Effective November 28, 2017

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

For staff competency concerns, refer to the following F tags:

- *F725 or 726, §483.35(a),(c) for Nursing Services;*
- *F741, §483.40 for any Behavioral Health staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;*
- *F801, §483.60(a) for Food and Nutrition staff; and*
- *F839, §483.70(f), Administration for any other staff not referenced above.*

If the surveyor has concerns about 1) the overuse of transmission-based ("isolation") precautions, 2) the inappropriate transferring of rooms unnecessarily; or 3) the inappropriate use of PPE such as gloves when used unnecessarily, where residents indicate they are "untouchable," dirty or unclean, review under §483.10(a)(1), F550, Resident Rights (Dignity) or §483.24, F675, Quality of Life.

For concerns related to possible involuntary seclusion, refer to §483.12 (a)(1), F603.

Data from injectable, scheduled drug tracking should be regularly reviewed and discrepancies or unusual access patterns are investigated including whether residents should be screened for exposure to bloodborne pathogens (refer to 483.45, F755, Pharmacy Services for further information on reconciliation concerns).

For concerns related to the QAA committee's responsibility to identify or correct quality deficiencies, which may include systemic infection control concerns, refer to 483.75(g)(2)(ii), F867, QAA Activities.

For concerns related to the medical director's role in responsibility for care, refer to §483.70(h), F841, Medical Director.

F881

§483.*80(a) Infection prevention and control program.*
The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

§483.*80(a)(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.*

INTENT

The intent of this regulation is to ensure that the facility:

- *Develops and implements protocols to optimize the treatment of infections by ensuring that residents who require an antibiotic, are prescribed the appropriate antibiotic;*
- *Reduces the risk of adverse events, including the development of antibiotic-resistant organisms, from unnecessary or inappropriate antibiotic use; and*
- *Develops, promotes, and implements a facility-wide system to monitor the use of antibiotics.*

DEFINITIONS

"Antibiotic": *a medication used to treat bacterial infections. They are not effective for infections caused by viruses (e.g., influenza or most cases of bronchitis).*

"Antibiotic Stewardship": *refers to a set of commitments and actions designed to optimize the treatment of infections while reducing the adverse events associated with antibiotic use.*[62] *This can be accomplished through improving antibiotic prescribing, administration, and management practices thus reducing inappropriate use to ensure that residents receive the right antibiotic for the right indication, dose, and duration.*[63]

"Clostridium difficile infection (C. difficile or CDI)": *an infection from a bacterium that causes colitis, an inflammation of the colon, causing diarrhea.*

"Colonization": *the presence of microorganisms on or within body sites without detectable host immune response, cellular damage, or clinical expression.*

"Methicillin-resistant Staphylococcus aureus (MRSA)" *(a.k.a. Oxacillin-resistant Staphylococcus aureus)**:** Staphylococcus aureus bacteria that are resistant to treatment with one of the semi-synthetic penicillins(e.g., Oxacillin/Nafcillin/Methicillin).*

"Multidrug-Resistant Organisms (MDROs)": *microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents.*[51] *Although the names of certain MDROs describe resistance to only one agent, these pathogens are frequently resistant to most available antimicrobial agents and include multidrug-resistant gram negative bacteria (GNB), Carbapenem-resistant Enterobacteriaceae (CRE), and extended spectrum beta-lactamase-producing Enterobacteriaceae (ESBLs).*

"Vancomycin resistant enterococcus (VRE)": *species of enterococcus which have developed resistance to the antibiotic, vancomycin.*

GUIDANCE

Antibiotic Stewardship

As part of their IPCP programs, facilities must develop an antibiotic stewardship program that promotes the appropriate use of antibiotics and includes a system of monitoring to improve resident outcomes and reduce antibiotic resistance. [64, 65, 66] *This means that the antibiotic is*

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62 Centers for Disease Control and Prevention. (2014). *Core elements of hospital antibiotic stewardship programs.* Accessed on June 9, 2017 from https://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html

63 Centers for Disease Control and Prevention. (2015). *The core elements of antibiotic stewardship for nursing homes.* Accessed on June 9, 2017 from https://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html

64 Centers for Disease Control and Prevention. (2013). *Antibiotic resistance threats in the United States, 2013.* Accessed on June 9, 2017 from http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf

65 Spellberg, B., Bartlett, J.G., & Gilbert, D. N. (January 24, 2013). The future of antibiotics and resistance. *The New England Journal of Medicine, 368,* 299-302.

66 The White House. (2014). *National Strategy for Combating Antibiotic Resistant Bacteria.* Accessed on June 9, 2017 from https://obamawhitehouse.archives.gov/sites/default/files/docs/carb_national_strategy.pdf

prescribed for the correct indication, dose, and duration to appropriately treat the resident while also attempting to reduce the development of antibiotic-resistant organisms.

Nursing home residents are at risk for adverse outcomes associated with the inappropriate use of antibiotics that may include but are not limited to the following:

- *Increased adverse drug events and drug interactions (e.g., allergic rash, anaphylaxis or death);*
- *Serious diarrheal infections from C. difficile;*
- *Disruption of normal flora (e.g., this can result in overgrowth of Candida such as oral thrush); and/or*
- *Colonization and/or infection with antibiotic-resistant organisms such as MRSA, VRE, and multidrug-resistant GNB.*

NOTE: *The Centers for Disease Control and Prevention (CDC) has identified core actions to prevent antibiotic resistance within the control of the nursing home. For more information, refer to CDC NH Core Elements at:*
http://www.cdc.gov/longtermcare/pdfs/core-elements-antibiotic-stewardship-appendix-a.pdf

NOTE: *For examples of antibiotic use protocols, policies and practices developed by the Agency for Healthcare Research and Quality, see: http://www.ahrq.gov/nhguide/index.html*

NOTE: *References to non-U. S. Department of Health and Human Services (HHS) sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.*

Antibiotic Stewardship Program

As summarized by the CDC [63], the core elements for antibiotic stewardship in nursing homes include:

- *Facility leadership commitment to safe and appropriate antibiotic use;*
- *Appropriate facility staff accountable for promoting and overseeing antibiotic stewardship;*
- *Accessing pharmacists and others with experience or training in antibiotic stewardship;*
- *Implement policy(ies) or practice to improve antibiotic use;*
- *Track measures of antibiotic use in the facility (i.e., one process and one outcome measure);*
- *Regular reporting on antibiotic use and resistance to relevant staff such as prescribing clinicians and nursing staff; and*
- *Educate staff and residents about antibiotic stewardship.*

The facility must develop an antibiotic stewardship program which includes the development of protocols and a system to monitor antibiotic use. This development should include leadership support and accountability via the participation of the medical director, consulting pharmacist, nursing and administrative leadership, and individual with designated responsibility for the infection control program if different.[63]

The antibiotic stewardship program protocols shall describe how the program will be implemented and antibiotic use will be monitored, consequently protocols must:

- *Be incorporated in the overall infection prevention and control program;*
- *Be reviewed on an annual basis and as needed;*
- *Contain a system of reports related to monitoring antibiotic usage and resistance data. Examples may include the following:*
  - *Summarizing antibiotic use from pharmacy data, such as the rate of new starts, types of antibiotics prescribed, or days of antibiotic treatment per 1,000 resident days;*[63]
  - *Summarizing antibiotic resistance (e.g., antibiogram) based on laboratory data from, for example, the last 18 months; and/or* [63]
  - *Tracking measures of outcome surveillance related to antibiotic use (e.g., C. difficile, MRSA, and/or CRE).* [63]
- *Incorporate monitoring of antibiotic use, including the frequency of monitoring/review. Monitor/review when the resident is new to the facility; when a prior resident returns or is transferred from a hospital or other facility* [63]*; during each monthly medication regimen review when the resident has been prescribed or is taking an antibiotic, or any antibiotic regimen review as requested by the QAA committee. In addition, establish the frequency and mode or mechanism of feedback (e.g., verbal, written note in record) to prescribing practitioners regarding antibiotic resistance data, their antibiotic use and their compliance with facility antibiotic use protocols.* [63] *Feedback on prescribing practices and compliance with facility antibiotic use protocols may include information from medical record reviews for new antibiotic starts to determine whether the resident had signs or symptoms of an infection; laboratory tests ordered and the results; prescription documentation including the indication for use (i.e., whether or not an infection or communicable disease has been documented), dosage and duration; and clinical justification for the use of an antibiotic beyond the initial duration ordered such as a review of laboratory reports/cultures in order to determine if the antibiotic remains indicated or if adjustments to therapy should be made (e.g., more narrow spectrum antibiotic);*
- *Assess residents for any infection using standardized tools and criteria* [63] *(e.g., SBAR tool for urinary tract infection (UTI) assessment* [67]*, Loeb minimum criteria for initiation of antibiotics* [68]*); and*
- *Include the mode (e.g., verbal, written, online) and frequency (as determined by the facility) of education for prescribing practicitioners and nursing staff on antibiotic use (stewardship) and the facility's antibiotic use protocols.* ***NOTE:*** *Prescribing practitioners can include attending physicians and non-physician practitioners (NPP) (i.e., nurse practitioners, clinical nurse specialists, and physician assistants).*

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67 Agency for Healthcare Research and Quality. (2016). *Toolkit 3. Minimum criteria for common infections.* Accessed on June 9, 2017 from http://www.ahrq.gov/nhguide/toolkits/determine-whether-to-treat/toolkit3-minimum-criteria.html

68 Loeb, M., Brazil, K., Lohfeld, L., McGeer, A., Simor, A., Stevenson, K., Zoutman, D…..Walter, S.D. (2005). Effect of a multifaceted intervention on number of antimicrobial prescriptions for suspected urinary tract infections in residents of nursing homes: Cluster randomised controlled trial. *BMJ*, 331, 669. Accessed on June 9, 2017, from http://www.bmj.com/content/bmj/early/2004/12/31/bmj.38602.586343.55.full.pdf

Effective November 28, 2017

The Antibiotic Stewardship Program in Relation to Pharmacy Services
The assessment, monitoring, and communication of antibiotic use shall occur by a licensed pharmacist in accordance with §483.45(c), F756, Drug Regimen Review. A pharmacist must perform a medication regimen review (MRR) at least monthly, including review of the medical record and identify any irregularities, including unnecessary drugs.

INVESTIGATIVE SUMMARY
Surveyors should use the Infection Control Facility Task to assess for compliance with the antibiotic stewardship program during the standard survey.

Antibiotic Stewardship Review
Determine whether the facility's antibiotic stewardship program includes antibiotic use protocol(s) addressing antibiotic prescribing practices (i.e., documentation of the indication, dose, and duration of the antibiotic; review of laboratory reports to determine if the antibiotic is indicated or needs to be adjusted; an infection assessment tool or management algorithm is used when prescribing) and a system to monitor antibiotic use (i.e., antibiotic use reports, antibiotic resistance reports).

Specific Concerns That May Warrant Further Investigation
If concerns have been identified, it may be necessary to conduct record reviews of one (or more) residents receiving antibiotics to identify whether the documented indication for the use of the antibiotic, dosage, and duration is appropriate. It may also be necessary to interview the appropriate person, (e.g., director of nursing, medical director, consulting pharmacist, administrator, or infection preventionist) to verify how antibiotic use is monitored in the facility. Furthermore, review records including evidence of actions taken by the QAA committee related to antibiotic use and stewardship.

KEY ELEMENTS OF NONCOMPLIANCE
To cite deficient practice at F881, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- *Develop and implement antibiotic use protocols to address the treatment of infections by ensuring that residents who require antibiotics are prescribed the appropriate antibiotics;*
- *Develop and implement antibiotic use protocols that address unnecessary or inappropriate antibiotic use thereby reducing the risk of adverse events, including the development of antibiotic-resistant organisms; and/or*
- *Develop, promote and implement a facility-wide system to monitor the use of antibiotics.*

DEFICIENCY CATEGORIZATION
An Example of Severity Level 4 Non-Compliance: Immediate Jeopardy to Resident Health or Safety includes but is not limited to:

- *The facility failed to develop and implement an antibiotic use protocol which included reporting results of laboratory data to the ordering practitioner. Medical record review indicated the prescribing practitioner had ordered a culture and sensitivity for a resident and prescribed an antibiotic for treatment of pneumonia prior to receipt of the results of the lab test. The facility received the results of the lab test which indicated that the*

bacteria was resistant to the antibiotic prescribed, however, they did not provide this information to the practitioner. As a result, the antibiotic was not adjusted accordingly and the resident was hospitalized for complications related to the pneumonia.

An Example of Severity Level 3 Non-Compliance: Actual Harm that is not Immediate Jeopardy includes but is not limited to:

- *The facility did not develop a protocol for antibiotic use, and did not develop or implement a system to monitor antibiotic use. Based on record review, two residents were currently being treated with antibiotics without an appropriate indication for use. The two residents had indwelling urinary catheters and were asymptomatic for UTIs. There was no established criteria for use in the facility for when to treat a catheter-associated urinary tract infection. As a result of the antibiotic therapy, the two residents developed numerous watery, foul-smelling stools, elevated temperature, nausea, and decreased appetite. The medical record revealed that stool cultures identified positive bacteria for antibiotic-related colitis (C. difficile). The two residents were treated for antibiotic-related colitis, but did not require hospitalization and fully recovered.*

An Example of Severity Level 2 Non-Compliance: No Actual Harm with Potential for more than Minimal Harm that is not Immediate Jeopardy includes but is not limited to:

- *The facility failed to implement its protocol for antibiotic use and failed to monitor actual antibiotic use. Record review indicated that the facility developed a protocol which indicated "residents with MDROs are not to be treated with antibiotics for colonization". However, record review revealed one resident colonized with an MDRO receiving an antibiotic to eliminate colonization. As a result, the potential exists for residents to develop antibiotic resistance.*

An Example of Severity Level 1 Non-Compliance: No Actual Harm with Potential for Minimal Harm includes but is not limited to:

- *The facility failed to implement their protocol to monitor the rate of new starts of antibiotics monthly. On review, the monitoring was not completed for 6 weeks. There were no findings of increased MDROs or CDI in the facility.*

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

Additionally, refer to §483.45(c), F756, for concerns related to the failure of the pharmacist to review and report any unnecessary antibiotic irregularity and §483.45(d), F757, for concerns related to unnecessary antibiotic use.

Refer to 483.10(c)(1), 483.10(c)(4) - (6):– the right to be fully informed in advance about care and treatment (F552) for concerns about education of residents and their representatives.

F882

§483.80(b) Infection preventionist

[§483.80(b) and all subparts will be implemented beginning November 28, 2019 (Phase 3)]

The facility must designate one or more individual(s) as the infection preventionist(s) (IP)(s) who are responsible for the facility's IPCP. The IP must:

<u>Effective November 28, 2017</u>

§483.80(b)(1) Have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field;

§483.80(b)(2) Be qualified by education, training, experience or certification;

§483.80(b)(3) Work at least part-time at the facility; and

§483.80(b)(4) Have completed specialized training in infection prevention and control.

§483.80 (c) IP participation on quality assessment and assurance committee.
The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.

F883
§483.80(d) **Influenza and pneumococcal immunizations**
*§483.80(d)***(1) Influenza. The facility must develop policies and procedures to ensure that-**
- **(i) Before offering the influenza immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;**
- **(ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;**
- **(iii) The resident or the resident's representative has the opportunity to refuse immunization; and**
- **(iv)The resident's medical record includes documentation that indicates, at a minimum, the following:**
  - **(A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of influenza immunization; and**
  - **(B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.**

§483.*80(d)***(2) Pneumococcal disease. The facility must develop policies and procedures** ***to*** **ensure that-**
- **(i) Before offering the pneumococcal immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;**
- **(ii) Each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;**
- **(iii) The resident or the resident's representative has the opportunity to refuse immunization; and**
- **(iv)The resident's medical record includes documentation that indicates, at a minimum, the following:**
  - **(A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and**