this point will be required.

The HSLDA stated that this requirement was not recommended by the Joint State Government Commission's Report. The HSLDA stated that varicella vaccine rates already meet Healthy People 2020 target vaccination rates.

The Department has not adopted its proposed change to this regulation. The Department would like to point out, however, that while the Department appreciates that the Joint State Government Commission's report did not include the language in the Department's proposal, ACIP, made up of vaccine experts from throughout the country, did. See "Prevention of Varicella," *supra*. In addition, the Department is pleased that varicella vaccine rates meet the Healthy People 2020 target vaccination rates, however, the proposed change in the regulation was not to improve rates. The Department has revised the regulations to ensure that if and when an outbreak occurs, children who are presumed to be immune, actually are immune.

Subsection (c). Special requirements for Tetanus and diphtheria toxoids and acellular pertussis vaccine and meningococcal conjugate vaccine.

The Department received multiple comments regarding the Tdap vaccine and the MCV vaccine required for entry into the 7th grade. The Department has not substantively changed the regulation, and addresses those comments below. The Department did make non-substantive changes to subsection (c), including in the title to the subsection, and in and in paragraph (1)(i), to correct references to the Tdap vaccine. Both diphtheria and tetanus toxoids are included in Tdap, and therefore the language has been changed from “tetanus and diphtheria toxoid” to “tetanus and diphtheria toxoids.” The Department also added the word “conjugate” to the title, to clarify that the type of meningococcal vaccine being added in paragraph (2) is meningococcal conjugate vaccine, as has been required for entry into the 7th grade since 2011. *See* 40 Pa.B. 2747 (May 29, 2010).

The March of Dimes supported the addition of the pertussis vaccine and the addition of a second meningitis vaccine before entry into 12th grade. According to the March of Dimes, meningococcal disease can result in permanent disability or death. The March of Dimes cited the CDC as stating that about 1000-1200 people get meningococcal disease each year in the United States, and even when they are treated with antibiotics, 10-15% of these people die. The March of Dimes further cited the CDC as stating that of those who live, 11%-19% lose their arms or legs, have problems with their nervous systems, become deaf, or suffer seizures or stroke. The March of Dimes stated that there is a vaccine to immunize children and young adults that covers four of the five major causes of bacterial meningitis and the vaccine is readily available. The March of Dimes stated that the CDC recommends routine administration of this vaccine at age 11 or 12, with a booster shot at 16 years of age.

The Department agrees with the March of Dimes, although it notes as discussed below that diphtheria and tetanus toxoids and acellular pertussis vaccine have been required for entry into the 7th grade since 2011. *See* 40 Pa.B. 2747 (May 29, 2010).

One commentator stated that requiring a combination form of MCV and Tdap was a decision that placed children at risk. The commentator stated that if the requirement was adopted, children who had received separate forms of these immunizations would be required to be revaccinated, not for any medical reason, but to comply with a nonsensical regulation that did not recognize their immunization status. The commentator stated that this placed children at risk if they needed separate antigen vaccinations for their health, and pitted their health against their education.

The Department disagrees with the commentator. The commentator is incorrectly reading the regulation. The Department is requiring combination forms of these vaccinations going forward, but will not require revaccination of children who are already immunized. As the Department has noted, there is no single antigen pertussis vaccine licensed in the United States. “Preventing Tetanus, Diphtheria, and Pertussis,” at 3. Tdap was added by the Department in 2011 to provide a booster dose of pertussis, in accordance with ACIP recommendations. *See* 40 Pa.B. 2747 (May 29, 2010). In the event a child has a medical contraindication to the pertussis vaccine, the child may obtain a medical exemption for the 7th grade Tdap requirement. With respect to MCV, the Department has eliminated any reference to either single antigen form or combination form, and is simply requiring the vaccine.

Several commentators opposed adding Tdap for 7th graders. Two commentators stated that the *B. pertussis* microbe has evolved to evade both whole cell and acellular pertussis vaccines in creating new strains that produce more toxin to suppress immune function and cause more serious disease. According to the commentators, immunity wanes and millions of fully vaccinated children and adults are silently infected with pertussis every year. The commentators stated that children show few or no symptoms but spread pertussis to unvaccinated and vaccinated children without doctors reporting the cases. The commentators quoted the July 2015 edition of the journal *Pediatrics* as stating that lack of long term protection after vaccination is likely contributing to increases in pertussis among adolescents. This commentators suggested that parents that wanted their children to have the vaccine could get it without the Department requiring the immunization.

One commentator stated that Paragraph 18 of the Regulatory Analysis Form fails to discuss the fact that vaccines are drugs, and therefore carry an inherent risk of injury and death, and opposed the requirement that Tdap be required in the 7th grade. She stated that even after six doses of Tdap, vaccine effectiveness declined to 34% after two to four years, likely contributing to increases in pertussis among adolescents. The commentator also stated that bundling diphtheria and pertussis with tetanus gives students unnecessary doses of vaccines for diseases they are unlikely to catch. Tetanus is not a communicable disease, and diphtheria is extremely rare in the United States.

The commentators misunderstand the purpose of the change to the subsection. The Department is not adding Tdap for 7th graders. Tdap has been required for entry into the 7th grade by the Department's regulations since 2011. (See former subsection (c)(1) (relating to tetanus and diphtheria toxoid and acellular pertussis vaccine (Tdap)); see also 40 Pa.B. 2747 (May 29, 2010). Under the previous regulation, however, Tdap could be administered as a single antigen vaccine or in a combination form. Because, however, single antigen vaccinations are no longer available in the United States, the Department has amended the regulation to require a dose of Tdap in combination form only. The combination form did and still does include a pertussis vaccine component. Pertussis vaccine and the importance of tetanus vaccine are discussed in this Preamble, *supra*, at pages 164-165, 169-171 (pertussis) and 161-162 (tetanus). In addition, in order to eliminate both tetanus and diphtheria from the list of diseases against which children must be vaccinated, the Department would have to propose a separate rulemaking, and the Department has no intention of taking that action.

The PACIC stated that contraindications for pertussis vaccine are listed with the pertussis requirement for school entry, but not for the newly proposed 7th grade Tdap requirement. IRRC also recommended that the Department include a similar exception regarding contraindications for pertussis in subsection (c)(1)(i).

As the Department has stated, the requirement for Tdap is not new, but was added to the required list in 2011. See 40 Pa.B. 2747 (May 29, 2010). The Department has merely changed the requirement that the vaccine could be given in single antigen forms to a requirement that the vaccine be given in the combination form, because there is no single antigen form of pertussis

vaccine licensed in the United States. “Preventing Tetanus, diphtheria, and Pertussis,” at 3. The PACIC is correct that ACIP recommends that the DTaP series to be completed with DT (a combination form vaccine) if there is a contraindication to the pertussis component. This provides immunity from diphtheria and tetanus, even if pertussis is contraindicated. There is no similar recommendation relating to Tdap if there is a contraindication for the pertussis component, because Tdap was added for 7th grade entry in 2011 to address the need for additional pertussis immunity. The appropriate response would be for the child’s physician or the physician’s designee to provide a medical exemption for the Tdap dose. The Department has not changed the regulation.

One commentator recommended that the Department work with vaccine manufacturers to produce single antigen vaccines.

The Department does not work with vaccine manufacturers to discuss production of vaccinations.

IRRC also noted that commentators have said that some doctors will not provide vaccine to children at the 6th grade physical if the child is not 12 years old at the time of the physical. IRRC recommended that the Department ensure that the implementation of the requirement is clear for the regulated community.

Two commentators asked what the Department's advice would be in the event a pediatrician chooses to wait to vaccinate a child until the 12-year old well child examination. This may not be scheduled, for insurance purposes, until after the beginning of 7th grade.

Another commentator stated that a large pediatric practice in her area would not give Menactra (a meningococcal vaccine) until the student was 12 years of age, so that if the child was not 12 at the time of the 6th grade physical, the practice would not give the vaccine. The commentator stated that the physician would tell the parents that the child is up to date, even though the child is not up to date with respect to the school immunization requirements. The commentator asked that the Department tie the meningococcal immunization requirement to the requirement that a child have a physical in the 6th grade, because having the 2 together might help with the compliance of both requirements.

Another commentator pointed out that getting 7th graders up to date on immunizations is a school nurse's greatest challenge. The commentator also pointed out that 6th grade students are required by the Commonwealth to have a physical examination. She, stated that many of these children are only 11 years of age at the time they get this physical, and although they can get Tdap at this time, they are not eligible for MCV until they are 12 years of age. Because of this, the student gets the physical, but gets neither the Tdap vaccine nor the MCV because the thought is the student will get both vaccines together. According to the commentator, because the next required examination in 7th grade is a dental examination, the child often gets neither vaccine, because the family does not want to return to the physician's office and pay an additional fee "just to get these immunizations." She recommended that the Department switch the dental and

the physical examination, so that the dental examination is required in 6th grade, and the physical in 7th grade.

One commentator stated that if Tdap and MCV are required for entry into 7th grade without a provisional enrollment period, then the Department should write the regulation to require these immunizations by May 1st of the year the child is in 6th grade. According to the commentator, it would be easier to encourage parents to get the child immunized with the 6th grade physical and school nurses would have additional time to notify parents and exclude students if that became necessary.

The Department has not changed the regulation. The Department believes, in response to IRRC's comment, that the implementation of the requirement is clear for the regulated community, which only tangentially includes health care practitioners. The Department does not have the authority to regulate the practice decisions made by a licensed health care practitioner. The Department and the Advisory Health Board are, however, following ACIP recommendations in setting these vaccine requirements. ACIP recommendations allow for adolescents at 11 years of age through 18 years of age, depending on previous vaccine history, to receive one dose of Tdap instead of tetanus or diphtheria toxoids "preferably at a preventative care visit *at age 11 or 12 years.*" "FDA Approval of Expanded Age Indication for Tetanus Toxoid, Reduced diphtheria Toxoid and Acellular Pertussis Vaccine," *MMWR* 60(37):1279-1280 (September 23, 2011) (*emphasis added*), retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6037a3.htm> (accessed August 6, 2016). ACIP recommends routine administration of a meningococcal vaccine for all persons aged 11

through 18 years. “Prevention and Control of Meningococcal Disease (2013),” at 14. If a practitioner chooses to wait until the 12-year-old well child examination to provide either Tdap or MCV immunizations, or both, and that occurs after entry into the 7th grade, it may be necessary for the physician or his or her designee to provide a medical exemption for that particular period of time until the physician believes the immunization may be safely given. Nothing in the recommendations from ACIP or in the regulations require the vaccines to be given in an unsafe or a medically inappropriate manner.

In addition, school nurses may start to encourage children and parents to obtain the required immunizations at any time. If the Department moved the requirement up 6 months, from the start of 7th grade to the end of 6th grade, a child could potentially be excluded at the end of a school year, raising questions of the child’s promotion to the next grade.

Further, the requirements relating to school health examinations are beyond the scope of this rulemaking, which are promulgated, in part, under the Department’s authority, with the approval of the Advisory Health Board, to set out a list of diseases against which children must be immunized to attend or enter school. *See* 24 P.S. § 13-1303a(a); 35 P.S. § 512.16(a)(6) & (b); 71 P.S. § 541(c.1).

One commentator asked whether, given the Department’s statement that pertussis was only being added by requiring a combination vaccine that included that antigen, Tdap should be considered to be part of a multiseried vaccination. The commentator asked whether the Department’s

statement in the Preamble that it was adding pertussis toxoid to an “existing vaccination requirement, that of diphtheria and pertussis” was a mistake.

The commentator was correct that the Department’s statement was a mistake, and “tetanus” should be read for “pertussis” in the statement quoted. With respect to the remainder of the commentator’s question, the Department considers Tdap to be a single dose vaccine. The ACIP recommendation is for one dose of Tdap. A child who does not have a vaccine for which only a single dose is required may not be admitted to school. *See* § 23.85(e)(2). Tdap is the only vaccine in the list of required immunizations that is a single dose vaccine.

Another commentator asked whether the statement that if a child is in 7th grade and has not had either Tdap or MCV immunizations, does not receive those immunizations throughout the 7th grade, and enters the 8th grade still unvaccinated, the child is to be provisionally enrolled in the 8th grade.

The commentator’s statement is incorrect. The child should not be *provisionally enrolled*, the child should be *excluded* on the first day of school, and remain excluded until the vaccinations are given. Section 23.83(c)(1)(iii), which the Department has added to the regulation to clarify this issue, states that if a child does not have an exemption as permitted by § 23.84 and does not receive the immunizations as required in subparagraphs (i) and (ii) as required, the child may be excluded in that school year and each succeeding school year that the child fails to obtain the required immunization. Although MCV may be a multidose vaccine, the child should not have been provisionally admitted without a medical certificate setting out the time frame for obtaining

the remaining required immunizations. If the child comes into the next school year and is out of compliance with that medical certificate, the child may be excluded without waiting for the 5-day provisional period to end. The Department notes that the same holds true for any other immunization listed in the Department's regulations. The regulations require the immunizations listed in § 23.83(b) (required for attendance) for continued *attendance* at school, not just for school entry. *See* § 23.83(b).

One commentator asked whether the 5-day provisional period applied to the single dose of MCV required in 7th grade, or whether a child that did not have the dose on the first day should be excluded.

One commentator asked what the requirements would be for a child who had not been enrolled in a school in the Commonwealth for 7th grade and did not receive the first MCV shot.

The Department has clarified the regulation to respond to these questions. The Department has added language to subsection (c)(1) stating that a child who does not have an exemption as permitted by § 23.84, and who does not receive the appropriate Tdap or MCV upon entry into 7th grade, may be excluded in that school year and each succeeding school year that the child fails to obtain the required immunization. *See* subsection (c)(1)(iii).

Further, the MCV dose in 7th grade is the first of a multidose series. Therefore, because § 23.85(e)(1) states that, "if a child has not received all of the antigens for a multiple dose vaccine series . . . the school administrator or the school administrator's designee may not provisionally

admit the child to school unless the child has at least one dose . . . ,” see § 23.85(e)(1), and, in this case, the child has not received at least one dose, the child may not be admitted.

The Department has also added language to the MCV requirement for 12th grade to make it clear that a dose received after the child turns 16 years of age should be counted as the dose required for entry into 12th grade. See subsection (c)(2). This comports with the ACIP recommendations.

With respect to the question regarding a child who is entering school in the Commonwealth without the required dose of MCV, the Department notes that the regulation allows a child moving or transferring into a school in the Commonwealth a 30-day period in which to provide immunization records to show proof of immunization, or to satisfy the requirements for and exemption under § 23.84 (relating to exemption from immunization). See § 23.85 (g)(2). To clarify that the Department expects all immunization requirements to be met by the end of that 30-day period, the Department has added language to § 23.85(g)(2) requiring the child to provide a medical certificate, if the child cannot provide proof of immunization or an exemption under § 23.84. Therefore, a child without an MCV dose who cannot provide proof of immunization, a medical certificate, or an exemption, or a combination of these records may be excluded at the end of the 30-day period until immunization requirements are met, and may also be excluded in each succeeding school year that they remain unmet.

Paragraph (2). MCV required for entry into 12th grade

The Department received many comments on its proposal to add a dose of MCV in the 12th grade. As stated, in order to clarify the requirements, the Department has added language to

make it clear that a dose received after the child turns 16 years of age should be counted as the dose required for entry into 12th grade. *See* subsection (c)(2). This comports with the ACIP recommendations. The Department has not otherwise changed the regulation.

Comments in support of the 12th grade MCV requirement

The National Meningitis Association (NMA), the March of Dimes, the Pennsylvania Immunization Coalition (PAIC) and PASA and one other commentator agreed with the Department's recommendation to add a dose of MCV for entry into the 12th grade. PASA stated that with nearly 70% of high school graduates planning to pursue post-secondary education opportunities, the additional immunization will ensure that students are protected from this potentially life-threatening disease.

The president of the NMA stated that it was an organization founded by families of children who were affected by meningococcal meningitis. She stated that she and three of the original five founders had lost children to the disease, and the other two founders had children who survived as quad amputees. She stated that they did not know that the disease was potentially vaccine preventable until it was too late. She stated that the only way to prevent the disease was through vaccination, and commended the Department efforts to ensure that adolescents in the Commonwealth receive vaccines as recommended by ACIP.

One commentator stated that she has already reviewed 1,100 9th to 12th grade immunization records in preparation for the addition of these requirements.

The Department appreciates the support of these commentators.

One commentator stated that she intended to send parents a letter with the proposed guidelines regarding the MCV requirement for 12th grade. The commentator requested a sample letter for parents, if one existed.

The Department does not have a sample letter to parents. The Department cautions the commentator that until the Final Rulemaking is published in the Pennsylvania Bulletin with an order making the regulation effective on a specific date, the requirements in the regulation are not in place, and no action should be taken.

Comments requesting addition of other meningitis vaccines

One commentator recommended that the Department add all meningococcal vaccines receiving an A or B recommendation from ACIP, which would then allow the new Meningitis B vaccines to be included in addition to MCV as a single dosage series. The commentator noted that there have been multiple outbreaks with Meningitis B at college campuses within the last few years and ACIP now recommends Meningitis B vaccine for children 16-23 years of age to provide short term immunity against Neisseria Meningitidis serogroup B.

The March of Dimes also pointed out that a vaccine exists for the remaining major circulating strain of the bacterial disease, meningitis B. The March of Dimes further commented that following outbreaks on college campuses, the federal Food and Drug Administration (FDA) approved 2 vaccines for this strain. According to the March of Dimes, the CDC has

recommended permissive use of this vaccine in all children and young adults, 10-25 years of age, with the preferred age of administration at 16 through 18 years of age.

The PACIC noted that there are 5 different types of meningitis, however the CDC recommended vaccine only includes 4 strains of bacterial type A. The PACIC noted that the vaccine does not contain strain B, which is the strain associated with more than 50 % of meningococcal cases and deaths, particularly in children under 5 years of age.

The Department acknowledges that the CDC has recommended permissive use of the meningitis B vaccination, however, it is not yet an ACIP recommendation. Until ACIP further reviews and recommends that vaccination, the Department will not add it to the recommended list.

Comments opposing the addition of an MCV requirement for cost and potential side effects

Multiple commentators, including the PACIC, disagreed with the Department's decision to require a dose of MCV prior to 12th grade. IRRC also noted that commentators state that this is unnecessary and significantly raises costs, and asked the Department to further explain the need for the additional dose, and how the benefits outweigh the costs.

Multiple commentators, including the PACIC, cited the Department's EDDIE database in 2014 as reporting only 16 new cases of meningitis. According to the other commentators, vaccinating the estimated 147,040 seniors in 2014 would have cost parents and taxpayers over \$16,000,000.00. Another commentator stated that even if every 12th grader was vaccinated, and the vaccine prevented all cases of meningitis, this would cost Pennsylvania citizens

\$1,000,000.00 for each case of meningitis prevented. One commentator stated that the vaccine was very expensive. Several commentators stated that the CDC has recognized that the majority of America's 320 million citizens will experience asymptomatic infection as children or young adults without complications and will develop antibodies against meningococcal disease that will protect them.

One commentator cited the Pink Book as stating that 0.3 percent of those with serious adverse events will die. The commentator went on to say that using Colorado data, if 400,000 of Colorado's college students were inoculated with older vaccines, 4000 adverse events can be expected, and 12 persons can be expected to die. The commentator states that the effects of widespread vaccination with the hastily-expedited B vaccine is not known, but according to the package inserts, 2 percent of students who receive the B vaccine will be sickened or hospitalized with a serious event. The commentator states that this could translate into an additional 8000 sick students and 24 deaths, for a total of 12,000 sick and 36 dead in an attempt to prevent 3 meningitis cases. The commentator stated that before the Department could even recommend the meningitis vaccine, let alone mandate it, it must do a detailed analysis of the number of cases of B strain meningitis in Pennsylvania in one year, and compare that number with the .3 % of 12th graders who are likely to have serious adverse events. The commentator asked how many serious adverse events the Department considers as acceptable collateral damage, and why does the Department not think a parent has a say in whether or not their child risks that collateral damage?

Several commentators raised issues relating to MCV's potential side effects. These commentators quoted the manufacturer's insert as predicting that 1% to 1.3% of inoculated children will suffer "serious adverse effects." These commentators stated that, therefore, the risk of dying from the vaccine was greater than dying from the disease. These commentators also cited the CDC Pink Book as forecasting that .3% of these will die from the vaccine. One of these commentators stated that since more people will die than will be helped by the vaccine, which costs \$84.00 to \$117.00 per shot, the vaccination is a financial windfall for the manufacturers at the expense of the public's health.

Multiple commentators stated that the CDC Pink Book states that 2% of the children to receive the vaccine suffer serious adverse events. The commentators stated that there have only been 390 cases of meningitis in the last year in the United States. The commentators stated that weighing the risks of serious adverse events having mandated meningitis vaccine and contracting the disease and having a serious reaction to receiving it, shows that the vaccines are likely to cause more illness and death than it claims to stop.

Several commentators, including the PACIC, listed the side effects from the MCV vaccine manufacturer package insert, stating that post marketing surveillance for the meningitis vaccine has shown the following: hypersensitivity reactions such as anaphylaxis/anaphylactic reaction, wheezing, difficulty breathing, upper airway swelling, urticarial, erythema, pruritus, hypotension, Guillain-Barre syndrome, paresthesia, vasovagal syncope, dizziness, convulsion, facial palsy, acute disseminated encephalomyelitis, transverse myelitis, and myalgia. One commentator stated that the most frequently reported adverse events were fever (16.8%),

headache (16.0%), injection site erythema (14.6%), and dizziness (13.4%). The commentator stated that syncope was reported in 10% of reports, and 6.6% were coded as serious (i.e., resulted in death, life-threatening illness, hospitalization, prolongation of hospitalization or permanent disability). The commentator stated that serious events included headache, fever, vomiting and nausea. The commentator stated that the proposal did not include costs of the serious side effects.

The PACIC stated that the clinical results of the brand name vaccine Menactra, a vaccine for meningitis, showed that 6.6% of events were coded to serious, that is, resulting in death, life-threatening illness, hospitalization, prolongation of hospitalization, or permanent disability. Serious adverse events included headache, fever, vomiting and nausea, and a total of 24 deaths, or 0.3 percent were reported. The PACIC and another commentator asked whether if the 147,040 12th graders were given Menactra, the Commonwealth could expect 9704 to have serious side effects and 29 to die. PACIC stated that this mandate would most benefit vaccine manufacturers who just happen to have offices in Pennsylvania. The PACIC stated that the Department did not include costs of the serious side effects from the students who could suffer a reaction to the vaccine, and that this could clearly amount to millions more as many of the reactions will cause lifelong health problems.

The PACIC stated that the MCV vaccine had an inherent risk, since it was an invasive medical procedure with documented side effects. The PACIC commented that the vaccine only had an 80% to 85% efficacy rate, and that after two to five years, the vaccine has been found to be, at

best, only 58% effective. The PACIC stated that from 10% to 20% of the cases are fatal, with another 10% to 20% ending in brain damage or loss of limbs.

Although the Department agrees that the case fatality rate from meningococcal disease is between 10%-20%, and that very serious effects from the disease may occur, the Department disagrees with the commentators. The Department would not expect 29 of the children who receive the MCV vaccine for entry into 12th grade to die. MCV has been required for entry into the 7th grade since 2011, and the Department has not been made aware of this type of death rate among 7th grade children getting the vaccine. The Department also does not expect to get a financial windfall from the vaccine.

The Department has not changed the regulation in response to these comments. Commentators have postulated certain costs using the cost of the vaccine and the number of students who would be seniors in a particular year. Some commentators have taken the figures given by the Department in its Regulatory Analysis Form to Proposed Rulemaking (RAF) of approximately \$16,000,000.00 and have stated that for only 16 children who might get the disease, this cost is too great. This statement is misleading. The Department qualified this cost figure by stating that this would be the cost to the regulated community, “*if every child were required to purchase the dose through private pay methods.*” RAF, at 18 (*emphasis added*). In fact, parents and guardians will not be required to pay for the cost of the vaccine itself, although there may be a co-pay depending on the type of insurance the parent or guardian has. In the case of no insurance, the child’s immunization will be paid for through the federal VFC Program. The Department went on to say that:

Because, however, fully one-half of the population is be [sic] eligible for the Vaccines for Children Program, and would receive the vaccine either free of charge or for a vaccine administration fee, the cost . . . would be roughly \$1,701,253. This is calculating the cost at the maximum regional charge in the Commonwealth, which is \$23.14 per administration of the dose.

Further, the MCV vaccine is covered by insurance pursuant to the Affordable Care Act, 42 U.S.C.A. § 300gg-13(a)(2), so that parents or guardians who have insurance (and according to the Pennsylvania Insurance Department, roughly 92% of Pennsylvanians are covered), should again only be paying a co-pay or administration fee. The ACA requires insurers to cover those vaccines that are recommended by ACIP, *id.*, and MCV is recommended by ACIP. *See generally*, “Prevention and Control (2013)”; *see also, generally*, “Prevention and Control of Meningococcal Disease,” *MMWR*, 54(RR07); at 1-21 (May 27, 2005).

Obviously, whether the parent and guardian purchases insurance, or whether the child is covered by the VFC Program, there is cost, to the parent or guardian for the premiums, on the one hand, and to the taxpayer, on the other, since federal tax dollars support the VFC Program. The Department’s addition of a second dose of MCV for students entering 12th grade should not impact either of these costs, however. Since ACIP includes MCV on its recommended list of immunizations, the cost of that immunization is already being calculated into the cost of insurance offered; the ACA requires MCV to be covered, regardless of whether it is on the Department’s list. Further, even if the parent or guardian fails to obtain insurance, or the insurance they do have does not cover the immunization, the federal VFC Program provides vaccines to children who are uninsured or underinsured. Again, the VFC Program covers MCV independently of whether the Department adds it to the list of required immunizations for school.

Further, the Department notes that as a part of ACIP's recommendation for administration of meningococcal vaccine, both in 2005 for the dose at 11 to 12 years of age, and again in 2013 with a second dose, a cost-effectiveness analysis was done. The latter study was done to determine the cost effectiveness of each of three strategies, a single dose at 11 years of age, a single dose at 15 years of age, and a dose at 11 years of age with a booster dose at 16 years of age. According to the recommendation:

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 1,442 quality-adjusted life years (range 610-2,130), 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.

In 2005, when ACIP first considered the cost effectiveness of recommending a dose of MCV, it specifically addressed the cost of vaccine for college students. The analysis considered the

economic costs and benefits of vaccinating a cohort of approximately 600,000 freshmen who lived in dormitories, and of all freshmen enrolled in United States' colleges, regardless of housing status. "Prevention and Control of Meningococcal Disease," *MMWR* 54(RR07); 1-21, 11 (May 27, 2005) (hereinafter referred to as "Prevention and Control (2005)"), retrieved from <http://www.cdc.gov/mmwr/pdf/rr/rr5407.pdf> (accessed August 6, 2016). The analysis assumed that the vaccine benefit would last 4 years. *Id.* In the analysis, costs were varied: costs vaccine and administration (range \$54-\$88), costs per hospitalization (\$10,924 -- \$24,020), the value of premature death on the basis of lifetime productivity (\$1.3 million -\$4.8 million), the cost per case of vaccine side effects (\$7,000 -- \$24,540 per 1 million doses), the average long term costs of treating a case of sequelae of disease (\$1,298-\$14,000). The study also varied vaccine efficacy and coverage for evaluation purposes. *Id.* According to ACIP's analysis, the vaccination of freshmen living in dormitories would result in the administration of approximately 345,950-591,590 doses of vaccine each year, preventing from 16 to 30 cases of meningococcal disease, and one to three deaths each year. The analysis found that a cost of case prevented was an estimated \$617,000 to \$1.85 million, at a cost per death prevented of \$6.8 to \$20.4 million and a cost per life-year saved of \$62,042 to \$458,185. *Id.* (*citations omitted.*) Given this data, ACIP recommended, in 2005, that there be routine vaccination of children 11-12 years of age. ACIP also recommended that routine vaccination for certain persons with a risk of meningococcal disease, including, college freshmen living in dormitories. *Id.*

At that time, the Department adopted ACIP's recommendation for children 11-12 years of age, but did not include a second dose. *See* 40 Pa.B. 2747 (May 29, 2010). This cost analysis

remains relevant, and the Department has reconsidered its original decision, particularly given ACIP's 2015 recommendations and analyses regarding MCV.

With respect to the statement that the cost of preventing only 16 children from getting meningococcal disease is too great for the community to bear, the Department again disagrees with the commentators, and directs them to the comments of the National Meningitis Association, *supra*, at page 202.

The Department acknowledges that there are risks to all vaccines. The only adverse events relevant to this rulemaking, however, are those in relation to MCV and to pertussis, which are the two vaccines added. The Department notes that in either case, a physician who has concerns about giving a child either vaccine may provide the child with a medical exemption. With respect to meningitis, the Department notes that 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; *see also Control of Communicable Diseases*, at 359. The fatality rate had been 50%, but antibiotics, intensive care units, and improved supportive measures have decreased the fatality rate. *Control of Communicable Diseases, supra*, at 359. MCV is transmitted from human to human through direct contact, including respiratory droplets. *Id.* at 361. These are the same *types* of cost (i.e., health care costs, potential deaths, loss of income for parents) to the state and families that the commentators contend arise from the vaccine itself; 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 disagrees with the statement that meningitis vaccine potentially causes Guillain-Barre Syndrome (GBS). After reviewing safety studies, ACIP voted to remove the precaution for persons with a history of GBS, because the benefits of meningococcal vaccination outweigh the risk for recurrent GBS in those persons. “Prevention and Control (2013),” at 12. Since June 2010, however, no specific concerns have been raised about GBS in persons who have a history of that condition and who have been vaccinated with MCV. *Id.* at 13.

The Department has considered the costs, including the possibility of side effects, and notes that ACIP’s original analysis assigned a cost to possible adverse effects, and still recommended the vaccination. *See* “Prevention and Control (2005),” at 12. In its most recent recommendation, ACIP has outlined the potential side effects as follows:

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, and 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.

The Department notes that there is a choice regarding costs, the choice of getting the vaccination, and potentially having a side effect of the magnitude referenced by commentators, or potentially 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 takes the recommendations of ACIP and its own staff seriously, and believes the risks are greater than if the vaccine is not required.

The Department notes that the General Assembly of this Commonwealth has already balanced that risk with regard to students living in high risk situations in college. The General Assembly considered the disease enough of a concern for college students, living in close proximity, and presumably sharing cups, toothbrushes and other items, to require that all institutions of higher education prohibit a student from residing in a dormitory or housing unit unless the student has been vaccinated against meningococcal disease. 35 P.S. §§ 633.1 *et seq.*¹⁰ The cost to obtaining the vaccine is covered, either by insurance or by the VFC Program, and is already factored into the costs of both. A parent may still, however, take the position that the risk of the vaccine is too great for their child. In that case, the exemption process is still in place.

The PACIC and multiple commentators stated that the disease is very rare. Two commentators cited Robert F. Kennedy, Jr., as stating that meningitis was a rare disease that affected only 390 people nationally last year. Another commentator stated that with only 30% of new cases being caused by the B strain, the conversation is about preventing only about 100 cases nationwide each year. Another commentator cited Kennedy as stating that the package inserts of Menactra and Menveo¹¹ produce serious adverse events in 1 percent of recipients. Multiple commentators stated that the FDA and industry testing show that the vaccine is unusually low efficacy and high risk. Several commentators, including the PACIC, stated that meningococcal bacteria become invasive only rarely, stating that “In a small proportion (less than 1%) of colonized persons, the organism penetrates the mucosal cells and enters the bloodstream.” Multiple commentators,

¹⁰ The law does provide for religious and medical exemptions. *Id.* at § 633.3(b).

¹¹ These are brand names of meningococcal vaccines.

including the PACIC, cited the CDC as giving the incidence rate as 0.3-0.5/100,000. Multiple commentators cited the CDC Pink Book as saying that these bacteria become invasive only rarely. The PACIC commented that it is difficult to develop the disease, because you must be susceptible, and you must have regular close personal contact, such as sharing a toothbrush or kissing a person who is colonizing meningococcal organisms.

One commentator stated that the CDC's website says that the disease is extremely rare, and that death happens to an even smaller percent of persons that are colonized with the bacteria. The commentator stated that all vaccines come with risk, and the risk of injecting all teens with yet another vaccine with a lot of risk for a disease they will not get is unfair.

One commentator stated that the vaccine is superfluous and that communicability is rare and that there are about 3000 cases in the United States annually. The commentator stated that this would be costly for 12th graders, and cost money through additional staff hours for paperwork and follow-ups.

Several commentators cited the CDC as stating that all serogroups of this disease are on the decline. Several commentators noted that Serogroup B, not included in the vaccine, declined along with the serogroups included in the vaccine for unknown reasons. These commentators cited the CDC as saying that the communicability of *Neisseria meningitidis* is generally limited. "In studies of households in which a case of meningococcal disease has occurred, only 3%-4% of households had secondary cases." Furthermore, "in the United States, meningococcal outbreaks account for less than 2% of reported cases (98% of cases are sporadic)." Therefore, according to

these commentators, transmission in the school setting is very unlikely. One commentator opposed any change to the immunization regulations, but particularly an additional dose of MCV in the 12th grade.

The Department disagrees with the commentators, and has not changed the regulation in response to the comments. Although a case of meningitis is rare, a single case of meningitis has a 10% risk of death and a high risk of long term disability (deafness, limb loss, intellectual impairment). The disease is misleading, and may at first appear to be something less serious. The initial symptoms are similar to those caused by influenza -- fever, intense headache, nausea, vomiting stiff neck and sensitivity to light. The onset is very fast, and serious symptoms develop quickly – the most severe form of infection includes petechial rash (caused by subcutaneous hemorrhage), hypotension, disseminated intravascular coagulation and multiple organ failure. *Control of Communicable Disease*, at 359. The case fatality rate had exceeded 50%, however, antibiotics, intensive care units and improved supportive measures have allowed more people to survive. *Id.*

Further, for each case, all close contacts require antibiotic prophylaxis, which creates a substantial effort, and cost, for the public health community. Four cases have been seen at Penn State University since 2008. In one case, no additional public health intervention was required, but in a case in 2009, the student was hospitalized in serious condition, and all fraternity members of the fraternity where he lived were advised to seek treatment. Forty did so. See <http://news.psu.edu/tag/meningitis> (accessed August 12, 2016).

The Department recognizes that the MCV vaccine does have side effects, and that no vaccine is 100% safe. In making the decision to license a vaccine, the FDA takes into consideration and weighs potential side effects and deaths in determining whether the vaccine is in fact safe for use. The FDA has licensed MCV because it has determined that the risks to contracting meningitis far outweigh the risks from the vaccine. ACIP has recommended it for that reason. Further, during 2009-2010, when routine vaccine use was recommended and supply of the vaccine sufficient, the CDC suggests that the decline seen in two serogroups, C and Y among adolescents aged 11 to 18 years suggested an impact of vaccination on adolescent disease. “Prevention and Control (2013),” at 5.

Further, studies of cost-effectiveness of the first dose of MCV, performed by groups other than ACIP, determined that routine vaccination of United States adolescents would prevent 270 meningococcal cases and 36 deaths in the vaccinated cohort over 22 years, which is 46% in the expected burden of disease. Shephard, Ortega-Sanchez, Scott, Rosenstein, “Cost-Effectiveness of Conjugate Meningococcal Vaccination Strategies in the United States,” *Pediatrics*, Vol. 115(5): 1220-1232 (May, 2005) at 1225.

Again, those parents who have lost children to meningitis, or have had their children severely disabled because the vaccine was not available or they were not aware of the vaccine feel as strongly that the vaccine should be required. See Preamble at page 202, *supra*.

The Department, reviewing ACIP recommendations, and relying upon the cost-benefit analysis done over both doses of the vaccine, has determined that the risks outweigh the benefits, and that for a child to die from a preventable illness is unconscionable.

The PACIC and another commentator stated that the meningitis vaccines contain neurotoxins such as formaldehyde, aluminum hydroxide, polysorbate 80 and thimerosal in multidose vials, among others.

The Department has addressed comments relating to vaccine additives in this Preamble at pages 43-44, and 126-130, *supra*.

The PACIC stated that VAERS, which includes only a small fraction of the health problems that occur after vaccination in the United States, reports 1,799 severe adverse effects resulting from meningococcal vaccine, which only began to be used in 2005. The PACIC stated that when Haemophilus influenzae type b (Hib) vaccine is included, the number jumps to 62,676. The PACIC stated that there are more than 2000 serious health problems, hospitalizations and injuries reported following meningococcal shots, including 33 deaths, with half the deaths occurring in children under six years of age.

The Department disagrees with the commentator. These numbers are not accurate for the vaccine that the Department is requiring. The Department is not requiring the Hib vaccine. The Department is requiring MCV for children in the 12th grade. Children under six years of age do

not receive the same meningococcal vaccine as children entering 12th grade. The Department is not requiring meningococcal vaccine for school entry.

One commentator provided several studies on efficacy, adverse events and conflicts of interest, pointing out that vaccine companies had provided financial support and employment to some of the researchers, that there were adverse effects noted in the studies that caused some participants to drop out, that there was evidence that immunity waned after five years, that cost effectiveness in a vaccine used for meningitis B was not as impressive as it had appeared pre-licensure, that the MMR vaccine caused measles inclusion body encephalitis, and six other vaccines, including one for meningitis caused syncope (fainting) and frozen shoulder, and that there was a possibility of Henoch-Schonlein Purpura.

The Department disagrees with the commentators and has not changed the regulation. The Department has relied upon the opinion of ACIP, which is made up of experts in the fields of immunization practices and public health, use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, clinical or laboratory vaccine research, assessment of vaccine efficacy and safety, consumer perspectives and/or social and community aspects of immunization programs.

The Department, with the approval of the Advisory Health Board, following ACIP recommendations, is of the opinion that the vaccine will save the lives of children, and that the cost effectiveness of the vaccine has been reviewed and the vaccine is determined to be cost

effective. In any case, raising the cost of the vaccine is misleading. The Department has discussed this more fully, *supra*.

Comments relating to vaccine “kick-backs”

Several commentators stated that this sounded like an income driven mandate, and that someone would make a lot of money with this single vaccine in Pennsylvania. One commentator stated that this was a game of profit for vaccine manufacturers and those who accept their money in government and health departments.

The Department will not receive money from the addition of this requirement.

Comments relating to reporting and paperwork requirements

Several commentators stated that adding MCV in the 12th grade will add a third reporting requirement, placing a burden on schools, adding more staff hours, paperwork regarding provisional timelines, filing of waivers, and individual follow ups.

The Department disagrees with the commentators. The addition of MCV into the 12th grade does not add any additional reporting requirements for schools. Schools are required to report on children in kindergarten and in the 7th grade, because those are the requirements on the Department’s reporting form. *See* 28 Pa. Code § 23.86(f)(2)-(7). There will be no additional reporting requirements for the 12th grade dose of MCV.

The additional 12th grade vaccine dose will require schools to conduct the same type of review prior to the start of school for compliance, and the same type of follow-up after the 5-day provisional period as is required for any child who fails to obtain any required vaccination under these amendments. The Department has extended the time period for implementation of the regulations and expects Final Rulemaking to be published early in 2017, so that schools, school nurses, parents and guardians will have nearly six months to obtain this required immunization for children entering 12th grade in the fall of 2017. This vaccine is not required for the entire student population, but only for those students entering 12th grade in the fall of 2017. The number of students in 12th grade in 2015-2016 was 146,320. The Department is hopeful that the five to six month period prior to the implementation of this requirement, and the outreach the Department intends to do will significantly reduce the numbers of students who will need to obtain a second dose of MCV at the beginning of the 2017-2018 school year.

Comments relating to college attendance

One commentator stated that MCV is already required by many colleges, and so students would be receiving the vaccine in a year or so already without adding a requirement to the public school schedule. The commentator stated that most cases of meningitis are sporadic and do not cause outbreaks.

One commentator stated that she disagreed strongly with this requirement because students who choose to go to college are not required to get a meningitis vaccine or can file for an exception.

One commentator stated that the MCV regulation was not required until a child went to college.

One commentator stated that it was ludicrous to add a vaccination to every high school student

with a reasoning that it is good for them for entering college, which they are not doing yet. The commentator stated that it should be a college requirement.

The Department has not changed the regulation to eliminate the requirement. The Department did not add the requirement to the regulation to ensure a child's admittance to college, but to protect that child and other children to the greatest extent possible from a very serious illness, that can result in death. In adding the requirement, the Department is following ACIP's recommendation, adopted by both AAP and AAFP, to ensure that the child receives the vaccination at the appropriate time in order to boost the child's immune system, and provide immunity when the child does enter college at a later date.

In fact, by law, children are required to have MCV vaccination before they may live in a college dormitory. 35 P.S. § 633.1 through § 633.3. It is partly in preparation of this requirement that the Department has added the 12th grade requirement to these regulations. The Department added one dose of MCV for entry into the 7th grade in 2011. ACIP now recommends an additional dose to ensure immunity. "Prevention and Control (2013)," at 12. Failure to receive this dose in a timely manner could result in a student being excluded from dormitories, and could thus result in additional cost to parents and students attending college.

With respect to the comment regarding the sporadic nature of the disease, while that is true, as the Department has stated, a single case of meningitis has a ten percent risk of death and a high risk of long term disability (deafness, limb loss, intellectual impairment). The Department has discussed this, *supra*. Further, for each case of meningitis, the public health response is intensive

and expensive. Health departments must locate all close contacts, by contact tracing methods, and then all close contacts require antibiotic prophylaxis, which is a substantial public health effort.

Legislative action to require 12th grade dose

Multiple commentators, including the PACIC, noted that the legislature was considering a bill to require MCV for children entering 12th grade, but the bill did not pass. Therefore, according to the PACIC and these commentators, the Department is seeking to circumvent the legislative process.

One commentator said the Department's continuing in this regard after the legislature refused to entertain the bill seems both unethical at best, and at worst, motivated by something other than care for these precious young people on the brink of their adult future, and begged the Department to reject the pressure from vaccine manufacturers with billions of dollars at stake.

The Department disagrees with the commentators' statement that it is circumventing the legislative process by adding MCV to the list of required immunizations through regulation. The Department also disagrees that it is acting unethically, or is motivated by money promised by vaccine manufacturers. The commentators should note that, as part of the regulatory process in the Commonwealth, the Department is required to serve its regulations on Standing Committees in both the House and the Senate, and those committees have the ability to review and approve or disapprove the Department's regulations.

In addition, the legislature gave to the Department the authority to determine against which diseases, infections and conditions a child must be immunized before entering or attending school. Generally, the Disease Prevention and Control Law of 1955 (35 P.S. § 521.1 *et seq.*) (Act) provides the Advisory Health Board (Board) with the authority to issue rules and regulations on a variety of matters relating to communicable and non-communicable diseases, including what control measures are to be taken with respect to which diseases, provisions for the enforcement of control measures, requirements concerning immunization and vaccination of persons and animals, and requirements for the prevention and control of disease in public and private schools. (35 P.S. § 521.16(a)). Section 16(b) of the Act (35 P.S. § 521.16(b)) gives the Secretary of Health (Secretary) the authority to review existing regulations and make recommendations to the Board for changes the Secretary considers to be desirable.

The Department also finds general authority for the promulgation of its regulations in the Administrative Code of 1929 (71 P.S. § 51 *et seq.*) Section 2102(g) of the Administrative Code (71 P.S. § 532(g)) gives the Department this general authority. Section 2111(b) of the Administrative Code of 1949 (71 P.S. § 541(b)) provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of the Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department.

The Department's specific authority for promulgating regulations relating to school immunizations is found in the Administrative Code and in the Public School Code of 1949 (24

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

Section 1303a of the Public School Code (24 P.S. § 13-1303a) provides that the Board will make and review a list of diseases against which children must be immunized, as the Secretary may direct, before being admitted to school for the first time. The section provides that the school directors, superintendents, principals, or other persons in charge of any public, private, parochial, or other school including kindergarten, must ascertain whether the immunization has occurred, and certificates of immunization will be issued in accordance with rules and regulations promulgated by the Secretary with the sanction and advice of the Board. Merely because the legislature may itself, from time to time, attempt to legislate in the area of public health does not mean it in any way has diminished the Department's authority to promulgate regulations pursuant to legitimately delegated authority.

Comments regarding the National Childhood Vaccine Injury Act and Program

Multiple commentators stated that persons injured because of the vaccine will not be able to sue the manufacturer for damages, because the manufacturer is protected by the National Childhood Vaccine Injury Act, which grants liability protection to manufacturers. These commentators state that the Act partially shields companies selling vaccines in the United States from civil

liability, and in 2011, the United States Supreme Court completely shielded vaccine manufacturers from liability for FDA-licensed and CDC-recommended vaccines in 2011.

According to the commentators, there is no product liability or accountability for pharmaceutical companies marketing federally recommended and state mandated vaccines that injure Americans or cause their death, which makes flexible medical and non-medical vaccine exemptions in vaccine policies and laws the only way Americans can protect themselves and their children from vaccine risks and failures. One commentator stated that in this program, records are sealed and there is no discovery, so that the true extent of acknowledged vaccine injuries is hidden from the public.

One commentator stated that until vaccine manufacturers are held accountable for the vaccines they produce, just like the drugs they produce, we should not be continuing to add vaccines to the schedule. The commentator stated that there are over 300 vaccines in the works right now, and children already receive 30 vaccines by the time they are six years of age.

Several commentators stated that both MCV and Tdap carry risks of injury or death. The commentators stated that Congress passed the National Childhood Vaccine Injury Act in recognition of this fact. The commentators stated that the federal vaccine injury compensation program has awarded more than 3.2 billion dollars to children, adults and families injured by vaccines. One commentator states that it is 3.3 billion dollars, and this with the majority of claims being denied in the closed, government run process. According to the commentators, two out of three persons are denied compensation

One commentator took issue with the Department's failure to reference the National Childhood Vaccine Injury Act in Section 9 of the RAF to Proposed Rulemaking, which asks for any relevant federal or state court decisions that impact upon the proposed rulemaking. The commentator is of the opinion that the law, which created the Vaccine Court, is of great relevance, since it prevents Pennsylvania families from suing vaccine manufacturers if they are injured by a vaccine. The commentator stated that all decisions by the Vaccine Court is relevant to the regulations.

The Department disagrees with the commentators. Section 9 of the RAF asks, "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." In fact, there is no state or federal law, regulation or court order that has an impact on these regulations. 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.

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 purpose of the act was both to set up a route to compensation for persons injured by vaccines that would be less costly and difficult than typical tort litigation, and to encourage vaccine manufacturers to continue production and development of new vaccines.

Bruesewitz v. Wyeth, LLC, 562 U.S. 223, 226-227 (2011). Awards are paid out of a fund created by an excise tax on each vaccine dose. *Id.*

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 United States, 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) (2009 WL 331968), *slip op.* at 2, *affirmed*, *Cedillo v. Secretary of Health and Human Services*, 617 F.3d 1328 (Fed. Cir. 2010). The petitioner must also establish a causal link between the vaccine and the injury. *Slip op.* at 2. 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 Supreme Court of the United States has characterized this program as “a no-fault compensation program.” *Bruesewitz*, 562 U.S. at 223.

The existence of this Program does not, however, completely shield a vaccine manufacturer from liability as alleged by commentators. The commentators make this claim because in *Bruesewitz*, the United States Supreme Court stated that a vaccine manufacturer could not be held liable for a design-defect, and that the act expressly eliminated liability for a vaccine’s unavoidable, adverse side effects. *Id.* at 230. Commentators would like to prohibit all vaccines that are not 100% safe and effective. The United States Supreme Court, like the CDC, the AAP, the AAFP, the Department and the Advisory Health Board, recognized the importance of childhood vaccines, *id.* at 226, and the need for their use and development despite the fact that they cannot be made 100% safe. This does not mean that manufacturers are shielded from all liability. A petitioner under the act who is not satisfied with his or her award may reject it and seek tort relief from the vaccine manufacturer. *Id.* at 228. Further, a vaccine manufacturer who fail to comply with regulatory requirements (which include certain warning requirements to physicians or the petitioner), who commit fraud, who intentionally or wrongfully withhold information, or who engage in other criminal or illegal activity are not shielded from liability. *Id.* at 229.

With respect to the comment that 300 vaccines are currently “in the works right now,” and children already receive 30 vaccines by the time they are six years of age, the Department has no way of knowing how many vaccinations are in research and development. The Department has already addressed the fact that although ACIP may recommend many vaccinations, the

Department and the Advisory Health Board do not adopt all vaccinations for school entry and attendance.

The Department has discussed safety of the meningococcal conjugate vaccine, DTaP, combination vaccines, multiple doses of vaccines, the number of vaccines and the issues of the credibility of the CDC and the federal government elsewhere in this Preamble.

The PACIC and another commentator stated that at any given time, between 20% and 40% of the population are asymptotically colonizing meningococcal organisms in nasal passages and throats, which boosts innate immunity to invasive bacterial infection. The PACIC and the commentator stated that by the time American children enter adolescence, the vast majority have asymptotically developed immunity to meningitis.

The Department disagrees with the commentators. While somewhere around 10% of the population carries *Neisseria meningitidis* in their nasopharyngeal at any given time, carriage is transient and does not result long term immunity. In addition, there are multiple serogroups of the organism, with little cross-immunity. The strains that cause colonization may not be the same as those that cause invasive disease. *See Control of Communicable Diseases*, at 361.

The PACIC stated that the Department already mandates 25 doses of 12 vaccines. The PACIC stated that the meningococcal vaccine is available for those who would like to use it.

The Department requires ten vaccinations for school entry. If a child has a medical or religious exemption, however, he or she may attend school without those requirements. The Department agrees that the MCV vaccine is available for those who choose to use it, but after reviewing recommendations by ACIP, and noting that AAP and AAFP have adopted ACIP's recommendations, the Department, with the approval of the Advisory Health Board is requiring this immunization for entry into the 12th grade.

Application of 12th grade MCV requirements

Several commentators questioned how the requirements for the 12th grade MCV would apply. One commentator asked the Department to revise the language relating to the meningitis vaccine to make the requirements more clear. IRRC also asked that the Department clarify whether the requirements apply only to those students entering kindergarten, 7th and 12th grades, whether they apply retroactively to all current students, and how they apply to students moving into new school districts. IRRC also asked that the Department clarify whether a third dose would be required for students who get MCV after 7th grade but before the child's 16th birthday.

Two commentators asked if a student going into the 12th grade would be required to have a second dose of MCV unless the student had received a dose of MCV on or after the student's 16th birthday. The commentators asked how this would affect a child in the 8th through 11th grades who does not have proof of even one MCV vaccine. The commentators asked whether the child would be required upon entry into any of those grades to get the first dose of MCV, and should they be excluded.

One commentator stated that school nurses had been asking for MCV to be required not just for entry into 7th grade, but for students in 7th grade and in every grade thereafter until graduation. Therefore, to have a second dose before 12th grade is really requiring two doses before entry into 12th grade.

Two commentators recommended that the Department change the regulation to require all children from grades 7 through 12 to receive the Tdap vaccine. One commentator recommended that this include both students transferring from outside the Commonwealth as well as homeschooled students.

One commentator asked whether, if a child had a MCV shot for entry into the 7th grade, and one at 16 years of age, whether an additional shot would be required upon entry into 12th grade.

The Department has revised the regulation to add language clarifying its intent. The language provides that, if a child does not have MCV or Tdap upon entry into the 7th grade, a child may be excluded in the 7th grade and in each succeeding school year that the child fails to obtain the required immunization. *See* subsection (c)(1)(iii). The Department has discussed the requirements in relation to Tdap and MCV in 7th grade, starting at page 191 of this Preamble, *supra*. With respect to MCV, because ACIP recommends a single dose for a child who has not received a previous dose on or after the 16th birthday, as commentators have noted, the Department has added language to subsection (c)(2) to make it clear that a dose of MCV received at the age of 16 years or older is to be counted as the 12th grade dose. *See* subsection

23.83(c)(2). There is no ACIP recommendation for a third MCV dose, and the Department's regulations do not contemplate a third dose.

IRRC asked how the amendments would apply to children entering kindergarten and whether they apply retroactively. The regulations apply to all students throughout their school careers, although the Department would not use of the term, "retroactively." The Department's regulations do not state that specific vaccines are required only upon *entry* to kindergarten, and that the immunizations required are "once and done." The Department's regulations require that certain immunizations be obtained for *school attendance*, not simply for school entry. See § 23.83(a)(relating to school attendance). The Department made this change to the regulations several years ago, to take into account and to emphasize the fact that immunizations were not just required when the child enters school for the first time, but throughout the child's attendance at school. If a child reaches the 6th grade, for example, without being excluded for not having the required polio immunizations, the child may still be excluded at any time during the 6th grade, since the immunization is required for attendance. Thus, a child may be excluded during any school year in which the child lacks the required immunizations and neither fits within a waiver nor has an exemption.

Further, the Department has added language to § 23.83(c) (relating to special requirements for tetanus and diphtheria toxoids and acellular pertussis vaccine and meningococcal conjugate vaccine (MCV)) to clarify that a child who does not have an exemption as permitted by § 23.84 and who does not receive the immunizations as required in § 23.83(c)(1)(i) and (ii) may be

excluded in that school year and each succeeding school year that the child fails to obtain the required immunization. *See* § 23.83(c)(1)(iii).

One commentator asked whether a child who had not previously received a dose of MCV before the child turned 16 years of age would fall within the exclusionary period relating to single dose vaccines. She stated that if that was the case, many seniors would be “one-dose” candidates, which could lead to exclusion on day one of school. She stated that school nurses and schools would need adequate preparation.

The Department does consider the meningitis conjugate vaccine to be a multiple dose series.

The Department agrees that adequate time for preparation and informing students and parents is necessary to avoid unnecessary exclusions, particularly in the senior year. In order to provide sufficient time for adequate preparation by parents, guardians, health care practitioners, schools and school nurses, the Department has altered the time frame for implementation of these regulations to the 2017-2018 school year. This will provide schools and school staff adequate time to provide information to parents and guardians and their children. The change in the time frame will also allow the Department adequate time to provide guidance to schools, school nurses and health care practitioners regarding these requirements.

Two commentators asked why the Department did not require MCV in the 11th grade, at which time a child is required to have a physical, rather than on entry into the 12th grade. One of these commentators stated that this would be more cost effective to the parents, because this would require only one trip to the doctor.

The Department has not changed the regulation. The Department is requiring that the child have the vaccine upon entry into the 12th grade. *See* subsection (c)(2). If the child gets the vaccine at the 11th grade physical and the child is 16 years of age or older, the immunization would be considered valid for the requirement that the child have the immunization upon entry into the 12th grade. *See* subsection (c)(2) (“A dose of MCV received at the age of 16 years or older shall count as the 12th grade dose”).

One commentator asked when it would be required that 12th grade students have the second dose of MCV, and whether it would be required for all students at that age level.

The requirement for MCV is for all students at entry into 12th grade, or in an ungraded class, for students in the school year that the student is 18 years of age. *See* subsection (c)(2). This is the case unless the child has a medical or religious/philosophical exemption, or if some other waiver is in place as contemplated by the regulations. *See* § 23.85(g) (relating to applicability). This requirement will be effective August 1, 2017, but it is the Department’s intention to have the Final Rulemaking published by March of 2017, allowing for five to six months’ notice to parents, guardians and schools.

IRRC asked that the Department clarify what would happen if a child came from out of state without the first dose of MCV. One commentator asked the Department to clarify what would happen if a child moved from another state into Commonwealth schools in grades 9 through 11 without a meningitis vaccination. The commentator asked whether the child would be excluded until one meningitis vaccination was obtained. Another commentator asked if a child was not in

the Commonwealth for 7th grade and missed the first dose, would the vaccine now be considered to be a two series vaccine.

The Department has revised the regulation to clarify this issue. The Department considers the MCV vaccine to be a two dose series, now that a second dose will be required for entry into the 12th grade. *See* § 23.83(c)(2). The fact that a child is not in the Commonwealth for the first dose does not have a bearing on the question of whether or not the vaccination is a one or two dose vaccination. There are other provisions that cover what action to take regarding a child who comes into the Commonwealth without a 7th grade dose of MCV, however, and what would happen in succeeding years if child continued to remain unvaccinated. The rulemaking provides that a child who moves into the Commonwealth has a 30-day period to obtain records of immunizations. *See* § 23.85(g)(2) (relating to applicability). If the child moves into the Commonwealth after grade 7 with no record of a Tdap or an MCV dose, or without records of a required immunization, the child may be excluded at the end of that 30-day period, until the requirements of the subchapter are met. This exclusion may continue into subsequent school years. The Department has added language to § 23.85(g)(2) to clarify that fact. *See also* Preamble, *supra*, at page 197. These regulations apply to children transferring into a school from outside the Commonwealth unless one of the provisions of § 23.85(g) (relating to applicability) applies. As a point of clarification, the rulemaking does apply to children being homeschooled, and has done so prior to this rulemaking, as the definition of a “school,” has not been changed, and includes home education programs. *See* § 23.83(a) (relating to immunization requirements).

As the Department has noted, MCV is a two dose series; there is no third dose recommended by ACIP, or required by the Department.

§ 23.85. Responsibilities of schools and school administrators.

Subsection (e). Provisional admittance to school.

Paragraph (1). Multiple dose vaccine series – Provisional Period.

The Department received many comments on its decision to change the 8-month provisional period to a requirement that a child have all single dose vaccines on the first day of the school year, and the most up-to-date dose of a multiple dose vaccination series within five days of the start of school, along with a signed medical certificate providing dates for the remaining required doses. Many of the comments received were from school nurses. Some commentators spoke up in support of the change, some disagreed with the change and recommended other time frames, and some disagreed with the 5-day time frame but did not offer any recommendations. Some commentators expressed concern with the time frame for implementation expected by the Department, which was for the regulations to be effective for the 2016-2017 school year.

IRRC noted that commentators generally supported the proposal, but that those commentators felt that the length of time was not feasible for school nurses or parents, and that it might put a child who needed multiple vaccines at risk. IRRC asked the Department to explain the reasonableness of the timeframe and how it adequately protects the public's health.

In the following paragraphs, the Department will explain its rationale for the 5-day provisional period within which children are expected to become vaccinated in order to enter and attend

school. The Department will then detail the specific comments received, as well as the different timeframes proposed by commentators but without reiterating its rationale each time a comment relates to the 5-day period.

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, 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, and 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, *see* section 2102(a) of The Administrative Code of 1929 (71 P. S. § 532(a)), the Department has decided to keep the 5-day period set out in the proposed rulemaking for a number of reasons.

A key reason for the 5-day period is to achieve "herd" or community immunity as quickly as possible. The Department has discussed the concept of herd or community immunity at length in the section titled "Comments regarding "herd" or community immunity, vaccine effectiveness and natural immunity" at pages 69-78 of this Preamble, *supra*, and will not repeat it here.

The Department notes that the regulations will be effective on August 1, 2017. The Department expects, however, to publish the Final Rulemaking in time for school registration by March of 2017 for the 2017-2018 school year to enable schools to provide information to parents and guardians regarding the changes to the regulation. The Department 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.

In addition, as a number of commentators pointed out, too lengthy a provisional period requires school nurses to send multiple written notices and make multiple phone calls to parents to attempt to gather all necessary immunization information.

Finally regarding the 5-day period, and contrary to some commentators' assumptions, neither the Department nor the regulation requires a child to obtain all immunizations at the same time on the same date or within the 5-day period. The Department's intention is not to require a child to obtain all required immunizations at the same time on the same date. 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. To the extent there are no grounds for either a medical or religious/philosophical exemption, the Department presumes that parents and guardians are acting responsibly, on the medical advice of their primary care practitioners and are giving their children vaccinations on schedule. 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, CRNP, or 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 in the medical certificate. This should allow for the child to receive vaccinations in a safe and medically appropriate way according to the child's health care practitioner.

Regarding commentators' concerns that multiple vaccines put children at risk, the Department disagrees. The Department has addressed those comments throughout this Preamble where raised in connection with other parts of the Rulemaking. A number of studies have been conducted to examine the effects of giving various combinations of vaccines simultaneously. In fact, neither ACIP nor AAP would recommend the simultaneous administration of any vaccines until these studies showed the combinations to be both safe and effective. These studies have shown that the recommended vaccines are as effective in combination as they are individually, and that these combinations carry no greater risk for adverse side effects. Consequently, both the ACIP and AAP recommend simultaneous administration of all routine childhood vaccines when appropriate.

The Department has discussed combination vaccines in more detail on pages 135-138 of this Preamble, *supra*.

One commentator stated that the commentator was not in favor of the proposed 8-month provisional period. The commentator stated that this would extend noncompliance from one school year to another. The commentator recommended that the Department implement a mass immunization model similar to ones carried out in the 1950s and 1960s. The commentator recommended utilizing school nurses to provide in-school team health screenings, and get the nursing staff more intimately involved with the student population, including discussions of subjects like hand hygiene to decrease the spread of disease. The commentator suggested that the mass immunization administration program could be designated as a revenue enhancement through allocated funding to the schools in support of improved health outcomes as demonstrated by decreased school absenteeism, and possibly improved academic scores.

The Department agrees that the 8-month provisional period is too long, and potentially harmful to students and the public. This concern is what led to the Department's determination to reduce that 8-month period to five days for multidose vaccines along with a medical certificate for remaining doses, and to immediate possibility of exclusion for single dose vaccines. While the Department appreciates the recommendations regarding mass immunization clinics and increased school nurse involvement in the student population, unlike the 1950s and 1960s, vaccines received by the Department through its federal immunization grant are reserved by the terms of that grant for a limited area of the population. Schools are able to utilize this vaccine in catch up programs for that population, but it is not available to the general public as it once was. Recommendations regarding the best use of school nurses and school health programs are beyond the scope of this particular regulation.

One commentator stated that the time period difference in the provisional period between single dose and multiple dose immunizations was a great idea.

The Department appreciates the commentator's support.

Several commentators recommended that all students beginning school in Pennsylvania have their immunizations before school starts. One of these commentators said that the process is extremely long, and involves many telephone calls and letters to get immunizations updated. The commentator complained that many times addresses and telephone numbers are incorrect, or messages cannot be left because of phone issues. The commentator said that it was very hard to get people to understand the process, even using the language line, because every school does immunizations differently.

The Department appreciates that school nurses work very hard to ensure that the children under their care have the appropriate immunizations. The Department acknowledges the difficulties a language barrier must make. The Department points out that while the Department has authority to list the diseases against which a child must be immunized, the Department does not have the authority to dictate the manner in which a school chooses to inform parents, guardians and students of those requirements. So long as the requirements are implemented, the Department cannot require schools to act uniformly in implementing them.

One commentator identified himself as an assistant principal, and stated that he strongly supported any effort that requires students to be immunized in order to attend school. He stated

that he believed in protecting individuals who could not be immunized by immunizing those who can be.

The Department appreciates the commentator's support.

Several commentators supported the Department's decision to change the 8-month provisional period, which they felt to be a logistical nightmare for school nurses due to letters and phone calls to parents who do not follow through with the required immunizations. One of these commentators stated that as a public health nurse, and having lived in states with no exemptions except for immediate homelessness and medical reasons, she strongly supported the Department's regulation. She stated that a child should not be allowed to enter school without adequate immunizations.

The Department appreciates the commentators' support. The Department believes that allowing a child to continue in school with a medical certificate adequately balances the need for up-to-date immunizations for protection of the child and others along with the importance of a child's education.

One commentator stated that she was in support of the changes to the regulations, but that she was concerned about the increase in clerical time for the school nurses who will need to review the immunization records before the first day of school. Without a provisional period, the time needed to do this review would be increased. The commentator also noted the need for publicity,

and mentioned that some small Christian schools have low vaccination rates, so that the regulatory change will be a big adjustment for them.

The Department appreciates the support of the commentator, but points out that the provisional period is not being eliminated, but is being reduced. The immunization requirements have not changed in the past five years -- the Department has added one entirely new immunization requirement in this rulemaking, MCV in the 12th grade. 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 component in their vaccination. As is borne out by the Department's school immunization law reports (SILR), the majority of students do have up-to-date vaccinations. The Department's hope is that the tightening of requirements will ensure that those parents, guardians and students who simply wait to get immunizations until the last minute will be encouraged to meet those requirements sooner, with less ensuing paperwork and follow-up for school nurses.

The Department agrees that there is a need for education and outreach on these regulations, and intends to do both with schools, school nurses, health care practitioners and parents and guardians. The Department will ensure that the regulations are published prior to kindergarten registration in March of 2017, which should provide ample time for information to be given to parents. The Department has already presented the regulations to the State Board of Medicine and intends to continue outreach efforts to health care practitioners on this subject. Finally, with respect to small religious schools, to the extent there is a need, the statutory religious exemption

is still in place and may be used, but the Department will ensure that information regarding the change in the requirements is provided to them as well.

One commentator suggested that children not be permitted to start school until they had received the necessary vaccinations, or they received the first dose of a vaccine series, and then the certificates be reviewed every 30 days.

The Department has not changed the regulation, because this is, in part, what the rulemaking requires. The amendments require a child to have the single dose vaccinations at school entry or face exclusion, although it should be noted that the only single dose vaccine required at the present time is Tdap. In the case of a multidose 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, CRNP or 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. The Rulemaking requires the schedule of immunizations set out in the medical certificate to be reviewed every 30 days for compliance.

One commentator stated that all children should have immunizations before attending school, and that there should be no grace period, however, the 5-day grace period is unrealistic due to the heavy amount of work expected of school nurses at the start of school. According to the commentator, school nurses should be required to come in over the summer to check immunizations.

The Department has not changed the regulation. The Department cannot require school nurses to work over the summer because the Department has no authority over school nurse schedules.

The Department has addressed the commentator's other concerns regarding the appropriateness of the 5-day provisional period starting on page 238 of the Preamble, *supra*; see also discussion starting on pages 256 and 261 of the Preamble, *infra*.

Two commentators noted that it was difficult to have kindergarten students immunized by the start of the school year because many of the children do not have their 5-year checkups until after the start of the school year. These commentators suggested that it be made standard practice that the 4th and 5th dose of DPT, the 3rd and 4th dose of polio, and the 2nd MMR/V vaccinations be given at the 4 year checkup and not at the 5 year checkup. Since, according to these commentators, all children are 4 when they enter kindergarten, this would eliminate many of those children whose insurance does not cover a well visit until 1 year after the 4 year checkup.

The Department has not changed the regulation. The Department notes that the requirement for a child to be immunized by the start of school has long antedated this amendment to the

regulations. The Department cannot dictate how the child's health care practitioner chooses to provide vaccinations to the child, but, as the Department follows ACIP guidelines with regard to setting the immunization requirements for school entry and attendance, the Department assumes that the health care practitioners act in a similar manner. If there is the need for a delay in a vaccination due to a health care practitioner's medical concern over whether or not a vaccination required for school should be given prior to school entry, a medical exemption is available.

Concerns with Implementation Timeline

Multiple commentators, including PSEA, PASA, PSBA and IRRC expressed concern about the regulations being effective for the 2016-2017 school year. Several commentators asked when the regulations would be effective and what the transition time would be. Both PSBA and PASA stated that school entities would not have time to develop policies, implement procedures, or communicate with parents or guardians about the new regulations. PSBA raised concerns about ensuring consistency with information given to current, transfer and newly-enrolled kindergarten students, and ensuring that the information is available in a format other than English for families with limited English proficiency. PSBA noted that this will be a particular issue for the 12th grade MCV requirement, since there are no vaccines currently required for entry into the 12th grade and students in that grade often postpone medical visits to prepare for any medical documentation and additional vaccinations required for college. PSEA stated that, from the perspective of the school nurse, it would be important for schools to develop processes to ensure that the 5-day time frame could be met within the framework of the responsibilities school nurses currently have to carry out during the first week of school. PSEA asked that policy makers

consider the challenges for implementation and barriers to compliance that would be presented should the regulations take effect at the start of the 2016-2017 school year. PSBA, PASA, PSEA and other commentators recommended making the regulations effective July 2017, or for the 2017-2018 school year. IRRC asked that the Department ensure that the effective date provides sufficient time for school entities to plan, implement policies and communicate with parents and guardians about the new requirements.

Several commentators stated that although they are proponents of immunizations, and agreed that children should be immunized to attend school, but stated that if the regulations were to be effective for the 2016-2017 school year, implementing them would be a difficult task for school nurses. School nurses do not work over the summer and collecting data and informing parents of the requirements would be difficult. School nurses would have to come in on their own time to send letters to parents, to make phone calls and to type up letters outlining the new regulations.

One commentator stated that many less students would be excluded from school if the regulations were not implemented until the 2017-2018 school year. This would allow an extra year for parents to learn about the new requirements, and would avoid them getting the information in the middle of the summer and right before children must start school.

After reviewing the comments to the regulation, the Department agrees with the commentators. The Department expects Final Rulemaking to be published in time for kindergarten registration for the 2017-2018 school year, that is, March of 2017, to enable schools to provide information to parents and guardians regarding the changes to the regulation, and to give parents of children

who have not yet attended school ample time to consult with the child's health care practitioner and obtain the necessary immunizations or exemptions. This should give schools time to develop policies, implement procedures or communicate with parents or guardians about the new regulations.

Two commentators asked whether the commentators should send notification to parents of the proposed immunization regulations before the end of the 2015-2016 school year, and whether a sample notice was available.

It was not the Department's intention that the proposed regulations be presented to parents and guardians of school-aged children before completion of the regulatory process, which allows for public comment and discussion. In order to avoid confusion, particularly in case a regulation changes or is not approved, the requirements must be published as Final Rulemaking before any official notice of new requirements may be provided to parents and guardians. Further, the Department does not intend to provide a sample notice. Communication with parents in this case should be left up to the individual school districts.

PSEA stated that reviewing immunization records and communicating with parents about the need for the second dosage within five days could be done but the change would need to go into effect with the establishment of clear systems and protocols to ensure implementation did not overwhelm parents, health care providers, school nurses and school administrators. PSEA stated that, from the perspective of the school nurse, it would be important for schools to develop processes to ensure that the 5-day time frame could be met within the framework of the

responsibilities school nurses currently have to carry out during the first week of school.

According to PSEA, for school nurses, that week is focused on collecting student emergency cards, writing student health plans, reviewing student paperwork for necessary medications, developing emergency plans for students with disabilities, life-threatening food allergies, asthma, and other things, and notifying teachers about student health needs.

The Department agrees with PSEA that it is important for schools to develop processes and communication strategies as it discusses. The Department also notes that, given the fact that the only new immunization added to the list of immunization requirements is MCV in the 12th grade, the number of children lacking all immunizations, or a good portion of those immunizations, should be limited, except in certain schools with low immunization rates. With the Department's decision to change the implementation date of the Final Rulemaking for school year 2017-2018, there will be sufficient time for schools and school nurses to develop processes for implementation, for schools and school nurses to provide information to parents and guardians regarding the changes to the regulation, and for the Department to conduct outreach to schools, school nurses, parents, guardians, and health care practitioners.

In Favor of a 5-Day Provisional Period

Several commentators agreed with the Department's regulation reducing the provisional period to five days. One of these commentators stated that the 8-month provisional was too long, and that this required school nurses to send multiple written notices and make multiple phone calls to attempt to gather all necessary immunization information. One of these commentators stated that

she sends a provisional letter in July of each year, sends a second letter the last week of August, allows 7th graders to start school, and then after the Labor Day Holiday, excludes children who are not up to date. The commentator stated that she sends home ten children on average every year, and the next day eight of the ten are compliant. The remaining two may miss three to four days of school, but they then get their immunizations.

Another commentator stated that although the change in the provisional period would require additional end of the year groundwork involving 6th graders, it would save an immense amount of time, paperwork and money in the future, including postage and paper.

One commentator stated that she was aware first hand of the amount of time and money is used dealing with vaccine preventable diseases and outbreaks.

One commentator stated that she had been a nurse for the past 45 years, and that if people have eight months to get appropriately vaccinated, they will take eight months, and if they have one day, they will get vaccinated in one day. She stated that if the Department required complete immunization on the first day of kindergarten it would get complete immunization.

Two commentators stated that they felt parents who do not immunize their children are a bit lazy. Both of these commentators stated that these parents feel no urgency to comply with the law. One commentator suggested if a child could not start school or there was a more realistic deadline to get the immunizations, parents might be more efficient about obtaining immunizations for their children. One commentator noted that parents often use the excuse that

vaccines might cause autism. This commentator stated she did not think education would help in this regard, because studies show parents do not understand the benefits of mass immunization, since they have not lived through epidemics of these preventable diseases. She commented that we need to create herd immunity for the benefit of those who cannot be vaccinated.

One commentator stated that most of these requirements are already in place in her school district, and that these regulations will merely shorten the time frame.

The Department appreciates the support of all of these commentators.

One commentator stated that she supported the 5-day provisional period only if a child may be excluded the day after the proposed second, third or fourth dose of a multidose vaccination is missed.

The Department appreciates the commentator's support. As the regulation is written, a child may be excluded if the second, third or fourth dose of a multidose vaccination is missed.

Opposed to a 5-Day Provisional Period.

Multiple commentators disapproved of a provisional period as short as five days, but did not offer any other recommendation.

Several commentators stated that a 5-day window period in which to allow parents to submit full immunizations, the next dose or a medical certificate was totally unrealistic, given the fact that that 5-day period was the busiest time within the school year.

Several commentators stated that the 5-day provisional period was not enough time to give a child all the vaccines needed, let alone multiple doses of the same vaccine. No one should be forced to give their child that many vaccines at once. One commentator stated that it was not healthy to cram the vaccination schedule into five days. One commentator stated that there are dangers to receiving too many vaccines too close together, and she would rather keep her child home from school than expose her to that danger. One commentator stated that a child could be ill with a viral illness, and requiring any vaccine, much less multiple vaccines, would add stress to the immune system and misery to the suffering child. The commentator also noted that children with generally fragile health would be extra-stressed by having so many vaccines administered within five days. Because the point of vaccines is to assure immunity to disease, it makes sense to maximize the success of each dose.

One commentator stated that the 5-day immunization catch-up window was insufficient. The commentator stated that she vaccinated her children on a delayed schedule, and did everything in her power to make sure they had all the legally required immunizations on time, but she was concerned that there was not consideration for parents who chose to space out vaccinations; instead, a large number of vaccinations might have to be given on the same day. She feels that harsher requirements like these will further isolate people like her, who are concerned about the safety of vaccines but still see their importance. She feels this is needlessly burdensome.

Another commentator stated that the 5-day period was too short because doctors give the shots over a period of months, not in a few days.

One commentator opposed removing the provisional period because requiring children to play catch-up when their bodies are not designed to handle an assault of toxins all at once is not in the best interests of the child or society. The commentator asked whether the Department would want to get all of these vaccines at once. The commentator stated that this is what would happen as parents and doctors raced to meet mandatory deadlines that have nothing to do with safety or health. It could and likely would be disastrous for many families with sick and injured children as a result.

Another commentator stated that, in her opinion, the vaccine industry had already managed to convince the CDC to schedule an unsafe amount of vaccines in just a few years in a child's life (49 vaccines by 6-years of age). The commentator stated that the shortening of any catch up time is just another way of putting children at risk. The commentator asked that the Department please not punish the children. The commentator stated that catching up on all vaccines in 5 days is actually criminal, because someone can seriously be hurt doing that. The commentator stated that all vaccines contain some of the following: carcinogens, neurotoxins, retroviruses and foreign, human, animal and insect proteins from a variety of different sources. The commentator stated that this overloaded the child's immune system with too much too fast and will most definitely cause some kind of disease process to begin. The commentator stated that a body needs time to manage and release all those toxins. The commentator asked that the Department

not decrease the provisional period. The commentator stated that a child should not be put at risk when it was not necessary to do so.

The Department has not changed the regulation based on the rationale it set out at the beginning of the section specifically related to § 23.85. The Department's intention is not to require a child to obtain all vaccinations at the same time on the same date. The Department believes that the number of children lacking all vaccines at school entry are minimal, and those children who have no or very few vaccinations have some type of medical exemption or religious/philosophical exemption. To the extent there are no grounds for an exemption, either medical or religious/philosophical, presumably parents and guardians are acting responsibly, taking the medical advice of their primary care practitioners and are giving their children vaccinations on schedule. If a child does lack immunizations upon school entry or for continued attendance, the child may enter school and attend school so long as the child has at least one dose of a multidose vaccine on the child's first day of attendance for that school year. 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, a CRNP or a PA. If the child is to receive the immunizations from the Department or a public health department, a public health official may sign the medical certificate. This allows for the child to receive vaccinations in a safe and medically appropriate way according to the child's

health care practitioner. A child must have the single dose of a single dose vaccine to enter school; however, there is only one single dose vaccine on the required list --Tdap.

Further, if a health care practitioner feels that the number or type of vaccines required for a particular child in order to meet the regulatory requirement is medically contraindicated, the child may also obtain a medical exemption. That exemption may be for a particular time period, or may exempt the child entirely from receiving a particular vaccine or vaccines. *See* § 23.84 (relating to exemption from immunization).

In addition, if a child is seriously ill at the time the child should be entering school, it seems unlikely that the child will be entering school, and the question of immunizations is moot or at least delayed until the child is well enough to start school. There is a medical exemption available for children in frail health whose medical providers determine should not have the vaccination, and the medical schedule allows the physician, CRNP or PA to set out an appropriate schedule for the immunizations to be completed.

In addition, the Department notes that there are no scientific studies showing that combination vaccines, or multiple vaccines at one time are harmful to children. In fact, neither ACIP nor the American Academy of Pediatrics (AAP) would recommend the simultaneous administration of any vaccines until these studies showed the combinations to be both safe and effective. Studies have shown that the recommended vaccines are as effective in combination as they are individually, and that these combinations carry no greater risk for adverse side effects. *See* Preamble, *supra*, at 135-138. Consequently, both the ACIP and AAP recommend simultaneous

administration of all routine childhood vaccines when appropriate. The Department has discussed these issues more fully elsewhere in this Preamble.

One commentator stated that the worst of the Department's changes would be to change the 8-month provisional to a 5-day provisional. She asked that the Department respect parental rights.

The Department understands that many commentators believe that the decision whether to vaccinate their children should be made by them alone, and that immunizations should not be mandated. The Department, however, is charged with protecting the health and safety of the citizens of this Commonwealth, and with choosing the most efficient and effective way of doing so. *See* section 2102(a) of The Administrative Code of 1929 (71 P. S. § 532(a)). After reviewing all the comments and its proposed rulemaking, the Department stands firm on its belief that the benefit of reducing and changing the provisional period outweighs risks and burdens. The Department notes that parents and guardians still have recourse to the statutorily provided medical and religious/philosophical exemptions, which are reflected in the Department's regulations at § 23.84 (relating to exemption from immunization).

One commentator asked what schools would do with children who receive live versions of vaccines. These children are contagious. The commentator asks whether schools will keep them separate from those who cannot receive vaccines, the "medically unable" who are mentioned in the proposal. The commentator states that this is hypocritical. Families should be allowed to retain their medical freedom and their choices, particularly those attending charter schools, those who are homeschooled and those in private institutions. The commentator asked who is

“medically unable?” Who makes that determination? Will all children be tested to make sure they aren’t going to have reactions before being injected? The commentator’s child was not tested before getting a round of vaccinations and ended up in the hospital for eight days. She stated that she has three different doctors telling her to skip vaccines but this may not be enough for proper “paperwork” or exemptions.

The Department disagrees with the commentator, and has not revised the regulations. There are several vaccines required for school entry that contain live virus, including varicella and MMR. A child who has received a live vaccine is rarely, if ever, contagious. Offit, at 88; *see also*, Pink Book, at 25. Transmission of measles and mumps vaccine viruses to household or other contacts has never been documented. Transmission of varicella virus has been reported very rarely. Pink Book, at 25. With respect to the commentator’s question regarding the Department’s reference to children who are medically unable to receive the vaccination, a child with a medical exemption is medically unable to receive a vaccination. One commentator stated that she has three doctors who have told her not to have her child vaccinated; the Department is certain that in that case one of them would sign a medical exemption. The Department has made no changes to the medical exemption language of the regulation, and cannot eliminate it, since it is required by law.

One commentator stated that a 5-day provisional period would be very difficult, and asked whether the Department had notified physicians of this change.

Several commentators stated that they are not paid by their school districts to come in before the beginning of the school year to go through records to determine a child's vaccination status and whether they should be excluded and to contact the family, and that they do not work over the summer. Contact numbers are not valid, and many families are away on holiday trips right before the start of school, making families difficult to reach. Many families move at this time and change school districts. The commentators stated that the amount of work involved in the first few days of school made it impossible to comply with a 5-day provisional period, particularly with respect to the 7th grade requirement for MCV and Tdap, and the 12th grade requirement for MCV.

One commentator stated that although the 8-month provisional period is too long, a 5-day provisional period would be too short. She stated that as of the date of her letter, she had 126 6th grade students who do not have the required immunizations needed for 7th grade. She stated that she has sent home notice explaining what was needed. She stated that she did the same thing last year, but started with 80 provisionally enrolled students.

Several commentators stated that high student-to-school-nurse ratios made it impossible to implement a 5-day provisional period. One commentator noted that school administrators are supportive of the work, but that they do not track students or learn the nuances of the immunization regulations. The commentator questioned whether they were willing to do so.

One commentator stated that five days was an unrealistic amount of time to police immunizations at the beginning of a school year.

One commentator stated that while school nurses are in agreement that the vaccine compliance rate in Pennsylvania needs to be increased to increase herd immunity, they do not see how they would be able to complete the new requirements on such short notice. According to the commentator, school nurses are so busy at the start of the school year gathering medications, organizing care plans, notifying teachers of health needs and developing emergency care plans that they cannot see clear at this time to organize a 5-day compliance/exclusion plan. One commentator noted that school administrations would need time to receive notification, understand the new requirements, and get notifications in place. More time would be needed to get the plan in place.

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.

In addition, as a number of commentators pointed out, too lengthy a provisional period requires school nurses to send multiple written notices and make multiple phone calls to parents to attempt to gather all necessary immunization information.

Several commentators asked the Department to add language to the regulations addressing paying certified school nurses for the time they would have to spend over the summer to check on the status of children's immunizations in order to have an accurate list of children to be excluded to the school administrator on the first day of school. If this were not in the regulations, one commentator stated that school nurses would be expected to come in on their own time, unlike school counselors who got paid to do so. Another commentator asked that the Department recommend school administrators adopt a plan for compensating school nurses for work done over the summer. One commentator asked that the Department encourage

administrators to provide school nurses paid days to come in before the start of school to review immunizations. The commentators stated that this was imperative if the school nurses were to be ready for exclusions and to provide assistance to families who genuinely wish to be immunized.

The Department has not changed the regulation. The Department has no authority to require payment for school nurses, or to recommend that school administrators allow for paid school days or adopt a plan for financial compensation. The Department would hope that school nurses receive the appropriate support necessary from their administrations to allow them to carry out their important job of taking care of the health of students.

One commentator stated that the 8 month period may be too long, but “5 days is just a shame.”

The Department has not changed the regulation based on the rationale it set out at the beginning of the section specifically related to § 23.85, and based on its discussion relating to herd and community immunity, in this Preamble at pages 69-78, *supra*.

One commentator stated that a child could not obtain a medical certificate within five days. The commentator stated that most of the students dealt with were from another state or country with no provider and no insurance. The local health bureau cannot accommodate a two to four week turn-around time now, and new patients will never get a private provider within five days.

One commentator stated that five days was definitely not enough time to interact with one’s health care provider or to create an immunization plan. The commentator noted that many

primary care physicians are not even open all days of the week. The commentator stated that it was difficult to schedule to see one's physician on a non-acute matter, and the health of some children warranted more than routine consideration when making an immunization decision.

The Department has not changed the regulation. The Final Rulemaking be published by March of 2017, in time for kindergarten registration, five or six months prior to the start of the 2017-2018 school year. The Department believes this is sufficient time to make schools and school staff aware of the changes, notify parents and guardians, and allow them to seek out a health care practitioner, if they do not already have one to provide medical care to their families. This will allow parents five to six months to bring their children's immunizations up-to-date, or in the alternative, to request a medical or religious/philosophical exemptions. Again, as the Department has stated, it should be rare for a child to be in the position of attempting to obtain all ten required immunizations within a 5-day provisional period at the start of kindergarten. The Department does not believe that a health care practitioner would agree to do this, and the Department would never require it. If the medical practitioner providing the vaccinations believes certain vaccinations are medically contra-indicated, then the child should be able to obtain a medical exemption.

In addition, a child from another state or another country transferring into a school in the Commonwealth and unable to provide vaccine information immediately has 30 days to obtain the information or to show proof of immunity. A child without insurance or who is underinsured may qualify for the VFC Program, although, again, revaccination if a child has been vaccinated is not the preferred solution. Further, although there may be pockets of unvaccinated children, as

the Department has previously noted, not every school in the Commonwealth will be faced with hundreds of unvaccinated children on the first day of school.

10-Day Provisional Period

One commentator supported a 10-day provisional period, rather than a 5-day provisional period. The commentator stated that a 10-day period would allow time for parents and guardians to make appointment, arrange time off for work, transportation and for records to be returned back to school and processed by the school nurse but still convey the sense of urgency created by the Final Rulemaking without creating undue hardship for school personnel. According to the commentator, parents do not always return records to the school.

The Department has not changed the regulation in response to this comment. For the reasons provided above at the beginning of the section specifically related to § 23.85, the Department believes a 5-day provisional period is commensurate with ensuring the public's health.

15-Day Provisional Period

PSBA recommended a 15-day time frame. PSBA supported replacing the current 8-month provisional period with a shorter time frame, but stated that a 5-day time period for compliance would be challenging to implement. PSBA noted that parents may, from no fault of their own, have difficulties scheduling an appointment with a provider during that time frame, may have to be absent from work, or have other commitments and circumstances that would prevented them from being able to comply within five days. PSBA stated that schools would have to develop education and communications procedures and notices for families to ensure that they are aware

of and fully understand the rules and consequences of noncompliance. PSBA pointed out that the surrounding states have provisional periods that run from 20 to 14 days. PSBA stated that a longer provisional period will be more successful in reaching the Department's goals.

The Department intends for the regulation to be published as Final Rulemaking by March of 2017, and effective for the 2017-2018 school year. Since kindergarten registration occurs in March, this should give schools and school nurses ample time to notify parents and develop communications regarding the rules and regulations. In fact, the Department typically provides school nurses with a draft communication to be given to parents outlining the terms of the regulation.

While the Department understands that some parents and guardians do delay in getting their child vaccinated, the regulation should not be based on those parents and guardians. Many parents ensure their children have appropriate vaccinations prior to the beginning of the school year. Parents and guardians will have five to six months to make appointments and ensure that their child is appropriately vaccinated in accordance with the amendments. The new regulation adds MCV in 12th grade, and adds pertussis to the list of diseases against which a child must be vaccinated to enter and attend school. Parents should be aware of all these requirements since the Department has added no new vaccination since 2011.

30-Day Provisional Period

PASA and several commentators supported a 30-day provisional period rather than a 5-day provisional period. PASA stated that the 5-day provisional enrollment period was unrealistic,

given limitations on the ability of parents to schedule appointments, particularly in rural areas with limited access. PASA stated that it believed the 5-day period would result in considerable disruption of student learning and parental work and other obligations. PASA recommended a 30-day period as a first step towards a stricter time frame, and pointed out that it comported with the McKinney-Vento Homeless Education Assistance Improvements Act of 2001, thereby creating a uniform standard that applies to all students – current residents, new residents, or students defined as homeless.

Many commentators stated that the start of the school year was the busiest time of the year, and adding reviewing immunization records and required exclusions to that period would be a strain on school nurses. One commentator stated that a 5-day provisional period was too drastic, and would be a strain not only on school nurses, students, and parents, but on doctors' offices and clinics. She asked the Department to explain why a 5-day period was selected.

One commentator agreed that an 8-month provisional time period was too long, the provisional period had provided a buffer to gather data and begin contacting parents of children without the required documentation. The commentator recommended a three-to-four week provisional period.

Two commentators stated that, although the provisional time period needed to be modified, a 5-day provisional period was unrealistic and advocated for a 30-day provisional period. One commentator made this recommendation because parents could not obtain an appointment with

the Department for six to eight weeks. This commentator stated that there needed to be a transitional period of at least one school year before enforcing the 5-day provisional period.

In responding, the Department must clarify the commentator's assumption that the Department will be able to provide immunizations for all children. Because of changes to the federal grant program, the Department's VFC Program is limited to providing vaccines for uninsured and underinsured children, and to those of certain heritages. Having said that, the Department does not see the 5-day provisional period as creating problems for parents to obtain appointments with providers. The Department intends for the regulation to be in place in by March of 2017, and effective for the 2017-2018 school year. Since kindergarten registration occurs in March, this should give schools and school nurses ample time to notify parents and develop communications regarding the rules and regulations. In fact, the Department typically provides school nurses with a draft communication to be given to parents outlining the terms of the regulation.

While the Department understands that some parents and guardians do delay in getting their child vaccinated, the regulation should not be based on those parents and guardians. Many parents ensure their children have appropriate vaccinations prior to the beginning of the school year. Parents will have five to six months to make appointments and ensure that their child is appropriately vaccinated in accordance with the existing regulation. The Department believes that this five to six month period is a sufficient transition time to inform parents and guardians, and encourage them to comply with the new regulation. In addition, the new regulation only adds one new vaccine, MCV in 12th grade, since 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 component in their vaccination. Parents should be aware of all these requirements since the Department has added no new vaccination since 2011.

60-Day Provisional Period

One commentator also pointed out that school nurses may or may not get paid over the summer, and that a 5-day provisional period would burden not only school nurses, but clinics and doctors' offices attempting to get children caught up in time, and school administrators who will be faced with large numbers of children to be excluded. This commentator recommended a 60-day provisional period.

Several commentators stated that a 5-day provisional period is not nearly enough time to allow school nurses to assess immunization status of every child and notify parents. The commentators recommended a 60-day time period. One of these commentators stated that it did not give nurses sufficient time to notify parents, or give parents the necessary time to obtain the vaccinations for their children. The commentator stated that this time period did not allow for the proper spacing of immunizations of children who receive their immunizations later than recommended.

One commentator stated that the 5-day provisional period was too short to complete the necessary work upon returning to school following summer vacation. The commentator stated that her 7th grade class was small compared to other school districts, but sorting through incoming medical forms is time consuming. The commentator stated that while her school

district provides for her to work during the summer to update immunization records, most parents do not provide medical information during the summer months. The commentator stated that parents send updated medical information into school on the first days of the new school year. Updated medical information includes physical forms, dental forms, immunization records, medication orders, allergy action plans, physical education restrictions, medical plans of care for food allergies, documentation of new diagnoses, and similar information. The commentator stated that the school nurse must prioritize what forms are reviewed first during the initial days of school, and the priority must be to review forms that relate to daily medical treatments, medication administration, physical education restriction and new diagnoses. The commentator stated that immunization documentation can only be reviewed once medical treatment processes are in place, teachers and school staff are informed of medical needs and the daily first aid needs of students are met. The commentator stated that these things take time, and it will take more than five days to put these things in place and to ensure the safety of the children. The commentator stated that more than five days are necessary to review new immunization information to ensure that errors are not made in allowing a student to enter or continue in attendance or to ensure that a student is not excluded unnecessarily.

The commentator went on to say that she was also concerned about excluding students who are missing a single dose vaccine on the first day of school. She recommended a 2-month provisional period in the case of both single dose and multiple dose vaccines. The commentator stated that a 2-month provisional period would provide time for physicians' offices to schedule visits for those parents who wait until the last minute, and also allows doctors to keep up with the supply of vaccine. The commentator stated that this would be beneficial to the student who has

no control over whether or not the student gets the vaccine, and prevents the student from missing the first valuable days of class. The commentator stated that in the first days of school, a teacher will review expectations, provide supplies and build a relationship with the class. The commentator stated that a 2-month provisional period would also be beneficial to other students, who would be impacted if a portion of the student body is missing at the beginning of the school year. The commentator stated that the parents in her school district do get immunizations done, although some do require the push of an impending exclusion. The commentator stated that all her 7th grade children are up to date, except those with religious and philosophical exemptions. The commentator stated that a 2-month provisional period would accomplish this without significant disruption that a first day exclusion would cause.

The Department has heard from many commentators who are also school nurses that they are not paid for any work they perform during the summer. The Department does not have the authority to govern the manner in which school nurses receive reimbursement, or how they conduct their work, as the Department has pointed out above. Further, as the Department has stated, few children, not already provided with exemptions, will have no vaccinations at the start of the 2017-2018 school year. This Final Rulemaking will be published five to six months prior to the start of that school year. Parents and guardians will have ample time to make decisions regarding vaccinating of children, and have no need to delay to a point where there is a concern that insufficient time is available to obtain the properly spaced vaccines, or that doctor's offices and clinics are burdened by an influx of children seeking vaccinations. Not every parent or guardian waits that long, or delays that number of vaccinations. Further, since a medical exemption is available, a parent or guardian may obtain a medical exemption for a child, and

develop a schedule that will allow for appropriately spaced vaccinations. If, however, a parent or guardian fails to adhere to this schedule, a child may be excluded from school.

The Department acknowledges that nurses will need to review immunization records, as they do currently, but within a shorter time period. The regulations in place prior to this amendment also required schools and school nurses to review a child's vaccination status prior to allowing that child to attend school, but gave the child a much longer time to obtain the required vaccinations before risking exclusion. *See* former § 23.85(e) (relating to provisional admittance to school).

The Department believes that its decision to extend the time for implementation from the 2016-2017 school year to the 2017-2018 school year will relieve some of the concerns expressed by schools and school nurses regarding implementation. This extended time frame for implementation, with publication of the Final Rulemaking in early 2017, in time for kindergarten registration, will enable schools to provide information to parents and guardians regarding the changes to the regulation in plenty of time for their effective date in August of 2017. The extension gives schools and school nurses a large part of the remaining school year to prepare themselves and their students for the upcoming changes. It gives parents and guardians nearly six months to obtain required immunizations (only two of which are new) and make plans to see a physician, PA or CRNP. Further, children entering kindergarten and their parents and guardians will be made aware of the new requirements, which, for kindergarteners, are limited to the addition of pertussis to the list of diseases against which a child must be immunized before entering and attending school. As the Department has noted, this simply acknowledges the fact that certain vaccines, like single antigen diphtheria, single antigen tetanus and single antigen

pertussis vaccines, are not available in the United States. The only new vaccine requirement for other students will be the second MCV dose for those children entering 12th grade in 2017.

Changing the time frame will also increase the amount of time the Department will have for education and outreach on these regulations, and particularly for the 5-day provisional period, which, as it has stated, it intends to conduct with health care practitioners, schools, school nurses and parents. Again, the Department believes that sufficient outreach will significantly reduce the numbers of students excluded or in a provisional status at the beginning of the 2017-2018 school year. Further, as the Department and other commentators have stated, parents and guardians who lag behind with immunizing their children, and who do not have a reason to obtain an exemption, should 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.

Multiple commentators, including the HSLDA, stated that five days was far too short a time period for parents who choose to delay immunizations due to age, illness or merely the individual's liberty to choose. Multiple commentators pointed out that no nearby state has as short a provisional period, and that the average was 58 days. The commentators stated that parents would not have enough flexibility to obtain the required vaccines, and there may be danger in requiring too many vaccine doses in a short period of time. Many of these commentators stated that a longer period, such as 60 days, would be more reasonable and safer. One commentator stated that a longer time period, perhaps 60 days, would be safer for anyone who might have developed an allergy to eggs or other components used in the vaccines. Several

commentators, including one who pointed out that parents who are citizens of the free nation of the United States, recommended a 60-day provisional period to allow parents a sufficient time to develop a plan to obtain vaccines for their children.

Although the Department has stated, above, that there is no evidence to indicate that multiple vaccines at one time create a health concern, the Department has taken into account the need for vaccines to be spaced out properly in developing its immunization requirements. Parents and guardians have ample time to make decisions regarding vaccinating of children, and have no need to delay to a point where there is a concern that insufficient time is available to obtain the properly spaced vaccines. Not every parent or guardian waits that long, or delays that number of vaccinations. Further, since a medical exemption is available, in the event that a child should not be vaccinated for medical reasons with the number of vaccinations needed for entry or attendance, a parent or guardian may obtain a medical exemption for a child. The parent or guardian also has ample time to work with the child's health care practitioner to develop an immunization schedule that will allow for appropriately spaced vaccinations. If, however, a parent or guardian fails to adhere to this schedule at a later date, a child may be excluded from school.

In response to the commentator's concern about eggs in vaccines, any child with a known allergy would be eligible for a medical exemption.

Multiple commentators, including PACIC, stated that reducing the 240-day provisional period to five days is too extreme. PACIC stated that trying to get those children who are totally

unvaccinated ten vaccines within five days could easily overwhelm the child's system. PACIC stated that this a reason that 60 days is the minimal provisional period appropriate. Several commentators stated that if children are ill, they need time to recover before they are vaccinated. Several of these commentators, including the PACIC, stated that no nearby states have such a short time frame, the average period is 58 days. Multiple commentators stated that five days is not enough time to schedule appointments or for students who may be sick to recover before being vaccinated.

PACIC takes the position that children who have no vaccinations will be overwhelmed if they have to get all ten vaccinations within five days. This is incorrect for several reasons. First, based on its immunization data, the Department has no reason to believe that a large number of children lack every dose of every required immunization, and PACIC does not provide a number. Secondly, children without an appropriate immunization have longer than five days to obtain the vaccination, if the vaccine is a multidose vaccine. In fact, the child may continue to attend school without all required vaccinations so long as the child has the next required dose in the series during the 5-day period, and presents a medical certificate with an immunization schedule during that same time frame. The child must adhere to that schedule. If it takes a child seven days to obtain the schedule, the child may return to school on the 7th day.

In addition, if children are ill when vaccines are required, and the child's physician believes that the child should not have a vaccination, the physician or the physician's designee may give a temporary medical exception, or a child can provide a medical certificate signed by those

practitioners with the time frame for obtaining the immunization set out in the medical certificate, and may then be admitted to school.

Finally, there is no scientific evidence that multiple vaccines “overwhelm” the child’s system. Offit, at 99-100; Pink Book, at 11. In fact, the Pink Book recommends that children receive all indicated vaccinations at the same time, because it increases the chances that a child will be fully immunized by the appropriate age. Pink Book, at 11, 27.

The PACIC further stated that there is a paragraph in which the Department implies that the only other state with an 8-month provisional has a high MMR rate of vaccination because the state does not have a religious or medical exemption. The PACIC stated that Section 10 of the Department’s RAF for the Proposed Rulemaking states that Pennsylvania schools have a relatively low number of exemptions. The PACIC stated that this proves that the low vaccination rates are a reporting error and have nothing to do with exemptions, so this statement should be removed from the Preamble to Proposed Rulemaking, because it is misleading. The PACIC stated that this could lead the reader to think that exemptions are a factor in these MMR percentage statistics, when they are not.

The Department’s Preamble for Proposed Rulemaking is not a part of the Final Rulemaking issued here. The Department cannot make a change to that document. It is and has always been the Department’s opinion that the long provisional period, rather than the number of exemptions given, is what allows children to remain unvaccinated for the majority of the school year.

Students eventually become vaccinated, but while they remain unvaccinated, there is still a

concern for their health and the health of others, as the Department has explained above in discussing herd or community immunity.

Several commentators supported shortening the provisional period to 60 days to improve record keeping and give parents adequate time to complete the necessary vaccinations and paperwork. Several commentators stated that the shortened period would cause parents stress and unnecessary expense by requiring them to file extensions and take their sick child to the doctor for a waiver. These commentators stated that it would substantially increase paperwork as numerous waivers are filed requiring individual follow ups. These commentators stated that a 60-day provisional period would meet the need of ensuring timely filing without causing undue stress on parents or endangering sick children by leading parents to seek out vaccines under duress. Several commentators pointed out that there were no surrounding states with such short provisional periods. One commentator stated that her doctor's office would not give same day appointments for shots, even if the child was behind. Given the later reporting date, a 60-day provisional period would not interfere with data collection and analysis.

The Department disagrees with the commentators, and has not changed the regulation. Commentators who are also school nurses have indicated that a longer provisional period requires more follow-up, since multiple letters must be sent to children and parents. Any regulation regarding exclusion for failure to obtain required immunizations will require follow-up by the school administrator or his or her designee.

Further, if a child were seriously ill at the time the child was about to enter school, and too ill to be taken to a physician's office, the child is unlikely to be attending school. The question of what vaccinations are to be given is moot at that point. Of course, once the child is ready to return to school, if an exemption is warranted in the opinion of the physician or his or her designee, the physician or physician's designee may provide a medical exemption. Otherwise, upon the child's return to school, the child would be required to comply with the immunization requirements. A child may provide a medical certificate with the time frame for obtaining the required immunization or immunizations, so long as the missing vaccination is not a single dose vaccine, and the other requirements of the regulations regarding provisional admittance to school in § 23.85(e) have been met. The child would then be admitted to school.

In addition, the Department has not reduced the provisional time frame in order to obtain more accurate reporting, although this may be a secondary benefit. The Department's concern is to ensure that children receive all necessary vaccinations upon entering school, ensuring their health and the health of those who cannot be vaccinated, in school and in the general public.

Finally, the commentator is correct that no surrounding state has as short a provisional period as five days. The Department notes, however, that West Virginia, which has a 240-day (8 month) provisional period, has very high vaccination rates. In the Department's opinion, however, this is because West Virginia has neither a religious/philosophical nor a medical exemption.

Several commentators recommended shortening the provisional period to 60 days to give parents more time to comply with the immunization requirements and to make appointments for missed

vaccines. One commentator stated that this time period would also allow a child to recover from any illness so that the child can receive the proper vaccinations. The commentator raised a concern that there could be a delay in the child's education because the parent might not be able to take time off from work immediately to file an exception. One commentator stated that this would be helpful in a variety of personal and medical circumstances.

As the Department has stated, the Department has taken into account the need for vaccines to be spaced out properly in developing its immunization requirements. The Department and school nurses try to give parents ample time to learn new requirements, and some of the existing requirements have been in place for over 20 years. Parents and guardians have ample time to make decisions regarding vaccinating of children, and have no need to delay to a point where there is a concern that insufficient time is available to obtain the properly spaced vaccines. Not every parent or guardian waits that long, or delays that number of vaccinations.

90-Day Provisional Period

One commentator stated that the beginning of the school year involved a great deal of work, including dealing with medically fragile students and their parents and developing individualized health plans for them, instructing teachers on first aid care and emergency plans and notifying teachers of students with allergies requiring EPI Pen use. This commentator also pointed out that foreign students entering school could take some time to get insurance. This commentator recommended a 90-day provisional period.

The Department has not changed the regulation. The Department acknowledges that the beginning of the school year involves a good deal of work for school nurses in a variety of areas, including review of immunizations. The Department has explained in this Preamble, *supra*, at page 272-273, that it believes the extended implementation time period will help with that issue. With respect to foreign students entering school, the Department has built in a 30-day period allowing students coming into school in the Commonwealth to provide immunization records. Further, if a child does not have insurance, or is underinsured, the child is immediately eligible for the VFC program.

One commentator stated that with delayed reporting, it seemed unreasonable to limit the provisional period to five days. The commentator recommended a 90-day provisional period, the same as the Commonwealth of Virginia. According to the commentator, this would give plenty of time for students to catch up on vaccines and for schools to complete their reports. The commentator stated that a 5-day provisional period would be problematic for parents, doctors' offices, school administrators, and a 90-day period would eliminate any problem they would have with completing paperwork.

One commentator stated that the 5-day provisional period did not give a parent enough time to make a doctor's appointment, because most doctor's offices make a person wait one to two weeks before the person can be fit into the office's busy schedule. The commentator recommended a 90-day provisional period.

One commentator stated that giving parents only five days to give their children what may end up being several vaccines at once has the potential to result in “catastrophic reaction” for any children who may have undiagnosed sensitivities or predisposition to adverse reactions to vaccines. The commentator noted that giving several vaccines at once has never been studied for safety, even though industry representatives insist it is safe. There is no science. The commentator stated that studies that compare vaccinated children with other vaccinated children, concluding that they have similar rates of health issues are not evidence of safety, and are not good science.

The commentator also stated that many of the current pediatric vaccines contain high levels of aluminum adjuvants, and some children are not able to quickly and effectively eliminate heavy metals. The commentator stated that recommending a rushed decision to receive several vaccines at once is not ethical when there is no health disease causing a public health emergency, and coercing such a decision by withholding education from children violates the principle of informed consent. The commentator stated that Pennsylvania has one of the highest vaccination rates in the country. The commentator stated if the Department were concerned about reporting accuracy being skewed by the provisional period, shortening the provisional period to 90 days and changing the reporting date to December 31 is a more accurate reflection of vaccination rates.

The Department has not changed the regulation. The Department is not requiring parents to make a rushed decision to vaccinate their child. The requirements relating to vaccination have been in place for many years. The last time an immunization was added to the list was in 2011,

and that included requiring Tdap and MCV for entry into the 7th grade. This regulation adds 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 component in their vaccination.

The Department is also requiring a dose of MCV for entry into the 12th grade. Some children have had years to become appropriately immunized. The Department is not requiring a list of 10 new immunizations for children in 2016 and requiring all of those immunizations for the upcoming school year. In fact, the Department has heard the comments of school nurses and the public and has moved the implementation date of the regulation to the 2017-2018 school year. Parents should be notified in March of 2017 of the publication of Final Rulemaking, and a child attending school in the Commonwealth will be required to be up to date with immunizations for the 2017-2018 school year.

Further, the Department is not coercing the decision by withholding education from a student.

The parent or guardian may choose to obtain a religious/philosophical or medical exemption from the requirements and the child may continue to attend school.

In addition, as the Department has explained, “informed consent” has a particular meaning in state law, *see* Preamble, *supra* at pages 119-120. However, as the Department has noted the parent or guardian still provides consent for an immunization of a child, and may choose to withhold his or her consent for an immunization. The child may still attend school by choosing to obtain a religious/philosophical or medical exemption from the immunization requirements.

Further, the Department has already discussed the issue relating to aluminum and other vaccine additives *supra*, at pages 43-44, 126-130.

With respect to the comment regarding vaccination rates, the Department believes that changing the provisional period will give it a more accurate reflection of vaccination rates, but that it is not the only reason it has chosen to add a requirement for MCV in the 12th grade to the list of required immunizations. According to the CDC, meningococcal disease can be devastating, and often – and unexpectedly – strikes otherwise healthy people. Although meningococcal disease is uncommon, teens and young adults 16 through 23 years of age are at increased risk.

Meningococcal bacteria can cause severe disease, including infections of the lining of the brain and spinal cord (meningitis) and blood stream infections (bacteremia or septicemia), and can result in permanent disabilities and even death. The Department has followed ACIP recommendations to add a second dose in the 12th grade.

30- to 60-Day Provisional Period

Several commentators pointed out that school nurses do not work during the summer, and that it would be too difficult to collect all the necessary information, particularly since they would not get paid. One of these commentators recommended a 30 to 60 day provisional period.

One commentator stated that it would be difficult to enforce the regulatory changes within the first 5 days of school, which was a very busy time for school nurses. The commentator recommended a 30 to 60 day time period.

The Department has not changed the regulation. For the reasons stated above, the Department believes the appropriate time frame for a provisional period is five days.

One commentator stated that although the 240-day provisional period is too long, a 30 to 60 day period would be more appropriate. The commentator stated that the 2013-2014 PA kindergarten MMR rate is 86%, however, by 7th grade, which is the next grade for which there is available data, the rate is 95.8%. Pennsylvania's exemption rate is just under 3%, so exemptions are not the reason for the low kindergarten rate. The commentator stated that the Department's provisional rate is 17.9%, and that should have been shared in Section 10 of the Regulatory Analysis Form, because it explains the low kindergarten rate. Since the median provisional period time frame around the country is 30-days, the commentator recommended a 30-60 day period. The commentator stated that this would raise the overall kindergarten vaccination rate and allow parents to plan accordingly.

As the Department has stated above, its review of the school-level data, rather than the school district level data, causes concern about the pockets of non-immunized children throughout the Commonwealth. The Department has provided the medical and religious/philosophical and medical exemption rates above at pages 18-19 of this Preamble, *supra*. Because these schools show no medical or religious exemption, the number of non-immunized children is clearly related to the number of provisionally enrolled students, which the data also show to be high in these same schools. The fact that numbers improve from one time period to another do not resolve the issue, as the Department has discussed, of children at a point in time in a school being under-immunized. This is particularly true for measles, and thereby creates a risk of a serious health event, which would take time and resources away from schools, school districts, the Department and the health care community. It would also create costs to parents, guardians, teachers and school employees, and children.

60 to 70-Day Provisional Period

The commentator agreed that the current provisional period was long, but stated that five days was difficult given the real day-to-day lives of families. The commentator stated that this would put ill or immuno-compromised children at risk for injury having so many vaccines in order to catch up in a 5-day period. The commentator stated that many of the most severe vaccine reactions and permanent injuries occur when multiple vaccines are given in a short period of time. The commentator recommended a more reasonable period of 60-70 days.

The Department has not changed the regulation. The Department has stated its reasons above, and points out that ill or immunocompromised children may obtain a medical exemption.

Further, the Department is not aware of any valid scientific study which states that the most severe vaccine reactions and permanent injuries occur when multiple vaccines are given in a short period of time. In fact, studies show that no ill effects occur in these circumstances. The Department has addressed multiple vaccines at pages 55-56 and 275-276 of the Preamble, *supra*, *see also* 241 and 257-278.

60 to 90-Day Provisional Period

One commentator stated that it would be very difficult to comply with the 5-day provisional period because nurses were so busy collecting emergency cards, writing health plans, making sure students who need medications have the paperwork and medications available. This commentator recommended a 60 to 90 day provisional period.

One commentator stated that a 5-day provisional period would not give school nurses adequate time to ensure the proper immunization status for all students involved. The commentator stated that school nurses are too busy and overwhelmed within the first few days of school dealing with chronic health issues, medications and assisting student transitions to a new school year. The commentator recommended a 60 to 90 day transition period to give school nurses adequate time to inform and educate parents, and for physicians to come on board with the new requirements. The commentator stated that if the provisional period were only five days, there would be a rise in moral or ethical exemptions, and those children would never be immunized.

One commentator identifying themselves as a homeschool parent whose children are vaccinated, as required by the regulations, and stated that the 5-day period was too short. The commentator

stated that parents who choose to delay immunizations will not have enough flexibility in obtaining the required vaccines. The commentator stated that there may be danger in requiring too many vaccine doses in a short period of time. Parents should have 60 to 90 days to develop a plan for their child to receive the required vaccinations.

In developing its immunization requirements, the Department has taken into account the need for vaccines to be spaced out properly. Parents and guardians have ample time to make decisions regarding vaccinating their children, and have no need to delay to a point where there is a concern that insufficient time exists to obtain the properly spaced vaccines. Not every parent or guardian waits that long, or delays that number of vaccinations. Further, since a medical exemption is available, in a truly problematic situation, a parent or guardian may obtain a medical exemption for a child and develop an immunization schedule that will allow for appropriately spaced vaccinations. If, however, a parent or guardian fails to adhere to this schedule, a child may be excluded from school. It is within the purview of a parent or guardian to obtain a religious/philosophical or medical exemption because of a shortened time frame.

Several commentators stated that a 5-day provisional period was too short, the shortest of any state, and that this would put sick children, especially immunocompromised children, at risk for injury having so many vaccines in order to catch up in a 5-day provisional period. The commentators pointed out that children are not supposed to have vaccines if they are sick, but when they are healthy. The commentators stated that a 60 to 90 day time period would be more reasonable and allow families time to plan and seek a schedule that is safer and more reasonable.

The Department's regulations do not require a child to have all the vaccines that the child is missing within a 5-day provisional period. The requirement is for the child to have the single dose of a single dose vaccine by the first day of school or face exclusion (this is limited to Tdap). In the case of a multidose 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 those first five days of school, or must have the next scheduled dose during that time period. During that same time period, the child must also provide a medical certificate setting out the schedule for the remaining needed doses. If the child needs additional doses, but 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 child may then be admitted to school. If the child is ill when the time comes for obtaining a vaccination, or a health care practitioner believes that the child is lacking so many vaccines that it would be medically inappropriate for the child to receive the required doses during the 5-day provisional period, the child may obtain a medical exemption from a physician or physician's designee. Further, if any dose of any vaccine is medically contraindicated, or if a child has a religious or philosophical objection to a vaccine, the child may obtain an exemption, and still be admitted to school. As the Department has noted, however, there are no competent studies showing that having multiple vaccines at one time create a risk of injury.

One commentator stated that if a provisional period was necessary, 30 to 60 day or 60 to 90 day would be easier to monitor and enforce. The commentator noted that no matter what the provisional period, there would parents who would not comply.

The Department has not changed the regulation. The Department is aware that there are parents and guardians who do not have their children vaccinated, choose not to have their children have certain vaccinations, or simply just fail to have their children vaccinated. The Department is issuing the regulation that it believes is necessary to protect children and the general public, regardless of the potential that some individuals will not comply.

The Department also acknowledges that monitoring will take some effort on the part of schools and school employees. The Department believes that the safety benefit to children and the school staff is outweighed by the increase in effort to monitor immunization requirements. The Department notes that some commentators believe that a shorter provisional period will be easier to monitor than a longer one, since the shorter period will reduce the number of letters and reminders that schools will need to send to parents and guardians.

3 to 6-Month Provisional Period

One commentator, identifying herself as a board certified family physician, recommended a three to six month provisional period, because missing a vaccine during this three to six month period was not likely to have any significant effect on outcomes, but no provisional period would unduly stress parents, children, school personnel, providers and staff. The commentator stated that there were too many other time sensitive issues like responding to laboratory and diagnostic results, calling patients, school nurses caring for sick children, parents getting their children fed, and helping their children with homework to make this school vaccination issue excessively and inappropriately time sensitive. The commentator stated that if a child has an illness, or is in an

accident, vaccination is not the first priority. The commentator stated that if children consistently get their vaccines within three to six months of the required date, the number vaccine preventable illnesses will go down.

The Department disagrees with the commentator. The Department agrees that, in certain circumstances, being concerned about whether or not a child has a vaccination would not be the first priority. In any event, if a child were seriously ill or in an accident, the child is unlikely to be attending school, and having his or her vaccinations checked. Of course, once the child returns to school, if the child has not again begun to obtain required vaccinations, the Department points out that a physician or the physician's designee may, in the case of a serious illness or accident, provide a medical exemption if need be. The Department, however, is following ACIP recommendations in only counting as valid immunizations provided within a specific time frame.

8-month Provisional Period

One commentator stated that the 8-month provisional period should stay as it is, because it was well thought out when the law was created, and the increased risk to the student is not worth the perceived benefit.

The Department disagrees with the commentator and has not changed the regulation. In fact, the provisional period does not exist in statute, that is, the law. Rather, the provisional period is a regulation drafted by the Department in order to implement the law, as is the present amendment to reduce that provisional period. The Department reviews its regulations periodically to ensure

that they serve the needs of the people of the Commonwealth. In reviewing this particular regulation in the light of school immunization data, and the recent outbreaks of vaccine preventable diseases in California and in this Commonwealth, the Department has decided that an 8-provisional period is too long, and must be shortened.

One commentator expressed shock and outrage over the attempt to reduce the provisional period, and recommended that it remain eight months because of the need for sufficient time for children to catch up with their vaccinations. The commentator stated that family friends had a son who had a severe reaction to so many vaccinations given at once in order to catch up. The commentator stated that there are many risks possible with the short time schedule proposed by the Department.

The Department has not changed the regulation. It is the Department's belief that the number of children who need multiple immunizations in order to attend school is small. Parents and guardians are aware of existing requirements, and should be planning to obtain the appropriate vaccinations. In the event of illness, or other unforeseen circumstance, the child has the option of obtaining a medical exemption. Further, the intention of the 5-day period is not to require a child to get all vaccinations within that period, but in the case of multiple dose vaccines, to have at least one dose of each, and a schedule for the remaining doses. Although the Department has sympathy for the commentator's family friend, the Department is not aware of any valid scientific study stating that receiving more than one vaccine at the same time causes injury. In addition, the Department notes that medical and religious/philosophical exemptions are available to parents and guardians.

9-Month Provisional Period

One commentator stated that although the commentator recognized the need to immunize children, requiring the needed vaccines in such a short span of time might have negative effects on the child. The commentator recommended that nine months be allowed for vaccinations.

The Department has not changed the regulation. The Department believes that to extend the provisional period further than it was originally, that is from eight to nine months, will add to the number of children provisionally enrolled, create cross-over from one school year to the next, and increase the number of schools with low vaccination rates. As the Department has stated, the Department is not aware of any valid scientific study stating that receiving more than one vaccine at the same time causes injury. In addition, the Department notes that medical and religious/philosophical exemptions are available to parents and guardians.

Provisional Period in Kindergarten and 6th Grade

One commentator also pointed out that school nurses may or may not get paid over the summer. One commentator stated that along with the many other things she has to do relating to health and safety, she is dealing with free and reduced lunch applications, that come in by the hundreds during the first week of school. She recommended that the provisional enrollment period be changed to eight months in the 6th grade. This would allow the school nurse and families to get vaccines and documentation, and would provide protection sooner. She also recommended the regulation be changed to a three month provisional period in kindergarten. In that way the school nurse could make kindergarten booster shots a priority.

The Department has not changed the regulation. As the Department has previously stated, the Department believes that the 5-day provisional period provides sufficient time to review records and take action as necessary, particularly given the Department's decision to extend the implementation period for the amendments, and make them effective for the 2017-2018 school year. Having different provisional periods in different grades will not work to increase vaccination rates overall. The Department is not attempting to raise rates simply from a reporting perspective, but to ensure that all children are safe from vaccine preventable diseases in schools.

Elimination of Provisional Period

All immunizations required on the 1st day of school

Several commentators disapproved of a 5-day provisional period because of work issues for school nurses and difficulties for children and families, but recommended eliminating the provisional period altogether.

One commentator stated that she was concerned about making a kindergartener's first days of school be fraught with worries of whether or not the kindergartener would be allowed to attend school. She stated that this was not the way to get the kindergartener's school career off to a good start, because, after a whole summer of being told they were going to "big kid school" and being excited about going on the bus, they would be pulled into the office and told they would have to go home. She stated that this would not be a "happy-faced child" and would not create a

good impression. She raised concerns that families from lower socioeconomic groups were the ones that were not complying with the immunization requirements.

Several commentators suggested eliminating the 5-day period, and not giving a child a start date until the child's parents have either provided proof that the child has all the required vaccinations, or a medical certificate. Four of these commentators recommended that for kindergarten, the Department eliminate the provisional enrollment period altogether, and require a child to be fully immunized before the child starts school. One commentator suggested that the only exceptions be those children with religious, moral, medical or homeless exemptions. One commentator stated that because the age of compulsory education is eight years of age, if parents attempting to register their child at the age of five do not submit proof of full immunization by the week prior to the start of school, the child would not be eligible for enrollment until the next school year at the age of six. One commentator suggested that starting and stopping school for a child entering kindergarten would not be in the best interests of the child. These commentators suggested that no child should be permitted to start school until a certified school nurse has given approval that the child has the necessary immunizations to start school. One commentator stated that provisional status does not seem to prompt parents to have the child's immunizations completed. Another commentator stated that eliminating the provisional period altogether would improve immunization rates.

The Department agrees that excluding all children without the required immunizations on the first day of school would be the best way to ensure that children attending school are as safe as possible from vaccine-preventable diseases. The Department thinks, however, that this would

truly create too much work for school administrators and their designees (presumably, school nurses). This is particularly the case in light of the fact that so many commentators stated that they would not be paid for working over the summer. For the reasons stated above, the Department believes that a 5-day provisional period achieves the same immunizations goal.

One commentator recommended eliminating the provisional period altogether, so that the time periods for single dose and multidose vaccinations would be the same. The commentator stated that a 5-day provisional period with a medical certificate was too complicated, and school nurses are too busy the first five days of school. The 5-day provisional period would put a tremendous pressure on the school nurse.

The Department has not changed the regulation. The Department does not believe that eliminating the 5-day provisional period altogether would eliminate work for the school nurse, as stated above.

No Set Time for Immunizations

One commentator stated that Pennsylvania was one of the most difficult states in which to home school students, and asked that it not be made more difficult. The commentator stated that parents who choose to delay immunizations will not have enough flexibility in obtaining the required vaccines, and that any day of the school year should be acceptable.

The Department has not changed the regulation. Reducing the provisional period does not make obtaining an education any more difficult for a child who is homeschooled than one who attends a brick and mortar school. The immunization requirements are the same for both.

Paragraph (1) (i) & (ii). Multiple dose vaccine series – Medical Certificate.

One commentator asked whether the Department had discussed or proposed the concept of a medical certificate with the American Academy of Pediatricians, meaning those pediatricians in Pennsylvania who would have to provide these certificates.

PSBA commented that the Department would need time to develop a new medical certificate and make it available. PSBA and PSEA stated that doctors and parents would have to be educated on the new requirements and how to use the certificate. PSBA recommended that the Department develop and provide training and education materials to school entities and families to assist in this implementation.

As the Department noted in Proposed Rulemaking, the medical certificate is a new requirement. The Department set out the contents of the medical certificate in Proposed Rulemaking, and has not changed that content here, except to specify the health care providers who may sign the form. The medical certificate is intended to contain student's immunization plan, setting out the schedule on which the student will receive the missing immunizations. The form is to be filled out and signed either by a physician, CRNP or PA, or, when the immunizations are being provided by the Department or a local health department, by a public health official. *See* § 23.82 (relating to definition of "medical certificate"). The Department will provide the medical

certificate form to schools. The Department has attached a draft of the medical certificate form to the RAF of this Final Rulemaking as Attachment 3, and will also share that form with physician's groups, including the AAP and other stakeholders, in order to obtain their input. The Department expects to post the medical certificate form on its website by March of 2017. The Department intends to provide training and educational materials to schools to use with families on this issue.

Several commentators asked whether the medical certificate was something new, and if the Department would provide an official medical certificate to school nurses so that the school nurse could have the physician complete the form for students. Several commentators asked about the form of the medical certificate and what it would look like. One commentator asked whether a printout from the child's physician, stating when the next appointment to get the immunizations completed was scheduled, was sufficient. Several commentators asked whether the medical certificate would be coming from the physician, and whether any writing from a practitioner would be sufficient. The commentators asked whether they should be providing a medical certificate.

The medical certificate is a new requirement. The Department will make a medical certificate form available to schools, by March of 2017. No other form of written communication, including an appointment printout will be sufficient.

One commentator said that she was trying to be proactive by sending out letters regarding the proposed regulations, and that people were confused about the term "medical certificate." She

stated that people were not going to know what that was and asked whether she could use the phrase “you may submit documentation from your physician.”

The Department cannot dictate to school nurses what letters they send to parents and children in their school districts; however, until the regulations are finally promulgated, they are not fully approved and may change. Therefore, the Department would recommend making no notification to parents until that time. With respect to the statement “you may submit documentation from your physician,” this is not accurate or compliant with the regulation. A parent must submit a medical certificate signed by a PA, CRNP or physician, that lists what immunizations remain to be obtained, and when they will be given. This is the only documentation acceptable to comply with the regulations. The regulations define “medical certificate” in those words. The Department has attached the draft medical certificate form to the RAF of this Final Rulemaking, and will publish the medical certificate form on its website, seek input from stakeholder groups, and provide the medical certificate form for school nurses to send out to parents in time for school registration in March of 2017.

One commentator asked whether a child could be excluded from school if the parent fails to adhere to the schedule on the certificate, and the practitioner keeps extending the date. Another commentator asked whether the school nurse was required to call the physician to see if the parents of a child with a medical certificate follows through with the appointment and completes the required immunizations. The commentator also asked what allowances were to be given for missed appointments. The commentator asked whether the child should be immediately excluded from school.

The Department's regulations place the responsibility on the school administrator and the school administrator's designee, who can be the school nurse, to check the medical certificate every 30 days to determine whether or not a child has received the required immunizations. It is certainly within the discretion of the school administrator or the designee to determine that the best way to carry out this responsibility is to telephone the physician's office, although HIPAA issues will arise unless the parent or guardian has given that office consent to speak with the school. With respect to the issue regarding missed appointments, the responsibility to obtain the required immunizations still remains on the parent and guardian of the child in question, however. If they do not provide the required information to the school, there is no requirement that the school go hunting for it, and the child is then at risk for exclusion for failure to comply with the immunization schedule included in the medical certificate.

If the child's practitioner continues to update the schedule, the school administrator will need to determine what if any action to take, although the Department notes it is within the practitioner's scope of practice to make that determination, and the Department assumes a school would accept that update. The Department does not provide advice on what actions to take under these circumstances, since the Public School Code places the responsibility on the school administrator or the school administrator's designee.

PSBA and PASA opposed the change from 60 to 30 days for reviewing the medical certificate.

While supporting a shortened time frame as a method to seek greater parental accountability, however, PSBA expressed concern that the increased requirement to monitor and contact parents

on a monthly basis would create an administrative burden for school district staff who have to schedule additional time to review files and communicate with parents. PASA stated that this time frame was too burdensome given the realities of current resources and administrative capacity in school districts and school entities across the state. PASA stated that due to budgetary reasons since 2011, school districts have lost more than 600 administrators and administrative positions. In these associations' view, reducing the review period, while noble in its objective, ignores the realities of already overstressed and limited administrative capacities of school districts. PSBA and PASA recommended an interim step of 45 days to review the medical certificate to provide for improved monitoring of compliance with the immunization schedule.

IRRC noted that commentators stated that the 30-day time frame creates an administrative burden, and that the commentators had requested a middle-ground time frame. IRRC asked that the Department explain the reasonableness of the time frame and how it adequately protects the public's health.

The Department is aware of budgetary issues that create difficulties in administering school districts. The Department notes, however, that it has received comments from school nurses stating that it is the school nurse, rather than the actual school administrator or other school staff, who oversees compliance with immunization requirements. The Department cannot speak to how each school district handles immunization compliance. The Department believes, however, that 45 days is too long a time period to determine whether or not a student remains in compliance with that student's vaccine schedule. The Department points out that it has

consistently sought throughout these amendments to shorten time frames in certain circumstances to the period of 30 days. For example, the time frame for immunization records to be produced for children who transfer into a school in the Commonwealth or who are in foster care is 30 days. Likewise, the time frame for review of the medical certificate is 30 days. While some risk remains for every day a child goes without an immunization, the Department has attempted to balance that risk with the school's need for time to carry out this requirement. The Department believes that 30 days is the appropriate period of time.

School nurses commenting on these amendments have not suggested that once the initial review of the immunization status of their students is completed, it is too onerous to review every 30 days the status of those students missing some immunization. Not all children will be without vaccinations. The number provisionally admitted in 2015-2016 school year was 21,175, or roughly 7.6% of students enrolled in reporting schools. *See* School Immunization Summary 2015-2016, *supra*. School administrators will only be required to follow up with those students with missing or incomplete immunization records; if the commentators are correct, the pressure of a serious deadline may bring about compliance. As other commentators have also noted, the shortened time period for compliance will shorten the time period for follow-up calls and letters from those required to call for that compliance. Further, by publishing this rulemaking in the *Pennsylvania Bulletin* by March of 2017, the Department will be providing ample notice of the shortened time frame for these compliance requirements. As has been discussed throughout this Preamble, the Department intends to conduct outreach to all the parties concerned in the hopes of reducing the numbers of noncompliant children without exemptions by the fall of 2017.

In addition, the Department is now requiring that, in the absence of an exemption or a waiver, a child may only remain in school without the required immunizations if he or she is complying with the immunization schedule in the medical certificate that has been signed by a physician, a CRNP or a PA. The Department's intention is to transform what was a seemingly endless time period (i.e., eight months) in which children could go without complying with the regulations and with little required compliance into a medically sanctioned time frame in which the child, his or her parents or guardians, and the physician, CRNP or PA giving the immunizations agree that this immunization will be completed. This change signals the seriousness of the Department's purpose to ensure that children obtain vaccinations for their own protection, and to protect others from vaccine-preventable diseases as quickly as possible, rather than allowing these children to be at risk for a seemingly-endless provisional period. If the school administrator or his or her designee takes up to 45 days to determine whether or not a child is complying with an immunization schedule set out by the physician, CRNP or PA, and only then seek to obtain compliance, the Department's attempt to shorten the period in which non-immunized children and adults remain at risk will seem unserious, and the Department's goal of stressing the importance of these compliance requirements will be undermined.

One commentator stated that she supported the change from 60 to 30 days for reviewing the medical certificate, but asked that the wording be changed to reflect that the school nurse would be excluding the children, since this is what actually occurs. One commentator asked that the regulation include the term, "designee," that is, the school nurse, since the school nurse actually looks at the certificates.

The Department has not changed the regulation, which already included the language allowing the school administrator's designee to review the medical certificate. Although the Department does not doubt that in many cases the onus of actually implementing exclusion falls upon the school nurse, the language in question comes specifically from the Public School Code. Further, for these purposes, as recognized by one commentator, the school nurse may act as the designee of the school administrator, and is in fact doing so.

Paragraph (1) (ii) & (iii). Multiple dose vaccine series -- Medical Certificate

IRRC commented that subparagraphs (ii) and (iii) of Paragraph (1) end with similar language that states that a child's parent or guardian must provide a medical certificate scheduling the required doses on or before the 5th school day. IRRC stated that it is unclear whether the parent or guardian is to schedule the dose on or before the 5th day, or provide the certificate on or before the 5th day, and asked the Department to clarify this matter.

The Department has changed the regulation. It was the Department's intention that the child either have the immunization on or before the 5th day, or that the parent or guardian present a medical certificate to the school on or before the 5th day. The regulation in both subparagraphs now reads that the parent or guardian must provide a medical certificate on or before the 5th school day scheduling the additional required doses. A minor change was made to the language of subparagraph (iii) to add the words "the" and "required," in order to parallel the language of subparagraph (ii).

A commentator also raised issues regarding the cost of obtaining a medical certificate, stating that this was not sufficiently addressed by the Department in the Proposed Rulemaking.

The Department acknowledged additional time and costs created by the need to obtain a medical certificate signed by a physician, CRNP or PA¹² in the event the child needs additional doses of a multiple dose vaccine in its RAF to Proposed Rulemaking as well as in the Preamble to Proposed Rulemaking. This should not add significantly to the time requirements for parents and guardians that have resulted from the Department's regulations. For more than 30 years, children have been required to have certain immunizations to attend school, and must go to a health care provider to get either those immunizations or a medical exclusion. The health care provider giving an immunization may fill out the certificate of immunization and sign it.¹³ See § 23.82(relating to definition of "certificate of immunization"). Although the number of immunizations may have changed over those years, the requirement for a certificate of immunization has not. The Department's regulations have always allowed children (those without medical or religious/philosophical exemptions) who are not appropriately vaccinated to attend school provisionally even if their vaccinations are not up to date. Under the regulations relating to the provisional period as they existed prior to this rulemaking, (*see* former 28 Pa.

¹² A child may also go to the Department or a local health department to obtain an immunization. The Final Rulemaking allows for a public health official to fill out and sign the medical certificate if the immunization is given by the Department or a local health department. The Department and local health departments do not, however, charge paperwork fees, and, if a parent or guardian cannot afford the minimal administration fee for the immunization that may be charged, the child cannot be refused the vaccination.

¹³ A parent, guardian or emancipated minor may also fill out the certificate of immunization, but it must be signed by a health care provider, public health official, or school nurse or designee. 28 Pa. Code § 23.82 (relating to definition of "certificate of immunization.")

Code § 23.85(e)(1) and (2)), the Department had required that parents and guardians have a “plan for the completion of the required immunizations [that] is made part of the child’s [school] health record,” *id.*, and that that plan be reviewed every 60 days by school administrators or their designees. *Id.* at § 23.85(e)(3). Immunizations were to be added to the child’s certificate of immunization, also defined by the regulations or entered into the school’s electronic data base. *Id.*

The Department’s immunization data, drawn from its SILR reports (*see* 28 Pa. Code § 23.86 (relating to school reporting)), shows that although many of the children admitted provisionally eventually do become vaccinated, they do not do so particularly quickly. *Compare* data on provisional admittance from the School Immunization Summary 2014-2015, *supra*, with the School Immunization Summary 2015-2016, *supra*. This concerns the Department because the longer the periods of time in which clusters of non-immunized children are allowed to remain in schools, the longer the remainder of children and adults who are not immunized or are unimmunized are at risk for potential outbreaks of disease. The Department has sought to shorten the provisional period for this reason. *See* discussion on 5-day period starting at page 238 of the Preamble, *supra*; *see also* pages 261-262, 268-269, and 272-273 of the Preamble, *supra*.

The Department has also attempted to address this concern by formalizing the requirement of the plan of immunization by requiring a medical certificate. The medical certificate is actually a reviewed and accepted plan of obtaining immunizations by a date certain. However, rather than a vague immunization plan, which is not required to be formally reviewed and accepted by the

provider who will be providing the immunizations, the Department has required the immunization plan, in the form of a medical certificate, to be formally signed by a physician, CRNP, PA or a public health official where the vaccines are given by the Department or a local health department. This at least provides some assurances that the immunization plan offered, and which permits the child to continue to attend school past the original 5-day period of the provisional admittance, has been discussed and approved between parents and guardians and health care providers. The Department believes this should encourage vaccinations to occur more quickly than is currently happening, at least among those children who will be immunized at some point during the school year. The Department acknowledges that those who do not believe in immunizations will continue to remain unvaccinated; they are permitted to do so under the law. This, to the Department, is one more reason to ensure the remainder of those children who have simply been slow to obtain up-to-date immunizations are immunized as quickly as possible.

Despite these facts, however, the Department has figured in a time cost, as well as a cost for the paperwork itself in addressing the cost to the regulated community in the RAF to this Final Rulemaking. The cost of obtaining a medical certificate should be the cost currently involved in obtaining sign off on certificates of immunization. If there is additional cost, this could be a co-payment, which the Department has determined, based on studies, to be at the highest amount \$29.07, if privately obtained, or an administration fee, at the highest, approximately \$24.13 if obtained from a public source (although one study used a public fee amount of approximately \$8.15, *see* "Supplement to Benefit," at 4, the Department's experience shows an administrative fee of approximately \$24.13), and a cost for completing paperwork. 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* <http://www.amednews.com/article/20071015/business312159994/4/> (accessed August 10, 2016).

The 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.

Again, in the Department's view, the savings in prevention of vaccine preventable illnesses for both the child in question, and other children and adults with whom that child comes into contact, would, however, outweigh the cost of the vaccine and the cost of the visit to obtain the medical certificate. The Department has developed a medical certificate format for schools to use.

Subsection (g)(2). Applicability -- 30 Day Waiver if Transferring in to School in the Commonwealth.

One commentator questioned the Department's allowing time for a student transferring into a school to provide proof of immunization. The commentator stated that a child transferring among schools within the Commonwealth should be able to obtain the child's immunization status when the child is withdrawn from school. The commentator noted that parents are routinely leaving schools and not withdrawing the child, so that they never pick up their immunization record. The commentator also noted that these children are not being enrolled immediately into school. In addition, the commentator questioned why the Department was

allowing children whose immunological status could not be verified to risk the health of children who need to be protected by herd immunity. The commentator noted that if a child is coming from out of state and there is not a question of the child being homeless there was a risk.

PACIC and two other commentators stated that a child should be given 60 days rather than 30 days to complete paperwork. According to one commentator, 30 days might not be enough, and a child might be pressured to be revaccinated to attend school. IRRC also asked that the Department explain the reasonableness of the time frame, and show how the timeframe protects the public's health. IRRC asked that the Department provide evidence for why it chose a 30-day time period rather than any other.

One commentator stated that a 90-day period would eliminate any problems with completing paperwork. The commentator was concerned that paperwork mix-ups in the 30-day window could result in revaccination.

The Department has not changed the regulation. If a child's school records exist, 30 days should be ample time to obtain them and to submit them to the new school. The Department agrees with some commentators that even 30 days may potentially put children and adults who cannot be vaccinated at risk from potential illness. The Department, however, is attempting to balance the need for protection against disease with the need to allow a child and his or her parents or guardians the time to settle into a new school, a new area, and to obtain necessary immunizations that may differ from those in other states. The Department is requiring children known to be unvaccinated, and who are being admitted provisionally on a formalized immunization plan

approved by a medical provider, to have that medical certificate checked every 30 days to make certain the child is in compliance. *See* § 23.85(e)(3). This 30-day period seems to the Department to be an appropriate time frame to ensure compliance with the immunization plan and protect the remainder of the school population. It seems appropriate to the Department that a child who states that he or she is vaccinated, but needs time to provide records, receive that same 30-day period to provide evidence of immunization. It is the Department's hope that with the increasing prevalence of electronic records, 30 days will be unnecessary.

Subsection (g)(3). Applicability – Waiver if the Child is in Foster Care

One commentator raised a question regarding what the implications of these amendments for children in foster care, and asked that the final regulations address that issue.

The Department has revised the regulations to include a section allowing for a 30-day waiver for children in foster care. *See* subsection (g)(3). A child will have 30 days to provide immunization records to the school showing proof of immunization, or to provide a medical certificate, or to satisfy the requirements for an exemption. A child who is unable to provide the necessary records may be excluded at the end of the 30-day period and in subsequent school years until the requirements of the subchapter are met.

Subsection (h). Temporary waiver.

PASA supported the Department's regulation permitting the Secretary to issue a temporary waiver of the immunization requirements if a disaster emergency prevents the child from obtaining immunization records, or if a national shortage of vaccines occurs.

The Department agrees with the commentator.

IRRC asked whether there could be a regional shortage of vaccine and whether that should also trigger a temporary waiver.

A regional shortage of vaccine is possible, although not likely. In the event of such an occurrence, the Department would apply to the CDC for help, and the CDC could choose to redirect available vaccine to the particular area in question. There would be no need to require a waiver.

§ 23.84. *Exemption to immunization requirements.*

Several commentators raised objections to the philosophical exemption, even though it was not a part of the Department's proposed rulemaking, stating that it was too generalized and encouraged parents who have secondary reasons to refuse immunizations to utilize that section as a loop hole to avoid complying with the requirements. One commentator said getting an exemption should be harder than just having to sign a card. One commentator recommended that the Department require church leaders in a child's denomination to legitimize a religious exemption in the same way that a physician signs off on a medical exemption. The commentator stated that this provision is a "catch-all." One commentator recommended that temporary exemptions be reviewed annually, unless a longer period is indicated by the treating physician, and should not exceed a 24-month period. One commentator said that if the exemption were eliminated, parents

could still refuse to immunize, but they would have to find alternative education arrangements rather than the public school systems where fragile children were put at risk.

The Department has made no change to the regulation. The medical and religious exemptions to vaccine requirements are set in statute, and, therefore, may only be changed by the General Assembly, rather than by the agency's promulgation of a regulation. The so-called "philosophical" exemption is merely an explication of existing constitutional law regarding what constitutes a religious exemption. In fact, the Department has noted that in many schools with lower MMR rates there are no religious or medical exemptions. *See* School Level Data, 2014 and 2015, Attachments 1 and 2 to the RAF for Final Rulemaking. Further, with the change in reporting times from October to December in 2014, and then into March of 2016 for the 2015 school year, the immunization rates increased, and the number of children in provisional status decreased. *Id.* This leads the Department to believe that students are simply waiting to be vaccinated. The Department does not believe that vaccination rates in the Commonwealth were impacted by large numbers of religious and medical exemptions; the 8-month provisional period was responsible for lower rates. Shortening the time period for providing a formalized immunization plan, now referred to as a medical certificate, and requiring adherence to that plan should increase vaccination rates more quickly.

One commentator, identifying herself as a board certified family practitioner, stated that there should be compelling philosophical reasons for parents to be permitted not to vaccinate their children. The commentator pointed out that the choice not to vaccinate a child impacts more than that child. There are children and adults who cannot be vaccinated (for example, with HIV

or undergoing chemotherapy). According to the commentator, several vaccine preventable diseases, like chickenpox, are contagious a day or two before any outward signs occur, so that unvaccinated children are subject to harm before anyone is aware of the danger.

The Department agrees with the commentator, but has made no change to the regulation. The medical and religious exemptions to vaccine requirements are set in statute, and, therefore, may only be changed by the General Assembly, rather than by the agency's promulgation of a regulation. The so-called "philosophical" exemption is merely an explication of existing constitutional law regarding what constitutes a religious exemption.

Multiple commentators, including PACIC, stated that each school district creates its own language in communicating with parents regarding vaccine requirements, provisional periods and reporting. The commentators recommended that the regulations be amended to require school districts to use uniform language provided by the Department which would include the text of 28 Pa. Code § 23.24 (relating to exemption from immunization). Several commentators stated that without this information on these important rights, persons will not know whether there are substances in the vaccines that could cause dangerous side effects, and persons with particular religious beliefs, particularly regarding abortion, will be unable to exercise that right since some vaccines have aborted fetal tissue. Another commentator stated that school districts who do not share this information are misrepresenting the truth when they inform parents that immunizations are required for school admission. Several commentators stated that the Department and the Department of Education should create and administer a standard form.

The Department has not revised the regulation. The Department believes that the language in the statute and in the regulations stating that religious and medical exemptions are available is sufficient to inform parents and guardians of their availability. The requirements relating to medical and religious exemptions are not enforced by the Department, however. The statutorily permitted exemptions are within the purview of the school administrator and the school administrator's designee to consider, and the Department does not have the statutory authority to regulate those exemptions. While the Department's enabling statutes give it, with the approval of the Advisory Health Board, the authority to create a list of diseases against which children must be immunized to attend school, those statutes do not give the Department the authority to provide guidance on what constitutes a religious or medical exemption, or how those exemptions should be explained by a school to its students and their parents and guardians. The issue of whether a child has a medical contraindication to a vaccine and should be granted a medical exemption is a medical issue to be decided by the physician who signs the exemption or his or her designee. The issue of whether a school will accept a religious/philosophical exemption is up to the school and its solicitor. The Department cannot provide legal advice on either of these matters, either to the school or the public. Further, the Department cannot dictate language to school administrators. The Department is happy to, and does when requested, provide advice on communications.

One commentator asked that no change to vaccine policy be made, and that the Department not take away the right to the current exemptions. The commentator stated that the number of unvaccinated children is not due to a lack of concern or unawareness of the risks involved in not vaccinating children; rather, it is a firm decision not to vaccinate based on religious beliefs and

on evidence that vaccines, with their harmful ingredients do more harm than good. Another commentator asked the Department to please continue to allow parents the right to refuse vaccinations for their children.

The Department has not eliminated the medical and religious exemptions that exist in statute and does not have the authority to eliminate those exemptions. Only the legislature can remove those exemptions. The Department disagrees with the commentator that valid, peer-reviewed, scientific studies exist that show vaccines do more harm than good, however. The Department points to the study, “Benefits from Immunization During the Vaccines for Children Program Era – United States, 1994-2013,” and the Supplement to that publication, discussed more fully in this Preamble, *supra*.

One commentator took issue with statements made by another commentator that a religious leader from a church legitimize a religious exemption. The commentator stated that this was just another way of trying to strip parents of their right to be in charge of their children’s healthcare. The commentator stated that parents do not need a religious leader to sign a paper saying that injecting our children with aborted fetal tissue or animal DNA is against the parents’ religion, the parent can state that themselves. The commentator stated that a parent’s beliefs are a parent’s beliefs. The commentator warned the Department that “[y]ou are not the parent.”

The Department cannot be responsible for the viewpoints of the commentators that write to express their opinions regarding these or any regulations. The Department has received a wide range of differing views, most passionately held, on the issue of vaccination, exemptions and

human and parental rights. As the Department has stated, however, the Department cannot make any change to the exemption requirements set out in the Public School Code. Parents and guardians will still have access to the same exemptions that have always been available.

§ 23.86. School reporting.

Multiple commentators, including PASA and PSBA, supported the change of the reporting date from October 15 of each school year to December 31 of each school year. Many of these commentators stated that the later reporting date would give the Department additional time to prepare more accurate reports. PSBA stated that this is consistent with the Department's current practice of granting extensions from the October deadline upon individual district request.

PASA asked that the Department ensure that the data collected is absolutely necessary, and that the electronic system being used is easy to use and designed to minimize the reporting burden on local educational agencies. PASA also stated that training on the system should include webinars and on demand videos to minimize staff time and travel.

The Department appreciates the commentators' support. In response to PASA's comments regarding the electronic system, the Department notes that the electronic system is currently in place, has been in place since approximately 2007, and is being utilized by school nurses now. Because not all school districts report electronically, the Department has determined that requiring electronic reporting will speed up the process at every level, and hopefully result in more accurate reporting. The Department has changed the wording of the proposed regulation from those schools who "cannot" report electronically, to those schools who are "unable to"

report electronically to emphasize that all schools that have the means to complete reports electronically should do so. *See* subsection (b). The Department intends to do training.

The PACIC commended the Department's decision to take action to correct statistical errors caused by years of insufficient data collection through the Department's flawed reporting system, which required data to be reported seven months before the students final deadline to turn their paperwork into schools. The commentator stated that the Department should not use this as an excuse to require additional immunization requirements, but should analyze the data and decide whether to make changes. The PACIC stated that since we know that the level of exemptions is low, we must realize that the low rate for MMR for kindergarteners is inaccurate. The PACIC stated that the responsible thing to do in the light of statistical errors to correct the reporting, and then based on accurate data determine whether further action is necessary to reach the herd immunity goal, which PACIC notes is unspecified.

The Department appreciates the support of the commentator, but does not believe its SILR reporting system to be flawed because reports were due seven months prior to a deadline for students. In fact, students are required to have their immunizations on school entry and to attend school. Simply because the Department's regulations allow for a provisional period to enable those students who may have had some problem in obtaining the required vaccination, does not mean that all students are permitted by the regulation to wait that length of time. The Department's change in the requirement is to allow schools additional time to get all information, not to correct some mistake on the Department's part. Further, the Department's decision to add MCV in the 12th grade and to clarify the pertussis requirement had nothing to do

with reporting of vaccine data. The Department's review of the rates of immunization in schools and school districts in the Commonwealth, which, admittedly, does rise with moving the report to a later date, did lead to the Department's concern with the length of the provisional period.

Three commentators have raised the question of privacy. One commentator asked how the Departments of Health and Education will protect medical privacy and ensure that children will not suffer the loss of privacy with the requirement of electronic reporting. The commentator stated that one school district places her child's immunization status on her lunch account, which means that everyone with access to her child's personal account can see her vaccination status on her lunch account. The commentator stated that this was a ridiculous system, and did not afford her daughter the privacy she deserves with respect to medical decisions.

The Department's electronic reporting requirement does not require reporting of student identifying information to the Department. No student names or records are provided to the Department when reports are made under § 23.86. Under that section, schools report aggregate data to the Department, for example, numbers of immunizations by type and in certain years.

With respect to the commentator's concern about a student's immunization information records, the Department's requirements for electronic reporting of aggregate immunization data have no impact on how a school chooses to keep its students' education records. In fact, that question involves the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. § 1232g, which protects a student's privacy. FERPA does not, however, apply to a child's immunization information, which is not considered to be a student education record within the purview of

FERPA.. See <http://www.astho.org/programs/preparedness/public-health-emergency-law/public-health-and-schools-toolkit/comparison-of-ferpa-and-hipaa-privacy-rule/> . If, however, a school chooses to maintain immunization information as part of an education record, rather than as part of the records of the nurse's office, and a school did place immunization information kept in that manner on a lunch account that may be viewed by any person, a FERPA violation may have occurred. Enforcement of FERPA is not, however, within the authority of either the Department, or of PDE.

IRRC asked whether the Department should also be seeking reporting of students in the 12th grade who were denied admission because they could not provide documentation of the required dose.

The Department has not changed the regulations. The Department's requirement for school reporting is based upon CDC requirements that the Department report certain information for the purposes of its federal vaccine grant. The CDC only looks at data for kindergarten and 7th grade. Without an additional federal reporting requirements, the Department is disinclined to place an additional administrative requirement on schools.

D. COST AND PAPERWORK ESTIMATE

1. Cost

a. Commonwealth

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, who are Medicaid eligible or who are Alaskan Native or American Indian. In addition, VFC Program vaccine is also made available to other public clinic sites (Federally Qualified Health Centers and Rural Health Clinics) for the same population, and also for underinsured children through 18 years of age. Vaccines are made available to schools at no cost through the Department's School Based Catch-Up Program for those students who have no medical home or are unable to seek the immunization through a public clinic site. The Commonwealth will realize savings, however, based on the amount of funds that will not be needed to control the outbreak of vaccine preventable diseases. The Department has discussed potential costs related to vaccine preventable diseases elsewhere in this Preamble.

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

b. Local Government

There will be no fiscal impact on local governments. Local governments 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 addresses the potential

impact of these proposed amendments on school districts, which may be considered to be local government, under the heading of “Regulated Community.”)

c. Regulated Community

Families whose children’s vaccinations are covered by their insurance plans (public or private) pursuant to the ACA will not see any out-of-pocket cost for MCV or DTaP vaccines, although they may have additional copayments. 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. According to the Pennsylvania Insurance Department, over 92% of Pennsylvanians are covered by insurance. No child may be denied a vaccine because of his or her family’s inability to pay the administrative fee, however. 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. In addition, obtaining a medical certificate signed by a physician, CRNP or PA or a medical exemption may require an additional visit to the practitioner, and either an additional co-payment, or a paperwork fee. 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. The Department has discussed the costs related to an illness in reference to an outbreak situation elsewhere in this Preamble. 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 6 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 work time lost.

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 as described by commentators. The Department has addressed the cost-benefit analysis of requiring MCV and pertussis vaccination and of childhood immunization in general elsewhere in this Preamble.

The Department has removed the requirement which potentially added the greatest cost for parents and guardians, the requirement that a school was to accept a history of immunity from varicella only from a physician, CRNP or PA, rather than from a parent or guardian.

School districts and schools may see added cost from time spent by school administrators and their designees (most likely school nurses) reviewing the 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. 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 six months prior to the start of the 2017-2018 school year. The Department believes that this additional time will enable schools to provide information to parents and guardians regarding the changes to the regulation nearly 6 months prior to their effective date, and allow parents and guardians ample time to make plans to either obtain immunizations for their children or to obtain an exemption.

The extended time for implementation will provide schools and school nurses with the remaining months of the 2016-2017 school year to begin to prepare for the changes to the required immunizations (which are minimal) and for the shortened provisional period. Schools and school nurses will be able to begin to review immunization status of students, to provide information to parents and guardians, and to determine which students may have issues in the fall of 2017-2018. The Department believes that the 5-day 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 elsewhere in this Preamble.

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 time frame for obtaining those vaccinations in order for the child to be allowed to enter and attend school.

d. General public

The general public will not see an increase in cost. Neither insurance costs nor the cost of the VFC Program should increase because Pennsylvania has chosen to add MCV to the list of required immunizations, or has formalized the addition of a vaccination against pertussis for school attendance. Because these immunizations are already recommended by ACIP, their cost has already been figured into both premium costs and the cost of the VFC Program.

The general public will see a decrease in costs resulting from a reduction in medical treatment needed to treat the disease and a reduction in the loss of work in order to stay home with a sick child. The general public may see a benefit in the reduction of vaccine preventable diseases, such as pertussis, chickenpox, mumps and meningitis. Since the school environment is conducive to the contracting and transmission of diseases among children with no immunity, failure to immunize properly not only puts children at risk for contracting these debilitating diseases, it also places the public at risk since these diseases are then easily spread by staff and children outside the school setting and into the general public. The Department has provided a more detailed explanation of studies supporting these conclusions elsewhere in this Preamble. (The Department addresses the cost of these amendments on parents, guardians and students under the heading of “Regulated Community.”)

2. Paperwork Estimates

a. Commonwealth and the Regulated Community

Schools will be required to report in accordance with the new reporting requirements, which push reporting back to December of each year. School administrators and their designees, mainly school nurses, will continue to report the number of doses of individual antigens that have been administered to students. 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, which is the vaccine that most children 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 and 7th grade. 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 is now requiring that schools provide their reports electronically, and will provide schools with training on the Department's electronic reporting system. Prior to this amendment, schools were encouraged to report electronically, but were not required to do so. The Department will continue to allow schools that are unable to complete reports electronically to provide paper reports, on forms provided by the Department.

School administrators and their designees, mainly school nurses, will be required to review the immunization status of incoming children, as they are currently required to do, but within a 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, the only new immunization schools must ensure that students have is MCV, and only among the students entering 12th grade.

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 the responsibility of the school, as it has always been. School administrators and their designees already review immunization plans and make decisions regarding provisional enrollment. Because of the reasons cited in this Preamble, this will now occur in a shorter time frame. The Department will provide a medical

certificate form to schools, and has attached a draft copy to the RAF for Final Rulemaking as Attachment 3.

The Department will need to review and include reported numbers of doses in its report to the CDC for students in kindergarten and in the 7th grade, as it currently does. There will be no new vaccine listed on those reports.

The additional paperwork requirements for the Commonwealth, including both the Department and PDE, and the regulated community would be minimal, however, since school districts already complete an annual report regarding the number of immunizations and follow up on provisional enrollment. Time frames will be shortened, however, for those reasons previously cited in this Preamble.

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 either a medical certificate from a physician, CRNP or PA setting out the schedule upon which immunizations will be given, and signed by that provider. That medical certificate must be submitted to the school within 5 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.

b. Local Government

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

c. General Public

There is no additional paperwork requirement for the general public. (The Department addresses the cost of these amendments on parents, guardians and students under the heading of “Regulated Community.”)

E. STATUTORY AUTHORITY

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

regulations and make recommendations to the Board for changes the Secretary considers to be desirable.

The Department also finds general authority for the promulgation of its regulations in the Administrative Code of 1929 (71 P.S. § 51 *et seq.*) Section 2102(g) of the Administrative Code (71 P.S. § 532(g)) gives the Department this general authority. Section 2111(b) of the Administrative Code of 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.

F. EFFECTIVENESS/SUNSET DATES

The amendments will be effective on August 1, 2017. This will allow parents, guardians and schools time to become familiar with the requirements, prepare for their implementation and obtain the required vaccinations prior to the start of the 2017-2018 school year. No sunset date has been established. The Department will continually review and monitor the effectiveness of these regulations.

G. REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act (71 P.S. §§ 745.1 – 745.15), the Department submitted a copy of a Notice of Proposed Rulemaking, published at 46 Pa.B. 1798 (April 9, 2016), to the Independent Regulatory Review Commission (“IRRC”) and to the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee. In compliance with Section 5(c) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of all comments received during the formal comment period, as well as other documentation.

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

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

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

H. CONTACT PERSON

Questions regarding these regulations may be submitted to Cynthia Findley, Director, Division of Immunization, Department of Health, 625 Forster St., Harrisburg, PA 17108, (717) 787-5681, within 30 days after publication of this notice in the Pennsylvania Bulletin. Persons with a disability who wish to submit comments, suggestions, or objections regarding the proposed regulation may do so by using the above number or address. Speech and/or hearing impaired persons may use V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800-654-

5984[TT]). Persons who require an alternative format of this document may contact Ms. Findley so that necessary arrangements may be made.

I. FINDINGS

The Department finds that:

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

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

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

J. ORDER

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

(1) The regulations of the Department at 28 Pa. Code Chapter 23 are amended by amending §§ 23.82-23.83, 23.85 and 23.86 as set forth in Annex A.

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

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

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

(5) This order shall take effect August 1, 2017.