Regulatory Analysis

Notice of Intended Action to be published: 641—Chapter 146
"Stroke Care Reporting"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 217.6
State or federal law(s) implemented by the rulemaking: Iowa Code section 135.191

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 19, 2024 10 a.m.	Microsoft Teams Meeting ID: 268 876 122 100 Passcode: QXqezE

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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321 East 12th Street
Des Moines, Iowa 50319
Phone: 515.829.6021
Email: compliancerules@hhs.iowa.gov

Purpose and Summary

The purpose of this proposed chapter is to improve stroke care in Iowa by promoting consistent adherence to the latest scientific treatment guidelines.

Analysis of Impact

1. **Persons affected by the proposed rulemaking:**

- **Classes of persons that will bear the costs of the proposed rulemaking:**

There are no costs associated with this rulemaking.

- **Classes of persons that will benefit from the proposed rulemaking:**

Iowans who have had or could possibly need stroke care will benefit.

2. **Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:**

- **Quantitative description of impact:**

There are no specific economic impacts to the state. The registry is supported by federal funding at approximately $11,000 per year. There are no state appropriations that contribute to the support of the stroke registry or stroke program support.

- **Qualitative description of impact:**

This rulemaking improves stroke care in Iowa by promoting consistent adherence to the latest scientific treatment guidelines.

3. **Costs to the State:**

- **Implementation and enforcement costs borne by the agency or any other agency:**

Personnel and other administrative costs.

- **Anticipated effect on state revenues:**

There is no impact on state revenues.

4. **Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:**

Without these rules, there would be no guidelines for the stroke reporting required by Iowa Code section 135.191.

5. **Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:**

None.

6. **Alternative methods considered by the agency:**

- **Description of any alternative methods that were seriously considered by the agency:**

None.

- **Reasons why alternative methods were rejected in favor of the proposed rulemaking:**

The nationally certified comprehensive stroke centers and the nationally certified primary stroke center operating in Iowa need to know what to report in order to comply with Iowa law.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

There is no impact on small business.

Text of Proposed Rulemaking

ITEM 1. Rescind 641—Chapter 146 and adopt the following **new** chapter in lieu thereof:

CHAPTER 146
STROKE CARE REPORTING

641—146.1(135) Definitions.

"Comprehensive stroke center" means a hospital certified as a comprehensive stroke center by a nationally recognized certifying body with certification criteria consistent with the most current nationally recognized, evidence-based stroke guidelines related to reducing the occurrence of and disabilities and death associated with stroke.

"Primary stroke center" means a hospital certified as a primary stroke center by a nationally recognized certifying body with certification criteria consistent with the most current nationally recognized, evidence-based stroke guidelines related to reducing the occurrence of and disabilities and death associated with stroke.

"Stroke" means a clinical diagnosis of acute stroke or principal International Classification of Disease, 10th Revision, Clinical Modification (ICD-10-CM) discharge code of "stroke," or "transient ischemic attack," or "cerebral infarction," or "cerebral hemorrhage."

"Stroke care" means care provided to individuals with confirmed cases of stroke.

641—146.2(135) Stroke care reporting.

146.2(1) *Iowa statewide stroke database.* The department designates the Get with the Guidelines stroke module of the American Heart Association/American Stroke Association as the Iowa stroke database established in Iowa Code section 135.191.

146.2(2) *Who is required to report.* All nationally certified comprehensive stroke centers and all nationally certified primary stroke centers operating in the state of Iowa are required to report stroke data. Nationally certified acute stroke-ready hospitals and emergency medical services operating in the state of Iowa are encouraged to report stroke care data.

146.2(3) *What is to be reported.* Reportable data are those data identified by a clinical diagnosis of acute stroke or by the following ICD-10 coding:

ICD-10-CM Code	Short Description
I60.00 - I60.9	Nontraumatic subarachnoid hemorrhage
I61.0 - I61.9	Nontraumatic intracerebral hemorrhage
I63.00 - I63.9	Cerebral infarction (occlusion and stenosis of cerebral and precerebral arteries, resulting in cerebral infarction)
G45.0 - G45.2	TIA and related syndromes
G45.8 - G45.9	TIA and related syndromes
O99.411 - O99.43	Diseases of the circulatory system complicating pregnancy, childbirth and puerperium
G97.31 - G97.32	Intraoperative hemorrhage and hematoma of a nervous system organ or structure complicating a procedure
G97.51 - G97.52	Postprocedural hemorrhage and hematoma of a nervous system organ or structure following a procedure
I97.810 - I97.821	Intraoperative and postoperative cerebrovascular infarction

641—146.3(135) Method and frequency of reporting.

146.3(1) Stroke centers shall report the required stroke care information for any reportable stroke case no later than 120 days after the patient was discharged, transferred to another hospital, or pronounced dead.

146.3(2) Reports shall meet the data quality, format, and timeliness standards prescribed by the Iowa statewide stroke database.

641—146.4(135) Confidentiality. The Iowa statewide stroke database will comply with federal and state law and other health information and data collection, storage, and sharing requirements of the department.

641—146.5(135) Penalties and enforcement. If a stroke center reporting under this chapter does not comply with the reporting requirements, the department may request a review of the certification of the comprehensive or primary stroke center by the certifying entity.

These rules are intended to implement Iowa Code section 135.191.