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 File Date: 7/6/12

# Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. § 4-5-204. For questions and copies of the notice, contact the person listed below.

<b>Agency/Board/Commission:</b>	Department of Health
<b>Division:</b>	Division of Healthcare Facilities
<b>Contact Person:</b>	Lucille F. Bond, Assistant General Counsel
<b>Address:</b>	Office of General Counsel 220 Athens Way, Suite 210 Nashville, Tennessee 37243
<b>Phone:</b>	(615) 741-1611
<b>Email:</b>	Lucille.F.Bond@tn.gov

Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

<b>ADA Contact:</b>	ADA Coordinator at the Division of Health Related Boards
<b>Address:</b>	227 French Landing, Suite 300, Heritage Place, Metro Center Nashville, Tennessee 37243
<b>Phone:</b>	(615) 532-3202 or (Toll Free) 1-800-778-4123
<b>Email:</b>	

**Hearing Location(s)** (for additional locations, copy and paste table)

Address 1:	Iris Board Room, Heritage Place, MetroCenter		
Address 2:	227 French Landing Drive		
City:	Nashville, Tennessee		
Zip:	37228		
Hearing Date :	9/12/2012		
Hearing Time:	9:00 a.m.	<input checked="" type="checkbox"/> CST/CDT	<input type="checkbox"/> EST/EDT

**Additional Hearing Information:**

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**Revision Type (check all that apply):**

- Amendment
- New
- Repeal

**Rule(s)** (ALL chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	Chapter Title
1200-08-12	Trauma Centers
Rule Number	Rule Title
1200-08-12-.03	Definitions

(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>)

#### Amendment

Rule 1200-08-12-.03 Definitions is amended by adding the following subparagraphs in the appropriate order and renumbering all subparagraphs accordingly:

- ( ) "Advisory Council" means the Tennessee Trauma Care Advisory Council.
- ( ) "Commissioner" means the Commissioner of the Tennessee Department of Health.
- ( ) "Data" means the original information contained on the report required by the regulations, including, but not limited to, both identifying and non-identifying information.
- ( ) "Health care practitioner" means a physician, surgeon, or other health care professional licensed under T.C.A. Title 63 who is engaged in diagnosing and/or treating patients within the trauma care system.
- ( ) "Identifying information" means any information that could lead to the identification of a patient who has been diagnosed or treated within the trauma care system.
- ( ) "Medical Record" means medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations, and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.
- ( ) "Person" means any member of the "medical, scientific, and academic research community."
- ( ) "Policies and Procedures Manual" means the document(s) maintained in the offices of the Tennessee Trauma Registry giving specific written instructions for the implementation of policies and procedures utilized by the registry and which may be updated from time to time.

Authority: T.C.A. §§ 68-11-209 and 68-11-259.

#### New Rule

Rule 1200-08-12 Trauma Centers is amended by adding a new Rule 1200-08-12-.06 Trauma Registry Data which shall read as follows:

##### 1200-08-12-.06 Trauma Registry Data

- (1) Confidentiality.
  - (a) T.C.A. 68-11-259 provides for the confidentiality of data obtained from the reports of trauma patients.
  - (b) Information contained in the trauma registry that could lead, or reasonably lead, to the identity of any patient or a reporting facility may not be made available to the public.
  - (c) Trauma registry responsibilities
    - 1. The trauma registry shall take strict measures to ensure that all patient identifying information is treated as confidential and privileged.
    - 2. All employees or consultants, including auditors of the trauma registry, shall sign a Tennessee Trauma Registry Employee Confidentiality Pledge and these signed pledges shall be kept on file.

3. Protection of report sources. Hospitals, laboratories, facilities, or health care practitioners who disclose trauma care data to the trauma registry or its employees in conformity with the act creating the trauma registry in 2005 and its amendments, as well as rules and regulations promulgated thereto, shall not be held liable for the release of such data to the department.
- (d) Protection of patient identifying information obtained by special studies and other research studies
1. All identifying information such as records of interviews, questionnaires, reports, statements, notes, and memoranda that are procured or prepared by employees or agents of the trauma registry shall be used solely for statistical, scientific and medical research purposes and shall be held strictly confidential by the trauma registry.
  2. This applies also to identifying information procured by any other person, agency, or organization, including public or private colleges and universities acting jointly with the trauma registry in connection with special health studies and research investigations.
- (2) Release of Data
- (a) Release of non-identifying information
1. To the Tennessee Department of Health:
    - (i) The trauma registry shall work closely with the Tennessee Department of Health in investigating the causes and consequences of traumatic injuries and in evaluating programs.
    - (ii) Because the trauma registry data are an integral part of the Tennessee Department of Health traumatic injury prevention and control programs, the use of trauma registry data by public health officials shall be considered an in-house activity.
  2. To the general public:
    - (i) Public reports published by the trauma registry shall include aggregate, not patient identifying information or facility identifying information.
    - (ii) Information that would potentially identify a trauma patient shall not be published.
    - (iii) Non-identifying information may be made available to the general public upon request to the department.
    - (iv) The availability of any data shall depend upon the department's financial or other ability to comply with such requests. The trauma registry shall respond to public requests as quickly as possible, subject to staffing constraints.
- (b) Release of identifying information
1. Identifying information collected from any hospital, laboratory, facility, or health care practitioner may be released to qualified persons for the purposes of traumatic injury prevention, control, care, and research provided that each request for identifying information follows the established procedure outlined in the trauma registry Policies and Procedures Manual and receives prior approval by the department.

2. Identifying information that is collected solely by the trauma registry for its own special studies shall not be released.
- (c) Annual Report. A statistical report shall be prepared at the completion of each year's data collection cycle and will be distributed as requested.
- (3) Request procedure for patient identifying information
  - (a) Requests for identifying information shall be reviewed and approved by the department according to the policies of the Tennessee Department of Health and the trauma registry.
  - (b) A detailed description of the procedures for requesting identifying information can be obtained from the trauma registry.

Authority: T.C.A. §§ 68-11-209 and 68-11-259

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

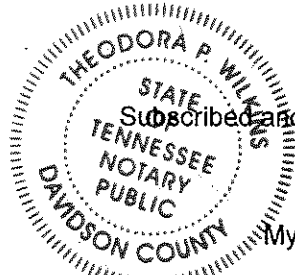
Date: June 29, 2012

Signature: Lucille F. Bond

Name of Officer: Lucille F. Bond

Assistant General Counsel

Title of Officer: Department of Health



Subscribed and sworn to before me on: 6/29/12

Notary Public Signature: Theodora P. Wilkins

My commission expires on: 11/3/12

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Filed with the Department of State on: 7/6/12

Tre Hargett by [Signature]  
POA Secretary of State

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