

To: Members of the State Board of Health

From: Diana Herrero, Deputy Director, Division of Disease Control and

Public Health Response (DCPHR)

Through: Scott Bookman, Director, DCPHR SB

Date: October 21, 2021

Subject: Request for a Rulemaking Hearing concerning 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 Engagement, and Proposed Amendments to 6 CCR 1009-2, The Infant Immunization Program and Immunization of Students Attending School.

The Colorado Department of Public Health and Environment (Department) 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 Colorado Board of Health (Board). Colorado's vaccine requirements have contributed to higher vaccine coverage, lower levels of vaccine-preventable disease, and fewer disruptions to in-person learning.

On November 18, 2020, the Board adopted updates to 6 CCR 1009-2, The Infant Immunization Program and Immunization of Students Attending School. The updates presented to the Board at that time 1) aligned this rule with new statutory requirements resulting from Colorado Senate Bill 20-163 (SB 20-163), or 2) were technical in nature and intended to clarify existing rule language and provide better alignment with statute without significant policy change.

Post-adoption, the Office of Legislative Legal Services (OLLS), reviewed the rules pursuant to Section 24-4-103(8), C.R.S., identifying one section of the rule where changes are necessary to ensure these regulations are consistent with Colorado State Law. As adopted, the rule language in this section suggests that immunization records are only required to be submitted upon a request by a school district, institute charter school, or private school where the student attends for a portion of the day. This rule language as adopted is consistent with Section 25-4-902 (1.5)(b), C.R.S.

OLLS has requested amended language in Section III so that this section of the rule also aligns with Section 25-4-902 (1.5)(a), C.R.S. Thus, the Department is proposing language that clarifies that school superintendents have the authority to request immunization records in certain circumstances as outlined in Sections 25-33-104.5 (3)(g), C.R.S. and 25-4-902 (6), C.R.S.

In total, the proposed amendments are necessary to comply with the findings of the \mbox{OLLS} review.

Changes to rule language appear in ALL CAPS and strikethroughs.

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 6 CCR 1009-2 upon school entry unless an 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 and broader communities.

The proposed changes to this rule were brought about by a review of this rule by the Office of Legislative Legal Services (OLLS), as mandated by statute at Section 24-4-103(8), C.R.S., following the Board's adoption of revisions in November 2020. OLLS identified one section of the rule as needing revision to ensure these regulations are consistent with current state law.

To this end, the Department proposes amendments and additions to Section III. Proposed rule changes in this Section align with Section 25-4-902 (1.5)(a), C.R.S. Pursuant to the proposed language, school superintendents have the authority to request immunization records in certain circumstances as outlined in Sections 25-33-104.5 (3)(g), C.R.S. and 25-4-902 (6), C.R.S.

Specific Statutory Authority. Statutes that require or authorize rulemaking: § 25-4-903, C.R.S. and § 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 include proposed rule language that incorporate materials by reference?
Yes URL
_X No
Does this rulemaking include proposed rule language to create or modify fines or fees? Yes X No
Does the proposed rule language create (or increase) a state mandate on local government? _X No.
• The proposed rule does not require a local government to perform or increase a

- specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule 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:
(i.e. requested by local governments and consensus was achieved)
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.

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/CLG/S/B
Approximately 2,150 public and private schools, approximately 2,100 licensed child cares, thousands of healthcare providers throughout the state, the Colorado Department of Education, the Colorado Department of Human Services, the Colorado Department of Higher Education, approximately 25 colleges/universities and 53 county, district or municipal public health agencies (LPHAs) rely on the rule to maintain their own businesses, agencies or operations.		C, CLG
Students enrolled in Colorado schools and, if under 18 years of age, their parents/legal guardians, and the public at large.		S, B

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, please use this relationship categorization key:

C = individuals/entities that implement or apply the rule.

CLG = local governments that must implement the rule in order to remain in compliance with the law.

- S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.
- B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

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.

The Department does not foresee an economic impact to any affected persons. The proposed changes to this rule will result in clarification for consistent interpretation by end-users of the rule and better alignment with statute; both of which the Department expects will result in improved customer experience.

- 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:

The proposed amendments are cost-neutral.

Anticipated CDPHE Revenues: NA

B. Anticipated personal services, operating costs or other expenditures by another state agency: NA

Anticipated Revenues for another state agency: NA

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

Along with the costs and benefits discussed above, the proposed revisions:

Comply with a statutory mandate to promulgate rules.	
Comply with federal or state statutory mandates, federal or state regulations, ar	าด
department funding obligations.	
Maintain alignment with other states or national standards.	
Implement a Regulatory Efficiency Review (rule review) result	
Improve public and environmental health practice.	
_X Implement stakeholder feedback.	

Advance the following CDPHE Strategic Plan priorities (select all that apply):

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric

tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023.
 Contributes to the blueprint for pollution reduction Reduces carbon dioxide from transportation Reduces methane emissions from oil and gas industry Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023.
 Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry. Supports local agencies and COGCC in oil and gas regulations. Reduces VOC and NOx emissions from non-oil and gas contributors
3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023.
 Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.
4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023.
Ensures access to breastfeeding-friendly environments.
5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.
 Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. Performs targeted programming to increase immunization rates. Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).
6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.
Creates a roadmap to address suicide in Colorado.Improves youth connections to school, positive peers and caring adults, and

promotes healthy behaviors and positive school climate. Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries. Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.
7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.
 Conducts a gap assessment. Updates existing plans to address identified gaps. Develops and conducts various exercises to close gaps.
8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.
 Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident. Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment. Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.
9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023.
 Implements the CDPHE Digital Transformation Plan. Optimizes processes prior to digitizing them. Improves data dissemination and interoperability methods and timeliness.
10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023.
 Reduces emissions from employee commuting Reduces emissions from CDPHE operations
11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023.
Used a budget equity assessment

_ Advance CDPHE Division-level strategic priorities.

Identify division strategic plan item or strategic priority

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:

NA. Inaction has neither monetary cost nor benefit; however, inaction results in non-compliance with statute, and the potential to invalidate these rules.

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

The proposed changes are neither costly nor intrusive, and, as the purpose is compliance with statute, no alternative method was considered.

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

No alternatives to this rulemaking were considered. Failure to implement requirements that are consistent with Colorado state law, as identified by the Office of Legislative Legal Services (OLLS), may result in the rule being negated or invalidated by the state legislature.

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 proposed changes did not require a data-based evaluation or analysis.

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 proposed revisions correct technical deficiencies to ensure compliance with the Colorado Revised Statutes. Due to the minor nature of the changes, no stakeholder processes or stakeholder meetings were conducted prior to the request for rulemaking. Stakeholders will be notified of the proposed changes prior to the rulemaking hearing, if scheduled.

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 10 th of the month following the Request for Rulemaking).
XX Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the loard of Health sets this matter for rulemaking.
Yes.
nummarize 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.
lo major factual or policy issues were encountered. The proposed changes are minor and are proposed to ensure the regulations are consistent with Colorado state law.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

The proposed rule continues to hold all persons to the same requirements regarding immunizations necessary for school attendance in Colorado.

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

<u> </u>	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.			
	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.			
X	Other: Complies with the Department's obligation to ensure all regulations are consistent with state law.	Other:			
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DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Disease Control and Public Health Response Division

THE INFANT IMMUNIZATION PROGRAM AND IMMUNIZATION OF STUDENTS ATTENDING SCHOOL

6 C	CR	1009-2	
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III. Exemptions from Immunization

B. ***

4. Immunization records shall be maintained by the parent or adult relative designated by the parent of students who participate in a nonpublic home-based education program pursuant to Section 22-33-104.5, C.R.S., and are only required to be submitted upon request by a school district, institute charter school, or private school which the student attends for a portion of the school day.

D.

- 1. IMMUNIZATION RECORDS SHALL BE MAINTAINED BY THE PARENT OR ADULT RELATIVE DESIGNATED BY THE PARENT OF STUDENTS WHO PARTICIPATE IN A NONPUBLIC HOME-BASED EDUCATION PROGRAM PURSUANT TO SECTION 22-33-104.5, C.R.S., AND ARE REQUIRED TO BE SUBMITTED:
 - a. WHEN A SCHOOL DISTRICT REQUIRES COMPLIANCE WITH SECTION 25-4-902, C.R.S. PURSUANT TO SECTION 22-33-104.5 (3)(G), C.R.S.
 - b. WHEN REQUESTED BY A SCHOOL DISTRICT, INSTITUTE CHARTER SCHOOL, OR PRIVATE SCHOOL WHICH THE STUDENT ATTENDS FOR A PORTION OF THE SCHOOL DAY.
- 2. A SCHOOL DISTRICT THAT IS EXERCISING ITS AUTHORITY PURSUANT TO SECTION 22-33-104.5(3)(G) IS ENTITLED TO ONLY:
 - a. A STUDENT'S IMMUNIZATION RECORDS, AS PROVIDED BY THE PARENT OR LEGAL GUARDIAN; OR

- b. A STATEMENT SIGNED BY A PARENT OR LEGAL GUARDIAN THAT THE STUDENT IS EXEMPT FROM IMMUNIZATION.
- DE. All information distributed to parent(s) by school districts regarding immunizations shall inform them of their rights in section III (A-CD).
