## TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 535. IMMUNIZATIONS REGULATIONS

#### **RULEMAKING ACTION:**

Notice of proposed PERMANENT rulemaking.

### **PROPOSED RULES:**

Chapter 535. Immunizations Regulations [AMENDED]

### **SUMMARY:**

The portion of Title 310, Chapter 535 permanent rule (effective September 11, 2020) requiring an approved brief, instructional presentation prior to parents receiving childhood immunization exemptions is in conflict with Title 70 O.S. § 1210.192.2, which establishes an exemption from immunization requirements if a parent, guardian, or legal custodian of a child presents: "A written statement by the parent, guardian or legal custodian of the child objecting to immunization of the child; whereupon the child shall be exempt from the immunization laws of this state."

This amendment to the rule removes the new educational instruction requirement to remove the conflict between the rule and the statute.

#### **AUTHORITY:**

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

### **COMMENT PERIOD:**

December 15, 2020 through the close of the Department's normal business hours, 5 PM, on January 14, 2021. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through the close of the Department's normal business hours, 5 PM, on January 14, 2021, 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 January 14, 2021, via WebEx accessible from the site <a href="https://oklahoma.gov/health/organization/public-hearings.html">https://oklahoma.gov/health/organization/public-hearings.html</a>, from 9AM to noon. The meeting may adjourn earlier if all attendees who signed up to comment have completed giving their comments. The alternate date and time in the event of extreme inclement weather is January 18, 2021, via WebEx accessible from the site <a href="https://oklahoma.gov/health/organization/public-hearings.html">https://oklahoma.gov/health/organization/public-hearings.html</a>, from 9AM to noon. Those wishing to present oral comments should be registered to speak by 9:15 a.m. Directions for comment registration will be provided on the website. The hearing will close at the conclusion of comments from those registered to speak. Interested persons may attend for the purpose of orally submitting data, views, or concerns 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 the close of the Department's normal business hours, 5 PM, on January 14, 2021, 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 <a href="https://www.ok.gov/health.">www.ok.gov/health.</a>

### **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 PERSON:**

Audrey C. Talley, Agency Rule Liaison, Oklahoma State Department of Health, 123 Robert S. Kerr Avenue, Oklahoma City, OK 73102, phone (405) 426-8563, e-mail <a href="mailto:AudreyT@health.ok.gov">AudreyT@health.ok.gov</a>.

### INITIAL RULE IMPACT STATEMENT

## TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 535. IMMUNIZATIONS REGULATIONS

### 1. <u>DESCRIPTION:</u>

The portion of Title 310, Chapter 535 permanent rule (effective September 11, 2020) requiring an approved brief, instructional presentation prior to parents receiving childhood immunization exemptions is in conflict with Title 70 O.S. § 1210.192.2, which establishes an exemption from immunization requirements if a parent, guardian, or legal custodian of a child presents: "A written statement by the parent, guardian or legal custodian of the child objecting to immunization of the child; whereupon the child shall be exempt from the immunization laws of this state."

This amendment to the rule removes the new educational instruction requirement to remove the conflict between the rule and the statute.

### 2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

No impact is expected as it relates to current immunization practices.

# 3. <u>DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED</u> HEALTH OUTCOMES:

This change will not have an impact.

### 4. <u>ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:</u>

This change will not have an impact.

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

There are no costs or benefits associated with implementation.

### 6. IMPACT ON POLITICAL SUBDIVISIONS:

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

### 7. ADVERSE EFFECT ON SMALL BUSINESS:

There is no anticipated adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act as this emergency change will uphold the current status quo.

### 8. <u>EFFORTS TO MINIMIZE COSTS OF RULE:</u>

There are no less costly means currently identified.

### 9. <u>EFFECT ON PUBLIC HEALTH AND SAFETY:</u>

There should be no effect on public health and safety from existing practices as the status quo will be maintained.

# 10. <u>DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:</u>

No detrimental effects have been identified.

### 11. PREPARATION AND MODIFICATION DATES:

This rule impact statement was prepared on November 4, 2020.

### TITLE 310. OKLAHOMA STATE DEPARMENT 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 Department. The school shall maintain a copy of the approved application in the child's records. All exemptions submitted prior to a student entering 7<sup>th</sup> grade shall expire at the end of the student's 6<sup>th</sup> 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 7<sup>th</sup> 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 grounds 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 prekindergarten, 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 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 child care center or 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 Department. The child care center or child care home shall maintain a copy of the approved application in the child's records.
  - (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 grounds 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.