## STATE OF COLORADO

John W. Hickenlooper, Governor Larry Wolk, MD, MSPH Executive Director and Chief Medical Officer

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Colorado Department of Public Health and Environment

To:	Members of the Colorado Board of Health
From:	Lynn Trefren, RN, MSN, Section Chief of the Colorado Immunization Section $LT$ Disease Control and Environmental Epidemiology Division (DCEED)
Through:	Tista Ghosh, MD, MPH Deputy Chief Medical Officer and Division Director, $\mathcal{TG}$ Disease Control and Environmental Epidemiology Division (DCEED)
Date:	June 18, 2014
Subject:	<b>Request for Public Rulemaking</b> regarding Proposed Amendments to 6 CCR 1009-2, Rules Pertaining to the Infant Immunization Program, the Vaccines for Children Program and the Immunization of Students Attending School.

In preparation for Request for Public Rulemaking, please find copies of the following documents: Proposed Amendments to 6 CCR 1009-2, Statement of Basis and Purpose and Specific Statutory Authority, and Regulatory Analysis.

Specific legal authority is established in Colorado statute with the expressed purpose of protecting students and the general population from vaccine preventable disease. Child cares, schools, and colleges/universities are bound by statute to ensure that students meet the immunization requirements as guided by the Colorado Board of Health (BOH).

The Department convened a group of immunization experts to review the current Board of Health rules and to discuss immunization topics pertinent to clarify and update required school immunizations for Colorado Students. This group of experts met twice in 2014 and made several recommendations to the Department. Based upon the work of the stakeholder group, the following changes are being recommended:

- 1. Line 8 Added definition of the Advisory Committee on Immunization Practices (ACIP)
- 2. Lines 12-94 Alphabetized all remaining definitions in this Section I.
- 3. Line 175 Updated internal reference to Section II.
- 4. Lines 179-184 Removed 2 dose Hepatitis B statement as this option will now be incorporated by reference into the ACIP schedule.
- 5. Lines 186-250 Removed reference to Tables 1 and 2, added a list of the diseases for which proof of immunization is required, and incorporated by reference of the ACIP Birth-18 years and Catch-up immunization schedules In the current and previous versions of this rule, the required

immunization schedule has closely aligned with the recommended immunization schedules approved by ACIP, but the rule has fallen just short of incorporating these recommendations. In order to eliminate confusion for clinicians, schools, and child cares, and to provide a bestpractice immunization schedule for required immunizations in schools, the Department proposes incorporating by reference the ACIP recommended Birth-18 years and Catch-up immunization schedules into 6 CCR 1009-2 only for those vaccines already required by this rule. We believe that these proposed amendments ensure that children will be optimally immunized against vaccine preventable diseases and the confusion about the two schedules will be eliminated. No new vaccines are being proposed.

- 6. Lines 251-256 Added detail about meningococcal vaccine requirements
- 7. Lines 257-262 Deleted reference to Tables 1 and 2 and related language in order to bring Varicella immunization requirements into accord with ACIP recommendations.
- 8. Line 269 Updated internal reference to definition in Section I.
- 9. Line 270 Added "approved".
- 10. Line 292-294 Removed language that instructions the Department.
- 11. Line 306 307 Deleted reference to Table 1
- 12. Lines 313-317 Updated language regarding the administration fee and deleted "the Vaccines for Children Program"
- 13. Line 325 Deleted Table 1 and related footnotes Table 1 and the associated footnotes provided much additional guidance to immunization providers regarding the optimal delivery of immunizations. This guidance is available at the Centers for Disease Control and Prevention website that publishes that ACIP schedule (http://www.cdc.gov/vaccines/schedules/index.html), and set forth in morbidity and mortality weekly reports (MMWR) February 7, 2014 Volume 63 (05). Nonetheless, the Department realizes that by deleting these tables and footnotes from the rule itself may remove this guidance from an easy reference document. As such, the Department is committed to creating and distributing a guidance document that summarizes and updates this guidance.
- 14. Line 385 Deleted Table 2 to bring Varicella immunization requirements into accord with ACIP recommendations.

The ACIP is a group of medical and public health experts who make recommendations to effectively schedule vaccines in the effort to control diseases in the United States. The ACIP holds three meetings each year at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia to make vaccine recommendations. During these committee meetings, members present findings and discuss vaccine research and scientific data related to vaccine effectiveness and safety, clinical trial results, and manufacturer's labeling or package insert information. Outbreaks of vaccine-preventable disease or changes in vaccine supply, such as vaccine shortages, also are reviewed during these meetings. The recommendations include the age(s) when the vaccine should be given, the number of doses needed, the amount of time between doses, and precautions and contraindications.

The CDC sets the U.S. childhood immunization schedule based on recommendations from the ACIP. This recommended schedule is also approved by the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists.

Incorporation by reference of the ACIP Birth-18 years (Figure 1) and Catch-up (Figure 2) schedules is appropriate at this time. The ACIP schedules are the Best Practice Standard for children's immunizations in the United States. As such, the ACIP schedules are followed by providers at local

public health agencies, health care providers and clinicians. Furthermore, clinical decision-making tools, such as the "recommender" in the Colorado Immunization Information System (CIIS), incorporate the ACIP schedules. The ACIP schedules are updated and posted annually on the CDC website as well as the Colorado Immunization Section's web site which provides easy access to the schedules. Because the schedules are updated annually, the Department anticipates amending these rules as necessary to reflect the most up-to-date schedules.

In addition, the Department is aware that there is some perceived discrepancy between the ACIP recommended immunization schedules, and the Colorado Required School Immunization schedule. These perceived discrepancies have been known to cause conflict between health care providers and school nurses. Parents typically get caught in the middle, wanting to honor their health care provider's advice yet also wanting to meet the school immunization requirements.

Therefore, in order to eliminate confusion for clinicians, schools, and child cares, and to provide a bestpractice immunization schedule for required immunizations in schools, the Colorado Immunization Section proposes incorporating by reference the Birth-18 years and Catch-up ACIP recommended immunization schedules into 6 CCR 1009-2. We believe that this proposed amendment ensures that children will be optimally immunized against vaccine preventable diseases and the confusion about the two schedules will be eliminated. No new vaccines are being proposed.

### Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – United States, 2014. (FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are in bold.

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16–18 yrs
Hepatitis B <sup>#</sup> (HepB)	1*dose	<b>≺−−</b> 2**	dose>		•		-3ª dose -		•							
Rotavirus? (RV) RV1 (2-dose series); RV5 (3-dose series)			1 <sup>4</sup> dose	2 <sup>nd</sup> dose	See footnote 2											
Diphtheria, tetanus, & acel- Iular pertussis <sup>1</sup> (DTaP: <7 yrs)			1*dose	2 <sup>nd</sup> dose	3 <sup>st</sup> dose			<del>&lt;</del> _4 <sup>+</sup>	dosa 🔶			5 <sup>e</sup> dose				
Tetanus, diphtheria, & acel- Iular pertussis <sup>e</sup> (Tdap: <u>&gt;</u> 7 yrs)														(Tdap)		
Haemophilus influenzae type b <sup>a</sup> (Hib)			1*dose	2 <sup>st</sup> dose	See footnote 5		<ul> <li>3<sup>er</sup> or 4 See for</li> </ul>	e dose, otnote 5								
Pneumococcal conjugate <sup>4</sup> (PCV13)			1*dose	2 <sup>nd</sup> dose	3 <sup>ni</sup> dose		<del>&lt;</del> 4ª(	dose 🍝								
Pneumococcal polysaccha- ride <sup>#</sup> (PPSV23)																
Inactivated poliovirus <sup>7</sup> (IPV) (<18 yrs)			1*dose	2 <sup>nd</sup> dose	*		3ª dose -		<b>,</b>			4ª dose				
Influenzat (IIV; LAIV) 2 doses for some: See footnote 8						A	nnual vaccin	ation (IV only	0			Ar	nual vaccinal	tion (IV or LA	N)	
Measles, mumps, rubella <sup>9</sup> (MMR)							<mark>←</mark> 1*o	iose <del>&gt;</del>				2ªidose				
Varicella <sup>®</sup> (VAR)							<u>←</u> 1*c	iose 🔶				2 <sup>st</sup> dose				
Hepatitis A <sup>rr</sup> (HepA)							<mark>≺ 2</mark>	dose series, S	see footnote 1	n <del>→</del>						
Human papillomavirus <sup>12</sup> (HPV2: females only; HPV4: males and females)														(3-dose series)		
Meningococcal <sup>12</sup> (Hib-Men- CY ≥ 6 weeks; MenACWY-D ≥9 mos; MenACWY-CRM ≥ 2 mos)						See foo	tnote 13							1ªdose		Roote
Range of recommended ages for actch-up ages for catch-up groups all children immunization groups groups ages for certain high-risk groups all children immunization groups all children ages for certain high-risk groups and for certa											4					

This schedule includes recommendations in effect as of January 1, 2014. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/hcp/aclp-necs/index.html. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Advisory Event Reporting System (VAERS) online (http://www.acs.hts.gov/vaccinases/hcp/aclp-necs/index.html.Clinically.gov/vaccines/index.html.cli This schedule is approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/vacches/adp), the American Academy of Pediatrics (http://www.aap.org), the American Academy of Family Physicians (http://www.aafp.org), and the American College of Obstetridans and Gynecologists (http://www.acog.org).

NOTE: The above recommendations must be read along with the footnotes of this schedule.

### FIGURE 2. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind — United States, 2014. The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table in conjunction with Figure 1 and the footnotes that follow.

			Persons aged 4 months through 8 years		
Vaccine	Minimum		Minimum Interval Between Doses		
vaccine	Age for Dose 1	Dose 1 to dose 2	Dose 2 to dose 3	Dose 3 to dose 4	Dose 4 to dose 5
Hepetitis B <sup>r</sup>	Birth	4 weeks	8 weeks and at least 10 weeks after first dose; minimum age for the final dose is 24 weeks		
Rotavirus <sup>2</sup>	6 weeks	4 weeks	4 weeks <sup>2</sup>		
Diphtheria, tetanus, & aceilular pertussis <sup>3</sup>	6 weeks	4 weeks	4 weeks	6 months	6 months <sup>2</sup>
Heemophilus Influenzee type b <sup>2</sup>	6 weeks	4 weeks if first dose administered at younger than age 12 morths 8 weeks (as final dose) If first dose administered at age 12 through 14 months No further doses needed If first dose administered at age 15 months or older	4 weeks <sup>2</sup> a current age is younger than 12 months and first does advinished at <7 months and doesn'f current age is younger than 12 months and first does advinishered between 7 through 19 months and first does advinishered between 7 through 11 months (regardless of Hib vaccine (PRP-T or PRP-OMP) most brist doesn's <u>OB</u> if current age is 12 through 59 months and first does advinishered at younger than age 12 months. <u>OB</u> first 2 doesn were PRP-OMP and advinishered at younger than 12 months. No further doesn needed if previous doesn advinishered at age 15 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 (PRP-1) doses before age 12 months and started the primary series before age 7 months	
Pneumococcal <sup>#</sup>	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose for healthy children) if first dose administered at age 12 months or older No further doses needed for healthy children if first dose administered at age 24 months or older	4 weeks if current age is younger than 12 months 8 weeks (as final dose for healthy children) if current age is 12 months of older No further doses needed for healthy children if previous dose administered at age 24 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 through 50 months who necelved 3 doses before age 12 months or for children at high risk who received 3 doses at any age	
Inactivated poliovirus7	6 weeks	4 weeks <sup>7</sup>	4 weeks <sup>7</sup>	6 months? minimum age 4 years for final dose	
Meningococcal <sup>27</sup>	6 weeks	8 weeks <sup>ts</sup>	See footnote 13	See footnote 13	
Measles, mumps, rubella <sup>9</sup>	12 months	4 weeks			
Varicella <sup>®</sup>	12 months	3 months			
Hepatitis A <sup>rr</sup>	12 months	6 months			
			Persons aged 7 through 18 years		
Tetanus, diphtheria; tetanus, diphtheria, & acellular pertussis	7 years4	4 weeks	4 weeks if first dose of DTeP/DT administered at younger than age 12 months 6 months if first dose of DTaP/DT administered at age 12 months or older and then no further doses needed for catch-up	6 months if first dose of DTaP/DT administered at younger than age 12 months	
Human papillomavirus <sup>12</sup>	9 years		Routine dosing intervals are recommended <sup>sp</sup>	•	
Hepatitis Arr	12 months	6 months			
Hepetitis B <sup>r</sup>	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Inactivated poliovirus?	6 weeks	4 weeks	4 weeks <sup>7</sup>	6 months <sup>7</sup>	
Meningococcal <sup>12</sup>	6 weeks	8 weeks <sup>12</sup>			
Measles, mumps, rubella <sup>8</sup>	12 months	4 weeka			
Varicella®	12 months	3 months if person is younger than age 13 years 4 weeks if person is aged 13 years or older			

NOTE: The above recommendations must be read along with the footnotes of this schedule.

### STATEMENT OF BASIS AND PURPOSE AND SPECIFIC STATUTORY AUTHORITY for Amendments to Proposed Amendments to Rules pertaining to THE INFANT IMMUNIZATION PROGRAM, THE VACCINES FOR CHILDREN PROGRAM, AND THE IMMUNIZATION OF STUDENTS ATTENDING SCHOOL6 CCR 1009-2

June 18, 2014

### **Basis and Purpose.**

Colorado requires all children to be immunized per the vaccine schedule established by Colorado Board of Health (BOH) rule 6 CCR 1009-2, upon school entry. The purpose of the immunization requirements for school entry are to protect students, staff, and the visiting public against vaccine-preventable diseases within schools. Accordingly, Colorado's immunization requirements have contributed to high vaccine coverage and low levels of vaccine preventable disease. The proposed amendments to this rule encompass two objectives. First, the proposed amendments incorporate by reference the 2014 Birth-18 years and Catch-up recommended immunization schedules approved by the Advisory Committee on Immunization Practices (ACIP) for those vaccines already required in this rule - Hepatitis B,

Pertussis/Tetanus/Diphtheria (DTaP), Tetanus/Diphtheria/Pertussis (Tdap), Haemophilus influenza type b (Hib), Pneumococcal Conjugate (PCV), Polio (IPV/OPV), Measles/Mumps/Rubella MMR), and Varicella. No new vaccines are being proposed. Second, the proposed amendments update the rule language to meet current requirements by adding a definition for the Advisory Committee on Immunization Practices (ACIP), alphabetizing existing definitions, adding a list of the diseases for which proof of immunization is required, clarifying the meningococcal vaccine requirements, aligning the rule with federal requirements, updating language regarding the administration fee, and deleting obsolete language.

### Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes: § 25-4-904, C.R.S.

### SUPPLEMENTAL QUESTIONS

### Is this rulemaking due to a change in state statute?

\_\_\_\_\_Yes, the bill number is \_\_\_\_\_; rules are \_\_\_ authorized \_\_\_ required. \_\_X\_\_\_ No

Is this rulemaking due to a federal statutory or regulatory change?

Yes \_\_\_\_\_ Yo Does this rule incorporate materials by reference?

> \_\_X\_\_\_ Yes \_\_\_\_\_ No

Does this rule create or modify fines or fees?

### **REGULATORY ANALYSIS**

for

Proposed Amendments to Rules pertaining to The Infant Immunization Program and The Immunization of Students Attending School 6 CCR 1009-2

June 18, 2014

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

The classes of people affected by the proposed amendments to the rule are children and adolescents immunized against vaccine preventable diseases as required for school attendance, physicians and clinicians who administer vaccines and school nurses and support staff who insure that children are appropriately vaccinated for attendance at Colorado schools. There is no anticipated cost of compliance with the proposed amendments to the rule. The proposed amendments to the rule incorporate the 'best practices' recommended immunization schedules (Birth-18 years and Catch-up) established by the Advisory Committee on Immunization Practices (ACIP) into the required Colorado school immunization rule, for those vaccines already required by this rule. The Advisory Committee on Immunization Practices schedules are standard immunization schedules and guide health care providers who administer vaccines for children and adolescents. As such, reimbursement for immunization is based on these schedules; neither providers nor patients should expect increased immunization costs because of this proposed rule. The other amendments proposed in the rule are for the purposes of clarification and there will not be a burden of increased costs for any class of people.

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.

Changing and clarifying the rules pertaining to children/adolescent immunizations in childcares and schools should have no economic impact upon the affected classes of persons. Aligning the required school immunization schedule with the Advisory Committee on Immunization Practices recommended schedules should optimally protect students from vaccine preventable disease and lessen any confusion about immunization schedules for health care providers and schools. The other amendments proposed in the rule are for the purposes of clarification and would further lessen any confusion about immunization requirements.

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.

There is no anticipated cost of compliance with the proposed amendments to the rule. There will be no anticipated effect on state revenues.

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

Our purpose in making these proposed amendments to the rule are to better protect children/adolescents from vaccine preventable diseases and enhance our collaborative efforts with our partners by providing clarity in the rule.

### Cost Comparison—

The costs of implementing the proposed amendments to the rule – There is no cost of compliance with the proposed amendments to this rule.

The costs of inaction – If the current rule is maintained, it is likely that confusion will continue among providers regarding required vaccines. This confusion could result in "missed opportunities" to vaccinate patients who are in their offices. These "missed opportunities" could lead to an increase in vaccine preventable disease. In the alternative, confusion among providers could result in vaccines being given at the wrong time, and students who are out of compliance with vaccines required for school entry. Any perceived discrepancy between the ACIP recommended immunization schedules that health care providers typically use, and the Colorado Required School Immunization schedule used by schools and child cares has been shown to cause conflict between health care providers and school nurses in many cases. Parents typically get caught in the middle, wanting to honor their health care provider's advice yet also wanting to meet the school immunization requirements.

**Benefit Comparison**—the benefits of implementing the amendments to the rule include:

- Because of perceived discrepancy between the School Required Immunization Schedule and the Advisory Committee on Immunization Practices schedules much confusion and conflict has been experienced between schools, parents, and health care providers. When all entities are following one immunization schedule, all entities will more likely experience agreement and consistency in regards to immunization records for Colorado's children.
- The Advisory Committee on Immunization Practices Recommended Immunization Schedules are the Best Practice Standard for children's immunizations. These schedules are approved by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians and the American College of Obstetricians and Gynecologists.
- The Colorado Immunization Information System incorporates the Advisory Committee on Immunization Practices schedules in its recommender which is now being accessed by health care providers, local public health agencies, child cares and schools in Colorado.
- Reimbursement for vaccines generally flows to those vaccines that meet the Advisory Committee on Immunization Practices Recommended Immunization Schedules.
- The other amendments proposed in the rule are for the purposes of clarification and implementing these changes would bring the rule into compliance with current requirements.

The benefits of inaction include:

- There is no benefit to inaction given that the current rule may cause confusion among vaccine providers, parents and Colorado schools regarding the timing and delivery of required vaccines.
- 5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

The proposed amendments to the rule are not intrusive as aligning the rule with nationally accepted standards provides clarity to immunization providers. Furthermore, the proposed

amendments should better protect children/adolescents against vaccine preventable disease and improve relationships with our immunization partners. The proposed amendments have no anticipated cost.

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

No alternative amendments were considered. The proposed amendments incorporate national recommendations for immunizations, and will provide clarity to immunization providers and parents going forward.

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 to the rules will provide clarity and support the immunization standards set by the Advisory Committee on Immunization Practices. The ACIP recommended immunization schedules have been a gold standard in the administration of children's immunizations for years. The American Association of Pediatrics, the American Academy of Family Physicians and more recently, the American College of Obstetricians and Gynecologists have approved these schedules for the administration of immunizations in their patient populations.

### STAKEHOLDER Comment for Amendments to RULES PERTAINING TO THE INFANT IMMUNIZATION PROGRAM, THE VACCINES FOR CHILDREN PROGRAM, AND THE IMMUNIZATION OF STUDENTS ATTENDING SCHOOL 6 CCR 1009-2

## The following individuals and/or entities were included in the development of these proposed rules:

A stakeholder process (the School Required Immunization Board of Health Work Group) was completed in Spring 2014 and included pediatric, family practice and local public health physicians as well as school nurses, state and local public health, child care representation as well as representation from the Department of Human Services. This group was convened to make recommendations to the Department regarding immunization requirements. Presentations were provided by epidemiologists from the Communicable Disease Division which contributed to the decision making and recommendations being proposed to the Department.

## The following individuals and/or entities were notified that this rule-making was proposed for consideration by the Board of Health:

The Department remains committed to fully engaging its stakeholders during this rulemaking process. Stakeholders that will be engaged include Local Public Health Agencies, Child Care Agencies, Federally Qualified Health Centers, Rural Health Centers, private physician offices and clinics, Colorado Medical Society, School Districts, Colorado Association of School Nurses, Colorado Chapters of the American Academy of Pediatricians, and Family Practice, Colorado Children's Immunization Coalition as well as Local Immunization Coalitions.

<u>On or before the date of publication of the notice in the Colorado Register, the Division</u> sent notice to persons and/or groups considered by the division to be interested parties to the proposed rule-making, and those who have requested notification/ information from the division regarding the proposed rule-making? \_\_\_\_X es \_\_\_\_ No. The Division provided notice on TBD.

# 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 convened a group of immunization experts to review the current Board of Health rules and to discuss immunization topics pertinent to clarify and update required school immunizations for Colorado Students. This group of experts met twice in 2014. Consensus was developed regarding two sets of amendments to the rule. First, the proposed amendments incorporate by reference the 2014 Birth-18 years and Catch-up recommended immunization schedules approved by the Advisory Committee on Immunization Practices (ACIP) for those vaccines already required in this rule - Hepatitis B, Pertussis/Tetanus/Diphtheria (DTaP), Tetanus/Diphtheria/Pertussis (Tdap), Haemophilus influenza type b (Hib), Pneumococcal Conjugate (PCV), Polio (IPV/OPV), Measles/Mumps/Rubella MMR), and Varicella.

The Department is aware that there is some perceived discrepancy between the ACIP recommended immunization schedules, and the Colorado Required School Immunization schedule. These perceived

discrepancies have been known to cause conflict between health care providers and school nurses. Parents typically get caught in the middle, wanting to honor their health care provider's advice yet also wanting to meet the school immunization requirements.

The CDC sets the U.S. childhood immunization schedule based on recommendations from the ACIP. This recommended schedule is also approved by the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists. The ACIP schedules are the Best Practice Standard for children's immunizations in the United States. As such, the ACIP schedules are followed by providers at local public health agencies, private health care providers and other clinicians. Furthermore, clinical decision-making tools, such as the "recommender" in the Colorado Immunization Information System (CIIS), incorporate the ACIP schedules. The ACIP schedules are updated and posted annually on the CDC website as well as the Colorado Immunization Section's web site which provides easy access to the schedules.

Therefore, in order to eliminate confusion for clinicians, schools, and child cares, and to provide a bestpractice immunization schedule for required immunizations in schools, the Colorado Immunization Section proposes incorporating by reference the Birth-18 years and Catch-up ACIP recommended immunization schedules into 6 CCR 1009-2. This proposed amendment ensures that children will be optimally immunized against vaccine preventable diseases and the confusion about the two schedules will be eliminated. No new vaccines are being proposed.

Second, the proposed amendments update the rule language to meet current requirements by adding a definition for the Advisory Committee on Immunization Practices (ACIP), adding a list of the diseases for which proof of immunization is required, clarifying the meningococcal vaccine requirements, aligning the rule with federal requirements, updating language regarding the administration fee, and deleting obsolete language.

## Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

There are no HEEJ impacts associated with this rule; the proposed amendments impact Colorado children equally and equitably. The Advisory Committee on Immunization Practices (ACIP) schedules are the Best Practice Standard for children's immunizations in the United States. The ACIP is a group of medical and public health experts who make recommendations to effectively schedule vaccines in the effort to control diseases in the United States. The ACIP meetings include discussions regarding vaccine research and scientific data related to vaccine effectiveness and safety, clinical trial results, and manufacturer's labeling or package insert information. Outbreaks of vaccine-preventable disease or changes in vaccine supply, such as vaccine shortages, also are reviewed during these meetings. The recommendations include the age(s) when the vaccine should be given, the number of doses needed, the amount of time between doses, and precautions and contraindications. As such, the ACIP schedules are followed by providers at local public health agencies, and private health care providers throughout the United States.

### 1 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2 Disease Control and Environmental Epidemiology Division

### 3THE INFANT IMMUNIZATION PROGRAM, VACCINES FOR CHILDREN PROGRAM, AND4IMMUNIZATION OF STUDENTS ATTENDING SCHOOL

5 6 CCR 1009-2

6

### 7 I. Definitions

- 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. § 2L7A).
- 12 B. CHILD ANY STUDENT LESS THAN 18 YEARS OF AGE.
- C. COLLEGE 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 BY CORRESPONDENCE ONLY.
- 17D.DOSE A MEASURED QUANTITY OF AN IMMUNIZING AGENT; QUANTITY AND18FREQUENCY OF ADMINISTRATION DETERMINED BY RECOGNIZED HEALTH19AUTHORITIES AND THE MANUFACTURER OF EACH AGENT. (PARTIAL, "SPLIT," HALF OR20FRACTIONATED "DOSES" ARE NOT ACCEPTABLE FOR CERTIFICATION.)
- 21E.EMANCIPATED STUDENT ANY STUDENT WHO HAS REACHED AGE 18; A LAWFULLY22MARRIED CHILD OF ANY AGE; A CHILD 15 YEARS OF AGE OR OLDER WHO IS MANAGING23HIS/HER OWN FINANCIAL AFFAIRS AND WHO IS LIVING SEPARATE AND APART FROM24HIS/HER PARENT.
- 25F.IMMUNIZATION TRACKING SYSTEM A COMPREHENSIVE IMMUNIZATION TRACKING26SYSTEM ESTABLISHED BY THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT27PURSUANT TO SECTION 25-4-1705(E), C.R.S.
- 28G.INDIGENT CHILD ANY CHILD WHOSE PARENT CANNOT AFFORD TO HAVE THE CHILD29IMMUNIZED OR IF EMANCIPATED, WHO CANNOT HIMSELF/HERSELF AFFORD30IMMUNIZATION AND WHO HAS NOT BEEN EXEMPTED.
- 31H.INFANT ANY CHILD UP TO TWENTY-FOUR MONTHS OF AGE OR ANY CHILD ELIGIBLE3232FOR VACCINATION AND ENROLLED UNDER THE COLORADO MEDICAL ASSISTANCE3333ACT, ARTICLE 4 OF TITLE 26, C.R.S.
- 34 I. IN-PROCESS STUDENT A STUDENT MAY BE CONSIDERED IN-PROCESS IF:

35	1.	WITHIN FOURTEEN DAYS AFTER RECEIVING DIRECT PERSONAL NOTIFICATION
36		THAT THE CERTIFICATE IS NOT UP-TO DATE ACCORDING TO THE
37		REQUIREMENTS OF THE STATE BOARD OF HEALTH, THE PARENT OR
38		EMANCIPATED STUDENT SUBMITS DOCUMENTATION THAT THE NEXT
39		REQUIRED IMMUNIZATION HAS BEEN GIVEN AND A SIGNED WRITTEN PLAN FOR
40		OBTAINING THE REMAINING REQUIRED IMMUNIZATIONS. THE SCHEDULING OF

41 42 43 44 45 46 47 48 49		IMMUNIZATIONS IN THE WRITTEN PLAN SHALL FOLLOW MEDICALLY RECOMMENDED MINIMUM INTERVALS CONSISTENT WITH THE U.S. PUBLIC HEALTH SERVICE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES, AMERICAN ACADEMY OF PEDIATRICS, OR THE VACCINE MANUFACTURER'S PACKAGE INSERT STATEMENT. IF THE STUDENT DOES NOT FULFILL THE PLAN, THE STUDENT SHALL BE SUSPENDED OR EXPELLED FROM SCHOOL FOR NON- COMPLIANCE AS NOTED IN 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.
50 51 52 53 54 55 56 57 58 59 60 61		2. WITH REGARDS TO COLLEGE OR UNIVERSITY STUDENTS AS DEFINED IN SECTION I PROVISION C AND O, THE STUDENT MUST PRESENT TO THE APPROPRIATE 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 REGISTER 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 YEARS OF AGE OR OLDER.
62 63	J.	PARENT - THE PERSON OR PERSONS WITH PARENTAL OR DECISION-MAKING RESPONSIBILITIES FOR A CHILD.
64 65 66	K.	PRACTITIONER - A DULY LICENSED PHYSICIAN, ADVANCED PRACTICE NURSE, OR OTHER PERSON WHO IS PERMITTED AND OTHERWISE QUALIFIED TO ADMINISTER VACCINES UNDER THE LAWS OF THIS STATE
67 68 69 70 71 72 73 74 75 76 77	L.	SCHOOL - A PUBLIC, PRIVATE, OR PAROCHIAL NURSERY SCHOOL, DAY CARE CENTER, CHILD CARE FACILITY, FAMILY CHILD CARE HOME, FOSTER CARE HOME, HEAD START PROGRAM, KINDERGARTEN, OR ELEMENTARY OR SECONDARY SCHOOL THROUGH GRADE TWELVE, OR A COLLEGE OR UNIVERSITY. "SCHOOL" DOES NOT INCLUDE A PUBLIC SERVICES SHORT-TERM CHILD CARE FACILITY AS DEFINED IN SECTION 26-6- 102 (6.7), C.R.S., A GUEST CHILD CARE FACILITY AS DEFINED IN SECTION 26-6- 102 (6.7), C.R.S., A GUEST CHILD CARE FACILITY AS DEFINED IN SECTION 26-6- 102 (6.7), C.R.S., OR COLLEGE OR UNIVERSITY COURSES WHICH ARE OFFERED OFF-CAMPUS; OR ARE OFFERED TO NONTRADITIONAL ADULT STUDENTS, AS DEFINED BY THE GOVERNING BOARD OF THE INSTITUTION; OR ARE OFFERED AT COLLEGES OR UNIVERSITIES WHICH DO NOT HAVE RESIDENCE HALL FACILITIES.
78 79 80	M.	SCHOOL HEALTH AUTHORITY - AN INDIVIDUAL WORKING FOR OR ON BEHALF OF THE CHILD CARE FACILITY OR SCHOOL WHO IS KNOWLEDGEABLE ABOUT CHILDCARE/SCHOOL IMMUNIZATIONS.
81 82	N.	SCHOOL OFFICIAL - THE SCHOOL'S CHIEF EXECUTIVE OFFICER OR ANY PERSON DESIGNATED BY HIM/HER AS HIS/HER REPRESENTATIVE.
83	Ο.	STUDENT - ANY PERSON ENROLLED IN A COLORADO SCHOOL AS DEFINED IN I (I)
84 85 86	P.	VACCINES FOR CHILDREN (VFC) PROGRAM - A FEDERALLY FUNDED PROGRAM FOR THE PURCHASE AND DISTRIBUTION OF PEDIATRIC VACCINES TO PROGRAM- REGISTERED PROVIDERS FOR THE IMMUNIZATION OF VACCINE-ELIGIBLE CHILDREN

87 88 89 90 91 92 93 94	Q.	VFC-ELIGIBLE CHILDREN - FEDERALLY PURCHASED VACCINES UNDER THE VFC PROGRAM WILL BE MADE AVAILABLE TO CHILDREN WHO ARE 18 YEARS OF AGE OR YOUNGER AND WHO ARE ELIGIBLE FOR MEDICAID OR WHO ARE NOT INSURED UNDER ANY FORM OF HEALTH INSURANCE OR WHO ARE NOT INSURED WITH RESPECT TO THE VACCINE AND WHO ARE ADMINISTERED PEDIATRIC VACCINES BY A FEDERALLY QUALIFIED HEALTH CENTER (FQHC) OR IN A RURAL HEALTH CLINIC OR WHO ARE AMERICAN INDIANS/ALASKAN NATIVES, AS DEFINED IN SECTION 4 OF THE INDIAN HEALTH CARE IMPROVEMENT ACT.
95 96 97	A	Emancipated student - Any student who has reached age 18; 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.
98 99	₿	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.
100 101 102	<del>C.</del>	College 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 by correspondence only.
103	Ð	Child - Any student less than 18 years of age.
104	E.	Parent - The person or persons with parental or decision-making responsibilities for a child.
105 106	F	School official - The school's chief executive officer or any person designated by him/her as his/her representative.
107 108	<del>G.</del>	School health authority - an individual working for or on behalf of the child care facility or school who is knowledgeable about childcare/school immunizations.
109	H	Student - Any person enrolled in a Colorado school as defined in I (I)
$     \begin{array}{r}       110\\       111\\       112\\       113\\       114\\       115\\       116\\       117     \end{array} $	ł	School - A public, private, or parochial nursery school, day care center, child care facility, family child care home, foster care home, Head Start program, kindergarten, or elementary or secondary school through grade twelve, or a college or university. "School" does not include a public services short-term child care facility as defined in section 26-6-102 (6.7), C.R.S., a guest child care facility as defined in section 26-6-102 (6.7), C.R.S., a guest child care facility as defined in section 26-6-102 (6.7), c.R.S., a guest child care facility as defined in section 26-6-102 (5), c.R.S., a ski school as defined in section 26-6-103.5 (6), C.R.S., or college or university courses which are offered off-campus; or are offered to nontraditional adult students, as defined by the governing board of the institution; or are offered at colleges or universities which do not have residence hall facilities.
118	<del>J.</del>	In process student A student may be considered in process if:
119 120 121 122 123 124 125 126 127 128		1. Within fourteen days after receiving direct personal notification that the certificate is not up to date according to the requirements of the state board of health, 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 U.S. Public Health Service Advisory Committee on Immunization Practices, American Academy of Pediatrics, or the vaccine manufacturer's package insert statement. If the student does not fulfill the plan, the student shall be suspended or expelled from school for non-compliance as noted in 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.

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129	2. With regards to college or university students as defined in Section I Provision D and I,	
130	the student must present to the appropriate official of the school either (i) a signed written	
131	authorization requesting local health officials to administer required immunizations or (ii) a plan	
132	for receipt of the required immunization or the next required immunization in a series within either	-
133	30 days or the medically approved minimum interval. If this does not occur, the college or	
134	university student will not be allowed to register for the current term or session. Such written	
135	authorizations and plans must be signed by one parent or guardian or the emancipated student o	r
136	the student eighteen years of age or older.	
137	K. Dose - A measured quantity of an immunizing agent; quantity and frequency of administration	
138	determined by recognized health authorities and the manufacturer of each agent. (Partial, "split,"	
139	half or fractionated "doses" are not acceptable for certification.)	
140	L. Practitioner - A duly licensed physician, advanced practice nurse, or other person who is	
141	permitted and otherwise qualified to administer vaccines under the laws of this state.	
142	M. Infant - Any child up to twenty-four months of age or any child eligible for vaccination and	
143	enrolled under the Colorado Medical Assistance Act, article 4 of title 26, C.R.S.	
144	N. Immunization Tracking System - A comprehensive immunization tracking system established by	¥
145	the Department of Public Health and Environment pursuant to Section 25-4-1705(E), C.R.S.	, 
146	O. Vaccines for Children (VFC) Program - A federally funded program for the purchase and	
147	distribution of pediatric vaccines to program-registered providers for the immunization of vaccine-	•
148	eligible children	
149	P. VFC-Eligible Children - Federally purchased vaccines under the VFC Program will be made	
150	available to children who are 18 years of age or younger and who are eligible for Medicaid or who	<del>)</del>
151	are not insured under any form of health insurance or who are not insured with respect to the	
152	vaccine and who are administered pediatric vaccines by a Federally Qualified Health Center	
153	(FQHC) or in a rural health clinic or who are American Indians/Alaskan Natives, as defined in	
154	section 4 of the Indian Health Care Improvement Act.	
155	II. Exemptions From Immunization	
150		

- 156 It is the responsibility of the parent(s) to have his or her child immunized unless the child is exempted. A 157 student may be exempted from receiving the required immunizations in the following manner:
- 158A.Medical exemption By submitting to the student's school a Certificate of Immunization with the159statement of medical exemption signed by an advanced practice nurse or physician licensed to160practice medicine or osteopathic medicine in any state or territory of the United States indicating161that the physical condition of the student is such that immunizations would endanger his/her life162or health or is medically contraindicated due to other medical conditions.
- 163B.Religious exemption By submitting to the student's school a Certificate of Immunization with the<br/>statement of religious exemption signed by the parent(s) or the emancipated student indicating<br/>that the parent(s) or emancipated student is an adherent to a religious belief whose teachings are<br/>opposed to immunizations.
- 167C.Personal belief exemption By submitting to the student's school a Certificate of Immunization168with the statement of personal exemption signed by the parent(s) or the emancipated student169indicating that the parent(s) or emancipated student has a personal belief that is opposed to170immunizations.

- 171<br/>172D.In the event of an outbreak of disease against which immunization is required, no exemption or<br/>exception from immunization shall be recognized and exempted persons may be subject to<br/>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 <del>II(A-C)</del>SECTION II, PROVISIONS A THROUGH C.
- 176F.If the school chooses to use the immunization tracking system to monitor compliance with the177school law, and the parent(s) or student submits an exemption, the school must submit the178exemption information to the immunization tracking system.
- G. A student who is 11 years of age or greater may be exempt from the three-dose requirement for hepatitis b vaccination if the student provides written documentation from a licensed physician that the student, when aged 11 to 15 years, has received two doses of Recombivax HB using the adult dose (1.0 ml containing 10 µg of hepatitis b surface antigen), with the second dose given 4 to 6 months after the first dose. The specific name of the vaccine, the exact dose of antigen per injection, and the dates of administration must be included as part of the documentation.
- 185 III. Minimum Immunization Requirements
- 186 The immunizations required for compliance with the school entry immunization law are outlined in Tables

187 <u>1 and 2. To attend school, a student must have an age- or grade-appropriate Certificate of Immunization.</u>

188 Initial certification does not exempt a student from meeting subsequent age or grade requirements. The

189 minimum number of doses required by level of school/age of student are listed in Table 1. The timetable 190 for implementation of requirements by specific grade and school year for varicella vaccine and tetanus.

190 for implementation of requirements by specific grade and school year for varicella vaccine and tetanus, 191 diphtheria, and pertussis vaccine are listed in Table 2. Grades K to 5 and Grades 6 to 12 are grouped in

191 applituenta, and perfussion vaccine are instead in rapide 2. Grades R to 9 and Grades 0 to 12 are grouped in 192 Table 1, but a student in a particular grade within these groups is not required to have the minimum

193 number of doses of varicella vaccine and tetanus, diphtheria, and pertussis vaccine prior to the school

- 194 year listed in Table 2.
- A. To attend school, a student must have an age- or grade-appropriate Certificate of Immunization.
   Initial certification does not exempt a student from meeting subsequent age or grade
   requirements. THIS CERTIFICATE MUST DEMONSTRATE IMMUNIZATION AGAINST THE
   FOLLOWING DISEASES:
- 199 1. HEPATITIS B
- 200 2. PERTUSSIS
- 201 3. TETANUS
- 202 4. DIPHTHERIA
- 203 5. HAEMOPHILUS INFLUENZA TYPE B (HIB)
- 204 6. PNEUMOCOCCAL DISEASE
- 205 7. POLIO
- 206 8. MEASLES
- 207 9. MUMPS
- 208 10. RUBELLA

RQ

#### 209 11. VARICELLA

- B. THE MINIMUM NUMBER OF DOSES REQUIRED BY LEVEL OF SCHOOL/AGE OF STUDENT IS
  SET FORTH IN THE 2014 BIRTH 18 RECOMMENDED IMMUNIZATION SCHEDULE OR THE
  2014 CATCH-UP IMMUNIZATION SCHEDULE OF THE ADVISORY COMMITTEE ON
  IMMUNIZATION PRACTICES (ACIP).
- 214 1. THE 2014 ACIP BIRTH-18 YEARS RECOMMENDED IMMUNIZATION SCHEDULE 215 (SCHEDULE) IS INCORPORATED BY REFERENCE FOR ONLY THOSE VACCINES 216 REQUIRED TO PREVENT THE DISEASES LISTED IN SECTION III, PROVISION A. 217 OTHER IMMUNIZATIONS INCLUDED IN THE ACIP RECOMMENDATIONS ARE NOT 218 REQUIRED. THIS SCHEDULE IS SET FORTH IN MORBIDITY AND MORTALITY 219 WEEKLY REPORTS (MMWR) FEBRUARY 7, 2014 VOLUME 63 (05), AND POSTED 220 ON THE CENTERS FOR DISEASE CONTROL AND PREVENTION WEBSITE AT: 221 HTTP://WWW.CDC.GOV/VACCINES/SCHEDULES/DOWNLOADS/CHILD/0-18YRS-222 SCHEDULE.PDF OR ON THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND 223 ENVIRONMENT WEBSITE AT [WWW.COLORADOIMMUNIZATIONS.COM], AND, ARE 224 AVAILABLE FOR PUBLIC INSPECTION DURING REGULAR BUSINESS HOURS AT 225 THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT, 4300 226 CHERRY CREEK DRIVE SOUTH, DENVER, COLORADO 80246. COPIES OF THE 227 RECOMMENDED SCHEDULES ARE AVAILABLE FROM THE COLORADO 228 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT FOR A REASONABLE 229 CHARGE THAT COMPORTS WITH THE DEPARTMENT'S RECORD REQUEST 230 PRACTICES. THIS RULE DOES NOT INCLUDE ANY LATER AMENDMENTS OR 231 EDITIONS OF THE ACIP SCHEDULE.
- 232 2. IN ADDITION, THE 2014 ACIP CATCH-UP IMMUNIZATION SCHEDULE IS 233 INCORPORATED BY REFERENCE FOR THOSE CHILDREN NOT FULLY IMMUNIZED 234 AND ONLY FOR THOSE VACCINES REQUIRED TO PREVENT THE DISEASES 235 LISTED IN SECTION III, PROVISION A. OTHER IMMUNIZATIONS INCLUDED IN THE 236 ACIP RECOMMENDATIONS ARE NOT REQUIRED. THIS RECOMMENDED 237 SCHEDULE IS SET FORTH IN MORBIDITY AND MORTALITY WEEKLY REPORTS 238 (MMWR) FEBRUARY 7, 2014 VOLUME 63 (05), AND POSTED ON THE CENTERS 239 FOR DISEASE CONTROL AND PREVENTION WEBSITE AT 240 HTTP://WWW.CDC.GOV/VACCINES/SCHEDULES/DOWNLOADS/CHILD/CATCHUP-241 SCHEDULE-PR.PDF OR ON THE COLORADO DEPARTMENT OF PUBLIC HEALTH 242 AND ENVIRONMENT WEBSITE AT [WWW.COLORADOIMMUNIZATIONS.COM], AND, 243 ARE AVAILABLE FOR PUBLIC INSPECTION DURING REGULAR BUSINESS HOURS 244 AT THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT, 245 4300 CHERRY CREEK DRIVE SOUTH, DENVER, COLORADO 80246. COPIES OF 246 THE RECOMMENDED SCHEDULES ARE AVAILABLE FROM THE COLORADO 247 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT FOR A REASONABLE 248 CHARGE THAT COMPORTS WITH THE DEPARTMENT'S RECORD REQUEST 249 PRACTICES. THIS RULE DOES NOT INCLUDE ANY LATER AMENDMENTS OR 250 EDITIONS OF THE ACIP CATCH-UP SCHEDULE.
- C. INFORMATION CONCERNING MENINGOCOCCAL DISEASE AND THE MENINGOCOCCAL
   VACCINE SHALL BE PROVIDED TO EACH NEW COLLEGE OR UNIVERSITY STUDENT, OR IF
   THE STUDENT IS UNDER 18 YEARS, TO THE STUDENT'S PARENT OR GUARDIAN. IF THE
   STUDENT DOES NOT OBTAIN A VACCINE, A SIGNATURE MUST BE OBTAINED FROM THE
   STUDENT OR IF THE STUDENT IS UNDER 18 YEARS, THE STUDENT'S PARENT OR
   GUARDIAN INDICATING THAT THE INFORMATION WAS REVIEWED.
- D. The timetable for implementation of requirements by specific grade and school year for varicella
   vaccine and tetanus, diphtheria, and pertussis vaccine are listed in Table 2. Grades K to 5 and
   Grades 6 to 12 are grouped in Table 1, but a student in a particular grade within these groups is not

required to have the minimum number of doses of varicella vaccine and tetanus, diphtheria, and
 pertussis vaccine prior to the school year listed in Table 2.IV. Examination and Audit of School
 Immunization Records

### 263 IV. Examination and Audit of 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
   Certificate of Immunization pursuant to paragraph I(I)(1) SECTION I, PROVISION I.1 of the rules,
   the student shall be suspended or expelled pursuant to Section 25-4-907, C.R.S.
- 271B.If the parent(s) or emancipated student was not informed by a direct personal notification of the272immunizations required and alternatives for compliance with the law, the school shall notify the273parent(s) or emancipated student within 7 calendar days of the finding and the student shall: a)274provide proof of immunization within fourteen days, b) continue as an in-process student, c) verify275that the student is exempt, or d) the student shall be suspended or expelled pursuant to Section27625-4-907, C.R.S.
- 277 \*\*\*\*\*

### 278 VI. Certification of Immunization

- 279A.An official Certificate of Immunization or an APPROVED Alternate Certificate of Immunization that<br/>has been approved by the Department of Public Health and Environment shall include one of the<br/>following forms of documentation that include the dates and types of immunizations administered<br/>to a student or the dates and types of exemption taken:
- 2831.A paper document that includes information transferred from the records of a licensed284physician, registered nurse, or public health official; or
- 2852.An electronic file or hard copy of an electronic file provided to the school directly from the286immunization tracking system established pursuant to Section 25-4-1705(5)(e), C.R.S. or287from a software program approved by the Department of Public Health and Environment.
- 288BAny immunization record (original or copy) provided by a physician licensed to practice medicine289or osteopathic medicine in any state or territory of the United States, registered nurse, or public290health official may be accepted by the school official as proof of immunization. The information is291to be verified by the school official and transferred to an official Colorado Certificate of292Immunization. The Department of Public Health and Environment shall provide guidance to293schools, licensed physicians, registered nurses, and local health agencies regarding the294acceptability of vaccination received outside the United States.
- C. A physician, nurse, or school health authority shall sign the appropriate section of the Certificate
   of Immunization when the child has met all immunization requirements.
- 297<br/>298D.Schools shall have on file an official Certificate of Immunization for every student enrolled. The<br/>Certificate of Immunization will be kept apart from other school records. When a student<br/>withdraws, transfers, or is promoted to a new school, the school official shall return the Certificate<br/>of Immunization to the parent(s) or emancipated student upon request or transfer it with the<br/>student's school records to the new school. Upon a college or university student's request, the<br/>Certificate of Immunization shall be forwarded as specified by the student.

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### 304 IX. Purchase, Storage, and Distribution of Vaccines

As necessary to comply with Section 25-4-905, C.R.S., the Department of Public Health and Environment
 shall assure the purchase, storage, and distribution of the vaccines included in, but not limited to, Table 1
 of these rules.

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### 309 XI. Fee for the Administration, Reporting, and Tracking of Vaccine

310 This rule applies to immunizations purchased by CDPHE that are recommended by the Advisory

311 Committee on Immunization Practices of the U.S. Department of Health and Human Services and

- 312 provided to Colorado practitioners.
- 313A.Practitioners may charge up to THE CENTERS FOR MEDICARE AND MEDICAID SERVICES314MAXIMUM REGIONAL FEE FOR THE ADMINISTRATION OF VACCINE. an administration fee315up to twenty-one dollars and sixty-eight cents per dose. These fees apply to all vaccines316purchased by CDPHE, including but not limited to the Infant Immunization Program, the Vaccines317for Children Program, and Immunization of Children Attending School.
- 318B.A vaccine recipient may not be denied vaccine provided by CDPHE because of inability to pay<br/>the administration fee.
- 320 C. If a practitioner's vaccine administration costs are less than twenty-one dollars and sixty-eight 321 cents, then they may only charge up to that lesser amount.
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### Table 1. MINIMUM NUMBER OF DOSES REQUIRED FOR CERTIFICATE OF IMMUNIZATION

326

### Approved for the 2013-14 School Year

327

		Level of School/Age of Student													
<b>VACCINE</b> <sup>a</sup>	Child Care 2-3 mos	Child Care 4-5 mos	Child Care 6-7 mos	Child Care 8-11 mos	Child Care 12-14 mos	Child Care 15 – 18 mos	Child Care 19 - 23 mos	Pre school 2-4 yrs	<del>K Entry</del> 4 <del>-6</del> <del>Yrs</del>	Grades K to 5 5–10 yrs	Grades 6 to 12 11-18+ yts	College			
Hepatitis B <sup>+</sup>	1	2			3				3	3	3				
Pertussis/ Tetanus/ Diphtheria	4	2	;	3		4			<del>5/4_<sup>b</sup></del>	<del>5/4 <sup>b c</sup></del>	<del>5/6-<sup>e d</sup></del>				
Haemophilus influenzae type b (Hib) <sup>j</sup>	4	2	2	<del>3/2</del>	4 <del>/3/2</del>	4 <del>/3/2/1</del>	4 <del>/3/2/1</del>	4 <del>/3/2/1</del>							
Pneumococcal	1	2	3	/ <del>2</del>		4/3	/2/1								

Conj	ugate *						see footnote	<del>ə k</del>						
Polio <sup>e</sup>		1 2 3				3			4/3- <sup>‡</sup>	4/3 <sup>-‡</sup>	4/3 <sup>‡</sup>			
Meas Mum Rube	<del>ps/</del>					1	see foot	<del>see footnote g</del>		<u>2</u> <sup>h</sup>	<u>2</u> <sup>h</sup>	<del>2</del> *		
Vario	ella <sup>m</sup>					1	see foot	note n	2 <sup>n</sup>	2/1 <sup>ª</sup>	2/1 <sup>n</sup>			
Meni	ngococcal											-€		
								•		<u>U</u>	•			
a	Vaccine d	loses adı	ninistered	l no mor	e than 4	davs befor	the minimum	interval or ac	ne are to be	counted a	as valid.			
<del>b</del>	Five dose given at 4 be at leas dose 3 an years of a	es of perte 48 month at 4 week ad dose 4 age (dose	ussis, teta is of age c s betweer and at le s 4 may be	inus, and or older ( or dose 1 ast 6 mc or given a	d diphthe (i.e., on o and dos onths bet at 12 mor	ria vaccine or after the e 2, at leas ween dose oths of age	s are required a lth birthday) in t 4 weeks betw 4 and dose 5. provided there	at school ent which case ( een dose 2 a The final doo is at least 4	ry in Colora only 4 doses and dose 3, se must be months bety	do unless s are requi at least 4 i given no s ween dose	the 4th doo red. There months be ooner thar	e mus tweer 1 4		
						0	of 4 years, no a							
e							olorado who ha ning vaccine ([							
	includes a	at least 4	weeks be	etween d	ose 1 an	d 2 and at	east 6 months this tetanus/di	between dos	se 2 and 3.	A student	7 years of	f age		
	requireme	ent for 6 <sup>th</sup>	through 1	12 <sup>th</sup> grad	<del>es</del>	oompick		Shahend requ	anement wi		met the 1	uup		
d		equirement for 6 <sup>th</sup> through 12 <sup>th</sup> grades One dose of Tdap is required for students 11 – 12 years of age at 6 <sup>th</sup> grade entry, regardless of the interval since the last lose of DTaP_DT_or Td_If a student has received a Tdap between the ages of 7 – 10 yrs_as noted in footnote "c." they												
	have met	dose of DTaP, DT, or Td. If a student has received a Tdap between the ages of 7 – 10 yrs, as noted in footnote "c," they have met the Tdap requirement for 6 <sup>th</sup> through 12 <sup>th</sup> grades.												
е	For polio,	in lieu of	<sup>:</sup> immuniza	ation, wri	itten evid	lence of a l	aboratory test s	howing imm	unity is acce	eptable.				
f	<del>or older (i</del> <del>between (</del> dose 4. T	<del>.e., on or</del> dose 1 ai he final c	after the nd dose 2 lose must	4th birth , at least be giver	day) in w 4 weeks 1 no soor	/hich case between oner than 4 y	in Colorado un only 3 doses ar lose 2 and dos rears of age. M od prior to July	e required. T e 3 and at lea linimum age	There must t ast 6 month	oe at least s between	4 weeks dose 3 an	d		
<del>g</del>	For meas acceptabl administe	les, murr le for the red at 12 liccine an	nps, and ru specific d months c	ubella, in lisease to of age or	lieu of ir ested. Th older (i.e	mmunizatio ne 1st dose e., on or aff	n, written evide of measles, mi er the 1st birthe mumps vaccine	nce of a labo umps, and ru lay) to be ac	ibella vaccir ceptable. D	ne must ha	ive been ion of 1 do			
h	The 2nd of calendar (				measles	<del>s, mumps,</del> ⊣	and rubella vac	cine must ha	ive been ad	ministered	at least 28	3.		
ii	Measles,	mumps,	and rubel	la vaccir	ne is not i	required fo	college studer	its born befo	re January <sup>-</sup>	1 <del>, 1957.</del>				
j	administe began the 12 month	ered. If ar series to s of age	i <del>y dose wa</del> efore 12 i or older (i.	as given months c .e., on or	at 15 mc of age, 3 r after the	onths of ag doses are 1st birthd	the student's cu or older, the F required of which ay). If the 1st do , no new or add	lib vaccine r ch at least 1 ose was give	equirement dose must f m at 12 to 1	is met. Fo have been 4 months (	r students administe	who red a		
<u>k</u>	The numb	per of pro	eumococc was adm	al conjug	gate vace I. If the 1	cine (PCV) <sup>st</sup> dose was	doses required administered t	depends on before 6 mor	the student	t's current the child is	age and th	<del>ie ag</del>		
	months of of age. F was giver	f age, the or any st at 12 to	child is re udent who 23 month	equired 1 oreceivens of age	to receive ed the 3 <sup>rd</sup> e, 2 dosee	e 2 doses, dose on o s are requir	between 12 – 1 wo months apa after the first b ed. If any dose age is 5 years	art and an ad rirthday, a 4 <sup>#</sup> ∺was given a	Iditional dos <sup>1</sup> dose is not at 24 monthe	e betweer required. s of age th	⊢12 <mark>—</mark> 15 r If the 1 <sup>st</sup> c rough 4 ye	lose ears o		
Į	dose is to after the f	be admi	nistered a and at lea	at least 4 ast 8 wee	weeks a eks after	fter the firs	of a laboratory t dose, and the dose. The find or to 6 months	third dose is al dose is to	to be admi	nistered at	least 16 v	veek		
m	For varice						ng immunity or							

n

If the second dose of varicella vaccine was administered to a child before 13 years of age, the minimum interval between dose 1 and dose 2 is three months, however, if the second dose is administered at least 28 days following the first dose, the second dose does not need to be repeated. For a child who is 13 years of age or older, the second dose of varicella vaccine must have been administered at least 28 calendar days after the 1<sup>st</sup> dose. See Table 2 for the school years/grade levels that the 1st and 2<sup>nd</sup> doses of varicella will be required.

Information concerning meningococcal disease and the meningococcal vaccine shall be provided to each new student or if the student is under 18 years, to the student's parent or guardian. If the student does not obtain a vaccine, a signature must be obtained from the student or if the student is under 18 years, the student's parent or guardian indicating that the information was reviewed.

## Table 2. TIMETABLE FOR IMPLEMENTATION OF REQUIREMENTS FOR SELECTED IMMUNIZATIONS FOR GRADES K TO 12

Refer to Table 1 for the minimum number of doses required for a particular grade level. Table 2 shows the year of implementation for a requirement from Table 1 and is restricted to varicella vaccine dose 1 (Var1) and dose 2 (Var2). Requirements and effective dates for other vaccines are listed in Table 1. In this table, after a vaccine is required for grades K to 12, it is no longer shown, but the requirements listed in Table 1 continue to apply.

School Year						1	Grade Leve	ł					
	ĸ	4	2	3	4	5	6	7	8	9	<del>10</del>	<del>11</del>	<del>12</del>
2012-13 (Var1 required for grades K to 12)	<del>Var2</del>	<del>Var2</del>	<del>Var2</del>	<del>Var2</del>	<del>Var2</del>	<del>Var2</del>	<del>Var1</del>						
<del>2013-1</del> 4	<del>Var2</del>	Var2	Var2	<del>Var2</del>	Var2	Var2	Var2	Var1	Var1	Var1	Var1	Var1	Var1
<del>2014-15</del>	<del>Var2</del>	<del>Var2</del>	Var2	<del>Var2</del>	<del>Var2</del>	Var2	Var2	Var2	Var1	Var1	Var1	Var1	Var1
<del>2015-16</del>	<del>Var2</del>	<del>Var1</del>	<del>Var1</del>	<del>Var1</del>	Var1								
<del>2016-17</del>	<del>Var2</del>	<del>Var1</del>	<del>Var1</del>	<del>Var1</del>									
<del>2017-18</del>	<del>Var2</del>	<del>Var1</del>	<del>Var1</del>										
<del>2018-19</del>	<del>Var2</del>	<del>Var1</del>											
2019-20 (Var2 required for grades K to 12)	<del>Var2</del>	Var2	<del>Var2</del>	<del>Var2</del>	Var2	<del>Var2</del>	<del>Var2</del>	<del>Var2</del>	<del>Var2</del>	<del>Var2</del>	Var2	Var2	<del>Var2</del>