

**Department of State Health Services
Council Agenda Memo for State Health Services Council
September 5-6, 2012**

Agenda Item Title: Amendments to rules concerning the reporting of health care-associated infections and preventable adverse events

Agenda Number: 5.g

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Emerging and Acute Infectious Disease Branch is responsible for implementing the proposed amended rules. The Branch is located within the Infectious Disease Control Unit, Infectious Disease Prevention Section, Division of Prevention and Preparedness Services. The Branch manages infectious disease surveillance activities for approximately 50 reportable conditions and assists local and regional health departments in disease control and prevention activities.

Texas Health and Safety Code, Chapter 98, requires DSHS to establish a reporting system for health care-associated infections (HAIs) and preventable adverse events (PAEs). The chapter requires the reporting system to collect data through a secure, electronic interface. Title 25, Texas Administrative Code, Chapter 200, specifies the reporting requirements for the HAI/PAE program. The program within the Branch implements and manages HAI/PAE reporting by Texas licensed hospitals and ambulatory surgery centers.

Summary:

The purpose of the amendments is to define and add the reporting of designated PAEs and clarify the reporting of PAEs to the public.

DSHS is using the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) reporting application for collecting data on designated HAIs and PAEs. NHSN is capable of collecting specific, but limited PAEs.

The Centers for Medicare and Medicaid Services (CMS) currently require that facilities report catheter-associated urinary tract infection (CAUTI) and DSHS will collect CAUTI data since it is currently reported by facilities to NHSN. As DSHS evaluates the resources needed to collect additional PAE data, DSHS will promulgate rule amendments adding designated PAEs to report.

Key Health Measures:

The data reported by Texas licensed facilities to the NHSN began in October 2011. DSHS will collect the data and present to the public via the DSHS HAI website in late 2013. This will provide consumers with data regarding surgical site infections, central line associated infections, and subsequently the reporting of designated PAEs.

With the addition of reportable PAEs and the public display of this data, the public will have information to compare infection rates and facility errors and thus make decisions that are more informed in regards to their health care.

The data can be compared to other facilities and against national averages. It will also allow facilities to review their data and other facilities' data, which may be conducive to improve health practices to reduce the incidence of these infections, and thus better health care and lower costs.

Records Entered in NHSN as of 8/22/12					
	Reporting Began	# Facilities Reporting	Type Facilities Reporting	# Infection Reports	# Denominators Reported
Central line-associated bloodstream infections	10/01/11	261	Pediatric and Adult General Hospitals	648	645,210 central line days
Knee arthroplasties and related surgical site infections (SSIs)	10/01/11	250	Adult General Hospitals and Surgery Centers	224	26,677 procedures
Ventriculoperitoneal shunt procedures and related SSIs	10/01/11	7	Pediatric Hospitals	13	604 procedures
Hip arthroplasties and related SSIs	01/01/12	229	Adult General Hospitals and Surgery Centers	154	9,711 procedures
Coronary artery bypass grafts with both chest and donor site incisions and related SSIs	01/01/12	124	Adult General Hospitals and Surgery Centers	103	6,010 procedures
Coronary artery bypass graft with chest incision only and related SSIs	01/01/12	72	Adult General Hospitals and Surgery Centers	11	463 procedures
Cardiac procedures and related SSIs	01/01/12	5	Pediatric General Hospitals	5	370 procedures
Heart transplant and related SSIs	01/01/12	2	Pediatric General Hospitals	0	9 procedures

Pediatric and Adult General Hospitals and Surgery Centers will begin reporting additional items January 1, 2013.

Summary of Input from Stakeholder Groups:

The proposed rule amendments will be discussed with the DSHS Advisory Panel on HAI/PAE at their September 7, 2012, meeting. Additionally, the Branch will work with the other stakeholder groups to obtain input, including:

- Texas Hospital Association,
- Children's Hospital Association of Texas,
- Texas Ambulatory Surgery Center Society, and
- Various chapters of the Association of Professionals in Infection Control and the Texas Society of Infection Control Practitioners.

DSHS does not expect any opposition to the rules since facilities are already reporting CAUTIs to NHSN due to the CMS requirements.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #5.g.

Approved by Assistant Commissioner/Director: Lucina Suarez, Ph.D., Acting Assistant Commissioner for Prevention and Preparedness Services Division **Date:** 8/20/2012

Presenter: Jeff Taylor, M.P.H. **Program:** Manager, Emerging and Acute Infectious Disease Branch **Phone No.:** 776-6355

Approved by CCEA: Carolyn Bivens **Date:** 8/22/2012

Title 25. HEALTH SERVICES

Part 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 200. Reporting of Health Care-Associated Infections and Preventable Adverse Events

Subchapter A. Control of Communicable Diseases

Amendments §§200.1 - 200.4, 200.6 - 200.8, 200.10

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §§200.1 - 200.4, 200.6 - 200.8, and 200.10 concerning the reporting of a preventable adverse event (PAE).

BACKGROUND AND PURPOSE

The Texas Health and Safety Code, Chapter 98, requires any health care facility to report the incidence of PAEs as defined in that chapter. The amendments are necessary to define and add the reporting of designated PAEs.

The department is using the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) web reporting application for collecting data on designated PAEs in accordance with Health and Safety Code, Chapter 98, and this chapter. NHSN is capable of collecting specific, but limited PAEs.

The Centers for Medicare and Medicaid Services currently require that facilities report catheter associated urinary tract infection (CAUTI) as part of their Value Based Purchasing program under the Inpatient Prospective Payment System. Initially, the department will collect CAUTI data since it is currently reported by facilities to NHSN. As the department evaluates the resources needed to collect additional PAE data, it will promulgate additional rule amendments adding designated PAEs to report.

SECTION-BY-SECTION SUMMARY

The chapter title is amended to align with the title of the Health and Safety Code Chapter 98 (Reporting of Health Care-Associated Infections and Preventable Adverse Events).

Also, the term "health care-associated infection" replaced the term "healthcare-associated" in §200.1, §200.2, §200.6, and §200.8, and the term "health care" replaced the term "healthcare" in §200.1, §200.6, and §200.10 to be consistent with Health and Safety Code, Chapter 98.

Section 200.1 is amended to revise a definition of the Internal Classification of Disease (ICD), and to add definitions for PAE, urinary catheter, and urinary tract infection (UTI). The numbering of these paragraphs is amended due to these additions.

Section 200.2 is amended to add the PAEs to the name of the rule and to subsection (a), (c), and (d) for reporting guidelines by health care facilities.

Section 200.3(a), (b), (d), and (e)(2) is amended to add how to report the PAEs by health care facilities.

Section 200.4(c) is amended to add the requirement that health care facilities report on urinary catheter device days and UTIs. Subsequent subsections are amended to change the lettering due to these additions.

Section 200.6(b) and (f) is amended to add the reporting of PAEs. Rule references are corrected in subsections (b) - (d) to be consistent with the renumbering of §200.4 of this title. Subsection (e) was added to include the timeframe for reporting urinary catheter device days and UTIs.

Section 200.7(a) is amended to add PAEs to the name of the rule and reporting timeframes.

Section 200.8(a) and (b) is amended to add PAEs to the verification process and corrections to errors and disputes.

FISCAL NOTE

Lucina Suarez, PhD Acting Assistant Commissioner, Division of Prevention and Preparedness Services, has determined that for each year of the first five years that the sections will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing or administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Dr Suarez has also determined that there will be no adverse effect on small businesses or micro-businesses that are required to comply with the sections as proposed because their business practices will not be altered.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

Dr. Suarez has determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The department will compile an annual summary, by health care facility, of the reporting infections. The summary will be made available on an Internet website. Showing infections rates by procedure and health care facility will benefit the public by providing information on infection risk at each health care facility. Efforts by health care facilities to reduce the infection rate for their facility will also benefit the public. The department and other Health and Human Service Commission agencies may use the reported data for research and analysis. In the case of the department, this will consist of earlier identification of outbreaks or infections associated with particular types of procedures, equipment or facilities.

REGULATORY ANALYSIS

The department has determined that the proposed rules are 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. The proposed rules are 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 rules do 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, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Ron Gernsbacher, Program Coordinator, Emerging and Acute Infectious Disease Branch, Infectious Disease Control Unit, Prevention and Preparedness Services Division, Department of State Health Services, Mail Code 1960, P.O. Box 149347, Austin, Texas 78714-9347, (512) 458-7676 or by email to ron.gernsbacher@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 rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendments are proposed under Health and Safety Code, §98.101, which authorizes the Executive Commissioner to adopt rules to implement Chapter 98; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorizes 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 Health and Safety Code, Chapter 1001.

The amendments affect the Health and Safety Code, Chapters 98 and 1001; and Government Code, Chapter 531.

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold Print and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§200.1. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) - (3) (No change.)

(4) Comments--Notes or explanations submitted by the health care **[healthcare]** facilities concerning the department's compilation and summary of the facilities' data that is made available to the public as described in the Texas Health and Safety Code, §98.106.

(5) Data--Facility and patient level information reported to the department for the purposes of monitoring health care-associated **[healthcare-associated]** infections.

(6) - (8) (No change.)

(9) Facility contact--Person identified by the health care **[healthcare]** facility responsible for coordinating communications related to data submission, verification and approval of data summary.

(10) - (12) (No change.)

(13) Health care-associated **[Healthcare-associated]** infection (HAI)--Localized or symptomatic condition resulting from an adverse reaction to an infectious agent or its toxins to which a patient is exposed in the course of the delivery of health care to the patient.

(14) Health care-associated **[Healthcare-associated]** infection data--Patient level information identifying the patient, procedures and events required by these rules, infections resulting from those procedures or events, and causative pathogens when laboratory confirmed.

(15) Health care **[Healthcare]** facility or facility--A general hospital or ambulatory surgery center.

(16) ICD-CM **[ICD-9-CM]**--The **[ninth revision of the]** International Classification of Diseases, Clinical Modification that is used to code and classify morbidity data from the inpatient and outpatient records of hospitals and [,] physician offices.

(17) - (19) (No change.)

(20) Preventable adverse event (PAE)--PAE as defined in Texas Health and Safety Code, §98.1045.

(21) [(20)] Reporting quarters--First quarter: January 1 through March 31; Second quarter: April 1 through June 30; Third quarter: July 1 through September 30; Fourth quarter: October 1 through December 31.

(22) [(21)] Risk adjustment--A statistical method to account for a patient's severity of illness and the likelihood of development of a health care-associated [healthcare-associated] infection (e.g., duration of procedure in minutes, wound class, and American Society of Anesthesiology (ASA) score).

(23) [(22)] Special care setting--A unit or service of a general, pediatric or adolescent hospital that provides treatment to inpatients who require extraordinary care on a concentrated and continuous basis. The term includes an adult intensive care unit, a burn intensive care unit and a critical care unit.

(24) Urinary catheter--As defined by the Centers for Disease Control and Prevention's National Health Care Safety Network at www.cdc.gov/nhsn or its successor.

(25) Urinary tract infection (UTI)-- As defined by the Centers for Disease Control and Prevention's National Health Care Safety Network at www.cdc.gov/nhsn or its successor. A UTI associated with an indwelling urinary catheter is a catheter associated urinary tract infection (CAUTI).

(26) [(23)] Validation--The process of comparing data submissions to original patient and facility records to ascertain that data submission processes are accurate.

(27) [(24)] Verification--Review of data submitted electronically to assure completeness and internal consistency.

§200.2. General Reporting Guidelines for Health Care-Associated [Healthcare-Associated] Infection and Preventable Adverse Event Data.

(a) All general hospitals and ambulatory surgical centers in operation during any part of a reporting quarter described in §200.1 of this title (relating to Definitions) shall submit health care-associated [healthcare-associated infection] (HAI) and designated preventable adverse event (PAE) data as specified in §§200.3 - 200.7 of this title to the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) or its successor.

(b) (No change.)

(c) HAI or PAE data submission does not constitute the report of a disease as defined and required in Chapter 97 of this title (relating to Communicable Diseases).

(d) HAI or PAE data submission does not constitute annual events or incident reporting as defined in §133.49 of this title (relating to Reporting Requirements), or §135.26 of this title (relating to Reporting Requirements).

(e) (No change.)

§200.3. How to Report.

(a) Facilities shall submit HAI and designated PAE data required by this section to NHSN or its successor.

(b) Facilities shall comply with the process prescribed by NHSN or its successor to allow the department access to HAI and designated PAE data as specified in §§200.3 - 200.7 of this title.

(c) (No change.)

(d) The department shall notify the facility contact by email 90 calendar days in advance of any change in requirements for reporting HAI and designated PAE data.

(e) Facilities shall report HAI data on patients identified with a surgical site infection associated with a procedure listed in §200.4 of this title (relating to Which Events to Report).

(1) (No change.)

(2) If the facility treating the patient did not perform the surgery, the treating facility shall notify the facility that performed the procedure, document the notification, and maintain this documentation for audit purposes. The facility that performed the procedure shall verify the data related to the SSI and designated PAE and shall report the infection to NHSN or its successor according to the surveillance methods described by NHSN or its successor and this chapter.

§200.4. Which Events to Report.

(a) - (b) (No change.)

(c) All general hospitals, including pediatric and adolescents hospitals shall report the number of urinary catheter device days and laboratory-confirmed catheter-associated urinary tract infections in special care settings.

(d) [(c)] General hospitals, other than pediatric and adolescent hospitals, and ambulatory surgical centers shall report the HAI data related to the following surgical procedures. The surgical procedure is defined by the NHSN operative procedure and the associated ICD-CM codes linked to that operative procedure in NHSN.

(1) Colon surgeries (Colon surgery).

(2) Hip arthroplasties (Hip prosthesis).

(3) Knee arthroplasties (Knee prosthesis).

(4) Abdominal hysterectomies (Abdominal hysterectomy).

(5) Vaginal hysterectomies (Vaginal hysterectomy).

(6) Coronary artery bypass grafts (Coronary artery bypass graft with both chest and donor site incisions and Coronary artery bypass graft with chest incision only).

(7) Vascular procedures (Abdominal aortic aneurysm repair, Carotid endarterectomy, and Peripheral vascular bypass surgery).

(e) ~~[(d)]~~ Pediatric and adolescent hospitals shall report the HAI data relating to the following surgical procedures. The surgical procedure is defined by the NHSN operative procedure and the associated ICD-CM codes linked to that operative procedure in NHSN.

(1) Spinal surgery with instrumentation (Spinal fusion, Laminectomy, and Refusion of spine).

(2) Cardiac procedures, excluding thoracic cardiac procedures (Cardiac surgery and Heart transplant).

(3) Ventriculoperitoneal shunt procedures (Ventricular shunt operations), including revision and removal of shunt.

(f) ~~[(e)]~~ Facilities shall also report denominator data for the events identified in this rule for calculation of risk adjusted infection rates as required in Texas Health and Safety Code, §98.106(b). NHSN protocols shall be used for the determination of denominator data.

§200.6. When to Initiate Reporting.

(a) All health care **[healthcare]** facilities who meet the criteria in §200.4 of this title (relating to Which Events to Report) shall enroll in NHSN within 90 calendar days of the designation of NHSN as the secure electronic interface.

(b) Facilities shall submit HAI and designated PAE data beginning with the entire reporting quarter of the effective date in subsection (a) of this section.

(1) (No change.)

(2) Ambulatory surgical centers and general hospitals, except pediatric and adolescent hospitals--HAI data relating to knee arthroplasties as defined in §200.4(d)(3) **[§200.4(c)(3)]** of this title.

(3) Pediatric and adolescent hospitals--HAI data relating to ventriculoperitoneal shunts as defined in §200.4(e)(3) [**§200.4(d)(3)**] of this title.

(c) In addition to the data listed in subsection (b) of this section, facilities shall submit the following data beginning January 1, 2012.

(1) Ambulatory surgical centers and general hospitals, except pediatric and adolescent hospitals - HAI data relating to hip arthroplasties as defined in §200.4(d)(2) [**§200.4(c)(2)**] of this title and coronary artery bypass grafts as defined in §200.4(d)(6) [**§200.4(c)(6)**] of this title.

(2) Pediatric and adolescent hospitals - HAI data relating to cardiac procedures and as defined in §200.4(e)(2) [**§200.4(d)(2)**] of this title.

(d) In addition to the data listed in subsections (b) and (c) of this section, facilities shall submit the following data beginning January 1, 2013.

(1) Ambulatory surgical centers and general hospitals, except pediatric and adolescent hospitals--HAI data relating to abdominal and vaginal hysterectomies as defined in §200.4(d)(4) and (5) [**§200.4(c)(4) and (5)**] of this title, colon surgeries as defined in §200.4(d)(1) [**§200.4(c)(1)**] of this title, and vascular procedures as defined in §200.4(d)(7) [**§200.4(c)(7)**] of this title.

(2) Pediatric and adolescent hospitals--HAI data relating to spinal surgeries with instrumentation as defined in §200.4(e)(1) [**§200.4(d)(1)**] of this title.

(e) In addition to the data listed in subsections (b), (c), and (d) of this section, all facilities shall submit the following data beginning July 1, 2013. All general hospitals, including pediatric and adolescents hospitals, shall report the number of urinary catheter device days and laboratory-confirmed catheter-associated urinary tract infections as defined by NHSN, from special care settings.

(f) [(e)] Facilities that are required to report after this initial enrollment period (e.g., newly licensed, change in provider status, etc.) shall enroll within 90 calendar days of the date they become eligible to report in accordance with §200.2 of this title (relating to General Reporting Guidelines for Health Care-Associated [Healthcare-Associated] Infection and Preventable Adverse Event Data) and §200.3 of this title (relating to How to Report) and shall submit data beginning with the entire reporting quarter after becoming eligible.

§200.7. Schedule for HAI and PAE Reporting.

(a) Facilities shall submit HAI and designated PAE data according to the following schedule in Table 1.

Figure: 25 TAC §200.7(a) [**Figure: 25 TAC §200.7(a)**]

(1) HAI and designated PAE data for device days and procedures occurring between January 1 and March 31 shall be submitted no later than May 31 of the same calendar year.

(2) HAI and designated PAE data for device days and procedures occurring between April 1 and June 30 shall be submitted no later than August 31, of the same calendar year.

(3) HAI and designated PAE data for device days and procedures occurring between July 1 and September 30 shall be submitted no later than November 30 of the same calendar year.

(4) HAI and designated PAE data for device days and procedures occurring between October 1 and December 31 shall be submitted no later than February 28 of the following calendar year.

(b) (No change.)

§200.8. Verification of Health Care-Associated [Healthcare-associated] Infection and Preventable Adverse Event Data and Correction of Errors.

(a) Data verification.

(1) (No change.)

(2) The department will notify the facility contact by email to acknowledge receipt of data and to communicate its acceptability within 15 calendar days after the facility data submission deadline described in §200.7 of this title (relating to Schedule for HAI and PAE Reporting). This notification will include specific information on any errors found.

(b) Correction of Errors and Disputes.

(1) (No change.)

(2) Corrections shall be submitted according to the following schedule.

(A) Not later than June 30 for HAI and designated PAE data for device days and procedures occurring between January 1 and March 31.

(B) Not later than September 30 for HAI and designated PAE data for device days and procedures occurring between April 1 through June 30.

(C) Not later than December 31 for HAI and designated PAE data for device days and procedures occurring between July 1 through September 30.

(D) Not later than March 31 for HAI and designated PAE data for device days and procedures occurring between October 1 through December 31.

(3) - (4) (No change.).

(c) (No change.)

§200.10. Data Validation.

All data submitted by facilities are subject to data validation. When requested by the department, a health care [**healthcare**] facility shall provide the department access to, copies of and/or information from the facility documents and records underlying and documenting the data submitted, as well as other patient related documentation deemed necessary to validate facility data.

Figure: 25 TAC §200.7(a)

Table 1. HAI and PAE Data Verification Deadlines				
Reporting Quarter	January 1- March 31	April 1- June 30	July 1- September 30	October 1- December 31
Facility Data Submission	As set forth in NHSN or its successor			
Departmental Data Reconciliation	June 1	September 1	December 1	March 1
Facility Correction	June 30	September 30	December 31	March 31
Departmental Data Summary	NA	October 15	NA	April 15
Facility Comment Period	NA	October 30	NA	April 30
Departmental Review of Comments	NA	November 15	NA	May 15
Posting of Summary	NA	December 1	NA	June 1

* Reporting deadline for infections related to implant procedures are the same dates but in the calendar year following the procedure.