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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: April 1, 2018

Subject: Request for Rulemaking Hearing

Proposed Amendments to 6 CCR 1009-2 - The Infant Immunization Program and Immunization of Students Attending School, with a request for a rulemaking

hearing to be set for June 20, 2018

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 with a request for the Board of health to set a rulemaking hearing to occur in June 2018.

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 policy. 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only K-12th grade schools are not required to report aggregate data to the Department, and remove language referring to repealed portions of statute.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. The Department remains committed to engaging its stakeholders during this rulemaking period. 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:

- 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 feels 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 X No
Does this rulemaking incorporate materials by reference? Yes URL or Sent to State Publications Library X No
Does this rulemaking create or modify fines or fees? YesX No
Does the proposed rule create (or increase) a state mandate on local government?
X 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?YesNo 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. <u>Identify each group of individuals/entities that rely on the rule to maintain their own businesses</u>, 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. <u>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:</u>

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 matter of public policy, this rulemaking is technical in nature. No changes are proposed to the list of required immunizations, or to medical and non-medical exemptions.

- C. <u>Identify each group of individuals/entities that benefit from, may be harmed by or atrisk because of the rule, and, if applicable, the size of the group:</u>
 - 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 immunization policy.
- 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.					
XX The proposed revisions are necessary to comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.XX 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.					
XX The proposed revisions implement stakeholder feedback.					
XX 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) XX Immunization (Goal 1) Air Quality (Goal 1)					

(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)

Data collection and dissemination (Goal 1, 2, 3, 4 and 5)

___ Implements quality improvement or a quality improvement project

Establish infrastructure to detect, prepare and respond to emerging issues (Goal 1, 2, 3, 4, and 5)

Other favorable and unfavorable consequences of inaction: NA

____ Water Quality (Goal 1)

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).

Per section 25-4-902, C.R.S., the Board of Health is authorized is 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.

 $^{{}^{1}\!}CDC.\ ACIP\ Recommendations.\ \underline{https://www.cdc.gov/vaccines/acip/recs/index.html}.\ Accessed:\ Mar,\ 20\ 2018.$

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).

X	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. To date, the Department has received feedback from 19 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. While the Department will continue to engage stakeholders throughout the development of the proposed rules, 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.

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	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.
Х	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.
Х	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:

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Disease Control and Environmental Epidemiology Division

THE INFANT IMMUNIZATION PROGRAM AND IMMUNIZATION OF STUDENTS ATTENDING SCHOOL

6 CCR 1009-2

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1	I.	Definitions
2 3 4 5 6 7	A.	Advisory Committee on Immunization Practices (ACIP) - a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States. ACIP was established under Section 222 of the Public Health Service Act (42 U.S.C. §217a).
8 9	B.	Child - any student less than 18 years of age.
10 11 12 13	C.	College or university student - any student who is enrolled for one or more classes at a college or university and who is physically present at the institution. This includes students who are auditing classes but does not include persons taking classes online or by correspondence only.
14 15 16 17	D.	Delegated physician assistant – a licensed physician assistant authorized under Section 12-36-106(5), C.R.S., to execute Certificates of Immunization, medical exemptions and/or supervise a public health or school nurse as authorized by part 9 of article 4 of title 25, C.R.S.
18 19 20	E.	DEPARTMENT (THE) - REFERS TO THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
21 22 23	<mark>∈F.</mark>	Dose - a measured quantity of an immunizing agent; quantity and frequency of administration determined by recognized health authorities and the manufacturer of each agent.
24 25 26 27	₽ G.	Emancipated student - any student who has reached age-18 YEARS OF AGE; a lawfully married child of any age; a child 15 years of age or older who is managing his/her own financial affairs and who is living separate and apart from his/her parent.
28 29 30 31 32 33 34 35	GH.	Immunization tracking system - a comprehensive immunization tracking system established by the Department of Public Health and Environment pursuant to Section 25-4-2403(2), C.R.S., that enables the gathering of epidemiological information from the sources delineated in Section 25-4-2403(2), C.R.S. and the investigation and control of communicable diseases. Individuals, parents and legal guardians may provide information to the immunization tracking system; however, pursuant to Section 25-4-2403(7), C.R.S., they have the option to exclude their or their student's immunization information from the immunization tracking system at any time.
36 37 38	<mark>⊭I</mark> .	Indigent child - any child whose parent cannot afford to have the child immunized or if emancipated, who cannot himself/herself afford immunization and who has not been exempted.
39 40 41	<mark>IJ</mark> .	Infant - any child up to twenty four months of age or any child eligible for vaccination and enrolled under the Colorado Medical Assistance Act, Articles 4, 5, and 6 of Title 25.5, C.R.S.
42	<mark>JK</mark> .	In-process student - a student may be considered in-process if:

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

- 2. With regard to eC ollege or university students, as defined in Section I (C), the student must present to the appropriate SCHOOL official of the school either (I) a signed written authorization requesting local health officials to administer required immunizations or (II) a plan for receipt of the required immunization or the next required immunization in a series within either 30 days or the medically approved minimum interval. If this does not occur, the college or university student will not be allowed to enroll, remain enrolled, or audit for the current term or session. Such written authorizations and plans must be signed by one parent or guardian or the emancipated student or the student eighteen—18 years of age or older.
- KL. Parent the person or persons with parental or decision-making responsibilities for a child.
- EM. Practitioner a duly licensed physician, advanced practice nurse, or other person who is permitted and otherwise qualified to administer vaccines under the COLORADO laws of this state.
 - MN. School all child care facilities licensed by the Colorado Department of Human Services including: child care centers, school-age child care center, preschools, day camps, resident camps, day treatment centers, family child care homes, foster care homes, and head start programs; public, private, or parochial kindergarten, elementary or secondary schools through grade twelve, or a college or university. Schools do not include a public services short-term child care facility as defined in Section 26-6-102(30), C.R.S., a guest child care facility as defined in Section 26-6-102(16), C.R.S., a ski school as defined in Section 26-6-103.5 (6), C.R.S., or college or university classes which are: offered off-campus; offered to nontraditional adult students as defined by the governing board of the institution; offered at colleges or universities which do not have residence hall facilities, or; online only.
 - NO. School health authority an individual working for or on behalf of the child care facility or school who is knowledgeable about child care/school immunizations.
 - OP. School official the school's chief executive officer or any person designated by him/her as his/her representative.
 - PQ. Student any person enrolled in a Colorado school as defined in section I (M), except:
 - a child who enrolls and attends a licensed child care center, as defined in sSection 26-6-102(5), C.R.S., which is located at a ski area, for up to fifteen days or less in a fifteen-consecutive-day period, no more than twice in a calendar year, with each fifteen-consecutive-day period separated by at least sixty days, and
 - 2. college and university students as defined in section I (C).

QR. 96 Titer – a titer is a laboratory test that measures the presence and amount of antibodies in blood. 97 Antibody titers can be used to show that a person is immune to some diseases. 98 99 II. **Minimum Immunization Requirements** 100 101 A. To attend school, a student must have an age appropriate Certificate of Immunization. Meeting 102 the initial immunization requirements does not exempt a student from meeting subsequent age 103 requirements. This certificate must demonstrate immunization against the following diseases: 104 105 1. Hepatitis B 106 107 2. Pertussis 108 109 3. **Tetanus** 110 4. Diphtheria 111 112 5. Haemophilus Influenzae Type B (HIB) 113 114 6. 115 Pneumococcal disease 116 7. 117 Polio 118 8. Measles 119 120 9. 121 Mumps 122 10. 123 Rubella 124 125 11. Varicella 126 127 В. EXCEPT AS REQUIRED IN SECTIONS II (C) AND II (D), WHEN HEALTHCARE PROVIDERS 128 ADMINISTER THE IMMUNIZATIONS IDENTIFIED IN SECTION II (A), THE IMMUNIZATIONS 129 WILL BE ADMINISTERED ACCORDING TO THE SCHEDULE ESTABLISHED BY THE ACIP. 130 The minimum number of doses required by age of the student is set forth in the 2017 ACIP Birth 131 - 18 Years Recommended Immunization Schedule or the 2017 ACIP Catch-Up Immunization Schedule. 132 133 The 2017 ACIP Birth 18 Years Recommended Immunization Schedule (Schedule) is 134 135 incorporated by reference for only those vaccines required to prevent the diseases listed in Section II (A). Other immunizations included in the ACIP recommendations are not 136 required. This schedule is posted on the Centers for Disease Control and Prevention 137 website at: https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-138 combined-schedule.pdf or on the Colorado Department of Public Health and Environment 139 140 website at: [www.coloradoimmunizations.com], and is available for public inspection 141 during regular business hours at the Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, Colorado 80246. Copies of the 142

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ACIP Schedule.

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

- prevent the diseases listed in Section III (A). Other immunizations included in the ACIP 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.

In addition, the 2017 ACIP Catch-Up Immunization Schedule is incorporated by

reference for those children not fully immunized and only for those vaccines required to

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 requireDment 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.

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- 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.
- Personal belief exemption By submitting a nonmedical exemption form signed by the parent(s) or the emancipated student indicating that the parent(s) or emancipated student has a personal belief that is 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 sSection 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.
- D. In the event of an outbreak of disease against which immunization is required, no exemption or exception from immunization shall be recognized and exempted persons may be subject to exclusion from school and quarantine.
- E. All information distributed to the parent(s) by school districts regarding immunization shall inform them of their rights under section III (A-D).

IV. 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 student not in full compliance shall be suspended or expelled from school according to the following rules:

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

٧. **Denial of attendance**

- A student who is: not in-process, not appropriately vaccinated for his/her age, or not exempt shall A. be denied attendance in accordance with the law.
 - If the student is attending a school THAT which is not subject to the School Attendance Law. Section 22-33-101 et seq., C.R.S., the school officials shall take appropriate action to deny attendance to the student in accordance with that school's procedures or contract with the

student. No indigent child shall be excluded, suspended, or expelled from school unless the immunizations have been available and readily accessible to the indigent child at public expense.

VI. Official school immunization records

- A. Official school immunization records shall include:
 - 1. An official Certificate of Immunization or an Alternate Certificate of Immunization approved by the Department-of Public Health and Environment, which shall-includes one of the following forms of documentation with the dates and types of immunizations administered to a student:
 - a. 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
 - b. An electronic file or hard copy of an electronic file provided to the school directly from the immunization tracking system established pursuant to Section 25-4-2403, C.R.S., or from a software program approved by the Department of Public Health and Environment, or
 - 2. An official medical exemption form with the date and vaccines exempted from, or
 - 3. A nonmedical exemption form with the date, type of exemption taken and the vaccines exempted from.
- B. Any immunization record (original or copy) provided by a physician licensed to practice medicine or osteopathic medicine in any state or territory of the United States, registered nurse, a delegated physician assistant, or public health official may be accepted by the school official as proof of immunization. The information is to be verified by the school official and transferred to an official Certificate of Immunization.
- C. Schools shall have on file an official school immunization record for every student enrolled. The official school immunization record will be kept apart from other school records. When a student withdraws, transfers, or is promoted to a new school, the school official shall return the Certificate of Immunization to the parent(s) or emancipated student upon request or transfer it with the student's school records to the new school. Upon a college or university student's request, the Certificate of Immunization shall be forwarded as specified by the student.

VII. Reporting of Statistical Information

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

Required data shall include:

- 1. Total number of students and total number of kindergarten students enrolled in the school;
- 2. Total number of students and total number of kindergarten students who are up-to-date with immunizations as required in section II;

- Total number of students and total number of kindergarten students who have a medical exemption for all immunizations as required in section II;
 - 4. Total number of students and total number of kindergarten students who have a medical exemption for one or more but not all immunizations as required in section II;
 - 5. Total number of students and total number of kindergarten students who have a religious exemption for all immunizations as required in 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 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 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 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 ssection II, with no exemption on file, and not inprocess; and
 - 11. Total number of students and total number of kindergarten students with no immunization records.
 - B. Schools not required to send aggregate immunization and exemption data to the Department of Public Health and Environment include: ONLINE ONLY K 12TH GRADE SCHOOLS, school-age child care centers, family child care homes, drop-in centers, day treatment centers, foster care homes, day camps, and resident camps.

VIII. Notification of noncompliance

- A. Section 25-4-907, C.R.S. requires that if a student is suspended or expelled from school for failure to comply with the immunization law, the school official shall notify the state or local department of health-DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY or public health nurse who shall then contact the parent(s) or emancipated student in an effort to secure compliance so that the student may be re-enrolled in school.
- B. Upon receipt of an immunization referral from the school, the DEPARTMENT OR COUNTY, DISTRICT, OR MUNICIPAL PUBLIC HEALTH AGENCY public health department or public health nurse-shall contact the parent(s) of the referred student or the emancipated student himself/herself to offer immunization and to secure compliance with the school immunization law in order that the student may provide a completed Certificate of Immunization to the school and in the case of an expelled or suspended student, be re-enrolled in school.
- IX. Requirements for college and university students, colleges and universities.

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

A. Minimum immunization requirements

1. Two valid doses of the MMR measles, mumps and rubella vaccine are required for all college or university students, unless the college or university student was born before

1957, or the college or university student can provide laboratory confirmation of disease as a criterion for acceptable evidence of immunity for measles, rubella, and mumps.

- a. LABORATORY CONFIRMATION OF POSITIVE TITERS ARE AN ACCEPTABLE ALTERNATIVE TO THE MMR VACCINE WHEN SUBMITTED TO THE STUDENT'S SCHOOL. FOR MMR SUBSTITUTION, TITERS FOR MEASLES, MUMPS, AND RUBELLA MUST BE POSITIVE.
- 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.

BA. Exemptions from immunization

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

- 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 college or university 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 college or university student attends.
- Religious exemption By submitting a nonmedical exemption form signed by the college or university student 18 years of age or older, the parent if the college or university student is under 18 years of age, or the emancipated college or university student indicating that the college or university student, parent or emancipated college or university student is adherent to a religious belief whose teachings are opposed to immunizations. As of July 1, 2016, beginning with college or university entry, a nonmedical exemption form must be submitted at enrollment.
- 3. Personal belief exemption By submitting a nonmedical exemption form signed by the college or university student 18 years of age or older, the parent if the college or university student is under 18 years of age, or the emancipated college or university student indicating that the college or university student, parent or emancipated college or university student has a personal belief that is opposed to immunizations. As of July 1, 2016, beginning with college or university entry, a nonmedical exemption form must be submitted at enrollment.
- 4. In the event of an outbreak of disease against which immunization is required, no exemption or exception from immunization shall be recognized and exempted persons may be subject to exclusion from school and quarantine.

B. Minimum immunization requirements

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- Two valid doses of the Measles, Mumps and Rubella vaccine are required for all college or university students, unless the college or university student was born before 1957, or the college or university student can provide laboratory confirmation of disease as a criterion for acceptable evidence of immunity for Measles, Rubella, and Mumps.
- 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 section 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 Section 25-4-903, C.R.S. Neo 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:
 - Α. 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, adelegated 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 Section 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. 2. Any immunization record (original or copy) provided by a physician licensed to practice medicine or osteopathic medicine in any state or territory of the United States, registered nurse, addlegated physician assistant, or public health official may be accepted by the school official as proof of immunization.
 - 3. Schools shall have on file an official school immunization record for every college or university student enrolled.
 - F. Reporting of statistical information on December 1, 2016, and each year thereafter, any college or university that constitutes a school as defined by section I (M) shall send aggregate immunization and exemption data, by antigen, to the Department of Public Health and Environment:

Required data shall include:

- 1. Total number of college or university students enrolled in the school;
- 2. Total number of college or university students who are up-to-date with immunizations as required in this section (IX);
- 3. Total number of college or university students who have a medical exemption for the MMR vaccine;
- 4. Total number of college or university students who have a religious exemption for the MMR vaccine;
- 5. Total number of college or university students who have a personal belief exemption for the MMR vaccine:
- 6. Total number of in-process college or university students;
- 7. Total number of college or university students who have a signed waiver for the Meningococcal vaccine;
- 8. Total number of college or university students not up-to-date for the MMR vaccine, with no exemption on file, no Meningococcal vaccine waiver on file, and not in-process; and
- 9. Total number of college or university students with no immunization records.
- X. Contract Requirements for Providers, Hospitals, and Health Care Clinics to be an Agent of the Department of Public Health and Environment for the Purposes of the Immunization Program
- A. To be an agent of the Department of Public Health and Environment for the purposes of administering immunizations to infants, children, and students, a provider, hospital, or health care clinic must agree to provide each patient receiving a vaccine, or the parent or legal guardian if such patient is an unemancipated minor, a copy of the currently approved vaccine Information statement.
- B. The Department of Public Health and Environment shall make such requirements as are necessary to assure the confidentiality and security of information in immunization tracking

539 540			em operated pursuant to Section 25-4- 1705(5)(e)(I)(H) 2403(3), C.R.S and Section 25-4- (7), C.R.S.			
541 542	XI.	Fee	for the Administration, Reporting, and Tracking of Vaccine			
543 544	This s	section	rule_applies to immunizations PROVIDED purchased by THE DEPARTMENT CDPHE -that			
545	are re	recommended by the ACIP Advisory Committee on Immunization Practices of the U.S. Department				
546 547			luman Śervices and <mark>AVAILABLE provided to Colorado practitioners.</mark>			
548 549	A.	regio	titioners may charge up to the Centers for Medicare and Medicaid <mark>sS</mark> ervices maximum anal fee for the administration of vaccine. These fees apply to all vaccines purchased			
550 551 552			VIDED by THE DEPARTMENT CDPHE , including but not limited to the Infant Immunization ram, and Immunization of Children Attending School.			
553 554 555	B.		ccine recipient may not be denied vaccine provided by THE DEPARTMENT CDPHE use of inability to pay the administration fee.			
556 557 558 559	C.	Medi	If a practitioner's vaccine administration costs are less than the Centers for Medicare and Medicaid Services maximum regional fee for the administration of vaccine, then they may only charge up to that lesser amount.			
560 561	XII.	On-li	ine educational module			
562 563 564 565	Envir	onment	/ To comply with PER sS ection 25-4-903 (2.5), C.R.S., the Department-of Public Health and shall provide immunization information to the public. The immunization information and his module shall include, but are not limited to:			
566		A.	Exemption rates in Colorado that are available to the public through the Department,			
567		B.	Evidence-based research,			
568 569		C.	Resources and information from credible scientific and public health organizations, and			
570		D.	Peer-reviewed studies.			