NOTICES

Reporting Requirements for Health Care Facilities under the Medical Care Availability and Reduction of Error (MCARE) Act

[38 Pa.B. 1120]
[Saturday, March 1, 2008]

Purpose

The purpose of this announcement is to give health care facilities final notice of their reporting requirements to the Patient Safety Authority (Authority) under 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 (Department) and the Patient Safety Authority's Health Care-Associated Infection (HAI) Advisory Panel.

Background of Final Notice

A public comment period for 30 days after publication of the first notice on December 22, 2007, resulted in the Authority receiving 14 public comments addressing 14 categories. A summary of the comments and responses are detailed as follows. The Authority has made changes as reflected in this document.

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 24 hours of their confirmation. If confirmation of an HAI occurs over a weekend or recognized holiday, reports must be submitted by 5 p.m. on the next workday. 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 previous 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 previous 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.

Summary of Comments and Responses

* **Serious Event Reporting--**We received 8 comments regarding treatment of all CDC-defined infections as Serious Events. The comments noted that all infections are not of equal severity and not all infections should be considered Serious Events. Some comments in this group objected to the requirement for providing written notice to the patient, as is required for all Serious Events.

* *Act 52 of 2007 mandates that all CDC-defined HAIs be reported as Serious Events. The Act provides no discretion in this requirement. No changes have been made in response to these comments.*

* **Reportable HAIs and Customization Requirements--**We received 10 comments on Reportable HAIs and Customization Requirements. The comments suggested that the data proposed for collection would not contribute to the elimination of HAIs, but rather, would create an additional burden for Infection Control Professionals.

* *The Authority developed uniform reporting requirements with the input of the Healthcare Associated Infection Advisory Panel per the requirements of Act 52 of 2007. The customization requirements are designed to collect data on best practices for infection prevention. The extent to which best practices were followed in the care of a patient who became infected may be of significance when determining the cause of an infection. While this does increase the reporting burden, if best practices are worth adopting, the Authority believes they are also worth monitoring. No changes have been made in response to these comments.*

* **Reporting Requirements for Hospitals--Dialysis Incident--**We received 8 comments regarding "Exhibit A, which identifies Dialysis Incident as a required event type for reporting purposes. The Department of Health (DOH) notified hospital CEOs in a letter dated December 5, 2007 that a Dialysis Event is primarily out-patient and therefore, will not be required for hospitals."

* *We have deleted the category Dialysis Incident from Exhibit A.*

* **CLABSI Event--Maximal Barriers--**We received 8 comments regarding Question 1. "Were maximal barrier precautions utilized during insertion of the central line, including hand hygiene, wearing a cap, mask, sterile gown and gloves?" The comments noted that "documentation in the medical records of maximal barrier usage is rare. Although many hospitals utilize checklists or insertion monitoring tools that may contain all or portions of the information, the burden of matching that document to the specific event would be time and resource consuming."

* *The elements of this question are based on the best practices defined in the IHI Central Line Bundle. For health care facilities that either have not adopted this IHI bundle or do not monitor performance of the bundle components, the Authority encourages them to do so. No changes have been made to Question 1.*

* **CLABSI Event--Skin Asepsis--**We received 9 comments regarding Question 2. "Was chlorhexidine skin asepsis with antiseptic/detergent chlorhexidine 2% in 70% isopropyl alcohol

utilized during insertion of the central line?" The comments noted that this question "did not allow for instances in which chlorhexidine may be contraindicated." Contraindications would include but not be limited to allergic reactions and use on infants less than 2 months of age.

* *We have added an additional response category "4" [contraindicated] to Question 2 in response to these comments.*

* **CLABSI Event--Line Necessity--**We received 9 comments regarding Question 3. "Was central line necessity evaluated daily and documented during the patient's hospitalization?" Comments noted that "central line medical necessity may be evaluated daily, but the evaluation is rarely documented by the physician, who holds ultimate responsibility for discontinuing the line."

* *This question is based on a key component of the IHI Central Line Bundle. The question as phrased does not name the responsible party for documentation of line necessity. For health care facilities that either have not adopted this IHI bundle or do not monitor performance of the bundle components, the Authority encourages them to do so. No changes have been made to Question 3.*

* **VAP Event--Head of Bed Elevation--**We received 10 comments regarding Question 1. "Was the head of the patient's bed elevated to between 30° and 45° at all times while the patient is receiving mechanically assisted ventilation?" Comments noted that "there is uncertainty that the head of bed can be elevated at all times due to necessary interventions requiring adjustment of the head of the patient's bed frequently throughout the day." In addition, the neonatal/pediatric population requires different head of bed elevation practices. Question 1 also fails to address contraindications to elevation of the head of bed in certain medical conditions.

* *Question 1 has been changed. The phrase "at all times" was deleted. Pediatric elevation was added. An additional response category "4" [contraindicated/not applicable] was also added.*

* **VAP Event--Daily sedation interruption, clinical contraindication, and readiness to extubate--** We received 8 comments regarding Question 2, 2a and 3. "Did the patient receive daily sedation interruption while the patient was receiving mechanically assisted ventilation"? "If the response to Question 2 is "no," was a daily sedation interruption clinically contraindicated?" The comments noted that "while all this information is readily noted on various nursing, medication and respiratory flow sheets, it is not noted on the patient's medical record, and would require consultation with Intensive Care personnel. A full review of various notes would be needed." In addition, it was noted that all 3 questions could be combined in one, per the IHI VAP bundle.

* *The elements of these questions are based on the best practices defined in the IHI VAP Bundle. For health care facilities that either have not adopted this IHI bundle or do not monitor performance of the bundle components, the Authority encourages them to do so. Question 2 and 2a have been combined, and an additional category "4" [contraindicated/not applicable] has been added. A clause addressing patients on intermittent or non-sedation protocols has been added to this question. No changes have been made to Question 3.*

* **CAUTI Event**--We received 9 comments regarding Question 1. "Was a daily assessment performed and documented of the necessity for continued catheterization?" The comments noted that "this documentation is not regularly collected, and hospitals will need time to improve documentation of this process measure."

* *The Authority wishes to collect this data for the purpose of monitoring best practices. Standardizing data collection practice is warranted to meet this goal. No changes have been made to Question 1.*

* **SSI Event**--We received 9 comments regarding 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?" The comments noted that "this information is currently collected under CMS SCIP reporting requirements and represents duplicate reporting." In addition, comments were received regarding removal of colon and vascular surgery from Question 1.

* *The Authority wishes to collect this data for the purpose of monitoring best practices. The Authority will continue to require a response to Question 1.*

* **Reporting Requirements for Nursing Homes--** We received 8 comments which reflected that "The CDC definitions were not designed to be applied to HAI surveillance activities in the nursing home resident population. Forcing nursing homes to utilize the CDC definitions has the potential to result in underreporting. It is recommended that other HAI definitions for this population be explored."

* *Separate definitions are being drafted for Nursing Homes based on CDC definitions. This includes the use of McGeer criteria, which are based on CDC criteria but are more applicable to nursing homes. They will be published in a separate Public Notice in the future.*

* **Phasing-in Reporting Requirements**--We received 3 comments suggesting that reporting requirements should be phased in over time. In addition, it was suggested that "The Department of Health begin with benchmarking and after data is collected, the Authority should create customized questions based on the results." It was also suggested that "the Authority pilot each module before mandating them."

* *While these suggestions were taken under advisement, no changes have been made to the reporting requirements.*

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 as follows. 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 as follows. 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. In addition, the HAI customization fact sheet released by the Authority to hospital Patient Safety Officers on January 23, 2008, is a step-by-step guide to customizing fields.

For each CDC-defined infection event type, select the appropriate form and modify the custom fields as instructed. 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. Only numbers are to be entered. Do not type the quotation marks, brackets, or words.

Device Associated Module

Form 1: Choose CDC defined event "BSI" to customize for 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]; "4" [contraindicated]

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: Choose CDC defined event "PNEU" to customize for Ventilator-Associated Pneumonia (VAP) Event

Question 1: Was the head of the patient's bed elevated to between 30° and 45° (adults) or 15° and 30° (pediatrics) 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] "4" [contraindicated/not applicable]

Question 2: Did the patient receive a daily sedation interruption while the patient was receiving mechanically assisted ventilation? Enter response category 4, "contraindicated/not applicable" for patients on intermittent sedation or non-sedation protocols.

Field Label Before Modification: Alphanumeric, Label 7

Customized Field Label: sedation interr

Response categories: "1" [yes]; "2" [no]; "3" [unknown]; "4" [contraindicated/not applicable]

Question 2a deleted as category "4" previously was added to address "contraindicated"

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: Choose CDC defined event "UTI" to customize for 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--AAA (ICD.9 procedure codes 38.34, 38.44, 38.64) and PVBY (ICD.9 procedure code 39.29)

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 Authority and the Department 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.

Persons with a disability who require an alternative format of this notice (for example large print, audio tape 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

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 percarditis
MED--Mediastinitis

EENT--Eye, Ear, Nose, Throat or Mouth Infection
CONJ--Conjunctivitis
EYE--Other than Conjunctivitis
EAR--Mastiod
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 Pneu monia
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])

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