

NOTICES

PATIENT SAFETY AUTHORITY

Reporting Requirements for Nursing Homes under the The Health Care-Associated Infection and Prevention Control Act (Act 52 of 2007)

Purpose

The purpose of this announcement is to give nursing home facilities notice of their reporting requirements to the Patient Safety Authority (Authority) and the Department of Health (Department) under the Health Care-Associated Infection and Prevention Control Act (Act 52 of 2007). The reporting requirements presented in this notice were developed in consultation with the Department and the Patient Safety Authority's Health Care-Associated Infection (HAI) Advisory Panel.

Reporting Requirements for Nursing Homes

In addition to reporting pursuant to the Health Care Facilities Act 1979 (P.L.130, No.48), Act 52 requires that nursing homes electronically report patient-specific health care-associated infections to the Authority and the Department using nationally recognized standards based on Centers for Disease Control and Prevention (CDC) definitions.

Method of Reporting HAIs

The timelines and format for reporting HAIs is being established and will be published in a future notice. However, the Authority does not expect that Nursing Homes will begin reporting before the end of 2008. A list of reportable infections is presented at the end of this notice as Exhibit A. The criteria for determining HAIs were developed utilizing the definitions for infection surveillance in long-term care by McGeer A, Campbell B, Emori TG, et al.(McGeer Criteria) together with modified CDC definitions for long-term care. The criteria are presented at the end of this notice as Exhibit B.

Serious Event Reporting

The occurrence of an HAI in nursing homes, defined as per criteria in Exhibit B is deemed to constitute a Serious Event as defined by the MCARE Act (Act 13), § 302. If an infection meets the criteria for reporting, 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 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 seven (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 infection 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 work day.

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 under 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 by means of e-mail to the Pennsylvania Patient Safety Authority at patientsafetyauthority@state.pa.us.

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

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. 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 Pneumonia

2.2 Influenza-like illness (ILI)

2.3 Sinusitis

2.4 Bronchitis/tracheobronchitis

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 for example:

- ❖ Tracheostomy site
- ❖ Peripheral/ Central IV catheter site
- ❖ G-tube site
- ❖ Supra pubic catheter site
- ❖ In-dwelling drain

4. Decubitus ulcer (pressure related) Infection

5. Gastrointestinal tract Infection

5.1 Bacterial (e.g. Campylobacter, Salmonella species, Shigella)

5.2 Viral-like (e.g. norovirus, rotavirus)

5.3 Clostridium difficile (C.difficile/ C.diff)

5.4 Other non viral/non bacterial (e.g. Amebiasis, Giardiasis, Cryptococcus)

- 6. Intra-abdominal infection**
 - 6.1 Peritonitis/deep abscess**
- 7. Conjunctivitis**
- 8. Mouth and perioral infection**
- 9. Meningitis**
- 10. Viral Hepatitis**
- 11. Osteomyelitis**
- 12. 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) 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

- The CDC defines an HAI as 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:** Discussion concerning the definition of temperature readings via alternative monitoring routes (e.g. tympanic and axillary) has ensued. As there is lack of standardization of readings for these alternative routes, we invite comments addressing this issue.

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:

If an appropriately collected and processed urine culture was taken and the resident was not receiving antibiotics at the time, then the culture must be positive IN the presence of defined signs and symptoms.

Respiratory Tract Infection

Pneumonia

Interpretation by a physician of a chest x-ray as demonstrating pneumonia, or probable pneumonia in the presence of an infiltrate and/or consolidation.

AND

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 and/or tachypnea (normal respiratory rate = 16 – 25 breaths/min)
- Change in mental and/or functional status from baseline in the presence of symptoms

Note:

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

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

Sinusitis

Physician diagnosis of sinusitis

AND

TWO or more of the following:

- Fever with no other recognized cause
- Pain or tenderness over the sinuses
- Headache
- Purulent exudate or nasal obstruction

Bronchitis/tracheobronchitis

Symptoms must be acute and either NO chest x-ray or x-ray does NOT meet the criteria for Pneumonia

THREE or more of the following:

- Fever
- 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 ($>$ breaths/min – normal respiratory rate = 16 – 25 breaths/min)
- Change in mental and functional status from baseline in the presence of symptoms

Skin and Soft Tissue Infection

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

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

Decubitus ulcer (pressure related) Infection

Resident has at least **TWO** of the following signs and symptoms with no other recognized cause:

- Redness
- Tenderness
- Swelling of decubitus wound edges

AND

At least **ONE** of the following:

- Organisms cultured from properly collected fluid or tissue (see note below)
- Organisms cultured from blood (no other recognized cause)

Note:

Purulent drainage alone is not sufficient evidence of an infection. Surface organisms cultured from the decubitus ulcer are not sufficient evidence of an infection. Needle aspiration of fluid or a biopsy of the tissue from the ulcer margin is required.

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:

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

Conjunctivitis

New pain, itching or redness of conjunctiva

AND

Purulent exudate from one or both eyes for ≥ 24 hours

Note:

Allergies and foreign body trauma should be ruled out

Mouth and perioral infection

Physician or Dentist diagnosis and treatment of infection

AND

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

- Abscess
- Ulceration
- Raised white patches on inflamed mucosa
- Plaque on oral mucosa

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

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

AND

EITHER

- Organism cultured from blood with no other recognized cause

OR

- Physician diagnosis of Osteomyelitis

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)

MICHAEL E. DOERING,
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