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November 15, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-3346-P Medicare and Medicaid Programs: Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction Proposed Rule

Dear Ms. Verma:

The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide input to the proposed rule "Regulatory Provisions to Promote Efficiency, Transparency and Burden Reduction." APIC is a nonprofit, multidisciplinary organization representing 16,000 infection preventionists whose mission is to create a safer world through prevention of infection. APIC appreciates and supports CMS's commitment to incorporate and integrate ongoing review of regulations to achieve a more streamlined and effective regulatory framework and environment through the Patients over Paperwork Initiative.

Although APIC supports coordination of multi-hospital infection control programs at the system level as CMS proposes, without the establishment of updated requirements for robust infection prevention and control programs (IPCP) as outlined in the pending proposed rule "Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (81 FR 39448-39480, Docket CMS-3295-P, June 16, 2016), with which to coordinate the system-wide program, CMS would weaken efforts identified in this proposed burden reduction rule to promote efficiency and furnish high quality patient care.

As CMS noted in the pending 2016 proposed rule, the infection control Condition of Participation (CoP) has not been updated since 1986 and the current requirements no longer fully conform to current standards for infection prevention and control. As APIC and the Society for Healthcare Epidemiology of America (SHEA) noted in our joint letter to CMS "…delay in finalizing [the 2016 proposed rule] represents a burden to the regulated community in that hospitals and CAHs are currently operating on regulations that are outdated and inefficient."[1] Although CMS states in the regulatory burden reduction proposed rule (CMS-3346-P, 2018) that "we seek to reduce burdens for health care providers and patients, improve the quality of care… and ensure that patients and their providers and physicians are making the best health care choices possible" the burden would more likely be increased by

perpetuating requirements that are no longer consistent with current evidence nor with CMS requirements for other care settings.

Proposed revisions to Medicare Conditions of Participation: Hospital Quality Assessment and Performance Improvement (QAPI) Program (42 CFR 482.21) and Infection Control (42 CFR 482.42)

APIC recognizes that multi-hospital systems are common in our healthcare environment and their number will likely continue to increase. As CMS notes, unified and integrated programs have the potential to enhance and encourage the spread of performance improvement initiatives and best practices to positively impact patient outcomes. APIC appreciates that this proposal includes requirements to consider each member hospital's unique circumstances and differences in patient populations and services; policies and procedures to ensure the needs and concerns of each separately certified hospital are established and implemented; and that a unified and integrated infection control program would have a mechanism in place to ensure that localized issues for a particular hospital are considered and addressed. Epidemiology is local, and these factors will be essential for successful outcomes in a unified program.

Additionally, APIC emphasizes the need for qualified infection preventionist (IP) staffing at the local hospital level in order to promote visible, timely guidance for infection prevention and control strategies. We express concern that program coordination at a system level could be perceived as not needing qualified IPs at each local hospital. The local level hospital IP is instrumental in coordinating and communicating key patient safety and quality of care issues, specifically related to multidrug-resistant organisms (MDROs), at transitions of care. This coordinated approach is well illustrated in the CDC infographic "Facilities work together to protect patients."[2] Without that coordination and communication, the risk for transmission in the receiving facility is increased.

We believe that without the adjustments outlined in the 2016 proposed CoP revisions, it would be more difficult for each hospital to assess its own unique circumstance and needs. In a recently published HAI prevalence study, the Centers for Disease Control and Prevention (CDC) notes that on any given day, about one in 31 hospital patients has at least one HAI.[3] The Department of Health and Human Services has identified HAIs and MDROs as a significant cause of morbidity and mortality in the U.S.[4] The 2016 proposed rule addressed these challenges by proposing to 1) add prevention as a component of the Infection Control Program to promote cultural changes in hospitals to recognize the importance and cost effectiveness of prevention initiatives on balance with traditional infection control efforts; 2) add antibiotic stewardship as part of the IPCP to emphasize the important role that a hospital should play in combatting antimicrobial resistance through implementation of a robust stewardship program that follows nationally recognized guidelines for appropriate antibiotic use; and 3) require that a hospital's IPCP and antibiotic stewardship programs be active and hospital-wide for surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship.[5]

Critical Access Hospitals: Provision of Services (42 CFR 485)

Recognizing that CAH policy reviews include "a system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel," APIC supports the proposed change from annual policy and procedure review to biennial review or more frequently as

assessed by the annual risk assessment and infection control plan review, if needed as a result of new evidence/information, or when local regulations require more frequent review. APIC believes this is an effective way to reduce regulatory burden in order to increase the focus on process improvement and patient outcomes.

Emergency Preparedness Requirements

APIC expresses concern for some of the proposed requirement changes for Emergency Preparedness (EP) Programs. According to an article in The Economist[6] last year, the number of natural disasters has quadrupled since 1970. The provisions of the Emergency Preparedness rule that this section would amend (81 FR 63860, CMS-3178-F, September 16, 2016) was only implemented one year ago, so it may be too soon to know if the training/practice requirements in it are too frequent. It is important that EP program integrity remains intact and risk and hazard vulnerability assessments are continued.

Recommendations:

- Successful emergency responses depend on frequent and consistent practice and training every other year may not be sufficient to sustain proficiency. We express concern that this could also lead to a reduction in staffing for EP programs.
- APIC supports elimination of Documentation of Cooperation Efforts, but we acknowledge the ongoing need for collaboration with all public agencies and entities that are required for successful Emergency Preparedness outcomes.
- APIC suggests that the presence of "Just in Time" programs for training and PPE review continue to remain in place to supplement annual training and drills.

Information Collection Requirements (ICRs) and Uncertainty of Burden Estimates

APIC expresses concern that CMS underestimates the financial calculations of burden reduction implementation and savings of reduction proposals. It does not appear that the estimate of implementation includes any consideration of technology changes for the unified and integrated QAPI and Infection Control programs or any other areas of this proposed rule. Technology and data systems constitute an immense outlay of resources and time. The estimates of $38,000 per hospital for Infection Prevention program regulatory burden and $10,000 per hospital for a QAPI program regulatory burden would be underestimated as well, due to the cost exclusions of salary, information technology, performance improvement initiatives and accreditation from the projected estimates.

Requests for Future Hospital Program Proposed Changes

APIC suggests for future consideration, that the Outpatient Treatment Centers which are often linked with existing multi-hospital systems become a part of the unified and integrated QAPI and Infection Prevention and Control programs. Likewise, Emergency Preparedness and Safety Programs may also be considered for unified and integrated programs for multi-hospital systems in the future.

Additionally, CMS's recent notice of delay in finalizing the Revisions to Requirements for Discharge Planning for Hospitals, CAHs, and Home Health Agencies proposed rule (83 FR 55105, CMS-3317-RCN, November 2, 2018) postpones implementation of integrated planning processes to ensure consistent

patient care throughout the healthcare continuum, whether different care settings are within the same healthcare system or not.

CMS currently has three proposed rules that, if implemented together, could improve efficiencies and patient care: the 2015 Discharge Planning Requirements (final rule delayed until 2019); the 2016 revisions to Hospital/CAH CoPs (will expire if not finalized in 2019), and Regulatory Burden Reduction (issued 2018, comment period open). High quality care, patient safety initiatives, antibiotic stewardship, and evidence-based practice reduce hospital readmissions and the spread of infection, which in turn should lead to reduced costs and burden. Instead of addressing each proposal separately, APIC recommends that CMS work to implement all three proposals together to provide consistent practice, best patient outcomes, and the most efficient care possible.

Thank you for the opportunity to provide input to this and other CMS efforts to improve healthcare quality, patient safety, and efficiency.

Sincerely,

Janet Haas, PhD, RN, CIC, FSHEA, FAPIC
2018 APIC President

[1] APIC/SHEA letter to Ms. Seema Verma re CMS 3295-P Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CHA) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care, proposed rule. Available at https://apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/APIC-SHEA_re_2016_Inpatient_CoP_Proposed_Rule_FINAL.pdf. Accessed November 5, 2018.

[2] 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 November 8, 2018.

[3] Magill S, O'Leary E, Janelle S, et al. Changes in prevalence of health care–associated infections in U.S. hospitals. N Engl J Med 2018; 379:1732-1744.

[4] CMS-3295-P: Medicare and Medicaid Programs; Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility and Improvement in Patient Care (81 FR 39454).

[5] 81 FR 39455

[6] Weather-related disasters are increasing. Economist.com, August 29, 2017. Available at https://www.economist.com/graphic-detail/2017/08/29/weather-related-disasters-are-increasing. Accessed November 9, 2018.