SHEA
The Society for Healthcare Epidemiology of America

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Mark R. Chassin, M.D., FACP, M.P.P., M.P.H.
President and Chief Executive Officer
The Joint Commission
Standards and Survey Methods
Antimicrobial Stewardship Field Review
One Renaissance Blvd.
Oakbrook Terrace, IL 60181

Re: Proposed New Standard on Antimicrobial Stewardship

Dear Dr. Chassin,

Thank you for the opportunity to provide comments on The Joint Commission's proposed new standard for Antimicrobial Stewardship in healthcare settings. SHEA is the preeminent professional society committed to providing expertise in infection prevention and control, antimicrobial stewardship, and infectious disease outbreak preparedness and response in all healthcare settings, as well as preventing and controlling morbidity, mortality, and the cost of care linked to healthcare-associated infections and antibiotic resistance. SHEA has been, and continues to be, committed to being the primary resource for healthcare facilities and their antimicrobial stewardship teams for educational programs, tools and resources, implementation guidance and representation before policymakers in all areas related to antimicrobial stewardship.

As stated in an April 2012 policy statement published in the *Journal* of *Infection Control and Hospital Epidemiology*, SHEA believes antimicrobial stewardship must be a fiduciary responsibility for all healthcare institutions across the continuum of care and recommends mandatory implementation of antimicrobial stewardship throughout healthcare. SHEA also recommends the implementation of process and outcome measures to monitor interventions, and to address deficiencies in education and research as well as the lack of accurate data on antimicrobial use. The major objectives of antimicrobial stewardship are to achieve best clinical outcomes related to antimicrobial use while minimizing toxicity and other adverse events, thereby limiting the selective pressure on bacterial populations that drives the emergence of antimicrobial-resistant strains. Antimicrobial stewardship may also reduce excessive costs attributable to suboptimal antimicrobial use[1].

[1]Infection Control and Hospital Epidemiology, Vol. 33, No. 4, Special Topic Issue: Antimicrobial Stewardship (April 2012), pp. 322-327

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SHEA appreciates the expeditious efforts of The Joint Commission to develop an antimicrobial stewardship standard for all healthcare settings. These efforts are aligned with the goals of SHEA and the broader infectious diseases professional community to incentivize the reduction of antimicrobial use and to combat antimicrobial resistance. In evaluating the proposed standard against the criteria established by The Joint Commission on the characteristics that would contribute to a valuable standard:

1) Has a strong evidence-base
2) Has a strong relationship to patient outcomes/clinical care
3) Supports a health care organization's achievement of patient safety and quality of care
4) Has benefits that outweigh the costs
5) Supports a health care priority that impacts quality and safety

SHEA believes that only three of the five healthcare settings outlined in the proposed standard meet these criteria. Please find attached recommended revisions for the proposed standard in the following settings:

- Critical Access Hospitals (CAH)
- Hospitals (HAP)
- Nursing Care Centers (NCC)

Based on the current literature and evidence available for implementation of antimicrobial stewardship programs in ambulatory (ABH) and outpatient (OBS) settings, SHEA is concerned that the lack of supporting data and infrastructure needed for proper implementation in these settings would not adequately support healthcare organizations' efforts to achieve patient safety and healthcare quality improvement goals through antimicrobial stewardship.

SHEA respectfully recommends The Joint Commission move forward with finalizing this standard, with recommended revisions, for the CAH, HAP, and NCC settings. While SHEA recognizes the need for optimizing the use of antimicrobials in ambulatory and outpatient settings, we recommend suspending the finalization of a standard for the ABH and OBS settings until more research and work can be done on developing data to identify the most effective approaches to implementing antibiotic stewardship programs in these settings.

For future inquiries on these comments, please contact Lynne Batshon at 703-684-0761 or lbatshon@shea-online.org.
Sincerely,

Anthony D. Harris, MD, MPH, FSHEA, FIDSA, President, SHEA

TJC Proposed Standard for Antimicrobial Stewardship
Critical Access Hospital Accreditation Program (CAH) MM.09.01.01

Standard
The critical access hospital has an antimicrobial stewardship program based on evidence-based national guidelines.

Elements of Performance (EP)
EP 1: Leaders establish antimicrobial stewardship as an organizational priority. (See also LD.01.03.01, EP 5)

Suggestions: Recommend including ways this can be demonstrated such as evidence of financial support of stewardship team members. Also consider requiring evidence of an accountability structure through appointment of an executive with knowledge of the benefit of antimicrobial stewardship on improving patient care for the antimicrobial stewardship program to report to and policies that describe the accountability structure.

EP 2: Educate staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and antimicrobial stewardship practices. Education occurs upon hire and annually thereafter.

Suggestions: Consider changing "annually" to "periodically." Consider adding that education is required for recredentialing.

EP 3: Educate patients, and their families as needed, regarding the appropriate use of antimicrobial medications, including antibiotics.

Note: An example of an educational tool that can be used for patients and families includes the Centers for Disease Control and Prevention's Get Smart document, "Viruses or Bacteria—What's got you sick?" at http://www.cdc.gov/getsmart/community/downloads/getsmart-chart.pdf.

Suggestions: Since these standards may already be overwhelming to CAHs, would recommend removing this as a standard, since education to patients and families is the primary responsibility of the healthcare providers administering direct care and other aspects of antimicrobial stewardship would arguably be higher priority.

EP 4: The critical access hospital has an antimicrobial stewardship multidisciplinary team that includes the following members, when available in the setting:

- Pharmacist(s)
- Infection disease physician
- Infection preventionist(s)

Note: Part-time or consultant staff are acceptable as members of the antimicrobial stewardship multidisciplinary team.

Suggestions: (1) Change “Infection disease physician” to “Infectious diseases physician(s).” Place “Infectious diseases physician(s)” at the top of the list.

(2) Change “Pharmacist(s)” to “Infectious diseases pharmacist(s).” We understand an infectious diseases-trained pharmacist may not be available in all institutions but the phrase “when available in the setting” obviates the requirement that all hospital accreditation programs must have an infectious diseases pharmacist.

(3) Remove “Infection preventionist(s)” from where it is currently written. Infection preventionists generally do not have the knowledge base (i.e., making diagnoses and prescribing antimicrobial agents) needed to lead an antimicrobial stewardship program with an infectious diseases physician and infectious diseases pharmacist. However they can be an important liaison to the infection prevention program and sharing data on multidrug resistant organisms, cluster investigations, etc. and should be members of the antimicrobial stewardship program. See suggestion #6 below.

(4) Remove the “Note” as if it is not explicitly stated that the staff must be full-time so this statement is not necessary.

(5) Add a note or bullet point that mentions the following: “If an infectious diseases-trained pharmacist and/or physician are not available, a pharmacist or physician knowledgeable about infectious diseases and antimicrobial use, as demonstrated at a minimum by evidence of participation in relevant accredited educational activities, are acceptable alternatives. Facilities may also consider the use of telemedicine or other remote infectious diseases resources.” We believe this statement is necessary so hospitals understand that at a minimum a pharmacist and a physician are required to be members of the antimicrobial stewardship program.

(6) Consider a note stating “Other important antimicrobial stewardship program members include an informatics specialist, a data analyst, a microbiologist, and an infection preventionist.”

EP 5: The critical access hospital's antimicrobial stewardship program includes the following core elements:

- Leadership commitment
- Accountability
- Drug expertise
- Action
- Tracking
- Reporting
- Education

(See also IC.02.01.01, EP 1 and NPSG.07.03.01, EP 5) Standard
The critical access hospital has an antimicrobial stewardship program based on evidence-based national guidelines.

Suggestions: Given redundancy with this EP and other EPs within this standard (e.g., leadership commitment and EP1, drug expertise and EP4, education and EP2), would strongly consider removing this EP in favor of keeping separate, more specific EPs as there are currently. Perhaps the CDC core elements could be referenced at the beginning.

EP 6: The critical access hospital's antimicrobial stewardship program uses organization-approved multidisciplinary protocols.

Note: Examples of protocols are as follows:

- Plan for Parenteral to Oral Antibiotic Conversion
- Guidelines for Antimicrobial Use in Adults
- Formulary Restriction
- Preauthorization Requirements for Specific Antimicrobials
- Assessment of Appropriateness of Antibiotics for Community Acquired Pneumonia
- Guidelines for Antimicrobial Use in Pediatrics

Suggestions: (1) Change the initial statement to state the following: "The hospital's antimicrobial stewardship program develops organization-approved multidisciplinary guidelines, policies, and procedures to improve the use of antimicrobials."

(2) Change the note to state "Examples are as follows:"

(3) Change "Assessment of Appropriateness of Antibiotics for Community Acquired Pneumonia" to state "Assessment of Appropriateness of Antibiotics for Community-Acquired Pneumonia, Skin and Soft Tissue Infections, and Urinary Tract Infections."

(4) Under the examples, add the statements "Avoidance of the testing and treatment of asymptomatic bacteriuria" and "Post-prescription review with feedback"

(5) Remove "Guidelines for Antimicrobial Use in Adults" and "Guidelines for Antimicrobial Use in Pediatrics" as these are less realistic for CAHs compared to others listed.

EP 7: The critical access hospital collects and analyzes data on its antimicrobial stewardship program, including antimicrobial prescribing and resistance patterns. (See also MM.08.01.01, EPs 1 and 2)

Suggestions: This will be very challenging in CAHs without significant information technology and analyst resources. For example, considering that most CAHs use send-out microbiology laboratories, it could be very burdensome to report on resistance patterns beyond what is already being reported by infection control. Antimicrobial prescribing data could be pulled from pharmacy purchasing data, but there is currently limited guidance on what to do with this information. Would recommend removing this standard at this time for CAHs and consider adding at a later date.

EP 8: The critical access hospital takes action on improvement opportunities identified in its antimicrobial stewardship program. (See also MM.08.01.01, EP 6)

Suggestion: Agree with the intent of this element. We Suggest the following rewording: "The critical access hospital takes action on improvement opportunities as they are identified by its antimicrobial stewardship program."

TJC Proposed Standard for Antimicrobial Stewardship
Hospital Accreditation Program (HAP) MM.09.01.01

Standard
The hospital has an antimicrobial stewardship program based on evidence-based national guidelines.

Suggestions: None

Elements of Performance (EP)
EP 1: Leaders establish antimicrobial stewardship as an organizational priority. (See also LD.01.03.01, EP5)

Suggestions: Recommend including ways this can be demonstrated such as evidence of financial support of stewardship team members. Also consider evidence of an accountability structure through appointment of an executive with knowledge of the benefit of antimicrobial stewardship on improving patient care for the antimicrobial stewardship program to report to and policies that describe the accountability structure.

EP 2: Educate staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and antimicrobial stewardship practices. Education occurs upon hire and annually thereafter.

Suggestions: Please consider moving this section to after EP 7. This will also make the order more consistent with the CDC Core Elements.

EP 3: Educate patients, and their families as needed, regarding the appropriate use of antimicrobial medications, including antibiotics. Note: An example of an educational tool that can be used for patients and families includes the Centers for Disease Control and Prevention's Get Smart document, "Viruses or Bacteria—What's got you sick?"

Suggestions: (1) As with EP 2, please consider moving this section to after EP 7.

(2) Although we agree that patients and families need more education about antimicrobial use, for inpatients we would suggest this should focus on improving the education of patients actively receiving antimicrobials or being discharged from the hospital with antimicrobials. The Get Smart document mentioned above is less relevant for hospitalized patients and we believe the focus should be on ensuring patients understand the purpose of the antimicrobials they are prescribed and their potential adverse reactions.

(3) It is also important to clarify that education to patients and families is the primary responsibility of the healthcare providers administering direct care to patients but the overall education of staff on how to best educate patients and families can be the responsibility of the Antimicrobial Stewardship Program.

EP 4: The hospital has an antimicrobial stewardship multidisciplinary team that includes the following members, when available in the setting:

- Pharmacist(s)
- Infection disease physician
- Infection preventionist(s)

Note: Part-time or consultant staff are acceptable as members of the antimicrobial stewardship multidisciplinary team.

Suggestions: (1) Change “Infection disease physician” to “Infectious diseases physician(s).” Place “Infectious diseases physician(s)” at the top of the list.

(2) Change “Pharmacist(s)” to “Infectious diseases pharmacist(s).” We understand an infectious diseases trained pharmacist may not be available in all institutions but the phrase “when available in the setting” obviates the requirement that all hospital accreditation programs must have an infectious diseases pharmacist.

(3) Remove “Infection preventionist(s)” from where it is currently written. Infection preventionists generally don't have the knowledge base (i.e., making diagnoses and prescribing antimicrobial agents) needed to lead an antimicrobial stewardship program with an infectious diseases physician and infectious diseases pharmacist. However they can be an important liaison to the infection prevention program and sharing data on multidrug resistant organisms, cluster investigations, etc. and should be members of the antimicrobial stewardship program. See suggestion # 6 below.

(4) Remove the “Note” as if it is not explicitly stated that the staff must be full time so this statement is not necessary.

(5) Add a note or bullet point that mentions the following: “If an infectious diseases-trained pharmacist and/or physician are not available, a pharmacist or physician knowledgeable about infectious diseases and antimicrobial use, as demonstrated at a minimum by evidence of participation in relevant accredited educational activities, are acceptable alternatives.” We believe this statement is necessary so hospitals understand that at a minimum a pharmacist and a physician are required to be members of the antimicrobial stewardship program.

(6) Consider a note stating “Other important antimicrobial stewardship program members include an informatics specialist, a data analyst, a microbiologist, and an infection preventionist.”

EP 5: The hospital's antimicrobial stewardship program includes the following core elements:

- Leadership commitment
- Accountability
- Drug expertise
- Action
- Tracking
- Reporting
- Education

(See also IC.02.01.01, EP 1 and NPSG.07.03.01, EP 5)

Note: These core elements were cited from the Centers for Disease Control and Prevention's Core Elements of Hospital Antibiotic Stewardship Programs (http://www.cdc.gov/getsmart/healthcare/pdfs/core-elements.pdf). The Joint Commission recommends that organizations use this document when designing their antimicrobial stewardship program.

Suggestions: Revise "Drug expertise," to "Drug expertise, including use of antimicrobials."

EP 6: The hospital's antimicrobial stewardship program uses organization-approved multidisciplinary protocols.

Note: Examples of protocols are as follows:

- Plan for Parenteral to Oral Antibiotic Conversion
- Guidelines for Antimicrobial Use in Adults
- Formulary Restriction
- Preauthorization Requirements for Specific Antimicrobials
- Assessment of Appropriateness of Antibiotics for Community Acquired Pneumonia
- Guidelines for Antimicrobial Use in Pediatrics

Suggestions: (1) Change the initial statement to state the following: "The hospital's antimicrobial stewardship program develops organization-approved multidisciplinary guidelines, policies, and procedures to improve the use of antimicrobials."

(2) Change the note to state "Examples are as follows:"

(3) Change "Assessment of Appropriateness of Antibiotics for Community Acquired Pneumonia" to state "Assessment of Appropriateness of Antibiotics for Community-Acquired Pneumonia, Skin and Soft Tissue Infections, Urinary Tract Infections and Sepsis."

(4) Under the examples, add the statement "Avoidance of the testing and treatment of asymptomatic bacteriuria"

(5) Under the examples, add the statement "Post-prescription review with feedback"

(6) Under the examples, add the statement "Formal implementation of antibiotic timeouts with de-escalation strategies"

EP 7: The hospital collects and analyzes data on its antimicrobial stewardship program, including antimicrobial prescribing and resistance patterns. (See also MM.08.01.01, EPs 1 and 2)

Suggestions: None

EP 8: The hospital takes action on improvement opportunities identified in its antimicrobial stewardship program. (See also MM.08.01.01, EP 6)

Suggestions: Agree with the intent of this element. Suggest the following rewording: "The hospital takes action on improvement opportunities as they are identified by its antimicrobial stewardship program."

TJC Proposed Standard for Antimicrobial Stewardship
Nursing Care Center Accreditation Program (NCC) MM.09.01.01

Standard
The organization has an antimicrobial stewardship program based on evidence-based national guidelines.

Suggestions: We agree with this standard but need to better define what an antimicrobial stewardship program is as well as specify evidence-based national guidelines specific to nursing homes. Perhaps a definition that states, "[a]n antimicrobial stewardship program (ASP) is a program with the objective of optimizing the use of antimicrobials in the nursing home," would be useful here as well.

Elements of Performance (EP)
EP 1: Leaders establish antimicrobial stewardship as an organizational priority. (See also LD.01.03.01, EP 5)

Suggestions: Recommend including ways this can be demonstrated such as evidence of financial support of stewardship team members. Also consider requiring evidence of an accountability structure through appointment of an executive with knowledge of the benefit of antibiotic stewardship on improving patient care to report o and policies that describe the accountability structure.

EP 2: Educate staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and antimicrobial stewardship practices. Education occurs upon hire and annually thereafter.

Suggestions: This is an acceptable standard.

EP 3: Educate residents, and their families as needed, regarding the appropriate use of antimicrobial medications, including antibiotics.
Note: An example of an educational tool that can be used for patients and families includes the Centers for Disease Control and Prevention's Get Smart document, "Viruses or Bacteria—What's got you sick?" at http://www.cdc.gov/getsmart/community/downloads/getsmart-chart.pdf.

Suggestions: This is appropriate. You might include upon admission and as necessary.

EP 4: The organization has an antimicrobial stewardship multidisciplinary team that includes the following members, when available in the setting:

- Pharmacist(s)
- Infection disease physician
- Infection preventionist(s)

Note: Part-time or consultant staff are acceptable as members of the antimicrobial stewardship multidisciplinary team.

Suggestions: Most nursing homes do not have access to an infectious diseases physician. With roughly 16, 000 nursing homes in the US, and 7, 000 infectious diseases physicians (with only a fraction of those interested or having the time available for antimicrobial stewardship activities in nursing homes), this is not currently feasible. While most nursing homes have a consultant pharmacist, this individual is typically not available on a routine basis. Suggest including consultant pharmacists as an optional member of the team who would be available for consultation and provide administrative support for the antibiotic stewardship program. We also suggest including a physician champion and nursing champion, in addition to the infection preventionist.

Change "Infection disease physician" to "Infectious diseases physician(s)."

We also suggest removing "Infection preventionist(s)" from where it is currently written. Infection preventionists generally don't have the knowledge base (i.e., making diagnoses and prescribing antimicrobial agents) needed to lead an antimicrobial stewardship program with an infectious diseases physician and infectious diseases pharmacist. However they can be an important liaison to the infection prevention program and sharing data on multidrug resistant organisms, cluster investigations, etc. and should be members of the antimicrobial stewardship program.

May be helpful to state that microbiologists do not need to be involved in daily activities of the ASP but could be involved with setting tone and direction of the program as well as to provide antimicrobial resistance data..

Also may consider adding an informatics specialist, and a data analyst as these people can really help streamline work of the ASP with day-to-day information and consolidation of data.

EP 5: The organization's antimicrobial stewardship program includes the following core elements:

- Leadership commitment
- Accountability
- Drug expertise
- Action
- Tracking
- Reporting
- Education

(See also IC.02.01.01, EP 1)
Note: These core elements were cited from the Centers for Disease Control and Prevention's "The Core Elements of Antibiotic Stewardship for Nursing Homes"

(http://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html). The Joint Commission recommends that nursing care centers use this document when designing their antimicrobial stewardship program.
Suggestions: Appropriate but very difficult to expect nursing homes to have done. Very few good examples of these programs exist right now. Suggest providing a timeline for implementation of these measures. Consider having the nursing homes be expected, at the outset, to include 2 of the 7 core elements, then hen 3 of 7 the following year, etc.

Additionally, accountability may be a challenge for nursing home providers, who are often carrying out plans for antimicrobials that were started at a hospital. Most nursing homes do not have the resources to track or report antimicrobial use.

Revise "Drug expertise," to "Drug expertise, including the use of antimicrobials"

EP 6: The organization's antimicrobial stewardship program uses organization-approved multidisciplinary protocols.
Note: Examples of protocols are as follows:

- Plan for Parenteral to Oral Antibiotic Conversion
- Formulary Restriction
- Preauthorization Requirements for Specific Antimicrobials
- Assessment of Appropriateness of Antibiotics for Community Acquired Pneumonia
- Facility Guidelines for Antimicrobial Use in Adults
- Care of the Long Term Care Patient with suspected Urinary Tract Infection

Suggestions: Some of these examples are quite unachievable for many nursing homes. But it appears that these are just examples. There may need to be greater clarity here from TJC to decide what constitutes a protocol as well as suggestions for resources to achieve this. As with EP5, a staged expectation may be best.

Specifically, we recommend not including the parenteral to oral conversion—largely irrelevant to most nursing homes (and some would include it just to meet a requirement rather than having meaningful stewardship).

EP 7: The organization collects and analyzes data on its antimicrobial stewardship program, including antimicrobial prescribing and resistance patterns. (See also MM.08.01.01, EPs 1 and 2)

Suggestions: Although tracking is one of the core elements, this is probably too much to include as a requirement for all nursing homes. Recommend deleting.

EP 8: The organization takes action on improvement opportunities identified in its antimicrobial stewardship program. (See also MM.08.01.01, EP 6)

Suggestions: Agree with the intent of this element. Suggest the following rewording: "The nursing care center takes action on improvement opportunities as they are identified by its antimicrobial stewardship program."