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

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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) pursuant to the Medical Care Availability and Reduction of Error Act (MCARE Act), relating to Health Care-Associated Infections. 40 P.S. §§ 1303.405(b)(3). The reporting requirements presented in this notice were developed in consultation with the Department, Authority's Board of Directors, and the Authority's Health Care-Associated Infection Advisory Panel’s Sub-committee for Long Term Care.

Background of Final Notice

An initial notice was published at 43 Pa.B. 2793 (May 18, 2013). Public comment was solicited for an initial period of 30 days after publication of the notice. However, in response to requests for an extension, the initial period was extended by an additional 30 days, which resulted in the Authority receiving a total of 34 responses, comprised of 19 responses, requesting an extension of the public comment period and 15 responses, addressing the proposed criteria. The 15 responses addressing criteria represented responses from individuals to industry organizations representing many of long-term care nursing facilities. The responses addressed 14 main categories. A summary of the comments and responses is detailed in this notice. In response to those comments and at the direction of the Health Care-Associated Infection Advisory Panel’s Sub-committee for Long Term Care, the Authority, when appropriate, revised some of the proposed reporting requirements that were contained within the initial notice.

Reporting Requirements for Nursing Homes

In addition to reporting under the Health Care Facilities Act (35 P. S. §§ 448.101, et seq.), Act 52 of 2007 amended the MCARE Act to require 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. 40 P.S. § 1303.404(a).
Nursing homes will begin utilizing the updated definitions for its mandatory reporting on April 1, 2014. Because these revisions require changes to the PA-PSRS reporting application, this date may be modified by a future public notice as the transition date approaches.

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 Revised McGeer Criteria together with CDC definitions, which were adapted to the long-term care setting in Pennsylvania.

Nursing homes will continue to 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 has been 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 online webinar-based education relating to the infection list, criteria and format for reporting. 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 Section 302 of the MCARE Act. 40 P.S. § 1303.405(a). If an HAI meets the criteria for reporting (per Exhibit A), that HAI shall be reported to the Authority as a Serious Event as required by the MCARE Act and amended by Act 52 of 2007, 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 the MCARE Act for all Serious Events. 40 P.S. § 1303.308(b). Therefore, 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 the MCARE Act, 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 business day.

Individuals with disabilities who require an alternative format of this notice (for example, large print, audio tape or Braille) should contact the Authority help desk at (866) 316-1070.

**Summary of Public Comments and Responses**

The following is a list that categorizes the comments the Authority received after its initial notice and during the public comment period along with the Authority's responses.
**Burden on Financial and Human Resources**--We received 3 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.

**Response**

*The MCARE Act, as amended by Act 52 of 2007, mandates that nursing homes electronically report HAI data to the Department and the Authority. There is no discretion in this requirement. No changes have been made in response to these comments.*

**ABUTI**--We received 9 comments requesting that ABUTI be eliminated. 1 comment stated that Asymptomatic Bacteremic Urinary Tract Infection was not a real term. 2 comments requested the criteria be removed as it is a rare finding. 2 comments state the criteria should be removed due to the fact the Authority is suggesting extra lab testing be required to survey for HAI. 3 comments requested the CFU/ml limit for straight in and out catheter specimens be raised from $\geq 10^2$ to $\geq 10^5$. Furthermore there could be confusion related to treatment without sensitivities and lead to overuse of antibiotics. 1 comment requested the name be changed to Asymptomatic Bacteremic Urinary Tract Infection to Asymptomatic Urinary Tract Infection with Secondary Bacteremia.

**Response**

*The criteria will not be removed.*

*The CFU/ml will remain at $\geq 10^2$ for straight in/out urine cultures.*

*The terminology defined by the CDC will be altered from Asymptomatic Bacteremic Urinary Tract Infection to Asymptomatic Bacteruria with Secondary Bacteremia in order to prevent confusion.*

**Rationale**

No literature were provided by the public comments that prove ABUTI is a rare finding in the Pennsylvania LTC environment.

*The CDC states “The point prevalence of asymptomatic bacteruria in LTC residents can range from 25-50%.”*¹

*The identification of the conversion rate of asymptomatic bacteruria to blood stream infection in LTC is currently unknown.*

*The Authority is not advocating for extra testing to fit ABUTI criteria. The most common clinical scenario where ABUTI is discovered would be when a patient is pan cultured in order to discover the etiology of systemic symptoms not localized to the urinary tract.*
Per the CDC, “the decision to use the lower colony count for urine cultures obtained from specimens collected through I/O catheter was based on the premise that these specimens may be less likely to be contaminated compared to ‘clean catch’ urine”. ²

**CAUTI**--We received 6 comments requesting a change in the CFU/ml limit for straight in/out catheter specimens from $\geq 10^2$ to $\geq 10^5$. The comments cite that the laboratory would not report sensitivities for CFU/ml for less than $10^5$. Furthermore there could be confusion related to treatment without sensitivities and lead to overuse of antibiotics.

**Response**

The CFU/ml will remain at $\geq 10^2$ for straight in/out urine cultures.

**Rationale**

Per the CDC “the decision to use the lower colony count for urine cultures obtained from specimens collected through I/O catheter was based on the premise that these specimens may be less likely to be contaminated compared to ‘clean catch’ urine”. ²

Per the CDC “if a person has local symptoms of a UTI (e.g., urgency, dysuria, etc.) than any amount of bacterial growth in a urine culture should be considered significant. In contrast, if a person has NO signs/symptoms then no amount of bacteruria would make that culture significant. Therefore, truly, if people only send urine specimens for symptomatic cases, then it doesn't matter what the growth count is in a culture. A final consideration is that the likelihood of getting a low colony count in this population, regardless of specimen collection method is pretty low given the high prevalence of asymptomatic bacteriuria.”²

Franz and Hörl state “it is likely that symptomatic bacteruria of $<10^5$ CFU/ml reflects ongoing UTI, and therefore the microbiological criteria should be reduced to $>10^2$ CFU/ml in symptomatic patients”.³

The long term care physician representation on the Authority Advisory Panel have expressed that several laboratory companies do in fact report sensitivities at $10^2$, and if currently not doing so it may need to be requested. Furthermore treating a symptomatic UTI at $10^2$ may prevent progression of infection. Treating without sensitivities, and waiting for a result of $10^5$ in order to scale back wide-spectrum treatment will lead to resistance and antibiotic overuse.

**SUTI**--We received 6 comments requesting a change in the CFU/ml limit for straight in/out catheter specimens from $\geq 10^2$ to $\geq 10^5$. The comments cite that the laboratory would not report sensitivities for CFU/ml for less than $10^5$. Furthermore there could be confusion related to treatment without sensitivities and lead to overuse of antibiotics.

**Response**

Refer to response and rationale for CAUTI.
ILI/FLU--We received 1 comment asking if, for a flu/ILI report to be filed, will the resident have to test positive for influenza.

Response

Pathways for reporting laboratory confirmed influenza and non-laboratory confirmed ILI will be incorporated into the reporting system.

PNA--We received 1 comment asking if there are any exclusions for aspiration pneumonitis.

Response

There will be no exclusion for pneumonitis; however, the Authority will evaluate overlap between these conditions and modify the system in the future if needed. There will be the ability to enter pathogen data into the pneumonia criteria pathway, but pathogen data does not determine the presence of pneumonia at present.

Rationale

Aspiration pneumonitis occurs by aspiration of sterile gastric contents, subsequent bacterial infection is latent. Pneumonitis can affect any age group, but occurs more so in young persons. Respiratory distress develops 2-5 hours after aspiration. Aspiration pneumonia occurs by aspiration of colonized oropharyngeal material, bacterial infection is acute. Aspiration pneumonia occurs usually in the elderly.4

Due to the contrasting features of aspiration pneumonitis as compared to aspiration pneumonia it is unlikely that a large amount of pneumonitis would be captured for reporting as a result of the criteria relying on radiologic, respiratory subcriteria, and constitutional criteria.

C. Diff--We received 2 comments asking if every resident had to be tested for C.diff prior to being tested for bacterial pathogens.

Response

There is a reporting pathway specifically for other pathogens outside of the C. diff pathway.

Norovirus--We received 1 comment requesting the addition of the Kaplan criteria. We received 2 requests to remove the laboratory testing criteria.

Response

Kaplan criteria will be added to the Norovirus pathway. Laboratory testing criteria will remain.

Rationale
Addition of the Kaplan criteria will provide a symptom based assessment of cases otherwise not reported due to laboratory testing requirements. Laboratory confirmed Norovirus pathway will remain an option if testing was performed per Stone, et al.\(^5\)

**Bacterial gastroenteritis**--We received 1 comment requesting we remove the term bacterial, and furthermore the revised McGeer criteria does not require a positive stool culture to define the gastroenteritis.

*Response*

The term “bacterial” will remain. Positive culture will remain as a criterion.

*Rationale*

The Authority is making a distinction between gastroenteritis caused by a variety of situations like new medications, initiation of tube feedings, and other non-infectious causes.

The revised McGeer criteria\(^5\) (Table 7.) states:

“Both of the following sign or symptom sub criteria”

a. A stool specimen testing positive for a pathogen

b. At least one of the following GI sub criteria

**CLABSI (dialysis, temporary, and permanent central lines)**--We received 6 comments requesting the deletion of CLABSI because:

In most cases the catheter is not cared for by the LTC staff, and is subject to manipulation by outside contractors (e.g., dialysis staff, and oncology staff). Because the infection is not attributable to the LTC facility it should not be reportable, and Act 13 letters should not be sent by the LTC facility because they may not be liable for the infection.

Nursing homes do not have nurses that are able to draw blood from central lines for comparison to peripheral cultures for identification of the source of bacteremia.

*Response*

The 3 categories for CLABSI will remain. Comparison of central line cultures to peripheral cultures is not included in the surveillance criteria for determination of CLABSI.

*Rationale*

Pursuant to Section 308 (b) of the MCARE Act, “[d]uty to notify patient.—A medical facility through an appropriate designee shall provide written notification to a patient affected by a serious event or, with the consent of the patient, to an available family member or designee
within seven days of the occurrence or discovery of a serious event. If the patient is unable to give consent, the notification shall be given to an adult member of the immediate family. If an adult member of the immediate family cannot be identified or located, notification shall be given to the closest adult family member. For unemancipated patients who are under 18 years of age, the parent or guardian shall be notified in accordance with this subsection. The notification requirements of this subsection shall not be subject to the provisions of section 311(a). Notification under this subsection shall not constitute an acknowledgment or admission of liability. 

Resident notification of the development of an HAI by the LTC aids in the transparency of the residents care, furthermore if contractors are not following best practices related to central line care or dialysis, reporting of infection will enable the Authority and the facilities to identify opportunities for improvement within contracted and non-contracted services in order to design educational programing aimed at providing safe care to this population of residents.

The CLABSI criteria are surveillance criteria not diagnostic criteria. The CLABSI criteria do not require blood cultures from the central line for the resident to fit CLABSI criteria.

The Authority realizes a physician may decide to compare peripheral to central blood cultures in order to match organisms for the purpose of determining a source or reservoir of infection. However in the LTC population, the likely source of infection in the resident with a central line is the central line. Furthermore, due to polymicrobial intraluminal or extraluminal biofilm formation in lines of long duration, it is possible that a centrally drawn culture may not match a peripheral culture despite the central line being the source of bacteremia.

Conjunctivitis--We received 7 comments requesting that conjunctivitis be eliminated as there are many non-infectious conditions that have an identical presentation. In addition, this group of infections has not been identified as a marker of significant morbidity and/or mortality in the nursing home population.

Response

Conjunctivitis will be reportable.

Rationale

The commenters have provided no published references to substantiate the claims that conjunctivitis does not cause morbidity and mortality.

MRSA infection of the eye has been associated with the presentation of conjunctivitis by as much as 31%.

Adenovirus-associated conjunctivitis may lead to significant ocular morbidity and is associated with substantial healthcare costs.
Scabies--We received 7 comments requesting that scabies be eliminated because it is not an infection, and has not been identified as a marker of significant morbidity and/or mortality in the nursing home population.

Response

Scabies will be reportable.

Rationale

The commenters have provided no published references to substantiate the claims that Scabies is not classified as an infection, nor causes morbidity and/or mortality.

Scabies is highly infectious and is spread through contact.

The pruritus associated with infection causes significant distress. Breaks in the epidermis due to the burrowing of the mites, and the skin damage caused by the excoriation serve as portals of entry for pathogenic bacteria. The clinical consequences of secondary bacterial infection, especially with group A streptococci (Streptococcus pyogenes) result in significant and frequently unrecognized morbidity.\(^{10}\)

Conditional criteria/terminology--We received 15 requests for a detailed listing of conditional criteria or requests for terminology changes or clarification to terms used in conditional criteria.

Response

Conditional criteria will be listed in their entirety in the revised PA-PSRS reporting manual and in the educational programing prior to the launch of the revised PA-PSRS LTC HAI reporting system.

Clarification/changes of terminology will be incorporated per public comment as needed for clarity.

Miscellaneous--We received 6 comments that were of a miscellaneous nature. They were as follows: Education prior to implementation (3). List time frames for criteria to distinguish between present on admission and LTC related (2). Requests for algorithms as part of the training materials (1).

Response

The Authority will roll out training and education prior to the implementation of the criteria.

Time frame qualifiers for LTC related HAIs will be listed in the training materials and the user manual.

Criteria algorithms will be included within the training materials and user manual.
Exhibit A. List of Reportable HAIs

A. Urinary tract infection
1. Asymptomatic bacteruria with secondary bacteremia
2. Catheter-associated urinary tract infection
3. Symptomatic urinary tract infection

B. Respiratory tract infection
1. Lower respiratory tract infection
2. Influenza like illness
3. Pneumonia

C. Gastrointestinal infection
1. Clostridium difficile
2. Norovirus
3. Bacterial gastroenteritis

D. Skin and soft-tissue infection
1. Cellulitis, soft-tissue or wound infection
2. Conjunctivitis
3. Scabies

E. Device-related bloodstream infection
1. Central-line-associated bloodstream infection—dialysis
2. Central-line-associated bloodstream infection—temporary
3. Central-line-associated bloodstream infection—permanent

MICHAEL C. DOERING,
Executive Director
Notes

2. Stone, Nimalie (Centers for Disease Control and Prevention). E-mail correspondence with: The Authority. 2013 July 28.