

TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 200. HEALTHCARE-ASSOCIATED INFECTIONS

SUBCHAPTER A. CONTROL OF COMMUNICABLE DISEASES

§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) Ambulatory surgical center--A facility licensed under Texas Health and Safety Code, Chapter 243.
- (2) Central line--An intravascular catheter that terminates at or close to the heart or in one of the great vessels which is used for infusion, withdrawal of blood or hemodynamic monitoring.
- (3) CMS--Centers for Medicare and Medicaid Services under the United States Department of Health and Human Services.
- (4) Comments--Notes or explanations submitted by the 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 healthcare-associated infections.
- (6) Data summary--Facility level information prepared by the department for each health care facility required to report in this state to facilitate comparisons of risk-adjusted infection rates.
- (7) Department--Department of State Health Services.
- (8) Device days--The number of patients in a special care setting who have 1 or more central lines for each day of the month, determined at the same time each day of the reporting quarter.
- (9) Facility contact--Person identified by the healthcare facility responsible for coordinating communications related to data submission, verification and approval of data summary.
- (10) Facility Identification Number--The unique, distinguishable, uniform number used to identify each health care facility.

(11) General hospital--A hospital licensed under Texas Health and Safety Code, Chapter 241, or a hospital that provides surgical or obstetrical services and that is maintained or operated by the state.

(12) Great vessels--Primary blood vessels to include aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, common femoral veins, and in neonates, the umbilical artery or umbilical vein.

(13) 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) 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) Healthcare facility or facility--A general hospital or ambulatory surgery center.

(16) 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, physician offices.

(17) Inpatient Treatment--An admission to an acute care hospital of greater than 24 hours for treatment of a post operative surgical site infection.

(18) NHSN--Federal Centers for Disease Control and Prevention's National Healthcare Safety Network or its successor.

(19) Pediatric and adolescent hospital--A general hospital that specializes in providing services to children and adolescents, as defined in Texas Health and Safety Code, §241.003.

(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.

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

(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.

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

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

§200.2. General Reporting Guidelines for Healthcare-Associated Infection 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 healthcare-associated infection (HAI) data as specified in §§200.3 - 200.7 of this title to the department.

(b) Facilities that fail to comply with reporting requirements are subject to the enforcement provisions of Texas Health and Safety Code, Chapter 98, Subchapter D.

(c) HAI 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 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) The facility shall ensure that the department has accurate email and phone information for a facility contact. Facilities may provide institutional contact information (e.g., IP@hospital.org, 1-800-INFECTS). The facility shall ensure that communications from the department are continuously monitored even if the position is vacant for any reason (vacation, illness, etc.).

§200.3. How to Report.

(a) Facilities shall submit HAI data required by this section to a secure, electronic interface designated by the department.

(b) Facilities shall comply with the process of the designated secure, electronic interface to allow the department access to HAI data as specified in §§200.3 - 200.7 of this title.

(c) Facilities shall use their facility identification number to identify their facility in the electronic data and correspondence with the department. Each facility meeting the definition of ambulatory surgical center or general hospital as defined in §200.1(1) and (11) of this title (relating to Definitions) shall have its own facility identification number.

(1) CMS certified health care facilities shall use the CMS-assigned provider number.

(2) If a facility has multiple campuses or a hospital and ambulatory surgical center are associated by ownership, each site shall each use a unique CMS provider number. In the

event that a facility is not CMS certified or a facility operates multiple facilities under one CMS number, the facility shall contact the designated electronic interface administrator to receive a facility identification number.

(3) The relationship between CMS-assigned and department-assigned facility identifiers and the name and license number of the facility is public information.

(d) The department shall notify the facility contact by email, fax, or in writing 90 calendar days in advance of any change in requirements for reporting HAI data.

(e) Facilities shall report HAI data on patients who are admitted to the facility for inpatient treatment of a surgical site infection associated with a procedure listed in §200.4 of this title (relating to Which Events to Report) within 30 calendar days of the procedure or within 1 year of the procedure if the procedure involved an implant.

(1) If the facility treating the patient performed the procedure, the facility shall report the infection in the designated electronic data interface according to the surveillance methods described by the interface and these rules.

(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 shall report the infection in the designated electronic data interface according to the surveillance methods described by the interface and these rules.

§200.4. Which Events to Report.

(a) ICD-9 codes as designated by the federal Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) or its successor shall constitute the definition of events listed in this rule. Facilities shall adapt to changes in ICD-9-CM specifications as directed by NHSN and the department.

(b) All general hospitals shall report the number of device days and laboratory-confirmed central line-associated primary bloodstream infections in special care settings including the causative pathogen.

(c) General hospitals, other than pediatric and adolescent hospitals, and ambulatory surgical centers (except those hospitals or ambulatory surgical centers described in subsection (d) of this section) shall report the HAI data related to the following surgical procedures. The surgical procedure is defined by the NHSN operative procedure and the ICD-9-CM codes linked to that operative procedure.

(1) Colon surgeries (Colon surgery--17.31 - 17.36, 17.39, 45.03, 45.26, 45.41, 45.49, 45.52, 45.71 - 45.76, 45.79, 45.81 - 45.83, 45.92 - 45.95, 46.03, 46.04, 46.10, 46.11, 46.13, 46.14, 46.43, 46.52, 46.75, 46.76, 46.94).

- (2) Hip arthroplasties (Hip prosthesis--00.70 - 00.73, 00.85 - 00.87, 81.51 - 81.53).
- (3) Knee arthroplasties (Knee prosthesis--00.80 - 00.84, 81.54, 81.55).
- (4) Abdominal hysterectomies (Abdominal hysterectomy--68.31, 68.39, 68.41, 68.49, 68.61, 68.69).
- (5) Vaginal hysterectomies (Vaginal hysterectomy--68.51, 68.59, 68.71, 68.79).
- (6) Coronary artery bypass grafts (Coronary artery bypass graft with both chest and donor site incisions--36.10 - 36.14, 36.19; Coronary artery bypass graft with chest incision only--36.15 - 36.17, 36.2).
- (7) Vascular procedures (Abdominal aortic aneurysm repair--38.34, 38.44, 38.64; Carotid endarterectomy--38.12; Peripheral vascular bypass surgery--39.29).

(d) A general hospital, other than a pediatric and adolescent hospital, or ambulatory surgical center that does not perform at least a monthly average of 50 of any combination of the procedures listed in subsection (c) of this section shall report HAI data relating to all of the three surgical procedures most frequently performed at the facility that are also listed by NHSN. The average number of procedures and the three most frequently performed procedures shall be determined based on the calendar year prior to the reporting year as determined by facility contact.

(e) Pediatric and adolescent hospitals except those described in subsection (f) of this section shall report the HAI data relating to the following surgical procedures. The surgical procedure is defined by the NHSN operative procedure and the ICD-9-CM codes linked to that operative procedure.

- (1) Spinal surgery with instrumentation (Spinal fusion--81.00 - 81.08, 81.62 - 81.64; Laminectomy--03.01, 03.02, 03.09, 80.50, 80.51, 80.53, 80.54, 80.59, 84.60 - 84.69, 84.80 - 84.85; Refusion of spine--81.30 - 81.39).
- (2) Cardiac procedures, excluding thoracic cardiac procedures (Cardiac surgery--35.00 - 35.04, 35.10 - 35.14, 35.20 - 35.28, 35.31 - 35.35, 35.39, 35.42, 35.50, 35.51, 35.53, 35.54, 35.60 - 35.63, 35.70 - 35.73, 35.81 - 35.84, 35.91 - 35.95, 35.98, 35.99, 37.10, 37.11, 37.24, 37.31 - 37.33, 37.35, 37.36, 37.41, 37.49, 37.60; Heart transplant--37.51 - 37.55).
- (3) Ventriculoperitoneal shunt procedures (Ventricular shunt operations), including revision and removal of shunt--02.2, 02.31 - 02.35, 02.39, 02.42, 02.43, 54.95).

(f) A pediatric and adolescent hospital that does not perform at least a monthly average of 50 of any combination of the procedures listed in subsection (e) of this section shall report the HAI data relating to all of the three surgical procedures most frequently performed at the facility that are also listed by NHSN. The average number of procedures

and the three most frequently performed procedures shall be determined based on the calendar year prior to the reporting year. Reporting of HAI data for all three surgeries shall begin for the entire quarter in which the enrollment deadline occurs as specified in §200.6 of this title (relating to When to Initiate Reporting).

(g) Facilities shall also report denominator data for the events identified above 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.

§200.5. Data to Report.

Data required to be submitted in §200.4 of this title (relating to Which Events to Report) shall be reported using the training, enrollment, case definitions and protocols required by the department in coordination with NHSN or its successor. Specific modules and variables will be identified for facilities prior to the enrollment deadline through training, departmental website, and notification of the facility contact. Content or data element changes will be communicated in the same manner 90 calendar days in advance of the change.

§200.6. When to Initiate Reporting.

(a) All healthcare facilities shall enroll in the secure, electronic interface within 90 calendar days of the effective date of this rule, or the designation of the secure electronic interface, whichever is later.

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

(1) All facilities--HAI data relating to central line-associated primary bloodstream infections in special care units.

(2) Ambulatory surgical centers and general hospitals, except pediatric and adolescent hospitals--HAI data relating to knee arthroplasties as defined in §200.4(c)(3) of this title (relating to Which Events to Report) or the three surgical procedures most frequently performed as described in §200.4(d) of this title.

(3) Pediatric and adolescent hospitals--HAI data relating to ventriculoperitoneal shunts as defined in §200.4(e)(3) of this title or the three surgical procedures most frequently performed as defined in §200.4(f) 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(c)(2) of this title and coronary artery bypass grafts as defined in §200.4(c)(6) of this title or HAI data

relating to the three surgical procedures most frequently performed as described in §200.4(d) of this title.

(2) Pediatric and adolescent hospitals - HAI data relating to cardiac procedures as defined in §200.4(e)(2) of this title or the three surgical procedures most frequently performed as described in §200.4(f) 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(c)(4) and §200.4(c)(5) of this title, colon surgeries as defined in §200.4(c)(1) of this title, and vascular procedures as defined in §200.4(c)(7) of this title or the three surgical procedures and associated infections most frequently performed as described in §200.4(d) of this title.

(2) Pediatric and adolescent hospitals--HAI data relating to spinal surgeries with instrumentation as defined in §200.4(e)(1) of this title or the three surgical procedures most frequently performed as described in §200.4(f) of this title.

(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 receipt of a CMS provider number or a HAI reporting facility identification number and shall submit data beginning with the entire reporting quarter after receipt of the identification number.

§200.7. Schedule for HAI Reporting.

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

Figure: 25 TAC §200.7(a)

(1) HAI 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 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 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 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) If any of the dates in subsection (a) of this section fall on a weekend or holiday, facilities shall submit on the following business day.

§200.8. Verification of Healthcare-associated Infection Data and Correction of Errors.

(a) Data verification.

(1) The department shall establish acceptance criteria to ensure the accuracy and completeness of all data submitted to the department and will make these criteria available.

(2) The department will notify the facility contact by email, fax, or in writing 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 Reporting). This notification will include specific information on any errors found.

(b) Correction of Errors and Disputes.

(1) Facilities shall correct all identified errors, including data determined to be missing, and resubmit the corrected data through the designated secure electronic interface.

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

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

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

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

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

(3) If the facility is unable to correct an identified error or disputes one or more of the identified errors, the facility contact shall notify the department by email, fax, or in writing the reasons why these are the best available data within 15 calendar days of receipt of notice of corrections.

(4) Data corrections that occur following publication of a data summary shall be submitted to the department for use in future data compilations.

(c) If any of the dates listed in subsection (b) of this section fall on a weekend or holiday, facilities shall submit on the following business day.

§200.9. Data Summary Display.

(a) Development of data summary.

(1) The department shall compile a data summary for each reporting facility. The data summary shall be made available to the public on an Internet website in a format to be determined by the department.

(2) The data summary shall be based on data submitted by the facility and may include raw numbers for numerator and denominator, rates, risk-adjustments, and state and national comparative data.

(3) Facilities that have failed to submit data or submitted data in a format other than that specified by the department shall be identified in the summary made available to the public.

(4) Data summaries based on data that the department has determined to be inaccurate or incomplete which has not or cannot be corrected by the facility in a timely fashion shall be included in the data summary. Explanatory notes shall be included in the summary to inform the public of the nature of the data deficiencies.

(5) Data displays shall be based on the best available data at the time the summaries are completed. Displays of trends over time may include updated or corrected data that are discrepant with previous summaries.

(b) Facility comments.

(1) Prior to publication of the data summary for public use, the department shall notify the facility contact by email, fax, or in writing of the opportunity to submit comments for publication with the data summary.

(2) The facility contact shall submit comments using the format determined by the department or notify the department by email, fax, or in writing that the facility does not wish to comment.

(3) The comments shall be 1,250 characters in length or less.

(4) The department shall review facility comments to assure that they are concise and pertain only to the facility and the current data. The department may edit comments that are not concise or do not pertain only to the facility and current data.

(5) Comments are due to the department on or before October 30 of the same calendar year for summaries of data collected January 1 through June 30 and on or before April 30 of the following calendar year for summaries of data collected July 1 through December 31.

§200.10. Data Validation.

All data submitted by facilities are subject to data validation. When requested by the department, a 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 Reporting Deadlines*				
Reporting Quarter	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
Facility Data Submission Deadline	May 31	August 31	November 30	February 28
Departmental Data Reconciliation	June 15	September 15	December 15	March 15
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.