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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205

Agency/Board/Commission:	Health
Division:	Communicable and Environmental Disease Services
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Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1200-14-01	Communicable and Environmental Diseases
Rule Number	Rule Title
1200-14-01-.29	Immunization Against Certain Diseases Prior to School Attendance in Tennessee

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

1200-14-01-.29 Immunization Against Certain Diseases Prior To School Attendance In Tennessee, is amended by deleting it in its entirety, and substituting instead the following so that as amended, the new 1200-14-01-.29 shall read:

- (1) Every nursery school, day care center, Head Start center, Kindergarten, or other pre-school, day care or grades Kindergarten through twelve of any public, private, or church related school shall obtain proof of adequate immunization against diphtheria, measles (rubeola), pertussis (whooping cough), poliomyelitis, rubella, mumps, hepatitis B and tetanus on the form prescribed by the Commissioner (unless otherwise exempted by law) prior to admitting a child. It shall be the duty of the school to enforce the provisions of this regulation, subject to the exemptions as set out in T.C.A. §49-6-5001(b).
- (2) The state and county health departments are authorized to provide proof of immunization to the admissions officer of any school in the state of Tennessee. For the purpose of this subsection, "school" shall include nursery schools, Kindergartens, other pre-schools, day care centers and facilities, after school day care facilities, grades Kindergarten through twelve of any public, private or church-related schools, vocational schools, technical schools, colleges and universities. The state and county health departments are further authorized to provide proof of immunization to physicians who are evaluating a school-aged patient's immunization status.
- (3) The Department shall publish an official Certificate of Immunization, ("Certificate"). A Certificate may be signed by an individual licensed by the Board of Medical Examiners, the Board of Osteopathic Examiners, or an Advanced Practice Nurse licensed by the Board of Nursing (hereinafter "providers") or by a local health department. The Certificate may include space to record vaccinations which are routinely recommended but not required by law.

Certificates shall be available online to authorized users of the Tennessee Web Immunization System (TWIS) or in hard copy to providers from local health departments or from the Department's central office.

- (4) For each disease identified in these rules, the Department adopts the recommended immunization schedule or the "catch-up" immunization schedule (when applicable), published by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC). An individual shall be presumed to be immunized against a particular disease when the individual has been immunized in a manner consistent with the recommendations of ACIP for that disease. The Department shall make the schedule available on its website and at local health departments, and shall revise the schedule from time to time in accordance with revisions published by ACIP, and shall publish the effective dates of any revisions.
- (5) For children aged between 8 weeks and 19 months of age enrolling in child care facilities, a provider shall issue a Certificate showing a child is age-appropriately immunized in accordance with the ACIP schedule at the time of enrollment. For these children, a provider shall issue an updated Certificate at no later than 19 months of age.
- (6) A provider may issue a Temporary Certificate for a child who has not received all required vaccines, but is in the process of completing required immunizations. A Temporary Certificate must have an expiration date that is one month after the date the next required immunization is due according to the minimum acceptable ("catch-up") dose interval published on the Official Immunization Schedule. An expired Certificate is not valid proof of immunization. The school shall obtain a current Certificate no later than the expiration date of a Temporary Certificate.
- (7) A provider shall certify adequate immunization against measles, mumps and rubella for admission into any child care facility and grades Kindergarten through twelve. For purposes of this paragraph adequate immunization is defined as:

- (a) For children 12 months of age or older admitted to a child care facility, one dose of vaccine against measles, mumps and rubella administered no earlier than 4 days before the first birthday; or
 - (b) For children admitted to grades Kindergarten through twelve, two doses of vaccine against measles, mumps and rubella, administered a minimum of 28 days apart and no earlier than 4 days before the first birthday; or
 - (c) For children 12 months of age or older, laboratory evidence of immunity against each disease.
- (8) A provider shall certify adequate immunization against *Haemophilus influenzae* type B ("Hib") for any child under the age of five years entering into any child care facility.
- (9) A provider shall certify adequate immunization against varicella, or a history of varicella disease, prior to admission of a child aged 12 months or older in licensed child care facilities. For purposes of this paragraph, adequate immunization is defined as:
- (a) One dose of varicella vaccine administered no earlier than 4 days before the child's first birthday; or
 - (b) Laboratory evidence of immunity; or
 - (c) A history verified by a physician, advanced practice nurse, physician's assistant or health department of varicella disease.
- (10) A provider shall certify adequate immunization against varicella, or a history of the disease, prior to a child's entry into Kindergarten.
- (11) Effective July 1, 2010, a provider shall certify adequate immunization against varicella for any child entering Kindergarten or 7th grade, and for new enrollees into any school. For purposes of this paragraph, adequate immunization is defined as one of the following:

- (a) Two doses of varicella vaccine; administered at least 28 days apart and no earlier than 4 days before the child's first birthday; or
 - (b) Laboratory evidence of immunity; or
 - (c) A history verified by a physician, advanced practice nurse, physician's assistant or health department of varicella disease.
- (12) Effective July 1, 2010, a provider shall certify adequate immunization against pneumococcal disease for enrollment of any child under the age of five years into any child care facility.
- (13) Effective October 1, 2010, a provider shall certify continued adequate immunization against tetanus, diphtheria and pertussis for any child entering the 7th grade (or, in the case of students in ungraded classrooms, any child age 13). For the purposes of this paragraph, adequate immunization is defined as a complete primary tetanus and diphtheria-containing vaccine series and a dose of vaccine against tetanus, diphtheria and pertussis administered at or after age 10 years; however, a pertussis booster dose is not required if the child has received a complete primary tetanus- and diphtheria-containing vaccine series and has received a tetanus- and diphtheria-containing containing booster dose within the previous five years.
- (14) Effective July 1, 2010, a provider shall certify adequate immunization against hepatitis A for any child aged 18 months or over, but under five (5) years, enrolling in child care facilities. For purposes of this paragraph, adequate immunization is defined as
- (a) one dose of hepatitis A vaccine; or
 - (b) documented laboratory evidence of immunity.
- (15) Effective July 1, 2011, a provider shall certify adequate immunization against hepatitis A for any child enrolling in Kindergarten. For purposes of this paragraph, adequate immunization is defined as
- (a) two doses of hepatitis A vaccine; or

- (b) documented laboratory evidence of immunity.
- (16) Unless exempted by law, any new full-time enrollee of a higher education institution with an enrollment greater than two hundred students who is not enrolled as a full-time distance learning student shall present proof of adequate immunization against the following diseases:
- (a) Measles, provided that this requirement shall only apply to those students born on or after January 1, 1957; for purposes of this subparagraph, adequate immunization is defined as:
 - 1. two doses of measles-containing vaccine, administered at least 28 days apart and no earlier than 4 days before the first birthday;
or
 - 2. laboratory evidence of immunity.
 - (b) Mumps, provided that this requirement shall only apply to those students born on or after January 1, 1957; for purposes of this subparagraph, adequate immunization is defined as:
 - 1. two doses of mumps-containing vaccine, administered at least 28 days apart and no earlier than 4 days before the first birthday; or
 - 2. laboratory evidence of immunity.
 - (c) Rubella, provided that this requirement shall only apply to those students born on or after January 1, 1957; for purposes of this subparagraph, adequate immunization is defined as:
 - 1. two doses of rubella-containing vaccine, administered at least 28 days apart and no earlier than 4 days before the first birthday; or
 - 2. laboratory evidence of immunity.
 - (d) Varicella, provided that this requirement shall not become effective until July 1, 2011, and shall only apply to those students born on or after

January 1, 1980. For purposes of this subparagraph, adequate immunization is defined as follows:

1. two doses of varicella-containing vaccine, administered at least 28 days apart; or
2. laboratory evidence of immunity; or
3. a history verified by a physician, advanced practice nurse, physician's assistant or health department of varicella disease.

For purposes of this paragraph, "full time" means, for an undergraduate, enrolled in twelve (12) or more educational credit hours, and for a graduate student, enrolled in nine (9) or more educational credit hours, or such lesser number as may be deemed full time by the institution. Such students may be enrolled or registered after a single dose of all required vaccines provided that the second dose is obtained within 2 months of registration, and at least 28 days after the first dose, and provided, further, that the institution has a procedure for identifying students who have failed to obtain the necessary immunizations and for taking appropriate action to ensure compliance.

- (17) Effective July 1, 2011, unless exempted by law, any student enrolled in a higher education institution who is a health science student expected to have patient contact shall present proof of protection against hepatitis B before patient contact begins. For purposes of this paragraph adequate immunization is defined as:

- (a) a complete hepatitis B vaccine series; or
- (b) laboratory evidence of immunity or infection

- (18) An individual may be exempted from the requirements of this section only under the following circumstances:

- (a) Where a physician licensed by the Board of Medical Examiners, the Board of Osteopathic Examiners or a Health Department determines that a particular vaccine is contraindicated for one of the following reasons :

1. the individual meets the criteria for contraindication set forth in the manufacturer's vaccine package insert; or
 2. the individual meets the criteria for contraindication published by the U.S. Centers for Disease Control or the ACIP;
 3. in the best professional judgment of the physician, based upon the individual's medical condition and history, the risk of harm from the vaccine outweighs the potential benefit.
- (b) An individual who has been exempted from a particular vaccination must comply with immunization requirements for any vaccines from which he/she has not been exempted.
- (c) Where a parent or guardian, or in the case of an adult student, the student, provides to the school a written statement, affirmed under penalties of perjury, that vaccination conflicts with the religious tenets and practices of the parent or guardian, or in the case of an adult student, the student.
- (19) If the Commissioner determines that insufficient vaccine is available to meet the terms of these rules, the Commissioner shall notify providers, the Commissioners of the Departments of Education and Human Services and the public of any necessary change in immunization requirements, consistent with any changes published by ACIP. The changes will be published as a temporary addendum to the Official Immunization Schedule and individuals vaccinated in accordance with that temporary schedule will be deemed adequately immunized until the Commissioner determines, in accordance with ACIP recommendations, that sufficient vaccine is again available. When sufficient vaccine is again available, Commissioner shall so notify providers, the Commissioners of Education and Human Services and the public and reinstate the Official Immunization Schedule. The reinstated Official Immunization Schedule shall not become effective until at

least 2 months after the determination that sufficient vaccination is again available.

Authority: T.C.A. §§4-5-202, 49-6-5001, 49-6-5002(a), 49-6-5003, 68-1-103, 68-5-103 and 68-5-105(a).

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
NA					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Department of Health on 05/26/2009, and is in compliance with the provisions of TCA 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 03/27/09

Notice published in the Tennessee Administrative Register on: 04/15/09

Rulemaking Hearing(s) Conducted on: (add more dates). 05/26/09

Date: 6/30/09

Signature: Mary Kennedy

Name of Officer: Mary Kennedy

Title of Officer: Deputy General Counsel

Subscribed and sworn to before me on: 6/30/09

Notary Public Signature: Theodora P. Wilkins

My commission expires on: 11/7/2014



All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Robert E. Cooper, Jr.

Robert E. Cooper, Jr.
Attorney General and Reporter

9-3-09
Date

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Filed with the Department of State on: 9/10/09

Effective on: 10/9/09

Tre Hargett

Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. §4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

The sole commenter at the rulemaking hearing was Ms. Christine Modisher, General Counsel for the Tennessee Board of Regents (TBR). Ms Modisher's comments were as follows:

1. The TBR appreciates the clarity the rules provide regarding which students must present proof of immunization. In particular, the TBR appreciates the exclusion of full-time distance learning students from the rules;

Department's Response: No response necessary.

2. The TBR has been operating under the assumption that students who fall into a category where immunization was previously required (born prior to 1957, graduated from a public or private high school after 1999, attended a public or private school L-12 after 2001) are adequately immunized, and has not been requiring proof of immunization; Along those lines, the TBR would prefer not to ask for proof of immunization for those students who have previously been required by law to be immunized;

Department's Response: The purpose of verification is to ensure that no student who should have been immunized, but in fact was not, arrives on campus and presents a potential health hazard to him/herself or others. For this reason, the Department respectfully declines to modify its rule.

3. The TBR requests that the definition of "higher education" used in 1540-1-9-.01 be added to these rules;

Department's Response: The purpose of the rules is to prevent disease, and thus the narrower definition proposed by the TBR could potentially leave some students at risk. For this reason, the Department respectfully declines to modify its rule.

4. The TBR is concerned about the programming cost of adding the requirement for varicella (chicken pox) to the rules and questions the reason for its inclusion.

Department's Response: Because the incoming higher education students are more likely not to have suffered varicella as children, the risk to them is greater than it is to older students. The consequences of the disease are significant. For example, pregnant women who contract the disease are at risk for fetal anomalies. Additionally, colleges, where a large number of students may be in a single classroom or lecture hall at one time, are particularly capable of spreading the disease because it is airborne (an individual can contract it from being in a room, even after the infected person has left the room) While the Department regrets that there will be some costs attendant to implementing the rule, the rule allows ample time to complete those changes, and the Department is willing to offer suggestions about the most efficient means of revising the TBR's information gathering system for this purpose. The Department respectfully declines to modify its rule.

Regulatory Flexibility Addendum

Pursuant to Public Chapter 464 of the 105th General Assembly, prior to initiating the rule making process as described in § 4-5-202(a)(3) and § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

Regulatory Flexibility Analysis

- (1) The proposed rules do not overlap, duplicate, or conflict with other federal, state, or local government rules.
- (2) The proposed rules exhibit clarity, conciseness, and lack of ambiguity.
- (3) The proposed rules are not written with special consideration for the flexible compliance and/or requirements because their intent is to obtain complete and accurate information for the purpose of safeguarding the health of Tennesseans.
- (4) The compliance requirements throughout the proposed rules are as “user-friendly” as possible while still allowing the Division to achieve its goal in obtaining accurate reporting in order to safeguard the health of Tennesseans.
- (5) Compliance requirements are not consolidated or simplified for small businesses in the proposed rules for the protection of the health, safety and welfare of Tennesseans.
- (6) The standards required in the proposed rules are very basic and do not necessitate the establishment of performance standards for small businesses.
- (7) There are no unnecessary entry barriers or other effects in the proposed rules that would stifle entrepreneurial activity or curb innovation.

Economic Impact Statement

1. Name of Board, Committee or Council: Bureau of Administrative Services, Communicable and Environmental Disease Services

2. Rulemaking hearing date: May 26, 2009

3. Types of small businesses that will be directly affected by the proposed rules:

All nursery schools, Kindergartens, other pre-schools, day care centers and facilities, after school day care facilities, grades Kindergarten through twelve of any public, private or church-related schools, vocational schools, technical schools, colleges and universities, as well as all health care providers whose scope of practice includes immunization

4. Types of small businesses that will bear the cost of the proposed rules:

Please see the answer to question 3.

5. Types of small businesses that will directly benefit from the proposed rules:

Please see the answer to question 3.

6. Description of how small business will be adversely impacted by the proposed rules:

These rules should not adversely impact the affected parties. Instead, they should simplify the paperwork to be prepared by the affected healthcare providers and collected and maintained by the affected child care facilities and schools.

7. Alternatives to the proposed rule that will accomplish the same objectives but are less burdensome, and why they are not being proposed:

There are no less burdensome alternatives to the new rule.

8. Comparison of the proposed rule with federal or state counterparts:

Federal: This rule specifically incorporates the federal recommendations for the vaccination of children which are published by the Centers for Disease Control.

State: .

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to TCA 4-5-226(i)(1).

- (A)** A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

This rule designates the diseases against which school children must be immunized prior to school attendance, the schedule for those immunizations and the way that those immunizations will be certified to school administrators. It makes exceptions for those with religious objections and those for whom certain vaccines may be medically contraindicated. It adds pneumococcal disease to the designated diseases against which preschoolers must be immunized, and varicella to the designated diseases against which students in higher education must be immunized. It adds Hepatitis B to the designated diseases against which students in higher education studying in a health care program will be immunized prior to having patient contact. It informs parents, health care providers and school administrators how to obtain a certificate of immunization.

- (B)** A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

T.C.A. § 49-6-5001 *et seq.* requires the immunization of school children, gives the commissioner of health the authority to designate the diseases against which children must be immunized, specifically including, but not limited to, Hepatitis B, and requires the use of a certificate of immunization on forms furnished by the Department of Health.

The Centers for Disease Control and Prevention (CDC) publishes the annually-updated Recommended Pediatric Immunization Schedule for the United States. This schedule outlines the vaccines that the CDC recommends for every child should have the ages at which those vaccines should be administered. It is available online at <http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>

- (C)** Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Tennessee Department of Health, TennCare, Governor's Office on Child Care Coordination, vaccine manufacturers, the Tennessee Academy of Pediatrics, Tennessee Academy of Family Physicians, colleges and universities, schools, child care facilities and, most importantly, Tennessee school children would be affected by these rules. Adoption of this rule is urged by healthcare providers, vaccine manufacturers and the Department of Health.

TennCare and the GOCCC would favor these requirements because they will help facilitate the provision of preventive health services to preteens and adolescents, as required by the consent decrees currently in effect for TennCare. The Department of Education will find that these requirements simplify the process of determining whether a child is adequately immunized. The Tennessee Board of Regents favors the clarity these rules provide for determining which students are required to be immunized, for example, by the exemption of distance-learning students. The Board of Regents, in its comments, did express concern about the necessity of making system changes in order to ensure compliance. The rule, however, gives higher education institutions until 2011 to implement, which should provide more than ample time.

- (D)** Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

No Attorney General opinions or judicial rulings directly relate to this rule.

- (E)** An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

Fiscal impact is minimal; all newly required vaccines are already routinely recommended for all children in these age groups by the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP). Costs associated with making the relevant changes to the state's official immunization certificate will be absorbed by the immunization program budget.

- (F)** Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Mary Kennedy, Deputy General Counsel, Tennessee Department of Health, 220 Athens Way, Suite 210, Nashville TN 37243; Kelly L. Moore, MD, MPH, Medical Director, Tennessee Immunization Program, Tennessee Department of Health, 1st Floor, Cordell Hull Building, 425 5th Avenue, North, Nashville, TN 37243

- (G)** Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Mary Kennedy, Deputy General Counsel, Tennessee Department of Health, 220 Athens Way, Suite 210, Nashville TN 37243; Kelly L. Moore, MD, MPH, Medical Director, Tennessee Immunization Program, Tennessee Department of Health, 1st Floor, Cordell Hull Building, 425 5th Avenue, North, Nashville, TN 37243

- (H)** Office address and telephone number of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Mary Kennedy, Deputy General Counsel, Tennessee Department of Health, 220 Athens Way, Suite 210, Nashville TN 37243 (615) 741-1611; Kelly L. Moore, MD, MPH, Medical Director, Tennessee Immunization Program, Tennessee Department of Health, 1st Floor, Cordell Hull Building, 425 5th Avenue, North, Nashville, TN 37243 (615) 741-9477

- (I)** Any additional information relevant to the rule proposed for continuation that the committee requests.