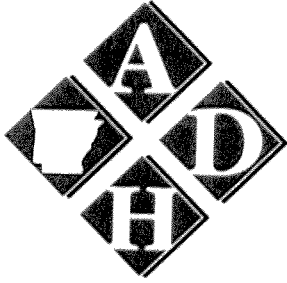


EXHIBIT I



Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000

Governor Mike Beebe

Paul K. Halverson, DrPH, FACHE, Director and State Health Officer

Summary of Proposed Rules Pertaining to Health Facility Infection Disclosure

It is proposed to promulgate Rules and Regulations pertaining to Health Facility Infection Disclosure pursuant to the procedures of the Administrative Procedures Act process, as amended, by authority of Act 434 of 1967 as amended.

These regulations are being developed pursuant to Act 845 of 2007 which establishes voluntary reporting of healthcare associated infections.

- The regulations adopt the definitions and responsibilities as set out in the Act.
- Health facilities which may report include hospitals, outpatient surgery centers, and public health centers or recuperation centers.
- Infections identified as reportable in the Act include:
 - Coronary artery bypass surgical site infections
 - Total hip or knee arthroplasty surgical site infections
 - Knee arthroscopy surgical site infections
 - Hernia repair surgical site infections
 - Central line-associated bloodstream infection in an intensive care unit.
- The regulations establish the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) as the data collection and analysis methodology for healthcare associated infections. NHSN was selected in consultation with the Advisory Committee on Healthcare Associated Infections, as required by Act 845.
- The Advisory Committee was established as designed in the Act and includes the following representatives:
 - Public and private hospitals, including representatives of hospitals with fewer than 50 beds and hospitals with more than 50 beds.
 - Outpatient surgery centers
 - Direct-care nursing
 - Physicians
 - Infection control professionals
 - Academic researchers
 - Consumers
- NHSN is a secure, internet-based surveillance system managed by CDC's Division of Healthcare Quality Promotion.
 - NHSN utilizes standard definitions and is risk-adjusted.
 - There is no charge for participation in NHSN.

December 17, 2008

DRAFT 8/28/08

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



ARKANSAS DEPARTMENT OF HEALTH
2008

Section 1: 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 2: 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 3: 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.

Section 4: 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) Central line-associated bloodstream infections in an intensive care unit; and
- (6) 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.

(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.

Section 5: 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 6: 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 7: 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 8: 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 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 9: 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 10: 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 _____, 2008.

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

A copy of the forgoing Rules have been filed in my office, and are hereby approved on the _____ day of _____, 2008.

The Honorable Mike Beebe
Governor

Baxter, Kim

From: Gail Gannaway [Gail.Gannaway@arkansas.gov]
Sent: Thursday, March 12, 2009 9:28 AM
To: Davis, Donna; Baxter, Kim
Subject: Proposed Rules and Regulations -- Health Facility Infection Disclosure

In December, the Department of Health sent you two copies of Proposed Rules and Regulations pursuant to Act 845 of 2007 (Health Facility Infection Disclosure), the Rules and Regulations Questionnaire, and Financial Impact Statement.

A Notice of Public Hearing ran in the Arkansas Democrat-Gazette on December 21-23, 2008. The public hearing was held January 29, 2009. No written or oral public comments were received and no changes are proposed to the rules and regulations as drafted.

We are requesting to move forward with Legislative review of the proposed regulations. Dr. James Phillips, Chief, Infectious Disease Branch is the contact person for the proposed rules and regulations.

Please let me know of anything we need to do or any additional information you need.

Thanks for your help.

Gail Gannaway
Infectious Disease Branch
Arkansas Department of Health
501-661-2305
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