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Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: CMS-3295-P Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care, proposed rule

Dear Mr. Slavitt:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide comment and offer recommendations on the proposed rule on changes to the Conditions of Participation (CoPs) for Hospitals and Critical Access Hospitals (CAHs). APIC is a nonprofit, multidisciplinary organization representing over 15,000 infection preventionists whose mission is to create a safer world through prevention of infection.

APIC applauds and supports the proposed Centers for Medicare & Medicaid Services (CMS) changes to the present infection control CoPs for hospitals and CAHs. We agree these proposed changes reflect the changing healthcare environment related to infection prevention needs within the acute and critical access hospital as well as outpatient settings.

APIC especially appreciates that CMS recognizes the "ever-evolving nature of medicine and patient care" and intends to intentionally build flexibility into the regulation, such as pursuing guidelines appropriate to the setting, along with infection prevention and antimicrobial stewardship program needs. This flexibility will allow innovation and program directed goals and will serve to enhance the use of resources and promote cost-effective approaches to patient safety efforts.

We agree that engagement of key organizational senior leaders in infection prevention and control as well as antibiotic stewardship activities is paramount to safe patient care and will promote quality. In review of the proposed changes, we noted that the terms governing body, leadership and responsible individual are used somewhat interchangeably and find it difficult to

interpret the intent of the conditions as a result. We suggest that CMS clarify the intent of "governing body", especially in relation to the Board of Directors/Governing Board. This distinction is important to further understand the intent of the governing body responsibilities. We do not believe that the day-to-day responsibilities of infection prevention and control, and antibiotic stewardship would be within the scope of the Board of Directors. Specifically, we are seeking clarification to the proposed language in §482.42. Our comments reflect our interpretation that the governing body be comprised of senior hospital leaders (e.g. Chief Executive Officer, Chief Operating Officer, Chief Quality Officer, Chief Financial Officer, Chief Medical Officer, Chief Nursing Officer, Chief Information Officer) that oversee the day-to-day activities of infection prevention and antibiotic stewardship programs.

In December of 2004, the National Quality Forum (NQF) published *Hospital Governing Boards and Quality of Care: A Call to Responsibility*.[1] The document lists one of the responsibilities of all boards is to "Recognize physicians' roles, the role of the medical staff within the hospital, and the roles of nursing executives and other clinical leaders (e.g., pharmacists, infection control professionals) in achieving quality by engaging them in quality improvement efforts."[2] APIC agrees with the NQF explanation. We strongly believe, as part of the overall Quality Assessment and Performance Improvement (QAPI) program, improvement initiatives identified by infection prevention and antibiotic stewardship programs, and outcomes from their work should be shared with the Board of Directors. Consistent with the NQF, we support the Board of Directors holding the governing body responsible for safety and quality performance.

> *Recommendation:* To eliminate misinterpretation of the term and facilitate compliance with the conditions of participation, the term governing body should be defined in the conditions of participation as the senior staff leadership. We propose that the term be differentiated from the Board of Directors.

Hospitals

§482.42(a) Standard: Infection Prevention and Control Program Organization and Policies

§482.42(a)(1) Infection Control Officer(s)

APIC strongly supports the change in terminology as it relates to infection prevention and control professionals. We support moving away from the outdated "infection control officer" terminology and endorse the use of the term "infection preventionist". We also endorse the reference to certification by the Certification Board of Infection Prevention and Control (CBIC) and to the adult or pediatric specialty board certifications, as appropriate.

> *Recommendation:* APIC supports the use of the term infection preventionist/infection control professional when referring to the qualified individual with primary responsibility for the infection prevention and control program.

Appointing the infection preventionist leader after seeking out and gathering recommendations, rather than simply designating an individual to function in this role, strengthens the importance of the role. A collaborative effort between medical staff and nursing leadership and the infection preventionists in appointing infection prevention staff will serve to educate leaders and elevate the needs of the infection prevention program.

> *Recommendation:* APIC supports the proposal to appoint the infection preventionist leader and also supports the proposal for the governing body oversight of the appointments.

§482.42(a)(2) Preventing and Controlling the Transmission of Infections within the Hospital and Between the Hospital and Other Institutions and Settings AND 482.42(a)(3) Healthcare-Associated Infections (HAIs)

Recognition of the broader scope of transmission of infections is imperative in our fast-paced, changing healthcare delivery systems. APIC members realize that we have to look beyond the traditional four walls of our facilities in order to prevent transmission of infection and resistant organisms. We also support the increased collaboration and communication with our counterparts in other facility types (skilled nursing facilities, inpatient rehabilitation facilities, long-term acute care hospitals, etc.) and public health to improve patient safety and quality of care across the healthcare continuum. This coordinated approach is well illustrated in the Centers for Disease Control and Prevention infographic "Facilities work together to protect patients."[3]

> *Recommendation*: APIC heartily endorses the inclusion of the outpatient setting reference in the proposed rule, as we recognize that healthcare beyond the walls of the hospital is rapidly growing.

§482.42(a)(4) Scope and Complexity

APIC endorses the requirement for an infection prevention and control program to reflect the scope and complexity of the services offered. An annual infection prevention and control risk assessment provides a guide to help facilities identify this scope and complexity in order to focus the priorities of their program. This reflects the importance of program flexibility and directed prevention strategies to combat issues that are specific to the population being managed.

> *Recommendation:* APIC supports the use of an annual risk assessment based on the scope and complexity of services offered in a facility to guide individual facility prevention strategies.

§482.42(b) Standard: Antibiotic Stewardship Program Organization and Policies

We strongly support the addition of antibiotic stewardship as a requirement. Requiring antibiotic stewardship programs to be coordinated with infection prevention programs, as part of the CoPs, will serve to endorse the need for sufficient resources to allow hospitals to pursue more robust efforts to promote and control antibiotic use and resistance. We believe that, while these programs are collaborative and complementary, the identification of antibiotic stewardship *as an area of infection control* would benefit from revision and clarification. Throughout the remainder of the proposed rule the need for separate leadership and operations for antimicrobial stewardship and infection prevention and control is clearly defined and supported.

> *Recommendation:* In order to clarify the organization of the antibiotic stewardship and infection prevention and control programs, we recommend the following change to the existing language: "Antibiotic Stewardship, as a **component of controlling infection**, has long been recognized as one of the special challenges that hospitals must meet in order to address the problems of multidrug-resistant organisms and *Clostridium difficile* infections (CDIs) in hospitals and outpatient settings."

§482.42(b)(1) Leader of the Antibiotic Stewardship Program

The current wording suggests that there needs to be a single leader of the stewardship program who is qualified through education, training or experience in infectious disease and/or antibiotic stewardship. We agree that having a local expert leader appointed for the program is essential. However, we also recognize that at this time many facilities cannot fulfill the role of a local leader with appropriate qualifications in a single individual. Much like the acknowledgement in § 482.42(a)(1) that "it is not necessary for all functions to rest with one individual", allowing more than one individual to fulfill the leadership functions of the antibiotic stewardship program while a single individual develops the needed qualifications will allow the essential stewardship efforts to move forward. This would allow for an interim network approach to stewardship many facilities have currently implemented utilizing a consultant to provide guidance to a local leader as stewardship efforts advance and expert leaders are groomed.

> *Recommendation:* In recognition that: antibiotic stewardship programs are currently not well established in many organizations; availability of individuals with the skills to lead such programs is limited; and developing leaders with expertise will take time, we suggest considering a modification to the current requirement that a single trained individual be responsible for the antibiotic stewardship program. Adjusting the current requirement to allow for two key functions during a phase-in period would allow programs to begin the necessary work while developing individuals capable of fulfilling the qualifications. We recommend the following key functions: 1) a local leader of the antibiotic stewardship program who is accountable to the hospital's governing body and is empowered to hold providers and others accountable for appropriate antibiotic use AND 2) access to an individual (pharmacist or physician) with qualifications and experience in antibiotic stewardship.

APIC appreciates the distinction that CMS provides in the responsibilities of the infection prevention and control program and the antibiotic stewardship program. We acknowledge that without collaboration neither program will be successful at controlling resistance, but also recognize the limitations of our members' expertise in antibiotic prescribing practices.

> *Recommendation:* We support the separate leadership roles for the infection prevention and control program and the antibiotic stewardship program.

§482.42(b)(2)(i), (ii), and (iii) Meeting the Goals of the Antibiotic Stewardship Program

The current proposal to allow flexibility in implementing stewardship program initiatives that meet the need of the hospital in a data-driven way is one we wholeheartedly support. APIC cautions that in citing the goal to "reduce CDI" that data is carefully reviewed, so that cases of colonization as opposed to infection are not held against hospital program efforts. Much work and discussion is occurring at a national level on this subject, realizing that the laboratory testing sensitivity can identify positive findings that may not represent true infection. We recognize that the associated interpretive guidance that is to be developed will be key to whether this is practical for facilities and meaningful in addressing antimicrobial resistance.

> *Recommendation:* It will be key to focus the interpretive guidance criteria on the outcomes of the intervention and not as much on the process details of what is included in each intervention.

§482.42(b)(3) and (4) Meeting Nationally Recognized Guidelines; and Scope and Complexity

APIC supports the proposed goals for the antimicrobial stewardship program and encourages CMS to promote the same flexibility with those goals to allow programs to identify the needs and priorities relevant to their specific settings.

> *Recommendation*: APIC supports the use of an annual risk assessment based on the scope and complexity of services offered in a facility to guide the antibiotic stewardship program strategies with guidance from nationally recognized guidelines and best practices.

§482.42 (c) Leadership Responsibilities

§482.42(c)(1)(i and ii) The Governing Body

APIC appreciates the fact that CMS recognizes the importance of the work infection preventionists do and are garnering support for our efforts through the requirement for greater leadership accountability. APIC agrees that hospital leadership accountability in the promotion and support of the infection prevention and control program, along with the antibiotic

stewardship program would enhance the ongoing success and sustainability of the programs and ultimately serve to create a sound patient safety foundation in these areas.

> *Recommendation:* We endorse adding Governing Body responsibilities for the Infection Prevention and Control program to the CoPs and the requirement for collaboration with and connection to the QAPI program. This will serve as another measure to promote solidification of these programs within the organizational structure of patient safety.
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> *Recommendation*: In addition to the proposed leadership responsibilities, we recommend adding a third requirement that the governing body is responsible for ensuring a leader for the antimicrobial stewardship program is identified and in place through a reporting mechanism similar to infection prevention and control. This is suggested in other sections, but not specifically tasked to the governing body which will be essential to successful antimicrobial stewardship.

§482.42(c)(2)(i, ii, iii, iv, v) The Infection Preventionists'/Infection Control Professionals' Responsibilities

We applaud the acknowledgement by CMS that the infection preventionist/infection control professional is responsible for the development and implementation of the infection prevention and control plan. This is the basis for our day-to-day work. Accepting that the program should be based on nationally recognized standards and guidelines, we appreciate the recognition that on occasion and/or in conjunction with research activities non-traditional approaches may be implemented in order to further best practices. Allowing facilities the ability to select the data collection, analysis and prevention efforts that best meet their needs will further infection prevention and patient safety at the local level.

> *Recommendation:* APIC supports a flexible approach to selecting and implementing infection prevention and control best practices. We acknowledge that at times that requires thinking outside the box.

APIC agrees that bringing the infection prevention and control program more fully into the hospital QAPI program will help to bring a more proactive and less reactive approach to infection prevention and control issues. We caution, however, as has aptly been pointed out in §482.42 (a)(1) that the individual performing the infection prevention and control responsibilities must be qualified. While the assessment and improvement principles inherent in QAPI programs can be applied to infection prevention and control, the specific content expertise is still required and must be recognized by facilities. While many of our members have been active participants in their facility QAPI Committee, the focus has been primarily on metrics reported to CMS.

> *Recommendation:* APIC supports a stronger communication and collaboration between infection prevention and control and QAPI.

While APIC strongly believes that a competent workforce is essential to safe care, we have some concerns and believe additional clarification is needed. The infection preventionist/ infection control professional should have direct responsibility for developing competency-based training content, but due to other facility priorities, may not have the time needed to assess and educate every employee. We believe an appropriately designed and developed "train-the-trainer" program can accomplish the same goal. We suggest that this section clearly state that the infection preventionist/infection control professional develops and oversees staff training, that may be delivered by a trained team of instructors. This will enforce with hospital administrators that competency-based training is required of all staff, and that, as one of many essential functions within the infection prevention and control program, using a team of trainers rather than relying solely on the infection preventionist/infection control professional will ensure timely training protocols.

> *Recommendation:* APIC supports the direct involvement of the infection preventionist/ infection control professional in the development of competency-based assessment and recommends the inclusion of a train-the-trainer delivery approach as needed.

We agree that auditing healthcare providers as they deliver care and services is integral to assuring implementation of infection prevention and control best practices and identifying opportunities for improvement. There are circumstances; however, such as hand hygiene observations, when observation by the infection preventionist/infection control professional might cause the "Hawthorne effect", where the direct healthcare providers recognize the infection preventionist/infection control professional and, realizing their practices are under observation change their behavior. Word travels quickly on a patient care unit when it is believed the infection preventionist/infection control professional is observing practice. For this reason and much like the train-the-trainer program used for competency assessment and training, a similar train-the-trainer approach could be used for infection prevention and control audits such as hand hygiene. The Joint Commission Targeted Solutions Tool® for Hand Hygiene uses this approach and has video vignettes to aid in the training of the observers. Additionally, in order to apply a valid analysis of hand hygiene observations, large sample sizes are needed across all care shifts. This could not be accomplished by the infection preventionist/infection control professional alone.

> *Recommendation:* APIC supports the requirement for infection preventionists/infection control professionals to audit adherence to policies and procedures and recommend a train-the-trainer approach to auditing for observations such as hand hygiene compliance where large numbers of observations are needed for valid data analysis.

Critical Access Hospitals
§485.640(a)(1) and (2) Infection Control Officer(s); and Prevention and Control of Infections Within the CAH and Between CAH and Other Healthcare Settings

APIC believes that the qualifications for and appointment of the infection preventionist/ infection control professional should be the same in critical access hospitals as those in acute care hospitals.

> *Recommendation*: We recommend the inclusion of certification by specialty boards in adult or pediatric infectious diseases, when appropriate, as qualifications for the role.

APIC supports ongoing training, education, and certification as a way to maintain the qualifications needed to lead the infection prevention and control program.

> *Recommendation*: The infection preventionist leader should be required to maintain the qualifications required for the role.

The remaining CAH requirements for the infection prevention and control program, and the antibiotic stewardship program are consistent with the requirements for acute care hospitals and therefore we have no additional recommendations.

APIC appreciates the proposed revisions to the infection prevention and control and antibiotic stewardship program and acknowledges that these changes will serve to help promote sustainability and innovation in the future. We look forward to continuing to work with CMS to ensure the safety of patients and prevention of infection in hospitals and critical access hospitals.

Sincerely,

Susan Dolan, RN, MS, CIC, FAPIC
2016 APIC President

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[1] Institute for Healthcare Improvement. Hospital Governing Boards and Quality of Care: A Call to Responsibility. Washington, DC: National Quality Forum; 2004. Available at: http://www.ihi.org/resources/Pages/Publications/HospitalGoverningBoardsandQualityofCareACalltoResponsibility.aspx Accessed August 11, 2016.

[2] Ibid.

[3] Centers for Disease Control and Prevention. Vital Signs. Making Healthcare Safer Infographics – Facilities work together to protect patients. August 2015. Available at: http://www.cdc.gov/vitalsigns/stop-spread/infographic.html. Accessed July 27, 2016.