

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH

CHAPTER 535. IMMUNIZATION REGULATIONS

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking.

PROPOSED RULES:

Subchapter 1. Childhood Immunizations

310:535-1-2. Criteria for immunizations required [AMENDED]

310:535-1-3. Criteria for immunizations required for ~~day~~ child care [AMENDED]

SUMMARY:

The proposed changes modify the process for obtaining and submitting religious and personal vaccine exemptions for children enrolled in Oklahoma schools or child care centers. Religious and personal exemptions may be obtained after receiving an approved brief educational presentation provided by any local county health department regarding the risks associated with not being vaccinated and the benefits vaccinations provide to the individual and the community. To be approved, the completed exemption form along with evidence of completed instruction is required.

The school shall maintain a copy of the approved exemption in the child's records. The proposed rule requires that exemptions submitted prior to a student entering 7th grade expire at the end of the student's 6th grade year. A new exemption is required to be completed and submitted to the Oklahoma State Department of Health by the parent or guardian prior to enrolling the child in 7th grade.

The proposed rule creates an expiration date to exemptions before entry to seventh grade and a new exemption form should be submitted to the department. Religious and personal exemptions may be obtained after submitting a completed exemption form and attending a brief instructional presentation regarding the value of vaccination and the risks of not being vaccinated.

AUTHORITY:

Commissioner of Health, Title 63 O.S. § 1-104

COMMENT PERIOD:

February 3, 2020, through March 7, 2020. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through March 7, 2020, submit written comment to the contact person identified below, or may, at the hearing, ask to present written or oral views.

PUBLIC HEARING:

Pursuant to 75 O.S. § 303(A), the public hearing for the proposed rulemaking in this chapter shall be on March 5, 2020, at the Oklahoma State Department of Health, 1000 Northeast Tenth Street, Oklahoma City, OK 73117-1207, in room 1102 from 1 PM to 4 PM. The alternate date and time in the event of an office closure due to inclement weather is March 9, 2020, in room 1102, from 1 PM to 4 PM. Those wishing to present oral comments should be present at that time to register to speak. The hearing will close at the conclusion of those registering to speak. Interested persons may attend for the purpose of submitting data, views or concerns, orally or in writing, about the rule proposal described and summarized in this Notice.

REQUESTS FOR COMMENTS FROM BUSINESS ENTITIES:

Business entities affected by these proposed rules are requested to provide the agency with information, in dollar amounts if possible, on the increase in the level of direct costs such as fees, and indirect costs such as reporting, recordkeeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred by a particular entity due to compliance with the proposed rule. Business entities may submit this information in writing through March 7, 2020, to the contact person identified below.

COPIES OF PROPOSED RULES:

The proposed rules may be obtained for review from the contact person identified below or via the agency website at www.ok.gov/health.

RULE IMPACT STATEMENT:

Pursuant to 75 O.S., § 303(D), a rule impact statement is available through the contact person identified below or via the agency website at www.ok.gov/health.

CONTACT PERSONS:

Kim Bailey, General Counsel, Oklahoma State Department of Health, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207; phone (405) 271-6017, e-mail KimB@health.ok.gov or Audrey C. Talley, Rule Liaison, Oklahoma State Department of Health, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207, phone (405) 271-9444 ext.56535, e-mail AudreyT@health.ok.gov.

INITIAL RULE IMPACT STATEMENT

(This document may be revised based on comment received during the public comment period.)

**ITL 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
Chapter 535 Immunization Regulations**

1. DESCRIPTION:

This proposal changes the vaccine exemption process in 310:535-1-2, Criteria for immunizations required, and in 10:535-1-3, Criteria for immunizations required for day care. The proposed changes modify the process for obtaining and submitting religious and personal vaccine exemptions for children enrolled in Oklahoma schools or child care centers. For parents or guardians who wish to exempt their children from receiving required immunizations due to religious or personal reasons, there would be a new process in place requiring education within the local county health department prior to completing an exemption form. The completed exemption form, along with proof of completion of the educational requirement, would need to be submitted for the exemption to be approved by Oklahoma State Department of Health.

The proposed changes also establish a vaccine exemption expiration date, which correlates with the end of the child’s 6th grade school year. For parents who desire an exemption for 7th grade through 12th grade, a new vaccine exemption form will need to be completed prior to entry into 7th grade.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE

This proposal will only affect parents or guardians who choose to pursue a personal or religious exemption for their children from required immunizations in Oklahoma. There will be no fee or cost to the parents or guardians associated with obtaining the educational information or completing the exemption form.

3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:

Parents and guardians will benefit from receiving factual information on risks and benefits of immunization, based on research and science-based data, as well as the opportunity to discuss any question or concerns with a public health nurse. Another benefit to parents or guardians, who qualify and make a decision to proceed with vaccination after receiving this education, would be the opportunity for their child to be vaccinated while at the county health department.

The new exemption for children with previous exemption upon entering the 7th grade will allow the school another opportunity to review the student’s immunization record for school vaccine compliance. It also provides an additional opportunity for parent education regarding the importance of vaccines and vaccine safety.

4. ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:

There is no significant economic impact, cost of compliance or fees associated with the proposed changes to the exemption process.

5. COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY :

There is minimal cost to the department to implement the proposed changes to the exemption form. There would be costs associated with using public health nurses within the local county health departments to deliver the educational message, as well as in answering parent or guardian questions regarding immunization.

6. **IMPACT ON POLITICAL SUBDIVISIONS:**

There will be no impact on political subdivisions and it will not require their cooperation in implementing or enforcing the proposed amendment.

7. **ADVERSE EFFECT ON SMALL BUSINESS:**

There is no known adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act.

8. **EFFORTS TO MINIMIZE COSTS OF THE RULE**

There is no less costly approach currently identified to assure parents or guardians are adequately informed regarding the immunization exemption process.

9. **EFFECT ON PUBLIC HEALTH AND SAFETY**

Oklahoma allows personal and religious vaccine exemptions, therefore almost all exemptions are approved, even those personal or religious exemptions based on incorrect or no information. The proposed changes would allow Oklahoma State Department of Health an opportunity to provide factual information to parents prior to approval of an exemption, as well as answer questions or discuss concerns. The expectation is, that the provision of vaccine education would decrease the number of children in Oklahoma who have vaccine exemptions, and increase the number of school-age children who are fully vaccinated. With more children fully immunized, the incidence of preventable communicable diseases in children in Oklahoma will decrease. Herd immunity will protect those children who cannot be vaccinated for medical reasons. More children will be healthier and better prepared to achieve in school and better economic prospects in the long run

10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**

If the proposed rule is not adopted, the ease of application and approval of exemptions submitted will continue to allow a high number of vaccine exemptions to be granted and approved by Oklahoma State Department of Health. Many of the exemptions submitted to OSDH cite inaccurate information as the reason they are choosing exemption over immunization. Convenience is another reason to apply for exemptions. As a result, many children with immunization exemptions are placed at higher risk of acquiring preventable childhood communicable diseases and resultant morbidity ranging from mild illness and days lost from school to more serious complications, hospitalization or even death. By replacing this misinformation with facts based on research and data, there is an expectation that parents will be better equipped to make an informed decision regarding the choice of vaccination for their school-aged child.

11. **PREPARATION AND MODIFICATION DATES:**

This rule impact statement was prepared on Monday, November 18, 2019.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 535. IMMUNIZATION REGULATIONS**

SUBCHAPTER 1. CHILDHOOD IMMUNIZATIONS

310:535-1-2. Criteria for immunizations required

(a) Each child shall present certification that he or she has received or is receiving the immunizations as specified below before he or she is admitted to any public, private, or parochial school.

(b) Certification shall include the following:

(1) Diphtheria, Tetanus and Pertussis (DTP/DTaP) vaccine in five doses unless the fourth dose is received on or after the fourth birthday in which case only four doses are required. If the doses are not completed by the seventh birthday, the series must be completed with Adult Td vaccine and/or Tdap vaccine based on the individual's age at the time the first dose was received and age at the time the series is completed and beginning with the fall 2011-12 school year one dose of Tdap vaccine for students entering the seventh grade. Each year following the 2011-12 school year, the Tdap requirement shall be extended one grade level so that in the 2016-17 school year and all subsequent school years, students in grades seven through twelve shall be required to have received one dose of Tdap vaccine.

(2) Poliomyelitis vaccine in four doses unless the last dose is on or after the fourth birthday in which case only three doses are required. If the doses are not started or completed by the eighteenth birthday, no additional doses are required.

(3) Measles, Mumps and Rubella (MMR) vaccine with the first dose on or after the first birthday and the second dose at least twenty-eight days thereafter for children in grades kindergarten through eighth grade in the school year beginning in 1998. In the school year beginning in 1999, this requirement shall apply to the children through the ninth grade. Each year thereafter the requirement shall be extended one grade level so that in the school year beginning in 2002, children in all grades shall be required to have the second dose of vaccine.

(4) Hepatitis B vaccine in three doses for students of any age or two doses for students eleven through fifteen years of age who complete the alternative dosage schedule providing that the alternative schedule is fully documented. Such documentation must include the name of the vaccine and the dosage received for each dose of that vaccine:

(A) before entering seventh and eighth grades in 1998. In the school year beginning in 1999, this requirement shall apply to the children entering the seventh through ninth grades. Each year thereafter the requirement shall be extended one grade level so that in the school year beginning in 2002, children in grades seven through twelve shall be required to have the three doses of the vaccine.

(B) before entering kindergarten in 1998. In the school year beginning in 1999, this requirement shall apply to the children entering kindergarten and first grade. Each year thereafter the requirement shall be extended one grade level so that in the school year beginning in 2004, all children entering school shall be required to have the three doses of the vaccine.

(5) Hepatitis A vaccine in two doses with the first dose on or after the first birthday and the second dose six to eighteen calendar months later:

(A) before entering kindergarten in 1998. In the school year beginning in 1999, this requirement shall apply to the children entering kindergarten and first grade. Each year thereafter the requirement shall be extended one grade level so that in the school year beginning in 2004, all children entering school shall be required to have the two doses of the vaccine.

(B) before entering grade seven in 1998. In the school year beginning in 1999, this requirement shall apply to the children entering the seventh and eighth grade. Each year thereafter the requirement shall be extended one grade level so that in the school year beginning in 2003, children in grades seven through twelve shall be required to have the two doses of the vaccine.

- (6) Varicella (chickenpox) vaccine in one dose on or after the first birthday: before entering kindergarten in 1998. In lieu of vaccination, a parent's statement of a history of the disease chickenpox will be accepted. In the school year beginning in 1999, this requirement shall apply to the children entering kindergarten and first grade. Each year thereafter the requirement shall be extended one grade level so that in the school year beginning in 2010, all children entering school shall be required to have the vaccine or a parent's statement of a history of the disease chickenpox.
- (c) The minimum intervals between doses and minimum ages for doses shall be as follows:
- (1) DTP/DTaP:
 - (A) First and second dose - 4 weeks
 - (B) Second and third dose - 4 weeks
 - (C) Third and fourth dose - 4 months
 - (D) Fourth and fifth dose - 6 months
 - (E) For all fifth doses given after January 1, 2003 the minimum age for the fifth dose is 4 years of age
 - (2) Polio:
 - (A) First and second dose - 4 weeks
 - (B) Second and third dose - 4 weeks
 - (C) Third and fourth dose - 4 weeks
 - (3) MMR: First and second dose - 4 weeks
 - (4) Hepatitis B 3-dose series:
 - (A) First and second dose - 1 month (4 weeks)
 - (B) Second and third dose - 2 months (8 weeks), and the third dose at least 4 months (16 weeks) after first dose, and the third dose not before 24 weeks of age
 - (5) Hepatitis B 2-dose series: First and second dose - 4 months
 - (6) Hepatitis A: First and second dose -- 6 months and for all doses given on or after January 1, 2003, 6 months will be defined as 6 calendar months
 - (7) Four day grace period: Vaccine doses administered 4 days or less before the minimum intervals or ages listed in the preceding sections will be counted as valid.
- (d) A child, through his parent or guardian, may apply for an exemption from this requirement by submitting a form to the school Department. The school shall maintain a copy of the approved application in the child's records ~~and send a copy to the Department for approval.~~ All exemptions submitted prior to a student entering 7th grade shall expire at the end of the student's 6th grade year. A new exemption is required to be completed and submitted to the Oklahoma State Department of Health by the parent or guardian prior to enrolling the child in 7th grade.
- (1) A request for exemption for medical reasons shall contain a certificate signed by a physician stating that the physical condition of the child is such that the immunization would endanger the life or health of the child and that the child should be exempt for immunization.
 - (2) ~~A request for exemption for religious or other personal reasons shall contain a signed written statement from the parent or guardian stating a summary of the objections. Lost or unobtainable immunization records are not a ground for personal exemption. Religious and personal exemptions may be obtained after receiving an approved brief instructional presentation provided by any local county health department regarding the risks associated with not being vaccinated and the benefits vaccinations provide to the individual and the community. To be approved, the completed exemption form along with evidence of completed instruction is required.~~
- (e) A child participating in a pre-kindergarten school program shall have received or be in the process of receiving the appropriate immunization for the listed diseases based on the child's age.
- (f) The Department may grant exemptions or substitutions in the immunization schedule based on a medical history of a physical condition such that the immunization would endanger the life or health of the child or a medical history stating the child is likely to be immune as a result of having had a vaccine-preventable disease if the following are met:
- (1) A history of having had diphtheria and/or tetanus is not acceptable as proof of immunity since infection with diphtheria or tetanus may not render an individual immune to either of these diseases,

- (2) A history of having had polio, pertussis, rubella, mumps, hepatitis B, or hepatitis A must be supported by laboratory evidence to be acceptable as proof of immunity to these diseases,
 - (3) A history of having had measles must be accompanied by a statement from a physician, public health authority, or laboratory evidence to be acceptable as proof of immunity to measles,
 - (4) A parental history of having had varicella is acceptable evidence of immunity to varicella.
- (g) Haemophilus influenzae type B (Hib) vaccine is not a requirement for children attending pre-kindergarten, kindergarten, or school.
- (h) In some circumstances, the United States Food and Drug Administration may approve the use of an alternative dosage schedule for an existing vaccine. These alternative schedules may be used to meet the requirements only when the alternative schedule is fully documented. Such documentation must include the name of the vaccine and dosage received for each dose of that vaccine.

310:535-1-3. Criteria for immunizations required for ~~day~~ child care

- (a) Each child two months of age or older shall present certification that he or she has received or is receiving the immunizations as specified below before he or she is admitted to, and while enrolled in, a ~~day~~ child care center or ~~day~~ child care home.
- (b) Certification shall include the following:
- (1) 5 DTaP/DTP doses at 2, 4, 6, and 12 to 18 months and 4 to 6 years or beginning at 6 weeks of age with minimum intervals of 4 weeks between doses 1 and 2 and doses 2 and 3 and 4 months between doses 3 and 4 and 6 months between doses 4 and 5, with all fifth doses given on or after January 1, 2003 given on or after the fourth birthday; The fifth DTaP/DTP is not required if the fourth DTaP/DTP is administered on or after the fourth birthday;
 - (2) 4 Polio doses at 2, 4 and 6 to 18 months and 4 to 6 years or beginning at 6 weeks of age with minimum intervals of 4 weeks between all doses; The fourth Polio is not required if the third dose is given on or after the fourth birthday;
 - (3) 1 to 4 Haemophilus influenzae type B (Hib) doses at 2, 4, 6, and 12 to 15 months of age or older depending upon age at first Hib immunization and type of vaccine used or beginning at 6 weeks of age with minimum intervals of 4 weeks between doses 1, 2, and 3, if a third dose is part of the primary series, and the booster dose no earlier than 12 months of age and at least 8 weeks after the previous dose;
 - (4) 2 Measles, Mumps, Rubella doses with the first dose on or after the first birthday and the second dose at 4 to 6 years or at anytime after the first dose provided at least 4 weeks have elapsed since the receipt of the first dose;
 - (5) 1 Varicella dose on or after the first birthday;
 - (6) 2 Hepatitis A doses with the first dose on or after the first birthday and the second dose six to eighteen months later and for all doses given on or after January 1, 2003, 6 months will be defined as 6 calendar months;
 - (7) 3 Hepatitis B doses with minimum intervals as follows: 1 month (4 weeks) between doses 1 and 2, two months (8 weeks) between doses 2 and 3, four months (16 weeks) between doses 1 and 3, and dose 3 no earlier than 24 weeks of age;
 - (8) 1 to 4 doses of pneumococcal conjugate vaccine (PCV) for children 2 months through 59 months of age at 2, 4, 6, and 12 to 15 months of age or older depending upon age at first PCV immunization with minimum intervals between doses as follows: 4 weeks between doses 1, 2, and 3 and 8 weeks between doses 3 and 4 or any dose given as the final dose at age >12 months.
 - (9) Vaccine doses administered 4 days or less before the minimum intervals or ages listed in the preceding sections will be counted as valid.
- (c) In the event that the parent, guardian, or responsible adult presenting a child for admission to a child care facility certifies in writing that a family emergency exists, the immunization requirements shall be waived for a period not to exceed thirty days. No such waiver shall be knowingly permitted more than once for any child.
- (d) Immunization records for children attending school-age programs are not required if those records are maintained by the school and are readily available.

(e) A child, through his parent or guardian, may apply for an exemption from this requirement by submitting a form to ~~the day care center or day care home~~ Department. The ~~day child~~ care center or day child care home shall maintain a copy of the approved application in the child's records ~~and send a copy to the Department for approval.~~

(1) A request for exemption for medical reasons shall contain a certificate signed by a physician stating that the physical condition of the child is such that the immunization would endanger the life or health of the child and that the child should be exempt for immunization.

(2) ~~A request for exemption for religious or other personal reasons shall contain a signed written statement from the parent or guardian stating a summary of the objections. Lost or unobtainable immunization records are not a ground for personal exemption~~ Religious and personal exemptions may be obtained after receiving an approved brief instructional presentation provided by any local county health department regarding the risks associated with not being vaccinated and the benefits vaccinations provide to the individual and the community. To be approved, the completed exemption form along with evidence of completed instruction is required.

(f) The Department may grant exemptions or substitutions in the immunization schedule based on a medical history of a physical condition such that the immunization would endanger the life or health of the child or a medical history stating the child is likely to be immune as a result of having had a vaccine-preventable disease if the following are met:

(1) A history of having had diphtheria and/or tetanus is not acceptable as proof of immunity since infection with diphtheria or tetanus may not render an individual immune to either of these diseases;

(2) A history of having had polio, pertussis, rubella, mumps, or hepatitis A must be supported by laboratory evidence to be acceptable as proof of immunity to these diseases;

(3) A history of having had measles must be accompanied by a statement from a physician, public health authority, or laboratory evidence to be acceptable as proof of immunity to measles;

(4) A parental history of having had varicella is acceptable evidence of immunity to varicella.

(5) A history of having had Hib before age two years is not acceptable as proof of immunity since infection with Hib prior to age two years may not render an individual immune.