A public hearing for this proposed rule was held on November 20, 2015 in Burlington, Vermont. The public comment period ended on December 2, 2015. The following is a summary of comments received from the public and the Department’s response to each comment. Comments of a similar or consistent nature have been consolidated and responded to accordingly.

1. **Comment:** The Vermont Immunization Advisory Council (VIAC) does not contain persons with diverse views of vaccines.

   **Response:** This comment is outside the scope of this rulemaking and the authority granted by statute. Act 37 (2015) sets forth the membership of the VIAC.

2. **Comment:** The VIAC should be charged with testing samples of vaccines sold in Vermont.

   **Response:** This comment is outside the scope of this rulemaking and the authority granted by statute. Act 37 sets forth the duties of VIAC. Moreover, the authority to require testing of vaccinations is exclusively held by the United States Food and Drug Administration.

3. **Comment:** Vaccines should require the signing of informed consent forms with information concerning the hazards of vaccines. This information should include the vaccine package inserts.

   **Response:** Vaccinations are an established medical practice and therefore do not require informed consent. Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention that explain both the benefits and risks of a vaccine to recipients. VISs must be provided to patients or parents prior to the administration of vaccines. Individual providers may also choose to use informed consent forms if they wish.

4. **Comment:** The proposed rules leave out a few items noted in Act 37 including the “Quality improvement measures” for schools, matters related to the vaccine registry, related requirement for the reporting to VAERS, and the report to the legislature concerning a recommendation as to whether school personnel should be required to be vaccinated.

   **Response:** The provisions of Act 37 (2015) speak for themselves and are not required to be in rulemaking or are not suitable for rulemaking.

5. **Comment:** The rule should contain penalties for doctors and agency officials who fail to provide adequate risk information.

   **Response:** This comment is outside the scope of this rulemaking. Without specific statutory authority, rules cannot impose penalties.
6. **Comment:** The VDH Parent Education Information should to be updated to incorporate changes pursuant to Act 37.

**Response:** This comment is outside the scope of this rulemaking. As the Parent Education Information is three years old, it is currently being reviewed and revised by the Department of Health.

7. **Comment:** Section 8.0 automatically adds vaccines to the schedule found in Section 7.0 of the rule. It should include a public process.

**Response:** Section 8.0 does not automatically add vaccine to the schedule found in Section 7.0. For any vaccine to be added or removed from the schedule, the rule will have to undertake rulemaking pursuant to 3 V.S.A. ch 25 with its attendant public process.

8. **Comment:** Section 4.7 still requires that a “health care practitioner” be authorized by law to practice “in this state” and should be changed to reflect Act 37 amended to remove the in-state qualification.

**Response:** Accepted.

9. **Comment:** Section 7.3.1 says “all immunizations listed in 7.1.”, but it should read 7.2.

**Response:** Accepted.

10. **Comment:** The rule title and other references to “immunization” should be changed to “vaccination.”

**Response:** According to the United States Department of Health Human Services, “An immunization is the process by which a person or animal becomes protected from a disease. Vaccines cause immunization, and there are also some diseases that cause immunization after an individual recovers from the disease.” “Immunization Rule,” is, therefore, the accurate title. See http://www.vaccines.gov/basics/

11. **Comment:** The rule should reflect that some vaccines should have phase-outs for vaccinations for diseases that no longer occur in this country, such as diphtheria.

**Response:** Diphtheria is part of the DTaP and Tdap vaccines which are used to prevent diphtheria, tetanus and pertussis and is still recommended by the Centers for Disease Control’s Advisory Committee on Immunization Practices (ACIP). If and when ACIP recommends removal of certain vaccines from the schedule, those removals will be reflected in this rule.

12. **Comment:** Section 5.1 that allows for provisional admittance of up to six months should be extended to allow for a longer “catch up” period, for up to five years.

**Response:** This comment is outside the scope of this rulemaking. The six-month provisional admittance period is contained in 18 V.S.A. § 1122.
13. **Comment:** Section 13.2 requires that each child care facility maintain a roster of students provisionally admitted. How will this information be protected?

**Response:** The childcare facility has the obligation to maintain confidentiality pursuant to the Vermont Department for Children and Families, Child Development Division regulations. In addition, 18 V.S.A. § 1121(c) provides that child care facilities may only share immunization rates to the extent permitted by the Health Insurance Portability and Accountability Act (HIPAA).

14. **Comment:** There is no penalty for disclosure of children’s personal health information.

**Response:** This comment is outside the scope of this rulemaking. Any information held by the Department of Health is protected by HIPAA which provide penalties for noncompliance, based on the level of negligence, that range from $100 to $50,000 per violation (or per record). Information held by schools is protected by the Family Educational Rights and Privacy Act which provides penalties that include the loss of federal funding, fines of $1,000 and imprisonment for not more than six months. In addition, 18 V.S.A. § 1001 provides that any person who “Willfully or maliciously discloses the content of any confidential public health record without written authorization or other than as authorized by…shall be subject to a civil penalty of not less than $10,000.00 and not more than $25,000.00.”

15. **Comment:** Section 6.2.2 should include information stating that vaccines do not prevent transmission.

**Response:** This is a rule that sets forth legal requirements, it is not informational or educational in nature.

16. **Comment:** Section 7.1.4 and 7.1.5 are confusing. Because they reference a range rather than a specific number of vaccines.

**Response:** The number of doses is dependent on the age at which the child first received the vaccine. The provider should administer the number recommended by ACIP based on individual circumstances.

17. **Comment:** Who is going to pay for the Section 9.4, the titers?

**Response:** The insuring entity. This has not changed.

18. **Comment:** Section 9.7 allows for a waiver of the requirement of the Varicella vaccine if the student has contracted it previously and is therefore immune. There should be waiver for other diseases.

**Response:** Varicella (chickenpox) has a classic presentation, is highly contagious and until the last decade was highly prevalent in the U.S. Parents of children with varicella-like symptoms are often advised not to seek medical care to avoid further contagion. No other vaccine preventable disease meets these same criteria.

19. **Comment:** Is there any way to prevent parents from switching their children’s exemption from philosophical to religious? If the religious exemption is not tightened up, immunization rates will not change.
Response: This comment is outside the scope of this rulemaking. Act 37 did not provide any additional authority to define or narrow the scope of the religious exemption.

20. Comment: Would a play/pre-school class for child aged 3-5 use the criteria from child care facilities?

Response: Yes.


Response: No. The exemption may apply to one or more immunizations. It is clear from the exemption forms that each immunization must either be received or a legal exemption may be claimed.

22. Comment: Do these rules expect strict adherence to the schedule or does it allow for school nurses to work with families to bring a child into compliance?

Response: The schedule must be adhered to consistent with the rule and statute.

23. Comment: Because there are risks associated with vaccines, there should be a right to decline the risk.

Response: This comment is outside the scope of this rulemaking. State law sets forth the requirement to be vaccinated before enrolling in childcare or school.

24. Comment: Many comments were received that indicated an opposition to Act 37 and the removal of the philosophical exemption and request the exemption be reinstatement.

Response: This comment is outside the scope of this rulemaking.

25. Comment: Comments were received that indicated an opposition to mandatory vaccinations for admittance to child care and schools.

Response: This comment is outside the scope of this rulemaking.

26. Comment: Act 37 should not require people to report on other person’s suspected illness.

Response: This comment is outside the scope of this rulemaking. Act 37 does “not require people to report on other person’s suspected illness.” 18 V.S.A. § 1001 provides, among other things that “physician, health care provider, nurse practitioner, nurse, physician assistant, or school health official [who] has reason to believe that a person is sick or has died of a diagnosed or suspected disease, identified by the Department of Health as a reportable disease and dangerous to the public health…” [Emphasis added.] must report it to the Department of Health.

27. Comment: If parents need to homeschool their children or move out of state, that will have an economic impact.

Response: This comment is outside the scope of this rulemaking. The rule itself does not impose an economic impact.
28.  **Comment:** How “enroll” is defined will impact homeschooled children.

   **Response:** The definition of “enroll” has not been amended substantively; it will not impact any more students than it does under the present rule. Students enrolled in a school, as defined by statute and rule, including those who are home schooled or part-time, need to meet immunization requirements.

29.  **Comment:** Several comments were received that recommended various sections of Title 18 be amended with accompanying recommendations and/or requests for clarification.

   **Response:** This comment is outside the scope of this rulemaking.

30.  **Comment:** The enforcement of Act 37 will require monitoring student immunization schedules and compliance. “Since the intent of the law is to separate non immunization compliant individuals from populations clusters, staffing such a system will present challenges…”

   **Response:** This comment is outside the scope of this rulemaking. Enforcement of state law is a requirement today.

31.  **Comment:** How will this affect the financial stability of schools as those out of compliance will represent loss of tuition or funding?

   **Response:** This comment is outside the scope of this rulemaking. This rule does impose an economic impact on schools that is different from existing requirements.

32.  **Comment:** There is some question as to the legality of this rule as it applies to independent schools that do not take public funding.

   **Response:** This comment is outside the scope of this rulemaking. 18 V.S.A. § 1120 defines, “‘School’ to mean a public or independent prekindergarten, kindergarten, elementary, or secondary school, or any postsecondary school as defined in 16 V.S.A. § 176(b)…” In Vermont, as in most instances, state school vaccination laws expressly apply to both public school as well as private schools with identical immunization and exemption provisions.

33.  **Comment:** Legislators were told that doctors would not face retaliation for signing medical exemptions. Please specify in the new law how the doctor's license will be safeguarded in this case.

   **Response:** This comment is outside the scope of this rulemaking. Medical exemptions are held by schools and not collected centrally.

34.  **Comment:** This [vaccine schedule] is intensive. With no liability for those administering the shots, will childcare facilities and schools be held liable if a child has a bad reaction?

   **Response:** Questions concerning legal liability are outside the scope of this rulemaking.

35.  **Comment:** When will you add the three shots of HPV to this list as you already bought the doses?
Response: For any vaccine to be added or removed from the schedule, the Department will have to undertake rulemaking pursuant to 3 V.S.A. ch 25 with its attendant public process.

36. Comment: In Section 11.3 does not take into account child missing one dose of series - partially vaccinated are dropped from calculations. We have no idea which vaccinated children are actually immune.

Response: The percent of children fully immunized will reflect those who meet the CDC criteria based on age and individual circumstances.

37. Comment: In re access to “Childcare and school admins shall make records available for inspection by health dept.” This should be in an emergency only to protect the privacy of health records.

Response: This comment is outside the scope of this rulemaking. Health information collected or maintained by the Department is protected by HIPAA.

38. Comment: New addition: Section 4.7.2 “Natural health care practitioner” means a medical professional who is certified in herbalism, acupuncture, traditional Chinese medicine, or chiropractic.

Response: This comment is outside the scope of this rulemaking. The qualifications for providers are set forth under 18 V.S.A. § 1122.

39. Comment: Supports the creation of a new Vaccine Injury Association of Vermont or VIAV will be made up of parents and family members of vaccine-injured individuals. It will be publicized by the VVAC and funded by the DOH. VVAC’s duties would include, but not be limited to: creating a very high level of transparency around the safety and efficacy of vaccines, sting monthly samples of vaccines sold in Vermont and reporting the actual levels of neurotoxins, publicize the federal Vaccine Injuries Claim Program, development the evidence-based educational material provided by the Department and develop the published exemption forms.

Response: This comment is outside the scope of this rulemaking. Many of the duties described are set forth under statute to other entities or persons.

40. Comment: Delete 7.1, 7.1.1, 7.1.2, 7.1.3, 7.1.4, 7.1.5

Response: Act 37 (2015) requires that the vaccine schedule be listed by rule. This comment is contrary to that directive.

41. Comment: Remove the new meningococcal vaccine as a required for vaccine for residential students and make it recommended instead.

Response: The meningococcal vaccine was added in 2008 and is in the current schedule, found here:
42. **Comment**: Section 13.5 - Can a person refuse to sign for parental consent?

**Response**: Yes.

43. **Comment**: Health Care Practitioners should not be authorized to provide vaccines until they have completed a mandatory course teaching the adverse health effects of vaccines and recognize people adversely affected by vaccines. All vaccinations in Vermont should be delayed until this is implemented.

**Response**: This comment is outside the scope of this rulemaking. This rule does not govern the curriculum of medical schools or the requirements for Continuing Medical Education. The qualifications for providers are set forth under 18 V.S.A. § 1122.

44. **Comment**: What is the protocol for doctor to report injuries as a result of vaccination?

**Response**: This comment is outside the scope of this rulemaking. Information on required reporting to the Vaccine Adverse Event Reporting System (VAERS) can be found here: https://vaers.hhs.gov/data/index

45. **Comment**: Data and education in 6.2.2 should include information concerning Polio.

**Response**: The revised Parent Education materials will include information on each required vaccine.

46. **Comment**: Would there be any time that someone other than a “practitioner” would authorize an alternate schedule? This statement is used in both 5.1 and 5.3.

**Response**: 5.1 and 5.3 refer to provisional admittance of a child in the process of coming into compliance with the immunization schedule. 18 V.S.A. § 1122 (a)(1) requires a practitioner authorized to prescribe vaccines or a health clinic provide the documentation that confirms the person is in the process of compliance.

47. **Comment**: If this form is completed by a health care provider, wouldn’t it make sense for it to be captured in the IMR? There is a section for “contraindications” and then anyone with authorized access would have access to this information. School Nurses have “read-only” access and cannot change IMR records.

**Response**: This comment is outside the scope of this rulemaking. The statute does not require submission of the form to the registry and few practices make use of the contraindications field in Vermont’s Immunization Registry.

48. **Comment**: Showing documentation of the correct number of immunizations does not guarantee that the dates/time frames are correct for compliance. This section needs to reference the VAIC/ACIP compliance with reference to correct age, and minimum intervals. “OTHERWISE an argument could be
made that there are the correct number of shots and the student can be admitted even if the dates are incorrect.”

**Response**: Accepted. The Sections have been amended to reflect the need to comply with the CDC’s immunizations schedule which specifies vaccination intervals.

49. **Comment**: In Section 7.1, ADD: as defined in Section 9.0 Acceptable Records,

**Response**: Accepted. The term “acceptable records” was inserted in place of the word “documentation.”

50. **Comment**: The definition of “school” includes prekindergarten, kindergarten, elementary, secondary and post secondary. However, Prekindergarten is not SPECIFICALLY mentioned in any of the sections. This can cause confusion when verifying/documenting Pre-K in Schools vs. Daycare. And in some cases, students attend both Pre-K and daycare each week. How do nurses/parents know when “child” is used verses “student” if Pre-K appears to be somewhere in the middle?

**Response**: Accepted. Pre-kindergarten is now specified in the relevant sections.

51. **Comment**: This documentation should be included in the IMR under “Varicella History.” However, school nurses are not authorized to update the database.

**Response**: This comment is outside the scope of this rulemaking. The statute does not permit school nurses to report to the registry and practices are not required to use this field.

52. **Comment**: Does this section reference 5.0 Provisional Admittance? This also refers to the CDC recommendations which is covered in 8.0 but not defined in 4.13 VIAC or 7.0 Required Immunization Schedule. In fact, the ACIP schedule is not included anywhere in the document 8.0 only references adopting the schedule but does not define the actual schedule.

53. **Response**: The Advisory Committee on Immunization Practices (ACIP) makes an annual recommendation for an immunization schedule for children, adolescents and adults. When approved by the CDC Director it becomes the CDC recommended immunization schedule. The schedule itself is found in Section 7.0.

54. **Comment**: Section 7.2.5.1 ADD: and acceptance by the Vermont Immunization Advisory Council.

**Response**: Acceptance by VIAC is not necessary as that is not VIAC’s role.

55. **Comment**: Section 10. The current wording in this section indicates the child care/school is only required to verify immunizations for childcare, Kindergarten, 7th grade, post-secondary or enrolling in a new school. 11.0 requires the day care/school to reporting immunization data including provisional admittance, but it is silent on non-compliance and continued surveillance until remedied. 12.0 Exclusion requires continued surveillance until immunizations are compliant but this will only be for non-compliances for day-care, Kindergarten, 7th grade or post-secondary (according to 10.0). No other grades are required to be verified.
Response: The statute and rule provide for proper surveillance of compliance. Verification of immunizations is required at enrollment and annually thereafter for child care/pre-kindergarten, and upon entry into kindergarten, 7th grade, post-secondary school, and anytime a student enrolls for the first time in a school (see section 10). Provisional admittance may not exceed six months according to section 5 and the statute. Section 12.5 provides that childcare facilities and schools are responsible to exclude children who do not present proper evidence of immunizations unless they have filed a valid exemption or are provisionally admitted.

56. Comment: Sections 12.1 and 12.4. REPLACE WITH: shall be used

Response: Accepted. Change made in 12.1 and 12.4.