

NOTICES

PATIENT SAFETY AUTHORITY and DEPARTMENT OF HEALTH

Reporting Requirements for Nursing Homes under Chapter 4 of the Medical Care Availability and Reduction of Error (MCARE) Act

[38 Pa.B. 5239]

[Saturday, September 20, 2008]

Purpose

The purpose of this notice is to give long-term care nursing facilities (nursing homes) final notice of their reporting requirements to the Patient Safety Authority (Authority) and the Department of Health (Department) under Chapter 4 of the Medical Care Availability and Reduction of Error Act, relating to Health Care-Associated Infections (Act 52 of 2007). The reporting requirements presented in this notice were developed in consultation with the Department and the Authority's Health Care-Associated Infection Advisory Panel.

Background of Final Notice

Under 40 P. S. § 1203-405, an initial notice was published at 38 Pa.B. 2542 (May 31, 2008). Public comment was solicited for a period of 30 days after publication of the notice, which resulted in the Authority receiving 61 public comments addressing 10 main categories. A summary of the comments and responses is detailed in this notice. The Authority has revised the reporting requirements in response to those comments as reflected in this document.

Reporting Requirements for Nursing Homes

In addition to reporting under the Health Care Facilities Act (35 P. S. § 3448.101 et seq.). Act 52 requires that nursing homes electronically report patient-specific health care-associated infections (HAI) to the Authority and the Department using Nationally recognized standards based on Centers for Disease Control and Prevention (CDC) definitions.

Nursing homes will begin mandatory reporting on April 1, 2009. The list of reportable HAI infections is presented at the end of this notice as Exhibit A. The criteria for determining HAIs were developed utilizing the McGeer Criteria together with CDC definitions, which were adapted to the long-term care setting. The criteria are presented at the end of this notice as Exhibit B.

Nursing homes will report HAIs to both the Authority and the Department through a single web-based interface: the Pennsylvania Patient Safety Reporting System (PA-PSRS). Using a single reporting system eliminates the need for duplicate reporting to both the Authority and the Department.

The format for electronic reporting is being established by the Authority in consultation with the Department and the HAI Advisory Panel and will be addressed during training programs for nursing homes.

Training will include opportunities for both in-person and online education relating to the infection list, criteria and format for reporting. A series of in-person training sessions will be held in locations throughout the State between January and March 2009. Nursing homes will be notified of available training opportunities through direct mailings, outreach to industry associations and future public notices.

Serious Event Reporting

The occurrence of an HAI in a nursing home is a Serious Event as defined by § 302 of the MCARE Act (Act 13). If an HAI meets the criteria for reporting (as per Exhibit B), that HAI 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.

HAIs reported to the Authority are subject to the same patient notification requirements set forth by Act 13 for all Serious Events. Under Act 13, all Serious Events require that the healthcare facility notify the patient or their legal representative in writing that a Serious Event has occurred. This written notification must occur within 7 calendar days. For purposes of meeting the 24-hour reporting requirement for Serious Events set forth by Act 13, nursing homes must submit reports of HAIs to the Authority within 24 hours of their confirmation (surveillance completed and HAI confirmed according to the criteria by a staff member responsible for infection control). If confirmation of an HAI occurs over a weekend or State government holiday, reports must be submitted by 5 p.m. on the next workday.

Summary of Public Comments and Responses

Following are the categories of comments the Authority received during the public comment period along with the Authority's responses.

* **Burden on Financial and Human Resources**--We received 56 comments regarding the reporting requirements potentially creating an economic and human resource burden for the nursing homes. The comments noted that unrealistic and onerous reporting requirements would not result in quality improvement or a positive effect on resident outcomes.

* *Act 52 mandates that nursing homes electronically report HAI data to the Department and the Authority. Act 52 provides no discretion in this requirement. No changes have been made in response to these comments.*

* **Infection List Too Long**--We received 40 comments regarding the infection list with requests for 14 infections to be eliminated. The comments noted that while nursing homes take HAI reporting seriously, they believe that there are a number of reportable HAIs on the list contained in Exhibit A of the notice that are vague, hard to define in the NH setting, will lead to misdiagnosis and most importantly, have no clinical or scientific basis to support improvement in resident outcomes.

> **Conjunctivitis**--We received 38 comments requesting that conjunctivitis be eliminated as there are many non-infectious conditions that have an identical presentation. This will result in an over-estimate of the actual number of cases. In addition, this group of infections has not been identified as a marker of significant morbidity and/or mortality in the nursing home population.

> **Sinusitis**--We received 35 comments requesting that sinusitis be eliminated due to the difficulty in diagnosing a true infection (versus allergic rhinitis and residual rhinitis from a viral syndrome) without invasive intervention. In addition, this group of infections has not been identified as a marker for significant morbidity and/or mortality in the nursing home population.

> **Mouth and Perioral Infections**--We received 34 comments requesting that mouth and perioral infections be eliminated due to the potential for numerous misdiagnosed cases. Many non-infectious causes mimic these infections, and criteria are too broad to be meaningful. In addition, this group of infections has not been identified as a marker for significant morbidity and/or mortality in the nursing home population.

> **Intra-abdominal infection (peritonitis/deep abscess), Osteomyelitis and Blood Stream Infections**--We received 21 comments for each of these infections. The comments noted that these infections are extremely uncommon in the nursing home setting and that resources would be better utilized in identifying the more common and costly infections for the purpose of improving quality and resultant positive outcomes.

> **Decubitus ulcer infections**--We received a total of 19 comments requesting that decubitus ulcer infections be eliminated. The comments noted that in order to diagnose a true decubitus ulcer infection, it is necessary to do a culture of properly collected fluid or tissue. The vast majority of facilities are not equipped to do needle aspiration culture or tissue biopsy culture, which will result in unreliable data that will substantially under-estimate the actual number of cases.

> **Urinary Tract Infections**--We received 12 comments requesting that UTIs be eliminated. Seven of the comments suggested that non-catheter associated UTIs be eliminated due to the inability to prevent these infections. The comment states that, typically, non-catheter related UTIs do not occur as a result of poor practices in the elderly. Five comments noted that the entire category should be eliminated as UTIs are endemic and closely monitored.

> **Bronchitis**--We received 11 comments requesting that bronchitis be eliminated as it is endemic in the nursing home population, particularly during the winter months when visitors and staff members who are carrying the cold virus infect residents.

> **All Respiratory Infections**--We received 10 comments requesting that all respiratory infections be eliminated as they are endemic at certain times of the year and are closely monitored. Reporting these infections will increase the surveillance burden.

> **Viral Hepatitis**--We received 5 comments requesting that viral hepatitis be eliminated as these infections are reported to the Department as a communicable disease.

> **Gastrointestinal, skin and soft tissue infections and influenza-like illness**--We received 5 comments for each of these infections requesting that they be eliminated as they are endemic and closely monitored.

* *Response: we eliminated the following infections*

* **Conjunctivitis**

* **Sinusitis**

* **Mouth and perioral infections**

* *Response: we combined the category of **decubitus ulcer infection** with skin and soft tissue (SST) infection per the McGeer criteria.*

* **Duplicate Notification of Change in Condition**--We received 35 comments regarding Act 52 Serious Event notification. The comments noted that duplicate notification would occur as CMS (F-Tag 157) together with the State, mandates immediate notification of a significant change in condition of a resident to the legal representative(s). This creates an additional workload.

* *Response: Act 52 requires that healthcare facilities provide written notification of a serious event within seven calendar days of identifying the HAI. The Act provides no discretion in this requirement and does not affect additional federal or state mandated reporting requirements. No changes have been made in response to these comments.*

* **Misinterpretation of MCARE/Act 13--Serious Event Reporting**--We received 24 comments regarding the applicability of the Act 13 provisions requiring written notification of a Serious Event to the resident or legal representative. The comments noted that Act 13 defines Serious Events as an event occurring within a "medical facility," while under the Act 13 definition, nursing facilities are not defined as a "medical facility" but rather as a "health care provider." They contend that Act 13 therefore does not require nursing facilities to provide written notification. Likewise, they contend that Act 52 does not add this requirement for nursing facilities. The comments request that the requirement for written notification be dropped.

* *Response: Act 52 amends MCARE by adding a chapter titled: Health Care Associated Infections. It has been determined that Serious Event reporting including written notification to the patient (resident) or legal representative is required. No changes have been made in response to these comments.*

* **Lack of Radiology/Laboratory Resources to Define Infections**--We received 22 comments regarding the inability to define certain HAI that require confirmation via radiology or laboratory resources. The comments noted that nursing homes are fundamentally a different type of clinical setting than the hospital, and diagnostic testing options are limited. Comments further state that laboratory and radiology services are virtually always off-site and are not readily available for every facility. For example, chest X-rays (CXRs) for pneumonia are often unavailable and subject to interpretation, resulting in the majority of physicians in nursing homes treating the resident versus "treating the CXR." Comments further State that HAIs will be missed if the criteria rely on lab/x-ray findings in conjunction with clinically based criteria and that physician diagnosis plays a key role in identifying infections in the NH setting.

** Response: The criteria for determining infections have been modified to reflect physician diagnosis as acceptable for determining HAIs that would have otherwise necessitated laboratory and/or radiology confirmation, with the exception of primary bloodstream infection.*

* **Clarification of HAI definition (incubation period)**--We received 18 comments regarding the lack of a defined incubation period as part of the HAI definition and the request to provide nursing homes with direction relating to accurately determining the incubation period.

** Response: Neither CDC nor McGeer define the incubation period of a HAI. CDC defines an HAI as an infection that is not present or incubating at the time of admission. McGeer applies seven important conditions to all definitions which are listed under "Key Points in Defining Infections in the Elderly" in this notice.*

* **Overlapping of Signs and Symptoms/Vague Criteria/atypical presentation in the elderly**--We received 15 comments regarding overlapping of signs and symptoms and atypical presentation of infections in the elderly. The comments noted that residents are often too clinically complex to be diagnosed and assessed accurately by the proposed criteria. The overlap of non-specific symptoms in the elderly patient is too broad to provide accurate data.

** Response: The criteria were developed utilizing the McGeer criteria which were developed in 1991 specifically to address these issues. In addition, CDC criteria that were applicable to long-term care were utilized taking into consideration that the nursing home population presents differently from acute care patients. No changes have been made in response to these comments.*

* **Duplicate Reporting of HAIs to the Department**--We received 11 comments regarding the list containing infections that are currently being reported to the Department as a reportable disease and/or infection as per 28 Pa. Code § 211.1 (Reportable Diseases). The comments requested that those infections that overlap with reportable diseases be eliminated from the list of infections.

** Response: The reporting requirements for 28 Pa. Code § 211.1 and Act 52 are separate requirements and nursing homes are mandated by separate laws to report to both. No changes have been made in response to these comments.*

* **Limited In-house Physician Consultation**--We received 11 comments regarding limited physician resources. The comments noted that nursing homes are different clinical settings than hospitals in that many nursing homes have limited in-house consultation from medical specialists, resulting in an increased need for telephone and remote monitoring. The limited presence of physicians can adversely affect the diagnosis and management of infections.

* *Response: HAI criteria and definitions will be included in the educational training programs for reporting requirements. Act 52 requires that health-care facilities provide mandatory educational programs for all personnel including physicians.*

* **Create a category of Lower Respiratory Tract Infection Combining Pneumonia with Bronchitis/Tracheobronchitis**--We received 11 comments regarding combining pneumonia, bronchitis and tracheobronchitis into one category. Comments noted that the criteria for pneumonia require a chest x-ray (CXR). In clinical practice, the diagnosis of respiratory infection is frequently documented without obtaining a CXR. The proposed criteria, if they rely on a CXR, would miss a large portion of clinical disease. If a CXR is not done, the criteria would result in a diagnosis of bronchitis, leading to inaccuracy in the reporting system (very low rates in the separate pneumonia category).

* *Response: We created a category of Lower Respiratory Infection (LRTI), which includes bronchitis/tracheobronchitis and pneumonia. We revised the criteria for LRTI in the event that a CXR is performed.*

Exhibit A. List of Reportable HAIs

1. Symptomatic Urinary Tract Infection

1.1 Indwelling urinary catheter related

1.2 Non-urinary catheter related

2. Respiratory Tract Infection

2.1 Lower Respiratory Tract Infection (Pneumonia/Bronchitis/tracheobronchitis)

2.2 Influenza-like illness

3. Skin and Soft Tissue Infection

3.1 Cellulitis

3.2 Burns

3.3 Vascular and diabetic ulcer (chronic/non-healing)

3.4 Device-associated soft tissue/wound infection

- * Tracheostomy site
- * Peripheral/Central IV catheter site
- * G-tube site
- * Supra pubic catheter site
- * In-dwelling drain
- * In-dwelling vascular catheters (dialysis)

3.5 Decubitus Ulcer (pressure related)

4. Gastrointestinal Tract Infection

5. Other infections

5.1 Intra-abdominal infection (peritonitis/deep abscess)

5.2. Meningitis

5.3. Viral Hepatitis

5.4. Osteomyelitis

5.5. Primary Bloodstream Infection

Exhibit B. Criteria for Defining HAIs in Long-term Care

The Centers for Disease Control and Prevention (CDC) definitions for health care-associated infections (HAIs) were developed for hospitals and are generally not applicable to nursing homes.

In 1991, McGeer et al developed a set of definitions for determining HAIs in long-term care. The criteria were developed by modifying the CDC definitions and taking into consideration the difference in population, services and resources.

The criteria set forth below have been developed in accordance with the requirements of Act 52, using McGeer criteria and further modification of the CDC- based criteria.

KEY POINTS IN DEFINING INFECTIONS IN THE ELDERLY

> An HAI is a localized or systemic condition that was not present or incubating upon admission to a facility.

- > All signs and symptoms of an infection must be acute, new or rapidly worsening.
- > Non-infectious causes should always be considered before defining an infection.
- > A change in mental or functional status is often indicative of a developing infection.
- > Physician diagnosis plays a significant role in defining certain infections particularly where laboratory and radiology resources would be preferable but are limited.
- > Antimicrobial treatment alone is not indicative of an HAI.
- > In the elderly population, a **fever** is defined as:
 - > an oral or equivalent temperature* of 100.4° F (38° C) or an increase of 2° F (1.1° C) over baseline.

***Note:** Tympanic thermometers are widely used in long-term care and manufacturer's recommendations together with baseline temperatures are utilized to determine a fever.

Symptomatic Urinary Tract Infection

Resident with Urinary Catheter

TWO or more of the following with no other recognized cause:

- > Fever and/or chills with no other source
- > Flank or suprapubic pain or tenderness (self described or identified upon examination)
- > Gross hematuria or change in character of urine
- > Change in mental and/or functional status from daily baseline

Resident without Urinary Catheter

THREE or more of the following:

- > Fever and/or chills
- > New burning pain on urinating (dysuria), frequency or urgency
- > Flank or suprapubic pain or tenderness (self described or identified upon examination)
- > Gross hematuria or change in character of urine
- > Change in mental and/or functional (including incontinence) status from daily baseline

Note:

a. If a urinalysis is obtained, one or more of the following must be positive IN the presence of defined signs and symptoms.

- > Positive leukocyte esterase and/or nitrate
- > Pyuria (≥ 10 white blood cells)

b. If a urine culture is obtained, $\geq 100,000$ microorganisms per cc of urine with no more than 2 species of microorganisms must be present together WITH defined signs and symptoms.

Lower Respiratory Tract Infection

THREE or more of the following:

- > Fever with no other cause
- > New or increased cough
- > New or increased sputum production
- > Pleuritic chest pain
- > Rhonchi, rales, wheezes and/or bronchial breathing
- > New and/or increased shortness of breath
- > Tachypnea (normal respiratory rate = 16 - 25 breaths/min)
- > Change in mental and/or functional status from baseline in the presence of symptoms

Note:

a. Congestive heart failure and other non-infectious causes of similar signs and symptoms should be ruled out.

b. If a chest x-ray is obtained, the presence of a pneumonia must be confirmed by a physician/radiologist IN the presence of defined signs and symptoms.

Influenza-Like Illness (ILI)

Fever

and

THREE or more of the following during Influenza season (October 1 to April 30):

- > Chills
- > Headache or eye pain
- > Malaise or loss of appetite
- > Sore throat
- > Dry cough
- > Myalgias

Skin and Soft Tissue Infection

Cellulitis, IV site, Burns, Vascular/diabetic ulcer, device associated, decubitus ulcer

Purulent drainage, pustules or vesicles at wound, skin, or soft tissue site

or

FOUR or more of the following signs and symptoms:

- > Fever with no other recognized cause
- > Heat
- > Redness
- > Swelling
- > Pain or tenderness
- > Serous drainage

Gastrointestinal Tract Infection

Symptoms for Viral and Bacterial Infections to include:

ONE or more of the following signs and symptoms

- > Two or more loose or watery stools above what is normal for the resident in a 24 hour period

- > Two or more episodes of vomiting within a 24 hour period
- > Laboratory confirmed enteric pathogen from stool WITH a compatible clinical syndrome
- > Stool toxin assay (C.difficile)
- > Single IgM or fourfold increase in IgG for pathogen in paired sera.

Note:

These criteria must include NO evidence of a non-infectious cause: e.g. DIARRHEA: laxatives, change in tube feeding or medication; VOMITING: change in medication, other G.I. diseases such as peptic ulcer disease.

CDC defines a C.difficile laboratory confirmed infection as health-care acquired if it presents > 3 days after admission (i.e. on or after day 4).

Intra-abdominal Infection (Peritonitis/deep abscess)

TWO or more of the following with no other recognized cause:

- > fever
- > nausea
- > vomiting
- > abdominal pain
- > jaundice

and

ONE of the following:

- > Physician diagnosis of an intra-abdominal infection
- > Radiographic evidence of infection
- > Organism(s) cultured from drainage from surgically placed drain or tube

Meningitis

Physician diagnosis of Meningitis

and

THREE or more of the following with no other recognized cause:

- > Fever
- > Headache
- > Stiff neck
- > Meningeal signs as determined by a physician
- > Cranial nerve signs as determined by a physician
- > Irritability

Viral Hepatitis

Positive antigen or antibody test for Hepatitis A, B, C or delta antigen

and

TWO or more of the following with no other recognized cause:

- > fever
- > anorexia
- > nausea
- > vomiting
- > abdominal pain
- > jaundice
- > history of transfusion within the previous 3 months

Osteomyelitis

Physician diagnosis of Osteomyelitis

and

TWO or more of the following with no other recognized cause:

- > Fever

- > Localized swelling
- > Tenderness at suspected site of bone infection
- > Heat at suspected site of bone infection
- > Drainage at suspected site of bone infection

Primary Bloodstream Infection

TWO or more blood cultures drawn on separate occasions documented with a common skin contaminant (e.g., diphtheroids, *Bacillus* sp., *Propionibacterium* sp., coagulase-negative staphylococci, or micrococci)

or

A **single** blood culture documented with a pathogenic organism (non-contaminant)

and

ONE of the following:

- > fever or new hypothermia
- > drop in systolic blood pressure of > 30 mm Hg over baseline
- > change in mental or functional status

Note:

Organism in blood culture is not related to infection at another site (secondary bacteremia)

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[Pa.B. Doc. No. 08-1740. Filed for public inspection September 19, 2008, 9:00 a.m.]

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The
Pennsylvania

BULLETIN

BULLETIN
TOC

• PREV •

NEXT •

NEXT
BULLETIN

• SEARCH •

HOME

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