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Patient Safety Authority Notice of Reporting Requirements for Health Care Facilities pursuant to the Medical Care Availability and Reduction of Error (MCARE) Act, Chapter 4. Health Care-Associated Infections 40 P.S. § 1303.401, et. seq. (2007)

Purpose

The purpose of this announcement is to give health care facilities notice of their reporting requirements to the Patient Safety Authority pursuant to the Medical Care Availability and Reduction of Error (MCARE) Act, Chapter 4, Health Care-Associated Infections. The reporting requirements presented in this notice were developed in consultation with the Department of Health and the Patient Safety Authority's Health Care-Associated Infection (HAI) Advisory Panel.

Reporting Requirements for Hospitals

Hospitals are required to report HAIs to the Centers for Disease Control and Prevention (CDC) through its National Healthcare Safety Network (NHSN). The infections that are reportable include all CDC-defined event types and specific events. This is presented at the end of this notice as Exhibit A.

Serious Event Reporting

The occurrence of a CDC-defined HAI in a hospital is deemed to constitute a Serious Event as defined by the MCARE Act, § 302. If an infection meets the criteria for reporting to the NHSN, that infection shall be reported to the Authority as a Serious Event as required by Act 13 and Act 52, subject to the additional requirements as described in this notice.

Health care-associated infections reported through the NHSN are subject to the same patient notification requirements set forth by Act 13 for all Serious Events. For purposes of meeting the 24-hour reporting requirement for Serious Events set forth by Act 13, hospitals must submit reports of HAIs to the NHSN system and to the Authority within twenty-four hours of their confirmation. If confirmation of an HAI occurs over a weekend or recognized holiday, reports must be submitted by 5:00 pm on the next work day. In addition, Serious Event disclosure letters must be completed for all infections submitted through the NHSN, with the exception of asymptomatic bacteriuria.

Reporting Other Events Related to Infection Control and Prevention

Act 13 requires hospitals to submit not only reports of Serious Events but also Incidents and Infrastructure Failures. Under Act 13, reporting of Incidents and Infrastructure Failures is mandatory, and hospitals must continue reporting other events related to infection control and prevention that can be classified as Incidents or Infrastructure Failures through the Pennsylvania Patient Safety Reporting System (PA-PSRS).

Examples of Incidents might include, but would not be limited to:

- Failure to put an infected patient on the appropriate level of isolation precautions.
- Failure to use maximum barrier precautions when inserting a central line.

- Failure to periodically evaluate a catheterized patient's continued need for a catheter.
- Breach in sterile technique during surgery.

If the above examples led to CDC-defined infections, they would be reportable in NHSN as Serious Events. If they did not lead to infections, they would be classified as Incidents and reported in PA-PSRS.

Examples of Infrastructure Failures might include, but would not be limited to:

- Contamination of sterile supplies due to a chemical leak that contaminates needed equipment.
- Unavailability of sterile supplies needed to implement isolation precautions on infected patients.
- Screening cultures on high risk patients are prevented due to failure of critical lab equipment.

If the above examples led to CDC-defined infections, they would be reportable in NHSN as Serious Events. If they did not lead to infections, they would be classified as Infrastructure Failures and reported in PA-PSRS.

Reportable HAIs and Customization Requirements

The Authority would like to avoid duplicate reporting of HAIs as a Serious Event to both PA-PSRS and the NHSN system. HAIs reported through the NHSN will not need to be reported through PA-PSRS as long as a reporting facility customizes the NHSN Data Collection Forms for several types of infections. The required customization is defined below. Until a facility customizes NHSN as described herein and answers the additional questions required by the Authority, the facility must continue to report HAIs as Serious Events through PA-PSRS. Please note, not every infection type requires customized questions—only those indicated below. However, once this condition is met, all CDC-defined infections do not need to be entered into PA-PSRS if they are entered timely into NHSN.

Detailed instructions for how to create custom fields for CDC-defined events may be found in the NHSN Online Manual, which can be accessed by clicking "Help" while logged onto NHSN. Once the Online Manual is accessed, go to the table of contents on the left and refer to Patient Safety Component>How to>Custom Options.

For each CDC-defined infection event type, select the appropriate form and modify the custom fields as instructed below. For each custom field to be modified, we provide the following information:

- The question to be answered.
- The custom field label before modification, which identifies which field to edit or customize.
- The customized field label, which is the short label that will display on the screen when completing an infection report.
- Response categories, in the format of ("1" [yes]) where the text in quotations ("1") is the text to be typed when completing an infection report, and where the text in brackets ([yes]) is the meaning of the text to be typed.

Device Associated Module

Form 1: Central Line-Associated Bloodstream Infection (CLABSI) Event

Question 1: Were maximal barrier precautions utilized during insertion of the central line, including hand hygiene, wearing a cap, mask, sterile gown, and gloves?

Field Label Before Modification: Alphanumeric, Label 7

Customized Field Label: maximal barrier

Response categories: "1" [yes]; "2" [no]; "3" [unknown]

Question 2: Was chlorhexidine skin asepsis with antiseptic/detergent chlorhexidine 2% in 70% isopropyl alcohol utilized during insertion of the central line?

Field Label Before Modification: Alphanumeric, Label 8

Customized Field Label: skin asepsis

Response categories: "1" [yes]; "2" [no]; "3" [unknown]

Question 3: Was central line necessity evaluated daily and documented during the patient's hospitalization?

Field Label Before Modification: Alphanumeric, Label 9

Customized Field Label: line necessity

Response categories: "1" [yes]; "2" [no]; "3" [unknown]

Question 4: [Reserved]

Field Label Before Modification: Alphanumeric, Label 10

Customized Field Label: [Reserved – Customization not required at this time]

Response categories: [Reserved – Customization not required at this time]

Form 2: Ventilator-Associated Pneumonia (VAP) Event

Question 1: Was the head of the patient's bed elevated to between 30 and 45 degrees at all times while the patient was receiving mechanically assisted ventilation?

Field Label Before Modification: Alphanumeric, Label 6

Customized Field Label: hob elevated

Response categories: "1" [yes]; "2" [no]; "3" [unknown]

Question 2: Did the patient receive a daily sedation interruption while the patient was receiving mechanically assisted ventilation?

Field Label Before Modification: Alphanumeric, Label 7

Customized Field Label: sedation interr

Response categories: "1" [yes]; "2" [no]; "3" [unknown]

Question 2a: If the response to Question 2 is "no," was a daily sedation interruption clinically contraindicated?

Field Label Before Modification: Alphanumeric, Label 8

Customized Field Label: sedation contra

Response categories: "1" [yes]; "2" [no]; "3" [unknown]

Question 3: Was a daily assessment of readiness to extubate performed and documented?

Field Label Before Modification: Alphanumeric, Label 9

Customized Field Label: assess extubate

Response categories: "1" [yes]; "2" [no]; "3" [unknown]

Question 4: [Reserved]

Field Label Before Modification: Alphanumeric, Label 10

Customized Field Label: [Reserved – Customization not required at this time]

Response categories: [Reserved – Customization not required at this time]

Form 3: Catheter-Associated Urinary Tract Infection (CAUTI) Event

Question 1: Was a daily assessment performed and documented of the necessity for continued catheterization?

Field Label Before Modification: Alphanumeric, Label 9

Customized Field Label: cath necessity

Response categories: "1" [yes]; "2" [no]; "3" [unknown]

Question 2: [Reserved]

Field Label Before Modification: Alphanumeric, Label 10

Customized Field Label: [Reserved – Customization not required at this time]

Response categories: [Reserved – Customization not required at this time]

Procedure-Associated Module

Form 4: Surgical Site Infection (SSI) Event

Question 1: Was a prophylactic antibiotic received within 1 hour prior to surgical incision (or within 2 hours of surgical incision if the patient received vancomycin or fluoroquinolone) for a patient who has undergone any of the following procedures:

- CBGB, CBGC, cardiac surgery
- hip arthroplasty
- knee arthroplasty
- abdominal hysterectomy
- colon surgery
- vascular surgery

Field Label Before Modification: Alphanumeric, Label 9

Customized Field Label: antibiotics rec

Response categories: "1" [yes]; "2" [no]; "3" [unknown]; "4" [not applicable because patient did not have one of the listed procedures]

Question 2: [Reserved]

Field Label Before Modification: Alphanumeric, Label 10

Customized Field Label: [Reserved – Customization not required at this time]

Response categories: [Reserved – Customization not required at this time]

Reporting Requirements for Nursing Homes

Nursing homes are required to electronically report patient-specific health care-associated infection data to the Patient Safety Authority and the Department of Health using nationally recognized standards based on CDC definitions. The time and format is to be determined by the Authority and the Department. The Authority and the Department anticipate that uniform reporting requirements for Nursing Homes will be determined by the summer of 2008.

Public Comment Period

For 30 calendar days from the date of this publication, the Patient Safety Authority is accepting public comment about the uniform reporting requirements established jointly by the Patient Safety Authority and the Department of Health pursuant to Chapter 4- Health Care-Associated Infections of the Medical Care Availability and Reduction of Error Act, 40 P.S. § 1303.401, et. seq., (2007).

Submit comments electronically via e-mail to the Pennsylvania Patient Safety Authority at patientsafetyauthority@state.pa.us.

The Authority will review comments received and publish a Final Notice in the Pennsylvania Bulletin. This notice may include updates or changes, based on public comments, to the Authority's reporting requirements.

Persons with a disability who require an alternative format of this notice (for example large print, audiotape or Braille) should contact the PA-PSRS help desk at 866-316-1070.

Exhibit A. Reportable HAIs (CDC Defined Event Types and Specific Events)

BSI – Bloodstream Infection

- LCBI – Laboratory-confirmed bloodstream infection
- CSEP – Clinical sepsis

DI – Dialysis Incident

PNEU – Pneumonia

- PNU1 – Clinically defined pneumonia
- PNU2 – Pneumonia with common bacterial or filamentous fungal pathogens and specific laboratory findings
- PNU2 – *Viral, Legionella*, and other bacterial pneumonias with definitive laboratory findings
- PNU3 – Pneumonia in immunocompromised patients

SSI – Surgical Site Infection

- SIP – Superficial incisional primary
- SIS – Superficial incisional secondary
- DIP – Deep incisional primary
- DIS – Deep incisional secondary
- Organ/Space*

UTI – Urinary Tract Infection

- ASB – Asymptomatic bacteriuria
- SUTI – Symptomatic urinary tract infection
- OUTI – Other infections of the urinary tract

BJ – Bone and Joint Infection

- BONE – Osteomyelitis

JNT – Joint or bursa

DISC – Disc space

CNS – Central Nervous System Infection

IC – Intracranial infection

MEN – Meningitis

SA – Spinal abscess without meningitis

CVS – Cardiovascular System Infection

VASC – Arterial or venous infection

ENDO – Endocarditis

CARD – Myocarditis or pericarditis

MED – Mediastinitis

EENT – Eye, Ear, Nose, Throat, or Mouth Infection

CONJ – Conjunctivitis

EYE – Other than Conjunctivitis

EAR – Mastoid

ORAL – Cavity (mouth, tongue, or gums)

SINU – Sinusitis

UR – Upper respiratory tract, pharyngitis, laryngitis, epiglottitis

GI – Gastrointestinal System Infection

GE – Gastroenteritis

GIT – GI tract

HEP – Hepatitis

IAB – Intraabdominal, not specified elsewhere

NEC – Necrotizing enterocolitis

LRI – Lower Respiratory Tract Infection, other than Pneumonia

BRON – Bronchitis, tracheobronchitis, tracheitis, without evidence of pneumonia

LUNG – Other infections of the lower respiratory tract

REPR – Reproductive Tract Infection

EMET – Endometritis

EPIS – Episiotomy

VCUF – Vaginal cuff

OREP – Other infections of the male or female reproductive tract

SST – Skin and Soft Tissue Infection

SKIN – Skin

ST – Soft tissue

DECU – Decubitus ulcer

BURN – Burn infection

BRST – Breast abscess or mastitis

UMB – Omphalitis

PUST – Infant pustulosis

CIRC – Newborn circumcision

SYS – Systemic Infection

DI – Disseminated infection (not to be confused with DI [Dialysis Incident])