

**Department of State Health Services
Agenda Item for State Health Services Council
January 30-31, 2008**

Agenda Item Title: Proposed new 25 TAC §97.14 concerning a program for reporting Methicillin-resistant *Staphylococcus aureus* (MRSA), a bacteria primarily associated with skin and soft tissue infections.

Agenda Number: 4g

Recommended Council Action: (Consumer Affairs Approves)

For Discussion Only

For Discussion and Action by the Council

Background:

The Infectious Disease Surveillance & Epidemiology (IDSE) Branch is responsible for implementing the proposed new MRSA rule. The IDSE Branch is located within the Community Preparedness Section in the Division of Prevention and Preparedness Services. The Branch manages infectious disease surveillance activities for approximately 50 reportable conditions and assists local and regional health department in disease control and prevention activities. There are 42 positions in the Branch. Federal funds from six different grants or cooperative agreements support 22 of the 42 positions. The other 20 positions are funded with general revenue funds.

Summary:

Health & Safety Code, §81.0445, was passed during the 80th Texas Legislative Session, and relates to a pilot program for reporting of methicillin-resistant *Staphylococcus aureus* (MRSA). A local health authority that 1) demonstrates an interest in conducting the program, and 2) possesses adequate resources to conduct the program will administer the pilot program. No later than September 1, 2009, the Department of State Health Services shall submit a report to the legislature concerning the effectiveness of the pilot program in tracking the prevalence of MRSA. Health and Safety Code, §81.0445 expires on September 1, 2009.

San Antonio Metropolitan Health District, Brazos County Health Department and the Amarillo Bi-City-County Health District have agreed to conduct the pilot program. Patients with MRSA infections will be reported. Reporting will occur for one year (July 1, 2008, through June 30, 2009). Physicians and clinical laboratories in Bexar, Brazos, Potter and Randall counties will be required to report. Information to be reported includes patient name, address, telephone number, age, date of birth, sex, race and ethnicity, date of culture, site of culture, drug susceptibility results, and physician name, address, and telephone number.

Summary of Input from Stakeholder Groups:

There is no advisory committee associated with communicable disease reporting. The Texas Association of Local Health Officials (TALHO) was consulted for identifying health authorities interested in conducting the program. The San Antonio Metropolitan Health District, Brazos County Health Department and the Amarillo Bi-City-County Health District will conduct this pilot program. Staff from the three health departments have participated in conference calls and other discussions on development of the rule and on aspects of implementing and managing the program. Representatives from the Texas Medical Association (TMA) and Texas Hospital Association (THA) have not reviewed the proposed rules at this time. Some representatives from TALHO were involved in writing the proposed rules. All parties interested in the pilot program for MRSA reporting will be able comment on the proposed rules during the 30-day comment period when the proposed rules are published in the *Texas Register*.

Proposed Motion: Motion to recommend HHSC approval for publication of rules contained in agenda item #4g.

Agenda Item Approved by Assistant Commissioner/Director: Casey Blass **Date:** 1/3/2008

Person Presenting: Jeffery P. Taylor, MPH **Program:** Infectious Disease Control Unit **Phone No:** 458-7111 x.6355

Final CAM Approved by Consumer Affairs: RMM **Date:** 12/19/07

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 97. Communicable Diseases
Subchapter A. Control of Communicable Diseases
New §§97.14

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes new §97.14 concerning a program for reporting methicillin-resistant *Staphylococcus aureus* (MRSA), a bacteria primarily associated with skin and soft tissue infections.

BACKGROUND AND PURPOSE

The new section is necessary to comply with House Bill (HB) 1082, 80th Legislature, Regular Session, 2007, (now codified in part as Health and Safety Code, §81.0445), which requires the department to conduct a pilot program for reporting MRSA. A health authority that demonstrates an interest and possesses the resources to conduct the program will manage the program.

The department is required to select a local health authority to administer the program. The program would require 1) all clinical laboratories within the area served by the local health authority to report all cases of MRSA; 2) study the cost and feasibility of adding MRSA to the reportable disease list; 3) collect data related to the possible sources and preventions; 4) provide information about MRSA; and 5) compile and make available to the public a summary of the program. Not later than September 1, 2009, the department shall submit to the legislature a report concerning the effectiveness of the program in tracking and reducing the number of MRSA infections.

SECTION-BY-SECTION SUMMARY

New §97.14(b) defines MRSA and MRSA infection. New §97.14(c) provides language stating that the pilot program will be conducted by health authorities serving Bexar, Brazos, Potter and Randall counties. New §97.14(c) provides language informing the medical provider and clinical or hospital laboratory staff where to report MRSA infections. New §97.14(d) provides language stating what information shall be reported for each MRSA infections. New §97.14(e) and §97.14(f) state when reporting of MRSA infections shall begin and the date when reporting will end.

FISCAL NOTE

Martha McGlothlin, Section Director, Community Preparedness Section, has determined that for each year of the first five years that the section will be in effect, there will be no fiscal implications to state government as a result of enforcing or administering the section as proposed. This rule and the statute that supports it, expires in September 2009. There are fiscal

implications for the three local health authorities that have agreed to conduct this reporting program. These authorities, San Antonio Metropolitan Health District, Brazos County Health District and Amarillo Bi-City-County Health District, are aware of the necessary resources needed to successfully complete the program.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. McGlothlin has also determined that there will be an effect on small businesses or micro-businesses required to comply with the section as proposed. It is estimated that laboratories and physician offices will make 8,800 MRSA reports during one year. From prior experiences, most (95%) of MRSA reports will be made by hospital and clinical laboratories, which are not small or micro-businesses. Only 5% or 440 reports a year will be made by small or micro-businesses. These small businesses would consist of single physician offices or physician group practices.

The primary reporters of MRSA would be physicians in the following practices: family practice, general practice, internal medicine, infectious diseases and pediatrics. From data provided by the Texas Medical Board, 1,713 physicians in these practices are licensed in these four counties. Neither the Texas Medical Association nor the Texas Workforce Commission have data to estimate the number of small or micro-businesses that would consist of these 1,713 physicians in the four counties comprising the three health districts, but some of these physicians are in large group practices whose income would disqualify them under the definition of “small business” used in the Government Code, §2006.001.

The number of small businesses subject to the proposed rule can only be estimated. Assuming four physicians comprise a single group practice, approximately 428 group medical practices would be located in the four county areas. Each would be considered a small business.

There is no anticipated negative impact on local employment.

ECONOMIC IMPACT STATEMENT

Health district staff estimate that a person takes approximately five minutes to make a disease report. From their experiences, health district staff believe nurses in medical offices are the primary reporters. Nurses earn an average of \$25 per hour. A single report would cost a business the amount of \$2.08. The estimated total cost to make 440 disease reports would be \$915.20.

Assuming each of the possible 428 group medical practices has 1 or 2 MRSA infections to report, the possible cost per practice would be approximately \$2.08 to \$4.16.

REGULATORY FLEXIBILITY ANALYSIS

The department considered several methods to determine the incidence of methicillin-resistant *Staphylococcus aureus* in the county populations, and minimize the impacts on small business. The department considered reducing the number of participating pilot sites, but each of the participating local health authorities expressed a strong desire to participate, and reducing the

number of participants would reduce the epidemiologic advantage of comparing disease prevalence in sites with different geographic and demographic characteristics. The department also considered taking reports only from laboratories, but many labs that will diagnose MRSA in participating counties will be located outside of the counties. Therefore the only method of achieving complete or near-complete reporting is to require physician reports. Requiring reporting from clinical and hospital laboratories and from physicians is the best and the least intrusive way to accomplish the important public health purpose of HB 1082, 80th Legislature, Regular Session, 2007, and minimizes the adverse impact of the rule on small businesses.

PUBLIC BENEFIT

Ms. McGlothlin has determined that for each year of the first five years the section is in effect, the public will benefit from adoption of the section. The institutions and individuals responsible for reporting communicable diseases will have clear guidance on what is reportable; the public health community will have clear guidance on its legal responsibilities regarding control and exposure to communicable disease; and the general public will be better served by the department as it fulfills its responsibility to monitor communicable disease, assess and respond to the threat it presents to the public's health.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed rule does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Jeff Taylor, Manager, Infectious Disease Epidemiology and Surveillance Group, Infectious Disease Control Unit, Community Preparedness Section, Division for Prevention and Preparedness, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, (512) 458-7676 or by email to Jeff.Taylor@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rule has been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed new section is authorized by Health and Safety Code, §81.004, which gives the commissioner of the department general statewide responsibility for the administration of the Communicable Disease Act and authorizes the adoption of rules necessary for its effective administration and implementation; Health and Safety Code, §81.0445, which requires the Executive Commissioner of the Health and Human Services Commission to develop rules to establish a pilot program to research and implement procedures for reporting cases of MRSA; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of the Health and Safety Code, Chapter 1001.

The proposed new section affects the Health and Safety Code, Chapters 81 and 1001; and Government Code, Chapter 531.

Legend: (Proposed New Rule(s))
Regular Print=Proposed new language

§97.14 Methicillin-resistant *Staphylococcus aureus* (MRSA) reporting

(a) Purpose. The Communicable Disease Prevention and Control Act, Health and Safety Code, §81.0445, requires the establishment of a pilot program for the reporting of methicillin-resistant *Staphylococcus aureus*.

(b) Definitions. For the purposes of this section, the following words and terms shall have the following meanings.

(1) Methicillin-resistant *Staphylococcus aureus* (MSRA)--*Staphylococcus aureus* for which resistance to oxacillin or ceftiofur is detected as defined by the Clinical and Laboratory Standards Institute, Wayne, Pennsylvania, for the specific test performed in the laboratory.

(2) Methicillin-resistant *Staphylococcus aureus* infection--Invasion and multiplication of MRSA in a bodily part or tissue, which produces cell or tissue injury.

(c) Where to report. The pilot program is being conducted in Bexar, Brazos, Potter and Randall counties only. These jurisdictions meet the requirements of Health and Safety Code, §81.0445(b).

(1) An administrative officer of a clinical or hospital laboratory or physicians located in Bexar County shall report MRSA to the Bexar County Health Authority.

(2) An administrative officer of a clinical or hospital laboratory or physicians located in Potter County or Randall County shall report MRSA to the Health Authority appointed by the Amarillo Bi-City-County Public Health District.

(3) An administrative officer of a clinical or hospital laboratory or physicians located in Brazos County shall report MRSA to the Brazos County Health Authority.

(d) Reportable information requirements.

(1) The information that shall be reported for each person with laboratory confirmation of an infection caused by methicillin-resistant *Staphylococcus aureus* is as follows: patient name, address, telephone number, age, date of birth, sex, race and ethnicity, date of culture, site of culture, drug susceptibility results, and physician name, address, and telephone number.

(2) Additional information necessary to determine and analyze the source and possible prevention of MRSA shall also be reported if requested.

(e) When to report. Reporting shall begin on the effective date of this rule. Methicillin-resistant *Staphylococcus aureus* infection shall be reported within five working days of identification.

(f) This section expires September 1, 2009.