Companion Guide to Using the Minnesota Sample Antibiotic Stewardship Policy for Long-Term Care Facilities

DEVELOP A POLICY THAT WORKS FOR YOUR FACILITY

As you review the Sample Antibiotic Stewardship Policy, use this document to guide development of a working policy for your long-term care facility. The sample policy is meant to be just that—an example of how a nursing home might get started with an antibiotic stewardship program. Two key objectives are identified by this fictitious facility and reflected in the sample policy: 1) meet the Centers for Medicare and Medicaid Services (CMS) requirements for 2017, and 2) outline additional stewardship actions that can be implemented immediately and in the second year of the stewardship program.

Your facility's policy might be longer or shorter, be more or less detailed, have more or fewer stewardship actions, or have different tracking and reporting priorities. It is important to get the necessary people together to discuss stewardship in your facility, get the priorities down on paper, and begin your own program, step by step.

Also provided, starting on page 5, are the interpretive guidelines for the antibiotic stewardship-related CMS requirements of participation, which take effect November 28, 2017.

BACKGROUND:

Write something here about why antibiotic resistance and antibiotic stewardship are important to individual residents, your facility, and the wider health care community.

POLICY:

Include a policy mission statement here. The statement should be agreed upon by administrative and clinical leaders (see Leadership section below)

We suggest including the 7 Centers for Disease Control and Prevention (CDC) core elements of antibiotic stewardship as a reference and as a preface to the rest of the policy document (1).

Include key objectives for the Antibiotic Stewardship Program (ASP) in the first and second years. Each year, when you update the policy, edit these objectives as needed to reflect your progress and priorities. Be specific and realistic, and make sure that everyone agrees upon these objectives.

In this sample policy, our key objectives for Year 1 are to meet CMS requirements (2) and to implement some stewardship actions targeted at UTI diagnosis and management.

PROCEDURE:

1. ### Administrative Leadership
   Identify administrative leadership and describe how commitment to antibiotic stewardship will be communicated by leadership to staff, residents, and families. Administrative leaders could have a role in identifying the ASP leader, if appropriate in your facility.

Develop a mission statement. We suggest that you include it in the Policy section, above, and use it in communications about the facility's commitment to antibiotic stewardship.

2. Accountability (Antibiotic Stewardship Team, AST)

In addition to defining the AST's role as a whole, specifically identify staff members (by role or job title) and their responsibilities. Often a physician, prescriber, or pharmacist will lead the AST.

Use the CDC's Core Elements of Antibiotic Stewardship for Nursing Homes document and checklist to guide your development of this section (1). That document has descriptions of medical, nursing, pharmacist, and laboratory roles. Some roles, like laboratory, might not be relevant to all facilities. Additionally, in some facilities, one individual might serve in multiple positions (e.g., director of nursing also performing in an infection prevention role).

This section should include information about how often the AST will review data (e.g., monthly, quarterly) and review the antibiotic stewardship policy. It should include specifics on what data will be reviewed, where the data is sourced, and who will collect it.

3. Antibiotic Expertise

As with the Accountability section, name specific people who will provide antibiotic expertise (including job titles and relationship to the facility). Examples of those in this role might include infectious disease physicians or infection disease-trained pharmacists. If you do not know of anyone already, the policy development process is a great time to identify these individuals in your health care community and at facilities to which you often transfer residents.

The CDC's Core Elements of Antibiotic Stewardship for Nursing Homes document can help guide development of this section (1).

4. Antibiotic Stewardship Actions

A. Background

Explain why it is important to have defined antibiotic stewardship actions to meet the mission of the ASP. Consider identifying your facility's key elements for action (e.g., nursing awareness of infection criteria, communication, appropriate diagnostics, appropriate prescribing, and identifying antibiotic-related outcomes).

B. Actions

In this section you will list the actions/procedures/protocols that will be carried out as part of the ASP. Be realistic in what your AST will be able to implement. It is OK to list actions that will not be carried out immediately but that you know are important. Identify target dates for implementing each action. That will help to keep you on task and develop a longer-term vision for your ASP.

Remember that the activities in the sample policy are just examples. As of November 28, 2017, CMS conditions of participation require nursing homes to implement two things: antibiotic-use protocols and a system to track antibiotic use (2). In this section, you should describe what antibiotic-use protocols you will implement and how you will track antibiotic use.

CMS requirements are outlined in Box 1 on pages 5–7. "Antibiotic-use protocols" might include a protocol for antibiotic record keeping (e.g., requirement to record indication and all pertinent information about prescription), protocol to determine when antibiotics are

indicated, implementation of antibiotic time-outs (review of antibiotic need, selection, dose, duration at 48–72 hours post-initiation), etc. "System to track antibiotic use" is also undefined at this time, so make a plan that is feasible and useful to your facility.

We suggest that in the main policy document you refer to Appendices, where technical documents, guidelines, and protocols will be kept. This keeps the policy document from being too long and complicated and makes it easier to change guidelines and protocols, since you can just change Appendix content.

Use the CDC Core Elements documents to write this section, as well as other resources such as the Minnesota Antibiotic Stewardship Toolkit for Nursing Homes (3) and references available on the Minnesota One Health Antibiotic Stewardship webpage (4).

5. Measuring Actions (Tracking)

A. Measurement objective
Explain why measurement and tracking are important. In other words, what will you measure and what will you do with the data?

B. What will be measured
Use this section to list what will be measured by the AST. At least some of the stewardship actions that you will put into place should be assessed by tracking compliance and/or related outcomes. For example, if you will require that indication, dose, and duration be recorded for all antibiotic starts, you could measure compliance with this requirement by checking resident records.

Examples of antibiotic use measurement include:
- Antibiotic starts
- Antibiotic days of therapy
- Antibiotic duration of therapy
- Antibiotic route

Examples of measurable stewardship actions include:
- Review of medical records for residents with antibiotic prescription for:
    - Proportion with complete documentation (indication, dose, duration)
    - Compliance with medical assessment protocols (e.g., Loeb criteria)
    - Appropriateness of antibiotic selection
    - Proportion of antibiotic starts receiving antibiotic time-out consideration
- Compliance rate for use of standardized Situation, Background, Assessment, Recommendation (SBAR) form when communicating about change in condition

Examples of outcomes measurement include:
- *C. difficile* infections
- Urinary tract infections (with and without catheter association)
- Multi-drug resistant infections

C. Measurement process
In this section, specify who is responsible for developing protocols for measurement, where the tracking/measurement protocols can be found (e.g., Appendix document), and how the data will be compiled and used. If you have an electronic health record system (e.g.,

PointClickCare, MatrixCare, etc.), we encourage you to work with the person at your facility who knows the most about how that system works. That person might help you identify simplified ways to record and collect the data that you need for your measurement priorities and might be able to reach out to the electronic health record system vendor with specific support requests.

6. Reporting

Describe here how data will be compiled and shared. Include information about any specific reports that will be developed and with whom the reports will be shared and discussed. This can include reports from the electronic health record system. Also, specify what outcome is expected from the reporting process (e.g., changes to ASP objectives or clinical and communication protocols).

7. Education

In this section, describe what you will do for education of staff, providers, residents, and families regarding antibiotic stewardship and when you will do it. If possible, include specific dates and identify the education materials that you will use.

APPENDICES A–D:

The appendices included in this sample reflect the example goals and objectives that are provided in the Sample Antibiotic Stewardship Policy. They are not representative of all the types of appendices that facilities might choose.

Choose the communication form(s), algorithms, and guidelines that will work best for you and are agreed upon by staff and providers.

APPENDIX E, Measurement Protocols:

These sample protocols are simple and reflect the example objectives for measurement and tracking in the Sample Antibiotic Stewardship Policy.

Your protocols might be more detailed, since you will be dealing with specific systems for record management and prescription tracking.

If you have an electronic health record system (e.g., PointClickCare, MatrixCare, etc.), we encourage you to work with the person at your facility who knows the most about how that system works. That person might help you identify simplified ways to record and collect the data that you need for your measurement priorities and might be able to reach out to the electronic health record system vendor with specific support requests.

Companion Guide References

1. CDC. The Core Elements of Antibiotic Stewardship for Nursing Homes. Atlanta, GA: US Department of Health and Human Services, CDC; 2015. Available at: http://www.cdc.gov/longtermcare/index.html
2. Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities. Centers for Medicare and Medicaid Services. Available at: https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities
3. Minnesota Antimicrobial Stewardship Program Toolkit for Long-term Care Facilities. Available at: http://www.health.state.mn.us/divs/idepc/dtopics/antibioticresistance/asp/ltc/index.html
4. Minnesota One Health Antibiotic Stewardship: resources for Long-Term Care Facilities. http://www.health.state.mn.us/onehealthabx/human.html

Interpretive Guidelines for CMS Requirements of Participation, Effective November 28, 2017

The following interpretive guidelines are reproduced from pp. 656–660, CMS Manual System Publication 100–07 State Operations Provider Certification, section F881, §483.80(a)(3). Available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf.

Guidance
Antibiotic Stewardship

As part of their infection prevention and control programs (IPCP), 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 [b, c, d]. 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 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.

As summarized by the CDC[a], 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[a].

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[a];
- Summarizing antibiotic resistance (e.g., antibiogram) based on laboratory data from, for example, the last 18 months; and/or [a]
- Tracking measures of outcome surveillance related to antibiotic use (e.g., C. difficile, MRSA, and/or CRE)[a].

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[a]; 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[a]. 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[a] (e.g., SBAR tool for urinary tract infection (UTI) assessment[d], Loeb minimum criteria for initiation of antibiotics[e]); 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).

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 Non-Compliance

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.

References
a   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/antibioticstewardship.html

b   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-2013508.pdf

c   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

d   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/toolkit3minimum-criteria.html

e   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