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For Department of State Use Only

Sequence Number: 06-06-13
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File Date: 6/13/13
Effective Date: 11/28/13

Proposed Rule(s) Filing Form

Proposed rules are submitted pursuant to T.C.A. §§ 4-5-202, 4-5-207 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within sixty (60) days of the first day of the month subsequent to the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by twenty-five (25) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of twenty-five (25) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.

Agency/Board/Commission:	Tennessee Department of Health
Division:	Health Services Administration Communicable and Environmental Disease Services
Contact Person:	Kelly L. Moore, M.D., MPH
Address:	Cordell Hull Building, First Floor 425 5th Avenue North Nashville, Tennessee
Zip:	37243
Phone:	615-741-9477
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Revision Type (check all that apply):
X Amendment
___ New
___ Repeal

Rule(s) Revised (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. 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)

Rule 1200-14-01-.29 Immunization Against Certain Diseases Prior to School Attendance in Tennessee is amended by deleting paragraph (3) in its entirety, and substituting instead the following, so that as amended, the new paragraph (3) shall read:

(3) (a) 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 public health nurse employed by a local health department. The Certificate also may be qualified as complete without the signature of a provider if a certificate that has been validated by the Immunization Registry is printed from the state Immunization Registry, indicating the patient's immunization records in the Registry meet all criteria for compliance with state requirements for that patient's age and grade. 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 SIIS or in hard copy to providers from local health departments or from the Department's central office. State Immunization Registry validated certificates may be produced by all authorized users of the Registry.

(b) As stated in subparagraph (3)(a), a certificate of immunization shall be considered "signed" by a qualified provider when it bears either

1. a hard copy signature of a qualified provider; or

2. an electronic validation of completed requirements, appropriate for the child's age and education level, generated by the Tennessee Web Immunization System pursuant to a secure login process.

Rule 1200-14-01-.29 Immunization Against Certain Diseases Prior to School Attendance in Tennessee is amended by deleting subparagraph (9)(c) in its entirety, and substituting instead the following, so that as amended, the new subparagraph (9)(c) shall read:

(c) A history verified by a physician, advanced practice nurse, physician's assistant or public health nurse employed by a local health department, of varicella disease. Documentation of the past illness is not required to confirm a history of disease;

Rule 1200-14-01-.29 Immunization Against Certain Diseases Prior to School Attendance in Tennessee is amended by deleting subparagraph (11)(c) in its entirety, and substituting instead the following, so that as amended, the new subparagraph (11)(c) shall read:

(c) A history verified by a physician, advanced practice nurse, physician's assistant or public health nurse employed by a local health department, of varicella disease. Documentation of the past illness is not required to confirm a history of disease;

Rule 1200-14-01-.29 Immunization Against Certain Diseases Prior to School Attendance in Tennessee is amended by deleting paragraph (13) in its entirety, and substituting instead the following, so that as amended, the new paragraph (13) shall read:

(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.

Rule 1200-14-01-.29 Immunization Against Certain Diseases Prior to School Attendance in Tennessee is amended by deleting part (16)(d)3. in its entirety, and substituting instead the following language, and by renumbering the unnumbered last paragraph of subparagraph (16)(d) as subparagraph (16)(e), so that as amended, the new part (16)(d)3. and the new subparagraph (16)(e) shall read:

3. a history verified by a physician, advanced practice nurse, physician's assistant or public health nurse employed by a local health department, of varicella disease. Documentation of the past illness is not required to confirm a history of disease.

(e) 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.

Rule 1200-14-01-.29 Immunization Against Certain Diseases Prior to School Attendance in Tennessee is amended by deleting paragraph (17), but not its subparagraphs, and substituting instead the following, so that as amended, the new paragraph (17) shall read:

(17) Effective July 1, 2011, unless exempted by law, any student enrolled in a higher education institution who is a student in a school of medicine, nursing, dentistry, laboratory technology or other allied health profession shall present proof of protection against hepatitis B before such trainee is expected to perform procedures with the potential to expose them to potentially infectious blood. For purposes of this paragraph adequate immunization is defined as:

Rule 1200-14-01-.29 Immunization Against Certain Diseases Prior to School Attendance in Tennessee is amended by deleting subparagraph (18)(a), but not its parts, and substituting instead the following, so that as amended, the new subparagraph (18)(a) shall read:

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

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 rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the Commissioner on 02/19/2013 and is in compliance with the provisions of T.C.A. § 4-5-222. The Secretary of State is hereby instructed that, in the absence of a petition for proposed rules being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of sixty (60) days of the first day of the month subsequent to the filing of the proposed rule with the Secretary of State.

BARBARA E. WEST
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
MY COMMISSION EXPIRES: May 5, 2015

Date: February 19, 2013

Signature: Mary Kennedy

Name of Officer: Mary Kennedy

Title of Officer: Deputy General Counsel, Department of Health

Subscribed and sworn to before me on: Feb. 19, 2013

Notary Public Signature: Barbara E. West

My commission expires on: 05/05/2015

All proposed 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.

R E Cooper Jr

Robert E. Cooper, Jr.
Attorney General and Reporter

6-10-13
Date

Department of State Use Only

Filed with the Department of State on: 6/13/13

Effective on: 11/28/13

Tre Hargett
Secretary of State

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2013 JUN 13 PM 4:29
SECRETARY OF STATE

Regulatory Flexibility Addendum
Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

This rule will affect small businesses in a positive way by lowering the burden attendant to the preparation of certificates of immunization.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (http://state.tn.us/sos/acts/106/pub/pc1070.pdf) of the 2010 Session of the General Assembly)

These rule amendments are not expected to have an impact on local governments.

Additional Information Required by Joint Government Operations Committee

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

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

This rule authorizes the acceptance of Official Immunization Certificates that have been validated by a new tool in the state immunization registry that compares a child's immunization records available in the state registry against state requirements. Registry-validated certificates can be printed by any authorized registry user, including school nurses, without further review or signatures. Under the current rule, all certificates require the review and signature of a qualified healthcare provider (a licensed medical doctor or doctor of osteopathy, an advanced practice nurse or physician assistant, or a local health department). A clarification of the rule states that the public health nurse at the local health department is authorized to sign the certificate; the previous rule did not specify this. The rule simplifies the requirement for a tetanus, diphtheria and pertussis (Tdap) vaccine booster before 7th grade entry, to match the current federal guidelines for the use of this vaccine. The previous rule included a 5-year waiting period between a previous tetanus booster and a Tdap dose: current federal immunization guidelines now do not recommend any delay if Tdap is needed. The final change clarifies the types of students who are required to receive hepatitis B vaccination in higher education programs where their training program will expose them to a significant risk of contact with infected blood from patients during training.

(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;

Tennessee Code Annotated §§ 4-5-202, 49-6-5001, 49-6-5002(a), 49-6-5003, 68-1-103, 68-5-103, and 68-5-105(a) and the guidelines published by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC).

(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;

Changes will simplify the process of issuing immunization certificates for children in child care and schools and streamline the process for all immunization providers who vaccinate children, including medical staff, health departments and immunizing pharmacists. Changes will reduce the burden on parents to obtain signatures of qualified providers in order to complete the certificate when registry records are complete. The changes will affect parents, healthcare providers and schools by simplifying the assessment of children who need pertussis booster doses before entering 7th grade. The changes will affect higher education institutions by simplifying the assessment of higher education students who need hepatitis B immunization before beginning patient care training in a healthcare profession. Persons and institutions affected by these changes should support adoption of the rule because changes all are intended to simplify and streamline the process of issuing immunization certificates and to simplify the assessment of immunization needs in accordance with current federal recommendations.

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

None

(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;

No increase or decrease projected

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

Kelly Moore, MD, MPH, 1st Floor, Cordell Hull Building 425 5th Avenue North, Nashville TN 37243, 741-9477; Mary Kennedy, Deputy General Counsel, 3rd Cordell Hull Building 425 5th Avenue North, Nashville TN 37243 253-4878

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

Kelly Moore, MD, MPH, 1st Floor, Cordell Hull Building 425 5th Avenue North, Nashville TN 37243, 741-9477; Mary Kennedy, Deputy General Counsel, 3rd Cordell Hull Building 425 5th Avenue North, Nashville TN 37243 253-4878

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

Kelly Moore, MD, MPH, 1st Floor, Cordell Hull Building 425 5th Avenue North, Nashville TN 37243, 741-9477, Kelly.Moore@tn.gov; Mary Kennedy, Deputy General Counsel, 3rd Cordell Hull Building 425 5th Avenue North, Nashville TN 37243 253-4878, Mary.Kennedy@tn.gov

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

None