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IDSA
Infectious Diseases Society of America

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Re: IDSA Feedback on Interpretive Guidance for Revised Hospital Conditions of Participation —Infection Prevention and Control and Antibiotic Stewardship Programs

Dear Ms. Brice-Payne and Ms. Palowitch:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide the Centers for Medicare & Medicaid (CMS) with feedback on the newly revised Hospital and Critical Access Hospital (CAH) Conditions of Participation (CoP), which were finalized through rulemaking on September 30, 2019.

IDSA represents more than 12,000 infectious diseases (ID) physicians and scientists devoted to patient care, prevention, public health, education, and research in infectious diseases. Our members care for patients of all ages with serious infections, treating meningitis, pneumonia, tuberculosis, HIV/AIDS, health care-associated infections, antibiotic resistant bacterial infections, as well as emerging infections such as the Middle East Respiratory Syndrome coronavirus (MERS-CoV), Ebola virus and Zika virus diseases. IDSA has long advocated for CMS to recognize the critical role of Antibiotic Stewardship Programs in hospitals. We were extremely pleased that the CMS acted last year to expand the scope of the Infection Prevention and Control CoP requirements.

As a follow up to our December 9, 2019 phone call with CMS staff, we are providing feedback gathered from our clinical expert leaders on specific final provisions of the hospital (§482.42) and CAH (§485.640) CoP related to Infection Control and Prevention and Antibiotic Stewardship Programs. IDSA appreciates the opportunity to provide CMS with this input and hopes the Agency will take our

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comments into consideration as it works to develop interpretive guidance for implementing the new CoP requirements.

If needed, we can schedule a follow-up call to discuss our recommendations in further detail. Should you have any questions or wish to schedule a call, please contact Kay Moyer, Program Officer, Clinical Affairs (kmoyer@idsociety.org).

Sincerely,

Thomas File, MD, MSc, FIDSA

President

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

The hospital must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.

IDSA feedback on § 482.42 introductory language: It is stated that "The hospital must have active hospital-wide programs for the surveillance, prevention and control of HAI's and other infectious diseases, and for the optimization of antibiotic use through stewardship." IDSA requests that CMS clarify in the introduction of the interpretive guidance that Infection Prevention and Control (IPC) is distinct from Antibiotic Stewardship Programs (ASPs) and that each requires distinct and dedicated resources. We also strongly recommend that the interpretive guidance explain that while an Infection Prevention program is ideally run by an Infectious Diseases (ID) physician(s) and one or more IPs, ASPs are ideally run by an ID physician and an ID- or stewardship-trained pharmacist.

(a) ***Standard: Infection prevention and control program organization and policies.***

The hospital must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;

(2) The hospital infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings;

IDSA feedback on section § 482.42 (a) (2): IDSA believes it is important for the interpretive guidance to address proper communication at the time of transfer (transition of care) related to recent culture results or history of colonization with multidrug resistant organisms, such as extended spectrum β-lactamases (ESBL) producing Enterobacteriaceae, carbapenem-resistant Enterobacteriaceae (CRE) etc. Similarly, communication about *Clostridioides difficile* infection testing and results around transition of care is important. Transfer forms, registries and documentation of recent antibiotic use and culture results in discharge documents are examples of various ways this can be achieved.

(3) The infection prevention and control program includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and addresses any infection control issues identified by public health authorities; and

IDSA feedback on section § 482.42 (a) (3): This is a broad topic that encompasses many different issues, some of which may also have antimicrobial stewardship implications. It will be important for the interpretive guidance to give examples of what different infection prevention and control domains should be addressed by IPC programs. IDSA recommends using the CDC acute care hospital ICAR survey as an example of various infection prevention and control domains that should be addressed.

(4) The infection prevention and control program reflects the scope and complexity of the hospital services provided.

(b) ***Standard: Antibiotic stewardship program organization and policies.***
The hospital must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;

IDSA feedback on section § 482.42 (b) (1): ASPs are best led by infectious diseases physicians with additional stewardship training.[1] IDSA offers resources to help practices and institutions implement stewardship programs such as the new Core Antimicrobial Stewardship (AS) Curriculum available through IDSA Academy.

(2) The hospital-wide antibiotic stewardship program:

(i) Demonstrates coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;

IDSA feedback on section § 482.42 (b) (2) (i): We recommend that CMS clarify in the interpretive guidance that this should also include coordination among IT/EHR support and microbiology labs. One of the ways that facilities may achieve this kind of coordination is to establish an antimicrobial stewardship committee that has representation from all of the different areas. The members will play an important role in updating the stewardship committee on various issues and planned interventions in their areas. The information will be important when deciding specific interventions related to antibiotic stewardship, executing the intervention in a coordinated manner, and avoiding duplication of efforts.

(ii) Documents the evidence-based use of antibiotics in all departments and services of the hospital; and

[1] Barlam TF, Cosgrove SE, Abbo LM, et al. Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America. *Clinical Infectious Diseases*, Volume 62, Issue 10, 15 May 2016, Pages e51–e77, https://doi.org/10.1093/cid/ciw118

IDSA feedback on section § 482.42 (b) (2) (ii): While IDSA appreciates CMS' effort to provide flexibility, we believe that this needs to be defined more clearly to ensure this requirement is properly adhered to and documented. One suggestion is to let hospitals perform an assessment of leading areas for antibiotic misuse in their facility and then target improvement on evidence-based prescribing. For example, if a facility is seeing an unnecessarily long duration of antibiotic use for community acquired pneumonia (CAP), documenting improvement in the antibiotic prescribing based on the CAP guidelines can be an intervention they focus on. Others may choose to focus on unnecessary broad spectrum use and maintain documentation of the efforts and results. IDSA would be happy to have a more in-depth discussion with CMS on how to better define this, while also preserving flexibility.

(iii) Documents any improvements, including sustained improvements, in proper antibiotic use;

IDSA feedback on section § 482.42 (b) (2) (iii): IDSA recommends "proper" be defined as evidence-based antibiotic use, as defined by evidence-based practice guidelines. In the absence of evidence-based guidelines, "proper" use should be evaluated using a framework for rational antibiotic use.[2]

(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

IDSA feedback on section § 482.42 (b) (3): Again, this language could use some clarification. While we support CMS' effort to maintain flexibility, it is not clear how this actually will be assessed. Also, what if a local group adapts or adjusts a guideline for local reasons (e.g. susceptibility patterns)? We request that the interpretive guidance address local adaptations of national guidelines such as those from IDSA.

(4) The antibiotic stewardship program reflects the scope and complexity of the hospital services provided.

IDSA feedback on section § 482.42 (b) (4): We interpret the "scope and complexity" statement as meaning that the resources for a tertiary care facility or high-complexity hospital have to be greater than those for a less-complex hospital, regardless of bed size, and that hospitals need to be able to show that they have given careful thought to the allocation of resources to these programs. We support this statement, but believe it is important for the interpretive guidance to describe how a CMS surveyor will assess that a stewardship program reflects the scope and complexity of the hospital services provided since this could be a subjective matter. One example may be an annual risk assessment or stewardship program assessment and/or annual goal setting (e.g., a start of the year goal setting by the stewardship committee based on their hospital needs and antibiotic use practices in their facility). Goal setting may include setting targets for improvement on process and/or outcome measures or introducing a new intervention (including diagnostic stewardship) based on the program assessment results. We also recommend

[2] Example: Tamma PD, Miller MA, Cosgrove SE. Rethinking How Antibiotics are Prescribed: Incorporating the 4 moments of Antibiotic Decision Making into Clinical Practice. JAMA 2018.

that consideration of these resources should account for either salary compensation or protected time from clinical responsibilities, or ideally both, for physician leaders.

(c) Standard: Leadership responsibilities.

(1) The governing body must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities. (ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with hospital QAPI leadership.

IDSA feedback on section § 482.42 (c) (1) (i): Measures that may be utilized to assess the impact of antimicrobial stewardship interventions both within and across various healthcare settings include, but are not limited to: rates of *C. difficile* infection, time to administration of appropriate therapy, adverse drug reactions or interactions related to antimicrobial therapy, drugs administered to patients with documented allergies, multidrug regimens with redundant antimicrobial spectra, regimens that are either inadequate or excessive, duration of intensive care, overall hospitalization for patients treated with antimicrobials, and finally 30-day readmission rates for infection and 30-day mortality rate for infections may also be measured. These data may be obtained through annual point-prevelance surveys of antimicrobial use and/or by reporting to the Antimicrobial Use and Resistance option of the Medication-Associated Module of CDC's NHSN.

While tracking these activities is critical, it is equally critical that the governing body ensure the availability of data analytics and administrative support to accurately and consistently evaluate the impact of these activities. According to a cross-sectional survey of members of IDSA, SHEA, and/or PIDS actively involved in antibiotic stewardship (*Essential Resources and Strategies for Antibiotic Stewardship Programs in the Acute Care Setting, 2018*), nearly all programs (97%) reported the presence of electronic medical records, and 64% reported having information technology add-ons to assist with stewardship. However, data analytics support was available at only 16% of the programs, while administrative support for ASPs was available in only 13% of the programs.

(2) The infection preventionist(s)/ infection control professional(s) is responsible for:

(i) The development and implementation of hospital-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines. (ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities. (iii) Communication and collaboration with the hospital's QAPI program on infection prevention and control issues. (iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of infection prevention and control guidelines, policies, and procedures. (v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures

by hospital personnel. (vi) Communication and collaboration with the antibiotic stewardship program.

(3) The leader(s) of the antibiotic stewardship program is responsible for:
(i) The development and implementation of a hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.
(ii) All documentation, written or electronic, of antibiotic stewardship program activities.
(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as with the hospital's infection prevention and control and QAPI programs, on antibiotic use issues.
(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

IDSA feedback on section § 482.42 (c) (3): IDSA recommends the interpretive guidance provide examples of resources needed to make this possible. We recommend citing the CDC core element documents and IDSA guidelines as examples. CDC also has information on select programs as an example for establishing successful programs which can also be used for resources, available at https://www.cdc.gov/antibiotic-use/healthcare/programs.html.

It is important to consider not only treatment guidelines, which can be used for development of protocols and order sets to ensure appropriate antibiotic selection and duration, but also diagnostic guidelines.[3] It should be highlighted that diagnostic stewardship (i.e. protocols for appropriate diagnostic testing) achieve both infection prevention goals (decreasing reportable HAIs) and stewardship goals (decreasing inappropriate antimicrobial use).

Additionally, regarding item (iii): The term "competency-based training" needs clarification. For example, how frequently? Does it need to be all personnel staff or just select ones? And what should competency-based training entail, at a minimum (e.g., just reviewing a slide set

[3] Nicolle LE, Gupta K, Bradley SF, et al. Clinical Practice Guideline for the Management of Asymptomatic Bacteriuria: 2019 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases*, Volume 68, Issue 10, 15 May 2019, Pages e83–e110, https://doi.org/10.1093/cid/ciy1121

Hooton TM, Bradley SF, Cardenas DD, et al. Diagnosis, Prevention, and Treatment of Catheter-Associated Urinary Tract Infection in Adults: 2009 International Clinical Practice Guidelines from the Infectious Diseases Society of America, *Clinical Infectious Diseases*, Volume 50, Issue 5, 1 March 2010, Pages 625–663, https://doi.org/10.1086/650482

McDonald LC, Gerding DN, Johnson S, et al. Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA), *Clinical Infectious Diseases*, Volume 66, Issue 7, 1 April 2018, Pages e1–e48, https://doi.org/10.1093/cid/cix1085

Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2018 Update by the Infectious Diseases Society of America and the American Society for Microbiology. *Clinical Infectious Diseases*, Volume 67, Issue 6, 31 August 2018, Pages e1–e94, https://doi.org/10.1093/cid/ciy381

should not count for competency-based training; it should also include follow-up question to assess competency)?

We also suggest that "competency-based training" align with The Joint Commission requirements to educate licensed independent practitioners (MDs, NPs, PAs), pharmacists and RNs upon hire and "periodically." It should also account for efforts to incorporate patient/family education.

(d) ***Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems.***

If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital;

(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the hospital as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to hospital staff.

IDSA feedback on section § 482.42 (d): The list above reads like items that are the responsibility of individual hospitals, rather than the responsibility of the system governing body. This could benefit from clarification in the interpretive guidance.

Similar to the previous comment, integration and coordination across hospitals will be a resource-intensive task. We recommend that CMS provide examples of how this integration should actually work or list examples of activities that support integration. For example, one way to achieve this kind of coordination and integration may be though appointing a responsible individual at each facility to be the point person who will represent their facilities in the unified

antimicrobial stewardship committee. The committee meeting should allow for remote participation to allow all the facilities in the system to raise issues that may be unique to their facility and allow for strategy modifications where needed to achieve their specific goals.

Regarding item (4): It is critical that the guidance highlight here the distinct roles and tasks related to IPC and ASPs. The guidance should also emphasize the importance of the system governing body ensuring that resources are available for each of these two related, but distinct activities.

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

The CAH must have active facility wide programs, for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in coordination with the facility-wide quality assessment and performance improvement (QAPI) program.

(a) ***Standard: Infection prevention and control program organization and policies.***
The CAH must demonstrate that:
(1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;
(2) The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the CAH and between the CAH and other healthcare settings;
(3) The infection prevention and control includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also addresses any infection control issues identified by public health authorities; and
(4) The infection prevention and control program reflects the scope and complexity of the CAH services provided.

(b) ***Standard: Antibiotic stewardship program organization and policies.***
The CAH must demonstrate that:
(1) An individual (or individuals), who is qualified through education, training, or experience in infectious
diseases and/or antibiotic stewardship, is appointed by the governing body, or responsible individual, as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;
(2) The facility-wide antibiotic stewardship program:

(i) Demonstrates coordination among all components of the CAH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;
(ii) Documents the evidence-based use of antibiotics in all departments and services of the CAH; and
(iii) Documents any improvements, including sustained improvements, in proper antibiotic use;

(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

(4) The antibiotic stewardship program reflects the scope and complexity of the CAH services provided.

(c) ***Standard: Leadership responsibilities.***

(1) The governing body, or responsible individual, must ensure all of the following:
(i) Systems are in place and operational for the tracking of all infection surveillance, prevention and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.
(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with the CAH's QAPI leadership.

(2) The infection prevention and control professional(s) is responsible for:
(i) The development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.
(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.
(iii) Communication and collaboration with the CAH's QAPI program on infection prevention and control issues.
(iv) Competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the practical applications of infection prevention and control guidelines, policies and procedures.
(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by CAH personnel.
(vi) Communication and collaboration with the antibiotic stewardship program.

(3) The leader(s) of the antibiotic stewardship program is responsible for:
(i) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.
(ii) All documentation, written or electronic, of antibiotic stewardship program activities.
(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the CAH's infection prevention and control and QAPI programs, on antibiotic use issues.
(iv) Competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAHs, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.