F881
(Rev. 211; Issued: 02-03-23; Effective: 10-21-22; Implementation: 10-24-22)

§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"** refers to 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.[1] 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.[2]
- **"Methicillin-resistant Staphylococcus aureus (MRSA)** (a.k.a. Oxacillin-resistant Staphylococcus aureus**)"** refers to Staphylococcus aureus bacteria that are resistant to treatment with one of the semi-synthetic penicillins (e.g., Oxacillin/Nafcillin/Methicillin).
- **"Vancomycin-resistant Enterococcus (VRE)"** refers to a 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. [3, 4, 5] This means that the antibiotic is 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 gram negative bacteria.

Resources are available to identify core actions to prevent antibiotic resistance within the control of the nursing home, such as:

- The Centers for Disease Control and Prevention's (CDC) "The Core Elements of Antibiotic Stewardship for Nursing Homes" http://www.cdc.gov/longtermcare/pdfs/core-elements-antibiotic-stewardship-appendix-a.pdf; and
- The Agency for Healthcare Research and Quality's "Nursing Home Antimicrobial Stewardship Guide" http://www.ahrq.gov/nhguide/index.html for examples of antibiotic use protocols, policies and practices.

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

Antibiotic Stewardship Program (ASP)

As summarized by the CDC, 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.[6]

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 (i.e., infection preventionist).[7]

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

- 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 or electronic health records, such as the rate of new starts, types of antibiotics prescribed, or days of antibiotic treatment per 1,000 resident days;
    - Summarizing antibiotic resistance (e.g., antibiogram) based on laboratory data from, for example, the last 18 months; and/or
    - Tracking measures of outcome surveillance related to antibiotic use (e.g., C. difficile, MRSA, and/or CRE).[8]
- Incorporate monitoring of antibiotic use, including the frequency of monitoring/review. Monitor/review response to antibiotics, and laboratory results when available, to determine if the antibiotic is still indicated or adjustments should be made (e.g., antibiotic time-out); when the resident is new to the facility; when a prior resident returns or is transferred from a hospital or other facility[9]; 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. Facilities should provide 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 to improve prescribing practices and resident outcomes.[10] 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; order 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 [11] (e.g., SBAR tool for urinary tract infection (UTI) assessment [12], Loeb minimum criteria for initiation of antibiotics [13]);
- Include the mode (e.g., verbal, written, online) and frequency (as determined by the facility) of education for prescribing practitioners 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); and
- Require antibiotic orders to include the indication, dose, and duration.

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 PROCEDURES

Use the Infection Prevention, Control & Immunizations Facility Task, along with the above interpretive guidance, when determining if the facility meets the requirements for, or when investigating concerns related to, the antibiotic stewardship program.

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). If there are concerns with the ASP, surveyors must include at least one resident on an antibiotic in the resident sample to assess whether the resident(s) is being prescribed an antibiotic(s) unnecessarily and whether there were any negative outcomes such as an adverse drug event.

Instances of prescribing antibiotics unnecessarily should be cited at §483.45(d), F757. These findings may support citing §483.80(a)(3), F881, as well, in which case the surveyor must also show that the facility does not have or is not implementing an ASP. 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 and confirm with findings from review of the antibiotic stewardship program or resident records. Furthermore, review records including evidence of actions taken by the QAA committee related to antibiotic use and stewardship.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- F756: for concerns related to the failure of the pharmacist to review and report any unnecessary antibiotic irregularity;
- F757: for concerns related to unnecessary antibiotic use; and
- F552: for concerns related to the right to be fully informed in advance about care and treatment.

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; or
- 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; or
- Develop, promote and implement a facility-wide system to monitor the use of antibiotics.

DEFICIENCY CATEGORIZATION

An example of Level 4, immediate jeopardy to resident health and 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 Level 3, actual harm that is not immediate jeopardy includes, but is not limited to:

- The facility did not develop a program for antibiotic stewardship, and did not develop or implement a system to monitor antibiotic use. Based on record review, one resident was currently being treated with antibiotics without an appropriate indication for use. The resident had an indwelling urinary catheter and was asymptomatic for an UTI. 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 resident developed nausea and diarrhea that caused avoidable dehydration and prevented the resident from participating in activities and appropriate sleep. The medical record revealed that the antibiotic was stopped and the resident did not have any further adverse effects. The resident was treated via oral rehydration but did not require hospitalization and fully recovered.

An example of Level 2, 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 the resident to develop an adverse drug event, antibiotic resistance, and/ or CDI.

An example of Level 1, 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 antibiotic uses. On review, the monitoring was not completed for 6 weeks. There were no findings of increased MDROs or CDI in the facility.

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[1] Centers for Disease Control and Prevention. "Core elements of hospital antibiotic stewardship programs." www.cdc.gov. Accessed on February 27, 2021 from https://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html

[2] Centers for Disease Control and Prevention. "The core elements of antibiotic stewardship for nursing homes." www.cdc.gov. Accessed on February 27, 2021 from https://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html

[3] Centers for Disease Control and Prevention. "Antibiotic resistance threats in the United States, 2013." www.cdc.gov. Accessed on February 27, 2021 from http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf

[4] 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.

[5] The White House. (2014). "National Strategy for Combating Antibiotic Resistant Bacteria." Accessed on February 27, 2021 from https://obamawhitehouse.archives.gov/sites/default/files/docs/carb_national_strategy.pdf

[6] See endnote 2

[7] See endnote 2

[8] See endnote 2

[9] See endnote 2

[10] See endnote 2

[11] See endnote 2

[12] Agency for Healthcare Research and Quality. "Toolkit 3. Minimum criteria for common infections." Accessed on February 27, 2021 from http://www.ahrq.gov/nhguide/toolkits/determine-whether-to-treat/toolkit3-minimum-criteria.html

[13] 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 February 27, 2021, from http://www.bmj.com/content/bmj/early/2004/12/31/bmj.38602.586343.55.full.pdf