

**Proposed Rule**  
LSA Document #12-617

DIGEST

Adds [410 IAC 34](#) to establish a state trauma registry for the collection of information regarding the delivery of traumatic injury care services in Indiana for purposes of improving the statewide trauma system. Effective 30 days after filing with the Publisher.

[IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses](#)

[410 IAC 34](#)

SECTION 1. [410 IAC 34](#) IS ADDED TO READ AS FOLLOWS:

**ARTICLE 34. STATE TRAUMA REGISTRY**

**Rule 1. Definitions**

[410 IAC 34-1-1](#) Applicability

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

**Sec. 1. The definitions in this rule apply throughout this article.**

(Indiana State Department of Health; [410 IAC 34-1-1](#))

[410 IAC 34-1-2](#) "Commissioner" defined

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

**Sec. 2. "Commissioner" means the state health commissioner or the state health commissioner's designee.**

(Indiana State Department of Health; [410 IAC 34-1-2](#))

[410 IAC 34-1-3](#) "Department" defined

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

**Sec. 3. "Department" means the Indiana state department of health.**

(Indiana State Department of Health; [410 IAC 34-1-3](#))

[410 IAC 34-1-4](#) "Emergency medical services" or "EMS" defined

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

**Sec. 4. "Emergency medical services" or "EMS" means the provision of emergency ambulance services or other services, including extrication and rescue services, utilized in serving an individual's need for immediate medical care in order to prevent loss of life or aggravation of physiological or psychological illness or injury.**

(Indiana State Department of Health; [410 IAC 34-1-4](#))

**[410 IAC 34-1-5](#) "Health care facility" defined**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 5. "Health care facility" includes the following:

- (1) Hospitals.
- (2) Trauma centers.
- (3) Rehabilitation hospitals.

(Indiana State Department of Health; [410 IAC 34-1-5](#))

**[410 IAC 34-1-6](#) "Hospital" defined**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-21-2](#)

Sec. 6. (a) "Hospital", except as provided in subsection (b), means a hospital that is licensed under [IC 16-21-2](#).

(b) "Hospital" means an institution, a place, a building, or an agency that holds out to the general public that it is operated for hospital purposes and that it provides care, accommodations, facilities, and equipment, in connection with the services of a physician, to individuals who may need medical or surgical services. The term does not include the following:

- (1) Freestanding health facilities.
- (2) Long-term acute care hospitals (LTACHs).
- (3) Hospitals that do not provide emergency services.
- (4) Hospitals or institutions specifically intended to diagnose, care, and treat the following:
  - (A) Individuals with a mental illness.
  - (B) Individuals with developmental disabilities.
- (5) Offices of physicians where patients are not regularly kept as bed patients.
- (6) Convalescent homes, boarding homes, or homes for the aged.
- (7) Rehabilitation facilities.

(Indiana State Department of Health; [410 IAC 34-1-6](#))

**[410 IAC 34-1-7](#) "Indiana EMS Data Dictionary" defined**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 7. "Indiana EMS Data Dictionary" means the collection of descriptions of the data objects in the database of fire and emergent run data maintained by the Indiana EMS program at the Indiana department of homeland security and referred to as the "Indiana Department of Homeland Security Emergency Medical Services (EMS) Data Dictionary and National EMS Information System (NEMSIS) Data Elements".

(Indiana State Department of Health; [410 IAC 34-1-7](#))

**[410 IAC 34-1-8](#) "Indiana Rehabilitation Hospital Registry Data Dictionary" defined**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 8. "Indiana Rehabilitation Hospital Registry Data Dictionary" means the collection of descriptions of the data objects in the database maintained by the Indiana state department of health and referred to as the "Indiana Rehabilitation Hospital Registry Data Dictionary".

(Indiana State Department of Health; [410 IAC 34-1-8](#))

**[410 IAC 34-1-9](#) "Indiana Trauma Registry Data Dictionary" defined**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 9. "Indiana Trauma Registry Data Dictionary" means the collection of descriptions of the data objects in the database maintained by the Indiana State Trauma Registry and referred to as the "Indiana Trauma Registry Data Dictionary".

(Indiana State Department of Health; [410 IAC 34-1-9](#))

**[410 IAC 34-1-10](#) "National EMS Information System" or "NEMSIS" defined**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 10. "National EMS Information System" or "NEMSIS" means the national repository for EMS data maintained by the University of Utah School of Medicine.

(Indiana State Department of Health; [410 IAC 34-1-10](#))

**[410 IAC 34-1-11](#) "National Trauma Data Bank" or "NTDB" defined**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 11. "National Trauma Data Bank" or "NTDB" is an aggregation of national trauma registry data maintained by the American College of Surgeons.

(Indiana State Department of Health; [410 IAC 34-1-11](#))

**[410 IAC 34-1-12](#) "National Trauma Data Standard" or "NTDS" defined**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 12. "National Trauma Data Standard" or "NTDS" means a data set defining standardized data elements collected by the American College of Surgeons within the National Trauma Data Bank.

(Indiana State Department of Health; [410 IAC 34-1-12](#))

**[410 IAC 34-1-13](#) "Patient medical record" defined**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 13. "Patient medical record" means written, electronic, or printed information possessed or maintained by a provider concerning any diagnosis, treatment, or prognosis of the patient, including such information possessed or maintained on microfiche, on microfilm, or in a digital format.

(Indiana State Department of Health; [410 IAC 34-1-13](#))

**[410 IAC 34-1-14](#) "Rehabilitation hospital" defined**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 14. "Rehabilitation hospital" means a hospital that is Prospective Payment System-excluded under 42 CFR 412.

(Indiana State Department of Health; [410 IAC 34-1-14](#))

**[410 IAC 34-1-15](#) "Risk adjustment" defined**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 15. "Risk adjustment" means methodologies applied to a data set in order to identify and control patient variables that are present that may influence patient outcome.

(Indiana State Department of Health; [410 IAC 34-1-15](#))

**[410 IAC 34-1-16](#) "Trauma center" defined**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 16. "Trauma center" means a hospital that provides trauma care and has been verified as a trauma center by the American College of Surgeons, has been designated a trauma center under a state designation system that is substantially equivalent to the ACS verification process, or has been deemed to be in the process of ACS verification pursuant to [836 IAC 1-2.1](#).

(Indiana State Department of Health; [410 IAC 34-1-16](#))

**Rule 2. Purpose of the Registry**

**[410 IAC 34-2-1](#) Purpose**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 1. (a) The purpose of the registry is to collect and analyze data that is necessary to evaluate the delivery of trauma care within the state.

(b) The data collected by the registry shall be of such a nature as to allow the department to identify and evaluate the following:

- (1) Frequency, type, severity, and outcome of trauma injuries.
- (2) Criteria used to establish triage protocols.
- (3) Geographic patterns of injury, including, but not limited to, areas or regions of the state where improvements are needed in the delivery of trauma care.
- (4) Other factors to consider in recommending, designing, or implementing the statewide trauma care delivery system, including, but not limited to, public education on trauma and injury prevention, access to trauma care, prehospital availability, and cost of trauma care.

(c) Registry data will be linked between EMS providers, health care facilities, and other agencies so that the entire continuum of trauma care can be assessed for quality purposes.

(Indiana State Department of Health; [410 IAC 34-2-1](#))

**Rule 3. Management of the Registry**

**[410 IAC 34-3-1](#) Management**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 1. (a) The actions and management of the registry will be overseen by the director of the trauma and injury prevention program at the department.

**(b) The department may contract with individuals or organizations with specific expertise in risk adjustment and statistical analysis of medical data in order to perform risk adjustment of registry data.**

*(Indiana State Department of Health; [410 IAC 34-3-1](#))*

#### **Rule 4. Required Reporting**

##### **[410 IAC 34-4-1](#) Required reporting**

**Authority:** [IC 16-19-3-28](#)

**Affected:** [IC 16-19-3-28](#)

**Sec. 1. The following entities shall submit data to the registry:**

**(1) Health care facilities, including any of the following:**

**(A) A hospital.**

**(B) A trauma center.**

**(C) Rehabilitation hospitals.**

**(2) EMS providers, both basic life support and advanced life support, that transport patients.**

**(3) At the request of the department, any state agency possessing data or information, or both, regarding trauma care.**

*(Indiana State Department of Health; [410 IAC 34-4-1](#))*

#### **Rule 5. Submission of Data**

##### **[410 IAC 34-5-1](#) Submission of data**

**Authority:** [IC 16-19-3-28](#)

**Affected:** [IC 16-19-3-28](#)

**Sec. 1. (a) The department shall establish and use the registry to collect and analyze data that is necessary to evaluate the delivery of trauma care within the state.**

**(1) Data collected by the department for the registry shall include, but not be limited to, data of such a nature as to allow the department to identify and evaluate the following:**

**(A) Incidence, mechanism, type, severity, and outcome of traumatic injuries.**

**(B) Criteria used to establish or refine, or both, triage and transport guidelines.**

**(C) Geographic patterns of injury, including, but not limited to, areas or regions of the state where improvements are needed in the delivery of trauma care.**

**(2) Data submitted to and maintained by the registry shall be in such a format that:**

**(A) protects the identity of specific patients to whom medical care has been rendered;**

**(B) identifies specific health care facilities by a code or other designation; and**

**(C) avoids or minimizes duplication of entries.**

**(b) Data required to be provided to the registry under this article shall be submitted by direct data entry or by electronic data transfer using an xml format and data scheme that is based on the Indiana Trauma Registry Data Dictionary.**

**(c) Hospitals will submit data to the registry using the criteria in the Indiana Trauma Registry Data Dictionary. Rehabilitation hospitals will submit data to the registry using the Indiana Rehabilitation Hospital Registry Data Dictionary.**

**(d) EMS providers will submit data to the registry using the National EMS Information System (NEMSIS) data elements specified at [836 IAC 1-1-5](#) and the criteria in the Indiana EMS Data Dictionary.**

*(Indiana State Department of Health; [410 IAC 34-5-1](#))*

#### **Rule 6. Reporting Deadlines**

#### **[410 IAC 34-6-1](#) Reporting deadlines**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 1. (a) The data required to be provided to the registry by health care facilities shall be reported to the registry according to the following schedule:

Patients Admitted	Report Due Date
January 1-March 31	June 30
April 1-June 30	September 30
July 1-September 30	January 15
October 1-December 31	May 1

(b) The data required to be provided to the registry by EMS providers shall be reported to the registry by the fifteenth day of the month following the month in which the incident occurred.

(Indiana State Department of Health; [410 IAC 34-6-1](#))

#### **Rule 7. Failure to Report**

##### **[410 IAC 34-7-1](#) Failure to report**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 1. Health care facilities that fail to submit data to the registry as specified in this article will be ineligible for designation by the department as a trauma center. Health care facilities and EMS providers that fail to submit data to the registry as specified in this article will be ineligible for other programs, including, but not limited to, grants and other ISDH-sponsored sources of funding.

(Indiana State Department of Health; [410 IAC 34-7-1](#))

#### **Rule 8. Risk Adjustment**

##### **[410 IAC 34-8-1](#) Risk adjustment**

Authority: [IC 16-19-3-28](#)

Affected: [IC 16-19-3-28](#)

Sec. 1. (a) The registry will work to improve trauma care in the state by calculating trauma-related incident response and health outcome indicator values for each health care facility and EMS provider, determining and disseminating information best practices that are associated with optimal indicator values, and establishing state benchmark standards to which each reporting entity is accountable.

(b) Individual and aggregated indicator values must be risk-adjusted before comparisons can be made across groups.

(c) Risk adjustment accounts for the impact of individual risk factors such as age and the severity of the initial injury that can put some patients at greater risk for medical complications and death.

(d) By risk-adjusting the indicator values, variation in patient types across groups can be controlled for and appropriate comparisons can be made.

(e) Risk adjustment of the indicator values will be conducted by registry staff primarily following the methodologies outlined by the American College of Surgeons.

**(f) Other methodologies may be evaluated and used as registry staff deems appropriate.**

*(Indiana State Department of Health; [410 IAC 34-8-1](#))*

## **Rule 9. Protected Information**

### **[410 IAC 34-9-1](#) Protected information**

**Authority:** [IC 16-19-3-28](#)

**Affected:** [IC 4-1-6-8.6](#)

**Sec. 1. (a) All data created by a provider and submitted to the department for inclusion in the registry will be treated as confidential and the department will follow all appropriate state and federal laws regarding the confidentiality of the medical information.**

**(b) The department may grant any person involved in a legitimate research activity access to confidential information included in the registry under [IC 4-1-6-8.6](#).**

*(Indiana State Department of Health; [410 IAC 34-9-1](#))*

### **[Notice of Public Hearing](#)**

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