



To: Members of the State Board of Health

From: Lynn Trefren, MSN, RN, Immunization Branch Chief, Disease Control and Environmental Epidemiology Division (DCEED) *LT*

Through: Tony Cappello, PhD, DCEED Director **TC**

Date: June 1, 2018

Subject: **Rulemaking Hearing - Proposed Amendments to 6 CCR 1009-2 - The Infant Immunization Program and Immunization of Students Attending School**

Please find copies of the following documents: Statement of Basis and Purpose and Specific Statutory Authority, Regulatory Analysis, Stakeholder Comment, and Proposed Amendments to 6 CCR 1009-2.

The Colorado Department of Public Health and Environment has the legal authority, established in Colorado law, to protect students and the general population from vaccine preventable disease. Child care facilities, schools, and colleges/universities are bound by law to ensure students meet the vaccine requirements as established by the Board of Health. Colorado's vaccine requirements have contributed to higher vaccine coverage and lower levels of vaccine preventable disease.

The proposed amendments are technical clarifications and do not represent changes to current immunization practice. The proposed changes will streamline language when referring to the Advisory Committee on Immunization Practices immunization schedule, clarify the acceptable documentation for positive titer tests in lieu of immunization for certain school-required vaccines, clarify that online only K-12th grade schools are not required to report aggregate data to the Department, and remove language referring to repealed portions of statute. Additionally, the Department proposes a minor reorganization of the rule that reverses the order of section IX (A) and IX (B).

The Department has contacted a wide variety of stakeholders to solicit input on these proposed amendments. To date, all informal feedback received by the Department that is relevant to the proposed changes has been supportive. **To the extent possible, the Department has responded to stakeholders who asked clarifying questions or referred them to the Frequently Asked Questions document on our website.** In total, the proposed amendments align our rules with statute, continue to bring clarity to the rules and minimize potential confusion among end-users of the rules.

Because the edits are very minor in some instances, yellow highlight has been used to assist the reader in reviewing the proposed changes.

STATEMENT OF BASIS AND PURPOSE AND SPECIFIC STATUTORY AUTHORITY
for Amendments to 6 CCR 1009-2
The Infant Immunization Program and Immunization of Students Attending School

Basis and Purpose.

Colorado requires all students to be immunized per the vaccine schedule established by Colorado Board of Health (BOH) rule 6 CCR 1009-2 upon school entry unless a medical or non-medical exemption is filed. The purpose of the immunization requirements for school entry is to protect students, staff, and the visiting public against vaccine-preventable diseases within schools.

The Department proposes technical changes to the rule that are intended to:

- Align our rule with statute;
- Continue to bring clarity to the rule;
- Minimize potential confusion among end-users of the rule; and
- Simplify the language of the existing rule.

In addition, the following noteworthy changes to the rule are proposed:

1. Per statute, vaccines required for school entry by the Board of Health are based on recommendations of the Advisory Committee on Immunization Practices. The Department proposes to simplify the language in section II (B) when indicating that, except where noted, school-required vaccines are to be administered according to the schedule established by the ACIP.
2. The Department proposes adding language to section II (E) and section IX (A)(1)(a) to clarify requirements when submitting documentation of a positive titer in lieu of immunization for certain school-required vaccines. The proposed language clarifies that laboratory confirmation of the positive titer must be submitted to the student's school in order for a student to be considered in compliance with minimum immunization requirements. This proposed change is responsive to stakeholder feedback indicating the rule was unclear about this issue and aligns with best practices from the Centers for Disease Control and Prevention (CDC).
3. The Department proposes adding language to section VII (B) to clarify that K-12th grade schools that are online only are not required to report aggregate immunization and exemption data to the Department. The Department believes that parents are less likely to seek and utilize immunization and exemption rates in their comparison of online only schools. Unless and until, the Department identifies an end-use for this aggregate data, the proposed changes remove the requirement to report aggregate immunization and exemption data for online only K-12 schools.
4. The Department proposes updating the statutory references in section X (B) to align with statute.
5. The Department proposes a minor reorganization within section IX "Requirements for college and university students, colleges and universities" such that section IX (A) "Exemptions from immunization" becomes section IX (B). Thus, current section IX (B) "Minimum Immunization Requirements" becomes section IX (A). This proposed change is intended to bring clarity to the rule; the Department has determined this rule should list the vaccine requirements before describing how to exempt from these requirements. This proposed change is a non-substantive change; neither the vaccine requirements nor exemption procedures are changing.

Specific Statutory Authority.

Statutes that require or authorize rulemaking:

§ 25-4-903, C.R.S.

§ 25-4-904, C.R.S.

Is this rulemaking due to a change in state statute?

Yes, the bill number is _____. Rules are authorized required.

No

Does this rulemaking incorporate materials by reference?

Yes URL or Sent to State Publications Library

No

Does this rulemaking create or modify fines or fees?

Yes

No

Does the proposed rule create (or increase) a state mandate on local government?

No. This rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed. Though the rule does not contain a state mandate, the rule may apply to a local government if the local government has opted to perform an activity, or local government may be engaged as a stakeholder because the rule is important to other local government activities.

No. This rulemaking reduces or eliminates a state mandate on local government.

Yes. This rule includes a new state mandate or increases the level of service required to comply with an existing state mandate, and local government will not be reimbursed for the costs associated with the new mandate or increase in service.

The state mandate is categorized as:

Necessitated by federal law, state law, or a court order

Caused by the State's participation in an optional federal program

Imposed by the sole discretion of a Department

Other: _____

Has an elected official or other representatives of local governments disagreed with this categorization of the mandate? Yes No

If yes, please explain why there is disagreement in the categorization.

Please elaborate as to why a rule that contains a state mandate on local government is necessary.

REGULATORY ANALYSIS
for Amendments to 6 CCR 1009-2
The Infant Immunization Program and Immunization of Students Attending School

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

- A. Identify each group of individuals/entities that rely on the rule to maintain their own businesses, agencies or operation, and the size of the group:

Approximately 2150 public and private schools, approximately 2100 licensed child cares, thousands of healthcare providers throughout the state, and 53 county, district or municipal public health agencies (LPHAs).

- B. Identify each group of individuals/entities interested in the outcomes the rule and those identified in #1.A achieve, and, if applicable, the size of the group:

LPHAs, advocacy organizations such as the Colorado Children’s Immunization Coalition, professional organizations such as the Colorado Chapter of the American Academy of Pediatrics or Colorado Academy of Family Physicians, federal agencies such as the Centers for Disease Control and Prevention, students and, if applicable, their parents/guardians who are interested in submitting documentation of a positive titer in lieu of immunization, and health care providers.

Though some individuals and entities disagree with immunization as a public health practice, this rulemaking is technical in nature. No changes are proposed to the list of required immunizations, nor to medical and non-medical exemptions.

- C. Identify each group of individuals/entities that benefit from, may be harmed by or at-risk because of the rule, and, if applicable, the size of the group:

Students enrolled in Colorado schools and, if under 18 years of age, their parents/guardians, school staff, child care staff and the public at large. While no individual or entity is harmed by the technical changes proposed, the Department recognizes that some individuals disagree with the Department’s position that immunization advances public health.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

- A. For those that rely on the rule to maintain their own businesses, agencies or operations:

Describe the anticipated favorable and unfavorable non-economic outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

Favorable non-economic outcomes: The proposed changes to this rule will result in clarification for consistent interpretation by end-users of the rule, more consistent terminology and simplification of language; all of which the Department expects will result in improved customer experience.

Unfavorable non-economic outcomes: N/A

- B. For those that are affected by or interested in the outcomes the rule and those identified in #1.A achieve.

Describe the favorable or unfavorable outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

The outcome is to reduce delays and technical assistance requests by simplifying and clarifying the rule. These technical edits are a process improvement for customers and stakeholders.

Unfavorable non-economic outcomes: N/A

Any anticipated financial costs monitored by these individuals/entities? N/A

Any anticipated financial benefits monitored by these individuals/entities? N/A

- C. For those that benefit from, are harmed by or are at risk because of the rule, the services provided by individuals identified in #1.A, and if applicable, the stakeholders or partners identified in #1.B.

Describe the favorable or unfavorable outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

Schools, licensed child cares and students and parents/guardians who are interested in school immunization and exemption rates will benefit from greater clarity about which schools are required to report aggregate data. The proposed changes are expected to positively impact end-users of the rule by making it easier to implement, potentially preventing the occurrence of vaccine-preventable diseases and potential outbreaks.

Financial costs to these individuals/entities: N/A

Financial benefits to or cost avoidance for these individuals/entities: N/A

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

- A. Anticipated CDPHE personal services, operating costs or other expenditures:

There is no anticipated cost associated with the proposed amendments to the rule. There is no anticipated effect on state revenues.

- B. Anticipated personal services, operating costs or other expenditures by another state agency: N/A

Anticipated Revenues for another state agency: N/A

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Check mark all that apply:

- Inaction is not an option because the statute requires rules be promulgated.
- The proposed revisions are necessary to comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
- The proposed revisions appropriately maintain alignment with other state or national standards.
- The proposed revisions implement a Regulatory Efficiency Review (rule review) result, or improve public and environmental health practice.
- The proposed revisions implement stakeholder feedback.
- The proposed revisions advance the following CDPHE Strategic Plan priorities:

Goal 1, Implement public health and environmental priorities
Goal 2, Increase Efficiency, Effectiveness and Elegance
Goal 3, Improve Employee Engagement
Goal 4, Promote health equity and environmental justice
Goal 5, Prepare and respond to emerging issues, and
Comply with statutory mandates and funding obligations

Strategies to support these goals:

- Substance Abuse (Goal 1)
 - Mental Health (Goal 1, 2, 3 and 4)
 - Obesity (Goal 1)
 - Immunization (Goal 1)
 - Air Quality (Goal 1)
 - Water Quality (Goal 1)
 - Data collection and dissemination (Goal 1, 2, 3, 4 and 5)
 - Implements quality improvement or a quality improvement project (Goal 1, 2, 3 and 5)
 - Employee Engagement (career growth, recognition, worksite wellness) (Goal 1, 2 and 3)
 - Incorporate health equity and environmental justice into decision-making (Goal 1, 3 and 4)
 - Establish infrastructure to detect, prepare and respond to emerging issues and respond to emerging issues (Goal 1, 2, 3, 4, and 5)
- Other favorable and unfavorable consequences of inaction: NA

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. For this rule, both apply. As there is no anticipated cost of compliance with the proposed amendments to the rule, there is no less costly method to achieving the purpose of the rule. Additionally, the Board of Health is required by section 25-4-904, C.R.S. to “establish rules and regulations for administering this part 9.” Furthermore, the proposed amendments should strengthen the department’s partnership with community stakeholders in schools, childcares and colleges and universities as the proposed amendments clarify or simplify existing requirements, or align requirements with statute.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

The only alternative considered was to leave the rule as adopted. This was rejected because stakeholders requested clarity about acceptable documentation for positive titer tests, and which schools are required to submit aggregate data to the Department.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

The ACIP develops recommendations on how to use vaccines to prevent disease in the United States. The recommendations include the age(s) when the vaccines should be given, the number of doses needed, the amount of time between doses, considerations for persons with high risk conditions, and precautions and contraindications. Professional organizations that work with the ACIP to develop the annual childhood and adult schedules include the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), and the American College of Physicians (ACP).¹

Per section 25-4-902, C.R.S., the Board of Health is authorized to require vaccines for school entry that are based upon the ACIP recommended immunization schedule. State and local vaccination requirements for daycare and school entry are important tools for maintaining high vaccination coverage rates, and in turn, lower rates of vaccine-preventable diseases (VPDs).² The Community Preventive Services Task Force recommends vaccination requirements for child care, school, and college attendance based on strong evidence of effectiveness in increasing vaccination rates and in decreasing rates of VPD and associated morbidity and mortality. These findings are based on studies demonstrating effectiveness of vaccination requirements for attendance in a variety of settings, for an array of recommended vaccines, and in populations ranging in age from early childhood to late adolescence.³

Additionally, the Department has noticed a pattern of requests for technical assistance from stakeholders asking the Department to clarify the acceptable documentation for positive titer tests and which schools must submit aggregate immunization and exemption data.

¹CDC. ACIP Recommendations. <https://www.cdc.gov/vaccines/acip/recs/index.html>. Accessed: Mar, 20 2018.

²CDC. State Vaccination Requirements. <https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html>. Accessed Mar. 19, 2018

³Community Preventive Services Task Force. Increasing Appropriate Vaccination: Vaccination Requirements for Child Care, School, and College Attendance. https://www.thecommunityguide.org/sites/default/files/assets/Vaccination-Requirements-for-Attendance_1.pdf. Oct. 31, 2016

STAKEHOLDER ENGAGEMENT
for Amendments to 6 CCR 1009-2
The Infant Immunization Program and Immunization of Students Attending School

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:

The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

The Department developed the proposed rules and has sought feedback through an early stakeholder engagement process. These early efforts included email notification of upcoming rule changes, summarization of draft changes, and a dedicated online survey where staff could collect feedback from stakeholders. Feedback was solicited from approximately 25,000 individuals representing: members of the public, parents/students, LPHAs, Federally Qualified Health Centers, Community Health Clinics, Rural Health Centers, Hospitals, Colorado colleges and universities, Vaccines for Children providers, Colorado Immunization Information System (CIIS) users, Colorado Association of Physician Assistants, local immunization coalitions, school nurses, child care health consultants, Colorado schools and child care facilities, Children's Campaign, Colorado Academy of Family Physicians, the Colorado Medical Society, Colorado Chapter of the American Academy of Pediatrics, Colorado Children's Immunization Coalition, Colorado Coalition for Vaccine Choice, Colorado Student Health Services Consortium, National Vaccine Information Center, Colorado Parents for Vaccinated Communities, the Weston A. Price Foundation, Voices for Vaccines, the Colorado Department of Education and the Colorado Department of Human Services.

Stakeholder Group Notification

The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The Department's outreach to stakeholders has been ongoing with open communication among all stakeholder groups. Stakeholders were sent two separate email notifications about the rulemaking and proposed changes; February 28, 2018 and April 25, 2018. The April email notification contained both a redline version of the proposed changes and a link to an online form where interested individuals could submit informal feedback or questions directly to the Immunization Branch. To date, the Department has received informal feedback from 32 stakeholders out of approximately 25,000 stakeholders contacted. All of the feedback that addressed the proposed changes was supportive and indicated the proposed changes were

helpful, and/or added clarity. The Department received a few questions that are unrelated to the proposed changes. To the extent possible, the Department responded to stakeholders who asked clarifying questions or referred them to the Frequently Asked Questions document on our website.

The Department also received feedback that it did not incorporate into the rule because 1) it had been previously considered by the division, or 2) it was not directly related to the rulemaking. Again, here, to the extent possible, the Department has responded to this feedback with resources and follow-up information. Immunization serves an important public health purpose. Some stakeholders support school-entry requirements for immunization and/or want the Department to go further, and other stakeholders disagree with immunization as a public health practice, and want the Department to consider other options. The Department balances all stakeholder feedback with current data to improve public health across Colorado.

To date, there have been no major factual or policy issues with the proposed changes encountered. Comments that were outside the scope of this rulemaking were not incorporated.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking. Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.	Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.	Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.	Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
X	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.	Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
X	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.	Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.	Ensures a competent public and environmental health workforce or health care workforce.
	Other:	Other:

1 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
2 Disease Control and Environmental Epidemiology Division
3 THE INFANT IMMUNIZATION PROGRAM AND IMMUNIZATION OF STUDENTS
4 ATTENDING SCHOOL
5
6 6 CCR 1009-2

7
8
9 I. Definitions

- 10
11 A. Advisory Committee on Immunization Practices (ACIP) - a group of medical and public health
12 experts that develops recommendations on how to use vaccines to control diseases in the United
13 States. ACIP was established under Section 222 of the Public Health Service Act (42 U.S.C.
14 §217a).
15
16 B. Child - any student less than 18 years of age.
17
18 C. College or university student - any student who is enrolled for one or more classes at a college or
19 university and who is physically present at the institution. This includes students who are auditing
20 classes but does not include persons taking classes online or by correspondence only.
21
22 D. Delegated physician assistant – a licensed physician assistant authorized under Section 12-36-
23 106(5), C.R.S., to execute Certificates of Immunization, medical exemptions and/or supervise a
24 public health or school nurse as authorized by part 9 of article 4 of title 25, C.R.S.
25
26 E. DEPARTMENT (THE) - REFERS TO THE COLORADO DEPARTMENT OF PUBLIC HEALTH
27 AND ENVIRONMENT
28
29 EF. Dose - a measured quantity of an immunizing agent; quantity and frequency of administration
30 determined by recognized health authorities and the manufacturer of each agent.
31
32 FG. Emancipated student - any student who has reached age-18 YEARS OF AGE; a lawfully married
33 child of any age; a child 15 years of age or older who is managing his/her own financial affairs
34 and who is living separate and apart from his/her parent.
35
36 GH. Immunization tracking system - a comprehensive immunization tracking system established by
37 the Department of Public Health and Environment pursuant to sSection 25-4-2403(2), C.R.S., that
38 enables the gathering of epidemiological information from the sources delineated in sSection 25-
39 4-2403(2), C.R.S. and the investigation and control of communicable diseases. Individuals,
40 parents and legal guardians may provide information to the immunization tracking system;
41 however, pursuant to sSection 25-4-2403(7), C.R.S., they have the option to exclude their or their
42 student's immunization information from the immunization tracking system at any time.
43
44 HI. Indigent child - any child whose parent cannot afford to have the child immunized or if
45 emancipated, who cannot himself/herself afford immunization and who has not been exempted.
46
47 IJ. Infant - any child up to twenty four months of age or any child eligible for vaccination and
48 enrolled under the Colorado Medical Assistance Act, Articles 4, 5, and 6 of Title 25.5, C.R.S.
49
50 JK. In-process student - a student may be considered in-process if:
51

52 1. Within fourteen days after receiving direct personal notification that the eCertificate of
53 immunization is not up-to-date according to the requirements of the state Board of
54 Hhealth , the parent or emancipated student submits documentation that the next
55 required immunization has been given and a signed written plan for obtaining the
56 remaining required immunizations. The scheduling of immunizations in the written plan
57 shall follow medically recommended minimum intervals consistent with the ACIP. If the
58 student does not fulfill the plan, the student shall be suspended or expelled from school
59 for noncompliance as noted in PER sSection 25-4-907, C.R.S. If the next dose is not
60 medically indicated within fourteen days, then the medically approved minimum intervals
61 would apply.

62
63 2. With regard to eCollege or university students, as defined in Ssection I (C), the student
64 must present to the appropriate SCHOOL official of the school either (I) a signed written
65 authorization requesting local health officials to administer required immunizations or (II)
66 a plan for receipt of the required immunization or the next required immunization in a
67 series within either 30 days or the medically approved minimum interval. If this does not
68 occur, the college or university student will not be allowed to enroll, remain enrolled, or
69 audit for the current term or session. Such written authorizations and plans must be
70 signed by one parent or guardian or the emancipated student or the student eighteen 18
71 years of age or older.

72
73 **KL.** Parent - the person or persons with parental or decision-making responsibilities for a child.

74 **LM.** Practitioner - a duly licensed physician, advanced practice nurse, or other person who is
75 permitted and otherwise qualified to administer vaccines under the COLORADO laws of this
76 state.

77
78 **MN.** School - all child care facilities licensed by the Colorado Department of Human Services
79 including: child care centers, school-age child care center, preschools, day camps, resident
80 camps, day treatment centers, family child care homes, foster care homes, and head start
81 programs; public, private, or parochial kindergarten, elementary or secondary schools through
82 grade twelve, or a college or university. Schools do not include a public services short-term child
83 care facility as defined in sSection 26-6-102(30), C.R.S., a guest child care facility as defined in
84 sSection 26-6-102(16), C.R.S., a ski school as defined in sSection 26-6-103.5 (6), C.R.S., or
85 college or university classes which are: offered off-campus; offered to nontraditional adult
86 students as defined by the governing board of the institution; offered at colleges or universities
87 which do not have residence hall facilities, or; online only.

88
89 **NO.** School health authority - an individual working for or on behalf of the child care facility or school
90 who is knowledgeable about child care/school immunizations.

91
92 **OP.** School official - the school's chief executive officer or any person designated by him/her as
93 his/her representative.

94
95 **PQ.** Student - any person enrolled in a Colorado school as defined in sSection I (M), except:

96
97 1. a child who enrolls and attends a licensed child care center, as defined in sSection 26-6-
98 102(5), C.R.S., which is located at a ski area, for up to fifteen days or less in a fifteen-
99 consecutive-day period, no more than twice in a calendar year, with each fifteen-
100 consecutive-day period separated by at least sixty days, and

101
102 2. college and university students as defined in sSection I (C).

103

104 **QR.** Titer – a titer is a laboratory test that measures the presence and amount of antibodies in blood.
105 Antibody titers can be used to show that a person is immune to some diseases.
106

107 **II. Minimum Immunization Requirements**
108

109 A. To attend school, a student must have an age appropriate Certificate of Immunization. Meeting
110 the initial immunization requirements does not exempt a student from meeting subsequent age
111 requirements. This certificate must demonstrate immunization against the following diseases:

- 112 1. Hepatitis B
- 113 2. Pertussis
- 114 3. Tetanus
- 115 4. Diphtheria
- 116 5. Haemophilus Influenzae Type B (HIB)
- 117 6. Pneumococcal disease
- 118 7. Polio
- 119 8. Measles
- 120 9. Mumps
- 121 10. Rubella
- 122 11. Varicella

123 B. **EXCEPT AS REQUIRED IN SECTIONS II (C) AND II (D), WHEN HEALTHCARE PROVIDERS**
124 **ADMINISTER THE IMMUNIZATIONS IDENTIFIED IN SECTION II (A), THE IMMUNIZATIONS**
125 **WILL BE ADMINISTERED ACCORDING TO THE SCHEDULE ESTABLISHED BY THE ACIP AS**
126 **AUTHORIZED IN SECTION 25-4-902(1)(a), C.R.S. The minimum number of doses required by**
127 **age of the student is set forth in the 2017 ACIP Birth – 18 Years Recommended Immunization**
128 **Schedule or the 2017 ACIP Catch-Up Immunization Schedule.**

129 1. ~~The 2017 ACIP Birth-18 Years Recommended Immunization Schedule (Schedule) is~~
130 ~~incorporated by reference for only those vaccines required to prevent the diseases listed~~
131 ~~in Section II (A). Other immunizations included in the ACIP recommendations are not~~
132 ~~required. This schedule is posted on the Centers for Disease Control and Prevention~~
133 ~~website at: [https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-](https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf)~~
134 ~~[combined-schedule.pdf](https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf) or on the Colorado Department of Public Health and Environment~~
135 ~~website at: [\[www.coloradoimmunizations.com\]](http://www.coloradoimmunizations.com), and is available for public inspection~~
136 ~~during regular business hours at the Colorado Department of Public Health and~~
137 ~~Environment, 4300 Cherry Creek Drive South, Denver, Colorado 80246. Copies of the~~
138 ~~recommended schedules are available from the Colorado Department of Public Health~~
139 ~~and Environment for a reasonable charge that comports with the Department's record~~
140 ~~request practices. This rule does not include any later amendments or editions of the~~
141 ~~ACIP Schedule.~~

142 2. ~~In addition, the 2017 ACIP Catch-Up Immunization Schedule is incorporated by reference~~
143 ~~for those children not fully immunized and only for those vaccines required to prevent the~~
144 ~~diseases listed in Section III (A). Other immunizations included in the ACIP~~
145 ~~recommendations are not required. This recommended schedule is posted on the~~

Centers for Disease Control and Prevention website at:
<https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf> or on the Colorado Department of Public Health and Environment website at [www.coloradoimmunizations.com], and is available for public inspection during regular business hours at the Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, Colorado 80246. Copies of the recommended schedules are available from the Colorado Department of Public Health and Environment for a reasonable charge that comports with the department's record request practices. This rule does not include any later amendments or editions of the ACIP Catch-Up Schedule.

- C. Students between the ages of 4 through 6 years are required to receive their final doses of Diphtheria, Tetanus, and Pertussis (DTaP), Inactivated Polio Vaccine (IPV), Measles, Mumps, and Rubella (MMR) and Varicella prior to kindergarten entry.
- D. Students are required to RECEIVE have administered Tetanus, Diphtheria, Pertussis (Tdap) prior to entry into 6th grade ENTRY. One dose of Tdap is a requirement for 6th through 12th grades.
- E. LABORATORY CONFIRMATION OF Positive titers are an acceptable alternative to the following vaccines WHEN SUBMITTED TO THE STUDENT'S SCHOOL: DTaP, Hepatitis B, Varicella and MMR. For DTaP substitution, both the diphtheria and tetanus titers must be positive. For MMR substitution, titers for measles, mumps, and rubella must be positive. A titer is not an acceptable replacement for *Haemophilus Influenzae* type b, Pneumococcal, IPV, or Tdap vaccines.

III. Exemptions from Immunization

It is the responsibility of the parent(s) to have his or her student immunized unless the student is exempted. A student may be exempted from receiving the required immunizations in the following manner:

- A. Medical exemption - By submitting a medical exemption form with the statement of medical exemption signed by an advanced practice nurse, a delegated physician assistant, or physician licensed to practice medicine or osteopathic medicine in any state or territory of the United States indicating that the physical condition of the student is such that immunizations would endanger his/her life or health or is medically contraindicated due to other medical conditions. This form is to be submitted once, and must be maintained on file at each new school the student attends.
- B. Religious exemption - By submitting a nonmedical exemption form signed by the parent(s) or the emancipated student indicating that the parent(s) or emancipated student is an adherent to a religious belief whose teachings are opposed to immunizations.

Beginning July 1, 2016,

1. Prior to kindergarten entry, a nonmedical exemption form must be submitted at each interval in the ACIP Birth-18 years immunization schedule at which immunizations are due. The ACIP immunization schedule is incorporated in Section II (B). This documentation is required only for those vaccines required to prevent the diseases listed in Section II (A). Exemptions will expire at the time next immunizations are due according to the ACIP birth-18 years immunization schedule or when the student is enrolled to attend kindergarten.
2. From kindergarten through twelfth grade, a nonmedical exemption form must be submitted once per school year. Exemptions will expire annually on June 30th, the last official day of the school year.

- 215 C. Personal belief exemption - By submitting a nonmedical exemption form signed by the parent(s)
216 or the emancipated student indicating that the parent(s) or emancipated student has a personal
217 belief that is opposed to immunizations.

218
219 Beginning July 1, 2016,

- 220
221 1. Prior to kindergarten entry, a nonmedical exemption form must be submitted at each
222 interval in the ACIP Birth-18 years immunization schedule at which immunizations are
223 due. ~~The ACIP immunization schedule is incorporated in Section II (B).~~ This
224 documentation is required only for those vaccines required to prevent the diseases listed
225 in ~~Section II (A)~~. Exemptions will expire at the time next immunizations are due
226 according to the ACIP birth-18 years immunization schedule or when the student is
227 enrolled to attend kindergarten.
228
229 2. From kindergarten through twelfth grade, a nonmedical exemption form must be
230 submitted once per school year. Exemptions will expire annually on June 30th, the last
231 official day of the school year.

- 232
233 D. In the event of an outbreak of disease against which immunization is required, no exemption or
234 exception from immunization shall be recognized and exempted persons may be subject to
235 exclusion from school and quarantine.

- 236
237 E. All information distributed to ~~the~~ parent(s) by school districts regarding immunization ~~S~~ shall inform
238 them of their rights ~~Section III (A-D)~~.

239 IV. Examination and audit of official school immunization records

240
241
242 The Department of ~~Public Health and Environment~~'s representative shall have the right to audit and verify
243 records to determine compliance with the law. Discrepancies found through audits shall be corrected by
244 school officials, and any student not in full compliance shall be suspended or expelled from school
245 according to the following rules:

- 246
247 A. If the parent(s) or emancipated student was informed of the deficiencies in the student's official
248 school immunization records pursuant to ~~Section I (J) (1)~~ of the rules, the student shall be
249 suspended or expelled pursuant to Section 25-4-907, C.R.S.
250
251 B. If the parent(s) or emancipated student was not informed by a direct personal notification of the
252 immunizations required and alternatives for compliance with the law, the school shall notify the
253 parent(s) or emancipated student within 7 calendar days of the finding and the student shall: a)
254 provide proof of immunization within ~~14 fourteen~~ days, b) continue as an in-process student, c)
255 verify that the student is exempt, or d) the student shall be suspended or expelled pursuant to
256 ~~Section 25-4-907~~, C.R.S.

257 V. Denial of attendance

- 258
259
260 A. A student who is: not in-process, not appropriately vaccinated for his/her age, or not exempt shall
261 be denied attendance in accordance with the law.
262
263 B. If the student is attending a school ~~THAT which~~ is not subject to the School Attendance Law,
264 ~~Section 22-33-101 et seq.~~, C.R.S., ~~the~~ school officials shall take appropriate action to deny
265 attendance to the student in accordance with that school's procedures or contract with the
266 student. No indigent child shall be excluded, suspended, or expelled from school unless the
267 immunizations have been available and readily accessible to the indigent child at public expense.
268

269 VI. Official school immunization records

270

- 271 A. Official school immunization records shall include:
 272
 273 1. An official Certificate of Immunization or an Alternate Certificate of Immunization
 274 approved by the Department of Public Health and Environment, which shall include ^S one
 275 of the following forms of documentation with the dates and types of immunizations
 276 administered to a student:
 277
 278 a. A paper or electronic document that includes information transferred from the
 279 records of a licensed physician, registered nurse, a delegated physician
 280 assistant, or public health official, or
 281
 282 b. An electronic file or hard copy of an electronic file provided to the school directly
 283 from the immunization tracking system established pursuant to ^sSection 25-4-
 284 2403, C.R.S., or from a software program approved by the Department of Public
 285 Health and Environment, or
 286
 287 2. An official medical exemption form with the date and vaccines exempted from, or
 288
 289 3. A nonmedical exemption form with the date, type of exemption taken and the vaccines
 290 exempted from.
 291
 292 B. Any immunization record (original or copy) provided by a physician licensed to practice medicine
 293 or osteopathic medicine in any state or territory of the United States, registered nurse, ^a
 294 delegated physician assistant, or public health official may be accepted by the school official as
 295 proof of immunization. The information is to be verified by the school official and transferred to an
 296 official Certificate of Immunization.
 297
 298 C. Schools shall have on file an official school immunization record for every student enrolled. The
 299 official school immunization record will be kept apart from other school records. When a student
 300 withdraws, transfers, or is promoted to a new school, the school official shall return the Certificate
 301 of Immunization to the parent(s) or emancipated student upon request or transfer it with the
 302 student's school records to the new school. Upon a college or university student's request, the
 303 Certificate of Immunization shall be forwarded as specified by the student.
 304

305 **VII. Reporting of Statistical Information**
 306

- 307 A. On December 1, 2016, and each year thereafter, any child care center, preschool or head start
 308 program that is licensed by the Colorado Department of Human Services to provide care to ten or
 309 more children and are not exempt from reporting pursuant to ~~Paragraph B of this Section VII (B),~~
 310 and; public, private, or parochial schools with kindergarten, elementary or secondary schools
 311 through grade twelve, shall send aggregate immunization and exemption data, by antigen, to the
 312 Department of Public Health and Environment.
 313

314 Required data shall include:

- 315
 316 1. Total number of students and total number of kindergarten students enrolled in the
 317 school;
 318
 319 2. Total number of students and total number of kindergarten students who are up-to-date
 320 with immunizations as required in ^sSection II;
 321
 322 3. Total number of students and total number of kindergarten students who have a medical
 323 exemption for all immunizations as required in ^sSection II;
 324
 325 4. Total number of students and total number of kindergarten students who have a medical
 326 exemption for one or more but not all immunizations as required in ^sSection II;

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5. Total number of students and total number of kindergarten students who have a religious exemption for all immunizations as required in ~~ss~~Section II;
 6. Total number of students and total number of kindergarten students who have a religious exemption for one or more but not all immunizations as required in ~~ss~~Section II;
 7. Total number of students and total number of kindergarten students who have a personal belief exemption for all immunizations as required in ~~ss~~Section II;
 8. Total number of students and total number of kindergarten students who have a personal belief exemption for one or more but not all immunizations as required in ~~ss~~Section II;
 9. Total number of in-process students and total number of in-process kindergarten students;
 10. Total number of students and total number of kindergarten students not up-to-date for immunizations as required in ~~part III ss~~Section II, with no exemption on file, and not in-process; and
 11. Total number of students and total number of kindergarten students with no immunization records.

350 B. Schools not required to send aggregate immunization and exemption data to the Department of
351 ~~Public Health and Environment~~ include: **ONLINE ONLY K - 12TH GRADE SCHOOLS**, school-age
352 child care centers, family child care homes, drop-in centers, day treatment centers, foster care
353 homes, day camps, and resident camps.
354

355 **VIII. Notification of noncompliance**
356

- 357 A. Section 25-4-907, C.R.S. requires that if a student is suspended or expelled from school for
358 failure to comply with the immunization law, the school official shall notify the ~~state or local~~
359 ~~department of health~~ **DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC**
360 **HEALTH AGENCY** or ~~public health nurse~~ who shall then contact the parent(s) or emancipated
361 student in an effort to secure compliance so that the student may be re-enrolled in school.
362
- 363 B. Upon receipt of an immunization referral from the school, the ~~DEPARTMENT OR COUNTY,~~
364 ~~DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY~~ **DEPARTMENT OR COUNTY,**
365 **DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY** ~~public health department or public~~
366 ~~health nurse~~ shall contact the parent(s) of the referred student or the emancipated student
367 himself/herself to offer immunization and to secure compliance with the school immunization law
368 in order that the student may provide a completed Certificate of Immunization to the school and in
369 the case of an expelled or suspended student, be re-enrolled in school.

370 **IX. Requirements for college and university students, colleges and universities.**
371

372 The provisions below apply only to colleges or universities, or students enrolled in a college or university.
373

374 A. **Minimum immunization requirements**
375

- 376 1. Two valid doses of the ~~MMR measles, mumps and rubella~~ vaccine are required for all
377 college or university students, unless the college or university student was born before
378 1957, ~~or the college or university student can provide laboratory confirmation of disease~~
379 ~~as a criterion for acceptable evidence of immunity for measles, rubella, and mumps.~~
- 380 a. **LABORATORY CONFIRMATION OF POSITIVE TITERS ARE AN**
381 **ACCEPTABLE ALTERNATIVE TO THE MMR VACCINE WHEN SUBMITTED**
382

383 TO THE STUDENT'S SCHOOL. FOR MMR SUBSTITUTION, TITERS FOR
384 MEASLES, MUMPS, AND RUBELLA MUST BE POSITIVE.
385

- 386 2. Pursuant to ~~s~~Section 25-4-901, C.R.S. et. seq., and ~~s~~Section 23-5-128 (3), C.R.S., each
387 college and university shall provide information concerning meningococcal disease and
388 meningococcal vaccine to each new college or university student residing in student
389 housing, or if the college or university student is under 18 years, to the college or
390 university student's parent or guardian. College and university students residing in
391 student housing who have not received a meningococcal vaccine within the last five
392 years shall review the information concerning meningococcal disease and meningococcal
393 vaccine. If the college or university student does not obtain a vaccine, a signature must
394 be obtained from the college or university student or if the college or university student is
395 under 18 years, the college or university student's parent or guardian indicating that the
396 information was reviewed and the college or university student or college or university
397 student's parent or guardian has declined the vaccine.
398

399 **BA. Exemptions from immunization**

400 A college or university student may be exempted from receiving required immunizations in the following
401 manner:

- 402 1. Medical exemption - By submitting a medical exemption form with the statement of
403 medical exemption signed by an advanced practice nurse, a delegated physician
404 assistant, or physician licensed to practice medicine or osteopathic medicine in any state
405 or territory of the United States indicating that the physical condition of the college or
406 university student is such that immunizations would endanger his/her life or health or is
407 medically contraindicated due to other medical conditions. This form is to be submitted
408 once, and must be maintained on file at each new school the college or university student
409 attends.
410
411 2. Religious exemption - By submitting a nonmedical exemption form signed by the college
412 or university student 18 years of age or older, the parent if the college or university
413 student is under 18 years of age, or the emancipated college or university student
414 indicating that the college or university student, parent or emancipated college or
415 university student is adherent to a religious belief whose teachings are opposed to
416 immunizations. As of July 1, 2016, beginning with college or university entry, a
417 nonmedical exemption form must be submitted at enrollment.
418
419 3. Personal belief exemption - By submitting a nonmedical exemption form signed by the
420 college or university student 18 years of age or older, the parent if the college or
421 university student is under 18 years of age, or the emancipated college or university
422 student indicating that the college or university student, parent or emancipated college or
423 university student has a personal belief that is opposed to immunizations. As of July 1,
424 2016, beginning with college or university entry, a nonmedical exemption form must be
425 submitted at enrollment.
426
427 4. In the event of an outbreak of disease against which immunization is required, no
428 exemption or exception from immunization shall be recognized and exempted persons
429 may be subject to exclusion from school and quarantine.
430

431 ~~B. Minimum immunization requirements~~

- 432 ~~1. Two valid doses of the Measles, Mumps and Rubella vaccine are required for all college~~
433 ~~or university students, unless the college or university student was born before 1957, or~~
434 ~~the college or university student can provide laboratory confirmation of disease as a~~
435 ~~criterion for acceptable evidence of immunity for Measles, Rubella, and Mumps.~~
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~~2. Pursuant to Section 25-4-901, C.R.S. et. seq., and Section 23-5-128 (3), C.R.S., each college and university shall provide information concerning Meningococcal disease and Meningococcal vaccine to each new college or university student residing in student housing, or if the college or university student is under 18 years, to the college or university student's parent or guardian. College and university students residing in student housing who have not received a Meningococcal vaccine within the last five years shall review the information concerning Meningococcal disease and Meningococcal vaccine. If the college or university student does not obtain a vaccine, a signature must be obtained from the college or university student or if the college or university student is under 18 years, the college or university student's parent or guardian indicating that the information was reviewed and the college or university student or college or university student's parent or guardian has declined the vaccine.~~

C. Examination and audit of official school immunization records

The Department of Public Health and Environment's representative shall have the right to audit and verify records to determine compliance with the law. Discrepancies found through audits shall be corrected by school officials, and any college or university student not in full compliance shall be denied attendance from school according to the rules in sSection IX (D).

D. Denial of attendance

1. A college or university student who is: not in-process, not appropriately vaccinated for his/her age, or not exempt shall be denied attendance in accordance with the law.
2. A school official shall deny attendance from school, pursuant to the provisions established by the school, any college or university student not in-process, not appropriately immunized for his/her age, or not exempt per sSection 25-4-903, C.R.S. No college or university student shall be denied attendance for failure to comply unless there has been a direct personal notification of noncompliance by the appropriate school authority to the college or university student's parent or guardian, the emancipated college or university student or the college or university student 18 years of age or older.

E. Official school immunization records

1. Official school immunization records shall include one of the following:
 - A. An official Certificate of Immunization or an Alternate Certificate of Immunization approved by the Department of Public Health and Environment, which shall include one of the following forms of documentation with the dates and types of immunizations administered to a college or university student:
 1. A paper or electronic document that includes information transferred from the records of a licensed physician, registered nurse, a delegated physician assistant, or public health official, or
 2. An electronic file or hard copy of an electronic file provided to the school directly from the immunization tracking system established pursuant to sSection 25-4-2403 C.R.S. or from a software program approved by the Department of Public Health and Environment, or
 - B. An official medical exemption form with the date and vaccines exempted from, or
 - C. A nonmedical exemption form with the date, type of exemption taken and the vaccines exempted from.

- 495 2. Any immunization record (original or copy) provided by a physician licensed to practice
496 medicine or osteopathic medicine in any state or territory of the United States, registered
497 nurse, a delegated physician assistant, or public health official may be accepted by the
498 school official as proof of immunization.
499
- 500 3. Schools shall have on file an official school immunization record for every college or
501 university student enrolled.
502

503 F. Reporting of statistical information – on December 1, 2016, and each year thereafter, any college
504 or university that constitutes a school as defined by sSection I (M) shall send aggregate
505 immunization and exemption data, by antigen, to the Department of Public Health and
506 Environment:

507
508 Required data shall include:

- 509
- 510 1. Total number of college or university students enrolled in the school;
 - 511
 - 512 2. Total number of college or university students who are up-to-date with immunizations as
513 required in this sSection (IX);
 - 514
 - 515 3. Total number of college or university students who have a medical exemption for the
516 MMR vaccine;
 - 517
 - 518 4. Total number of college or university students who have a religious exemption for the
519 MMR vaccine;
 - 520
 - 521 5. Total number of college or university students who have a personal belief exemption for
522 the MMR vaccine;
 - 523
 - 524 6. Total number of in-process college or university students;
 - 525
 - 526 7. Total number of college or university students who have a signed waiver for the
527 Meningococcal vaccine;
 - 528
 - 529 8. Total number of college or university students not up-to-date for the MMR vaccine, with
530 no exemption on file, no Meningococcal vaccine waiver on file, and not in-process; and
 - 531
 - 532 9. Total number of college or university students with no immunization records.

533

534 X. **Contract Requirements for Providers, Hospitals, and Health Care Clinics to be an Agent of**
535 **the Department of Public Health and Environment for the Purposes of the Immunization**
536 **Program**

537

538 A. To be an agent of the Department of Public Health and Environment for the purposes of
539 administering immunizations to infants, children, and students, a provider, hospital, or health care
540 clinic must agree to provide each patient receiving a vaccine, or the parent or legal guardian, if
541 such THE patient is an unemancipated minor, a copy of the currently approved vVaccine
542 information sStatement, AS REQUIRED BY FEDERAL LAW.

543

544 B. The Department of Public Health and Environment shall make such requirements as are
545 necessary to assure the confidentiality and security of information in immunization tracking
546 system operated pursuant to sSection 25-4-1705(5)(e)(I)(H)2403(3), C.R.S and Section 25-4-
547 1705(7), C.R.S.

548

549 XI. **Fee for the Administration, Reporting, and Tracking of Vaccine**

550

551 This ~~section rule~~ applies to immunizations PROVIDED purchased by THE DEPARTMENT CDPHE that
552 are recommended by the ACIP Advisory Committee on Immunization Practices of the U.S. Department of
553 Health and Human Services and AVAILABLE provided to Colorado practitioners.

- 554
- 555 A. Practitioners may charge up to the Centers for Medicare and Medicaid sServices maximum
556 regional fee for the administration of vaccine. These fees apply to all vaccines purchased
557 PROVIDED by THE DEPARTMENT CDPHE, including but not limited to the Infant Immunization
558 Program, and Immunization of Children Attending School.
 - 559
 - 560 B. A vaccine recipient may not be denied vaccine provided by THE DEPARTMENT CDPHE
561 because of inability to pay the administration fee.
 - 562
 - 563 C. If a practitioner's vaccine administration costs are less than the Centers for Medicare and
564 Medicaid Services maximum regional fee for the administration of vaccine, then they may only
565 charge up to that lesser amount.

566 **XII. On-line educational module**

567

568 ~~As necessary To comply with PER s~~Section 25-4-903 (2.5), C.R.S., the Department of Public Health and
569 ~~Environment~~ shall provide immunization information to the public. The immunization information and
570 contents of this module shall include, but are not limited to:

- 571
- 572 A. Exemption rates in Colorado that are available to the public through the Department,
 - 573
 - 574 B. Evidence-based research,
 - 575
 - 576 C. Resources and information from credible scientific and public health organizations, and
 - 577 D. Peer-reviewed studies.