

EXHIBIT N



Arkansas Department of Health

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Governor Mike Beebe

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Summary of Proposed Changes to Rules Pertaining to Health Facility Infection Disclosures

It is proposed to amend the Rules Pertaining to Health Facility Infection Disclosures pursuant to the procedures of the Administrative Procedure Act process.

The rules are being revised pursuant to Act 634 of 2011 which made changes to Ark. Code Ann. §§ 20-9-1202 – 20-9-1204. The act deleted certain types of infections that facilities had to maintain records of and requires that facilities must share data with the Department of Health that they report as a participant in the Centers for Medicare and Medicaid Services Hospital Inpatient Quality Reporting Program.

Proposed Changes to Current Rules:

Section IV:

Deleted subsections (a)(1) through (a)(4)

Subsection (b)(1)(A) amended to ensure that facilities could voluntarily submit data to the Department that it has collected.

Added subsection (c)(1) regarding the sharing of data collected for the Hospital Inpatient Quality Reporting Program.

Added subsection (d) to ensure that data shared with the National Healthcare Safety Network may be shared with the Department.

**RULES PERTAINING TO:
“THE HEALTH FACILITY
INFECTION DISCLOSURE ACT OF
2007”**

DRAFT

ARKANSAS DEPARTMENT OF HEALTH

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SECTION I. Authority

These Rules are promulgated pursuant to the authority of Act 845 of 2007 as codified in Ark. Code Ann. §20-9-1201 et seq. and Ark. Code Ann. §20-7-101 et seq.

SECTION II. Purpose

In addition to the purposes provided by the Act, these rules are promulgated to protect the public health and safety of patients in health facilities in the State.

SECTION III. Definitions:

(1)(A) “Health facility” means any of the following facilities:

- (i) A hospital, outpatient surgery center, public health center, or recuperation center, as those facilities are defined in § 20-9-201; and
- (ii) Any other facility determined to be a source of healthcare-associated infections and designated as such by the Department of Health.

(B) “Health facility” does not include:

- (i) A physician's office unless the office is otherwise licensed as an outpatient surgery center; or
- (ii) An establishment furnishing primarily domiciliary care;

(2) “Healthcare-associated infection” means a localized or systemic condition in a person that:

- (A) Results from adverse reaction to the presence of an infectious agent or a toxin of an infectious agent; and
- (B) Was not present or incubating in the person at the time of admission to the health facility; and

(3) “Department” means the Department of Health.

(4) "National Healthcare Safety Network" means the secure Internet-based data collection surveillance system managed by the Division of Health Quality Promotion at the Centers for Disease Control created by the center for accumulating, exchanging, and integrating relevant information on infectious adverse events associated with healthcare delivery.

SECTION IV. Responsibility - Health Facility Reports.

(a) A health facility shall collect data on healthcare-associated infection rates for the following:

- ~~(1) — Coronary artery bypass surgical site infections;~~
- ~~(2) — Total hip or knee arthroplasty surgical site infections;~~
- ~~(3) — Knee arthroscopy surgical site infections;~~
- ~~(4) — Hernia repair surgical site infections;~~
- ~~(5)~~(1) Central line-associated bloodstream infections in an intensive care unit; and
- ~~(6)~~(2) Other categories as provided under § 20-9-1204(e) and Section 5(e) herein.

(b)(1)(A) A health facility may voluntarily submit quarterly reports to the Department of Health on the health facility's healthcare-associated infection rates for any one or more of the following healthcare-associated infections:

- (i) The healthcare-associated infections specified in subsection (a) above; and
- (ii) Any other healthcare-associated infections accepted by the Department.

(B)(i) If a health facility elects to submit quarterly reports, the reports shall be submitted to the department:

- (a) In a format prescribed by the department; and
- (b) By April 30, July 31, October 31, and January 31 of each year.

(ii) Each quarterly report shall cover the immediately preceding calendar quarter.

(C) Data in the quarterly reports shall cover a period ending not earlier than one (1) month before the submission of the report.

(2) If the health facility is a division or subsidiary of another entity that owns or operates other health facilities, the quarterly report shall be for the specific division or subsidiary and not for the other entity.

(c)(1) A health facility participating in the Centers for Medicare and Medicaid Services Hospital Inpatient Quality Reporting Program or its successor shall authorize the department to have access to the following information that the health facility submits to the National Healthcare Safety Network:

- (A) The name of the health facility; and

(B) Any information submitted to the National Healthcare Safety Network in order to satisfy the requirements of the Hospital Inpatient Quality Reporting Program.

(d) Any health facility participating in the National Healthcare Safety Network may authorize the department to have access to all or part of the information that the health facility submits. Any identifying information shared with the department shall be kept confidential and fully protected under the provisions of Ark. Code Ann. § 20-9-1206 and Section VIII of these rules.

(e) The information contained in the National Healthcare Safety Network database and obtained by the department under this section may be used by the department for surveillance and prevention purposes only and shall not be used for regulatory purposes.

SECTION V. Advisory Committee on Healthcare Associated Infections.

(a) The Director of the Department of Health shall appoint an Advisory Committee on Healthcare Acquired Infections, including without limitation representatives of:

- (1) Public and private hospitals, including representatives of hospitals with fewer than fifty (50) beds and representatives of hospitals with more than fifty (50) beds;
- (2) Outpatient surgery centers;
- (3) Direct-care nursing staff;
- (4) Physicians;
- (5) Infection-control professionals with expertise in healthcare-associated infections;
- (6) Academic researchers; and
- (7) At least one (1) representative of a consumer organization.

(b) The advisory committee shall assist the Department of Health in the development of all aspects of the department's methodology for collecting, analyzing, and disclosing the data collected under this subchapter, including without limitation:

- (1) Collection methods;
- (2) Formatting; and
- (3) Methods and means for the release and dissemination of the data.

(c)(1) In developing the methodology for collecting and analyzing the infection-rate data, the department and the advisory committee shall consider existing methodologies and systems for data collection.

- (2) Any data collection and analytical methodologies used shall be:
 - (A) Capable of being validated; and
 - (B) Based upon nationally recognized and recommended standards that may include those developed by the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, the Agency for Healthcare Research and Quality, or the National Quality Forum.

(3) The proposed data collection and analysis methodology shall be disclosed for public comment before any public disclosure of healthcare-associated infection rates in an annual report under § 20-9-1205.

(4)(A) The data collection and analysis methodology shall be presented to all health facilities in this state on or before September 1, 2008.

(B) The methodology may be amended based upon input from the health facilities.

(5)(A) The first voluntary quarterly report under § 20-9-1203(b) shall be presented to the department on or before January 31, 2009.

(B) Health facilities may begin voluntarily reporting data on January 31, 2009, or at any time thereafter.

(d) The department and the advisory committee shall evaluate on a regular basis the quality and accuracy of health facility data reported under this subchapter and the data collection, analysis, and dissemination methodologies used under this subchapter.

(e) After release of the second annual report published under § 20-9-1205 and upon consultation with the advisory committee and with other technical advisors who are recognized experts in the prevention, identification, and control of healthcare-associated infections and the reporting of performance data, the department may add categories of infections to those set forth in § 20-9-1203(a).

SECTION VI. Data Collection and Analysis Methodology

Upon recommendation of the Advisory Committee on Healthcare Associated Infections, the Arkansas State Board of Health adopts the following Data Collection and Analysis Methodology:

The National Healthcare Safety Network (NHSN) Manual

Patient Safety Component Protocol

Division of Healthcare Quality Promotion

National Center for Infectious Diseases

Centers for Disease Control and Prevention

Atlanta, GA, USA

Last Updated January 2008

SECTION VII. Reports Regarding Healthcare-Associated Infections

(a)(1)(A) In consultation with the Advisory Committee on Healthcare Acquired Infections, the Department of Health shall submit annually a report summarizing the health facility quarterly reports required under these Rules to the Chair of the House Interim Committee on Public Health, Welfare, and Labor and the Chair of the Senate Interim Committee on Public Health, Welfare, and Labor.

(B) No health facility-identifiable data shall be included in the annual report, but aggregate statistical data may be included.

(2) The department shall publish the annual report on the department's website.

- (3) The first annual report shall be submitted and published on or before January 1, 2010.
- (b) The annual report prepared by the department under this subchapter regarding healthcare-associated infections shall be appropriately risk-adjusted.
- (c) The annual report shall include an executive summary written in plain language that shall include without limitation:
- (1) A discussion of findings, conclusions, and trends concerning the overall status of healthcare-associated infections in the state, including a comparison to previous years; and
 - (2) Policy recommendations of the department and the advisory committee.
- (d) The annual report shall be made available to any person upon request.
- (e) No health facility report or department disclosure shall contain information identifying a patient, employee, or healthcare professional in connection with a specific infection incident.
- (f) No annual report or other department disclosure shall contain information that identifies or could be used to identify a specific health facility.
- (g)(1) As part of the process of preparing the annual report, effective safeguards to protect against the dissemination of inconsistent, incomplete, invalid, inaccurate, or subjective health facility data shall be developed and implemented.
- (2) These safeguards may include the exclusion of certain data or data from health facilities with a low volume of patients or procedures if the use of the data would skew the results reported.
- (h) The department shall develop, with the assistance of the advisory committee, a process of regular and confidential feedback for health facilities regarding the data collected so that each health facility's data will be available to that health facility for its quality improvement efforts.

SECTION VIII. Privacy and Confidentiality

- (a) It is the intent of the Arkansas State Board of Health that a patient's right of confidentiality shall not be violated in any manner under these Rules.
- (b) Social security numbers and any other information that could be used to identify an individual patient shall not be released under this subchapter.
- (c) Except for the annual report that shall be a public document available to any person upon request, any data and materials collected or compiled by a health facility or obtained by the Department of Health under this subchapter rule shall be exempt from discovery and disclosure to the same extent that records of and testimony before committees evaluating quality of medical or hospital care are exempt under § 16-46-105(a)(1) and shall not be admissible in any legal proceeding.
- (d) Data collected and reported under this subchapter shall not be deemed to have established a standard of care for any purposes in a private civil litigation.

SECTION IX. Funding

These Rules are contingent upon the appropriation and availability of funding necessary for the Department of Health to implement these provisions, and any requirements that actions be accomplished by a specific date shall be extended until the necessary funding is available.

SECTION X. Severability

If any provision of these Rules or the application thereof to any health facility or circumstances is held invalid, such invalidity shall not affect other provisions or applications and to this end the provisions hereto are declared severable.

CERTIFICATION

This is to certify that the foregoing **RULES PERTAINING TO "THE HEALTH FACILITY INFECTION DISCLOSURE ACT OF 2007"** were adopted by the Arkansas State Board of Health at a regular session of said Board held on _____, 20____.

Paul Halverson, DrPH, FACHE
Director and State Health Officer
Arkansas Department of Health

**QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS
WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE**

DEPARTMENT/AGENCY Department of Health
DIVISION Applied Epidemiology Branch
DIVISION DIRECTOR Shirley Louie
CONTACT PERSON Robert Brech
ADDRESS 4815 West Markham, Slot 31, Little Rock, AR 72205
PHONE NO. 501-661-2297 FAX NO. 501-661-2357 E-MAIL robert.brech@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Robert Brech
PRESENTER E-MAIL robert.brech@arkansas.gov

INSTRUCTIONS

- A. Please make copies of this form for future use.
- B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
- C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
- D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
Room 315, State Capitol
Little Rock, AR 72201

1. What is the short title of this rule? Health Facility Infection Disclosure

2. What is the subject of the proposed rule? Amending the rules to be consistent with Act 634 of 2011.

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes No
If yes, please provide the federal rule, regulation, and/or statute citation.

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes No
If yes, what is the effective date of the emergency rule? _____

When does the emergency rule expire? _____

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes No

5. Is this a new rule? Yes No
If yes, please provide a brief summary explaining the regulation.

Does this repeal an existing rule? Yes No
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does.

Is this an amendment to an existing rule? Yes No
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule?
If codified, please give Arkansas Code citation.

Ark. Code Ann. § 20-9-1207

7. What is the purpose of this proposed rule? Why is it necessary?

To ensure the rule is consistent with current law following the passage of Act 634 of 2011.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).

<http://www.healthy.arkansas.gov/aboutADH/Pages/RulesRegulationsProposed.aspx>

9. Will a public hearing be held on this proposed rule? Yes No
If yes, please complete the following:

Date: 1/13/2012

Time: 10:00 a.m.

Place: Media Room, Fifth Floor, of the Arkansas Department of Health, 4815 W. Markham Street, Little Rock, AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.) 1/13/2012

11. What is the proposed effective date of this proposed rule? (Must provide a date.) 07/15/12

12. Do you expect this rule to be controversial? Yes No
If yes, please explain. _____

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

Arkansas Hospital Association (For)

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Health
DIVISION Legal Services
PERSON COMPLETING THIS STATEMENT Robert Brech
TELEPHONE NO. 501-661-2297 **FAX NO.** 501-661-2357 **EMAIL:** robert.brech@arkansas.gov

To comply with Act 1104 of 1995, please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Health Facility Infection Disclosure

1. Does this proposed, amended, or repealed rule have a financial impact? Yes No
2. Does this proposed, amended, or repealed rule affect small businesses? Yes No
If yes, please attach a copy of the economic impact statement required to be filed with the Arkansas Economic Development Commission under Arkansas Code § 25-15-301 et seq.

3. If you believe that the development of a financial impact statement is so speculative as to be cost prohibited, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please give the incremental cost for implementing the rule. Please indicate if the cost provided is the cost of the program.

Current Fiscal Year

General Revenue NA
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____
Total _____

Next Fiscal Year

General Revenue NA
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____
Total _____

5. What is the total estimated cost by fiscal year to any party subject to the proposed, amended, or repealed rule? Identify the party subject to the proposed rule and explain how they are affected.

Current Fiscal Year

\$ N/A

Next Fiscal Year

\$ N/A

There should be no costs to hospitals. They would simply share data if they are a participant in the Hospital Inpatient Quality Reporting Program

6. What is the total estimated cost by fiscal year to the agency to implement this rule? Is this the cost of the program or grant? Please explain.

Current Fiscal Year

\$ N/A

Next Fiscal Year

\$ N/A

There should be no additional costs to implement the proposed amendments.