

# RULES AND REGULATIONS

## Title 28—HEALTH AND SAFETY

### DEPARTMENT OF HEALTH

[ 28 PA. CODE CH. 23 ]

#### School Immunizations

The Department of Health (Department), with the approval of the Advisory Health Board (Board), amends Chapter 23, Subchapter C (relating to immunization) to read as set forth in Annex A.

#### A. *Purpose and Background*

This final-form rulemaking amends the Department's requirements for school immunizations and is based, in part, upon recommendations of the Advisory Committee on Immunization Practices (ACIP), an advisory committee of the Federal Centers for Disease Control and Prevention (CDC). This final-form rulemaking replaces the 8-month provisional period for immunizations with a new requirement. Previously, the regulations allowed a child to be provisionally admitted to school even though the child did not have all the required immunizations for entry or continued attendance as set out in § 23.83 (relating to immunization requirements) for 8 months before facing exclusion.

This final-form rulemaking requires a child to have any single dose vaccine upon school entry, or risk exclusion. In the case of a multidose vaccine, this final-form rulemaking requires 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 5 days of school, the child shall have either the final dose during that 5-day period, or shall have the next scheduled dose and shall 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 5 days of school, the child may provide a medical certificate on or before the 5th school day scheduling those doses.

The medical certificate shall be signed by a physician, certified registered nurse practitioner (CRNP) or physician assistant (PA). If the child will be receiving the immunizations from the Department or a public health department, a public health official may sign the medical certificate. A child who meets these requirements may continue to attend school even if the child does not have all the required vaccinations, so long as the child complies with the vaccination schedule in the medical certificate. School administrators or their designees are required to review that medical certificate every 30 days to ensure that the child is in compliance. Even with this final-form rulemaking, the child still has the ability to be exempted from the immunization requirements if the child has a medical or religious/philosophical exemption. This final-form rulemaking also provides for certain waivers of the regulation under specified conditions—for example, if the child is homeless or if the child is unable to locate his records due to a disaster.

This final-form rulemaking also adds a dose of meningococcal conjugate vaccine (MCV) for entry into the 12th grade or, in an ungraded class, for entry into the school year when the child turns 18 years of age. This is

in accordance with ACIP's recommendations. The Department also adds pertussis to the list of diseases against which a child shall 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 this Commonwealth prior to this final-form rulemaking were receiving diphtheria and tetanus toxoids and acellular pertussis (DTaP) in accordance with ACIP recommendations (unless the child had a contraindication for the pertussis vaccine or a religious/philosophical exemption) and are already receiving a pertussis component in their vaccinations.

This final-form rulemaking allows the Department to waive the immunization requirements in the case of a National vaccine shortage, or an emergency, and also provides a child transferring into school in this Commonwealth who is unable to provide vaccine records immediately to provide those records or an exemption within 30 days.

Finally, this final-form rulemaking changes the manner and time frames for schools to report immunization rates to the Department to ensure the most accurate immunization data possible from schools.

This final-form rulemaking also amends existing vaccine requirements to acknowledge that certain types of vaccine are no longer available in the United States, including changing the requirements allowing for either a single antigen vaccine for both diphtheria and tetanus and acknowledging that the acceptable immunization is a combination vaccine for diphtheria, tetanus and pertussis. This final-form rulemaking allows for a child with a contraindication for the pertussis component of the vaccine to obtain a combination diphtheria and tetanus vaccination. This final-form rulemaking also adds a second dose of MCV before entry to 12th grade.

This final-form rulemaking does not amend the requirements allowing a child to obtain an exemption from immunization requirements for either religious or medical reasons. Those requirements are statutory and may not be altered through the regulatory process.

Notice of proposed rulemaking was published at 46 Pa.B. 1798 (April 9, 2016), with a 30-day public comment period. The comments and the Department's responses follow.

#### B. *Summary and Overview of General Comments*

The Department received close to 300 letters of comment on the proposed rulemaking. Commentators included individual school nurses, physicians, chiropractors, parents, grandparents, members of the general public, vaccine manufacturers and interest groups such as the March of Dimes, the Pennsylvania Association of School Administrators (PASA), the Pennsylvania State Education Association (PSEA), the Pennsylvania School Boards Association (PSBA), the Pennsylvania Immunization Coalition (PAIC), the Home School Legal Defense Association (HSLDA), the National Meningitis Association (NMA) and the Pennsylvania Coalition for Informed Consent (PACIC). The Independent Regulatory Review Commission (IRRC) also commented.

The comments fell into several broad categories: general support for school immunizations; general opposition to required school immunizations; opposition to vaccines

in general; concerns regarding the cost and benefit of vaccines in general, the meningococcal and pertussis vaccinations in particular; opposition to and support for the reduction of the provisional period; and opposition to and support for requiring a statement of history of varicella disease from a physician, CRNP or PA. There were also demands for Pennsylvania-specific data regarding numbers and costs of outbreaks of disease in this Commonwealth. Many commentators commented on specific sections of the proposed rulemaking. This preamble sets out those general comments as well as comments that are related to specific sections.

*General comments in support of the proposed rulemaking*

PAIC supported the proposed rulemaking. PAIC stated that it is critical to do all that can be done to maintain high rates of childhood/student immunizations, and that the proposed amendments to the immunization regulations would definitely increase "community immunity" in schools and communities, as well as more accurate data collection. PAIC also stated that the rulemaking would decrease the time and labor dedicated by school nurses to remind parents to complete required vaccine series.

The Department agrees with the commentator.

The March of Dimes supported the proposed rulemaking. The March of Dimes stated that it had led successful efforts to develop a vaccine for polio, which ultimately ended the polio epidemic in the United States. The March of Dimes further stated that the CDC declared vaccines to be one of the top ten public health achievements of the 20th century.

The Department agrees with the commentator.

PASA supported the Department's efforts to increase immunization rates of school-aged children to decrease the risk of exposure of communicable disease to students, staff, parents and visitors to public schools. According to PASA, inadequate immunization of school-aged children increases the potential for outbreaks and major disruption in student learning. PASA stated that this has the potential to increase the cost to taxpayers of operating schools during an outbreak by requiring schools to hire substitute teachers and other staff to fill in for staff impacted by the disease outbreak.

PASA also stated that the Department must balance the budgetary limitations and administrative capacity of school districts and other school entities to carry out the new requirements against the public health objective to maximize compliance with the regulations. PASA stated that the cost and paperwork estimates severely understated the increased administrative and paperwork burden on schools. PASA stated that since 2011, school districts have lost more than 23,000 positions due to budgetary reasons, including 600 administrators and administrative positions. Policy change that requires increased staff time to oversee, track, intervene and report on compliance with childhood immunization requirements will either require existing staff to shift existing priorities or require the school district to add staff, perhaps at the expense of addressing other critical needs. The positive intent of the amendments is too important to be lost in the administrative burden that will undoubtedly occur as school districts work to manage the myriad of unfunded mandates that are passed down in the form of regulations and legislation.

The Department appreciates PASA's support of the Department's public health objective. The Department is aware of the budgetary and administrative concerns of schools and school districts. The Department notes that

according to the comments received from many school nurses throughout this Commonwealth, the implementation of this final-form rulemaking will fall on them. According to those school nurses, they are the school staff that are currently checking immunizations, raising exclusion issues and reporting to the Department. Yet PSEA, which provided comments supporting school nurses, did not raise an issue with respect to the shortening of time frames to review medical certificates from 60 days to 30 days, or with respect to reporting requirements. The Department acknowledges that the manner in which school districts are operated is within the purview of school districts, and that having school nurses perform these functions may not be how every school district functions. The Department cannot comment on how many positions in schools have been cut due to budgetary considerations or on how many of those positions were actually concerned with daily immunization compliance in schools.

PSEA supported the proposed rulemaking, although it stated that it understood and respected the concerns that were raised in some of the other public comments submitted to the Department. PSEA stated that it strongly supported the Department's effort to establish a sense of urgency around the issue of immunization by reducing the provisional period from 8 months to 5 days. PSEA stated that this Commonwealth can be proud of its record for immunizing school-aged children, but stated that more needed to be done to reach the herd immunization levels of 95% or greater recommended by the CDC. PSEA stated that this was particularly important for students who are immune-compromised to help reduce their exposure to infections that could have been prevented with a vaccine. According to the PSEA, ensuring that children are healthy is a critical factor for keeping them in school ready to learn. PSEA said that school nurses play an integral part in helping to protect children and entire school communities from vaccine preventable diseases.

PSEA urged the Department to implement evidence-based strategies to increase access to vaccinations where needed. PSEA lauded the Department's "Don't Wait. Vaccinate." program, and urged the Department to work with schools and other community-based partners to increase awareness of this program for students and families.

PSEA also recommended that the Department consider school-located vaccination clinics in areas where there are gaps in providers or other challenges to providing vaccinations to increase vaccine rates by increasing direct access to care in schools. PSEA noted that school-based clinics could be an alternative to vaccination at a physician's office or a public clinic, and would reduce barriers to vaccine access because of family schedules, transportation, or concerns about additional copays or visits to providers.

The Department appreciates PSEA's support of its "Don't Wait. Vaccinate." program, and its recommendations regarding how to increase access to vaccines. Unfortunately, the Department cannot offer school vaccination clinics as PSEA envisions. The Department can only provide vaccines to those children eligible for the Federal Vaccines for Children (VFC) Program. See sections 1902(a)(62) and 1928 of the Social Security Act (42 U.S.C.A. §§ 1396a(a)(62) and 1396s). The only children eligible for this program are children who meet one of a list of criteria. Two of those criteria are that the child shall be either uninsured or underinsured (that is, the insurance that the child has does not cover immuniza-

tions). See section 1928 of the Social Security Act. The Department does provide vaccine for “catch-up” clinics in schools for vaccine-eligible children if the school applies to the Department. The vaccine may only be given to those children who meet the eligibility criteria for the VFC Program. The Department will address the remainder of PSEA’s comments as they apply to specific sections of the regulations.

One commentator, identifying himself as an infectious disease physician, stated that he absolutely agreed with the proposed amendments requiring children attending school to have the appropriate indicated vaccinations to prevent diseases such as measles and other vaccine-preventable diseases.

The Department agrees with the commentator.

One commentator, identifying herself as a school nurse, stated that the proposed amendments were minimal and would help school nurses maintain optimal immunization rates in this Commonwealth, as well as help dispel the misperception that vaccines cause autism and other related complications. The commentator stated that she would like the Department to take on the misinformation that is being spread by a vocal minority, the chiropractic community, as well as certain belief systems that immunizations cause disease rather than protect against it.

The Department thanks the commentator for her support and will address the question of vaccines and their relationship to disease as follows.

PSBA supported the Department’s goals and approach to ensure that children are appropriately vaccinated to safeguard the school community from the spread of certain diseases, but stated that further refinement to the proposed rulemaking would give school districts sufficient time to update the mechanisms used to implement the amended regulations.

The Department appreciates PSBA’s support and will address the remainder of PSBA’s comments as they apply to specific sections of the regulations.

One commentator stated she was in full agreement with the immunization requirements because in her school district there was an outbreak of pertussis at the end of 2015 and “it was a real mess.”

One commentator stated that she supported the proposed amendments because in her area there is an influx of students lacking adequate immunizations and there have been varicella, measles and pertussis outbreaks in her district and in surrounding areas.

One commentator, identifying herself as school nurse writing on behalf of children who are not immunized or who cannot be immunized for health-related reasons, relayed a situation with which she was currently dealing in a school. It involved a suspected case of mumps to which three unimmunized children were exposed. One of those children had leukemia and could not be vaccinated. According to the commentator, it was difficult to tell the parents of the child with leukemia that the potential case of mumps had not been confirmed by a serology test, because without that information a well-considered decision about whether to risk the vaccine for their child or risk the disease could not be made. The commentator pointed out that this also raised questions about excluding the other nonimmunized students who had exemptions based on strong moral and religious beliefs. She stated that parents were questioning the validity of the diagnosis and asking for conclusive information, which she did not have. She stated that if health care providers

would have to confirm cases of communicable diseases by simple means such as serology, the course of action in this case would have been clear. She stated that she is still evaluating the impact of the suspected case of mumps on her school and hoping that no further cases arise.

The Department appreciates the support of these commentators.

One commentator supported the proposed rulemaking and the Department’s efforts to reduce vaccine-preventable diseases in this Commonwealth. The commentator cited the World Health Organization, the CDC and other leading health authorities in stating that vaccines are one of the most valuable health innovations in modern times, and help save and improve the lives of people of all ages around the world. The commentator also cited the CDC as stating that if vaccine rates fall below a certain level, there may be an increase in vaccine-preventable diseases, even if these diseases are no longer common in the United States.

The Department appreciates this commentator’s support and agrees that childhood immunizations play an important role in reducing the incidence of vaccine-preventable diseases.

#### *General comments, recommendations and concerns*

One commentator recommended that the Department simply adopt ACIP’s recommendations regarding vaccinations by reference and avoid the need for the Department’s updating of regulations every time ACIP makes a change to its recommendations. The commentator noted that this would take into account the fact that ACIP’s recommendations evolve over time and would give the Department greater flexibility to modify vaccine requirements on an ongoing basis.

The Department considered this particular comment with regard to ACIP’s recommendations on several previous occasions. After reviewing its previous responses, the Department will not revise the regulations as the commentator requested.

In determining what immunizations to require for school attendance, the Department reviews ACIP’s guidelines and recommendations. The Department does not typically or uniformly accept or adopt all of ACIP’s recommendations, either for the immunizations the Department will require, or for the standards applicable to those immunizations. ACIP’s recommendations are helpful and often definitive but may not take into consideration issues that may be important to the adopting state jurisdiction.

Further, because ACIP’s recommendations are based on the purely public health reason of protecting children from every possible disease, the group does not take into account the possibility of community reaction, nor should it. Practitioners, too, seeking to recommend the best health practices to their patients are not constrained by the need to accept and review public comment regarding the efficacy and necessity of obtaining a particular vaccine. Through this final-form rulemaking the Department is in the position of mandating that a child obtain a particular disease vaccine or be denied access to the educational system for some period of time. To that end, the Department must allow for the public to review and present its concerns regarding this mandate. For example, to have adopted the ACIP recommendations without further review would have mandated the provision of human papillomavirus (HPV) to students attending school without allowing for public comment. Regardless of one’s position with respect to the efficacy of and necessity for

receiving this particular vaccine, the HPV vaccine has given rise to some controversy and concern among the public.

In addition, there are groups of individuals who strongly disagree with any immunization of children, and many of them commented on the proposed rulemaking. Regardless of one's view of this issue, in the context of a regulation that requires immunizations for school attendance, rather than recommending them for personal health reasons, these persons, too, should have a meaningful opportunity to voice their concerns.

Adopting ACIP recommendations upon their issuance would raise other issues. Some immunizations for diseases that are not prevalent in this Commonwealth would involve unnecessary cost to patients. For example, with respect to the hepatitis A vaccine, although ACIP is careful to recommend vaccination against hepatitis A in states that are considered to be at high risk, a simple adoption of ACIP requirements would be insufficient to fully explain to the regulated community, that is, children, parents and guardians, and schools, whether the immunization is or is not required. These persons are unlikely to know that this Commonwealth is, in fact, not considered to be a high risk state for this disease due to low prevalence of hepatitis A disease. This would necessitate additional guidance from the Department in some form.

While the issuance of additional guidance does not, at first glance, appear to be overly burdensome, it is not the effect on the Department that raises the issue here. The Department attempts to make its school immunization regulations as simple as possible to aid schools and school nurses in their responsibilities to make certain only children who are appropriately vaccinated are attending school. To this end, the Department attempts to limit the number of communications with respect to existing requirements. ACIP issues recommendations three times a year and adopting ACIP recommendations wholesale would require schools and school nurses to review children for the appropriate vaccine requirements at least three times each year to ensure compliance with recommended changes.

Adopting ACIP's recommendations, without being able to review and affirmatively accept each one, with whatever modifications deemed necessary, would inhibit the flexibility needed by the Department to apply its and the Board's expertise to the question of what immunizations are appropriate as a condition of school attendance. This requires a balancing of the importance of immunization to children in this Commonwealth in preventing morbidity and mortality, versus the burden the requirements would place upon schools, parents and the community.

In fact, the General Assembly has recognized the Department and the Board as authoritative on the issue of immunizations. In section 16(a)(6) and (b) of the Disease Prevention and Control Law of 1955 (35 P.S. § 521.16(a)(6) and (b)), section 2111(c.1) of The Administrative Code of 1929 (71 P.S. § 541(c.1)) and section 1303(a) of the Public School Code of 1949 (24 P.S. § 13-1303a(a)), the General Assembly authorizes the Department, with the Board and without reference to ACIP, to create a list of diseases against which children must be immunized. To cede this authority to create a list of diseases to a Federal advisory committee that has no rulemaking authority or responsibility, and whose recommendations are not subject to a rigorous rulemaking process prior to issuance, is not in accord with the General Assembly's direction to the Department. It is the

Department's responsibility, with the approval of the Board and the Commonwealth's regulatory review bodies, including the General Assembly, to determine when and how to add required immunizations to the list.

The Department may review standards from groups with expertise in the matters the Department is seeking to regulate and may consult with those groups as well. The Department has done just that, and continues to do, in many areas falling under its purview. When the General Assembly delegates a responsibility to the Department the final execution of that responsibility rests with the Department under the law. Therefore, the Department may review and approve standards recommended by independent entities, but cannot adopt future unspecified and unknown standards and guidelines.

Then, too, there is a question as to whether it is beneficial to allow some time to pass before accepting an ACIP recommendation as a mandate for school attendance. There may be problems with a vaccine that ACIP has not anticipated. The Department notes that, although the vaccine against the rotavirus was not recommended by ACIP for the age group in question here, within 4 months of ACIP's recommendation regarding that immunization, problems arose and children suffered severe injury and death from twisting of the bowel, attributable to the vaccine. If this were to occur following the adoption of an immunization mandate for school attendance, the public's trust in State government to properly protect them could be irreparably damaged.

The Department understands the concern that the regulatory process lags behind current thinking of the scientific community. New vaccinations continue to be developed and recommendations of knowledgeable bodies change from day to day. What remains a constant is the Department's commitment to protect the health and safety of the children of this Commonwealth by ensuring that it exercises its discretion and expertise to review recommendations and only require the most appropriate immunizations for school attendance in this Commonwealth. The fact that this may take some time only means that these vaccinations are not required for a child's attendance at school immediately upon their recommendation by ACIP. It does not prevent a physician from recommending and offering the vaccination to patients when the recommendations are issued. The Department would rather be cautious in the exercise of its discretion than place additional burdens on the citizens of this Commonwealth by relying too much on outside groups and abdicating its responsibilities to take the most efficient and practical means necessary to prevent and control the spread of disease.

One commentator stated that she felt school nurses had not been consulted as to what was best practice in a school setting.

The Department disagrees with this comment. The Department has always been aware of the need for comment by school nurses and, in this case, specifically sent notice by e-mail of the proposed rulemaking to school nurses to solicit their comments. The Department received multiple comments from school nurses.

PACIC stated that the Department did not solicit input from the public in a manner that would allow the most affected parties, parents of school-aged children in this Commonwealth, to participate and comment. PACIC stated that publishing a proposed rulemaking in the *Pennsylvania Bulletin* is insufficient advertising to reach the public. The commentator stated that parents will be

affected but have not been properly involved in the process as the law and regulations suggest they should. The commentator stated that the Department technically followed the regulatory procedure, but should have advertised more broadly to parents as to how they could comment.

As the commentator noted, the Department complied with the requirements of section 5(b) of the Regulatory Review Act (71 P.S. § 745.5(b)), regarding the solicitation of public comment. The Department also advertised and held a public meeting of the Board on November 4, 2015, which is required to approve the list of immunizations. See 45 Pa.B. 6332 (October 24, 2015). See also section 1303(a) of the Public School Code of 1949, section 2111(c.1) of The Administrative Code of 1929 and section 16(a)(6) of the Disease Prevention and Control Law of 1955.

The Department notes that the State Board of Education held public meetings at which its proposed rulemaking regarding nonimmunized children, published at 46 Pa.B. 1806 (April 9, 2016), was discussed. The proposed rulemaking published at 46 Pa.B. 1806 proposed to amend 22 Pa. Code Chapter 11 (relating to student attendance). Opportunities for comment on that proposed rulemaking were provided during meetings of the committee and the Council of Basic Education on January 13, 2016, and the meeting of the State Board of Education on January 14, 2016.

The Department provided information on the proposed rulemaking to school nurses. Finally, the Department notes that although PACIC stated that parents were not involved as they should have been, the Department received nearly 300 letters of comment, many of which were from interested parents, grandparents and other interested persons.

One commentator raised a concern that there are so many students whose parents sign waivers that the actual impact of the final-form rulemaking could be very minimal. The commentator's student population includes a large number of students with autism and special needs, and a large number of underimmunized students.

The Department disagrees with the commentator. The Department believes that its data shows that the number of students obtaining medical and religious exemptions is nominal in general and does not greatly impact the number of overall students not receiving immunizations. The number of children in the 2014-2015 school year, with 4,450 schools reporting, follows. The number of children with medical exemptions in kindergarten was 462 (0.32%) and in 7th grade was 799 (0.54%). The number of children with religious/philosophical exemptions in kindergarten was 2,536 (1.76%) and in 7th grade was 4,010 (2.69%). The number of children admitted provisionally in kindergarten was 13,890 (9.66%) and in 7th grade was 25,265 (16.92%).

For the 2015-2016 school year, with 3,908 schools reporting, the data showed the following.<sup>1</sup> The number of children enrolled with medical exemptions in kindergarten was 795 (0.4%) and in 7th grade was 1,274 (0.5%). The number of children with religious/philosophical exemptions in kindergarten was 4,181 (1.8%) and in 7th grade was 6,580 (2.3%). The number of children admitted provisionally in kindergarten was 6,792 (5.1%) and in 7th grade was 14,383 (10%).

<sup>1</sup> In the 2015-2016 school year, the Department pushed the school reporting deadline back to March 2016.

See School Immunization System, School Immunization Summary both Public and Private Schools, School Year: 2014-2015 (School Immunization Summary 2014-2015), [http://www.health.pa.gov/My%20Health/Immunizations/schoolimmunizationrates/Documents/2014\\_15\\_SILR.pdf](http://www.health.pa.gov/My%20Health/Immunizations/schoolimmunizationrates/Documents/2014_15_SILR.pdf), and School Immunization Law Report System, School Immunization Summary both Public and Private Schools, School Year: 2015-2016 (School Immunization Summary 2015-2016), [http://www.health.pa.gov/My%20Health/Immunizations/schoolimmunizationrates/Documents/2015\\_16\\_SILR.pdf](http://www.health.pa.gov/My%20Health/Immunizations/schoolimmunizationrates/Documents/2015_16_SILR.pdf).

The Department believes that the change in the way children are provisionally admitted to school will reduce the potential for disease at those periods during the school year in which children are underimmunized. There is always the potential for there to be areas with a large percentage of underimmunized children. The Department hopes that education and outreach to health care practitioners as well as to parents and guardians can increase immunization rates school-by-school.

PACIC stated that the Department only provided data regarding the provisional period and did not provide data regarding its reasoning to increase the required number of vaccines. PACIC stated that this was a proposal to force a medical procedure on every student in this Commonwealth, and this is a very serious undertaking and must be considered with the utmost scrutiny. PACIC stated that every aspect of the proposed rulemaking must be supported by data and the Department was lacking in its answer to the questions posed by IRRC. PACIC asked that oversight personnel comb through these comments and consider the seriousness of the matter. PACIC stated that this final-form rulemaking will have serious impacts on the majority of families in this Commonwealth as well as the Commonwealth.

The Department disagrees with the commentator's statement that this final-form rulemaking is an attempt to force a medical procedure on every student in this Commonwealth. A vaccine is not a medical procedure. The Department understands that many commentators believe that the decision whether to vaccinate their children should be made by parents, guardians and grandparents alone, and that immunizations should not be mandated. The Department 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 the comments to the proposed rulemaking, the Department stands firm in its belief that the benefits of requiring certain vaccinations for school entry and attendance outweigh the potential risks raised by commentators. Therefore, the Department did not make changes regarding this topic. The Department addresses the request that it supply data for the additional dose of meningococcal vaccine it is requiring in its responses to that specific section. The Department also supplies additional information regarding the pertussis component of the vaccination in response to comments on that section.

One commentator stated that the proposed amendments would not improve the situation in schools, but changes like requiring a fourth polio dose, a second meningitis dose and a medical certificate with a change in review from 60 days to 30 days will simply create more paperwork for the certified school nurses.

The Department acknowledges the amount of good work school nurses do and will continue to do in the course of changes to the immunization requirements. This

final-form rulemaking is intended to continue to keep children safe in the face of emerging and re-emerging diseases, which requires revisions like adding an additional meningitis dose. The Department notes that former § 23.83(b)(3), final-form § 28.83(b)(2), regarding polio stated that three or more doses were required. As amended in this final-form rulemaking, § 28.83(b)(2) specifies four doses to clarify the regulation. The Department expects that school nurses, in carrying out their responsibilities to ensure the safety of students, are continually reviewing vaccination records and ensuring that children are up to date. The Department is hopeful that with continuing education and the work of dedicated school nurses, the situation in schools regarding immunization levels has improved and will continue to improve.

One commentator commented on the following sentence in the preamble to the proposed rulemaking:

Parents believe that they no longer need fear, as they did in the past, that a child will be blinded, seriously disabled or killed by measles, polio, diphtheria, pertussis, tetanus, hepatitis B or chickenpox since, up to the present time, these diseases do not occur with the frequency that they did in the past.

The commentator stated that in the past families were not as transient as they are now, and that family doctors did not change with the frequency that now may occur. The commentator stated that they did not have to get their medical records to go from one place to another, risking their loss or improper transcription.

The Department does not disagree with the commentator. The Department's only intention in making this particular statement in the preamble was to note that it believed this was a potential cause for the vaccine rates being seen by the Department. Other commentators have seen the same trend. See *Bruesewitz v. Wyeth, LLC* (Bruesewitz), 562 U.S. 223, 226 (2011). ("But in the 1970's and 1980's vaccines became, one might say, victims of their own success. They had been so effective in preventing infectious diseases that the public became much less alarmed at the threat of those diseases.")

*Comments regarding cost and paperwork estimate and affected persons sections of the preamble and Regulatory Analysis Form to the proposed rulemaking*

One commentator stated that the fact that parents would need proof of a medical certificate, or would have to obtain titers to prove an immunization, would result in substantial cost to the parents, and that the Department had not adequately addressed this issue under the cost and paperwork estimate section of the preamble to the proposed rulemaking. The commentator stated that most titers would not be covered by insurance because it is cheaper to revaccinate if in doubt, and titers are very expensive. The commentator also raised the question of additional paperwork and took issue with the Department's statement in the preamble to the proposed rulemaking that the general public would not have additional paperwork, since parents are the general public.

The Department acknowledged the additional cost, time and paperwork to parents of obtaining a history of immunity from a physician, CRNP or PA in the preamble to the proposed rulemaking. Parents are considered part of the regulated community and are addressed in the regulated community section of the Regulatory Analysis Form (RAF) for the proposed rulemaking, and not in the general public section. After reviewing comments regarding paperwork and cost issues of changing the history of immunity language relating to varicella, including the

potential costs of obtaining a blood test to prove immunity, the Department revised the regulation. Further responses to individual comments regarding final-form § 23.83(b)(5)(ii)(B), regarding varicella (chickenpox), are addressed as follows in this preamble. Further costs regarding obtaining a medical certificate are discussed with comments regarding § 23.85(e)(1)(ii) and (iii) (relating to responsibilities of schools and school administrators).

One commentator raised a question regarding the following statement in the affected persons section of the preamble to the proposed rulemaking:

The effects of time and funds spent should be outweighed by the benefits to children and their parents, however. Because requiring these immunizations or a more accurate proof of immunity would protect children from contracting measles, polio, diphtheria, pertussis, meningitis, chickenpox and mumps, and other childhood diseases, their parents or guardians would not have to miss work, worry or pay medical bills related to these diseases. Physicians and health care providers would not have to treat sick children. Department staff would not need to become involved in the prevention of outbreaks of vaccine-preventable diseases as they do now. Children and school staff members who are unable to be vaccinated would be protected as well.

The commentator asked what the actual data shows for this Commonwealth and Nationally. In the commentator's high school, there have been no outbreaks in the past decade. The commentator stated that they have had to participate in two pertussis investigations and a chickenpox investigation, with no student contracting the diseases. The students were in contact with students from 13 other school districts on a daily basis.

The Department disagrees with the commentator. While the commentator stated that her school district had no confirmed a case or outbreak, the school district was still involved in case investigations, all involving time and money invested in contact tracing and immunization of those at risk and all stemming from at least one case with the disease which sparked the investigation. These investigations could potentially result in the exclusion of susceptible students and adults, that is, children and adults without immunizations or evidence of immunity. In the case of a measles outbreak, exclusion may last for as long as 14 days after the appearance of the last case of measles. A disruption, for both parents and the child, even as a potential rather than an actuality, far outweighs cost concerns.

Several commentators, including PACIC, stated that the specific costs in sections 19 and 20 of the RAF for the proposed rulemaking were insufficient to support the rulemaking. The commentators took issue with the Department's reference to the costs of the California measles outbreak and stated that these costs seemed excessive. One commentator requested costs for outbreaks in this Commonwealth, which the commentator believed were much lower. Commentators, including PACIC, demanded more reliable data and a total dollar cost to the Commonwealth before further action could be taken.

Several commentators, including PACIC, stated that the Department should address the cost to the Commonwealth and the cost to families of adverse effects from vaccines. PACIC noted that these adverse reactions can include Guillain-Barre syndrome (GBS), encephalopathy and paralysis, all of which require a lifetime of care at high cost to both the family and the state.

PACIC commented that the cost of a pertussis outbreak, according to a CDC study, is approximately \$2,172 per case. PACIC stated that in 2014 there were 813 reported cases of pertussis in this Commonwealth, and that approximately 50% of those were in school-aged individuals. PACIC stated that the total cost based on these number is \$882,918.

PACIC stated that the Department did not sufficiently describe the cost to each party and did not do due diligence by providing any actual data. PACIC stated that this was an important question that needed to be addressed in detail, with numbers as to the financial and economic impact of this, with copays, lost work hours, lab fees, more reporting procedures and personnel hours. PACIC stated that this would easily total several million dollars, which warrants further examination.

One commentator stated that the Department claimed no costs but many benefits of blanket vaccination. The commentator stated that the Department said there were benefits of sparing children the disease, but no discussion of the costs of side effects. The commentator stated that every vaccine comes with extensive warnings of serious side effects including death, and vaccine manufacturers paid out \$3 billion, so it is clear there are costs. The commentator stated that there is no discussion of the effectiveness of needed levels of compliance to meet the “mysterious” goals of the Department. The commentator asked how many deaths in the United States will balance out the 18 reported disease deaths. The commentator asked how many more cases this Commonwealth had than more highly vaccinated nearby states. If there is no significant difference, the commentator asked why is the Department pushing so hard to force vaccinations. The commentator asked for a real cost benefit analysis instead of “skewed propaganda.”

IRRC also noted that many commentators raised questions with regard to the Department’s answers to the RAF, including sections 17, 18 and 19, stating that costs will run into millions of dollars. IRRC commented that many commentators questioned the applicability of insurance to vaccinations and noted their possible expense. IRRC also stated that commentators have complained that the Department has significantly understated the increased administrative and paperwork burden to school districts. IRRC requests specific cost estimates regarding the impact of the final-form rulemaking on the regulated community.

The Department is aware that some commentators, including IRRC, raised issues regarding insurance and cost, and the issue of when physicians choose to give immunizations. The Department responded to those questions as follows.

The Department disagrees with the comments regarding cost, and has not revised this final-form rulemaking regarding this topic. The Department is not implementing an entirely new school immunization requirement and reporting system. In this final-form rulemaking, the Department reduced the provisional period, which already existed in some form, added a vaccine requirement for entry into the 12th grade and, by adding pertussis to the list of diseases against which a child shall be vaccinated for school entry and attendance, clarified that the ACIP-recommended vaccine for the diphtheria and tetanus requirement is a vaccine that includes a pertussis component, DTaP, unless pertussis is contraindicated for that child. Although the diphtheria-tetanus toxoid vaccine (DT) is available, there are no single antigen diphtheria,

single antigen tetanus or single antigen pertussis vaccines available in the United States.

In determining a cost/benefit of adding vaccine, the Department looked at recommendations by ACIP, including ACIP’s own cost/benefit analysis, the fact the vaccine was licensed by the United States Food and Drug Administration (FDA), which reviews safety trials before licensing vaccines, and the costs of outbreaks and disease on students, their families and the Commonwealth. The Department did provide cost data from a recent measles outbreak in California and also provided data regarding cases of that disease in this Commonwealth. While it has not done a study on costs of outbreaks in this Commonwealth, the Department believes the costs of outbreaks in other states, including California, should be sufficient to provide information on what the cost of a vaccine-preventable disease in this Commonwealth could be. The claim that actual costs in this Commonwealth might be different is correct, depending upon the relative dollar amounts for the costs that go into an outbreak response. However, the types of costs are the same, because the methodologies used for disease control are the same. These costs are discussed generally as follows and discussed regarding MCV separately.

With respect to the cost of adverse events regarding vaccines, and the cost effectiveness of vaccines, the Department disagrees with the commentators. At least 1 study suggests that childhood vaccination will prevent an estimated 322 million illnesses, 21 million hospitalizations and 732,000 deaths over the lifetimes of children born between 1994 and 2013. Whitney, MD, C. G., Zhou, PhD, F., Singleton, PhD, J. and Schuchat, MD, A. (2014), “Benefits from Immunization During the Vaccines for Children Program Era—United States, 1994—2013” (Benefits from Immunization), *Morbidity and Mortality Weekly Report (MMWR)*, 63(16), 352—355, retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6316a4.htm>. The “Benefits from Immunization” study concluded that vaccination would potentially avert \$402 billion in direct costs and \$1.5 trillion in societal costs because of illnesses prevented in birth cohorts between 1994—2013.<sup>2</sup> The study found routine childhood vaccination to have created \$107 billion in direct costs and \$121 billion in societal costs. After accounting for these costs, this study found the net present values, or net savings from payers’ and societal perspectives, to be \$295 billion and \$1.38 trillion, respectively. While no one has undertaken a specific analysis of Pennsylvania data for these studies, data from this Commonwealth figured into this research.

With respect to the data provided by PACIC regarding costs of a pertussis outbreak, the Department notes that this is not Pennsylvania cost data, but is data from a school-based pertussis outbreak over 3 months in 2008 in Omaha, NE. “Local Health Department Costs Associated with Response to a School-Based Pertussis Outbreak—Omaha, Nebraska, September—November 2008” (Omaha

<sup>2</sup>The study considered program costs, including cost of the vaccine, cost of administration, vaccine adverse events, and parent travel and work time lost. The cost analysis was conducted from both health care (direct) and societal (indirect and direct) perspectives. Direct costs included outbreak control and outpatient and inpatient visits. Indirect costs included the productivity losses from premature mortality, which was estimated using the human capital approach. Costs for work were determined by the number of days of missed work (for provision of care to sick children, for illness among cohort members or for resulting disability) multiplied by the daily wage rate associated with the value of lost wage-earning work and the imputed value of housekeeping and home-care activities. The cost of vaccine administration from a private provider was estimated at \$29.07. The cost of vaccine administration at a public clinic was estimated at \$8.15. The study’s authors assumed that caregivers take 2 hours off from work to take the child for a vaccination, based on previous economic studies. The study’s authors then assumed that the average cost for these caregivers was \$18.19 per hour, and that the cost for travel to a clinic was \$23.45. See VFC Publications: Supplement, Appendix: Methods for the cost-benefit analysis in “Benefits from Immunization,” retrieved from <http://www.cdc.gov/vaccines/programs/vfc/pubs/methods/>.

Study), *MMWR*, 60(1) (2011), 5–9, retrieved from <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a2.htm>. The “Omaha Study” found that the cost per case was indeed \$2,171 and that cost was attributable to the local health department, approximately 1% of the local health department’s annual budget, which would affect taxpayers. The “Omaha Study” stated that:

1) staff members reported 1,032 person-hours spent responding to the outbreak, and 2) the total cost of outbreak response, including overhead, labor, travel, and other costs, was \$52,131 (measured in 2008 U.S. dollars). The majority of costs (59%) occurred during an intensive 10-day period, when most of the contact tracing and prophylaxis recommendations were made.

The outbreak took up a great deal of staff time according to the “Omaha Study,” which found that each case of pertussis required nearly 42 regular person-hours and approximately 1 hour of overtime. The time spent investigating a pertussis case included tracing of all close contacts and each pertussis case led to an average of 21 telephone calls and chemoprophylaxis recommendations for 6 close contacts. The health department did not pay for antibiotics or laboratory testing, which presumably was borne by the individuals through insurance or otherwise. According to the “Omaha Study,” “[o]f the total cost, the largest components were investigations (37.2%) and decisions and implementation (22.9%). Resource use was most intensive during the outbreak period for all divisions [of the health department involved] Epidemiology (156% of budgeted hours), Administration (46%), and Media Relations (41%).” The Epidemiology Division had a resource use of 156%, reflecting overtime and compensation hours worked during the outbreak period. In total, staff members reported 28 hours of overtime with the largest component of overtime allocated to investigation-related activities.

In reviewing the findings, an editorial note to the “Omaha Study” stated that they were subject to at least three limitations:

First, this report focused on the direct public cost incurred by a local health department in response to a pertussis outbreak. The private costs of pertussis, including those costs borne by patients, persons recommended chemoprophylaxis, health-care providers, or institutions, were not analyzed in this study. However, private costs of pertussis are well studied elsewhere and can be substantial (8,9). Second, although this report measured the total delay in projects resulting from the outbreak, it did not measure the type or number of projects delayed. Future cost analyses also should measure the “opportunity cost” of outbreaks in more detail. Finally, although these data offer a picture of public health cost when responding to an outbreak, they only reflect the resource use of one health department and might differ for other health departments. For example, health departments that pay for laboratory testing and antibiotic courses for patients would incur additional costs.

In short, the costs to the government, including taxpayers, and to the health system of any outbreak response can be significant.

The Commonwealth would respond to an outbreak in the same way that Nebraska did. Once a case is reported, the individual, or the parents or guardians of a child, is interviewed and close contacts are identified. Those individuals are contacted and interviewed to find more

contacts. Depending on CDC recommendations, different drug regimens may be prescribed. Depending on the disease, children and adults who are presumed susceptible or are unvaccinated, those who cannot prove a history of immunity depending on the disease in question, or those showing symptoms may be excluded from school until they are treated or until the exclusionary period ends. That period differs for different diseases. For example, with measles, the exclusionary period for susceptible children is 14 days from the date of the last case. The more cases that are reported, the longer the exclusionary period.

In the Nebraska case, chemoprophylaxis was recommended for those persons who had direct face-to-face contact with an ill person, who shared a confined space with an ill person for more than 1 hour, or who had direct contact with respiratory, nasal or oral sections from a symptomatic person. The health department in that case recommended exclusion from school of persons with a cough until they were evaluated by a doctor and then, when more cases were reported, recommended students with a cough be excluded until evaluated by a physician and either treated or determined to have pertussis.

The Department has not looked at cost in a school-based outbreak of pertussis, but it has looked at cost in a pertussis outbreak in a health care facility. In that circumstance, it took upwards of 2 weeks to diagnose the case, and by that time there were a number of symptomatic health care workers and many exposed contacts. The costs to the health care facility approximated \$74,870, including laboratory tests, antibiotic treatment and prophylaxis, and incidental costs (labor and postage). There were also indirect costs to the health care facility of \$11,200, including furloughs of workers. The health care workers themselves ended up with direct costs of \$4,679 in outpatient visits, hospitalization and medications, and indirect costs of \$1,730 in time lost from work.

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

In addition, the Department knows of a circumstance that would certainly involve cost in a situation with a potential disease outbreak involving health care workers. In that situation, an unvaccinated child was seen at a provider with a potentially highly infectious disease. The suspect case was reported to the Department. The following day specimens were taken and sent to the CDC for testing. The 3rd day press releases regarding exposure were issued (the child had been in various places during the period of communicability) and immunization clinics were set up. Immunization clinics continued on the 4th day. The 4th day additional titers from unvaccinated health care personnel or those without immunization records were drawn for testing. On the 5th day, the provider office and building where the child had been were closed. The results from the CDC came back negative on the 6th day, and the office reopened 1 week later.

During this potential outbreak, 186 contacts were followed by the Department, 93 of them were quarantined

and 119 were immunized. This involved intense coordination with multiple practices located in the building, to talk to staff and to notify patients who could have been at risk. In addition, multiple employees of the practice who did not have titers drawn or records of immunization could have been quarantined until either titers were drawn, or the situation resolved itself. There was a disruption in the lives of patients and employees, loss of revenue to the practices and loss of work by the employees.

The CDC also looked at the economic burden of 16 measles outbreaks on public health departments in 2011. In that study, the estimated number of contacts was 8,936 to 17,450 persons. The estimated number of personnel hours ranged from 42,645 to 83,133. The estimated economic burden ranged from \$2.7 million dollars to \$5.3 million dollars.

The Department also did a literature review regarding the costs of measles outbreaks and found the following: Iowa, 2004, \$142,452; California, 2008, \$176,980; Arizona, 2008, \$799,136; Kentucky, 2010, \$24,569; Utah, 2011, \$130,000; and Challam County, Washington, 2015, \$200,000. Dayan, G. H., Ortega-Sánchez, I. R., LeBaron, C. W. and Quinlisk, M. P. (2005), "The Cost of Containing One Case of Measles: The Economic Impact on the Public Health Infrastructure—Iowa, 2004," *Pediatrics*, 116(1) retrieved from <http://pediatrics.aappublications.org/content/116/1/e1>. Chen, S. Y., et al. (2011), "Health Care-Associated Measles Outbreak in the United States After an Importation: Challenges and Economic Impact," *The Journal of Infectious Diseases*, 203, 1517—1525, retrieved from <http://jid.oxfordjournals.org/content/early/2011/04/25/infdis.jir115.full.pdf+html>. Iannelli, MD, V. (2016), "Costs of a Measles Outbreak: Measles Outbreaks are Expensive to Contain," *Verywell*, retrieved from <https://www.verywell.com/costs-of-a-measles-outbreak-2633850>.

The Department weighed the potential costs of an outbreak to this Commonwealth to the Department, to the regulated community, including parents, guardians and children, both vaccinated and unvaccinated, to the health care sector and to the wider community against the costs of copayment, the potential for adverse reactions to children from these vaccinations and the costs of those adverse reactions. In the end, the Department believes it is appropriate to require these immunizations. The Department also relied upon ACIP's recommendations, including its cost and benefit analysis, the cost and safety analysis done by the FDA in licensing both MCV and DTaP. Additional cost benefit information regarding MCV, including references to the cost-benefit analysis performed by ACIP, is included in the Department's responses to § 23.83(c)(2). The General Assembly has given the Department the authority to balance these costs and concerns and to then create the list of diseases and conditions against which children must be vaccinated to enter and attend school. The Department has exercised its discretion in this regard in promulgating this final-form rulemaking.

PACIC commented that the Department's response to section 23 of the RAF, which requires an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government and State government for the current year and 5 subsequent years, did not contain data and that the estimated cost to the State government should read "at least \$1,701,245."

The Department addresses the question of the cost-effectiveness of meningococcal vaccine in the response to

comments on § 23.83(c)(2), and notes that cost-effectiveness studies leading to ACIP's recommendations included adverse events. With respect to PACIC's comment regarding the appropriateness of the information in section 23 of the RAF, regarding to cost to State government, PACIC misunderstands the purpose of this section. To determine State costs of a proposed or final-form rulemaking, the cost to the State government is considered to be cost that must be made up by new State dollars. The Immunization Program is not new and is not funded by State dollars, so there are no costs reflected for State government in section 23 of the RAF. The cost of the Immunization Program, or program expenditures, is reflected in section 23a of the RAF and includes the potential amount for administration of vaccine doses. Section 23a of the RAF showed the budgeted amount for the Immunization Program for that fiscal year and for the past 5 years. In the RAF for this final-form rulemaking, the Department shows no new State dollars in the cost because there are no new State dollars funding the Federally-funded Immunization Program.

#### *Comments regarding the VFC Program*

PACIC stated that the box allocated for the economic cost of the regulated population should include copayments for at least 868,823 students not eligible for the VFC Program, as students entering 12th grade have no other requirement for a doctor's visit (such as a physical or other examination). PACIC stated that this will incur an office visit fee estimated at \$20. PACIC stated that this totals \$17,376,460. PACIC asked how many children are using the VFC Program and requested data and details about the popularity and funding of the VFC Program.

The Department disagrees with the commentator. The number of students cited by PACIC is not the number of children entering 12th grade in any given year, but the number of children in this Commonwealth eligible for the VFC Program in 2014 in all grades. PACIC appears to be arguing that, since children entering the 12th grade have no other reason to be seen by a health care provider, there will be additional copayments that cannot be attributable otherwise than to administration of the vaccine. If this is the case, and the Department notes that children may receive the dose at 16 years of age, which may coincide with other scheduled childhood physicals, the total number of students entering 12th grade in 2014 was 147,040, as the Department pointed out in the RAF for the proposed rulemaking. A study of the VFC Program from 1994 to 2013 suggested that 70% of children obtained their vaccines from private providers, and the cost of administering a vaccine was roughly \$29.07 per child (in 2013 dollars). See Appendix: Methods for the cost-benefit analysis in "Benefits from Immunization."

The Department noted in the RAF for the proposed rulemaking that in this Commonwealth, approximately 50% of the children are eligible for the VFC Program. However, the Department does not collect utilization data for the VFC Program. For public clinics, the Department noted that the maximum regional charge in this Commonwealth was \$23.14 per administration of the dose to a child. Using the study numbers, the total cost of copayments for persons not obtaining their vaccines from the public sector would be roughly \$2.9 million dollars, or \$29.04 per child. The Department again points to the study done on the net cost savings from childhood vaccines from 1994 to 2013, the fact that ACIP has done a cost-effectiveness study of two doses of the MCV vaccine and recommends that second dose, and the fact that the

FDA has licensed the vaccine. Cohn, MD, A. C., et al. (2013), "Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" (Prevention and Control (2013)), *MMWR*, 62(RR 2), 1–27, retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>. The Department finds that the requirement of MCV in the 12th grade is safe and cost effective. The Department also notes that parents and guardians have the option of seeking both medical and religious exemptions.

In response to the commentator's question regarding funding for the VFC Program, the program is funded by Federal dollars. The Pennsylvania VFC Program budget for Fiscal Year 2015-2016 was \$77,363,406.70.

*Comments regarding whistleblower law suit against Merck*

Several commentators mentioned that Merck, which has offices in this Commonwealth, is currently defending its measles, mumps and rubella (MMR) vaccine against Federal antitrust law suits. These commentators noted that employee physicians and scientists claim that data regarding the vaccine's efficacy was falsified, the drug was mislabeled and information was intentionally concealed. They further noted that these factors have implications for the Federally-granted monopoly for the MMR vaccine recommended by the Federal government, and mandated by all states for entry into schools.

Another commentator also raised the Merck lawsuit and asked if this was why children must now get two doses of the MMR vaccine, since the company claims that the 20% of the population will not be properly immunized with just one dose anymore. The commentator asked how pharmaceutical companies can be held accountable for failing products if children's titers are not checked after routine vaccination. The commentator stated that her youngest daughter was tested several years after her first MMR and had no immunity to rubella afterwards. The commentator asked how likely it was that she was just one of the supposed 20% that will not respond and will need a second booster. The commentator asked whether the same phenomenon was occurring with the combination diphtheria, pertussis and tetanus vaccine, where it is being proposed that 12th graders receive a third dose of this combination vaccine. The commentator asked how many times adverse reactions and permanent injury in children should be risked. The commentator questioned who was actually checking the children to see if they possess the titers to these diseases in their blood stream. She asked whether it was safe to give all these vaccines at once. The commentator asked that the Department require titers to be routinely tested in children following vaccination, for example. The commentator stated that it was her hope that children can one day be vaccinated safely for their health and not for a drug company to prosper.

Two commentators stated that Merck's MMR vaccine is the subject of a separate whistleblower claim and that the data linking the vaccine to autism was suppressed by the CDC. One commentator stated that this is especially significant since this tainted study is the one that was relied upon by the National Institutes of Medicine when it investigated and concluded that there was no autism link.

The Department's requirement that a child have immunity to MMR is not the subject of this final-form rule-making. The Department did not require that all children have the MMR vaccine because Merck has offices in this

Commonwealth. The Department is not requiring all children receive titers to determine immunity; for measles and mumps immunity, children may show a physician, PA or CRNP history, or a blood test result to prove immunity if they cannot show a vaccination. The Department proposed to require the same level of history of immunity for chickenpox. However, the Department decided to withdraw that requirement because of the cost of the blood test. The same concern regarding requiring a titer to show measles immunity would apply here. There would be a concern regarding coverage by insurance for the test in the absence of an actual outbreak. Regarding the commentator's concern about a third dose of MMR in the 12th grade, the regulations do not require this. The Department is requiring a second dose of MCV in the 12th grade. The Department's responses to comments regarding that requirement follow.

The Department believes that combination vaccines are safe. In making that determination, the Department relies upon ACIP, the licensure requirements of the FDA and the credible scientific literature; studies have found no evidence of harm in combination vaccinations.

The Merck whistleblower case involves questions surrounding the efficacy of the mumps vaccination. The Merck case is ongoing. The Department deplores the act of placing children at risk by falsifying data, if that occurred. Commentators' allegations that information connecting the MMR to autism were suppressed by the CDC are addressed as follows.

*Relation of vaccines to autism, chronic disease, injuries and illness*

Several commentators stated that the autism rate is now 1 in 45 according to a UPI report, while in the 1980s the rate was 1 in 10,000. The commentators stated that the rise in the autism rate correlated with the increased number of vaccines children are required to take. The commentators stated that although it was not the only cause for the rise, it was a cause that needed to be addressed. The commentators stated that there are many stories of mothers taking perfectly healthy children to the pediatrician and after the child is given multiple vaccines at the same time they regress and are never the same. According to the commentators, many mothers know that this was the exact day their child developed autistic behavior. They are told it is coincidental and forced to fight for their rights in Vaccine Court. The commentators stated that the National Vaccine Injury Compensation Program has awarded more than \$3.3 billion over the life of the program to families whose children were injured by a vaccine. According to the commentators, there is massive underreporting of adverse vaccine events because many parents do not realize the ensuing illness could be related directly to the vaccine recently received. The commentators asked that if vaccines have been proven safe and effective, why has the "vaccine industry" been protected from liability and lawsuits. The commentators asked that if they are "deemed to be extraordinarily safe" by a leading proponent of vaccine in the Philadelphia medical community, why are they shielded from lawsuits. According to the commentators, the same doctor stated that he believes that a child's "immune system could theoretically handle 10,000 vaccines at one time." The commentators asked whether "any professional in their right mind could believe such a statement."

The Department has not revised this final-form rule-making in response to these comments. The Department addresses the issue of liability of vaccine manufacturers as follows in this preamble. In response to the question

asked regarding why there is a need for the Vaccine Court if vaccines are safe, the Department notes, as it has always stated, no vaccine is either 100% effective or 100% safe. To determine whether or not a vaccine should be approved or given, the question that must be weighed is whether it is safer to take the vaccine or risk the disease. The Department maintains that for those children without contraindications to vaccines, receiving the vaccines recommended by ACIP and included in the Department's list of immunizations that are required prior to school entry and for school attendance, a child is safer receiving the vaccine than not doing so.

One commentator stated that there was no merit in the contention that unvaccinated persons posed a health threat to others. The commentator stated that the literature shows that unvaccinated persons are generally healthier and have good immune systems that are not assaulted by numerous toxins found in vaccines. The commentator stated that prior to the massive number of vaccines being given to children, there were not as many cases of the diseases of asthma, atopy, allergy (often life threatening), autoimmunity, autism, learning disorders, communication disorders, developmental disorders, intellectual disability, attention deficit disorder, disruptive behavior disorder, tics, Tourette's syndrome, seizures, febrile seizures and epilepsy, and diabetes. According to the commentator, these events "scream for a response." According to the commentator, the Department should not be adding to the misery of parents and children by increasing the mandate for more vaccinations.

One commentator stated that as a grandparent, she and her daughter have done research so that they could make an informed decision on vaccinations. Based on their findings and their beliefs, they have opted not to vaccinate their children and stated that no one can be more concerned for the safety and welfare of their children than they are. The commentator asked that the Department help protect their parental rights. The commentator stated that there are proven concerns regarding the safety and efficacy of vaccines, as recent outbreaks of mumps and measles show. The commentator stated that nonvaccinated children are not a threat to the public at large.

Several commentators stated that known problems with vaccines are rarely acknowledged by public health officials. One commentator noted that chronic conditions in children have skyrocketed in recent decades and according to the CDC one in six children have learning disabilities. The commentator stated that public health officials cannot explain this decline in children's health and why 43% to 54% of all American children suffer with one chronic illness requiring health insurance reimbursement, including 26% of children under 6 years of age at high risk for developmental, social or behavioral delays. Two commentators stated that developmental disabilities among American children have increased by 17%, a fact which is admitted by government officials, and is led by a rise in autism and attention deficit hyperactivity disorder (ADHD).

One commentator also stated that as a physical therapist, she has witnessed the epidemic of autism that plagues the Nation. The commentator stated that since the government deregulated the field of biotechnology in the 1980s, there are no long-term studies measuring the effects of genetically modified organisms (GMO) and adjuvants such as aluminum on human tissues located throughout various places of the body, especially the nervous system. The commentator stated that since

GMOs have been introduced, there has been a steady upward trend of autism, various autoimmune diseases, Alzheimer's disease and cancers throughout our population. The commentator stated that the situation is completely out of control, and various health and environmental changes brought about by the biotechnology field need to be examined before more potential harm is done.

The Department disagrees with the commentators. The Department's final-form rulemaking does not involve all vaccines available for children, or even all vaccines on the Department's list of immunizations that are required for school entry and attendance. This final-form rulemaking only deals with the addition of one dose of MCV in the 12th grade and a pertussis dose for attendance. One commentator references GMOs, yet does not point to any specific organism in either of those vaccinations that would be considered a GMO. With regard to aluminum, about which several commentators raised issues, the Department notes that DTaP does include a form of aluminum. It is included in vaccines to enhance the immune system's response to the vaccine. It has been safely used for decades. Brown, MD, FAAP, A. "Clear Answers and Smart Advice About Your Baby's Shots" (Clear Answers and Smart Advice), Immunization Action Coalition, item No. P2068 (8/16), retrieved from [www.immunize.org/catg.d/p2068.pdf](http://www.immunize.org/catg.d/p2068.pdf). The National Vaccine Program Office and the World Health Organization have determined that the amount of aluminum in vaccines is safe. If a baby follows the standard immunization schedule, the baby is exposed to about 4–6 milligrams of aluminum at 6 months of age. By comparison, the baby is exposed to 10 milligrams if he is breastfed, 40 milligrams if he is fed cow's milk-based formula or 120 milligrams if he is fed soy formula. A standard antacid tablet contains about 200 milligrams of aluminum. "Clear Answers and Smart Advice," citing Children's Hospital of Philadelphia, Vaccine Education Center, [www.vaccine.chop.edu/service/vaccine-education-center/hot-topics/aluminum.html](http://www.vaccine.chop.edu/service/vaccine-education-center/hot-topics/aluminum.html) (accessed July 30, 2016).

One commentator stated that vaccines are medical procedures that can cause serious injury and death, and additional information should be provided before mandating that children in this Commonwealth receive more of them to attend school. The commentator asks that the Department and the Department of Education provide annual statistics to IRRC and the public that compare the number of vaccines suggested by ACIP and mandated by the Commonwealth along with the number of children who have autism, learning disabilities and require additional support in school. It would be informative to have the educational costs associated with special education learning support, and the like, over the past 30–40 years. Another commentator asked the Department of Education to provide statistics to evaluate the increase in special education teachers, aides and funding over the last 50 years. The commentator also requested studies that compare the health of vaccinated versus unvaccinated children, which would enable more informed decisions about the overall health of children in this Commonwealth, rather than focusing so single-mindedly on vaccination rates.

One commentator stated that there is much concern over vaccines right now due to the number and type of vaccines that are being given to babies and young children. The commentator stated that more and more information and research is coming out every day and people are starting to become educated on what they are injecting into their children. The commentator asked that the Department slow down changes and additions to the

vaccine policy for young children. The commentator stated that responsibility must be taken for the safety of children in this Commonwealth because the vaccine manufacturers do not.

One commentator stated that the three of her children had been affected by vaccinations—one child has ADHD, one child has autism and one child is prone to epilepsy. She stated that she had to do extensive therapies to restore their immune systems.

One commentator stated that her child received vaccinations until he was 8 years of age because by that time he had had several years of pneumonia vaccinations but got sick with pneumonia four times.

One commentator, speaking for himself and his spouse, stated that vaccines were a violation of their religious beliefs. The commentator further stated that there was overwhelming evidence that vaccinations were connected with autism and various other serious health issues. The commentator stated that this was vindicated for his spouse and himself by a personal experience with a relative when the relative was a child because the relative was perfectly normal prior to the vaccine.

The Department disagrees with the commentators and has not revised this final-form rulemaking. The Department is not promulgating a new regulation that would, for the first time, require vaccines for school entry and attendance. The Department is only adding MCV in the 12th grade to the list of required immunizations and is formalizing the requirement of a first dose of pertussis, which, due to the lack of single antigen vaccines for diphtheria and tetanus in the United States, has been in place de facto for some time. The Department discussed the risks versus the benefits of pertussis and MCV vaccines in the sections of this preamble regarding those immunizations and also addressed the safety of combination vaccines in this preamble. The Department notes that the religious exemption is available for persons for whom vaccination is a violation of their religious beliefs.

The Department can and will address cost issues regarding a second dose of MCV and pertussis, but does not have access to and does not see the utility of a set of numbers showing the number of children with autism, learning disabilities and who require additional support in school, and the number of children who have vaccines. The fact that either of the two numbers go up or down, or are large or small, without more, does not prove a theory, show a corollary or provide causation. There is no credible study showing a link between autism and the MMR.

In fact, the Department is not aware of any valid, scientific study that finds that any of the diseases of asthma, atopy, allergy, autoimmunity, autism, learning disorders, communication disorders, developmental disorders, intellectual disability, attention deficit disorder, disruptive behavior disorder, tics, Tourette's syndrome, seizures, febrile seizures and epilepsy, and diabetes are caused by childhood vaccinations. A study by two British doctors published in the British publication *The Lancet* claiming to have found a link between autism and the MMR vaccine was later retracted by *The Lancet* following controversy regarding the conduct of the study. Wang, S. S. (February 3, 2010), "Lancet Retracts Study Tying Vaccine to Autism," *The Wall Street Journal*. Other researchers were unable to replicate the results and eventually there were allegations of fraud against the lead author. "Clear Answers and Smart Advice"; Offit, MD, P. A. and Bell, MD, L. M. (2003), *Vaccines: What You Should Know*, New Jersey: Wiley. The lead author even-

tually lost his medical license to practice in England. See <http://briandeer.com/solved/gmc-wakefield-sentence.pdf>.

One commentator stated that the Department is using scare tactics to force parents to inject their children with known toxins with no regard to their actual safety. The commentator noted that the United States was the most widely vaccinated country with the highest rate of chronic illness in the world. The commentator stated that more honest research needed to be done on the true effects of the vaccinations being forced on the unsuspecting public.

The Department cannot force parents to inject their children, nor can it forcibly inject children itself. The Department can based on recommendations by ACIP following licensure by the FDA, and based on the advice of its staff of experts, choose to add certain vaccinations to the list for which students are to be vaccinated to attend school. The Department notes that the medical and religious/philosophical exemptions still exist for parents or guardians who wish to avail themselves of them.

One commentator stated that vaccines cannot protect health; only a strong immune system can protect health. The commentator stated that the immune system needs whole foods, clean water, sunshine and fresh air to function at its optimum level. According to the commentator, the immune system is incredibly powerful when it is given what it needs. The commentator stated that vaccines introduce into the body nothing but known toxins, carcinogens and undigested proteins from animal and human tissues on which they are grown. The commentator stated that they are contaminated with other diseases causing viruses and bacteria including retroviruses, tuberculosis, SV40 virus and syphilis. The commentator stated that vaccines stimulate the wrong part of the immune system. Natural infection stimulates the first line of defense, cell-mediated immunity. This is what is needed for long-term immunity and to effectively clear the virus from the body. According to the commentator, a vaccine triggers a humoral response, which is an inflammatory response. Inflammation causes disease, and this response is not desirable and is not the body's natural response to infection. A humoral response cannot effectively eliminate the injected virus or bacteria from the body. The commentator stated that the body's protective barriers are designed to prevent viruses and bacteria from gaining access to the body's vital organs. The commentator stated that the vaccines bypass the protective barriers and put toxins into the muscle which in turn go directly into the bloodstream and then circulate to the body's vital organs. The commentator stated that death rates from diseases in the 1850s and 1950s fell 90% before vaccines were introduced, due to improved sanitation and better nutrition. The commentator stated that to date at least 413 abortions were performed specifically for the development of vaccines. The commentator stated that the already born person is not more valuable than the unborn person. The commentator stated that infectious disease is not epidemic in this country because of public sanitation, but the real epidemic is that one in six children have learning disabilities, autism, asthma and allergies. The commentator stated that true public health cannot be attained when true measures of health are ignored in favor of allopathic medicine. Allopathic medicine offers only toxic drugs or surgery to cover symptoms. The body uses symptoms to cure itself. According to the commentator, health care and science cannot advance positively if only one model of health is forced on society. The commentator asked that the Department research the harmful effects of vaccines before mandating them.

The Department disagrees with the commentator. The Department respects the views of the commentator regarding allopathic medicine and the commentator's wish that more than one health care model be considered. The Department points to the public health achievements of the 20th century, including the near eradication of polio and the eradication of smallpox, both of which were achieved with vaccination programs. The Department takes issue with the statistic quoted by the commentator regarding the decline in disease, and the attribution that a decline was due merely to sanitation. The Department notes that the great polio outbreaks during the century occurred in the 1950s. "Achievements in Public Health, 1900—1999 Impact of Vaccines Universally Recommended for Children—United States, 1990—1998" (Achievements in Public Health), *MMWR*, 48(12) (1999), 243—248, retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/00056803.htm>. The Department is aware that no vaccine is 100% effective and that in some cases, including with smallpox, immunity has been found to have waned. However, even if immunity has waned, a vaccinated individual still has some protection and is likely to have a less virulent form of the disease.

The Department does not disagree that chronic disease is an issue in the United States, but it does not agree that a link between those diseases and immunizations has been scientifically shown. Instead, the Department agrees with the commentator that good food, fresh water, sunshine and fresh air would go far in lessening incidence of diabetes and obesity and the health problems attendant on these conditions. Better hygiene and sanitation may help prevent the spread of disease but they will not eradicate the germs that cause disease. As long as those organisms still exist, people will continue to get ill. A review of the history of vaccine preventable disease shows that a drop in disease almost always occurs when a vaccine is introduced. If the decline in diseases were due to better hygiene and sanitation, the expectation would be that the number of cases for all diseases would begin to drop at the same time. For example, while the number of polio cases started to decline in 1955, the number of Haemophilus influenzae b (Hib) cases began to drop in 2000, corresponding to the introduction of vaccinations for those diseases. See <https://www.vaccines.gov/basics/effectiveness/index.html>.

As to how vaccines work, vaccines help develop immunity by imitating an infection. Vaccines mimic disease agents, without making the person sick, and stimulate the person's immune system to build up defenses against them.

One commentator asked how long children in the United States would be healthy if they are repeatedly injected with diseases, formaldehyde, mercury, aluminum, polysorbate 80, neomycin, animal DNA and aborted fetal DNA. The commentator asked if chickenpox is being traded for cancer. The commentator stated that there had been an epidemic of childhood cancers, autoimmune disorders and neurological disease including autism, and some studies show the excessive vaccines are the cause. The commentator stated that looking at the time line between the increase in these problems and the increase in vaccines. The commentator stated that the CDC found out in 2001 that the MMR vaccine causes autism, and committed fraud in 2004 to cover up the results. The commentator stated that the MMR given early under 36 months of age most definitely causes autism in many children, particularly African American boys. The CDC cannot be trusted to manage the safety of vaccines.

The Department disagrees with the commentators regarding childhood vaccines and any causal link to autism. In fact, no study has shown that the number of vaccines given to children cause autism. The Department cannot speak to the "neurological diseases" referenced, since the statement is not specific. With respect to autism, the only study purporting to show a link between a vaccine and autism was disproven; 10 of the 12 authors withdrew their support from the 1998 study; *The Lancet*, which published the article, retracted it; and the lead author lost his medical license in Britain in 2010.

With respect to the reference to the CDC "cover-up" regarding autism and the MMR vaccine, the Department's review of the information available leads it to disagree with commentators. The allegations are specifically that data suppressed by the CDC proved that the MMR vaccine produces a 340% increased risk of autism in African American boys. The Department notes that the putative CDC whistleblower, Dr. William W. Thompson, released the following statement through his attorneys:

I regret that my coauthors and I omitted statistically significant information in our 2004 article published in the journal *Pediatrics*. The omitted data suggested that African American males who received the MMR vaccine before age 36 months were at increased risk for autism. Decisions were made regarding which findings to report after the data were collected, and I believe that the final study protocol was not followed.

I want to be absolutely clear that I believe vaccines have saved and continue to save countless lives. I would never suggest that any parent avoid vaccinating children of any race. Vaccines prevent serious diseases, and the risks associated with their administration are vastly outweighed by their individual and societal benefits.

My concern has been the decision to omit relevant findings in a particular study for a particular subgroup for a particular vaccine. There have always been recognized risks for vaccination and I believe it is the responsibility of the CDC to properly convey the risks associated with receipt of those vaccines.

I have had many discussions with Dr. Brian Hooker over the last 10 months regarding studies the CDC has carried out regarding vaccines and neurodevelopmental outcomes including autism spectrum disorders. I share his belief that CDC decision-making and analyses should be transparent. I was not, however, aware that he was recording any of our conversations, nor was I given any choice regarding whether my name would be made public or my voice would be put on the Internet.

Retrieved from <http://morganverkamp.com/statement-of-william-w-thompson-ph-d-regarding-the-2004-article-examining-the-possibility-of-a-relationship-between-mmr-vaccine-and-autism/>.

Dr. Brian Hooker, mentioned in Dr. William W. Thompson's statement, published an article in *Translational Neurodegeneration* concluding that "African American males receiving the MMR vaccine prior to 24 months of age or 36 months of age are more likely to receive an autism diagnosis." The article was removed from public domain due to issues of competing interests on the part of the author which compromised the peer review process. Further, post-publication peer review raised concerns about the validity of the methods and statistical analysis. The retraction note is posted at <http://translationalneurodegeneration.biomedcentral.com/articles/10.1186/2047-9158-3-22>.

The CDC published a statement regarding the original article and the data used in the study is available for analysis by others. CDC (2015), "CDC Statement Regarding 2004 Pediatrics Article, 'Age at First Measles-Mumps-Rubella Vaccination in Children with Autism and School-matched Control Subjects: A Population-Based Study in Metropolitan Atlanta,'" retrieved from <http://www.cdc.gov/vaccinesafety/Concerns/Autism/cdc2004pediatrics.html>. As the CDC noted in this statement "[a]dditional studies and a more recent rigorous review by the Institute of Medicine have found that MMR vaccine does not increase the risk of autism."

The Department addresses comments regarding the following topics in this preamble: vaccine additives; multiple vaccines; combination vaccines; and vaccine manufacturer liability.

One commentator stated that she read that the CDC has covered up actual harm from the MMR vaccine. She stated that she believes the vaccine industry and the CDC collude to keep information from the public regarding the safety of vaccines. The commentator stated that the public has long been led to believe that vaccines are safe and not a choice. The commentator stated that she has read many accounts of children and adults suffering harm and dying from vaccines where the chance of getting the disease or dying from it was much lower. The commentator stated that persons making decisions about mandatory vaccinations should consider the facts from someone other than the vaccine manufacturers, whose only concern is "keeping the cash flowing." In addition, the commentator stated that she was gravely concerned about the direction the country was moving where parents were losing their right to make informed decisions. The commentator stated that for too long the vaccine industry has been allowed to dictate an ever increasing schedule. The commentator stated that just because vaccines have always been considered safe, safety should not be assumed, particularly in light of the fact that 1 in 45 children is autistic. The commentator stated that the vaccine industry has no testing and vaccines contain many requirements that do more harm than good.

Although the Department is not in a position to change the commentator's view of the pharmaceutical industry or the CDC, the Department notes that no vaccine is licensed for use by the FDA without going through clinical trials. In certain instances, a compassionate use exception may be granted, or the approval process accelerated, for example, as with the Ebola vaccine when the FDA in 2016 granted "breakthrough therapy" designation to the investigational vaccine for the Ebola Zaire virus. See Eslava-Kim, PharmD, L. (2016), "Investigational Ebola Vaccine Granted Breakthrough Therapy Status," MPR, retrieved from <http://www.empr.com/drugs-in-the-pipeline/investigational-ebola-vaccine-granted-breakthrough-therapy-status/article/511504/>. The Department is comfortable with the recommendations of ACIP regarding MCV and pertussis. The Department addresses issues regarding autism in this preamble.

Several commentators made the comment that unvaccinated children are healthier than vaccinated children. One commentator stated that many doctors who take care of both unvaccinated children and vaccinated children report the unvaccinated children are much healthier than vaccinated children. The commentator stated that unvaccinated children have fewer earaches, sinus infections, stomach problems and allergies. The commentator stated that unvaccinated children have healthier immune systems because they have not been injected with an over-

load of diseases their whole lives which overload and compromise the immune system. When they get sick, they are able to fight off infections. The unvaccinated children are not the threat to schools. Vaccinated children are getting sick with the diseases they were vaccinated for and proving that the vaccines do not provide the "immunity," so how are vaccines immunizations. The commentator stated that this is a good reason for a philosophical exemption.

One commentator stated that the proposed amendments were highly problematic, and that there were several issues of concern which must be noted and thoroughly discussed. The commentator stated that the Department was assuming incorrectly that immunocompromised individuals are unable to be vaccinated, and that all vaccines prevent vaccinated individuals from transmitting disease to the immunocompromised. The commentator stated that several vaccines contain live virus, and when given to others can shed and potentially infect immunocompromised individuals for up to 3 weeks. Requiring children to receive live virus vaccines to protect the immunocompromised may possibly backfire by spreading the very diseases they are meant to protect against.

With respect to the comment that unvaccinated children are healthier than vaccinated children, the Department respectfully suggests that no support exists for that statement. The Department disagrees that vaccinations suppress a child's natural immune system. Children are exposed to many foreign antigens every day. Eating food introduces new bacteria into the body and numerous bacteria live in the mouth and nose, exposing the immune system to still more antigens. An upper respiratory viral infection exposes a child to 4 to 10 antigens and a case of strep throat exposes a child to 25 to 50 antigens. According to *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*, "[i]n the face of these normal events, it seems unlikely that the number of separate antigens contained in childhood vaccines... would represent an appreciable added burden on the immune system that would be immunosuppressive." Institute of Medicine (1994), *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality (Adverse Events Associated with Childhood Vaccines)*, Washington, DC: National Academy Press, retrieved from <http://www.nap.edu/read/2138/chapter/5?term=%22normal+events%22#62>. See also *Vaccines: What You Should Know*, p. 100. Available scientific data show that simultaneous vaccination with multiple vaccines has no adverse effect on the normal childhood immune system. In fact, the CDC states:

Simultaneous administration (that is, administration on the same day) of the most widely used live and inactivated vaccines does not result in decreased antibody responses or increased rates of adverse reaction. Simultaneous administration of all vaccines for which a child is eligible is very important in childhood vaccination programs because it increases the probability that a child will be fully immunized by the appropriate age.

CDC (2015), *Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book)*, Washington, DC: Public Health Foundation, retrieved from <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>.

The Department further disagrees with the proposition that vaccinated children are getting sick with the diseases against which they were vaccinated. In a study of the risk of vaccine-preventable diseases among children 3

to 18 years of age in Colorado who have philosophical and religious exemptions, researchers determined that exemptions were 22.2 times more likely to acquire measles and 5.9 times more likely to acquire pertussis. Feikin, MD, MSPH, D. R., et al. (2000), "Individual and Community Risks of Measles and Pertussis Associated with Personal Exemptions to Immunization," *JAMA*, 284(24), 3145—3150, retrieved from <http://jama.jamanetwork.com/article.aspx?articleid=193407>. See also Glanz, J. M., et al. (2009), "Parental Refusal of Pertussis Vaccination is Associated with an Increased Risk of Pertussis Infection in Children" (Parental Refusal of Pertussis Vaccination), *Pediatrics*, 123(6). The commentators did not cite a study for their proposition or offer other evidence other than an anecdotal statement that many doctors believe this. The Department can point to doctors that disbelieve the proposition. Live attenuated vaccinations contain live viruses that are a weakened strain. See *Pink Book*, p. 5, and *Vaccines: What You Should Know*, p. 100. These vaccines usually do not cause disease as may occur with the "wild form" of the organism. In fact, the *Pink Book*, p. 21, states that MMR and varicella, both live attenuated vaccines, may be given when an immunosuppressed person lives in the same house. If an infection does occur, it is usually much milder than the natural disease and is referred to as an adverse reaction. *Pink Book*, p. 5. Further, *Vaccines: What You Should Know*, p. 101, states that "vaccinated children are not at greater risk of other infections meaning infections not prevented by vaccines than unvaccinated children."

The Department is respectful of commentators' beliefs that the decision whether to vaccinate their children should be made by them alone, and that immunizations should not be mandated. The Department understands that many commentators believe that vaccines cause more harm than good. As several commentators noted, the Department acknowledges that there is no absolutely safe vaccine. The Department has never denied that reports of adverse events and serious adverse events are made for every vaccine. The Department is also aware of the side effects listed on the manufacturer's labels. Manufacturers of products warn users of products of possible problems with products in part out of concern for liability. Because a manufacturer cannot prove that a vaccine is effective for a lifetime, it cannot say so without the possibility of legal ramifications. The Department 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. After reviewing the comments and the proposed rulemaking, the Department stands firm in its belief of the benefits of childhood vaccination, despite the fact that vaccines may cause adverse and serious adverse events. These factors are taken into account by the FDA when a vaccine is licensed and by ACIP when it recommends a vaccine. Before the FDA licenses a vaccine, and before ACIP makes a recommendation regarding a vaccine, these experts determine that the possibility of adverse and serious adverse events are outweighed by the dangers of the disease itself. See *Vaccines: What You Should Know*, p. 24, and this preamble. Therefore, the Department has not revised this final-form rulemaking regarding this topic. Tables of reported cases and vaccine-preventable diseases from 1950—2013 published by the CDC show the decrease in deaths from childhood diseases like polio and measles that have occurred with the advent of vaccinations. See *Pink Book*, Appendix E, p. E-1—E-8. At least 1 study determined that vaccination will prevent an estimated 322 million illnesses, 21 million hospitalizations

and 732,000 deaths during the course of the lifetime of children born between 1994 and 2013. "Benefits from Immunization," p. 1.

The Department also disagrees with the commentators' statement that massive underreporting of adverse vaccine events occurs because many parents do not realize the ensuing illness could be related directly to the vaccine recently received. Neither the Department nor the commentators are in a position to know the truth of this statement.

Multiple commentators stated that the Institute of Medicine, in a series of reports on vaccine safety spanning 25 years, acknowledged that there is individual susceptibility to vaccine reactions for genetic, biological and environmental reasons that have not been fully defined by science; doctors cannot predict ahead of time who will be harmed. The commentators stated that long standing gaps in vaccine safety research and emerging evidence that certain vaccines do not prevent infection or transmission of disease urgently require legal protection of physician and parental rights regarding medical and religious exemptions to vaccination for minor children. For these reasons, physician's rights and parents' and legal guardians' rights to philosophical and religious exemptions are an absolute imperative of health and civil liberty.

The Department is not amending the religious/philosophical or medical exemptions, both of which are provided for in statute.

PACIC and several commentators stated that although the Department mentioned adverse reactions to vaccines, it does not discuss them. One commentator stated that the Department dismissed the possibility of these reactions as fairly rare. The commentator stated that complications from having a disease are rare as well. The commentator stated that since the Vaccine Adverse Event Reporting System (VAERS) is a voluntary reporting system, it is unknown how rare the adverse reactions are. The commentator stated that the risk of adverse reactions must be weighed against the risk of vaccine-preventable disease in the United States. The commentator stated that this is never done, as the risks of these diseases in developing nations is the risk we are asked to consider.

The Department disagrees with the commentators. In fact, ACIP reviews the costs of adverse events as part of cost-effectiveness studies done before adding vaccines to its recommended list. Cost-effectiveness studies of meningococcal vaccines do exist. The Department reviewed them, along with ACIP's recommendations, and discussed them more fully in the comments regarding § 23.83(c)(2). Further, the Department cited the "Benefits from Immunization" study in which adverse effects are reviewed as part of a review of the cost-effectiveness of the VFC Program in cohorts of children born between 1994 and 2013. The study finds that vaccines save both lives and money. Childhood vaccines clearly reduce the incidence of disease and death. Although no vaccine is 100% effective, vaccines have prevented millions of deaths each year from preventable infectious diseases. See generally "Benefits from Immunization." School settings are an ideal place for unprotected children to contract communicable and potentially dangerous diseases. Requiring immunity for school attendance protects that child and others from unnecessary illnesses.

One commentator stated that it is not true that there is no cost to the public when one examines the amount of disease which now exists in the Nation after vaccination

rates have increased with much fuller schedules. The commentator asked that the Department consider holding pharmaceutical companies more accountable for possibly failing products rather than taking more and more rights away from parents and guardians.

The commentator noted that each disease poses a different level of risk, as does each vaccine, and it cannot be assumed that all vaccines are risk free, nor should it be assumed that all diseases are deadly in the United States. The commentator stated that measles is undoubtedly deadly in developing countries lacking adequate food and clean water, but has never been particularly problematic in the United States, not even in the prevaccine era. According to the commentator, the death rate for measles in 1921 and 1922 was 4.3 per 100,000 infected, which is extremely low. Since it was so low then, without antibiotics or other treatment regimens, the commentator stated that it would surely be less problematic today. The commentator noted that since 1990, the MMR vaccine has been reported in conjunction with serious side effects, such as stroke, hearing loss, pancreatitis, seizure and other things, in 7,502 reports in VAERS, as well as 358 deaths, the vast majority in children under 3 years of age. The commentator stated that every case of children with measles, however mild, is reported but not about vaccine reactions and “surely those children matter too.”

The commentator stated that not all reactions are in children. According to the commentator, incidences of arthritis and arthralgia are generally even higher in vaccinated women than in vaccinated children, and the reactions are more marked and of longer duration. The commentator wondered who had decided that months or even years of joint pain in up to 26% of women is acceptable, and exactly who had decided that this pain is well tolerated.

The Department disagrees with the commentators. The Department disagrees that vaccines have not been effective in preventing and controlling vaccine preventable childhood diseases. See *Pink Book*, Appendix E. The Department notes that disease rates have fallen over the last century due to vaccination. See “Achievements in Public Health,” which stated that “[t]his report documents the decline in morbidity from nine vaccine-preventable diseases and their complications—smallpox, along with [diphtheria, pertussis, tetanus, poliomyelitis (paralytic), measles, mumps, rubella and Haemophilus influenzae type b].” Polio caused by wild-type viruses has been eliminated from the Western Hemisphere. See “Achievements in Public Health,” p. 2; *Vaccines: What You Should Know*, p. 46; Haymann, MD, D. L., editor (2004), *Control of Communicable Diseases Manual*, Washington, DC: American Public Health Association. An average of 16,316 paralytic polio cases and 1,879 deaths from polio were reported each year from 1951 to 1954. With the licensure of polio vaccine in the United States in 1955, polio incidence declined sharply to less than 1,000 cases in 1962 and remained below 100 cases after that year. See “Achievements in Public Health,” p. 2. Per “Achievements in Public Health,” p. 2, “[i]n 1994, every dollar spent to administer oral poliovirus vaccine saved \$3.40 in direct medical costs and \$2.74 in indirect societal costs” and the last documented indigenous transmission of wild poliovirus in the United States occurred in 1979.

Measles cases have also declined since the introduction of a vaccination. According to the *Pink Book*, before 1963 (which was the year the first measles vaccine was licensed), approximately 500,000 cases and 500 deaths of measles were reported annually, with epidemic cycles

every 2 years. *Pink Book*, p. 214. After the introduction of the vaccine, the incidence of measles decreased by more than 95%. *Pink Book*, p. 214. In 1983, 1,497 cases were reported, the lowest annual total ever reported up until that time. After that date, there was an occurrence of measles among already vaccinated children, which led to a recommendation for a second dose in children 5 years of age to 19 years of age. *Pink Book*, p. 214. From 1989 to 1991, there was a dramatic increase in cases reported, along with a change in age distribution. Forty-five percent of the cases appeared in children younger than 5 years of age. According to the *Pink Book*, the most important cause of the resurgence of measles from 1989 to 1991 was low vaccination coverage, although measles susceptibility of infants under 1 year of age may have decreased, since mothers who were vaccinated transferred less antibodies to infants in utero than mothers who had had the “wild disease.” *Pink Book*, p. 215. Rates again dropped significantly because of intensive efforts to vaccinate preschool-aged children.

The outlier in this evidence is pertussis. The waning of pertussis immunity provided through vaccination has been well documented and has been noted by numerous commentators. The waning of immunity is due to concerns with the safety of the whole-cell pertussis vaccine (DTwP<sup>3</sup>), which led to its replacement by the acellular pertussis vaccine, DTaP. “Pertussis Epidemic—Washington, 2012” (Pertussis Epidemic), *MMWR*, 61(28) (2012), 517–522, retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6128a1.htm>. See also *Pink Book*, p. 266, which states that “[t]he epidemiology of pertussis has changed in recent years, with an increasing burden of disease among fully-vaccinated children and adolescents, which is likely being driven by the transition to acellular vaccines in the 1990s.” The “Pertussis Epidemic” study of an epidemic of pertussis in Washington in 2012 led the authors of the study to conclude that although vaccinated children can develop pertussis, they are less infectious, have milder symptoms and shorter illness duration, and are at reduced risk for severe outcomes, including hospitalization. “Pertussis Epidemic,” p. 4. The “Pertussis Epidemic” study recommended that efforts should focus on full implementation of DTaP and tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap) recommendations to prevent infection and protect infants. “Pertussis Epidemic,” p. 4.

The Department further notes with respect to the MMR vaccine that the individual antigens that make up the MMR vaccine are no longer available in the United States. The Department continues to include the single antigens in final-form § 23.83(b)(3) because of the possibility that a child from another country may enter this Commonwealth with single antigen vaccines. As the Department has stated, childhood vaccines reduce the incidence of disease and death. Although no vaccine is 100% effective, vaccines have prevented millions of deaths each year from preventable infectious diseases.

Further, the Department notes that this final-form rulemaking is limited to: clarifying that the diphtheria and tetanus vaccinations are no longer available without a pertussis component, thereby in effect adding a pertussis dose for school attendance; adding a dose of MCV in the 12th grade; extending the school reporting period; and reducing the provisional period during which a child may be admitted to school without the required immuniza-

<sup>3</sup> DTwP is diphtheria and tetanus toxoids, and whole cell pertussis vaccine. Diphtheria and tetanus toxoids and pertussis is also whole cell pertussis vaccination and is acknowledged by the Department as an appropriate vaccination along with DTaP.

tions. The cost implications of this final-form rulemaking are limited to those provisions, and do not extend to the general requirement of vaccination for school entry and attendance.

#### *Homeschooling*

PACIC and another commentator stated that most other states do not require home-educated students to comply with immunization regulations. PACIC and the commentator stated that children who do not attend a traditional public school should be exempt from the regulations because they will not be contributing to the school's herd immunity. One commentator noted that this would increase the vaccination rates in schools.

Several commentators raised the issue of vaccines related to homeschooling their children. One commentator stated that she had made decisions to vaccinate her child for some things, but not others, when she felt they were unnecessary or the risk was too high, and that she refuses vaccines for herself as well. Several commentators stated that their children were not around other children on a daily basis, in a classroom where they can affect others by being ill, since they were homeschooled. Another commentator stated that she believed the urgency for homeschooled children was considerably less than for children in school situations, so that these children should have wider parameters for compliance. One commentator stated that as a homeschooling parent, she should have the right to decide what was right for her child. She stated that while vaccines are necessary in certain instances, there needs to be flexibility with the requirements. One commentator stated that it concerned her that the regulations applied to all children, regardless of whether they are in a public school setting or a homeschool setting.

The Department has not amended the requirement of when immunizations are required and who is required to get them. Immunizations are required for school entry and attendance, and have always applied to homeschooled children. In § 23.83(a), "school" includes homeschools, cyber schools and charter schools. Further, the Department notes that a parent or guardian who refuses to obtain the vaccinations for his child because of a religious belief or a strongly held moral or ethical conviction that rises to the level of a religious belief, or who has a medical contraindication to a vaccine, may seek an exemption from these requirements, and still attend school, whether in a brick and mortar building or in a homeschool environment.

IRRC also noted that commentators asked the Department to exempt homeschool and cyber school students, and asked whether the Department had considered this concern.

The Department has not newly included children who are homeschooled or in cyber schools in this final-form rulemaking. They are already required by law to comply with the vaccination requirements in § 23.83(b). The Department would have to amend its regulations to exempt homeschooled and cyber-schooled students. While the regulations regarding immunizations in schools are primarily aimed at protecting children in brick and mortar schools, that is not its only aim. Although homeschooled children and children in cyber schools may not be around other children on a daily basis in school, they are around children and adults in grocery stores, malls, playgrounds, movie theaters and other public areas. The dangers of passing diseases to persons who cannot receive vaccinations are present in places other than schools. Herd immunity is really "community immu-

nity" and a student's wider community, as well as the school, is impacted by failure to immunize.

The Department does have the authority to make certain decisions considered within its police powers, that is, its authority to protect the general public from harm. The courts have upheld this authority. See *Stull v. Reber et al.* (*Stull*), 215 Pa. 156 (1906). Requiring immunizations for school entry and attendance falls within that police power. The General Assembly has delegated, as it is legally authorized to do, that authority to the Department to implement through the Public School Code of 1949 (24 P.S. §§ 1-101—27-2702), The Administrative Code of 1929 (71 P.S. §§ 51—732) and the Disease Prevention and Control Law of 1955 (35 P.S. §§ 521.1—521.21). The Department cannot force a parent to have a child vaccinated. The parent always has the choice whether or not to comply with the requirements. Making certain choices may have certain consequences. For example, refusal to obtain vaccinations may result in exclusion from school until the appropriate exemptions or medical schedules are put into place. Further, if an outbreak were to occur, unvaccinated persons could be excluded from school for a relatively longer period of time; for a measles outbreak, for example, persons who are susceptible, that is, persons without immunity, may be excluded from school for a protracted period of time. As one commentator mentioned, this might not seem to be as much of an issue with children who are homeschooled. However, failure to obtain vaccinations may have implications beyond the child or the school, since a child who is homeschooled has contact with other children and adults in public areas.

#### *Comments regarding "herd" or community immunity, vaccine effectiveness and natural immunity*

Multiple commentators, including PACIC, stated that the Department's citation of "herd" or community immunity as a basis for requiring additional immunizations is incorrect, and that the Department did not explain how herd immunity prevents the spread of disease. IRRC also requested that the Department provide specific data to support the need for this final-form rulemaking regarding herd immunity. Some commentators stated that the theory of herd immunity was first developed during the study of individuals who had attained natural immunity through the course of infection, that is, had the "wild disease," not those who had been vaccinated. According to PACIC, children would experience illness from wild virus exposure, and nonvaccinated adults were naturally re-exposed to the wild virus as they cared for sick children, so their natural immunity was boosted. PACIC stated that this immunity is life long, and can be transmitted from mothers to children through breastfeeding. PACIC stated that this protects children until they are old enough to acquire the wild virus naturally and begin building life-long immunity. PACIC stated that vaccines do not replicate this natural cycle for the following reasons:

- Mothers who receive vaccines can have a lower concentration of virus-specific antibodies than mothers with naturally acquired immunity.
- As viruses mutate over time, static vaccines offer limited protecting from evolving disease strains.
- Vaccine immunity is temporary and frequently ineffective, with up to 76% of people not responding to repeated vaccinations. Persons with nearly 100% vaccination compliance are still experiencing outbreaks. In 18 different measles outbreaks in North America, vaccinated children constituted 30% to 100% of measles cases.

- Vaccination sometimes shifts the disease from childhood to more vulnerable age groups, including the infants and the elderly, when they can be more serious.
- Even after six doses of Tdap vaccine, effectiveness declined to 34% after 2 to 4 years, likely contributing to increases in pertussis among adolescents.

Many other commentators agreed with these comments. Several commentators requested that herd immunity be responsibly omitted as a scientific basis for increasing vaccination schedules. One commentator stated that no vaccine has ever prevented a disease, it has merely lessened the symptoms.

One commentator stated that the Department made the statement regarding herd immunity without statistics or studies. The commentator stated that this theory, which was based on the assumption that natural immunity is the same as vaccine-based immunity, can no longer be used. Two commentators stated that a recent mumps outbreak at Harvard University was among students who were all vaccinated. The commentators noted that there was a recent whistleblower lawsuit filed by two Merck immunologists in this Commonwealth who claimed that mumps efficacy data was manipulated by the addition of rabbit blood to boost immunity markers. One commentator stated that Merck could lose its MMR monopoly in the United States if its effective rate dropped too low. According to the commentators, a PubMed study found 18 reports of measles where 71% to 99.8% of students were immunized against measles. According to the commentators, 30% to 100% of all measles cases in these outbreaks occurred in previously immunized students. According to the commentator, the study's authors determined that as immunization rates rise, measles becomes a disease of immunized persons.

The Department disagrees with the commentators. The question of childhood immunization in general is not at issue here. The Department already requires certain immunizations for school entry and attendance, including Tdap in the 7th grade, and those requirements will not change regardless of the outcome of this final-form rule-making. Vaccines have prevented millions of deaths each year from preventable infectious diseases, and will continue to do so.

The Department did use the concept of community or herd immunity to support its decision to reduce the provisional period. Maintaining or increasing herd immunity will decrease the threat of vaccine-preventable diseases in schools, and therefore in the general populations. Many of these are diseases are more prevalent among school age children, but can quickly spread to the adult population as well. Protection of the public from vaccine-preventable diseases can be accomplished by ensuring the continuance of herd immunity or community immunity among children in schools. Low vaccination rates can lead to a waning of herd immunity, which is defined as the protection for the community against certain communicable diseases that arises when a critical mass of persons are immunized against those diseases. Herd or community immunity is a means of protecting a whole community from disease by immunizing enough people so that no sustained chain of disease transmission can be established. By breaking the chain of a disease transmission, vaccination protects more than just the vaccinated person; it also protects people who have not been, or cannot be, vaccinated because they are too young or too sick. Willingham, E. and Helft, L. (2014), "What is Herd Immunity," PBS Online, retrieved from <http://www.pbs.org/wgbh/nova/body/herd-immunity.html>. Salathe, M.

(2015), "Herd Immunity and Measles: Why We Should Aim for 100% Vaccination Coverage," The Conversation, retrieved from <http://theconversation.com/herd-immunity-and-measles-why-we-should-aim-for-100-vaccination-coverage-36868>.

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

The level of immunization in a population required to achieve herd immunity does differ from disease to disease, and some diseases, for example, pertussis, seem unaffected by it.<sup>4</sup> To determine thresholds of immunity, epidemiologists set a value, called a basic reproduction number ( $R_0$ ), to determine vaccination rates necessary to prevent spread of disease. Marshall, MD, G. S. (2012), *The Vaccine Handbook: A Practical Guide for Clinicians (Vaccine Handbook)*, New York: Professional Communications, Inc. This is a complex calculation and differs depending on the factors, assumptions, and methodologies various researchers use. See *Vaccine Handbook*, p. 42.<sup>5</sup> These factors include how effective the vaccine is, how long-lasting immunity from both the vaccine and the infection is, and which populations form critical links in the spread of disease, since there may always exist pockets of susceptible individuals who are capable of spreading the disease. See *Vaccine Handbook*, p. 44.

Measles, for example, is easily spread through droplets and the air, is highly contagious and has a relatively high threshold to protect a community. Thus, experts postulate that between 92% and 95% of the population must be vaccinated to prevent the disease from spreading. Bednarczyk, R. A., Orenstein, W. A. and Omer, S. B. (2016), "Estimating the Number of Measles-Susceptible Children and Adolescents in the United States Using Data from the National Immunization Survey—Teen

<sup>4</sup> This does not mean that vaccination against pertussis has no benefit. The Department has discussed this issue more fully in this preamble.

<sup>5</sup> The history and theory of herd immunity, the methodologies and theories different researchers use to determine disease transmission is discussed in an article by Fine, P. E. M. (1993), "Herd Immunity: History, Theory, Practice," *Epidemiologic Reviews*, 15(2), 265–302. This article, at p. 282, points out the difficulties of making precise estimates of herd immunity thresholds in any particular context based on differing assumptions (for example, maternal immunity, variation in age of vaccination and geographical heterogeneity). Table 5 of this article shows threshold rates from different studies for measles of from 55% to 96% to not specified, based on the methods of calculation and assumptions used by various authors, and raises issues with the assumptions used in several of those calculations. This article did not offer an opinion as to the appropriate basic reproduction value and threshold rates for measles. This article stated on p. 286 instead that "experience does suggest that most theoretically-derived estimates of vaccination uptake and herd immunity thresholds [for measles] have been optimistically low, because they do not cater for important heterogeneity within real populations." The Department has utilized a threshold rate of 92% to review its data, based on the articles it has reviewed, and the clear acknowledgement by those articles that measles is extremely infectious. "What is Herd Immunity" provided a threshold range of between 83% and 95% for measles, citing "Herd Immunity: History, Theory, Practice," while acknowledging that measles is so infectious that the threshold immunity required to protect a community is 95%.

(NIS—Teen)” (Estimating the Number of Measles-Susceptible Children and Adolescents), *American Journal of Epidemiology*, 184(2), 148—156. Polio, which is less contagious and spreads in a different way, has a lower threshold, at around 83%. For a variety of reasons, certain other diseases are not strongly affected by herd immunity. For example, a disease in which immunity from vaccine and from infection wane over time, and for which a human host could colonize the disease without becoming ill, would not be as impacted by herd immunity as other diseases. This may be an issue with certain meningitis vaccines, although there have been studies showing that vaccination for meningitis serogroup C in Britain did create herd immunity. See “Prevention and Control (2013),” p. 10.

The Department does not claim that herd immunity will protect students from every infectious disease. It will protect students and adults in schools and in surrounding communities from highly contagious and serious diseases. To maintain levels of immunity to prevent the spread of potentially dangerous and highly infectious diseases—for example, measles, polio and chickenpox—approximate vaccination rates need to be 92% to 95% for measles, 83% for polio and 89% to 90% for chickenpox. See “Estimating the Number of Measles-Susceptible Children and Adolescents,” p. 153; and Glass, PhD, G. E. (2006), “Measuring Disease Dynamics in Populations: Characterizing the Likelihood of Control,” lecture retrieved from <http://ocw.jhsph.edu/courses/publichealthbiology/PDFs/Lecture2.pdf>. When herd immunity wanes because of pockets of persons susceptible to disease or for other reasons, the remainder of the population is at risk. See “Estimating the Number of Measles-Susceptible Children and Adolescents,” p. 153 and 154. “[W]ith approximately 8.7 million children aged 17 years or younger who are susceptible to measles, there is a potential for large measles outbreaks even in the context of generally high vaccination coverage.” See “Estimating the Number of Measles-Susceptible Children and Adolescents,” p. 153. “[A] substantial number of children and adolescents aged 17 years or younger in the United States are susceptible to measles, with some clustering raising concerns that endemic measles transmission could be reestablished despite the overall high level of immunity.” See “Estimating the Number of Measles-Susceptible Children and Adolescents,” p. 154.

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

In the 2014-2015 school year, when schools reported in December, approximately 26% of the kindergarten and 7th grade classes in noncyber schools in this Commonwealth<sup>6</sup> had vaccination rates below 92% for the MMR vaccine at some point in the school year. For some of those classes, the rates were below 85%. Rates in indi-

vidual schools substantially improved in the 2015-2016 school year (approximately 10% of kindergarten and 7th grade classes were below 92%) when school reporting was extended to March, but there still were schools significantly below the vaccine rates necessary for herd immunity. This means there is a period during the year in which not enough children have been vaccinated to create herd immunity for diseases like measles, which was responsible for 481,530 cases Nationwide in 1962, prevaccine, and 408 deaths of those children and adults.

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

For example, in 1962 before there was a measles vaccine, according to the CDC, there were 481,530 measles cases and 408 deaths were reported Nationwide, with epidemic cycles every 2 to 3 years. After licensure of the measles vaccine in 1963, the incidence of measles decreased by more than 95%, and the 2-year to 3-year epidemic cycles no longer occurred. A resurgence of measles cases from 1989 to 1991 was the result of low vaccination coverage. Reported cases of measles declined rapidly after the 1989 to 1991 resurgence, due primarily to intensive efforts to vaccinate preschool-aged children. Measles vaccination levels among children 2 years of age increased from 70% in 1990 to 91% in 1997.

The Department also disagrees with the commentators’ views that vaccines are ineffective. The Department has already provided data regarding the decline in childhood illness due to the introduction of vaccinations. The Department recognizes that outbreaks can occur even if vaccination rates are high. According to “Estimating the Number of Measles-Susceptible Children and Adolescents,” even though the overall level of immunity to measles is generally at or higher than the lowest threshold rate for herd immunity of 92%, a substantial number of children and adolescents are susceptible to measles, with clustering of unvaccinated children raising concerns that endemic measles transmission could be reestablished despite the overall high level of immunity. See “Estimating the Number of Measles-Susceptible Children and Adolescents,” p. 154. “Herd Immunity: History, Theory, Practice” suggests that current measles immunity levels are high enough to prohibit continued transmission throughout most of the country, but insufficient in certain urban areas where social conditions are least conducive to

<sup>6</sup> Based on Department of Education information relating to cyber schools.

high vaccination rates. According to “Herd Immunity: History, Theory, Practice,” p. 286, given population movement, it is not surprising that measles repeatedly escapes from urban centers into schools throughout the country. This is what concerns the Department about the low vaccination rates in schools in this Commonwealth.

Further, the Department acknowledges that not all vaccines are 100% effective and, that, on occasion, immunity from some vaccines is shown to have waned. This occurred with pertussis and is why in 2011, the Department added Tdap<sup>7</sup> as a dose for entry into the 7th grade. See 40 Pa.B. 2747 (May 29, 2010). The fact that immunity can wane does not mean that children, and adults, should not be vaccinated. The MMR vaccine, according to the *Pink Book*, is approximately 95% effective. Measles antibodies develop in approximately 95% of children vaccinated at 12 months of age, and 98% of children vaccinated at 15 months of age. More than 99% of persons who receive two doses of measles vaccine, with the first dose administered at no earlier than the first birthday, develop serologic evidence of measles immunity. *Pink Book*, p. 218. Seroconversion rates are similar for single antigen measles vaccine and the MMR. *Pink Book*, p. 218. Two doses of the mumps or MMR vaccine is 88% effective, with a range of 66% to 95%. *Pink Book*, p. 253. Rubella vaccine is 95% effective, with the same seroconversion rate for single antigen vaccine and MMR. *Pink Book*, p. 331. Three doses of DTaP and one dose of Tdap have a similar efficacy, 80% to 85%. *Pink Book*, p. 268. Varicella vaccine is 70% to 90% effective against any varicella disease, and 90% to 100% effective against severe varicella disease. *Pink Book*, p. 362. MCV wanes unless a booster is administered, which is why the Department is adding a second dose of meningitis for entry into the 12th grade. The fact that there may be a potential for waning of immunity does not mean that vaccinations should not be required.

The Department also disagrees with the commentators’ discussions regarding the benefits of “natural” immunity versus vaccinated immunity. The Department acknowledges that natural infection may provide better immunity than vaccination.<sup>8</sup> During natural infection, the immune system recognizes a pathogen as foreign and makes an immune response. When a pathogen causes an immune response, it is known as an antigen. Unfortunately, while the immune response gathers strength, a person is likely to be ill, as there is a struggle between the pathogen and the immune response. Antibodies are created by the immune response. Antibodies are specific to antigens, and have the ability to remember them, so that if the same or a very similar antigen tries to infect the person again, the immune response will be faster and stronger and will protect the person from infection and illness. The cost of attaining natural immunity can be great. A child can be paralyzed from a natural polio infection, liver failure from a natural hepatitis B viral infection, deafness from having the measles or pneumonia from varicella. See *Vaccines: What You Should Know*, p. 99.

The commentators argued that only natural immunity can be passed from a mother to child through breastfeeding and that this then protects the child until the child can catch the disease and build up natural immunity itself.

The Department acknowledges that antibodies passed from mothers who have had a disease to children may

last longer than antibodies from vaccinated mothers. See *Pink Book*, p. 215. The Department disagrees with commentators’ argument that vaccinations do not work as well as “natural” immunity because mothers who have not been vaccinated, but who have had disease, pass stronger immunity to their children, which lasts until the children develop their own immunity. Once the mother’s antibodies wear off, the child is vulnerable and must either be vaccinated or risk the disease. For example, maternal antibodies against measles may only last as long as 10 months. “Estimating the Number of Measles-Susceptible Children and Adolescents,” p. 153. After this time, children are susceptible and if left to develop their own immunity risk contracting a serious disease with a serious risk of high fever, painful rash, ear infections, oral sores, dehydration, diarrhea, blindness and death.

One commentator stated that not all medical professionals see people as cattle that can be lined up at a “mass immunization clinic,” as was suggested by another commentator. The commentator stated that it could as easily be argued that herd immunity does not work and the science is clear for those that choose to do their research beyond the education prepared and paid for by the pharmaceutical/vaccine industry, which is a billion dollar industry, and laughs all the way to the bank. The commentator stated that it is offensive to suggest that people should line up at clinics and let nurses and pharmacy technicians who do not know their medical history give vaccines instead of at doctors’ offices.

The Department questions the use of the term “mass immunization,” which is not appropriate in the context of this final-form rulemaking. The type of mass immunization clinics referred to by some of the commentators, who have suggested that this might help to “catch-up” children who do not have all the required vaccines, are not viable in the present circumstances. Unlike smallpox and polio, there is not a public health “push” to eradicate a disease, which involved public health at the Federal, state and local levels, and during which children were lined up to be given vaccinations. As the Department has noted, the funding for the provision of vaccine in this way no longer exists, and there are eligibility requirements that children must meet to get immunizations with Federal vaccine. It should be noted that even though children were lined up to receive immunization at those immunization clinics, which were run as part of a public health effort to eradicate polio and smallpox, parental consent was required. In the event immunization clinics are held again for a public health reason, parental consent will always be required. A parent or guardian who denies consent does run the risk of having his child excluded from school unless the parent or guardian can provide an exemption.

It should also be pointed out that these circumstances do not technically meet the terms of 42 Pa.C.S. § 8334 (relating to civil immunity in mass immunization projects), which sets out the circumstances under which a private physician, not receiving remuneration, may operate a clinic and, if approved by the Department, have immunity for those actions.

PACIC commented that the Department stated that vaccine rates were lower than optimal, that this statement was vague and should be quantified. IRRC also requested that the Department provide specific data to address vaccination rates.

The Department’s immunization data is derived from its School Immunization Law Reports (SILR). The “School Immunization Summary 2014-2015” and the “School Im-

<sup>7</sup> DTaP is the pediatric formulation of the tetanus and diphtheria toxoids and acellular pertussis vaccine. Tdap is the adolescent and adult formulation.

<sup>8</sup> This does not hold true for all vaccines, for example, tetanus.

munization Summary 2015-2016," which contain county level data, are available on the Department's web site, as previously provided. Data from individual schools, referred to as "school level data" in this preamble, for 2014 and 2015 are attached to the RAF for this final-form rulemaking as Attachments 1 and 2, respectively. The Department provides county level data routinely. For purposes of this final-form rulemaking, the Department is providing school level data, but is redacting the names and addresses of the schools to protect the confidentiality of those schools. It is not the Department's intention to call attention to any one school, but to underscore the importance of vaccine rates.

*Comments regarding number of required immunizations*

Several commentators stated that the vaccine schedule has increased over threefold from the mid-1980s, when there were 23 vaccines on the schedule. One commentator stated that there are over 500,000 reports in VAERS, and that these reports include deaths and disabilities. The commentator stated that public health officials claim that the two events are not linked, but that parents of disabled children frequently cite recent vaccination as the catalyst for their children's decline. One commentator stated that it comes as no surprise that children are required to receive an ever increasing amount of immunizations to attend school, since many of government officials also have heavy ties to the major pharmaceutical companies, demonstrating a major conflict of interest to the American people. The commentator stated that in 1983 a child was only required to have 10 vaccines during his lifetime, but in 2013 a child will be required to have 36 to 38 vaccines, nearly 4 times the amount.

One commentator stated that his children were his to raise, and not the Commonwealth's. He stated that in the 1960s students received around eight vaccines. In the 1980s, students received around 11 vaccines. He stated that the Department was asking parents to allow their children to have 70 plus vaccines, and asked why. He asked whether there was one safety study showing that these vaccines are safe for all children. He stated that children with peanut allergies are not asked to eat peanuts for school lunches. He stated that people react differently to penicillin, and all children should not be expected to be served by one route of prevention.

One commentator stated that another drug should not be added to the absolutely unprecedented number of vaccines currently on the child vaccination schedule, especially because there was zero data on giving this extremely high number of vaccines to children.

The Department respects the commentators' views, but disagrees with them. The Department does not adopt the entire vaccine schedule recommended by ACIP, and only adds those immunizations it believes are appropriate for children in this Commonwealth. For example, influenza vaccine is not required for school entry or attendance, although it is recommended by ACIP. In fact, the Department requires ten immunizations for school attendance, and has added only four new immunizations since 1998 (Hepatitis B, varicella, MCV and Tdap). The Department did add a second MMR dose prior to this final-form rulemaking and is now, in effect, requiring a pertussis dose for attendance because ACIP recommendations are to give doses of DTaP and diphtheria and tetanus toxoids and pertussis as a vaccination for diphtheria and tetanus. The Department is also now adding an MCV dose in 12th grade. ACIP recommends many more vaccines for children. However, the Department does not adopt the ACIP recommendations wholesale. The Department reviews

ACIP's recommendations and determines which it believes are appropriate for children in this Commonwealth, obtains the approval of the Board and then proposes to add them to the existing list, as it has done in this final-form rulemaking.

The Department also disagrees that there is no data regarding the safety of providing this number of vaccinations, as discussed in this preamble.

One commentator stated that the decision to vaccinate should be based on the heavy consideration of factors such as the severity of different illnesses, their speed of transmission and the number of people sickened when weighing their benefits versus their adverse reactions and potential permanent injury. The commentator stated that in current society, vaccines are being overused with mandated legislation being passed very quickly, removing a parent or guardian's right to make informed decisions regarding a child's vaccine schedules and health. The commentator stated that she just turned 40 years of age, and when she was a child, the vaccine schedule for school aged children was shorter than it is now and spaced out so that combinations of different antigens to various diseases were not administered all at once. The commentator noted that more and more childhood vaccinations, including Hepatitis B, rotavirus and HPV, contain genetically engineered components with foreign DNA segments and adjuvants, such as aluminum, capable of triggering autoimmune responses which can contribute to multiple disabilities later on in life, such as allergies and autism. Because of these uncertainties, the commentator is against the Department's proposed rulemaking.

The Department disagrees with the commentator. The Department, with the approval of the Board, is acting within its statutory authority by promulgating this final-form rulemaking. The Department is not seeking to include all ACIP recommended vaccines for attendance at school. The regulations in this final-form rulemaking do not involve all vaccines available for children, or even all vaccines on the Department's current list of immunizations that are required for school entry and attendance. This final-form rulemaking only adds one dose of MCV in the 12th grade and the de facto requirement of pertussis for school attendance because of the unavailability of single antigen vaccines.

The Department agrees with the commentator that severity of illness, speed of transmission and safety of the immunization should be considered in deciding whether or not to require an immunization for school entry and attendance. The Department does take all this into account, and considers the advice of experts on staff, the Board and recommendations made by ACIP. ACIP, which is a committee made up of physicians and scientists with extensive experience in the field of infectious disease, immunology and vaccine research, performs a cost-benefit analysis, makes determinations of how to use vaccines and then issues recommendations. See *Vaccines: What You Should Know*, p. 24. The Department also considers the FDA's decisions to license vaccines. The FDA reviews vaccines to determine whether or not to license them, and considers the safety of the vaccine and its efficacy. See *Vaccines: What You Should Know*, p. 24. Neither the FDA nor ACIP requires that a child be given immunizations. The Department, based on the authority given to it by the General Assembly, and with the approval of the Board, has the discretion to review these determinations and decide what will be added to the list of diseases and conditions against which a child should be immunized.

The Department notes that the MMR vaccination and a requirement for immunization against hepatitis B are already in place. The MMR is only the subject of this final-form rulemaking to the extent that the Department rewrote the requirements to acknowledge that, in the United States, the vaccine is given as a combination vaccine. Because single antigen vaccines are still available outside of the United States, the Department left that requirement in this final-form rulemaking to account for the possibility that a child could enter school from another country with single antigen vaccines.

The Department is also not requiring a rotavirus immunization or an HPV immunization for school entry or attendance, although both are recommended by ACIP. The Department also agrees that several immunizations have been added to the list of required immunizations since the commentator was a child. When the commentator was at school age, in the early 1980s, several of the required immunizations were not available. For example, the varicella vaccination was not licensed in the United States until 1995, and was not added to the list of required immunizations until 1998. Vaccines against meningitis only became available in the mid-2000s. The Department addressed the reputed link of the MMR vaccine to autism previously in this preamble.

One commentator stated that researchers have shown that waning immunity is a problem with vaccines and diseases that previously occurred in children, so that the outbreaks are pushed off to a later date in older individuals, when they are more serious. The commentator stated that perhaps the Department should investigate ways to increase a healthy immune response instead of promoting more and more vaccines.

The Department disagrees with the commentator. Vaccine efficacy is still high regardless of waning immunity in some vaccines. No vaccine is 100% effective. Even if immunity wanes, as, for example, with pertussis, the vaccinated child is less likely to contract the disease, and is still protected against the most severe case of the disease.

Unvaccinated children have at least an eightfold greater risk for pertussis than children fully vaccinated with DTaP. . . Although vaccinated children can develop pertussis, they are less infectious, have milder symptoms and shorter illness duration, and are at reduced risk for severe outcomes, including hospitalization. . . [V]accination continued to be the single most effective strategy to reduce morbidity and mortality caused by pertussis.

See "Pertussis Epidemic," p. 4.

Several commentators stated that medical "experts" disagreed over vaccine safety and effectiveness, and that many studies that were done were epidemiological in nature, where data can be manipulated to show whatever one wishes to show. The commentators stated that few people believe that pharmaceutical companies are ethical or have the best interests of the public at heart, the opposite is true. The commentators stated that no one should be required to accept their products when one knows they are criminal (remember VIOXX). According to the commentators, it has been proven that the CDC has close contacts to pharmaceutical companies, and that "Vaccinate Adults," a newsletter published by the Immunization Action Coalition, condones and promotes increasing vaccine rates among adults. The commentators pointed out that the major supporters whose generosity they appreciate are eight drug companies and that the

CDC is their primary supporter. The commentators asked how anyone can ever think the CDC is truly in the business of controlling diseases and most especially controlling them for children.

The Department disagrees with the commentators' views, but is not in a position to convince them otherwise. The commentators have a particular viewpoint with regard to the motives of pharmaceutical companies, epidemiologists and the CDC. The Department is charged by the General Assembly with making decisions regarding which immunizations are required for school-aged children to protect them and the public's health. The Department has been carrying out this function for many years to the best of its ability and with great care for the safety of the children of this Commonwealth. The Department reviews and has relied upon the opinion of ACIP.

ACIP 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. ACIP does not include any person who is currently employed by or involved with employees of vaccine manufacturing companies or who holds a patent for a vaccine. In addition, ACIP includes ex officio members from Federal agencies involved with vaccine issues and nonvoting liaison representatives from medical and professional societies and organizations. Smith, J. C. (2010), "The Structure, Role, and Procedures of the U.S. Advisory Committee on Immunization Practices (ACIP)," *Vaccine*, 28(S 1), A68—A75, retrieved from <https://www.cdc.gov/vaccines/acip/committee/downloads/article-2010-role-procedures-ACIP.pdf>. ACIP's charter states:

The committee shall provide advice for the control of diseases for which a vaccine is licensed in the U.S. The guidance will address use of vaccines and may include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling a disease for which a vaccine is available. Guidance for use of unlicensed vaccines may be developed if circumstances warrant. For each vaccine, the committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended. The committee develops guidance on route, dose and frequency of administration of the vaccine, associated immune globulin, or antimicrobial agent. The committee also provides recommendations on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events. Committee deliberations on use of vaccines to control disease in the U.S. shall include consideration of disease epidemiology and burden of disease, vaccine efficacy and effectiveness, vaccine safety, economic analyses and implementation issues. The committee may revise or withdraw their recommendation(s) regarding a particular vaccine as new information on disease epidemiology, vaccine effectiveness or safety, economic considerations or other data become available.

The committee also may provide recommendations that address the general use of vaccines and immune globulin preparations as a class of biologic agents. These general recommendations may address principles that govern administration technique; dose and dosing interval; recognized contraindications and precautions; reporting adverse events; correct storage,

handling, and recording of vaccines and immune globulin preparations; and special situations or populations that may warrant modification of the routine recommendations.

In accordance with Section 1928 of the Social Security Act, the ACIP also shall establish and periodically review and, as appropriate, revise the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children Program, along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric vaccines. The Secretary, and as delegated the CDC Director, shall use the list established by the ACIP for the purpose of the purchase, delivery, and administration of pediatric vaccines in the Vaccines for Children Program.

Further, under provisions of the Affordable Care Act (Section 2713 of the Public Health Service Act, as amended), immunization recommendations of the committee that have been adopted by the Director of the Centers for Disease Control and Prevention must be covered by applicable health plans.

Retrieved from <http://www.cdc.gov/vaccines/acip/committee/charter.html>. The Department's own experts review ACIP recommendations, considering the unique needs of the children of this Commonwealth and with the approval of the Board, as required by law, determines to add those immunizations to the list that it believes are necessary for that protection.

*Comments regarding communication of proposed rulemaking*

Several commentators asked whether the proposed rulemaking was communicated to family practice doctors and pediatricians in this Commonwealth. One commentator stated she had heard many doctors' offices were not aware of the proposed rulemaking, and asked what was being done to inform them so that they do not become a barrier to care. Several commentators recommended that the Department educate new and existing health care practitioners regarding the school immunization requirements, because in her opinion some licensed practitioners were not familiar with them. One commentator expressed concern that in her experience immunizations were being given on the wrong schedule. One commentator stated that physicians would have to play a major role in implementing this final-form rulemaking.

Several commentators recommended educating parents as well as health care practitioners and school staff. One commentator stated that she hoped the general public would be educated as well as physicians and their offices.

PSEA and several other commentators expressed a need for education of the groups impacted by this final-form rulemaking. PSEA recommended that the Department do an educational campaign for parents, schools and health care providers that administer immunizations, including pediatricians, family physicians, internists, CRNPs, pharmacists and health clinics. PSEA recommended that the campaign include model guidance and educational materials that schools can use for educating parents about vaccine requirements, provisional periods, exceptions and reporting. PSEA recommended that the training for providers, including support staff, include medically sound information about the revised immunization requirements, schedule and timing of shots, and indications and contraindications, as well as best prac-

tices for maximizing patient contacts, including acute office visits for minor illnesses, to keep a child's immunizations current.

The Department agrees that education of health care providers and practitioners that provide vaccines, including pharmacies, regarding these requirements would be useful and helpful, and will reach out to stakeholders and medical organizations for this purpose when this final-form rulemaking is approved. The Department will ensure that the immunization requirements are made available to schools prior to kindergarten registration, which begins in March 2017, so that all affected persons are aware of the new requirements 5 to 6 months before the start of the 2017-2018 school year.

*Comments regarding HIPAA and the sharing of immunization information between physicians and schools*

Several commentators who identified themselves as school nurses stated that doctors' offices refuse to provide immunization records to school nurses, claiming that it was a violation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub.L. No. 104-191). Two commentators stated that it would be helpful if HIPAA did not apply between doctors' offices and schools, because it would be helpful to get records directly from doctors' offices instead of having to depend upon parents who do not follow through with obtaining the required information. One commentator stated that she had actually excluded a student from school who had already had a vaccine but the doctor refused to send her the record, and the parent refused to pick up the record at the doctor's office. She did not find out that this is why the child's record indicated the child did not have the vaccine until after the exclusion had occurred, but she found the situation to be "just ridiculous."

One commentator recommended that the Commonwealth allow for the free exchange of immunization records between school nurses, doctors' offices and health clinics without the need for a medical release and that doctors' offices should be required to comply with this "mandate."

PSEA and several commentators strongly supported the Department's Statewide Immunization Information System (SIIS) as a very useful tool to allow for sharing of information between health care providers and schools. SIIS allows for the voluntary participation of providers to report immunization delivery in an electronic information system. PSEA encouraged the Department to determine effective strategies to increase physician and health care provider participation and utilization of SIIS. PSEA noted that central collection of the immunization information would help address some health care providers' hesitation, based on HIPAA and privacy concerns, in sharing immunization information with schools without parental consent.

Several commentators recommended that persons authorized to administer immunizations should be required to record immunizations given in SIIS. One commentator noted that a school nurse could look in SIIS to find the immunizations and would be able to concentrate on students who do not have the necessary immunizations. One commentator recommended that general and pediatric practitioners need to make sure that all vaccinations given at the 4th year well baby visit are entered into SIIS. The commentator stated that it did not appear that licensed practitioners are familiar with mandated school immunizations. The commentator noted that if the immunizations were given and put into SIIS, the school nurses

would at least be able to locate them and avoid many phone calls, unanswered certified letters and attempts to enforce compliance through education, which many parents have already had, as well as threats of exclusion. Another commentator stated that many times the child has the immunization, but the school nurse does not have the proper documentation. The commentator stated that parents are often charged a form fee when they request a print out of their children's immunization records at a time other than at the regular well child checkup. SIIS would eliminate this issue.

Two commentators expressed surprise and frustration that more practitioners did not use SIIS and input all immunization data into it. One of these commentators suggested a monetary fine might force practitioners to participate. She stated that physician participation in SIIS was a critical component for stricter provisional enrollments to be enforced.

PSEA and another commentator noted that it made sense to use an electronic system, since children who were homeless or who switched schools frequently would always have their electronic immunization information available, whatever school district they were in.

One commentator recommended that the Department strongly consider a Statewide system of online school-based charting for kindergarten to 12th grade to which all school nurses would have access. According to the commentator, this is the only way to seamlessly track the health of students in this Commonwealth. She recommended that new students be immediately entered upon registering in schools, and parents, or in the case of children in the custody of Children and Youth, the Children and Youth Worker responsible for the child, should be required to sign a release. The commentator stated that at the present time, they do not always receive records from schools out-of-State or from school districts in this Commonwealth because children move around.

While the Department understands the frustration of school nurses over the difficulty in obtaining immunization information, the Department cannot change the requirements of HIPAA, which is a Federal law. Health care providers are legally correct in hesitating to turn over immunization information to schools without parental consent. The Department understands the need for an option that provides immunization information more quickly. HIPAA does have an exception for public health programs, including reporting programs. If the Department were to add a section to Chapter 27 (relating to communicable and noncommunicable diseases) requiring reporting of vaccine administration to the Department's SIIS, this could address the concerns raised by school nurses on this issue. The Department has the authority to do so under the Disease Prevention and Control Law of 1955. This action would require a separate rulemaking.

The Department agrees that no child should be required to be revaccinated or excluded from school if there is a record that is obtainable. The only way the Department can eliminate the need for a consent under HIPAA to transfer personal health information is for the Department to bring the requirement for provision of the information under the public health laws of the Commonwealth. Reporting to SIIS is voluntary. The Department cannot set up a system for school health records.

One commentator stated that vaccinations are a medical procedure and do not belong in a virtual database. This is a violation of privacy and HIPAA laws. The

commentator stated that it was no wonder physicians were not entering their vaccination records there. The commentator stated that this played right into the vaccine industry's billion dollar business of using the government to force their agenda of more vaccines on children. Neither the Commonwealth nor the Federal government has the right to have citizens' medical records in their databases.

As the Department has stated, use of SIIS is voluntary and does not require reporting of student identifying information to the Department. Information reported by schools to the Department under § 23.86 (relating to school reporting) does not contain student names or health records. Under § 23.86, schools report aggregate data to the Department, for example, numbers of immunizations by type and in certain years. No identifying information is passed between the school and the Department through the SILR. The Department does have SIIS, its vaccine registry. As has been stated, reports to SIIS by providers are voluntary, and the only information included in that registry comes from providers who have obtained the appropriate consents from their patients to include that information in the Department's system. There is no HIPAA violation.

Should the Department choose to promulgate separate regulations requiring the reporting of vaccine delivery by persons administering vaccines, the Department has the authority to do so. See section 3 of the Disease Prevention and Control Law of 1955 (35 P.S. § 521.3), section 16(a)(6) and (b) of the Disease Prevention and Control Law of 1955 and Section D of this preamble. If vaccine delivery does, at some future time, become a reportable disease, infection or condition under the Disease Prevention and Control Law of 1955, the information in SIIS going forward would be protected under the confidentiality provisions of this law. The Department would be prohibited from releasing that information with three very limited exceptions: upon the consent of the individual; for research purposes under Department supervision; and if the Department determines that to release the information would further the prevention and control of the spread of disease. See section 15 of the Disease Prevention and Control Law of 1955 (35 P.S. § 521.15). Because HIPAA contains a public health exception in these instances, there would be no HIPAA violation. See 45 CFR 164.512 (relating to uses and disclosures for which an authorization or opportunity to agree or object is not required).

#### *Comments regarding insurance coverage for immunizations*

One commentator stated that the cost for vaccinations needed to be covered by the parent or guardian's health care insurance, or some form of Statewide health care. The commentator stated that the cost could not be passed on to the schools.

The Department appreciates the commentator's concern regarding cost. It was not the Department's intention that the cost of the vaccinations be passed on to schools. If a school elects to request participation in the Department's School Immunization Catch-Up Program, the school is provided the vaccine by the Department, free of charge.

One commentator asked what the required immunizations were for children in pre-kindergarten through 12th grade.

The list of diseases against which children shall be immunized to attend school is in § 23.83, which is amended in this final-form rulemaking. The list of dis-

eases against which children attending a child care group setting shall be immunized are in § 27.77 (relating to immunization requirements for children in child care group settings). That list will not be impacted by this final-form rulemaking.

One commentator asked whether the Department would provide clinics over the summer for students to get the required immunizations since doctors' offices might not be able to accommodate the increase in number of children seeking vaccinations.

One commentator stated that she knew the Department was increasing clinics to get children vaccinated, but said she could not understand why these were only open to those children who did not have health insurance or whose insurance did not cover vaccinations. The commentator stated she thought it would be more helpful if the clinics were open to all who felt they needed an alternative.

The Department no longer has the ability to run clinics for all children due to changes in Federal funding requirements that limit the provision of the vaccine the Department obtains through its Federal grant to uninsured or underinsured children (that is, children whose insurance does not cover vaccines) or because they are American Indian or Alaskan Native. See sections 1902(a)(62) and 1928 of the Social Security Act. Schools may apply for the Department's School Immunization Catch-Up Program, which provides VFC Program vaccines to eligible children.

One commentator asked what the role of the Department of Health would be and whether school nurses could send students to State health centers if they had insurance.

One commentator stated that there was a State health center within 10 miles of the commentator's school, but noted that families still lack transportation and other resources to access the State health center. The commentator noted that her school district was rural and covered over 224 square miles. The commentator questioned how the proposed rulemaking would help those families.

The Department cannot immunize children who are insured, so the ability of an insured child to access a State health center does not impact the regulations. By law, the vaccine received by the Department through its Federal grant through the Federal VFC Program may only be given to children who are uninsured and underinsured, or meet one of the program's other eligibility requirements. Under that program, the Department may give vaccine to schools if there is a need to catch up the VFC-eligible children in the school's population. Any school may apply to the Department for vaccine for this purpose. There are VFC Program providers throughout this Commonwealth. In addition, a child who is eligible for the VFC Program may also obtain vaccine at a Federally qualified health center (FQHC). The Department also administers vaccine to VFC Program-eligible children in most of its State health centers through agreements with FQHCs. The Department has a list of these FQHCs and VFC Program providers, and can provide that information to a parent or guardian with a VFC Program eligible child seeking to find a provider.

One commentator asked how parents were to pay for the immunizations if an insurer claimed the child's coverage would not cover the immunizations before the start of the school year. The commentator stated that she received calls on many occasions that an insurer would not cover the visit until after the start of the school year.

Under the Patient Protection and Affordable Care Act (ACA) (Pub.L. No. 111-148), enacted March 23, 2010, an insurer is required to cover all immunizations recommended by ACIP. See section 2713(a)(2) of the ACA (42 U.S.C.A. § 300gg-13(a)(2)), regarding coverage of preventative health services. Failure to do so is a violation of the law. The immunizations required for school attendance by the Department are ACIP recommended vaccinations. Both the health care practitioner and the parent should be aware of the insurance coverage, and plan to receive the required vaccinations in accordance with the Department's requirements and their insurance coverage. Delay in obtaining the vaccinations could create problems.

#### *General comments*

One commentator asked what steps a school nurse should take if a child did not comply with mandated health screening. The commentator stated that some parents will turn in forms that state that the children will have a private dental or physical examination, and then turn nothing in.

This final-form rulemaking does not deal with mandated health screenings. Questions regarding those screenings should be directed to the Department's Division of School Health.

One commentator stated that she hoped the Department would have a sufficient supply of vaccine available to accommodate the new requirements.

The Department does not anticipate any vaccine shortages in the near future. The Department no longer provides vaccine to the general public and would only make vaccine available for children eligible for the VFC Program.

One commentator asked whether the Department would provide a form letter to send home to kindergarten students currently in a provisional status if the regulations were effective for the 2015-2016 school year. The commentator also asked whether there will be a form letter available for future kindergarten students.

This final-form rulemaking will be effective August 1, 2017. Publication of this final-form rulemaking is expected to be in time for registration for the 2017-2018 school year to enable schools to provide information to parents and guardians regarding the amendments to the regulations. The Department will not be providing a form letter.

Two commentators raised issues about children with late summer birthdays or who are "young for their grade." One commentator stated that she had taken her son for a physical required for entry into 6th grade, but the doctor would not give him his immunizations because he was not yet 11 years of age. He was 13 days from turning 11 years of age and had to make a return trip to the doctor's office. The commentator noted that there are children who have skipped grades or have moved from areas where school start dates are different, which places them in a pocket of not being able to receive the vaccine and then not being able to go to school. The commentator noted that medical immunizations are based on age, while school immunizations are based on grade, which causes problems with compliance. One commentator asked that a delay exemption be added to the regulations so that children who enter school early, or who advance more quickly, are not forced to receive vaccinations at an accelerated rate relative to their biological age if the medical recommendations for their biological age conflict with educational requirements.

The Department is not aware that the immunization requirements would conflict with the possible age of a child entering school. Most vaccinations necessary for school entry and attendance are licensed for a child younger than 5 years of age, and, therefore, school entry and attendance is not an issue. The same applies for a child at entry into 7th grade. There is no issue with respect to Tdap and the first dose of MCV is recommended at 11 to 12 years of age. If there were to be an issue with an exceptionally accelerated child, the medical exemption is available for use. With respect to the commentator's son, there is a 4-day grace period built into the regulations, that is to say that a child receiving a vaccination within 4 days of the minimum age for vaccination may be counted, but a dose given further than 4 days before may not. See § 23.83(f). The Department encourages parents to take this into consideration when seeking immunizations.

One commentator stated that he was very concerned because he did not understand how the Department and the Department of Education had overlapping duties and roles. He stated that the Department of Education was to educate and the Department was to keep this Commonwealth safe. According to the commentator, only when a wild virus might happen should the Department be involved in local schools. The commentator stated he thought it was "really weird" when the Department and the Department of Education have joined the CDC as the experts, in the jurisdiction of medicine, dictating to children, families and health care practitioners what to ingest and inject and when to do so. The commentator recommended that the Department read an article in on the *Washington Post* web site posted on May 3, 2016, "Researchers: Medical Errors Now the Third Leading Cause of Death in the United States." He also asked that the Department look at the top ten causes of death, stating that only one cause, the flu, can possibly be prevented by vaccination, and those deaths usually occur in the elderly and not in school-aged children.

The Department agrees with the commentator insofar as the Department's intention is to keep this Commonwealth safe and healthy. The Department disagrees that childhood diseases cannot be prevented by vaccination. Vaccination has prevented disease and death among children and will continue to do so. See "Benefits from Immunization." Falling disease and death rates in measles, mumps, rubella, diphtheria and other diseases bear this out as well. See *Pink Book*, Appendix E.

With respect to the comment that the Department has made itself an expert, the General Assembly has provided the Department with the legal authority to set the list of diseases against which children shall be immunized to enter and to maintain attendance at schools. See Section E of this preamble. The Department and the Department of Education share responsibilities in schools, as it is for school administrators to enforce the requirements set out by the Department under the Public School Code of 1949, unless there is an unusual expression of illness or any type of disease outbreak. The Department's authority to prevent and control the spread of disease in public and private schools is specifically set out in section 3 of the Disease Prevention and Control Law of 1955. Parents and guardians with strong objections to the regulations may still seek a medical or religious/philosophical exemption to obtaining an immunization, but in the event of a disease outbreak necessitating isolation or quarantine measures, or measures involving exclusion of persons not adequately vaccinated, an unvaccinated child will be excluded from school. See Chapter 27, Subchapter C

(relating to quarantine and isolation) and sections 5, 7 and 11 of the Disease Prevention and Control Law of 1955 (35 P.S. §§ 521.5, 521.7 and 521.11).

One commentator recommended that everyone in a position of authority to change vaccination laws should watch "VAXXED: From Cover-up to Catastrophe" and get educated as to what is really going on. Another commentator recommended that everyone should see "VAXXED: From Cover-up to Catastrophe," which is a very important documentary. The commentator stated that this is not an anti-vaccination documentary, it is a documentary explaining a CDC fraud regarding the MMR vaccine. The commentator stated that locations where the documentary are playing are limited because the pharmaceutical/vaccine industry is doing everything they can to keep this out of the mainstream.

One commentator asked that the Department hear the cries of concerned mothers from this Commonwealth who oppose the proposed amendments to current vaccination policy.

The Department understands that some parents are concerned about the efficacy and safety of vaccines. As previously noted, vaccines, like medication, can cause side effects, and no vaccine is 100% effective. The most common side effects are mild, but many vaccine-preventable diseases can be serious, or even deadly. Although many of these diseases are now rare in the United States, they are present in other parts of the world and can be brought into this country, putting unvaccinated children and adults at risk. The Department recommends that parents talk further about their concerns with their children's primary care physician.

*Comments opposing imposition of school vaccine requirements in violation of parental and human rights*

Multiple commentators opposed what they considered to be mandatory vaccination in general, provided anecdotal reasons why requiring immunizations was illegal and immoral, and a violation of individual rights. The Department has detailed those comments as follows, and then provided a response to all of the comments.

Multiple commentators stated that parents should have rights to make decisions for the best interests of their children and about their children's health, including whether or not to vaccinate their children. One commentator was opposed to government regulations interfering in the choices of the commentator's health concerns. One commentator stated that it was a violation of human rights to force vaccines on people. One commentator opposed changes to vaccine policy that interferes with a parent's God-given right to make medical decisions for their children. The commentator stated that informed consent is a priority. The commentator opposed an increase to the number of vaccines currently on the childhood schedule and opposed adding more vaccines as a requirement for school. One commentator said that one size fits all is not a safe policy. One commentator stated that it was a disgrace to have that right taken from parents. The commentator expressed the belief that this was headed toward socialism. The commentator prayed that the Department take the time to listen to the voice of the people, and defend the rights of parents and citizens of the United States. The commentator stated that this was not about vaccinations, but about government control of personal rights, and where rights and freedoms lie, with citizens or with government officials.

One commentator stated that she completely opposed the mandatory vaccine requirement for all school-aged

children. The commentator stated that these policies are unconstitutional, and that the Department, the Department of Education and individual schools will be subjected to massive future liability as there is increasingly more evidence past and present, being exposed by individuals across multiple spectrums and disciplines within and without the medical and scientific communities of the injury and death caused by vaccines. The commentator stated that by removing an individual or parental right to take responsibility for their own or their children's health, these entities are taking on full responsibility and liability for this child's health and any injury or death that may occur due to these mandates. The commentator stated that the Department, the Department of Education and individual schools for all levels of education are placing themselves in an extremely liable position of not giving parents and college students true informed consent. The commentator stated that the current illegal, unconstitutional practice of these entities threatening, bullying, coercing, administering vaccines without signed informed consent and misinforming (deceiving by downplaying and omitting risks and alternatives to vaccines) parents and students into vaccinating to attend any educational institution, public or private, must be stopped. The commentator stated that vaccines cause injury and death as even the Federal government acknowledges. The commentator asked that the Department be informed, and defend the constitutional rights of the citizens of the United States and the residents of this Commonwealth. The commentator stated that this was the citizens' inalienable right. The commentator stated that she respected science, and that while people lie, that science never lies. People manipulate data. Science never manipulates data. She stated that people compromise for gain, science never compromises for gain.

One commentator stated that it is very important to the commentator's family and other families that elected officials uphold a family's right to decide what is best for the family's children, including choices involving vaccines: whether, when and which vaccines to give the child. The commentator stated that the list of vaccines continues to grow, and parents must have the right to decide whether or not the list and schedule are what is truly best for children in this Commonwealth. The commentator appreciated the Department working to ensure parental freedoms were not compromised.

One commentator stated that she was very concerned that the proposed rulemaking would compromise the commentator's rights as a parent to provide the commentator's child with proper medical care and might even be dangerous to the children affected by the amendments.

One commentator stated that it was not the government that would be living with death or mental or physical disabilities that the vaccination might cause, and that the loss was bad enough, but no one could be sued for the loss.

One commentator stated that many people have deep personal convictions and religious beliefs that are strongly against vaccination, and many children have reactions to them. According to the commentator, taking parental choice out of vaccination is wrong. The choice of whether the commentator wants these inoculations is a basic human right.

Several commentators supported comments provided by PACIC. One commentator stated that it was the inalienable right of citizens in a free country to maintain informed consent for all medical procedures, including vaccines.

One commentator stated that the Department should not take her God-given right to choose for her child away from her or her family. The commentator stated that some vaccines have been banned in other countries, and forcing these on kids against the will of the parent should be illegal, but the Department is trying to legalize it and say it is helping. Too many people die from these vaccines to say this is helping. The commentator stated that no one should be forced into receiving an injection or procedure of any kind that they or their parent or guardian does not agree with, especially when the injection contains known carcinogens, neurotoxins, and animal or fetal tissue, or both.

One commentator stated that she valued the opportunity to be an active voice on behalf of children, and for ourselves as members of a country unique in the world for its enshrined defense of individual conscience and religious conviction.

One commentator stated that the citizens of the United States have medical freedom, freedom over their own bodies, without fear of losing the privileges of citizenship, like education or employment. The commentator stated that vaccines are a medical intervention involving risk, and the right to opt out of them must be maintained. Because it is unknown how sensitive a child or adult might be to a vaccination, the right to opt out of them must be maintained. This is a very basic human freedom and must be preserved. The commentator stated that this is a vital matter that concerns every parent and child in this Commonwealth and should be fully publicized so that citizens may give input to their legislators. The commentator urged the protection of parental choice.

One commentator stated that this Commonwealth was not a third world country, and that there was only one single reported measles case in this Commonwealth last year. The commentator stated that there was absolutely no threat to the public's health. The commentator stated that adding more questionably safe vaccines to the mix is pointless and expensive. The commentator stated that above all it is imperative that a parent decide their child's health, and not some bureaucrat. The commentator stated that vaccines can and have injured children. The commentator stated that unvaccinated children pose no more threat than vaccinated children. The commentator was personally aware of several children who are exceptionally healthy and intelligent and have never had a vaccine through childhood. The commentator counts himself as one of many that live productive lives without vaccines, boosters or prescription drugs. The commentator asked that parents be allowed to exercise their human rights to raise children in their own way. The commentator stated that vaccines are not for everyone just as prescription drugs are not for everyone, and that everyone deserves a choice.

One commentator opposed the proposed rulemaking in solidarity with a friend whose life had been affected by a routine vaccination, and to amplify her words.

One commentator stated that given links of problems to vaccines and the unreliability of the CDC to conduct unbiased studies, no additional vaccines should be mandated.

One commentator stated that there is much concern over vaccines right now due to the number and type of vaccines that are being given to babies and young children. The commentator stated that more and more information and research is coming out every day and people are starting to become educated on what they are

injecting into their children. The commentator asked that the Department slow down changes and additions to the vaccine policy for young children. The commentator stated that we must take responsibility for the safety of children in this Commonwealth because the vaccine manufacturers do not.

One commentator stated that there should be no further mandates pushed on the citizens of this Commonwealth without the provision of choice based on the negative side effects the vaccines could have.

One commentator stated that the proposed rulemaking should be withdrawn and no additional vaccine mandates be issued.

Several commentators stated that they had done intensive research on vaccines and their effects. One commentator stated that from her research she had ascertained that today's vaccines contain ingredients which are highly toxic synergistically or alone, or both. The commentator stated that vaccines cause life-long autoimmune disease, such as autism, paralysis pain and death, and they are usually ineffective. The commentator stated that people have been given a highly effective immune system, and vaccines make it less effective. She stated that she has many friends who have received the flu vaccine which is full of toxic mercury and then have come down with the flu in 3 weeks. The commentator stated that vaccines should never ever be mandated. The commentator stated that this was a gross violation of the Fourth Amendment to the United States Constitution. The commentator stated that the sale and use of vaccines is a crime against nature solely for the profit of big pharma.

HSLDA commented that the law should generally defer to a parent's right to make medical decisions for a child.

Two commentators stated that it was a violation of human rights to force vaccines on people. Vaccinations should be recommendations and not requirements. Vaccinations are medical treatments with serious risks that should be a private matter between patients and doctors, and should only be administered by family doctors and pediatricians in their offices, and not in drug stores or schools. The commentators stated that schools should not be allowed to ask for medical information, such as vaccination status. The commentators stated that if it is not permissible to discriminate against people who have communicable diseases like AIDS, hepatitis or herpes, then no one should discriminate against disease-free people and prevent them from keeping jobs or attending school because of vaccination status.

One commentator stated that it was wrong and unethical to strip Americans of their freedom to make decisions regarding medical procedures for themselves and their families. The commentator asked that the Department withdraw the proposed rulemaking and not issue mandates regarding vaccinations.

One commentator stated that she prided herself on teaching her chiropractic patients about true health to take charge of their health and the health of their families. According to the commentator, a large part of this involves having the right to choose what medical procedures are best given the specific health needs of the family. The commentator stated that she had made it her life's work to better understand the human body and how to restore and maintain health, and that she was appalled that the Commonwealth wants to completely strip the individual's freedom to choose what is best for the individual's family. The commentator stated that she had spent more time studying to understand vaccinations

than most politicians who are often blinded by the truth given their political positions.

One commentator stated that parents care more about children than life itself. They should be able to make informed decisions. The commentator asked that no more laws be passed to "keep us safe." The commentator stated that the United States is the "land of the free," not land of the legislated.

Another commentator stated that every child has a right to a free and public education without discrimination for not having a dangerous procedure—vaccinations. The commentator stated that vaccines have serious side effects and are known to actually shed the diseases they supposedly protect persons from. Outbreaks like the one in California occur in populations that are 100% vaccinated. According to the commentator, there is an urgent need to require legal protection of parental rights regarding medical and religious exemptions to vaccinations for minor children. The commentator stated that she was proud to have been born and raised in this Commonwealth, and she would be saddened to have this Commonwealth known for restrictive and unjust amendments to the law on vaccines.

One commentator stated that parents who interact with their children daily are more adept to make medical decisions than medical doctors who see children for 15-minute to 30-minute well child annual visits. The commentator stated that herd immunity debases the individual needs of each child of all races. The commentator believed that some immunizations are an effective means of keeping children healthy. The commentator stated that they chose to immunize when their children are otherwise healthy. The commentator stated that they chose to spread out their immunizations, ten immunizations at one time is unhealthy. The commentator stated that they respect other parents' decisions not to immunize their children. The commentator stated that the number of immunizations demanded in today's world is disconcerting. The commentator stated that antibiotics exist in today's world which quickly heal. The commentator stated that her nephew had seized after immunizations. The commentator stated that friends have children who, after the chickenpox vaccine, have developed severe allergies, lameness and hearing loss. The commentator stated that a parent whose child adversely reacts to an immunization is legally and morally responsible for the child's well-being. Because of that responsibility, the parent should be able to make the choice.

One commentator stated that there are too many questions without answers regarding vaccine safety. The commentator stated that there are recalls, failures and many are for diseases that would not cause great danger to the public. The commentator stated that vaccines need to remain a personal decision because they are not safe for all people and therefore cannot be required of all.

One commentator stated that people deserve the right to deny vaccinations under the United States Constitution. The commentator requested that the Department represent the citizens of this Commonwealth as it should. If the Department were to read the ingredients in the vaccinations, it would know they were not safe for humans.

One commentator stated that she homeschooled her seven children, three of whom she adopted from China, which has decided it knows what is best for its families—the two-child policy, which causes millions of baby girls to be abandoned every year. She stated that she adopted

these three children in an effort to protect, love and provide a home for them, and she is working for the parental rights of all parents to do that. She stated that the United States has always been regarded as the land of liberty, and was founded on the principles of individual liberty and self-government. She stated that more and more the rights of American parents to direct the care and upbringing of their children is being lost. She stated that it is the function of government to protect individual liberty and prosecute crime, and the rights of good parents, who know and love their children best, should be protected and not infringed. She stated that to assume the government knows best how to raise children is to assume that it has some superior intelligence or ability. The commentator asked that if the decisions made by people are so bad that it is not good to permit people to be free, how is it that the decisions made by legislators are always good. She asked whether legislators belonged to the human race. She asked whether the Department believed that if left undirected, mankind would destroy itself because the people's ability to self-govern is inadequate. She asked whether the Department believed that it had a superior intelligence that placed it above them. She asked that the Department give up its idea of forcing parents to acquiesce to the latest vaccination requirements. Not only are they oppressive and unjust, they imply that the government thinks it is infallible and parents are incompetent. The commentator stated that parents are not required to immunize their children until they are admitted to school, and this should be left unchanged. She asked that the rights of parents to raise and direct the upbringing of children in the way the parent believes is right be protected.

One commentator stated that the Federal government has shielded the vaccine industry from effective oversight and liability, and that horrific scandals continue to emerge. The commentator stated that the public has been willfully misled about "vaccine safety and effectiveness," as succeeding generations continue to suffer permanent injury and death. The commentator stated that in this decades-long battle for the truth, people who share her beliefs state that "vaccines should not be mandated, vaccines should be banned." She provided ten reasons why this was the case, and included links and citations to articles supporting these positions, as well as additional information, movies, videos and books regarding vaccine dangers, vaccine reaction symptoms:

(1) Vaccines cause catastrophic and permanent damage and death. The commentator stated that total compensation from the Vaccine Court over the life of the VAERS program was \$3.3 billion, that since 1988 over 16,878 petitions have been filed with the VAERS program but only 4,582 of those were determined to be compensable. The commentator stated that the flu vaccine is the most dangerous shot in the United States, and in June 2014, a report covering a 3-month period shows that 78 cases were awarded settlements for vaccine injuries, with 55 being for the flu shot, including 1 death. Flu vaccine injuries include GBS, chronic inflammatory demyelinating polyneuropathy, rheumatoid arthritis, shingles, brachial plexus neuropathy, Bell's palsy, brachial neuritis, transverse myelitis, lichenoid drug eruption and narcolepsy.

(2) There is massive underreporting in a government-operated passive reporting system of adverse reactions to vaccines. The Federal Department of Health and Human Services (HHS) admits that there is systemic underreporting in VAERS, since it is a system of passive reporting, and information is not automatically collected,

but can be voluntarily submitted by anyone. The commentator noted that reports vary in quality and completeness. The National Vaccine Information Center states that it is estimated that less than 10% of vaccine-related health problems are reported to VAERS.

(3) HHS promotes the "coincidence myth" of sudden infant death syndrome and other adverse health effects of vaccines. The commentator quoted an HHS statement that 10 million vaccines a year are given to children between 2 and 6 months of age, and at this age infants are at greatest risk for certain medical adverse events, including high fevers, seizures and sudden infant death syndrome. The commentator highlighted a statement by HHS that some infants experience these events shortly after a vaccination by coincidence.

(4) Vaccines contain numerous toxic ingredients. The commentator provided several links to government and industry documents to support this statement. The commentator stated that a highly toxic mercury preservative remains in flu vaccines, including nonmercury flu shots, and provided several links in support of this information. The commentator stated that the government admitted that even in single dose flu vaccines thimerosal is present in trace amounts. The commentator stated that mercury has been replaced by aluminum, which some consider even more toxic than mercury.

(5) Vaccines spread disease. The commentator stated that the vaccinated population actually threatens the unvaccinated population by spreading or shedding disease. The commentator stated that herd immunity is a shocking reversal of the truth by the vaccine industry to confuse the issue, deny responsibility for spreading diseases and target those who refuse to be vaccinated.

(6) There is no effective Federal oversight of vaccine studies, of vaccines' safety or effectiveness, or the actual number of people who have been harmed. The commentator stated that the Federal government created a passive reporting system, VAERS, which relies upon reports from the industry, medical professionals and victims, but does not check the accuracy of the reporting system.

(7) There is no effective Federal oversight of manufacturers' facilities, including foreign manufacturers in China and India who produce the most vaccines and medicines. The commentator stated that these manufacturers are not being inspected by the main United States regulatory agency charged with protecting the health of the American consumer.

(8) Government institutions are protecting the "vaccine industry from liability and lawsuits and are not protecting the public's health." The commentator asked why, if vaccines are stated to be "extraordinarily safe" by a major vaccine proponent physician why are they shielded by Congress and the United States Supreme Court from pharmaceutical corporation product liability and physician malpractice lawsuits when vaccinations cause the death or injury of an individual. The commentator stated that the vaccine industry was going out of business due to law suits from vaccination victims until Congress came to its rescue in 1986, by passing the National Childhood Vaccine Injury Act of 1986 (42 U.S.C.A. §§ 300aa-1—300aa-34), which created the National Vaccine Injury Compensation Program and the Vaccine Court. The commentator stated that the Vaccine Court places the burden on victims to prove harm, rather than on vaccine manufacturers to prove safety. According to the commentator, despite these onerous burdens \$3.3 billion has been awarded to victims since then. The commentator stated

that the National Childhood Vaccine Injury Act of 1986 allows vaccine injury victims to sue manufacturers when they did not receive compensation. Since 2011, the Supreme Court has shut off all access to the courts.

(9) The history of the vaccine fraud is the all-too-familiar history of collusion between government and business.

(10) Vaccinations are a violation of the “precautionary principle” and the Hippocratic Oath, “first do no harm.” The commentator stated that the medical profession’s reputation is in shambles because preventable medical errors are the third leading cause of death in the United States and claim the lives of approximately 400,000 patients each year. The commentator stated that the medical profession’s general support for vaccination will worsen these statistics and justifiably destroy the public’s trust.

The Department disagrees with these commentators, and has not changed the final-form rulemaking regarding this topic. The Department has the authority, through the delegation of the General Assembly and the application of its police powers, to require certain immunizations for school entry and attendance, and the Department and the Department of Education have the authority through the application of their police powers to exclude a child who fails to comply with that requirement. The Fourth Amendment to the United States Constitution protects individuals from unreasonable searches and seizures by the government. The commentator raising the Fourth Amendment to the United States Constitution neither explained how a requirement that children be vaccinated prior to school attendance or entry is an unreasonable search or seizure, nor has the commentator cited any case law to that effect. In fact, the Department’s ability to require vaccinations upon school entry and attendance is in Commonwealth law and has been upheld by the Pennsylvania Supreme Court, which stated that it is within the police powers of the Commonwealth to exclude from school children who have not been appropriately vaccinated. *Stull*.

In *Stull*, the plaintiff received notice from the school that his daughter, beginning December 11, 1905, would be excluded from school in violation of the act of June 18, 1895 (P.L. 203, No. 124), which requires students be vaccinated prior to admission into school. In deciding the case, the Pennsylvania Supreme Court pointed out that the question in the case, whether the act that requires vaccination as a condition precedent is a valid exercise of the police powers of the Commonwealth, had been decided twice—once in *Duffield v. School District of Williamsport*, 162 Pa. 476 (1894) and again in *Field v. Robinson*, 198 Pa. 638 (1901). In *Stull*, the court stated that “vaccination is a highly useful ameliorative if not always a preventive of one of the greatest scourges that have in past times afflicted humanity, and that the regulation of it by statute is not only a justifiable but a wise and beneficent exertion of the police power over the public health.” See also *Nissley v. Hummelstown Borough School Directors (Nissley)*, 18 Pa.C.C. 481 (1896). The case law is old, but remains good law.

Although the Department, with the approval of the Board, has the authority to create the list of immunizations for school attendance, it is still the case that a parent who chooses to refuse vaccinations for his child because of a religious belief or a strongly held moral belief that rises to the level of a religious belief, or because a child has a medical contraindication to a

vaccine, may seek an exemption from these requirements. With an exemption, the child may still attend school.

The Department does question several statements made by these commentators. For example, the statement by a commentator that vaccines are not effective and they are full of toxic mercury because several friends developed influenza after having been vaccinated against influenza. While the Department notes that it is not adding flu vaccine to the list of recommended immunizations, the Department believes some discussion of the flu vaccine is warranted. The Department is aware that not all vaccinations are 100% effective; in fact, the yearly flu vaccine may or may not be effective dependent on which strain of flu is actually present in this Commonwealth. Flu vaccine is developed several months before flu season in the United States, and it contains antigens against strains that are being seen in other countries, whose flu season occurs before that of the United States. The flu vaccine usually includes antigens against three strains, and some years the vaccine is a better match for the actual strain than others. In all cases, getting the flu vaccine tempers the severity of the flu if the individual happens to get it in spite of being vaccinated. In no case can the flu vaccine cause the flu. It is a killed vaccine, and cannot give any person the flu. A person may have a reaction to the flu vaccine that includes achiness and a low-grade fever for a short period of time. This, again, is minimal compared to the 2-week to 4-week time frame of the actual flu, complete with fever, pains, malaise and cough. Further, many persons believe they have had the flu, but have not. There are viruses that include the same types of symptoms. It is impossible to tell whether one actually has the flu without having a test done.

With respect to the statement that the Department, the Department of Education and schools are acting unconstitutionally and bullying, coercing and administering vaccines without true informed consent, the Department reiterates that its actions with respect to setting a list of diseases against which children shall be immunized is a legal delegation of legislative authority to it through the Public School Code of 1949, and falls within the accepted police powers of the Commonwealth. See *Stull*. The Department notes that it does promote vaccination and require childhood immunizations for school entry and attendance because it strongly believes based on its research and its experts that vaccines are important, safe and effective in preventing childhood disease.

The Department notes that while consent may be required for a child to be vaccinated, “informed consent” is not. The term “informed consent” is specific in Commonwealth law. In fact, although a parent or guardian (or a minor in some cases) is requested to give consent to a vaccination, a vaccination does not, by law, fall upon the list of medical procedures that requires “informed consent.” See section 504(a) of the Medical Care Availability and Reduction of Error (MCARE) Act (40 P.S. § 1303.504(a)). The Department, when it does provide vaccinations, provides a Vaccine Information Statement to a child receiving a vaccine from the Department, which contains side effects and risks of vaccines, and does seek written consent from the child’s parent or guardian.

The Department reiterates that a parent or guardian has the power to withhold consent for a child to be vaccinated. If the parent or guardian refuses, the health care provider does not vaccinate the child against the will of the parent or guardian. The Department has no authority to change that requirement, and would not forcibly vaccinate a child without consent. The Depart-

ment is, under law and its police power, requiring a child to have certain immunizations to attend school. A parent or guardian who has a firmly held conviction in the nature of a religious belief, or who obtains a medical exemption, can have the child admitted to school even if he does not consent to a vaccination.

With respect to concerns regarding schools obtaining medical information, that information is required to be provided to schools by law and becomes part of the student's education record. The requirements for education record information in schools are covered by section 444 of the Family Educational Rights and Privacy Act of 1974 (FERPA) (20 U.S.C.A. § 1232g), which protects a student's privacy. A student's immunization records are 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/>.

In any case, what school districts report to the Department regarding vaccines is in the aggregate, and does not include any child's identifying information. The Department does note that if an outbreak of diseases were to occur in a school that requires the Department's public health intervention, the Department would be able to obtain information regarding the outbreak, including identifying information regarding children. Once the Department had that information, the information could only be released by the Department to prevent and control the spread of disease. See Chapter 27, Subchapter C and sections 3 and 15 of the Disease Prevention and Control Law of 1955.

With respect to comments regarding manufacturer's labels, manufacturers of products warn users of products of possible problems with products in part out of concern for liability. The studies of the safety for MCV and pertussis were sufficient for ACIP to determine that the vaccine's benefits outweigh its risks. The Department has accepted, and the Board has approved, these recommendations.

The Department previously addressed comments regarding vaccine safety and the risks versus the benefits of pertussis and MCV vaccines in this preamble.

*General comments in opposition to vaccination and vaccine additives*

One commentator provided a letter he sent to United States Senator Pat Toomey stating that vaccines never healed anyone and have done massive damage to the people throughout history. The commentator stated that mercury, aluminum, formaldehyde, antifreeze, live virus from degraded (rotted) monkey kidney tissue, cancer-causing S40 in blood, or cow or dog blood and aborted baby's human cells are found in vaccines. The commentator stated that vaccines contain monosodium glutamate (MSG), and that this toxin blocked leptin, which signals to the brain that the body is full. The commentator stated that this was a major causative in the obesity in the United States. The commentator asked why this was in vaccines, and what good it did. The commentator asked whether there was any sanity to this scenario, and whether the Department really believed in the safety of vaccines. The commentator stated that the Department was reviewing only one side of the story, "reports coming from the CDC and so called peer reviews from reliable, hmm, sources." The commentator stated that the peer review issue was a scam, and that facts and numbers do not lie. The commentator provided a number of links to

various articles that prove the truth about vaccinations and about herd immunity, and stated that herd immunity is a lie.

The commentator stated that he has hundreds of links that show who the CDC and the World Health Organization really are, how they have been caught lying and defrauding people for many years and how they have caused damage to people worldwide throughout the ages. The commentator stated that the measles pandemic is nothing more than a lie on the part of vaccine manufacturers fueled by propaganda of the "MSM." The commentator stated that there were 176 cases of measles in the United States related to the Disneyland outbreak and that there are about 650 cases of measles Nationwide every year. No deaths and a lifetime of immunity for the unvaccinated. It is common knowledge that there are vaccine-related deaths and permanent disabilities from vaccines by the thousands. The commentator noted that there is no liability for vaccine manufacturers and no repercussions. Drug manufacturers are permitted to continue maiming and killing over 100,000 people every year. The commentator asked how this is saving lives. The commentator asked if United States Senator Pat Toomey would be willing to have his children and grandchildren vaccinated fully, with the 300 vaccines that are awaiting the mandate. The commentator stated that this was not in line with the United States Constitution, particularly the Fourteenth Amendment. The commentator stated that one child or one adult compromised or killed by vaccines is one too many. The commentator stated that those who do not learn from their mistakes are bound to repeat them.

One commentator stated that much of the commentator's concern rested with the presence of life-destroying aluminum salts, preservatives and fetal human cells in vaccines. The commentator stated that the safety of aluminum in humans rests on a study in which healthy adults were given a miniscule amount of aluminum intravenously. According to the commentator, most medical professionals can testify that intravenous intake is vastly different in kind from intramuscular injection. The commentator stated that it is this single study on which the claim that aluminum or aluminum salts in vaccines is safe rests. The commentator cites an article which confirms that there is no safe alternative antigen prepared for market. Jefferson, T., Rudin, M. and Di Pietrantonj, C. (2004), "Adverse Events after Immunisation with Aluminium-Containing DTP Vaccines: Systematic Review of the Evidence," *The Lancet Infectious Diseases*, 4(2), 84-90. The commentator quoted the article as stating "[d]espite a lack of good quality evidence, we do not recommend that any further research on this topic is undertaken." According to the commentator, this means that because there is no safe alternative, the problem will not be looked at too closely. The commentator cited other studies examining aluminum intramuscular injection into children and rabbits, and stated that these studies confirmed that aluminum did not exit the body but went directly to organs and to bone mass. The commentator provided a list of peer reviewed articles on the damage of aluminum and aluminum hydroxide. The commentator stated that they are waiting for an effective and safe vaccine, and until then should not be required to inject a verifiably corrosive and neurological damaging antigen. The commentator claimed the ongoing and untouchable freedom of religious conscience, along with the freedom of parents to assume the financial and time burden of homeschooling without medical interference from the government.

One commentator stated that she is a mother of four children and has done research into the issue of immunizations. She stated that she vaccinated her first two children because that is what she was led to believe. She stated that she then started educating herself and that there was so much change with the amount of vaccines given when smallpox was an issue, and even then there was an increase in the disease. The commentator stated that there is no herd immunity and that no resurgent epidemics have occurred. The commentator stated that vaccine effectiveness cannot be determined unless one is exposed to the disease following vaccination, but she has not found research. The commentator stated that vaccines contain toxic poisons linked to neurological damage, including aluminum, thimerosal, antibiotics, MSG, formaldehyde, lead, cadmium, glycerine, acetone and yeast proteins. She commented that one cannot even sue a manufacturer if there is harm because Congress has eliminated the ability to directly sue providers or manufacturers responsible for vaccine injuries. Knowing all this, she asks why she would choose to vaccinate her child. The commentator stated that if people choose to vaccinate their children or themselves for protection against a harmful disease because that is what they believe, why should they concern themselves that others have not. The commentator states that they would then have to have faith that they are protected and the ones that are not vaccinated would get the disease. She asked why we are letting the government tell us what to do with our children.

Several commentators mentioned that vaccines are derived from fetal tissue. One commentator stated that vaccines are derived from murdered babies, through abortions. The commentator stated that it is a common myth that the cell lines being used to develop vaccines were taken from an abortion in the 1960s and that they self-replicate, making it possible to produce more vaccines without procuring more abortions. According to the commentator, this could not be farther from the truth, and a new cell line called WALVAX2 has been developed from new abortions recently.

The Department is not in a position to dissuade these commentators from their beliefs. The Department has given its reasons for relying on herd immunity. The Department and those who choose to vaccinate most likely do not do so through a belief or faith that they will be protected by the vaccination, but rather through an informed choice, just as one commentator stated that she made in choosing not to vaccinate her children. Religious/philosophical and medical exemptions remain available for those who are eligible for them.

With respect to concerns raised about vaccine ingredients, particularly about the statement that vaccines cause healthy children to become unhealthy and their immune systems are becoming compromised, children are exposed to many foreign antigens every day. *Adverse Events Associated with Childhood Vaccines*, p. 63. Eating food introduces new bacteria into the body, and numerous bacteria live in the mouth and nose, exposing the immune system to still more antigens. An upper respiratory viral infection exposes a child to from 4 to 10 antigens, and a case of strep throat exposes a child to from 25 to 50 antigens. According to *Adverse Events Associated with Childhood Vaccines*. According to *Adverse Events Associated with Childhood Vaccines*, “[i]n the face of these normal events, it seems unlikely that the number of separate antigens contained in childhood vaccines. . . would represent an appreciable added burden on the immune system that would be immunosuppressive.”

Available scientific data show that simultaneous vaccination with multiple vaccines has no adverse effect on the normal childhood immune system.

Millions of doses of vaccines are administered to children in this country each year. Ensuring that those vaccines are potent, sterile and safe requires the addition of minute amounts of chemical additives. Chemicals are added to vaccines to inactivate a virus or bacteria and stabilize the vaccine, helping to preserve the vaccine and prevent it from losing its potency over time. The amount of chemical additives found in vaccines is very small. The Department does not believe this concern invalidates this final-form rulemaking. The possibility that the small amount of additives may cause a serious allergic response is outweighed by the efficacy of the vaccine in preventing serious disease and disease outbreaks. Formaldehyde is used to inactivate toxic proprieties in vaccines that contain toxins (for example, tetanus). It is also used to kill unwanted viruses and bacteria that might be found in cultures used to produce vaccines. Aluminum gels or salts of aluminum are added as adjuvants to help the vaccine stimulate production of antibodies to fight off diseases and aid other substances in their action. In vaccines, adjuvants may be added to help promote an earlier response, more potent response or more persistent immune response to disease. Some, like gelatin and MSG, are added to prevent deterioration and to stop the vaccine sticking to the side of the vial. Some, like antibiotics, yeast protein and egg protein, are remains of the vaccine production process. “Clear Answers and Smart Advice,” p. 5. None have proven harmful in animals or humans. “Clear Answers and Smart Advice,” citing Offit, MD, P. A. and Hackett, PhD, C. J. (2003), “Addressing Parents’ Concerns: Do Vaccines Cause Allergic or Autoimmune Diseases,” *Pediatrics*, 111(3), 653–659, retrieved from <http://pediatrics.aappublications.org/content/111/3/653>.

Specific attention was drawn by commentators to aluminum. If a baby follows the standard immunization schedule, he is exposed to about 4 to 6 milligrams of aluminum at 6 months of age. By comparison, a baby is exposed to 10 milligrams if he is breastfed, 40 milligrams if he is fed cow’s milk-based formula or 120 milligrams if he is fed soy formula. There are about 200 milligrams of aluminum in a standard antacid tablet. “Clear Answers and Smart Advice,” p. 6, citing Children’s Hospital of Philadelphia, Vaccine Education Center, [www.vaccine.chop.edu/service/vaccine-education-center/hot-topics/aluminum.html](http://www.vaccine.chop.edu/service/vaccine-education-center/hot-topics/aluminum.html) (accessed July 30, 2016).

Specific concern is also raised relating to thimerosal, which contains ethyl mercury. This differs from methyl mercury, which is the type of mercury that has given concerns in connection to the consumption of fish. These two forms of mercury are processed differently in the human body. While methyl mercury is known to cause psychiatric problems, including mad hatters disease, ethyl mercury is rapidly eliminated from the body within 1 week. The inclusion of mercury in vaccines is a frequent concern raised by persons who are of the opinion that vaccines are more dangerous to health than the disease itself. While most vaccines became thimerosal free after 2001, some, like flu vaccines, still include it. “Clear Answers and Smart Advice,” p. 4. Most importantly, influenza vaccine is not on the Department’s list of required immunizations. The only vaccine on the Department’s list that still retains a small amount of thimerosal is one of the MCV vaccines, although there are thimerosal alternatives. The Department notes that if a person receives single antigen doses of vaccines against tetanus, rather than Tdap or DTaP, there would be small amounts

of thimerosal in the vaccine. Levels of thimerosal in vaccines may be found at [www.vaccinesafety.edu](http://www.vaccinesafety.edu).

In addition, commentators raised issues regarding fetal tissue, and specifically stated, in some instances, that babies were being killed to make vaccines. The Department has not revised this final-form rulemaking in response to these comments. Fetal tissue is not currently used to produce vaccines. Cell lines generated from a single fetal tissue source are used to produce vaccines. Some vaccines, including varicella vaccine, are made from human cell line cultures. Vaccine manufacturers obtain human cell lines from FDA-certified cell banks. Commentators stated that existing cell lines are dying out, and that studies show that new fetal tissue lines are being used, citing a Chinese researcher as developing these lines. The Department is unaware that any existing vaccine includes any new cell line, or that it is likely to do so. In any event, these commentators, and persons with religious objections to the use of cell lines in vaccines, may make use of the religious and philosophical exemption to refuse a vaccination and continue to attend school.

Several commentators also raised issues regarding formaldehyde use in vaccines. Formaldehyde has a long history of safe use in the manufacture of certain viral and bacterial vaccines. It is used to inactivate viruses so that they do not cause disease (for example, polio virus used to make polio vaccine) and to detoxify bacterial toxins, such as the toxin used to make diphtheria vaccine. Formaldehyde is diluted during the vaccine manufacturing process, but residual quantities of formaldehyde may be found in some current vaccines. The amount of formaldehyde present in some vaccines is so small compared to the concentration that occurs naturally in the body that it does not pose a safety concern.

Formaldehyde is also produced naturally in the human body as a part of normal functions of the body to produce energy and build the basic materials needed for important life processes. This includes making amino acids, which are the building blocks of proteins that the body needs.

Formaldehyde is also found in the environment and is present in different ways. It is used in building materials, as a preservative in labs and to produce many household products.

The body continuously processes formaldehyde, both from what it makes on its own and from what it has been exposed to in the environment. When the body breaks down formaldehyde, it does not distinguish between formaldehyde from vaccines and that which is naturally produced or environmental. The amount of formaldehyde in a person's body depends on their weight; babies have lower amounts than adults. Studies have shown that for a newborn of average weight of 6 to 8 pounds the amount of formaldehyde in their body is 50 to 70 times higher than the upper amount that they could receive from a single dose of a vaccine or from vaccines administered over time.

Excessive exposure to formaldehyde may cause cancer, but the latest research has shown that the highest risk is from the air when formaldehyde is inhaled from breathing, and occurs more frequently in people who routinely use formaldehyde in their jobs. There is no evidence linking cancer to infrequent exposure to tiny amounts of formaldehyde through injection as occurs with vaccines. See FDA (2014), "Common Ingredients in U.S. Licensed Vaccines," retrieved from <http://www.fda.gov/Biologics/BloodVaccines/SafetyAvailability/VaccineSafety/ucm187810.htm>.

One commentator pointed out that the HHS' National Vaccine Injury Compensation Program has a Vaccine Injury Table that supplies a run-down of health conditions and associated vaccines. The commentator noted that there is quite a list of health consequences that result from getting vaccines. The commentator also noted the list of warnings on the package inserts placed there by pharmaceutical companies. The commentator pleaded with the Department, for the sake of children and future generations, not to make the amendments in the proposed rulemaking.

The commentator stated that her grandchildren have an exemption based on medical, philosophical and religious reasons, out of a legitimate concern for her grandchildren's safety.

The Department is not in a position to dissuade the commentator from her beliefs. The Department notes that the exemptions exist in the law for those who have a strong moral and ethical aversion to vaccination. The Department agrees that there are potential health consequences listed with respect to vaccines in the Vaccine Injury Table issued by HHS' National Vaccine Injury Compensation Program. With respect to manufacturer's labels, manufacturers of products warn users of products of possible problems with products in part out of concern for liability. Because a manufacturer cannot prove that a vaccine is effective for a lifetime, it cannot say so without the possibility of legal difficulties. Safety studies have been done of both MCV and pertussis, which are included in this final-form rulemaking, and the Department has chosen to follow ACIP recommendations in including these vaccines.

#### *Comments regarding combination vaccines*

IRRC noted that many commentators opposed the idea of doses of vaccines being administered in a combined form and asked the Department to state this clearly in this preamble and in the RAF to clearly explain the need for the amendment.

Multiple commentators, including PACIC, opposed the Department's requiring combination vaccinations and recommended that the Department list each antigen separately. According to some commentators this would simplify the amendment process should combinations change in the future. This would also ensure accuracy in data collection and publication. Commentators noted that some vaccines were still available separately, and listing each antigen separately is best, and should not be changed. Further, the commentators stated that evidence of immunity was different for some of the vaccines, and that the regulation was unclear. Commentators recommended that each disease individually list what could be given as evidence of immunity. One commentator stated that the Department should list antigens and number of doses separately and that this would make the regulations easier to understand. Since vaccines are regularly changing, and some children get vaccinations in other countries where other options are available, this would be easier. The commentator recommended a chart which explains what can be used as evidence would also be easier.

One commentator stated that she disagreed with the Department's proposed amendment to delete separate listings for measles, mumps, rubella, tetanus, diphtheria and pertussis vaccines that are currently most commonly consumed as combination shots. The commentator stated that instead of listing them separately, they will only be listed in their combination forms. The commentator stated that she was against this, and her information

comes from the FDA's vaccine insert web page. The commentator stated that she did not believe in mixing vaccines and giving them in combination. The commentator stated that changing the listings by eliminating single vaccinations that are still available is not fair and not necessary and only encourages vaccine manufacturers to eliminate individual vaccines.

One commentator stated that he and his siblings had typical childhood diseases without complications or visits to the doctor. He stated that when he was a child, it was rare to know any child who had cancer, diabetes, allergies, asthma, ADHD or autism. He stated that these chronic conditions are much more prevalent since the vaccine schedule has tripled, and common and reasonable people have to ask why public health officials refuse to examine the connection between them and vaccines. He stated that this is especially troubling when thousands of parents link the decline in their children's health to vaccinations. He stated that administering multiple doses of combination vaccines overloads the fragile systems of babies and young children.

One commentator stated that it is common for vaccines to be given in combination and not spaced out as previously practiced. The commentator stated that the safety and efficacy of these vaccines have not been studied and it is quite possible that a lifetime of immunity is not being established, which is the intended result of vaccination. The commentator stated that vaccines have to be changed periodically for the goal of herd immunity to take place over a period of several decades. The commentator stated that since most vaccines are made by one manufacturer, essentially there is a monopoly when fair competition does not exist, and possibly a superior vaccine is not being delivered to the public.

The commentator specifically referenced the MMR vaccine, stating that people are starting to be educated on the dangers of mixing vaccines in one dose. The commentator stated that the MMR vaccine is currently under scrutiny by reputable medical professionals and hopefully will one day be removed from the schedule completely. The commentator asked that the Department help her to educate persons on what is actually in the vaccine and the dangers listed on the vaccine insert sheet from Merck. The commentator stated that the vaccine has three different live viruses in one injection. The commentator stated that there are live measles virus cultured in a chicken embryo cell culture, which is chicken DNA, live mumps virus, cultured in chicken embryo cells, which is chicken DNA, and live rubella virus cultured in human DNA, which is aborted fetal lung cells. The commentator stated, as if that is not repulsive enough, these cultures are then mixed with growth medium of fetal bovine serum, which is fetal cow blood. The commentator stated that the cow blood is screened, but that does not guarantee that a person will not be infected by Creutzfeldt-Jakob disease. The commentator noted that there would be no liability for the manufacturer. The commentator stated that the Merck insert clearly states that the MMR vaccine has not been evaluated for carcinogenic or mutagenic potential. The commentator stated that no studies have been done but let's keep injecting babies and do it again as young children. The commentator stated that it makes absolutely no sense to inject a perfectly healthy infant with these diseases all at once in a vaccine filled with toxins and do it again right before they start school. The commentator asked that the Department not remove individual vaccines from the list, and stated that she was counting on the Department to help keep children in this

Commonwealth safe, and to keep the door opened for individual vaccines, not bundling vaccines.

One commentator stated that it was misleading to list vaccinations in their combination forms, since parents are not aware that combination vaccinations are actually multiple vaccinations in one dosage. The commentator stated that they should be listed separately since it is still optional to receive combination vaccinations separately, and this will ensure accuracy in reporting.

One commentator stated that referencing combination shots rather than individual antigens further reinforces the misinformed and dangerous concept that vaccines are one size fits all. Not all antigens are appropriate for all children. Many people strongly advocate for safer vaccines through single antigens. In many countries combination shots are not required due to safety concerns.

Two commentators stated that the antigens for MMR and Tdap should be listed separately as they are separately available. The commentators stated that information should not be general, and should be as specific as possible.

One commentator stated that with combination vaccinations, if a child has an allergic reaction, how will parents know to which of the antigens the child reacted. The commentator stated that it would probably be after the autopsy.

The Department has not revised this final-form rule-making regarding this topic. Even if the Department listed the diseases separately, there are no single antigen vaccines available in the United States for measles, mumps, rubella, diphtheria, tetanus or pertussis. The Department originally added language allowing for combination vaccinations in 2010, to take into account the fact that single antigen vaccinations were becoming scarce:

The Department supports the commentator's position that combination vaccines are preferable because of the reduction in cost by eliminating multiple visits, stocking and storing multiple vaccines and stress on the child. The Department's existing regulations neither encourage nor discourage the use of combination vaccines; it should be noted that many vaccines are not available in this Commonwealth or United States as single antigen vaccines. The Department believes that health care professionals, if they have single antigen vaccines available to them, will take these issues into consideration in deciding which vaccine to use. Given the concern expressed by commentators, however, the Department has decided to revise this subsection to add language acknowledging that a combination vaccine is an acceptable vaccine for purposes of school attendance, as well as a single antigen vaccine. The Department added this language even in situations when a combination vaccine currently does not exist to anticipate the continuing development of these vaccines. The Department agrees with the commentators and strongly encourages the use of combination vaccines when appropriate and available.

40 Pa.B. 2747. See generally § 23.83(b). Since that time, certain single antigen vaccines have become unavailable. Tetanus toxoid vaccine production was discontinued in 2013. The CDC, when asked, was unaware of any diphtheria toxoid single-antigen vaccines historically being available or used in the United States.

The Department is acknowledging that single antigen vaccines for measles, mumps, rubella, diphtheria, tetanus and pertussis are no longer available in the United

States. The Department did not delete the single antigen vaccinations for the MMR vaccine. The Department amends § 23.83 to specifically reference all three diseases at once, rather than separately, and to specifically allow for both a combination antigen vaccine in § 23.83(b)(3)(i) and single antigen vaccines in § 23.83(b)(3)(ii). The language allowing for the immunization to be given as a single dose vaccine and as a multiple dose vaccine was in the regulation prior to this final-form rulemaking and still exists.

The Department currently takes into account the issue of what immunizations are available in other countries, and would provide advice to a school nurse in that regard were he to question whether or not an immunization could be accepted. The Department notes that for this reason the language regarding single antigens for MMR vaccination has not been amended, but the paragraphs have been combined into one paragraph to acknowledge that the individual antigen vaccines are no longer available in the United States.

The Department also disagrees that what is required for evidence of immunity is unclear. In addition to proof of the immunization, immunity to measles and rubella may be shown by evidence of immunity proved by laboratory testing, immunity to mumps may be shown by a written history of mumps disease from a physician, CRNP or PA, and immunity to varicella may be shown by a history of disease either by a parent or guardian or physician, CRNP or PA. Immunity for any other listed disease requires a record of the immunization itself. This is specifically set out in the regulation. The Department believes that there is no need to create a chart for the four instances in which a history of disease or a laboratory test is acceptable as proof of immunity.

The Department disagrees with the commentators regarding the safety and efficacy of combination vaccines. Studies have found that combination vaccines in fact benefit children, because fewer injections will be required to protect against disease, allowing for the introduction of new vaccines into the immunization schedule, and thereby preventing additional disease. "Combination Vaccines for Childhood Immunization," (Combination Vaccinations), *MMWR*, 48(RR 5) (1999), 1–15, retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4805a1.htm>; Halsey, MD, N. A. (2001), "Safety of Combination Vaccines: Perception Versus Reality," *The Pediatric Infectious Disease Journal*, 20(11), S40–S44. The Department notes that a study done by the University of Rochester with a grant from GlaxoSmithKline Biologicals, makers of Pediarix, a DTaP and inactivated poliovirus vaccination, published in *The Journal of Pediatrics*, also found that no efficacy or safety is compromised when clinicians administer a combination vaccine that streamlines the process. See <https://www.urmc.rochester.edu/news/story/1673/combination-vaccine-okay-for-infants-rochester-study-shows.aspx>. According to ACIP, the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP), "[t]he use of combination vaccines is a practical way to overcome the constraints of multiple injections, especially for starting the immunization series for children behind schedule. The use of combination vaccines might improve timely vaccination coverage." "Combination Vaccinations," p. 6. ACIP, AAP and AAFP stated that "use of licensed combination vaccines is preferred over separate injection of their equivalent component vaccines. Only combinations approved the U.S. Food and Drug Administration (FDA) should be used." "Combination Vaccinations," p. 6. The Department, with the approval of the Board, is following the recommenda-

tions of ACIP, AAP and AAFP, and allowing combination vaccines that are licensed by the FDA.

With respect to one commentator's statements regarding the safety of the MMR vaccine, and her wish to see it eliminated, the Department's regulation regarding the requirement of an MMR for school attendance is in place, and is not impacted by this final-form rulemaking. The Department does note that no peer reviewed valid scientific study has yet shown the link between vaccines and autism. What had been the seminal study in this area, a 1998 research study, was severely criticized, discredited and later retracted by *The Lancet*, the British medical journal that published it. The Department discussed the issue of autism previously in this preamble.

Further, the Department notes that between 1950 and 1963, when a licensed measles vaccine was introduced, there were 320,000 to 760,000 cases of measles yearly in the United States, the highest year being 1958 with 763,094 cases reported and 552 deaths. Measles is a highly contagious acute viral illness with a fever of equal to or greater than 101°F, rash, cough, coryza and conjunctivitis. It is airborne or droplet spread. Persons are communicable 4 days before the rash appears through 4 days after the rash appears. Measles can remain infectious for up to 2 hours after the infected person has left the room. Complications include otitis media, pneumonia, laryngotracheobronchitis (croup), diarrhea and encephalitis. It is more severe in the very young and may be associated with hemorrhagic rash, protein losing enteropathy, oral sores, dehydration, diarrhea, otitis media, blindness and severe skin infection.

From the introduction of the measles vaccine in 1962 to 1989, when a spike in the number of measles cases occurred, the number of cases Nationwide dropped roughly from 1481,530 with 408 deaths in 1962 to 3,396 with 3 deaths in 1988. See *Pink Book*, Appendix E. A spike in measles cases occurred in 1989 to 1991, with the number of cases increasing to 27,786 in 1990. See *Pink Book*, Appendix E. This was attributable to low immunization rates. See *Pink Book*, p. 214 and 215. A second dose was recommended by the American Academy of Family Practitioners in 1989. In 1991, the number of cases fell to 9,643 Nationwide. Endemic measles was eliminated from the United States in 2000, although spikes in cases continue to be seen. No vaccine is either 100% effective or 100% safe. According to the *Pink Book*, the efficacy rates for these vaccinations are as follows: measles, 95%; mumps, 88% (range 66%–95%); and rubella, 95%.

The Department notes that while some vaccines only have one manufacturer and, therefore, the quality of the vaccine may suffer because of the lack of competition, there are several vaccines that are manufactured by more than one company. Meningococcal conjugate vaccine, for example, is made by Sanofi Pasteur and Novartis. DTaP is manufactured by Sanofi Pasteur and GlaxoSmithKline. The Department does not mandate the brand name vaccine, but lists the disease against which the child shall be vaccinated. The Department notes that all vaccines that are added to the list of those required for school entry are first licensed by the FDA and then reviewed and approved by ACIP.

With respect to the comment regarding fetal bovine serum, and concerns that this additive may expose children to Creutzfeldt-Jakob disease, commonly referred to as "mad cow disease," the Department disagrees with the commentator. Fetal bovine serum is used in some vaccines as a growth medium. A "mad cow disease" scare

regarding vaccines arose in the early 2000s following publications of newspaper articles regarding a “mad cow disease” outbreak in the United Kingdom and the potential that several drug manufacturers had used fetal bovine serum from countries at risk for “mad cow disease.” *Vaccines: What You Should Know*, p. 112 and 113. The FDA asked the Transmissible Spongiform Encephalopathy Advisory Committee and the Vaccines and Related Biological Products Advisory Committee to meet on July 27, 2000, to discuss this matter and the CDC then issued a public health service statement in the *MMWR* on December 22, 2000. The FDA found the threat of “mad cow disease” to be remote and theoretical, and no known case of transmission exists. FDA (2013), “Vaccines and Variant CJD (vCJD) Questions and Answers” (Vaccines and Variant CJD), retrieved from <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm143522.htm>. However, to maintain public trust in immunizations, the FDA recommended the elimination of the use of bovine materials from countries at risk for “mad cow disease.” *Vaccines: What You Should Know*, p. 115; also cited by Children’s Hospital of Philadelphia, “Vaccines and Mad-Cow Disease” (CHOP Vaccines), retrieved from [http://www.chop.edu/centers-programs/vaccine-education-center/vaccines-and-other-conditions/vaccines-mad-cow-disease#.V6YC1k\\_2aUk](http://www.chop.edu/centers-programs/vaccine-education-center/vaccines-and-other-conditions/vaccines-mad-cow-disease#.V6YC1k_2aUk). The FDA stated:

The FDA has looked at the benefit of vaccines and the risk of contamination of vaccines with the BSE agent. The Public Health Service, FDA, and FDA’s advisory committees on Transmissible Spongiform Encephalopathy (TSEAC) and Vaccines and Related Biological Products (VRBPAC) believe the risk that anyone will get vCJD from a vaccine to be remote and theoretical. Vaccines have a proven benefit in reducing the incidence of serious, often life-threatening diseases. The absence of high levels of routine vaccination leads to an increased incidence of vaccine preventable diseases. Therefore, removal of licensed vaccines from the market for a remote, theoretical risk can have serious medical and public health consequences. In considering the balance of risks and benefits, the use of all vaccines, even those which were manufactured with bovine derived materials from unapproved sources, should continue.

“Vaccines and Variant CJD,” p. 2. It should also be noted that in terms of the use of fetal bovine serum in the vaccine process, serum comes from blood, and blood from infected animals or blood from infected people has never been shown to be a source of infection to humans. *Vaccines: What You Should Know*, p. 115; see also “CHOP Vaccines.” The serum is diluted and eventually removed from cells during the growth of vaccine viruses. Prions are propagated in mammalian brains and not in cell culture used to make vaccines. Therefore, prions are unlikely to be propagated in the cells used to grow vaccine viruses. See “CHOP Vaccines.” The Department has not revised this final-form rulemaking regarding this topic.

The Department addressed concerns regarding vaccine additives and the safety of multiple vaccines being given at one time elsewhere in this preamble.

#### *Comments regarding vaccine safety*

Two commentators stated that they had recently become grandparents for the first time, and that the granddaughter received her 3-month vaccinations in accordance with CDC recommendations. The commentators stated that she had a very severe reaction, which in-

cluded fever, diarrhea and an encephalitic cry, which each of the commentators recognized because each is a nurse in the health care industry. The commentators stated that with each cry she thrashed her arm backwards. The commentators stated that the behavior lasted 10 days before she returned to a more normal status. The commentators stated they would like to have her sensibilities tested before proceeding with the recommended scheduled vaccines to ensure she will not suffer more permanent damage. The commentators stated that they did not understand why the United States Supreme Court has labeled vaccines as unavoidably unsafe but that the Department is not taking safeguards. The commentators stated that it was absurd that great risks were being taken with the lives of so many young and fragile children.

One commentator stated that she is a parent of a child whose health declined with every round of routine immunizations. The commentator stated that her child is now suspected of having a mitochondrial disorder that has been noted in medical literature and vaccine compensation court legal proceeding as being associated with childhood vaccination. The commentator stated that she did not understand how vaccines could be labeled as “unavoidably unsafe” and yet precautions are not being taken on a public health level to screen for those children and individuals who may be vulnerable or most harmed by vaccine injury and vaccine reactions in an attempt to prevent vaccine harm.

One commentator stated that she is not opposed to the development and distribution of vaccinations to support the therapy involved in developing immunities. However, the commentator is opposed to basic freedoms being restricted by over-complicated legislation. The commentator stated that her own children were vaccinated, but shortly after vaccinating each one they were hospitalized with complications that she did not recognize as being related to the vaccines. The commentator stated that she chose to vaccinate because she was told that it had to be done, and if the children were not vaccinated, the children would likely contract the diseases which the vaccines were supposed to prevent. The commentator stated that one daughter ended up with whooping cough after she went to the doctor’s office for an unrelated vaccine, and the commentator had to care for her day and night for nearly a month. The commentator stated that another daughter was hospitalized as an infant and had to suffer through a spinal tap before the commentator realized that the child’s condition was due to the vaccine she had been given 2 weeks before. The commentator stated that she has since spent a great deal of time learning about vaccinations, immunization and the risk associated with undergoing the schedule of vaccines dictated by the Department. The commentator uses the word “dictated,” because she sees her freedom to choose how the health and well-being of children are being managed being taken away.

One commentator stated that she had studied vaccinations as a lay person for several years, and has concluded that she is not comfortable with their safety. She declined Tdap and MCV for 7th grade for her children for this reason. She raised the following issues in general:

- Litigation against HPV manufacturers began in June 2016 in Japan; the Japanese government removed HPV from the recommended vaccine list.
- A CDC whistleblower, granted whistleblower status by the Obama administration and requested to be subpoenaed by Congress, has yet to be acknowledged; his story

was made public in 2014, and he submits that he and his colleagues at the CDC destroyed documents that supported a link between the MMR vaccine and autism in certain cohorts.

- A letter of complaint by Sin Hang Lee, MC, FRCP, FCAP, Director, Milford Molecular Diagnostics Laboratory, Milford, CT, was written to the Director General of the World Health Organization against the Global Advisory Committee on Vaccine Safety, the CDC and others for misrepresentation of facts regarding safety of the HPV vaccine.

- The American College of Pediatrics issued a statement in January 2016 regarding new concerns about the HPV vaccine.

- Pharmaceutical representatives are coming out of the woodwork with stories about horrible corruption within the pharmaceutical industry.

Because of this she stated that she believes there is a high likelihood of corruption surrounding how recommendations for vaccinations are made. The commentator stated that because of this her choice is to be conservative and hold off on further vaccines for her own children.

One commentator stated that although everyone wants to protect immunocompromised children, all children need to be protected from the excessive number of vaccinations they are being given. The commentator stated that we need to work together and demand accountability from vaccine manufacturers, and require cleaner, safer vaccines before they are mandated on healthy children. The commentator stated that we need to demand that the CDC does its job and require longer testing on vaccines before clearing them for use and mandating them on children. The commentator stated that parents who have exemptions are sometimes the children of vaccine injured children that want to protect their other children. The commentator asked who were we to stand to protect immunocompromised children and not stand to protect children that have already been injured by vaccinations. The commentator stated that there are millions of these children and they are not being supported. The commentator stated that vaccine manufacturers have absolutely no liability so they have no incentive to make safer vaccines. The commentator stated that when a lawsuit is filed and won by these families, which is rare, taxpayers are paying for it instead of the vaccine companies. The commentator stated that pharmaceutical companies have all the money and their lobbyists and representatives are out there making sure the laws and regulations are in place for them to keep selling the government unsafe vaccines.

Several commentators stated that the government and the medical and pharmaceutical industries should first do no harm. One commentator expressed concern that children were being harmed, families were being devastated and futures were being destroyed. The commentator stated that a parent has the right to make a truly informed choice about what is injected into a child's body which has the risk of permanent injury and death. The commentator stated that the government has a moral and ethical imperative to provide that right. One commentator stated that she had been a registered nurse for 16 years and had worked in a hospital all that time. She stated that as a citizen of the United States and as a resident of this Commonwealth, she must defend the United States Constitution and the Pennsylvania Constitution and she expected the Department to do the same. The commentator stated that she had taken an oath to be an advocate

for the truth regarding the persons she cares for, and if medical personnel compromise, and do not defend these oaths, there is no limit to the evil and atrocities that will be committed in the name of medicine. She stated that together Federal, state and local governments should be held accountable to defend Constitutional rights to maintain truth and integrity in the process and conveyance of all medical and scientific information (all benefits, risks and alternatives) to obtain an individual's true consent. She stated that this true consent includes defending a citizen's or a resident's right to refuse based on the integrity of these truths.

The Department has not revised this final-form rule-making regarding this topic. The Department is not creating a new immunization program. The only new immunization requirements the Department is adding are a dose of MCV for entry into the 12th grade, or, in an ungraded class, for entry into the school year where the child turns 18 years of age, and a pertussis component, since certain vaccines, like single antigen diphtheria, single antigen tetanus and single antigen pertussis vaccine, are not available in the United States. The Department addressed the safety of those vaccines in the specific sections relating to those requirements. The Department is not adding HPV to the list of required immunizations for school entry and attendance. Further, the Department notes that exemptions still exist in law to allow concerned parents to exempt children from vaccinations under certain circumstances. Any claim of a link between MMR and autism has been sufficiently debunked by the retraction in 2010 by *The Lancet*, the British medical journal, of what was until then the seminal study in England. Further, safety of combination vaccines, multiple vaccines at one time, the number of required vaccines and additives to vaccines and other safety issues have been discussed elsewhere in this preamble.

In addition, the Department notes that the right to request a medical, religious, or strong moral or ethical conviction exemption still exists in the law and in the regulations. The Department addresses the issue of informed consent previously in this preamble.

PACIC asked that the Department provide the average number of children in this Commonwealth who are "medically unable to obtain a vaccination." PACIC stated that the CDC is seeking to severely limit the conditions for which children may be eligible for a medical exemption. PACIC stated that requiring someone else to undergo a medical procedure that carries inherent risks for the sake of another individual is a novel concept in the United States where individual rights have always been honored. PACIC stated that upending this foundational principle should not be taken cavalierly.

With respect to the commentator's question regarding the Department's reference to children who are medically unable to receive the vaccination, these are children with medical contraindications, for example, children with a contraindication to pertussis. A child with a medical exemption is medically unable to receive a vaccination. Although the Department has provided the number of children in school years 2014-2015 and 2015-2016 who had medical exemptions at the time data was collected, the Department also notes that a child's situation may change, and that a doctor may determine that a child cannot receive a vaccine at one point, but may be able to receive it at a later date. The Department has no way of knowing whether these children are in a provisional status at the present time, or have medical exemptions.

Further, the CDC has no authority to limit what condition may warrant a medical exemption, nor does the Department. The decision that a particular condition warrants a medical exemption is determined by the child's doctor. ACIP lists contraindications to certain vaccines, but the decision regarding whether to a child should receive a medical exemption is within the scope of practice of the physician or a designee. The regulations do not affect that relationship. Further, the Department notes that, while it strongly encourages persons to think about whether their actions regarding vaccination impact other persons, it has not impinged on personal liberty by promulgating this final-form rulemaking. Acting under the statutory authority, the Department has added to the list of diseases and conditions for which an immunization is required to enter and attend school. The Department has not, and cannot, change the General Assembly's directive that children be able to obtain medical and religious exemptions to these requirements. A child who possesses an exemption is not impacted by this final-form rulemaking. That child may, in the case of an outbreak of a vaccine-preventable disease in a school, be excluded from school under the Department's authority to prevent and control disease in schools. See section 3(a) of the Disease Prevention and Control Law of 1955. In the event that the child contracts the disease, the child may be isolated or quarantined under that same authority. See section 11 of the Disease Prevention and Control Law of 1955. The Department notes that these exclusionary principles have long been upheld in the Commonwealth. *Stull and Nissley*.

*Comments regarding pharmaceutical companies and vaccines*

One commentator stated that the pharmaceutical industry was stirring up hysteria to continue this revenue stream, whether it is necessary, beneficial or not. The commentator stated that there are too many uncertainties about the safety and effectiveness of so many vaccines just to bulldoze ahead because of media hype. The commentator stated that the inclusion of heavy metals like mercury in some of these vaccines is horrible. The commentator asked how pumping mercury into her grandchildren could improve their health.

One commentator said that it should be up to the parents to decide if a child should get more immunizations, but if a pediatrician recommends it, most persons will comply.

The Department hopes that physicians and parents discuss the medical issues, including immunizations, relating to their children and make decisions that are in the best medical interests of children. The medical exemption is in place for those who need it.

One commentator stated that she was vehemently opposed to mandatory vaccinations, and that she and her sister had nearly died from the pertussis vaccination. The commentator stated that she believed strongly in scientific-based evidence that childhood illnesses build the immune system. The commentator stated that the proposed rulemaking was a violation of personal rights in many ways. The commentator stated that in these times of "sinister profits" being made by the "likes of Dick Cheney" and others, who buy up patents on vaccinations prior to ramping up general hysteria about Zika virus, flus and other diseases, it is imperative that the government is not allowed to control protecting immune systems from the hubris of scientists and their financial partners.

One commentator stated that the number of vaccines on the childhood vaccination schedule have tripled since

the 1980s and doubled since 2000. The commentator noted that the pharmaceutical industry has become a multibillion dollar industry attracting individuals looking to make money from all ends. The commentator stated that we must be mindful of an industry paying large sums of money to control the conversation regarding the health and safety of children. Another commentator hoped that, as a voting citizen in this Commonwealth, that the Department would choose to represent the commentator's views rather than those of "big pharma."

One commentator stated that the only benefit of vaccines is the great financial gains of the pharmaceutical companies and the government that makes laws based on the companies' lobbyists. According to the commentator, vaccines cannot produce health or protection from disease. The commentator stated that they are loaded with nothing but toxic chemicals and DNA and RNA fragments from the tissues on which the bacteria and viruses are grown. The commentator stated that they have historically been and are now contaminated with retroviruses. The commentator stated that the health risks of vaccines are great, and are listed in the package inserts of the vaccines. The commentator stated that a vaccine is a pharmaceutical drug, and that healthy people do not need drugs to maintain their health. The commentator stated that the right to refuse vaccinations and any other medical treatment is a basic human freedom. The Hippocratic Oath states first do no harm but the Department is doing harm.

One commentator said she would thank the Department for doing what was right and not giving in to pharmaceutical company bullying.

The Department disagrees with any inference that its decisions to add to the list of immunizations required for entry and attendance at school is controlled by the pharmaceutical companies. The Department bases its decisions on recommendations from ACIP, and only adds those immunizations to the list that it believes are appropriate for children in this Commonwealth. The Department added varicella immunity to the list shortly after that vaccine became licensed for use. The Department then added Tdap and MCV for entry into the 7th grade when those vaccines became available and as recommended by ACIP, and is now adding a second dose of MCV in accordance with ACIP recommendations. As the Department has explained, the addition of pertussis to the list is made de facto due to the fact that single antigen diphtheria, tetanus and pertussis immunizations are not available in the United States. Currently, a child will either receive DTaP or Tdap to meet the requirement in the existing regulations that children be immunized against diphtheria and tetanus, depending upon the age of the child and previous vaccination status in accordance with ACIP recommendations, unless he has a contraindication to the pertussis component. *Pink Book*, p. 114. A child who has a contraindication to the pertussis component of the vaccine may obtain the DT vaccination to finish the DTaP series, and, for entry into the 7th grade, may obtain a medical exemption from the Tdap vaccination. 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 United States. See 40 Pa.B. 2747. If the child does not receive Tdap in the 7th grade, there is no alternative other than an exemption.

The Department also acknowledges that an individual may indeed choose to refuse a certain medical treatment for the individual or the individual's children, but notes

that that choice may have consequences. For example, a person with tuberculosis may choose to refuse treatment, but if the person does so, the Department has the authority, by law, to quarantine that person until he undergoes medical treatment or recovers. See section 11 of the Disease Prevention and Control Law of 1955. In this case, the General Assembly has given the Department the authority to set a list of diseases against which children shall be vaccinated to attend school. If the parent refuses the vaccination for the child without a religious or medical exemption, the child may be excluded from school because, as with tuberculosis, the implications of the parent's choice go beyond the health of the child. Particularly in cases of mumps and of measles, the child's lack of immunity can seriously impact not only children who are unable to be vaccinated, but adults as well. The decision is still within the parent or guardian's purview to make.

*Comments regarding accuracy of electronic medical records*

The commentator stated that at her son's 5 years of age well child checkup, the nurse refused to provide 5-year vaccinations that she had requested, and as a parent she knew her child needed the shots. Upon investigation of the electronic medical record, the commentator determined that the nurse was reviewing the wrong medical record. The commentator stated that she has had to correct her child's electronic vaccination records showing dated, hand-written copies as documentation.

The Department acknowledges the commentator's concerns regarding accuracy of records and information. The Department cannot and does not regulate the use of medical records in physician offices.

*Comments regarding specific sections of this final-form rulemaking*

§ 23.82. *Definitions*

IRRC requested that the Department make clear its use of "health care provider" in the definition of "medical certificate" to clarify which professions may fill out and sign a medical certificate.

The Department revised this definition. The Department intends for only those practitioners within whose scope of practice diagnosis or examination fall to be able to make a determination of the appropriateness of the scheduling of future vaccines and to sign the medical certificate. The Department revised the definition of "medical certificate" to clarify that only a physician, CRNP or PA may sign that medical certificate. The Department notes that in a situation when the immunizations are being received from the Department, or a local health department, a public health official may sign the medical certificate, as they may sign the certificate of immunization.

§ 23.83. *Immunization requirements*

§ 23.83(a)—*Duties of a school director, superintendent, principal or other person in charge of a public, private, parochial or nonpublic school*

Three commentators suggested that school administrators be required to "buy-in" to the regulations and that repercussions should occur if the immunization laws were not followed. One of these commentators stated that in the 2015-2016 school year, she had 30 of 190 kindergarten students who were not fully immunized. Under the 5-day provisional rule, she would have had to exclude those students. She would have needed the support of her school administrator.

One commentator requested that the Department enforce the regulation regarding medical certificates and noted that although the Philadelphia School District would not exclude a child who lacked the required immunizations, she herself excluded a child transferring from that district for that reason. She complained that it is unfair that those who enforce the immunization laws, and who are stretched to the limit by having so much to do in the school health setting, to have to deal with school districts in this Commonwealth who ignore them.

Several commentators, including PSEA, stated that they supported the proposed rulemaking and recommended that the regulations state "shall exclude" rather than "may exclude." According to several commentators, unless exclusion is required, school districts will not exclude, and there will be no change for the better. One commentator noted that the administrators in her school district take their exclusion responsibility seriously, but this has not always been the case. One commentator wondered why the Department would go to the trouble to amend the regulation and then leave a loop hole for administrators to use. PSEA stated that without this language, there would not be consistent application across this Commonwealth or even across school buildings. PSEA stated that even though the provision was intended to provide local discretion, the effect is to undermine the goal of achieving optimal immunization levels for students.

IRRC asked why the Department would allow discretion when requiring immunizations for attendance. IRRC asked the Department to explain the reasonableness of providing flexibility in the regulation and how allowing nonimmunized children to attend school adequately protects the public's health.

Two commentators stated that the Department should change "may" to "will" in proposed § 23.85(e)(1)—"the child may not be admitted to school, unless the child has at least one dose of the multiple dose. . . ."

The proposed rulemaking did require exclusion of children not meeting immunization requirements. The term "may not" used in a regulatory context is a prohibition on an action. "May not" denotes the curtailment of a right, power or privilege" under § 6.7 (relating to use of "shall," "will," "must" and "may") of the *Pennsylvania Code and Bulletin Style Manual*. The Department revised § 23.85(e)(1) to emphasize that, even though obtaining certain immunizations to attend school is a requirement, a school administrator or a designee may provisionally admit a child under certain circumstances. Under this final-form rulemaking, a child who lacks the single dose of a single dose vaccine, or who does not meet the requirements for provisional admittance for multiple dose vaccines under § 23.85(e)(1), may not be admitted to school, absent a medical or religious/philosophical exemption or under another waiver provision. See § 23.85(e)(2) and (g). The Department notes that the only required vaccination that meets this single dose definition is Tdap.

In addition, the Department acknowledges the hard and dedicated work of school nurses in this Commonwealth, and understands that they may at times be frustrated. The Department notes that enforcement of these provisions is not an easy matter. The enforcement provisions of the Public School Code of 1949 and the various public health statutes under which the Department derives its authority to require certain immunizations for school entry and attendance with Board approval make violation of those statutory provisions a summary offense, with corresponding monetary fines or

imprisonment. See section 1303(b) of the Public School Code of 1949,<sup>9</sup> section 16(a)(6) of the Disease Prevention and Control Law of 1955, section 20 of the Disease Prevention and Control Law of 1955 (35 P.S. § 521.20), section 2111(c.1) of The Administrative Code of 1929 and section 16 of the act of April 27, 1905 (P.L. 312, No. 218) (71 P.S. § 1409). Some of these statutes date back to 1905, a time period when failure to comply with certain orders of health departments were considered to be akin to criminal offenses because of the severity of the consequences attendant on ignoring those orders (for example, failure to comply with an immunization requirement for smallpox, an easily spread disease with an extremely high mortality rate (between 20% and 50%)).

Although these penalty provisions remain available at the present time, the Department has not used one in recent memory. The Department's position in areas of compliance with public health laws has been that cooperation and voluntary compliance are more effective than coercion, and this holds true for immunizations and at the local level as well. For the Department or the Department of Education to take action to force a school administrator to enforce the regulations in a particular way would require the Department to file a private criminal complaint, seek the approval of the local district attorney to prosecute the case and would, at the least, impinge upon local control of schools. School administrators know their student populations and how to reach those populations better than the Department does or could. Allowing school administrators to encourage voluntary compliance from their school populations in a way best suited to the unique local needs of those populations is, in the Department's opinion, the best way to ensure that there is compliance with the requirements, and, therefore, that students are appropriately protected. The Department notes that the Department itself can, under its public health authority, exclude children and "susceptibles" (that is, persons lacking immunity from a particular disease, whether because of lack of vaccination or waning immunity) from schools during an outbreak of disease. See Chapter 27, Subchapter C and sections 3(a), 7 and 11 of the Disease Prevention and Control Law of 1955. The day-to-day decisions regarding administration of school immunization requirements more appropriately rest with school administrators and their designees. Section 1303(a) of the Public School Code of 1949 states that "[i]t shall be the duty of all *school directors, superintendents, principals, or other persons in charge of any public, private, parochial, or other school* including kindergarten, to ascertain that every child, prior to admission to school for the first time has been immunized. . ." (emphasis added).

§ 23.83(b)—Required for attendance

General

One commentator stated that a child at 7 years of age beginning a series of DTaP would not get four doses of pertussis, the child would only get one dose of Tdap, and asked if this was correct. The commentator referenced the Department's current regulations and guidance manual for school nurses and noted that it provides the amount of adult tetanus and diphtheria toxoid (Td) needed, but not pertussis vaccine. She asked if there would be a section such as this in the new manual, because she did not believe this followed ACIP guidelines.

<sup>9</sup> This section does not specify whether the prosecution would be carried out at the instigation of the Department or the Department of Education, or both.

The commentator is correct that for children 7 years of age and older, ACIP recommends that a child would not get four doses, and would get one dose of Tdap:

Vaccines containing reduced diphtheria (i.e., Td and Tdap) are indicated for children 7 years and older and for adults. A primary series is three or four doses, depending on whether the person has received prior doses of diphtheria-containing vaccine, and the age these doses were administered. . . . For unvaccinated persons 7 years and older. . . the primary series is three doses. The first two doses should be separated by at least 4 weeks, and the third dose given at 6 to 12 months after the second. ACIP recommends that one of these doses (preferably the first) be administered as Tdap.

*Pink Book*, p. 114. A child entering the 7th grade who cannot receive a dose of Tdap would need to obtain an exemption; 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 United States. See 40 Pa.B. 2747.

The Department will update its immunization manual for school nurses upon approval of this final-form rulemaking. The Department believes its regulations follow ACIP requirements and will ensure that the updated manual does as well.

§ 23.83(b)(1)—Diphtheria, tetanus and pertussis

The March of Dimes supported the Department's proposal to require immunization against pertussis. The March of Dimes stated that pertussis is a very contagious bacterial disease that invades the upper respiratory system and releases toxins, which cause airways to swell. The disease is very contagious, and is spread by coughing or sneezing, or by spending time in close proximity to another person. According to the March of Dimes, many babies who get pertussis are infected by older siblings, parents or caregivers who are unaware they have the disease. According to the March of Dimes, infected individuals are most contagious about 2 weeks after the cough begins and the best way to prevent pertussis is to receive the vaccination.

The Department agrees with the March of Dimes.

One commentator stated that she supported the addition of pertussis as a required vaccination. According to the commentator, requiring a vaccine with a pertussis component is essential to slow down the increasing number of students being diagnosed with the disease. The commentator stated that the diagnosis is typically made after the child has been in school during the time of active disease transmission. Further, according to the commentator, the student often misses several days of school until a 5-day course of antibiotics is completed and suffers a prolonged recovery period of suboptimal health due to persistent cough and fatigue.

The Department is in agreement with the commentator. The Department needs to clarify the statements it made in its preamble to the proposed rulemaking that it was adding a dose of pertussis to the required list of immunizations. In fact, this is not completely accurate. The Department added pertussis to the list of diseases against which a child shall be immunized before entering and attending school in acknowledgment of the fact that 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 this Commonwealth prior to this final-form rulemaking are receiving DTaP, in accordance

with ACIP recommendations (unless the child had a contraindication for the pertussis vaccine or a religious/philosophical exemption) and are already receiving a pertussis component in their vaccination. There is also a pertussis component in Tdap, which the Department currently requires for entry into the 7th grade. See § 23.83(c)(1). Because of the recent outbreaks of pertussis, the Department found the addition of pertussis to the list of diseases to ensure vaccination to be appropriate. A child who has contraindications to the pertussis immunization may, as indicated in the regulation, receive the less widely available DT vaccination to complete the series.

One commentator asked why the Department includes tetanus vaccine in its list of immunizations, when it is not a communicable disease.

The requirement that children be immunized against tetanus is already in place under § 23.83(b) and is not impacted by this final-form rulemaking. In fact, tetanus is a communicable disease, as defined by the Disease Prevention and Control Law of 1955. A “communicable disease” is defined in section 2 of the Disease Prevention and Control Law of 1955 (35 P.S. § 521.2) as “[a]n illness due to an infectious agent or its toxic products which is transmitted, directly or indirectly, to a well person from an infected person, animal or arthropod, or through the agency of an intermediate host, vector [or] the inanimate environment.” The Department and the Board have the authority under the section 16(a)(6) of the Disease Prevention and Control Law of 1955 to “issue rules and regulations with regard to . . . the immunization and vaccination of persons . . .,” as well as to create a list of diseases against which a child shall be immunized to enter school under section 1303(a) of the Public School Code of 1949, and to make and revise a list of communicable diseases against which children are required to be immunized against as a condition of attendance at a public, private or parochial school under section 2111(c.1) of The Administrative Code of 1929. Therefore, the Department, with the approval of the Board, has the authority to include tetanus on the list. Tetanus is a disease that is often fatal and can result from a small puncture wound or an animal bite. Often times there is no history of injury. From 2001–2008, the last years for which data was compiled, the case fatality rate was 13%. *Pink Book*, p. 345. This can vary depending on whether experienced intensive care unit personnel and resources are available. Once contracted, tetanus is extremely difficult to treat. Because it is characterized by painful muscular contractions, first of the jaw and neck, and then of the trunk, there is the possibility that the child would be hospitalized and on a ventilator for some time. A full recovery without lasting effects is not assured. *Control of Communicable Disease Manual*, p. 529. ACIP recommends the immunization, and the Department has not seen a reason to remove it from the list, despite the fact that it is not spread through human-to-human contact. The efficacy rate of tetanus vaccination is 100%. *Pink Book*, p. 347.

One commentator recommended the addition of a requirement allowing for parental confirmation of pertussis, since the commentator knew a school-aged child who had pertussis, and the vaccination would be pointless for him.

The Department disagrees with this recommendation, and has not revised this final-form rulemaking. Diagnosis of pertussis can be difficult to confirm, particularly with tests other than a culture for *B. pertussis*. Kretsinger, MD, K., et al. (2006), “Preventing Tetanus, Diphtheria,

and Pertussis Among Adults: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and Recommendation of ACIP, Supported by the Healthcare Infection Control Practices Advisory Committee (HICPAC), for Use of Tdap Among Health-Care Personnel,” *MMWR*, 55(RR 17), retrieved from <http://www.cdc.gov/mmwr/pdf/rr/rr5517.pdf>. Further, vaccination with Tdap for children with a history of pertussis disease is recommended, because the duration of the protection by pertussis is unknown. *Pink Book*, p. 271.

Multiple commentators, including PACIC, opposed the inclusion of a pertussis vaccination. PACIC stated that it was not effective, and did not add to herd immunity, according to a 2013 study. The commentators stated that given the fact that the CDC and top doctors are verifying that the vaccine lacks efficacy and there is early waning of immunity from the vaccine, it is hasty to add a vaccine that is already under scrutiny from the medical community. PACIC and another commentator cited the FDA as stating the vaccine does not prevent transmission of pertussis. The other commentator quoted the CDC as saying that despite high levels of vaccination pertussis outbreaks continue to occur, and as reporting no school-aged deaths from 2012 to 2014. The deaths were in children younger than 3 months of age. The commentator stated that since the vaccine comes with severe risks of adverse effects up to and including death, the benefits must be weighed against the risks. One of these commentators noted outbreaks of pertussis among fully vaccinated. Several commentators cited a February 2016 AAP publication that stated Tdap provided moderate defense against pertussis during the first year of vaccination but not much longer, immunity waned in the second year and little protection remained after 2 to 3 years. One commentator cited the period as from 2 to 4 years, another as 2 to 5 years. One commentator stated that immunization might prevent clinical symptoms, but could not block infection, carriage or transmission. The commentator stated that people who get four to six vaccinations can get silently infected and transmit infection without any symptoms, showing the illusory nature of vaccine acquired herd immunity.

One commentator stated that she had personally studied the CDC, FDA, the National Institutes of Health and other scientific documents concerning this particular vaccine showing that historically and presently it has been and is a complete failure since its inception. The commentator has watched the rate of pertussis skyrocket since 2005 when ACIP gave a recommendation for pregnant and post-partum women to receive this vaccine, despite the fact that the majority of physicians’ opinions are that the safety of this practice had not and still has not been established. The commentator stated that pregnant women are being experimented on without their knowledge. The commentator stated that the vaccine manufacturers clearly state in all their brochures that the pertussis vaccine does not prevent the carrying or transmitting of pertussis. According to the commentator, it simply potentially decreases an individual’s symptoms to that of a common cold or the flu allowing them to further perpetuate the disease unknowingly with extensively delayed diagnosis and treatment of antibiotics. The commentator stated that ACIP also found indicators that when the mother has received Tdap, it lessened the potential benefit of pertussis vaccine in their children due to cellular changes. The commentator stated that *Bordetella pertussis* has a long history of outsmarting the

vaccine industry by RNA changes and mutation. The commentator stated also that there are 32 different strains of Bordetella all with similar signs and symptoms and that makes it difficult to diagnose the particular disease.

The Department disagrees with the commentators and has not revised this final-form rulemaking. Although there have been breakthrough pertussis outbreaks, the response of the CDC and AAP has been to recommend booster vaccines and other vaccination strategies, not to recommend no vaccination. See "FDA Approval of Expanded Age Indication for a Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine" (FDA Approval of Expanded Age Indication), *MMWR*, 60(37) (2011), 1279-1280, retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6037a3.htm>; and American Academy of Pediatrics (2011), "AAP Updates TDAP Recommendations," retrieved from <https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/AAP-Updates-TDAP-recommendations.aspx>.

Even if there is some waning of immunity from the vaccine, there is still also some protection being afforded by it. Several studies of outbreaks have noted that those who refused pertussis immunizations were at greater risk for contracting the disease than those who had the immunization. See "Parental Refusal of Pertussis Vaccination" and "Pertussis Epidemic," p. 4 ("[u]nvaccinated children have at least an eightfold greater risk for pertussis than children fully vaccinated with DTaP."). In addition, pertussis vaccine is already present in DTaP, which is recommended by ACIP for vaccination against diphtheria and tetanus, which has been on the list of diseases against which children shall be immunized to enter and attend school in this Commonwealth. See former § 23.83(b)(1) and (2). It is also a component of Tdap, which has been required for entry into the 7th grade since 2011. See former § 23.83(c)(1)(i). The Department has also taken into account the need to address possible pertussis vaccine contraindications, and has allowed for a child to have DT to complete the vaccination series. See final-form § 23.83(b)(1). A parent may also obtain a medical or religious exemption for a child. See § 23.84 (relating to exemption from immunization).

Multiple commentators opposed the inclusion of pertussis vaccine for kindergarten. One commentator stated that she had a very severe reaction to the DTaP vaccine as an adult, when her child was born, and it has changed her and left her the shell of a person she used to be. She stated that she is only starting to regain her health 7 years later. She stated that every case of pertussis she sees in the area is in fully vaccinated children, which leads her to believe there is a problem with the vaccine, not the unvaccinated children. The commentator stated that she is coming from a place of wanting informed decisions made for her family between her doctor and herself. One commentator stated that he had a friend whose child received the vaccination only to be infected with whooping cough. The commentator said that 40 years ago a child was asked to stay home for 5 days of school. He asked when was the last time there was a whooping cough outbreak among the nonvaccinated. There has not been one in this Commonwealth to his knowledge. One commentator stated that she opposes vaccinating her child again with the vaccine for kindergarten admission. She stated that her child had the vaccine and still had to undergo whooping cough testing, so not only did her child have to undergo vaccination, but also the testing, which was equally painful. One commentator stated that they are the parents of a child who had

a severe reaction to the shot and needed two brain surgeries which they believe were related to the vaccine side effect. The commentators believed that a parent has the right to consider family history and predisposition to negative reactions and reject it if they choose.

One commentator's son, on receiving the first of diphtheria, pertussis and tetanus (DPT) as an infant, reacted within hours with inconsolable crying. The commentator stated that a State health department worker recommended not giving the remaining doses of DPT. The commentator stated that not all children can receive all vaccines.

The Department agrees that not all children can receive all vaccines. In fact, if a child has a medical contraindication, there is a medical exemption available. Further, in a case where it appears there may be a medical contraindication to the pertussis component of the vaccine, the regulation provides for the completion of the series with DT, which does not include a pertussis component. See § 23.83(b)(1).

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 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 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 United States 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, 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 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 3 years of age. According to the commentator, 93% of the 2,628 deaths reported in association

with pertussis-containing vaccines are also in children under 3 years of age. 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 the risk.

The commentator stated 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 Td and Tdap.

The Department disagrees with the commentators and has not revised this final-form rulemaking based on the 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: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" (Use of Acellular Pertussis Vaccines), *MMWR*, 46(RR 7) (1997), 1–25. The AAP also recommends vaccination against diphtheria, tetanus and pertussis. See American Academy of Pediatrics (2015), "DTaP Vaccine: What You Need to Know (VIS)," retrieved from <https://www.healthychildren.org/English/safety-prevention/immunizations/Pages/diphtheria-Tetanus-Pertussis-Vaccines-What-You-Need-to-Know.aspx>.

Children in this Commonwealth are being immunized with DTaP 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 7th grade. See School Level Data for 2014 and 2015 included in the RAF for this final-form rulemaking. The Department acknowledges that no vaccine is completely safe, and that adverse effects do occur. ACIP recommended the use of DTaP and the FDA licensed it, taking safety issues into consideration. See generally "Use of Acellular Pertussis Vaccines." The Department, and the Board, are following ACIP's recommendations. If the pertussis antigen is contraindicated for a child, as contraindications are described by ACIP (*Pink Book*, p. 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 final-form § 23.83(b)(1)), or if the child would be receiving Tdap (see final-form § 23.83(c)(1)(i)).

In addition, the waning of pertussis immunity among vaccinated and unvaccinated individuals has been documented. However, ACIP and AAP 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," p. 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" and "Pertussis Epidemic," p. 4 ("[u]nvaccinated 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 1 to 2 weeks; a paroxysmal phase: characterized by spasmodic cough, posttussive vomiting and an inspiratory whoop, which lasts 4 to 6 weeks; and a convalescent phase, during which symptoms slowly improve, but which can last months. Broder, MD, K. R., et al. (2006), "Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" (Preventing Tetanus, Diphtheria, and Pertussis), *MMWR*, 55(RR 3), 1–34, retrieved from <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5503a1.htm>. Complications during the illness include hypoxia, pneumonia, seizures, weight loss, encephalopathy and death. See "Preventing Tetanus, Diphtheria, and Pertussis." The Department and the Board, relying on ACIP's and AAP's recommendations, and the FDA's licensure of the vaccine, determined to include pertussis in the list of diseases against which children shall be immunized. The Department notes, again, that a parent or guardian has recourse to the medical and religious/philosophical exemptions if the 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 final-form rulemaking changes that requirement. If a child has a contraindication for pertussis, the response for entry into 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 7th grade in 2011 to account for the waning pertussis immunity being seen across the United States. See 40 Pa.B. 2747.

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, PhD (MA), D.Hom. N.D., B.Ec (Hon), Australia.

The Department disagrees with the commentator. In promulgating this final-form rulemaking, the Department notes that it, with the approval of the Board, is following the recommendations of ACIP and in agreement with the recommendations of 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.

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 revised this final-form rule-making. The Department notes that there is no single antigen pertussis vaccine available. "Preventing Tetanus, Diphtheria, and Pertussis," p. 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.

§ 23.83(b)(2)—*Poliomyelitis*

Multiple commentators recommended that the Department change final-form § 23.83(b)(2) 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 revised "enhanced activated polio vaccine" to "inactivated polio vaccine" in final-form § 23.83(b)(2). This accords with ACIP recommendations in July 1999 that inactivated polio vaccine be used exclusively in the United States, beginning in 2000. *Pink Book*, p. 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. *Pink Book*, p. 301 and 302. "Exclusive use of [inactivated polio vaccine] eliminated the shedding of live vaccine virus, and eliminated any indigenous VAPP." *Pink Book*, p. 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 fourth polio dose is unnecessary.

The Department disagrees with the commentator and has not revised this final-form rulemaking. The Department notes that former § 23.83(b)(3) regarding polio stated that three or more doses were required. Specifying four doses in this final-form rulemaking clarifies the regulation.

PACIC stated that the Department 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 the United States. 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 (2016), "Pakistan Polio: Seven Killed in Anti-vaccination Attack," retrieved from <http://www.bbc.com/news/world-asia-36090891>; see also Scales, D. (2013), "At Least Nine Polio Workers Killed in Nigeria," *The Disease Daily*, retrieved from <http://www.healthmap.org/site/diseasedaily/article/>

least-nine-polio-workers-killed-nigeria-21113. The possibility of a case coming to the United States cannot be discounted.

§ 23.83(b)(3)(iii)—*Evidence of immunity (for measles, mumps, rubella)*

IRRC commented that the Department's use of "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 revised § 23.83(b)(3)(iii) to more specifically refer to a "certified registered nurse practitioner" and to use the correct term "physician assistant."

§ 23.83(b)(5)(ii)—*Evidence of immunity for varicella (chickenpox)*

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

Several commentators misunderstood the Department's intentions regarding the regulation. One commentator opposed the proposed amendment to immunize for chickenpox. The commentator stated that she thought this requirement was bogus, and 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.

HSLDA 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 were confused as to the proposed amendment to the regulation. Varicella immunization has been a required immunization since 2001. See 31 Pa.B. 5525 (September 29, 2001). The Department did not intend to require children who have already had the disease to be revaccinated. The Department proposed to amend the proof of immunity provision that 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. Marin, MD, M., et al. (2007), "Prevention of Varicella: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *MMWR*, 56(RR 4), 1—40, retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5604a1.htm>. The amendment 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, the Department decided to keep the parental history requirement in place as previously discussed. In originally proposing the amendment, 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 nonclinical individual, even a parent, to definitively identify the etiology of any rash.

PASA and two other commentators agreed with the Department's requirement that a history be provided by a physician, CRNP or PA. 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 the support, and agrees that it is difficult for a nonclinical individual to definitively identify the etiology of any rash. The Department is not adopting the proposed deletion and will allow the submission of a parental history of disease to continue to stand as proof of immunity for varicella. In the proposed rulemaking, the Department proposed to adopt ACIP recommendations and amend 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 amendment 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 regarding cost to parents and guardians and time constraints on them, the Department 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 decided not to make the proposed amendment that would have only allowed a history from those practitioners. The Department will adopt the amendment expanding the type of practitioners allowed to provide a history in addition to a physician, but making the requested changes to "nurse practitioner" and "physician's assistant" as IRRC recommended. The Department will keep the provision allowing, in the alternative, a history from the parent or guardian in § 23.83(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, 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 be by a blood test. A blood test would involve the parent or guardian in additional costs that are potentially not covered by insurance. Because of this, the Department has not adopted this proposed amendment. Parents and guardians may still provide history of disease under § 23.83(b)(5)(ii)(B).

The Department notes that in the event of an outbreak of disease in a school, 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, 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 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 amending 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 nondangerous 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 spreads 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 do not 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 this 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

asked 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 2-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 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 proposed rulemaking 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 1 year of age, because of antibodies in the mother's blood. She stated that before the vaccine, of 4 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 and giving consideration to the potential costs of this requirement, the Department eliminated the proposed requirement that only physicians, CRNPs and PAs may provide history of disease, as previously discussed. The Department makes it clear in response to IRRC's comment regarding whether parents may diagnose that only certain health care practitioners are permitted, within the scope of their practice, to diagnose. The issue here was not one of diagnosis 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 when 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 amendment. The Department makes it clear that the Department does not and has never taken the position that chickenpox is simply a mild childhood disease. In the preamble to the final-form rulemaking published at 31 Pa.B. 5525 adopting varicella immunity as required for school entry and entry into the 7th grade in 2001, the Department stated:

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.

One commentator 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 doctors' 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 proposed amendment was prompted by the fact that obtaining a history of disease from a nonmedical individual, even if the nonmedical individual 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, which 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," p. 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 proposed amendment 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 proposed amendment would remove the individual's right to a health system of his own choosing. The commentator stated that agencies cannot constitutionally demand or define how or through what means or entity an individual shall receive medical care.

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

PACIC asked that data be provided relating to proof of immunity. PACIC asked whether there was data showing that parents stating that their children have chickenpox is untrue. The commentator stated that there was data showing that parents are no longer capable of identifying chickenpox. Another commentator stated that if the Department was proposing this amendment because the current system was being abused, the Department should produce proof of the abuse. The commentator did not believe that there was any basis for this proposed amendment. One commentator asked whether the Department had data showing that parents were no longer capable of identifying childhood diseases such as chickenpox.

The Department revised the regulation in this final-form rulemaking, so the request for data is moot. The Department notes that ACIP recommendation was based on the following from "Prevention of Varicella":

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 (131—133). 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 (134). 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.

The Department did not intend to suggest that parents and guardians were lying about the status of their children, or that this provision was being abused. The proposed amendment was prompted by the fact that obtaining a history of disease from a nonmedical individual, even if the nonmedical individual 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 and 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, decided against adopting the proposed amendment.

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 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 Commonwealth 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 revised this final-form rulemaking after consideration of the potential costs of the requirement. In response to the commentators' concerns, 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 ACA, 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 10 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 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 not to amend the regulation. With respect to the commentator's comments regarding the pharmaceutical industry, 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 amending 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 revised 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 revised the regulation so that no education on this point will be required.

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

The Department has not adopted the proposed amendment this regulation. The Department would like to point out 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." In addition, the Department is pleased that varicella vaccine rates meet the Healthy People 2020 target vaccination rates. However, the proposed amendment was not to improve rates. The Department revised the regulations to ensure that if and when an outbreak occurs, children who are presumed to be immune actually are immune.

§ 23.83(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 amended the regulation, and addresses those comments as follows. The Department did make nonsubstantive changes to subsection (c), including in the heading of the subsection and in paragraph (1)(i) to correct references to the Tdap vaccine. Both diphtheria and tetanus toxoids are included in Tdap, and therefore "tetanus and diphtheria toxoid" has been amended to "tetanus and diphtheria toxoids." The Department also added "conjugate" to the heading of this subsection to clarify that the type of meningococcal vaccine being added in paragraph (2) is MCV, as has been required for entry into the 7th grade since 2011. See 40 Pa.B. 2747.

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 1,000 to 1,200 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 11 or 12 years of age, with a booster shot at 16 years of age.

The Department agrees with the March of Dimes, although it notes as discussed as follows 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.

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 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 incorrectly read the proposed rulemaking. 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," p. 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. 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 deleted any reference to either the 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 issue of *Pediatrics* as stating that lack of long-term protection after vaccination is likely contributing to increases in pertussis among adolescents. The 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 section 18 of the RAF 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 2 to 4 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 amendment to this subsection. The Department is not adding Tdap for 7th graders. Tdap has been required for entry into the 7th grade by the regulations since 2011. See former subsection (c)(1) and 40 Pa.B. 2747. Under the previous regulation, Tdap could be administered as a single antigen vaccine or in a combination form. Because single antigen vaccinations are no longer available in the United States, the Department 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 previously in this preamble. In addition, to eliminate both tetanus and diphtheria from the list of diseases against which children shall be vaccinated, the Department would have to propose a separate rulemaking, and the Department has no intention of taking that action.

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. The Department has merely amended 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," p. 3. 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 amended 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 said that some doctors will not provide vaccine to children at the 6th grade physical if the child is not 12 years of age 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 years of age 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 years of age 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 two 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 1 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 amended 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 Board are 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." See "FDA Approval of Expanded Age Indication." ACIP recommends routine administration of a meningococcal vaccine for all persons 11 through 18 years of age. See "Prevention and Control (2013)," p. 14. If a practitioner chooses to wait until the 12 years of age well child examination to provide either the Tdap or MCV immunization, or both, and that occurs after entry into the 7th grade, it may be necessary for the physician or a 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 regarding school health examinations are beyond the scope of this final-form rulemaking, which are promulgated, in part, under the Department's authority, with the approval of the Board, to set out a list of diseases against which children shall be immunized to attend or enter school. See section 1303(a) of the Public School Code of 1949, section 16(a)(6) and (b) of the Disease Prevention and Control Law of 1955 and section 2111(c.1) of The Administrative Code of 1929.

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 multidose series vaccination. The commentator asked whether the

Department's statement in the preamble of the proposed rulemaking 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 quoted text. With respect to the remainder of the commentator's question, the Department considers Tdap to be a single dose vaccine. 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 added in this final-form rulemaking 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 subsection (c)(1)(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 in the regulations. The regulations require the immunizations in § 23.83(b) for continued attendance at school, not just for school entry.

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 this Commonwealth for 7th grade and did not receive the first MCV shot.

The Department clarified the regulation to respond to these questions. The Department added subsection (c)(1)(iii) to state 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.

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" and, in this case, the child has not received at least one dose, the child may not be admitted.

The Department 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 this Commonwealth without the required dose of MCV, the Department notes that the regulation allows a child moving or transferring into a school in this 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. 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 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.

§ 23.83(c)(2)—*MCV required for entry into 12th grade*

The Department received many comments on the proposal to add a dose of MCV in the 12th grade. As stated, to clarify the requirements, the Department adds language in subsection (c)(2) 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. This comports with the ACIP recommendations. The Department has not otherwise revised the regulation from the proposed rulemaking.

*Comments in support of the 12th grade MCV requirement*

NMA, the March of Dimes, 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 postsecondary education opportunities, the additional immunization will ensure that students are protected from this potentially life-threatening disease.

The President of 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's efforts to ensure that adolescents in this 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 publication of this final-form rulemaking with an order making the regulations effective on a specific date, the requirements in the final-form rulemaking 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 to 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 FDA approved two vaccines for this strain. According to the March of Dimes, the CDC recommended permissive use of this vaccine in all children and young adults, 10 to 25 years of age, with the preferred age of administration at 16 to 18 years of age.

PACIC noted that there are five different types of meningitis, however the CDC recommended vaccine only includes four strains of bacterial type A. 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 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 PACIC, cited the Department's Enterprise Data Dissemination Informatics Exchange 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 million. Another commentator stated that even if every 12th grader was vaccinated, and the vaccine prevented all cases of meningitis, this would cost citizens in this Commonwealth \$1 million 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 the 320 million citizens in the United States 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% 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, 4,000 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% 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 8,000 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 this Commonwealth in 1 year and compare that number with the 0.3% 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 regarding 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 *Pink Book* as forecasting that 0.3% 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 to \$117 per shot, the vaccination is a financial windfall for the manufacturers at the expense of the public's health.

Multiple commentators stated that the *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 vaccine is likely to cause more illness and death than it claims to stop.

Several commentators, including PACIC, listed the side effects from the MCV vaccine manufacturer package insert, stating that post marketing surveillance for the meningitis vaccine has shown hypersensitivity reactions such as anaphylaxis/anaphylactic reaction, wheezing, difficulty breathing, upper airway swelling, urticaria, erythema, pruritus, hypotension, GBS, 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 (that is, 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 proposed rulemaking did not include costs of the serious side effects.

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 (0.3%) were reported. PACIC and another commentator asked if the 147,040 12th graders were given Menactra, the Commonwealth could expect 9,704 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 this Commonwealth. 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.

PACIC stated that the MCV vaccine had an inherent risk since it was an invasive medical procedure with documented side effects. PACIC commented that the vaccine only had an 80% to 85% efficacy rate, and that after 2 to 5 years, the vaccine has been found to be, at best, only 58% effective. 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% to 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 revised the regulation in response to these comments. Commentators 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 the RAF for the proposed rulemaking of approximately \$16 million 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 on page 18 of the RAF for the proposed rulemaking that this would be the cost to the regulated community "if every child were required to purchase the dose through private pay methods" (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 copay 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 on page 18 of the RAF for the proposed rulemaking 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 under section 2713(a)(2) of the ACA so that parents or guardians who have insurance (and according to the

Insurance Department, roughly 92% of residents of this Commonwealth are covered), should again only be paying a copay or administration fee. Section 2713(a)(2) of the ACA requires insurers to cover those vaccines that are recommended by ACIP, and MCV is recommended by ACIP. See generally “Prevention and Control (2013).” See also generally Bilukha, MD, PhD, O. O. and Rosenstein, MD, N (2005), “Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP)” (Prevention and Control (2005)), *MMWR*, 54(RR 7), 1–21, retrieved from <http://www.cdc.gov/mmwr/pdf/rr/rr5407.pdf>.

Obviously, whether the parent or guardian purchases insurance or 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. 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 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 in 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 the 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 ages 11 years and 16 years has a similar cost-effectiveness compared with moving the single dose to age 15 years or maintaining the single dose at 11 years. However, the number of cases and deaths prevented is substantially higher with the 2-dose strategy (Table 5).

“Prevention and Control (2013),” p. 13. According to ACIP, the two-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 two-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. The analysis assumed that the vaccine benefit would last 4 years. “Prevention and Control (2005).” 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) and 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. 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 1 to 3 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. Given this data, ACIP recommended, in 2005, that there be routine vaccination of children 11 to 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. “Prevention and Control (2005).”

At that time, the Department adopted ACIP’s recommendation for children 11 to 12 years of age, but did not include a second dose. See 40 Pa.B. 2747. This cost analysis remains relevant, and the Department 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 NMA.

The Department acknowledges that there are risks to all vaccines. The only adverse events relevant to this final-form rulemaking 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),” p. 4; *Control of Communicable Diseases Manual*, p. 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 Manual*, p. 359. MCV is transmitted from human to human through direct contact, including respiratory droplets. *Control of Communicable Diseases*

*Manual*, p. 361. These are the same types of cost (that is, health care costs, potential deaths and loss of income for parents) to the Commonwealth 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, the parents of the affected child, the health system and the school system.

The Department disagrees with the statement that meningitis vaccine potentially causes 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),” p. 12. Since June 2010, no specific concerns have been raised about GBS in persons who have a history of that condition and who have been vaccinated with MCV. “Prevention and Control (2013),” p. 13.

The Department 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),” p. 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),” p. 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 chose 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 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. See the College and University Student Vaccination Act (35 P.S. §§ 633.1—633.3).<sup>10</sup> 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 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.

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 cause by the B strain, the conversation is about preventing only about 100 cases Nationwide each year. Another commentator cited Robert F. Kennedy, Jr. as stating that the package inserts of Menactra and Menveo<sup>11</sup> produce serious adverse events in 1% 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

<sup>10</sup> Section 3(b) of the College and University Student Vaccination Act (35 P.S. § 633.3(b)) does provide for religious and medical exemptions.

<sup>11</sup> These are brand names of meningococcal vaccines.

PACIC, stated that meningococcal bacteria become invasive only rarely, stating that “[i]n a small proportion (less than 1%) of colonized persons, the organism penetrates the mucosal cells and enters the bloodstream.” Multiple commentators, including PACIC, cited the CDC as giving the incidence rate as 0.3–0.5/100,000. Multiple commentators cited the *Pink Book* as saying that these bacteria become invasive only rarely. PACIC commented that it is difficult to develop the disease because an individual must be susceptible and 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 web site says that the disease is extremely rare and that death happens to an even smaller percentage of persons than are colonized with the bacteria. The commentator stated that all vaccines come with risk, and the risk of injecting all teenagers 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 3,000 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 amendment to the immunization regulations, but particularly an additional dose of MCV in the 12th grade.

The Department disagrees with the commentators and has not revised 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 or 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 Manual*, p. 359. The case fatality rate had exceeded 50%. However, antibiotics, intensive care units and improved supportive measures have allowed more people to survive. *Control of Communicable Disease Manual*, p. 359.

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 Pennsylvania State University since 2008. In one case, no additional public health intervention was required. 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 and 40 did so. See <http://news.psu.edu/tag/meningitis>.

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 licensed MCV because it determined that the risks to contracting meningitis far outweigh the risks from the vaccine. ACIP 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 11 to 18 years of age, suggested an impact of vaccination on adolescent disease. “Prevention and Control (2013),” p. 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 a decrease of 46% in the expected burden of disease. Shephard, C. W., Ortega-Sanchez, I. R., Scott, II, R.D. and Rosenstein, N. E. (2005), “Cost-Effectiveness of Conjugate Meningococcal Vaccination Strategies in the United States,” *Pediatrics*, 115(5), 1220–1232.

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.

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

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 addressed comments regarding vaccine additives previously in this preamble.

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. PACIC stated that when *Haemophilus influenzae* type b (Hib) vaccine is included, the number jumps to 62,676. PACIC stated that there are more than 2,000 serious health problems, hospitalizations and injuries reported following meningococcal shots, including 33 deaths, with half the deaths occurring in children under 6 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 6 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 provided financial support and employment to some of the researchers, there were adverse effects noted in the studies that caused some participants

to drop out, there was evidence that immunity waned after 5 years, cost effectiveness in a vaccine used for meningitis B was not as impressive as it had appeared pre-licensure, the MMR vaccine caused measles inclusion body encephalitis and six other vaccines, including one for meningitis caused syncope (fainting) and frozen shoulder, and there was a possibility of Henoch-Schonlein purpura.

The Department disagrees with the commentators and has not revised the regulation. The Department 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 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 previously in this preamble.

*Comments regarding 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 this Commonwealth. 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 regarding 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 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 § 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 this final-form rulemaking. The Department extended the time period for implementation of this final-form rulemaking so that schools, school nurses, parents and guardians will have nearly 6 months to obtain this required immunization for children entering 12th grade in fall 2017. This vaccine is not required for the entire student population, but only for those students entering 12th grade in fall 2017. The number of students in 12th grade in the 2015-2016 school year was 146,320. The Department is hopeful that the 5-month to 6-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 regarding college attendance*

One commentator stated that MCV is already required by many colleges, and 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 for 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 revised 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 to boost the child's immune system, and provide immunity if 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 under the College and University Student Vaccination Act. It is partly in preparation of this requirement that the Department added the 12th grade requirement in 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)," p. 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 10% risk of death and a high risk of long-term disability (deafness, limb loss or intellectual impairment). The Department previously discussed this. Further, for each case of meningitis, the public health response is intensive and expensive. Health departments shall 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 PACIC, noted that the General Assembly was considering a bill to require MCV for children entering 12th grade, but the bill did not pass. Therefore, according to 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 General Assembly 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, the Department is required to serve its regulations on the standing committees of the House of Representatives and the Senate of Pennsylvania, and the standing committees have the ability to review and approve or disapprove the regulations.

In addition, the General Assembly gave to the Department the authority to determine against which diseases, infections and conditions a child shall be immunized before entering or attending school. Section 16(a) of the Disease Prevention and Control Law of 1955 provides the Board with the authority to issue rules and regulations on a variety of matters regarding communicable and noncommunicable diseases, including what control measures are to be taken with respect to which diseases, provisions for the enforcement of control measures, requirements concerning immunization and vaccination of persons and animals, and requirements for the prevention and control of disease in public and private schools. Section 16(b) of the Disease Prevention and Control Law of 1955 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. Section 2102(g) of The Administrative Code of 1929 gives the Department this general authority. Section 2111(b) of The Administrative Code of 1929 provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of this Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department.

The Department's specific authority for promulgating regulations regarding school immunizations is found in The Administrative Code of 1929 and in the Public School Code of 1949. Section 2111(c.1) of The Administrative Code of 1929 provides the Board with the authority to make and revise a list of communicable diseases against which children are required to be immunized as a condition of attendance at any public, private or parochial school, including kindergarten. Section 2111(c.1) of The Administrative Code of 1929 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 1303 of the Public School Code of 1949 provides that the Board will make and review a list of diseases against which children shall be immunized, as the Secretary may direct, before being admitted to school for the first time. That section provides that the school directors, superintendents, principals or other persons in charge of any public, private, parochial or other school, including kindergarten, shall ascertain whether the immunization has occurred, 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 General Assembly 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 under legitimately delegated authority.

*Comments regarding the National Childhood Vaccine Injury Act of 1986 and program*

Multiple commentators stated that persons injured because of vaccines will not be able to sue the manufacturer for damages because the manufacturer is protected by the National Childhood Vaccine Injury Act of 1986, which grants liability protection to manufacturers. These commentators stated that the National Childhood Vaccine Injury Act of 1986 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. 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 nonmedical 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, vaccines should not be added 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 6 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 of 1986 in recognition of this fact. The commentators stated that the National Vaccine Injury Compensation Program has awarded more than \$3.2 billion to children, adults and families injured by vaccines. One commentator states that it is \$3.3 billion, 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 of 1986 in section 9 of the RAF for the 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 National Childhood Vaccine Injury Act of 1986, which created the Vaccine Court, is of great relevance, since it prevents families in this Commonwealth from suing vaccine manufacturers if they are injured by a vaccine. The commentator stated that all decisions by the Vaccine Court are 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 Vaccine Court and the National Childhood Vaccine Injury Program, created by the National Childhood Vaccine Injury Act of 1986. The purpose of the National Childhood Vaccine Injury Act of 1986 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*, p. 226 and 227. Awards are paid out of a fund created by an excise tax on each vaccine dose. *Bruesewitz*, p. 226 and 227.

The program allows children who are harmed by vaccines to obtain compensation for injuries suffered after receiving immunizations. To receive an award, a petitioner must make a number of factual demonstrations, including that the child received a vaccination covered by the National Childhood Vaccine Injury Act of 1986, 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 (Cedillo)* (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 shall also establish a causal link between the vaccine and the injury. *Cedillo*, 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 National Childhood Vaccine Injury Act of 1986, 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. *Cedillo*, slip op. at 2.

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. *Cedillo*, slip op. 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. *Cedillo*, slip op at p. 3. The United States Supreme Court characterized the National Vaccine Injury Compensation Program as “a no-fault compensation program.” *Bruesewitz*, p. 223.

The existence of the National Vaccine Injury Compensation Program does not 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. *Bruesewitz*, p. 230. Commentators would like to prohibit all vaccines that are not 100% safe and effective. The United States Supreme Court, like the CDC, AAP, AAFP, the Department and the Board, recognized the importance of childhood vaccines, *Bruesewitz*, p. 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

National Childhood Vaccine Injury Act of 1986 who is not satisfied with his award may reject it and seek tort relief from the vaccine manufacturer. *Bruesewitz*, p. 228. Further, a vaccine manufacturer who fails 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. *Bruesewitz*, p. 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 6 years of age, the Department has no way of knowing how many vaccinations are in research and development. The Department previously addressed the fact that although ACIP may recommend many vaccinations, the Department and the Board do not adopt all vaccinations for school entry and attendance.

The Department previously discussed safety of the MCV, 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.

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. 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 tract 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 Manual*, p. 361.

PACIC stated that the Department already mandates 25 doses of 12 vaccines. 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, he 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 Board, is requiring this immunization for entry into 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 regarding 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 revise the regulation to require all children from 7th through 12th grades to receive the Tdap vaccine. One commentator recommended that this include both students transferring from outside this Commonwealth as well as homeschooled students.

One commentator asked 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 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 § 23.83(c)(1)(iii). The Department previously discussed the requirements regarding Tdap and MCV in 7th grade. 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 noted, the Department added language to § 23.83(c)(2) to make it clear that a dose of MCV received at 16 years of age or older is to be counted as the 12th grade dose. There is no ACIP recommendation for a third MCV dose and the regulations do not contemplate a third dose.

IRRC asked how the final-form rulemaking 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 the term "retroactively." The regulations do not state that specific vaccines are required only upon entry to kindergarten, and that the immunizations required are "once and done." The regulations require that certain immunizations be obtained for school attendance, not simply for school entry. See § 23.83(a). 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 added language to § 23.83(c) 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 under § 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 regarding 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. To provide sufficient time for adequate preparation by parents, guardians, health care practitioners, schools and school nurses, the Department revised the time frame for implementation of this final-form rulemaking 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 revised the final-form rulemaking. The Department is requiring that the child have the vaccine upon entry into the 12th grade. See § 23.83(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 16 years of age 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 § 23.83(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). This requirement will be effective August 1, 2017, allowing for 5 to 6 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 9th to 11th grades 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 this Commonwealth for 7th grade and missed the first dose, would the vaccine now be considered to be a two series vaccine.

The Department 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 this Commonwealth for the first dose does not have a bearing on the question of whether or not the vaccination is a one-dose or two-dose vaccination. There are other provisions that cover what action to take regarding a child who comes into this Commonwealth without a 7th grade dose of MCV and what would happen in succeeding years if child continued to remain unvaccinated. This final-form rulemaking provides that a child who moves into this Commonwealth has a 30-day period to obtain records of immunizations. See § 23.85(g)(2). If the child moves into this Commonwealth after 7th grade 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 Chapter 23, Subchapter B (relating to school nurse services) are met. This exclusion may continue into subsequent school years. The Department added language to § 23.85(g)(2) to clarify that fact. These regulations apply to children transferring into a school from outside this Commonwealth unless one of the provisions of § 23.85(g) applies. As a point of clarification, this final-form rulemaking does apply to children being homeschooled, and has done so prior to this final-form rulemaking, as the definition of “school” has not been amended and includes home education programs. See § 23.83(a).

As the Department has noted, MCV is a two-dose series. A third dose is not recommended by ACIP, or required by the Department.

§ 23.85. *Responsibilities of schools and school administrators*

§ 23.85(e)(1)—*Multiple dose vaccine series—provisional period*

The Department received many comments on the proposed amendment 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 5 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 proposed amendment, some disagreed with the proposed amendment and recommended other time frames, and some disagreed with the 5-day time frame but did not offer recommendations. Some commentators expressed concern with the time frame for implementation expected by the Department, which was for the proposed rulemaking to be effective for the 2016-2017 school year.

IRRC noted that commentators generally supported the proposed amendment, 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 time frame 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 to enter and attend school. The Department will then detail the specific comments received, as well as the different time frames proposed by commentators but without reiterating its rationale each time a comment relates to the 5-day period.

The Department reviewed data regarding 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, the Department decided to adopt the 5-day period 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 discussed the concept of herd or community immunity at length in the “comments regarding ‘herd’ or community immunity, vaccine effectiveness and natural immunity” section of this preamble and will not repeat it here.

The Department notes that this final-form rulemaking will be effective August 1, 2017. The Department acknowledges the need for education and outreach on these regulations, 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 or 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. This final-form rulemaking requires a child to have any single dose vaccine upon school entry, or risk exclusion. In the case of a multidose vaccine, this final-form rulemaking requires 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 5 days of school, the child must have either the final dose during that 5-day period or have the next scheduled dose and 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 5 days of school, the child may provide a medical certificate on or before the 5th school day scheduling those doses. The medical certificate shall 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 5 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 when raised in connection with other parts of this final-form 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, ACIP and AAP recommend simultaneous administration of all routine childhood vaccines when appropriate.

The Department discussed combination vaccines in more detail previously in this preamble.

One commentator was not in favor of the 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 5 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 this Commonwealth 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 shall 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 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 proposed rulemaking, 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 amendments will be a big adjustment for them.

The Department appreciates the support of the commentator, but points out that the provisional period is being reduced, not eliminated. The immunization requirements have not changed in the past 5 years. The Department added one entirely new immunization requirement in this final-form rulemaking, MCV in the 12th grade. Children being immunized against diphtheria and tetanus in this 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 Depart-

ment's 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, parents and guardians. The Department will ensure that this final-form rulemaking is published prior to kindergarten registration in March 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 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 revised the regulation, because this is, in part, what the final-form 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 5 days of school, the child shall have either the final dose during that 5-day period, or shall have the next scheduled dose and also provide a medical certificate setting out the schedule for the remaining doses. If the child has at least one dose, and needs additional doses, and those doses are not medically appropriate during the first 5 days of school, the child may provide a medical certificate on or before the 5th school day scheduling those doses. The medical certificate shall 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. This final-form 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. 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 revised this final-form rulemaking. The Department cannot require school nurses to work over the summer because the Department has no authority over school nurse schedules. The Department addressed the commentator's other concerns regarding the appropriateness of the 5-day provisional period elsewhere in this preamble.

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 fourth and fifth doses of DPT, the third and fourth doses of polio, and the second 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 years of age 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 revised this final-form rulemaking. The Department notes that the requirement for a child to be immunized by the start of school has long antedated this final-form rulemaking. 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 final-form rulemaking being effective for the 2016-2017 school year. Several commentators asked when the final-form rulemaking would be effective and what the transition time would be. PSBA and PASA stated that school entities would not have time to develop policies, implement procedures or communicate with parents and guardians about the amendments. 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 this final-form rulemaking 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, if the final-form rulemaking 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 sum-

mer 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, make phone calls and type up letters outlining the amended regulations.

One commentator stated that many less students would be excluded from school if the final-form rulemaking 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 start school.

After reviewing the comments, the Department agrees with the commentators. The Department expects this final-form rulemaking to be published in time for kindergarten registration for the 2017-2018 school year to enable schools to provide information to parents and guardians regarding the amendments 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 and guardians about the amendments to the 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 if a sample notice was available.

It was not the Department's intention that the proposed amendments be presented to parents and guardians of school-aged children before completion of the regulatory process, which allows for public comment and discussion. To avoid confusion, particularly in case a regulation is revised or is not approved, the requirements are published as a final-form rulemaking before 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 individual school districts.

PSEA stated that reviewing immunization records and communicating with parents about the need for the second dosage within 5 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 this final-form rulemaking for the 2017-2018 school year, 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 amendments 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 proposal reducing the provisional period to 5 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 the 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 after the Labor Day 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 3 to 4 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 8 months to get appropriately vaccinated, they will take 8 months, and if they have 1 day, they will get vaccinated in 1 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 herd immunity needs to be created 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 5 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 5 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 5 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 felt 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 felt this was 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 deleting 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 children 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 race 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 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 revised this final-form rule-making based on the rationale it set out at the beginning of this section. 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 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 5 days of school, the child shall have either the final dose during that 5-day period, or shall have the next scheduled dose and 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 5 days of school, the child may provide a medical certificate on or before the 5th school day scheduling those doses. The medical certificate shall be signed by a physician, CRNP or 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 shall 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 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.

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 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 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. Consequently, ACIP and AAP recommend simultaneous administration of all routine childhood vaccines when appropriate. The Department discussed these issues more fully elsewhere in this preamble.

One commentator stated that the worst of the Department's proposed amendments would be to change the 8-month provisional period to a 5-day provisional period. 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 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. After reviewing all the comments and the 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 § 23.84.

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 proposed rulemaking. The commentator stated 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; and will all children be tested to make sure they are not 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 8 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 this final-form rulemaking. 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. *Vaccines: What You Should Know*, p. 88; *Pink Book*, p. 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*, p. 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 not revised the medical exemption language of the regulation, and cannot eliminate it as it is required by law.

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

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 did 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 5 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 this Commonwealth 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 this final-form rulemaking within the time frame originally proposed, the Department decided to extend the time for implementation. This final-form rulemaking is 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 amendments. This will provide schools and school nurses with the remaining months of the 2016-2017 school year to begin to prepare for implementing the amendments. Schools and school nurses will be able to begin to review implementation status of students, provide information to parents and guardians, and determine which students may have issues in fall 2017-2018. Although not all issues regarding the time necessary to implement the amendments will be resolved by this extended period prior to August 1, 2017, the Department is hopeful that the 5-month to 6-month period prior to 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 2017-2018 school year. The Department also ac-

knowledges the need for education and outreach on this final-form rulemaking, 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 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 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 revised this final-form rulemaking. 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 revised this final-form rulemaking based on the rationale it set out at the beginning of this section, and based on its discussion regarding herd and community immunity.

One commentator stated that a child could not obtain a medical certificate within 5 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 2-week to 4-week turnaround time now, and new patients will never get a private provider within 5 days.

One commentator stated that 5 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 nonacute

matter, and the health of some children warranted more than routine consideration when making an immunization decision.

The Department has not revised this final-form rulemaking. This final-form rulemaking is published in time for kindergarten registration, 5 to 6 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 amendments, 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 5 to 6 months to bring their children's immunizations up-to-date or, in the alternative, to request a medical or religious/philosophical exemption. 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 contraindicated, 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 this 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 previously noted, not every school in this 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 appointments, arrange time off work, transportation and records to be returned back to school and processed by the school nurse but still convey the sense of urgency created by the final-form 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 revised this final-form rulemaking in response to this comment. For the reasons provided at the beginning of this section, 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 former 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, through 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 5 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 14 to 20 days. PSBA stated that a longer provisional period will be more successful in reaching the Department's goals.

This final-form rulemaking is effective for the 2017-2018 school year and published in March 2017. Since kindergarten registration occurs in March, this should give schools and school nurses ample time to notify parents and develop communications regarding the 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 5 to 6 months to make appointments and ensure that their child is appropriately vaccinated in accordance with this final-form rulemaking. The new regulation adds MCV in 12th grade, and adds pertussis to the list of diseases against which a child shall be vaccinated to enter and attend school. Parents should be aware of all these requirements since the Department has not added a 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 (42 U.S.C.A. §§ 11431—11435), 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 also 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 3-week to 4-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 6 to 8 weeks. This commentator stated that there needed to be a transitional period of at least 1 school year before enforcing the 5-day provisional period.

In responding, the Department clarifies 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. This final-form rulemaking is 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 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 5 to 6 months to make appointments and ensure that their children are appropriately vaccinated in accordance with the existing regulation. The Department believes that this 5-month to 6-month period is a sufficient transition time to inform parents and guardians, and encourage them to comply with the amendments. In addition, final-form rulemaking only adds one new vaccine, MCV in 12th grade, since children being immunized against diphtheria and tetanus in this Commonwealth prior to this final-form rulemaking 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 prioritizes what forms are reviewed first during the initial days of school, and the priority is 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 5 days to put these things in place and to ensure the safety of the children. The commentator stated that more than 5 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 students 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. 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. 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 doctors' 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 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 final-form rulemaking 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). 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, 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 the August 1, 2017, effective date. 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 6 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 shall 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 this final-form rulemaking, particularly for the 5-day provisional period, which it intends to conduct with health care practitioners, schools, school nurses and parents. 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 HSLDA, stated that 5 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 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 with the number of vaccinations needed for entry or attendance for medical reasons, 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 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 5 days is too extreme. PACIC stated that trying to get those children who are totally unvaccinated ten vaccines within 5 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 PACIC, stated that no nearby states have such a short time frame; the average period is 58 days. Multiple commentators stated that 5 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 5 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 5 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 shall adhere to that schedule. If it takes a child 7 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. *Vaccines: What You Should Know*, p. 99 and 100; *Pink Book*, p. 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*, p. 11 and 27.

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. PACIC stated that section 10 of the RAF for the proposed rulemaking states that schools in this Commonwealth have a relatively low number of exemptions. 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 the proposed rulemaking, because it is misleading. 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 cannot make a change to the preamble to the proposed rulemaking. Further, 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 in discussing herd or community immunity.

Several commentators supported shortening the provisional period to 60 days to improve recordkeeping 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 revised this final-form rulemaking. Commentators who are also school nurses have indicated that a longer provisional period requires more follow-up, since multiple letters are sent to children and parents. Any regulation regarding exclusion for failure to obtain required immunizations will require follow-up by the school administrator or a 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 the physician's designee, the physician or the 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 for the purpose of obtaining 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 a provisional period as short as 5 days. The Department notes that West Virginia, which has a 240-day (8-month) provisional period, has very high vaccination rates. In the Department's opinion, 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 previously 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, developing individualized health plans for them, instructing teachers on first aid care and emergency plans, and notifying teachers of students with allergies requiring EpiPen 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 revised this final-form rulemaking. 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 previously explained in this preamble 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 this 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 5 days. The commentator recommended a 90-day provisional period, the same as 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 and 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 doctors' offices make a person wait 1 to 2 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 5 days to give their children what may end up being several vaccines at once has the potential to result in a catastrophic reaction for 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 the decision by withholding education from children violates the principle of informed consent. The commentator stated that this Commonwealth has one of the highest vaccination rates in the country. The commentator stated that 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 revised this final-form rulemaking. The Department is not requiring parents to make a rushed decision to vaccinate their child. The requirements regarding 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 final-form rulemaking adds pertussis to the list of diseases against which a child shall 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 this Commonwealth prior to this final-form rulemaking 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 ten 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 moved the effective date of this final-form rulemaking to the 2017-2018 school year. Parents should be notified in March 2017 of the publication of this final-form rulemaking, and a child attending school in this 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 previously explained, "informed consent" has a particular meaning in Commonwealth law. 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 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 discussed the issue regarding aluminum and other vaccine additives previously in this preamble.

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-day 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-day to 60-day provisional period.

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

The Department has not revised this final-form rulemaking. For the reasons previously stated, the Department believes the appropriate time frame for a provisional period is 5 days.

One commentator stated that although the 240-day provisional period is too long, a 30-day to 60-day period would be more appropriate. The commentator stated that the 2013-2014 school year kindergarten MMR rate was 86%. By 7th grade, which is the next grade for which

there is available data, the rate was 95.8%. This Commonwealth'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 RAF, because it explains the low kindergarten rate. Since the median provisional period time frame around the United States is 30 days, the commentator recommended a 30-day to 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 previously stated, its review of the school level data, rather than the school district level data, causes concern about the pockets of nonimmunized children throughout this Commonwealth. The Department provided the medical and religious/philosophical exemption rates previously in this preamble. Because these schools show no medical or religious exemption, the number of nonimmunized 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 does not resolve the issue, as the Department has discussed, of children at a point in time in a school being underimmunized. 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-day to 70-day provisional period*

One commentator agreed that the current provisional period was long, but stated that 5 days was difficult given the real day-to-day lives of families. The commentator stated that this would put ill or immunocompromised children at risk for injury having so many vaccines 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 60-day to 70-day period.

The Department has not revised this final-form rulemaking. The Department previously stated its reasons 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 addressed multiple vaccines previously in this preamble.

#### *60-day 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, and making sure students who need medications have the paperwork and medications available. This commentator recommended a 60-day 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 commenta-

tor recommended a 60-day 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 5 days, there would be a rise in moral or ethical exemptions, and those children would never be immunized.

One commentator, a homeschool parent whose children are vaccinated, as required by the regulations, 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 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 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-day 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 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 5 days of school, the child must have either the final dose during those first 5 days of school or the next scheduled dose during that time period. During that same time period, the child shall 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 5 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 physi-

cian or a 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, 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 days or 60 to 90 days would be easier to monitor and enforce. The commentator noted that no matter what the provisional period, there would be parents who would not comply.

The Department has not revised this final-form rule-making. 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 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-month to 6-month provisional period*

One commentator, identifying herself as a board-certified family physician, recommended a 3-month to 6-month provisional period, because missing a vaccine during this 3-month to 6-month period was not likely to have any significant effect on outcomes, but eliminating a 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 3 to 6 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 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 a designee may, in the case of a serious illness or accident, provide a medical exemption if need be. The Department 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 revised this final-form rulemaking. In fact, the provisional period does not exist in statute. Rather, the provisional period is a regulation promulgated by the Department 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 this Commonwealth. In reviewing this particular regulation in the light of school immunization data, and the recent outbreaks of vaccine preventable diseases in California and this Commonwealth, the Department decided that an 8-month provisional period was 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 at 8 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 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 revised this final-form rulemaking. It is the Department's belief that the number of children who need multiple immunizations 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 a short time span might have negative effects on the child. The commentator recommended that 9 months be allowed for vaccinations.

The Department has not revised this final-form rulemaking. The Department believes that to extend the provisional period further than it was originally, that is from 8 months to 9 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 previously 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 regarding 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 8 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 3-month provisional period in kindergarten. In that way the school nurse could make kindergarten booster shots a priority.

The Department has not revised this final-form rulemaking. As 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 first 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 and 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 8 years of age, if a parent attempting to register a child at 5 years of age did 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 6 years of age. 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 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 previously stated, 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 5 days of school. The 5-day provisional period would put a tremendous pressure on the school nurse.

The Department has not revised this final-form rulemaking. The Department does not believe that eliminating the 5-day provisional period altogether would eliminate work for the school nurse, as previously stated.

#### *No set time for immunizations*

One commentator stated that this Commonwealth is one of the most difficult states in which to homeschool 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 revised this final-form rulemaking. 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.

#### *§ 23.85(e)(1)(i) and (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 Pediatrics, meaning those pediatricians in this Commonwealth 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 educational materials to school entities and families to assist in this implementation.

As the Department noted in the proposed rulemaking, the medical certificate is a new requirement. The Department set out the contents of the medical certificate in the proposed rulemaking, and has not revised that content in this final-form rulemaking 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 the definition of "medical certificate" in § 23.82 (relating to definitions). The Department will provide the medical certificate form to schools. The

Department attached a draft of the medical certificate form to the RAF for this final-form rulemaking as Attachment 3, and will also share that form with physician's groups, including AAP and other stakeholders, to obtain their input. The Department expects to post the medical certificate form on its web site by March 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 school nurses could have physicians 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 2017. No other form of written communication, including an appointment printout, is sufficient.

One commentator was trying to be proactive by sending out letters regarding the proposed rulemaking 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. Until this final-form rulemaking is finally promulgated, the amended regulations are not effective. 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 shall 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 attached the draft medical certificate form to the RAF for this final-form rulemaking and will publish the medical certificate form on its web site, 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 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 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 a 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. 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 of 1949 places the responsibility on the school administrator or a designee.

PSBA and PASA opposed the proposed amendment from 60 to 30 days for reviewing the medical certificate. While supporting a shortened time frame as a method to seek greater parental accountability, 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 this Commonwealth. 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 that it 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 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 30 days. For example, the time frame for immunization

records to be produced for children who transfer into a school in this 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 the proposed 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. Further, not all children will be without vaccinations. The number provisionally admitted in the 2015-2016 school year was 21,175, or roughly 7.6% of students enrolled in reporting schools. See "School Immunization Summary 2015-2016." 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 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, the Department is 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 fall 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 is complying with the immunization schedule in the medical certificate that has been signed by a physician, CRNP or PA. The Department's intention is to transform what was a seemingly endless time period (that is, 8 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 parents or guardians, and the physician, CRNP or PA giving the immunizations, agree that this immunization will be completed. This amendment 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 a 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 seeks to obtain compliance, the Department's attempt to shorten the period in which nonimmunized children and adults remain at risk will not seem serious, and the Department's goal of stressing the importance of these compliance requirements will be undermined.

One commentator stated that she supported the proposed amendment 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 a child, 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 revised this final-form rule-making, 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 the exclusion falls upon the school nurse, the language in question comes specifically from the Public School Code of 1949. 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.

§ 23.85(e)(1)(ii) and (iii)—Multiple dose vaccine series—medical certificate

IRRC commented that proposed § 23.85(e)(1)(ii) and (iii) ended with similar language that states that a child's parent or guardian shall 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 revised this final-form rulemaking. 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. In this final-form rulemaking, § 23.85(e)(1)(ii) and (iii) states that the parent or guardian shall provide a medical certificate on or before the 5th school day scheduling the additional required doses. A minor change was made to § 23.85(e)(1)(iii) to add "the" and "required" to parallel § 23.85(e)(1)(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 in the preamble and the RAF for the proposed rulemaking additional time and costs created by the need to obtain a medical certificate signed by a physician, CRNP or PA<sup>12</sup> in the event the child needs additional doses of a multiple dose vaccine. This should not add significantly to the time requirements for parents and guardians that have resulted from the 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.<sup>13</sup> See the definition of "certificate of immunization" in § 23.82. Although the number of immunizations may have changed over those years, the requirement for a certificate of immunization has not. The 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 former § 23.85(e)(1) and (2), the provisional period as they existed prior to this final-form rulemaking, the Department 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," and, under former § 23.85(e)(3), that the plan be reviewed every 60 days by school

administrators or their designees. Under former § 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 database.

The Department's immunization data, drawn from its SILR reports, see § 23.86, 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" with the "School Immunization Summary 2015-2016." This concerns the Department because the longer the periods of time in which clusters of nonimmunized 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 shortened the provisional period for this reason.

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. 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 is requiring the immunization plan, in the form of a medical certificate, to be formally signed by a physician, CRNP or PA, or a public health official when 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 or 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, 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 for this final-form 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 copayment, 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, and a cost for completing paperwork. Although one study used a public fee amount of approximately \$8.15, the Department's experience shows an administrative fee of approximately \$24.13. See "Supplement to Benefit," p. 4. The cost for completing paperwork can cost \$5 to \$55, although it appears that practices charging more than \$21 are in the minority. See <http://www.mgma.com/blog/should-your-medical-group-practice-charge-for-patient-forms> and <http://www.amednews.com/article/20071015/business/310159994/4/>. The Department assumed a cost of approximately \$20 per form, which appears to be roughly the most common

<sup>12</sup> A child may also go to the Department or a local health department to obtain an immunization. This final-form 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 charge paperwork fees and, if a parent or guardian cannot afford the minimal administration fee for the immunization that may be charged, the child will not be refused the vaccination.

<sup>13</sup> A parent, guardian or emancipated minor may also fill out the certificate of immunization, but it shall be signed by a health care provider, public health official, or school nurse or designee. See the definition of "certificate of immunization" in § 23.82.

amount charged. The Department and local health departments do not charge a paperwork fee.

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 outweigh the cost of the vaccine and the cost of the visit to obtain the medical certificate. The Department developed a medical certificate format for schools to use.

*§ 23.85(g)(2)—Applicability—30-day waiver if transferring into school in this 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 in this 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 children, so that they never pick up immunization records. 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 time frame 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 revised this final-form rulemaking. 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 is attempting to balance the need for protection against disease with the need to allow a child and his 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 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.

*§ 23.85(g)(3)—Applicability—waiver if the child is in foster care*

One commentator raised a question regarding the implications of the proposed rulemaking for children in foster care, and asked that the final-form rulemaking address that issue.

The Department adds § 23.85(g)(3) to allow for a 30-day waiver for children in foster care. A child will have 30 days to provide immunization records to the school showing proof of immunization, 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 Chapter 23, Subchapter C are met.

*§ 23.85(h)—Temporary waiver*

PASA supported the proposed subsection 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 this 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 from immunization*

Several commentators raised objections to the philosophical exemption, even though it was not a part of the 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 not revised the regulation. The medical and religious exemptions to vaccine requirements are set in statute and may only be changed by the General Assembly. 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 this final-form rulemaking. Further, with the change in reporting times from October to December in 2014, and then into March 2016 for the 2015-2016 school year, the immunization rates increased, and the number of children in provisional status decreased. See School Level Data 2014 and 2015,

Attachments 1 and 2 to the RAF for this final-form rulemaking. This leads the Department to believe that students are simply waiting to be vaccinated. The Department does not believe that vaccination rates in this 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, those with HIV or undergoing chemotherapy). According to the commentator, several vaccine preventable diseases, like chickenpox, are contagious 1 or 2 days 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 not amended the regulation. The medical and religious exemptions to vaccine requirements are set in statute and may only be changed by the General Assembly. 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 § 23.24. 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 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 regarding medical and religious exemptions are not enforced by the Department. The statutorily permitted exemptions are within the purview of the school administrator and the 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 Board, the authority to create a list of diseases against which children shall 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 a 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 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 General Assembly 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. The Department points to the "Benefits from Immunization" study and supplement discussed more fully in this preamble.

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 health care. The commentator stated that parents do not need a religious leader to sign a paper saying that injecting 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 received a wide range of differing views, most passionately held, on the issue of vaccination, exemptions and human and parental rights. As previously stated, the Department cannot make any an amendment to the exemption requirements in the Public School Code of 1949. 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 proposed amendment 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 determined that requiring electronic reporting will speed up the process at every level, and hopefully result in more accurate reporting. The Department revised the language in proposed subsection (b) 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. The Department intends to do training.

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 7 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. PACIC stated that since the level of exemptions is low, it must be realized that the low rate for MMR for kindergarteners is inaccurate. 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 7 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 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 amendment to 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 this 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 raised the question of privacy. One commentator asked how the Department and the Department of 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 this 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 section 444 of FERPA, which protects a student's privacy. FERPA does not 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 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 within the authority of the Department or of the Department of Education.

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 revised this final-form rulemaking. 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.

Several commentators raised concerns that the Department is requiring electronic reporting of homeschool programs, but is not permitting those who homeschool their children, and are unable to report electronically, to report on paper forms.

Significantly, these concerns were not raised during the public comment period on proposed rulemaking, but only during the period prior to the hearing before IRRC on October 20, 2016. The Department responded to those concerns at the hearing and revised this preamble to include its response. In fact, the commentators misapprehended the pertinent sections of this final-form rulemaking. Section 23.86(a) defines by example "public, private, parochial or nonpublic school," and includes in that definition "home education programs." This language has always existed in this section and is not new to this final-form rulemaking. In this final-form rulemaking, the Department adds subsection (b) that states that if "a public, private, parochial or nonpublic school is unable to complete its report electronically, it shall report to the Department. . . using a form provided by the Department." The Department does not repeat the definitional phrase "including vocational school, intermediate units, special education and home education programs" in subsection (b). The Department does not need to carry the definitional phrase from subsection (a) to subsection (b). Once defined, the term remains defined throughout § 23.86. Accordingly, "public, private, parochial or nonpublic

school” includes a home education program in subsections (a) and (b), regardless of whether the definitional phrase is included in both subsections. Therefore, even if a homeschool parent *were* required to report directly to the Department under subsection (a), which the parent is not, that parent could report on a paper form if he were to be unable to report electronically under subsection (b).

In addition, the Department has never required, and does not require in this final-form rulemaking, a homeschool parent to report directly to the Department. The Department does not collect information on individual students. Under this final-form rulemaking, homeschool parents will continue to provide information on their children’s immunization status *to the school* in the school district in which they reside; it is the school that then reports to the Department. This final-form rulemaking does not change that process. A homeschool parent is not required to report to the Department directly, either electronically or on paper, but will continue providing information to the school their child would have attended.

### C. *Cost and Paperwork Estimate*

#### 1. *Cost*

##### a. *Commonwealth*

The Commonwealth will incur some costs for the purchase of MCV 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 final-form 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 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 (FQHCs 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 Immunization 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 based on the amount of funds that will not be needed to control the outbreak of vaccine preventable diseases. The Department 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 schools in this Commonwealth.

##### 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 this final-form rulemaking on school districts, which may be considered to be local government, as follows.

##### c. *Regulated community*

Families whose children’s vaccinations are covered by their insurance plans (public or private) under the ACA

will not see any out-of-pocket cost for MCV or DTaP vaccines, although they may have additional copayments. According to the Insurance Department, over 92% of the residents of this Commonwealth are covered by insurance. 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 FQHCs. A child may not be denied a vaccine because of his family’s inability to pay the administrative fee. The Department is available to provide a list of providers if necessary. The Department also provides vaccines to schools through its School Immunization 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 copayment 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 discussed the costs related to an illness in reference to an outbreak situation elsewhere in this preamble. In addition, the Department made the effective date of this final-form rulemaking coincide with the beginning of the 2017-2018 school year but is publishing this final-form rulemaking in March 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 addressed the cost-benefit analysis of requiring MCV and pertussis vaccination and of childhood immunization in general elsewhere in this preamble.

The Department deleted the proposed 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 also extended the time to prepare for the implementation of the regulations in the 2017-2018 school year by publishing this final-form rulemaking in March 2017 in time for kindergarten registration and nearly 6 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 amendments to the regulations nearly 6 months prior to the 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 amendments 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 beginning of the 2017-2018 school year. 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 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 will also be affected by the fact that children missing doses of multiple dose vaccines will need the practitioner to sign a medical certificate setting out the time frame for obtaining those vaccinations 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 the Commonwealth 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 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 provided a more detailed explanation of studies supporting these conclusions elsewhere in this preamble. The cost of this final-form rulemaking on parents, guardians and students is addressed under "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 final-form rulemaking, 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 shall 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 must 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 attached a draft copy to the RAF for this final-form 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 the Department of Education, and the regulated community would be minimal since school districts already complete an annual report regarding the number of immunizations and follow up on provisional enrollment. Time frames will be shortened for those reasons previously cited in this preamble.

Parents and guardians of children attending school in this 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 shall be submitted to the school within 5 days of the start of school 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 immunizations, or risk exclusion. A parent or guardian may provide the school with a medical or religious/philosophical exemption instead 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 included school districts, which may be considered to be local government, under the "regulated community" heading.

*c. General public*

There is no additional paperwork requirement for the general public. The Department addresses the cost of this final-form rulemaking on parents, guardians and students under the “regulated community” heading.

*D. Statutory Authority*

The Department obtains its authority to promulgate regulations regarding immunizations in schools from several sources. Generally, the Disease Prevention and Control Law of 1955 provides the Board with the authority to issue rules and regulations on a variety of matters regarding communicable and noncommunicable diseases, including what control measures are to be taken with respect to which diseases, provisions for the enforcement of control measures, requirements concerning immunization and vaccination of persons and animals, and requirements for the prevention and control of disease in public and private schools. See section 16(a)(6) of the Disease Prevention and Control Law of 1955. Section 16(b) of the Disease Prevention and Control Law of 1955 gives the 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. Section 2102(g) of The Administrative Code of 1929 gives the Department this general authority. Section 2111(b) of The Administrative Code of 1929 provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of this Commonwealth. Section 2111 of The Administrative Code of 1929 further provides that the regulations of the Board shall become the regulations of the Department.

The Department’s specific authority for promulgating regulations regarding school immunizations is in The Administrative Code of 1929 and the Public School Code of 1949. Section 2111(c.1) of The Administrative Code of 1929 provides the Board with the authority to make and revise a list of communicable diseases against which children are required to be immunized as a condition of attendance at any public, private or parochial school, including kindergarten. The section requires the Secretary to promulgate the list, along with any rules and regulations necessary to insure the immunizations are timely, effective, and properly verified.

Section 1303 of the Public School Code of 1949 provides that the Board will make and review a list of diseases against which children shall be immunized, as the Secretary may direct, before being admitted to school for the first time. The section provides that the school directors, superintendents, principals or other persons in charge of any public, private, parochial or other school, including kindergarten, shall ascertain whether the immunization has occurred, 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.

*E. Effective and Sunset Dates*

This final-form rulemaking will be effective 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. A sunset date has not been established. The Department will continually review and monitor the effectiveness of these regulations.

*F. Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on March 29, 2016, the Department submitted a copy of the notice of proposed rulemaking, published at 46 Pa.B. 1798, to IRRC and the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee for review and comment.

Under section 5(c) of the Regulatory Review Act, the Department shall submit to IRRC and the House and Senate Committees copies of comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department considered all comments from IRRC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on October 19, 2016, the final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on October 20, 2016, and approved the final-form rulemaking.

*G. Contact Person*

Questions regarding this final-form rulemaking may be submitted to Cynthia Findley, Director, Division of Immunization, Department of Health, 625 Forster Street, Harrisburg, PA 17108, (717) 787-5681. 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 final-form rulemaking may contact Cynthia Findley so that necessary arrangements may be made.

*H. 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 statutes.

*I. Order*

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

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

(2) The Secretary 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 shall submit this order and Annex A to IRRC and the House and Senate Committees for their review and action as required by law.

(4) The Secretary 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.

KAREN M. MURPHY, PhD, RN,  
Secretary

(*Editor's Note:* See 46 Pa.B. 7051 (November 5, 2016) for IRRC's approval order.)

**Fiscal Note:** Fiscal Note 10-197 remains valid for the final adoption of the subject regulations.

#### Annex A

### TITLE 28. HEALTH AND SAFETY

#### PART III. PREVENTION OF DISEASES

#### CHAPTER 23. SCHOOL HEALTH

#### Subchapter C. IMMUNIZATION

#### § 23.82. Definitions.

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

*Ascertain*—To determine whether or not a child is immunized as defined in this subchapter.

*Attendance at school*—

(i) The attendance at a grade, or special classes, kindergarten through 12th grade, including public, private, parochial, vocational, intermediate unit and home education students, and students of cyber and charter schools.

(ii) The term does not cover the attendance of children at a childcare group setting, defined in § 27.1 (relating to definitions), located in a public, private or vocational school, or in an intermediate unit.

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

*Department*—The Department of Health of the Commonwealth.

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

*Immunization*—The requisite number of dosages of the specific antigens at the recommended time intervals under this subchapter.

*Medical certificate*—The official form furnished by the Department setting out the immunization plan for a student who is not fully immunized, filled out and signed by a physician, certified registered nurse practitioner or physician assistant, or by a public health official when the immunization is provided by the Department or a local health department, and given to a school as proof that the student is scheduled to complete the required immunizations.

*Record of immunization*—A written document showing the date of immunization—that is, baby book, Health Passport, family Bible, other states' official immunization documents, International Health Certificate, immigration

records, physician record, school health records and other similar documents or history.

*Secretary*—The Secretary of the Department.

#### § 23.83. Immunization requirements.

(a) *Duties of a school director, superintendent, principal or other person in charge of a public, private, parochial or nonpublic school.* Each school director, superintendent, principal, or other person in charge of a public, private, parochial or nonpublic school in this Commonwealth, including vocational schools, intermediate units, and special education and home education programs, cyber and charter schools, shall ascertain that a child has been immunized in accordance with the requirements in subsections (b), (c) and (e) prior to admission to school for the first time, under section 1303 of the Public School Code of 1949 (24 P.S. § 13-1303a), regarding immunization required; penalty.

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

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

(2) *Poliomyelitis.* Four properly-spaced doses of either oral polio vaccine or inactivated polio vaccine, which may be administered as a single antigen vaccine, or in a combination form. The fourth dose shall be administered on or after the 4th birthday and at least 6 months after the previous dose.

(3) *Measles (rubeola), mumps and rubella (German measles).* One of the following:

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

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

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

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

(C) Two properly-spaced doses of live attenuated mumps vaccine, administered at 12 months of age or older.

(iii) *Evidence of immunity.* Evidence of immunity may be shown by a history of measles and rubella immunity proved by laboratory testing by a laboratory with the appropriate certification and a written statement of a history of mumps disease from a physician, certified registered nurse practitioner or physician assistant.

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

(5) *Varicella (chickenpox)*. One of the following:

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

(ii) *Evidence of immunity*. Evidence of immunity may be shown by one of the following:

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

(B) A written statement of a history of chickenpox disease from a parent, guardian, physician, certified registered nurse practitioner or physician assistant.

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

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

(i) *Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap)*. One dose of Tdap in a combination form.

(ii) *Meningococcal conjugate vaccine (MCV)*. One dose of MCV.

(iii) *Exclusion*. A child who does not have an exemption as permitted by § 23.84 (relating to exemption from immunization) and who does not receive the immunizations as required in subparagraphs (i) and (ii) may be excluded in that school year and each succeeding school year that the child fails to obtain the required immunization.

(2) *Required for entry into 12th grade*. In addition to the immunizations listed in subsection (b) and this subsection, one dose of MCV is required for entry into 12th grade at any public, private, parochial or nonpublic school in this Commonwealth, including vocational schools, intermediate units, special education and home education programs, and cyber and charter schools, or, in an ungraded class, for students in the school year that the student is 18 years of age, if the child has not received a previous dose on or after the child's 16th birthday. A dose of MCV received at 16 years of age or older shall count as the 12th grade dose.

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

(e) *Prekindergarten programs, early intervention programs' early childhood special education classrooms and private academic preschools*. Attendance at a prekindergarten program operated by a school district, an early intervention program operated by a contractor or subcontractor including intermediate units, school districts and private vendors, or at private academic preschools is conditional upon the child's satisfaction of the immunization requirements in § 27.77.

(f) *Grace period*. A vaccine dose administered within the 4-day period prior to the minimum age for the

vaccination or prior to the end of the minimum interval between doses shall be considered a valid dose of the vaccine for purposes of this chapter. A dose administered greater than 4 days prior to minimum age or interval for a dose is invalid for purposes of this regulation and shall be repeated.

**§ 23.85. Responsibilities of schools and school administrators.**

(a) *Inform of requirements and ascertain immunization status*. The administrator in charge of a school shall appoint a knowledgeable person to perform all of the following:

(1) Inform the parent, guardian or emancipated child at registration or prior to registration, if possible, of the requirements of this subchapter.

(2) Ascertain the immunization status of a child prior to admission to school or continued attendance at school.

(i) The parent, guardian or emancipated child shall be asked for a completed certificate of immunization.

(ii) In the absence of a certificate of immunization, the parent, guardian or emancipated child shall be asked for a record or history of immunization which indicates the month, day and year that immunizations were given. This information shall be recorded on the certificate of immunization and signed by the school official or the school official's designee, or the details of the record shall be stored in a computer database.

(b) *Admission to school or continued attendance*. If the knowledgeable person designated by the school administrator is unable to ascertain whether a child has received the immunizations required under § 23.83 (relating to immunization requirements) or under subsection (e) or is exempt under § 23.84 (relating to exemption from immunization), the school administrator may admit the child to school or allow the child's continued attendance at school only according to the requirements of subsections (d) and (e).

(c) *Inform of specific immunization requirements*. The parent or guardian of a child or the emancipated child who has not received the immunizations required under § 23.83 shall be informed of the specific immunizations required and advised to go to the child's usual source of care or nearest public clinic to obtain the required immunizations.

(d) *Requirements under which admission or continued attendance is permitted*. A child not previously admitted to or not allowed to continue attendance at school because the child has not had the required immunizations shall be admitted to or permitted to continue attendance at school only upon presentation to the school administrator or school administrator's designee of a completed certificate of immunization or immunization record, upon submission of information sufficient for an exemption under § 23.84, or upon compliance with subsection (e).

(e) *Provisional admittance to school*.

(1) *Multiple dose vaccine series*. If a child has not received all of the antigens for a multiple dose vaccine series described in § 23.83 on the child's first day of attendance for that school year, the school administrator or the school administrator's designee may not provisionally admit the child to school unless the child has at least one dose of each multiple dose vaccine series required under § 23.83, and one of the following occurs:

(i) The child receives the final dose of each multiple dose vaccine series required under § 23.83 within 5

school days of the child's first day of attendance, and the child's parent or guardian provides a certificate of immunization on or before the 5th school day.

(ii) If the child needs additional doses of a multiple dose vaccine series to meet the requirements of § 23.83, the child receives the next scheduled dose during the 5 school days referenced in subparagraph (i), and the child's parent or guardian provides a medical certificate on or before the 5th school day scheduling the additional required doses.

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

(2) *Single dose vaccines.* If a child has not received a vaccine for which only a single dose is required on the child's first day of attendance for that school year, the child may not be admitted to school.

(3) *Completion of required immunizations.* The medical certificate shall be reviewed at least every 30 days by the school administrator or the school administrator's designee. Subsequent immunizations shall be entered on the certificate of immunization or entered in the school's computer database. Immunization requirements described in § 23.83 shall be completed in accordance with the requirements of the medical certificate. If, upon review, the requirements of the medical certificate are not met, the school administrator or the school administrator's designee may exclude the child from school.

(4) *Medical certificate.* A school shall maintain the medical certificate until the official school immunization record is completed.

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

(g) *Applicability.* This section does not apply to a child if one of the following occurs:

(1) The child has not been immunized or is unable to provide immunization records due to being homeless. A school shall comply with Federal laws pertaining to the educational rights of homeless children, including the McKinney-Vento Homeless Education Assistance Improvements Act of 2001 (42 U.S.C.A. §§ 11431—11435).

(2) The child, when moving or transferring into a school in this Commonwealth, is unable to provide immunization records immediately upon enrollment into the school. The child's parent or guardian shall have 30 days to provide immunization records to the school to show proof of immunization as set forth in § 23.83, a medical certificate as set forth in subsection (e) or to satisfy the requirements for an exemption as set forth in § 23.84. A child who is unable to provide the necessary records, medical certificate or exemption may be excluded at the end of the 30-day period and in subsequent school years until the requirements of this subchapter are met.

(3) The child has not been immunized or is unable to provide immunization records on the first day of attendance for the school year due to being in foster care. A school shall comply with Federal laws pertaining to the educational rights of children in foster care, including the Fostering Connections to Success and Increasing Adoptions Act of 2008 (42 U.S.C.A. §§ 670—679c). The child's foster parent shall have 30 days to provide immunization records to the school to show proof of immunization as set forth in § 23.83, a medical certificate as set forth in subsection (e) or to satisfy the requirements for an exemption as set forth in § 23.84. A child who is unable to provide the necessary records, medical certificate or exemption may be excluded at the end of the 30-day period and in subsequent school years until the requirements of this subchapter are met.

(4) The child obtains an exemption under § 23.84.

(h) *Temporary waiver.* The Secretary may issue a temporary waiver of the immunization requirements in § 23.83. The details of the temporary waiver will be set out in a notice published in the *Pennsylvania Bulletin*. A temporary waiver may be issued under either of the following circumstances:

(1) The Centers for Disease Control and Prevention, United States Department of Health and Human Services, recognizes a Nationwide shortage of supply for a particular vaccine.

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

#### **§23.86. School reporting.**

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

(b) In the event a public, private, parochial or nonpublic school is unable to complete its report electronically, it shall report to the Department by December 15 of each year using a form provided by the Department.

(c) The school administrator or the school administrator's designee shall forward the reports to the Department as indicated on the reporting form provided by the Department.

(d) Duplicate reports shall be submitted to the county health department if the school is located in a county with a full-time health department.

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

(f) Content of the reports must include all of the following information:

(1) The month, day and year of the report.

(2) The number of students attending school in each grade-level, or in an ungraded school, in each age group, as indicated on the reporting form.

(3) The number of doses of each individual antigen given in each grade-level, or in an ungraded school, in each age group, as indicated on the reporting form.

(4) The number of students attending school who were classed as medical exemptions in each grade-level, or in an ungraded school, in each age group, as indicated on the reporting form.

(5) The number of students attending school who were classed as religious exemptions in each grade level, or in an ungraded school, in each age group, as indicated on the reporting form.

(6) The number of students provisionally admitted in each grade level or, in an ungraded school, in any age group, as indicated on the reporting form.

(7) The number of students in kindergarten, 7th grade or in an ungraded school, 12 years of age only, who were denied admission because of the student's inability to provide documentation of the required vaccine doses.

(8) Other information as required by the Department.

[Pa.B. Doc. No. 17-377. Filed for public inspection March 3, 2017, 9:00 a.m.]

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