



March 1, 2019

Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
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 Secretary Azar:

We write to request your intervention to improve infection prevention and antibiotic stewardship to protect patients across the continuum of care. On June 16, 2016, the Centers for Medicare & Medicaid Services (CMS) published the Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care proposed rule. According to the CMS summary,

“...these proposals are intended to conform the requirements to current standards of practice and support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate workforce shortage concerns.”

As professional associations representing infection preventionists, antibiotic stewards, and healthcare epidemiologists, the Association for Professionals in Infection Control and Epidemiology (APIC) and The Society of Healthcare Epidemiologists of America (SHEA) reiterate our strong support for CMS' proposal to update the Infection Prevention and Control requirements of the Hospital and Critical Access Hospital (CAH) Conditions of Participation (CoP) and applaud the recommendation to include antibiotic stewardship programs in the regulation. In initiating this rulemaking, CMS demonstrated its ongoing commitment to reducing healthcare-associated infections (HAIs) and preventing the spread of antibiotic resistance, a federal priority for improving healthcare quality. However, CMS has neglected to finalize this rule, which, without further action, will expire on June 16, 2019. As such, APIC and SHEA urge you to call on CMS to finalize the proposed revisions to update and clarify existing requirements to reflect state-of-the-art practices and terminology. Not only will this update hospital practices, but in light of recent updates to requirements for long-term care facilities and home health agencies, it will harmonize practices across the continuum of care.

As noted in the proposed rule, infection control was elevated to a CoP in 1986. Except for technical amendments, it has remained essentially unchanged for more than 30 years. APIC and SHEA agree with CMS that the current requirements no longer fully conform to current standards for infection prevention and control. Our organizations share the concerns expressed by the Department of Health and Human Services that HAIs are a significant cause of morbidity and mortality in the United States, and of the growing threat to patient safety posed by multidrug-resistant organisms (MDROs). The Centers for

Disease Control and Prevention (CDC) estimates that MDRO infections cause 2 million illnesses and 23,000 deaths each year in the United States. Within the last decade, multiple agencies under HHS have led initiatives^{1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19} in an effort to reduce the prevalence of HAIs and MDROs. These efforts have received broad support and active participation from the patient, medical research, and healthcare professional communities^{20,21,22,23,24,25,26,27,28,29,30,31,32,33,34} and are reflected in the comments received in the docket for this proposal.³⁵ We encourage you to build the momentum toward ending this threat by finalizing this rule as soon as possible.

Unlike in 1986, we now know that patient safety depends on the ability of hospitals to be able to balance traditional infection control efforts with organization-wide infection prevention practices. The proposed rule takes critical steps to reflect the evolution of research and the closing of knowledge gaps to prevent the spread of HAIs and MDROs. Changing the title of the CoP by adding the words “prevention” and “antibiotic stewardship” and emphasizing coordination between the quality assessment and performance improvement (QAPI) and the infection prevention and control programs (IPCP) underscore the importance of collaboration throughout every department, including outpatient care, in protecting patients from transmission of infection.

Healthcare professionals overseeing the IPCP must be well qualified and must maintain those qualifications through education, training, experience, or certification. Additionally, a successful IPCP program executed alongside an active hospital-wide antibiotic stewardship program must be supported by appropriate levels of personnel and have access to robust health information technology capability to support surveillance, tracking, reporting, and clinical decision support. These concepts are captured within the proposed rule and also include the agency’s expectation of enhanced accountability of hospital leadership.

Further delay in finalizing this proposal represents a burden to the regulated community in that hospitals and CAHs are currently operating on regulations that are outdated and inefficient. Support for revising these outdated regulations received broad stakeholder support during the comment period of the proposal. Patients cannot wait for federal action any longer. If antibiotic resistance is left unchecked, researchers estimate that by 2050, it could surpass cancer as a leading cause of death.³⁶ Updating the hospital CoPs is a continuation of our sustained national and global efforts to advance the cause of eliminating HAIs and combating antibiotic resistance. It is of utmost importance given the threat posed to patient safety today and in the immediate future. Therefore, it is imperative that you make every effort to finalize this rule immediately, before it expires in June, 2019.

Thank you for your time and attention on this matter. Future inquiries on this letter should be directed to Nancy Hailpern (nhailpern@apic.org or 202-454-2643) or Lynne Batshon (lbatschon@shea-online.org or 703-684-0761).

Sincerely,



Karen Hoffmann, RN, MS, CIC, FSHEA, FAPIC
2019 APIC President



Hilary Babcock, MD, MPH, FIDSA, FSHEA
2019 SHEA President

CC: HHS Deputy Secretary Eric D. Hargan

-
- ¹ National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination. <https://health.gov/hcq/prevent-hai-action-plan.asp>
 - ² Prevention Epicenters Program. <https://www.cdc.gov/HAI/epiCenters/about.html>
 - ³ Healthcare Infection Control Practices Advisory Committee (HICPAC). <https://www.cdc.gov/hicpac/index.html>
 - ⁴ Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement. <https://www.cdc.gov/ncezid/dpei/epidemiology-laboratory-capacity.html>
 - ⁵ Emerging Infections Programs. <https://www.cdc.gov/ncezid/dpei/eip/index.html>
 - ⁶ National Healthcare Safety Network. <https://www.cdc.gov/nhsn/index.html>
 - ⁷ Developing Healthcare Safety Research (SHEPheRD). <https://www.cdc.gov/hai/research/safehealthcare.html>
 - ⁸ Environmental Hygiene in Healthcare. <https://www.cdc.gov/hai/research/eic-meeting.html>
 - ⁹ Modeling Infectious Diseases in Healthcare Network (MInD - Healthcare). <https://www.cdc.gov/hai/research/MIND-Healthcare.html>
 - ¹⁰ Antibiotic Resistance Threats Report – 2013. https://www.cdc.gov/drugresistance/biggest_threats.html
 - ¹¹ U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria (National Action Plan). <https://www.cdc.gov/drugresistance/us-activities/national-action-plan.html>
 - ¹² The AMR Challenge. <https://www.cdc.gov/drugresistance/intl-activities/amr-challenge.html>
 - ¹³ Antibiotic Resistance (AR) Solutions Initiative. <https://www.cdc.gov/drugresistance/solutions-initiative/index.html>
 - ¹⁴ Containment Strategy Responding to Emerging AR Threats. <https://www.cdc.gov/hai/containment/index.html>
 - ¹⁵ AR Isolate Bank. <https://www.cdc.gov/ARIsolateBank/>
 - ¹⁶ Antibiotic Resistance Laboratory Network (AR Lab Network). <https://www.cdc.gov/drugresistance/solutions-initiative/ar-lab-network.html>
 - ¹⁷ Guidance for Antibiotic Prescribing and Use. <https://www.cdc.gov/antibiotic-use/healthcare/index.html>
 - ¹⁸ NIAID's Antibacterial Resistance Program. <https://www.niaid.nih.gov/research/antibacterial-research-program-accomplishments>
 - ¹⁹ FDA Five-Year Plan for Supporting Antimicrobial Stewardship in Veterinary Settings. <https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm620378.htm>
 - ²⁰ Association for Professionals in Infection Control and Epidemiology. <http://cqrcengage.com/apic/stewardship>
 - ²¹ The Society for Healthcare Epidemiology of America. <http://www.shea-online.org/index.php/practice-resources/priority-topics/antimicrobial-stewardship>
 - ²² Infectious Diseases Society of America. <https://www.idsociety.org/policy--advocacy/antimicrobial-resistance/>
 - ²³ Pediatric Infectious Diseases Society. <https://cmeonline.wustl.edu/asp/>
 - ²⁴ Society of Infectious Diseases Pharmacists. <https://sidp.org/PoliticalAdvocacy>
 - ²⁵ Association of State and Territorial Health Officials. <http://www.astho.org/Infectious-Disease/Antimicrobial-Resistance/>
 - ²⁶ Council of State and Territorial Epidemiologists. <https://www.cste.org/page/ARS>
 - ²⁷ National Association of County and City Health Officials. <https://www.naccho.org/programs/community-health/infectious-disease/healthcare-associated-infections>
 - ²⁸ Research!America. [https://www.researchamerica.org/sites/default/files/Antibiotic Resistance Fact Sheet.pdf](https://www.researchamerica.org/sites/default/files/Antibiotic%20Resistance%20Fact%20Sheet.pdf)
 - ²⁹ National Foundation for Infectious Diseases. <http://www.nfid.org/links/antimicrobial-resistance/antibiotic-stewardship-pledge.html>
 - ³⁰ Center for Infectious Disease Research and Policy. <http://www.cidrap.umn.edu/>
 - ³¹ The Pew Charitable Trusts. <https://www.pewtrusts.org/en/topics/antibiotics>
 - ³² The Joint Commission. <https://www.jointcommission.org/hai.aspx>
 - ³³ American Society of Consultant Pharmacists. <https://www.ascp.com/page/asp>
 - ³⁴ The Peggy Lillis Foundation. <https://peggyfoundation.org/c-diff-101/what-can-be-done/>
 - ³⁵ Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care CMS-3295-P. <https://www.regulations.gov/docket?D=CMS-2016-0095>
 - ³⁶ O'Neill J. Review on Antimicrobial Resistance Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations. London: Review on Antimicrobial Resistance. 2014. https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf