December 28, 2020

Eric D. Hargan
Deputy Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Room 713F
Washington, DC 20201
Submitted via Regulations.gov

RE: Regulatory Relief To Support Economic Recovery; Request for Information (RFI) Docket ID: HHS-OS-2020-0016-0001; Recommendation to Suspend the Use of Quality Performance Program HAI assessments for the second half of 2020

Dear Mr. Hargan:

The Society for Healthcare Epidemiology of America (SHEA), the Society for Infectious Diseases Pharmacists (SIDP), and the Association for Professionals in Infection Control and Epidemiology (APIC) represent healthcare professionals globally with expertise in infectious diseases, healthcare epidemiology, infection prevention, and antibiotic stewardship. Our societies have a shared goal of safe, high-quality care that is achieved through appropriate healthcare staffing, allowing provision of adequate time and attention to care delivery at the bedside.

As the number of COVID-19 cases surge, hospitals are becoming overwhelmed with more patients than can be managed with typical care standards. Requiring reporting and enforcing penalties on hospitals related to quality measures during the pandemic will only shift critical resources to non-essential surveillance activities and result in reduction of resources and funding available to support necessary patient care and staffing. This further exacerbates the very conditions leading to patient harm. Therefore, we request that the Centers for Medicare & Medicaid Services not use 2020 quality measure data for healthcare-associated infections to assess reimbursement for hospital inpatient services.

Changes in workforce staffing:

Many of our members are expressing frustration with the persistent shortages of staff and supplies despite earlier efforts to address workforce resilience and supply chain disruptions. Workforce shortages continue to persist after the initial surge in places where elective hospital procedures had to be suspended in order to care for the influx of COVID-19 patients. Since that time, nursing positions were permanently eliminated or hired away by other hospital and healthcare systems through bidding wars among hospitals that continue to struggle financially through the pandemic. There has been emergent deployment of traveling nurses, locum physicians, national guard military service members, and redeployment of specialists and local primary care physicians to treat COVID-19 in hospitals around the country; all with inadequate time to train for an intensive care unit (ICU) care role, local treatment protocols, and

antimicrobial stewardship policies. The emergent use of new equipment without adequate familiarity by staff, e.g., ventilators and central line kits, may lead to increased medical device complications such as infection.

Changes in supplies:

Additionally, hospitals are continuing to experience shortages in personal protective equipment (PPE), alcohol-based hand rub, cleaning and disinfection supplies and testing supplies. In many cases disposable PPE is reused. These disruptions to critical supplies may lead to transmission of multidrug-resistant organisms (MDROs) such as methicillin-resistant *Staphylococcus aureus* (MRSA) or *Clostridioides difficile* infections (CDI) or carbapenem-resistant Enterobacteriaceae (CRE). Medication and equipment shortages require the use of substitute, sometimes inferior products that may also inadvertently impact patient safety.These combined issues present ongoing pandemic-induced challenges to optimal infection prevention practice.

Changes in hospitalized patient population:

Changes in patient volumes and admitted patient population due to COVID-19 may cause inaccuracies in the National Healthcare Safety Network (NHSN) metrics as well. The types of patients admitted during the pandemic are not representative of the patient population during non-pandemic times. Suspending elective surgeries and fear of hospital exposure means that sicker patients make up a greater portion of admitted patients. These patients may be more likely to be colonized with MRDOs, require more invasive devices for longer durations and thus be predisposed to increased device-associated infections, and MRSA and CDI rates. The reduction in surgical site infection (SSI) calculation denominators may also impact SSI rates.

Changes in care sites:

Many hospitals have had to expand ICUs and modify many patient care locations and practices. ICUs and patient care areas have been created in pediatric ICUs, Emergency departments and even tents. ICUs established in emergency settings outside of traditionally equipped ICU are likely to lead to increased risk of infection.

COVID-19 has disrupted many aspects of care for hospitalized patients. Patient care staffing, supplies, care sites and standard practices have all changed during this extraordinary time. As such, quality metrics measured during this time frame are not comparable to non-COVID-19time frames.

The degree of disruption and the variability of the hospitals affected is difficult to quantify. The hardest-hit COVID hospitals are often also the most overwhelmed and least financed (in part due to patient demographics, in part due to the greater reduction in elective surgeries). Penalizing these hospitals for stepping up to meet the challenges of the ongoing pandemic is both unfair and counterproductive.

CMS has already understood these challenges and responded early in the pandemic by allowing hospitals to choose whether or not to comply with HAI reporting requirements for Q4 2019, Q1 2020 and Q2 2020; however, because some facilities did report and some did not, the data is not comparable for nationwide incentive/penalty programs. We ask that CMS continue to allow hospitals flexibility in complying with HAI reporting requirements, but that HAI data from Q4 2019 through the duration of the public health emergency not be used for payment determination under value-based purchasing programs.

Thank you in advance for your consideration of our recommendation. Please do not hesitate to reach out with questions to Lynne Batshon, SHEA Director of Policy and Practice, at (703) 684-0761 or lbatshon@shea-online.org, or Nancy Hailpern, APIC Director of Regulatory Affairs at (202) 454 2643 or nhailpern@apic.org.

Sincerely,

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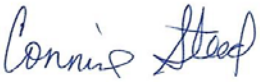

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