

APA-1
6/93

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Department or Agency Alabama Department of Public Health

Rule Number 420-4-5

Rule Title Healthcare-Associated Infections Reporting

 New X Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? Yes

Healthcare facilities would bear the cost of training and maintaining staff to enter Healthcare Associated infection (HAI) data. However, in the long-term, consumers will be able to make more informed decisions regarding healthcare facility choices, potentially saving thousands of dollars in healthcare costs, and reducing the length of hospital stay and risk of mortality due to HAIs.

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? No

Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public? Yes

Does the proposed rule have an economic impact? Yes

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of Certifying Officer  Date 7/18/13

FORM APA2
11/96

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-4-5 Healthcare-Associated Infections Reporting

INTENDED ACTION: Amend Rule

SUBSTANCE OF PROPOSED ACTION: The Mike Denton Infection Reporting Act requires that the Alabama Department of Public Health (ADPH) shall promulgate rules and regulations to facilitate the mandatory reporting and collection of specific healthcare-associated infections by healthcare facilities. Rules mandate the use of the National Healthcare Safety Network (NHSN) system and definitions to report HAI data. The locations of all adult and neonatal intensive care units from which central line-associated bloodstream infections (CLABSIs), and all adult and pediatric intensive care units from which catheter-associated urinary tract infections (CAUTIs) can be reported have been added to mandatory reporting through NHSN. These locations are included in national reporting to the Center for Medicaid and Medicare Services, and with the added locations, ADPH will be better prepared to provide appropriate comparisons for the public.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on August 13, 2013 at 201 Monroe Street, RSA Tower, Suite 1540, Montgomery, AL 36104 at 9:00 am.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on September 4, 2013. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Kelly Stevens, Director of Epidemiology, Department of Public Health, 201 Monroe Street, Suite 1460, Montgomery, Alabama 36104. Telephone number: (334) 206-7934.



Pat Ivie, Agency Secretary

ECONOMIC IMPACT STATEMENT

FOR APA RULE

(Section 41-22-23(f))

Control No. 420 Department or Agency: Alabama Department of Public Health

Rule No: 420-4-5

Rule Title: Healthcare-Associated Infections Reporting

New Amend Repeal Adopt by Reference

This rule has no economic impact.

This rule has an economic impact, as explained below:

1. NEED/EXPECTED BENEFIT OF RULE:

The Mike Denton Infection Reporting Act, Code of Ala. 1975, §22-11A-110, et seq., requires that the Alabama Department of Public Health (ADPH) promulgate rules to facilitate the mandatory reporting and collection of healthcare facility data related to healthcare associated infections (HAIs).

2. COSTS/BENEFITS OF RULE AND WHY RULE IS THE MOST EFFECTIVE, EFFICIENT, AND FEASIBLE MEANS FOR ALLOCATING RESOURCES AND ACHIEVING THE STATED PURPOSE:

Nationally, there are an estimated 1.7 million HAIs and 99,000 associated deaths each year (CDC, 2002). Applying CDC's National HAI rates, Alabama has the potential for 33,892 to 67,788 HAIs annually. There are an estimated \$35.7 billion to \$45 billion in annual healthcare costs for hospitals across the Nation due to HAIs.

The implementation of the rules will allow for the comparison of HAI data across hospitals in the State and allow for earlier identification of HAI trends.

3. EFFECT OF THIS RULE ON COMPETITION:

Hospital infection rates will be made public for all healthcare facilities. HAI rates may be reviewed and compared by consumers and healthcare facility stakeholders resulting in increased motivation to adhere to best practices in the reduction of HAIs.

4. EFFECT OF THIS RULE ON THE COST OF LIVING AND DOING BUSINESS IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:

The Healthcare-Associated Infections Reporting Rules mandate the use of the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) to report certain HAIs to public health. Therefore, key personnel at the healthcare facilities will need to be trained in the use of NHSN. Training will result in some additional cost. However, the benefits of comparative, risk-adjusted data, and early identification of trends will result in maintenance of insurance reimbursement based on pending Medicaid reimbursement changes related to patients with HAIs and reduced inpatient days/or loss of life related to HAIs.

5. EFFECT OF THIS RULE ON EMPLOYMENT IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:

The effects of this rule might cause an increase in the employment of infection control hospital staff to meet the data collection and reporting requirements.

6. SOURCE OF REVENUE TO BE USED FOR IMPLEMENTING AND ENFORCING THIS RULE:

Monies awarded by the Centers for Disease Control and Prevention, Epidemiology and Laboratory Capacity Grant, fund the State HAI Coordinator who oversees the HAI Reporting and Prevention program.

7. THE SHORT-TERM/LONG-TERM ECONOMIC IMPACT OF THIS RULE ON AFFECTED PERSONS, INCLUDING ANALYSIS OF PERSONS WHO WILL BEAR THE COSTS AND THOSE WHO WILL BENEFIT FROM THE RULE:

The short-term economic impact will require hospitals to train or possibly hire infection control staff. The long-term economic impact on hospitals will hopefully reduce the cost of healthcare due to expected decrease in the occurrence of HAIs.

8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING QUALITATIVE/QUANTITATIVE BENEFITS AND BURDEN COMPARISON:

The quantitative benefits include a potential reduction in the cost of healthcare. The quantitative burden includes the initial time increase necessary for the implementation of data collection and reporting. The qualitative benefits include a reduction in the occurrence of HAIs in Alabama which will improve the quality of healthcare. The qualitative burden includes the possible misinterpretation of the reported data.

9. THE EFFECT OF THIS RULE ON THE ENVIRONMENT AND PUBLIC HEALTH:

This rule will increase public awareness of HAIs, allow hospitals to identify data trends, allow comparison of best practices, and reduce HAIs.

10. DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE RULE IS NOT IMPLEMENTED:

If these rules are not implemented, the health and cost burden of HAIs will continue to negatively impact Alabama's quality of healthcare.

ALABAMA STATE BOARD OF HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH
DIVISION OF DISEASE CONTROL
ADMINISTRATIVE CODE

CHAPTER 420-4-5
HEALTHCARE-ASSOCIATED INFECTIONS REPORTING

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420-4-5-.01 Definitions and Acronyms. For the purpose of this chapter, the following terms and acronyms shall have the following meanings respectively ascribed to them.

(a) "Accuracy" means the correctness of data reported about Healthcare-Associated Infections (HAIs) submitted to the Alabama Department of Public Health (ADPH) according to standards recommended by the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN).

(b) "ADPH" means the Alabama Department of Public Health, Bureau of Communicable Disease, Division of Epidemiology, HAI Branch: The RSA Tower, 201 Monroe Street, Montgomery, Alabama 36104, P.O. Box 303017, Montgomery, Alabama 36130-3017.

(c) "Advisory Council" means the Healthcare Data Advisory Council as referenced in Code of Ala. 1975, § 22-11A-118.

(d) "Board" means the State Board of Health.

(e) "CAUTI" means Catheter-Associated Urinary Tract Infection.

(f) "CDC" means the Centers for Disease Control and Prevention.

(g) "CLABSI" means Central Line-Associated Bloodstream Infection.

(h) "Critical Care Unit" means a care area that provides intensive observation, diagnosis, and therapeutic procedures for adults or children or both, or neonatal patients, who are critically ill. "Critical Care" and "Intensive Care" are used interchangeably. Care areas that provide step-down, intermediate care, or telemetry only, and specialty care areas are excluded.

(i) "Data" means patient information submitted by healthcare facilities to carry out the requirements of the Mike Denton Infection Reporting Act, Code of Ala. 1975, § 22-11A-110, et seq.

(j) "Electronic Data Submission" means transferring data from a computer used by a reporting entity to the National Healthcare Safety Network (NHSN).

(k) "General Care Ward" means a multidisciplinary care area that provides moderate observation, diagnosis, and therapeutic procedures for adults or children or both who are ill.

(l) "Healthcare-Associated Infection (HAI)" means a localized or systemic condition that results from adverse reaction to the presence of an infectious agent or agents or its toxins, and that was not present or incubating at the time of admission to the healthcare facility. The terms "Health Care Facility Acquired Infection" and "Healthcare-Associated Infection" are synonymous as used in these rules.

(m) "Healthcare Facility" means general, critical access, and specialized hospitals, including pediatric hospitals but excluding psychiatric, rehabilitation, long-term care, and eye hospitals, licensed pursuant to Code of Ala. 1975, § 22-21-20.

(n) "Mixed Acuity Ward" means a hospital area for the evaluation and treatment of adult patients whose conditions are of varying levels of acuity (e.g., critical care, ward-level care, step down type care, etc.). Such a care area may be comprised of patients followed by different hospital services (e.g., coronary, medical, surgical, etc.). This care area may

or may not include "acuity adaptable" or "universal" beds (i.e., this model of patient care allows a patient to stay in the same bed during all phases of his care, from critical care through lower levels of care).

(o) "Mixed Age, Mixed Acuity Ward" means a hospital area for the evaluation and treatment of a mixture of adult and pediatric patients whose conditions are of varying levels of acuity (e.g., critical care, ward-level care, step down type care, etc.). Such a care area may be comprised of patients followed by different hospital services (e.g., coronary, medical, surgical, etc.). This care area may or may not include "acuity adaptable" or "universal" beds (i.e., this model of patient care allows a patient to stay in the same bed during all phases of his care, from critical care through lower levels of care).

(p) "NHSN" means the National Healthcare Safety Network, the electronic system developed by the CDC used to capture HAI data.

(q) "Risk Adjusted" means a process used to identify and adjust for variation in patient HAI outcomes which stem from differences in patient characteristics across healthcare organizations. Risk adjustment accounts for patient-related attributes, such as age, gender, and pre-existing conditions.

(r) "SSI" means Surgical Site Infection.

(s) "Validate" means to evaluate the quality and accuracy of patient information submitted by a healthcare facility to ensure consistency across reporting facilities.

Authors: Kelly M. Stevens, M.S., Nina C. Hassell, M.P.H.

Statutory Authority: Code of Ala. 1975, §22-11A-113; 22-11A-119; 22-2-2(6).

History: New Rule: Filed June 23, 2010; effective July 28, 2010. **Amended:** Filed January 20, 2012; effective February 24, 2012.

420-4-5-.02 Healthcare Facility Responsibilities.

(1) Healthcare facilities shall begin collecting inpatient HAI data using NHSN to report to ADPH no later than January 1, 2011. Healthcare facilities may begin collecting HAI data to report to ADPH using NHSN prior to January 1, 2011.

Data reported prior to January 1, 2011, will be considered test data and will not be publicly reported.

(2) HAI data shall be reported to ADPH from the following categories:

(a) Central Line-Associated Bloodstream Infections (CLABSI) from the following critical care units within a healthcare facility:

- ~~1. Medical Critical Care Units~~
- ~~2. Surgical Critical Care Units~~
- ~~3. Medical/Surgical Critical Care Units~~
1. Adult Critical Care Units
4. 2. Pediatric Critical Care Units
3. Neonatal Critical Care Units

(b) Surgical Site Infections (SSI) from the following procedures:

1. Colon
2. Hysterectomy - abdominal

(c) Catheter-Associated Urinary Tract Infections (CAUTI) from the following ~~general care wards~~ patient care locations within a healthcare facility:

1. General Medical Wards
2. General Surgical Wards
3. General Medical/Surgical Wards
4. Adult Critical Care Units
5. Pediatric Critical Care Units

6.4. Healthcare facilities that cannot comply with reporting CAUTIs from General Medical, General Surgical, and General Medical/Surgical Wards shall report CAUTIs from Mixed Acuity and Mixed Age, Mixed Acuity Wards.

(3) The Advisory Council and ADPH shall review and make recommendations for regulatory modifications of HAI reporting categories annually.

(4) Healthcare facilities shall perform the following NHSN administrative responsibilities no later than January 1, 2011.

(a) Assign an NHSN Facility Administrator and primary HAI contacts.

(b) Submit contact information to ADPH including the healthcare facility name, and names, email addresses, and phone numbers of the NHSN Facility Administrator and primary HAI contacts.

(c) Notify ADPH in writing of changes in healthcare facility staff assigned as NHSN Facility Administrator and primary HAI contacts no later than 30 days after the change occurs.

(d) Ensure appropriate personnel, including healthcare facility individuals with HAI surveillance program oversight responsibilities and other facility personnel responsible for entering data into NHSN, complete the initial CDC NHSN training modules and any subsequent updates.

(e) Maintain a list of NHSN users and their initial and subsequent CDC NHSN training dates, and submit this information to ADPH by January 31 of each calendar year.

(f) Distribute the appropriate NHSN instruction manuals, training materials, data collection forms, and methods for data entry submission to appropriate staff.

(g) Join the ADPH NHSN group and report mandatory HAI data to ADPH.

(h) Follow the CDC NHSN definitions and guidelines for reporting HAI data as referenced in The National Healthcare Safety Network (NHSN) Manual: "Patient Safety Component Protocol", CDC, Atlanta, GA, March 2009, which is hereto adopted by reference, including but not limited to definitions, key terms, location codes, and selected module protocols.

(i) Follow the collection methods as described in Rule 420-4-5-.04.

(j) Ensure a method of quality control in reporting HAI data is established and maintained.

Author: Kelly M. Stevens, M.S.

Statutory Authority: Code of Ala. 1975, §22-11A-113; 22-11A-119; 22-2-2(6).

History: New Rule: Filed June 23, 2010; effective July 28, 2010. **Amended:** Filed November 19, 2010; effective December 24, 2010. **Amended:** Filed January 20, 2012; effective February 24, 2012. **Amended:**

420-4-5-.03 Healthcare Data Advisory Council

Responsibilities. The Advisory Council shall review and serve as consultants to ADPH on all matters pertaining to the collection and reporting of HAI rates including the cost of providing this information.

(a) Specifically, the Advisory Council shall assist in activities such as the development of reporting categories, the corresponding definitions and the development of reports, both internal and to the public.

(b) The Advisory Council shall review and approve any amendments to the rules and regulations, or policies and procedures, on healthcare facility infection reporting.

(c) All meetings of the Advisory Council shall be announced in advance and conducted pursuant to the Open Meetings Act, Code of Ala. 1975, § 36-25A-1, et seq.

(d) A quorum shall be a majority of the appointed members of the Advisory Council.

(e) Voting by proxy shall not be allowed.

(f) The State Health Officer shall serve as chair of the Advisory Council, without a vote, except where there is a tie vote of the other members present at the meeting.

(g) The Advisory Council may appoint technical advisory committees. The technical advisory committee members do not have to be members of the Advisory Council.

(h) The Advisory Council shall meet at least annually to review reports, and may meet more often at the call of the chair, or upon written request of at least three members of the Advisory Council, to review and approve amendments to the rules and regulations.

Author: Kelly M. Stevens, M.S.

Statutory Authority: Code of Ala. 1975, §22-11A-113; 22-11A-119; 22-2-2(6).

History: New Rule: Filed June 23, 2010; effective July 28, 2010.

420-4-5-.04 Collection Methods.

(1) ADPH shall establish a group NHSN account for healthcare facilities to join.

(2) Healthcare facilities shall report inpatient HAI data using the NHSN internet-based surveillance system and submit this information through the established ADPH group NHSN account. Healthcare facilities shall report HAI data monthly. Monthly reporting of HAI data shall be completed by midnight on the final day of the subsequent month.

Author: Kelly M. Stevens, M.S., Nina C. Hassell, M.P.H.

Statutory Authority: Code of Ala. 1975, §22-11A-113; 22-11A-119; 22-2-2(6).

History: New Rule: Filed June 23, 2010; effective July 28, 2010. **Amended:** Filed November 19, 2010; effective December 24, 2010.

420-4-5-.05 Risk Adjustment. ADPH shall develop policies and procedures, or protocols, or both, approved by the Advisory Council, to ensure that reported HAI data are risk adjusted to allow for comparisons between healthcare facilities and to reduce the possibility that reported data will be misleading.

Author: Kelly M. Stevens, M.S., Nina C. Hassell, M.P.H.

Statutory Authority: Code of Ala. 1975, §22-11A-113; 22-11A-119; 22-2-2(6).

History: New Rule: Filed June 23, 2010; effective July 28, 2010.

420-4-5-.06 Data Validation and Quality Assurance.

(1) ADPH, with input from the Advisory Council, shall devise a method to quality check HAI reported data, and shall develop and test a data validation program. Methodologies for data validation shall be approved by the Advisory Council.

(2) Each healthcare facility shall utilize and maintain the NHSN data dictionary and coding schema contained in the NHSN Patient Safety Component Protocol of the National Healthcare Safety Network Manual which is adopted by reference in Rule 420-4-5-.02.

(3) The NHSN has several inherent validation checkpoints. ADPH shall monitor and assess the information, and provide operational guidance for healthcare facilities that target the detected issues.

(4) Healthcare facilities shall be open to site visits by ADPH to assure the timeliness of reporting and to cooperate in problem resolution.

Author: Kelly M. Stevens, M.S., Nina C. Hassell, M.P.H.

Statutory Authority: Code of Ala. 1975, §22-11A-113; 22-11A-119; 22-2-2(6).

History: New Rule: Filed June 23, 2010; effective July 28, 2010.

420-4-5-.07 Studies and Publications.

(1) Reports and studies prepared and released by ADPH, and approved by the Advisory Council, based on healthcare facility HAI data shall be public information, and shall follow the privacy and confidentiality provisions as described in Rule 420-4-5.08.

(2) ADPH shall provide comparative HAI rates among healthcare facilities.

(3) ADPH shall allow all healthcare facilities that have submitted HAI data which will be used in any report to review and comment on the healthcare facility specific information prior to its publication or release for general public use.

(a) Comments of healthcare facilities shall be included, at the option of the healthcare facility, with information

publically reported if it is not changed based upon those comments.

(b) Comments must be submitted in a format approved by ADPH and the Advisory Council within 45 days of the receipt of the report.

(4) ADPH shall prepare and publish reports providing comparative HAI rates for general public use at least annually. Reports may be produced electronically or in hard copy at the discretion of ADPH and the Advisory Council.

Author: Kelly M. Stevens, M.S.

Statutory Authority: Code of Ala. 1975, §22-11A-113; 22-11A-119; 22-2-2(6).

History: New Rule: Filed June 23, 2010; effective July 28, 2010.

420-4-5-.08 Privacy and Confidentiality.

(1) Individual patient information submitted to ADPH shall not be public records and shall not be subject to discovery.

(2) ADPH shall not release the HAI data or any information obtained from the data in a form which could be used to identify a patient.

(3) ADPH shall develop policies and procedures, approved by the Advisory Council, addressing the release of HAI data to legitimate research organizations so that patient confidentiality and privilege protections are maintained.

(4) Individual patient data submitted to ADPH by healthcare facilities shall at all times remain confidential and privileged from discovery.

(5) All information and records acquired or developed shall be secured, have restricted access, and shall be maintained based on the policies established by the Advisory Council and ADPH.

Author: Kelly M. Stevens, M.S.

Statutory Authority: Code of Ala. 1975, §22-11A-113; 22-11A-119; 22-2-2(6).

History: New Rule: Filed June 23, 2010; effective July 28, 2010.

420-4-5-.09 Penalties.

(1) The willful and intentional failure of a healthcare facility to comply with the HAI reporting requirements of these rules may result in the imposition of a civil monetary penalty not to exceed \$5,000 per violation.

(a) Willful and intentional failure to comply with the reporting requirements of these rules includes the following:

1. Failure to submit required data by the deadline set forth in these rules, followed by the facility's failure to submit the data within 60 days of being notified by ADPH of the overdue submission, and

2. Deliberate falsification of data submitted.

(b) A healthcare facility may appeal the assessment of a civil penalty by requesting a hearing that shall be held in accordance with the Board's Rules for Hearing of Contested Cases, Ala. Admin. Code, Chapter 420-1-3, and the Alabama Administrative Procedure Act, Code of Ala. 1975, § 41-22-1, et seq.

(2) All civil monetary penalties collected shall be deposited into the General Fund.

Author: Kelly M. Stevens, M.S.

Statutory Authority: Code of Ala. 1975, §22-11A-113; 22-11A-119; 22-2-2(6).

History: New Rule: Filed June 23, 2010; effective July 28, 2010.

420-4-5-.10 Force or Effect. These rules shall no longer have any force or effect and shall not be enforceable after ADPH determines that there has been an enactment of a United States government program for collecting and disseminating HAI data which mandates, at a minimum, the reporting, collection, and dissemination of the same categories of data required in Rule 420-4-5-.02.

Author: Kelly M. Stevens, M.S.

Statutory Authority: Code of Ala. 1975, §22-11A-113; 22-11A-119; 22-2-2(6).

History: New Rule: Filed June 23, 2010; effective July 28, 2010.