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September 16, 2019

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

RE: CMS-3347-P: Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency, proposed rule

Dear Ms. Verma:

The Association for Professionals in Infection Control and Epidemiology (APIC) is a nonprofit, multi-disciplinary organization representing over 15,000 infection preventionists whose mission is to create a safer world through prevention of infection. We are pleased that CMS continues to demonstrate its commitment to improving the quality of resident care in the long-term care setting. APIC wishes to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide input into its proposed rule *Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency*.

We appreciate the changes that have resulted from the person-centered competency-based care approach; however, it is with overwhelming concern that APIC reads the proposals within the CMS *Requirements for Long-Term Care Facilities Regulatory Provisions to Promote Efficiency and Transparency*, especially in regard to Infection Prevention and Control proposed changes. Proposing changes before the final rule on *Reform of Requirements for Long-Term Care Facilities* is fully implemented and the impact can be measured is particularly concerning. Advancing the practices of infection prevention and control, in all healthcare settings, has taken an inordinate amount of stamina and fortitude on the part of many healthcare providers. But it is through that stamina and fortitude that progress in the arena of healthcare-associated infections (HAIs) has been made.

It is disappointing to see the regulatory approach acquiesce to an “it is too difficult to comply” philosophy. If that same philosophy had been embraced for acute care, it is unlikely that the decreases in HAIs that the Centers for Disease Control and Prevention (CDC) reported from 2016 to 2017 would have occurred.¹ A recent review of HAI data in acute care settings from 2011 to 2015 also showed the prevalence of HAIs had decreased.² It has not been easy for acute care to achieve the reductions, and in



some cases, it may have been the pressure from CMS that pushed us along more quickly than we would have liked. CDC reports 1 to 3 million serious infections and as many as 380,000 deaths from infection in long-term care facilities (LTCFs) each year.³ In April 2013, the *National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination* recognized the complex medical care provided in long-term care settings and the need to develop an action plan specific to long-term care settings.⁴ The *Reform of Requirements for Long-Term Care Facilities* began to address some of the concerns highlighted in the long-term care action plan, namely a trained infection preventionist (IP) and dedicated time for the IP to discharge the responsibilities of the role. The action plan identified a priority area as enrollment in the CDC National Healthcare Safety Network (NHSN) with several priority areas identified including goals and timelines. It acknowledged the obstacles to NHSN reporting but recognized the successful implementation of NHSN in acute care settings, partially driven by the CMS Hospital Inpatient Quality Reporting Program. While the number of LTCFs enrolled in NHSN increased from 262 in 2015 to 1,956 in 2016, this still represented only 12.2 percent of United States nursing homes.⁵ If LTCFs are not pushed along now, it will not be any less difficult in the future. Change is never easy. We believe that in order to protect one of our most vulnerable populations, the strength must be found to continue developing robust, prevention focused programs in long-term care settings.

We offer the following comments for consideration.

Administration (§483.70)

We viewed the requirement for an annual facility risk assessment as a very positive step forward in informing how each facility establish the risks and needs of their residents. Through the assessment of LTCFs, several of our members have observed that LTCFs have not embraced the facility assessment process. We express concern that one of the goals put forth by CMS in the *Reform of Requirements for Long-Term Care Facilities* “to ensure that our regulations align with current clinical practice and allow flexibility to accommodate multiple care delivery models to meet the needs of the diverse populations that are provided services in these facilities”⁶ will only be addressed on a biennial basis. The annual facility assessment requirement was implemented in Phase 2 and; therefore, became effective November 28, 2017. At this point, even facilities that have embraced the process would only have completed one re-assessment. Facility capabilities and capacities can change quickly and if there is not a proactive requirement to assess them on a regular basis, the assessment will likely be lost in the frenetic daily activities in many LTCFs. An annual risk assessment has been required in acute care facilities for several years and is the basis for establishing the annual program goals. Eliminating the annual requirement would put long-term care even further behind the improvements accomplished in acute care.

Recommendation:

- APIC opposes the proposal to change the facility risk assessment from annual to biennial.

Quality Assurance and Performance Improvement (§483.75)

APIC believes that Infection Prevention and Control is an integral part of a facility’s Quality Assurance and Performance Improvement (QAPI) program.

APIC agrees that a facility’s QAPI program should be designed to fit a facility’s individual needs, thus



serving as a valuable tool to promote safe, quality resident care. The QAPI program is informed by the facility assessment. Feedback, data collection systems, and monitoring are integral parts of the QAPI program and key components of an effective Infection Prevention and Control Program. The CDC Healthcare Infection Control Practices Advisory Committee has identified “performance monitoring and feedback” as a core practice category for safe healthcare delivery in all settings.⁷

We agree that facilities should be provided flexibility to tailor their QAPI program to meet their specific needs; however, we are concerned that removing all of the detailed requirements (§483.75 (b)(1) through(4), §483.75 (c)(1) through(4), and §483.75 (d)(2)) will provide facilities little guidance on the expected structure of a strong program. Because this process is new to LTCFs, they may flounder without some guidance.

Recommendations:

- We support CMS’s effort to retain the existing requirements for review and inclusion of the QAPI program documents and performance improvement actions in a survey process.
- We endorse including an IP as an active member of the LTCF quality assessment and assurance committee.
- APIC supports retention of the language requiring facilities to establish and implement written policies and procedures for feedback, data collection systems, and monitoring.
- We suggest that the State Operations Manual include examples relative to the specific requirements that will be removed from §483.75 (b)(1) through (4), §483.75 (c)(1) through (4), and §483.75 (d)(2).

Infection Control (§483.80)

We believe that the requirement for an IP in LTCFs was a significant step forward in recognizing the unique skill set that the IP possess and the important functions they perform. While we recognize that there are components of an Infection Prevention and Control Program (IPCP) that are dependent on the facility size, complexity of services performed and acuity of the residents, APIC restates its belief that “many of the core functions required for an effective IPCP are not dependent upon the size of the facility or number of personnel. Establishing an effective IPCP involves developing sound policies and procedures; developing training materials to educate personnel and train existing and new personnel, contractors, etc.; developing and implementing a system to ensure competency and compliance; ensuring appropriate equipment and supplies are procured, accessible and utilized properly; performing ongoing surveillance, prevention and control efforts; and preparing for emergencies.”⁸ APIC respectfully requests that CMS reconsider its proposal to remove the requirement for a part-time individual designated as an IP in LTCFs. Facilities have not had the opportunity to fully implement this requirement, nor the time to demonstrate the effectiveness and cost efficiencies that can be experienced from this investment in prevention strategies. Residents of LTCFs deserve the benefit of onsite expertise.

CMS has asked for specifics on defining “sufficient time” as relates to the proposed change of removing the “part-time” requirement for an individual designated as an IP. We do not believe that the evaluation of a facility’s IP staffing needs can be justifiably met without a solid regulatory reference such as “part-



time.” “Sufficient time” can be widely interpreted and brings the risk of “insufficient time” being spent. The risk assessment document is a cornerstone to evaluate the needs of any facility’s IPCP but because the requirement to link the IPCP to the facility risk assessment was not implemented until Phase 2, the resulting evaluations and documents/plans are very immature and less than optimal at this stage. To gage the amount of time needed on an immature process would likely result in an inaccurate assessment. We again suggest using a formula similar to a staffing model proposed by Health Canada of one IP per 150-250 beds in long-term care settings based on the time requirements for infection prevention activities, facility size, and acuity of the resident population.⁹ Results of infection prevention and control-related performance improvement projects, as well as achievement of program goals could be used to gage adequate IP staffing. Including the actual number of full-time equivalent IPs as part of the IPCP assessment might be powerful information to inform “sufficient time.”

Recommendation:

- APIC opposes removing the requirement that the infection preventionist (IP) “Work at least part-time at the facility”. In order to be a consistent part of improving and maintaining quality resident care, we emphasize the absolute need to have an onsite, designated, and trained individual as an IP.
- To gage sufficient IP staffing, APIC recommends that CMS utilize the annual facility assessment and IPCP program assessment to determine if the identified risks have been adequately addressed and goals met.

Physical Environment (§483.90)

The cornerstone of reducing transmission of emerging and multidrug-resistant organisms is spatial separation and environmental surface disinfection. We encourage CMS to continue to strive toward protecting LTCF residents by addressing the physical environment with minimal room-sharing as a proactive and protective mechanism for infection prevention. Additionally, we encourage CMS to place a focus on isolation room capability wherever possible. Many facilities have only a few private rooms, which can be utilized for transmission-based precautions (i.e. isolation). This will be important as more residents need to access the long-term level of care. APIC is concerned that modifying the current requirements before the impact can be measured puts residents cared for in older facilities at greater risk for infection and colonization. A double standard for safety and dignity will result. Communities where new LTCFs are not being built will likely be at greater risk than communities where new facilities are constructed. We suggest an alternative approach where the facility would present its request for exemption from the no more than two residents per room requirement to the local authority having jurisdiction (AHJ). The AHJ will be familiar with the geographic epidemiologic data and transmission patterns of resistant microorganisms in LTCFs. Risks the AHJ should consider when reviewing construction/renovation exemption requests would be recent outbreaks at the facility, acuity of the resident population (e.g. ventilator-dependent residents, residents with tracheostomies, the provision of onsite dialysis) and a change in the services provided resulting in a higher acuity resident population. As acuity increases, more medical equipment is added to the resident bed space often resulting in expansion of one resident’s personal care space into another resident’s person care space. For example, one resident’s ventilator may be a few inches from another resident’s ventilator. The close proximity of medical equipment makes it easier for caregivers to move from one resident’s equipment to the other



without performing hand hygiene or changing necessary personal protective equipment, potentially putting patient safety at risk. Consideration could be given to the acuity and type of floor in the facility when the AHJ reviews the exemption request. Based on that information, the AHJ could determine that only certain floors would be required to meet the no more than two residents requirement. Infrastructure improvements such as piped suction and medical gases are needed to support the high acuity care being provided. Alternatively, as a phase in approach, if there was a mechanism established to categorize facilities caring for medically complex high acuity residents, those facilities could be required to update the infrastructure including a move to two-bed rooms before they are allowed to accept the higher acuity residents.

Recommendation:

- APIC opposes the revision that results in only newly constructed and/or newly certified facilities having to comply with the no more than two residents per room requirement.

We urge CMS to carefully consider the impact on the safety of LTCF residents resulting from proposals to reduce the burden on staff and facilities. Interventions to improve the safety and wellbeing of residents should not be delayed or avoided because it is too difficult or costly. As a stakeholder, APIC is ready and willing to partner with CMS and others to create a solution that supports safe care.

Sincerely,

A handwritten signature in black ink that reads "Karen Hoffmann".

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

¹ Centers for Disease Control and Prevention. Patient Safety Atlas. National Data for Acute Care Hospitals, Year 2017. Available at: <https://gis.cdc.gov/grasp/PSA/HAIreport.html> Accessed September 1, 2019.

² Magill SS, O'Leary E, Janelle SJ, et al. Changes in Prevalence of Health Care-Associated Infections in U.S. Hospitals. *N Engl J Med* 2018 Nov 1;379(18):1732-1744.

³ Centers for Disease Control and Prevention. Nursing Homes and Assisted Living (Long-term Care Facilities [LTCFs]).

⁴ National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination April 2013. Chapter 8: Long-Term Care Facilities. Available at: <https://health.gov/hcq/pdfs/hai-action-plan-ltcf.pdf> Accessed September 1, 2019.

⁵ Dick AW, Bell JM, Stone ND, et al. Nursing Home Adoption of the National Healthcare Safety Network Long-term Care Facility Component. *Am J Infect Control* 2019; 47: 59-64.

⁶ Department of Health and Human Services. Centers for Medicare & Medicaid Services. 42 CFR Parts 405, 431, 447, 482, 483, 485, 488, and 489. Medicare and Medicaid Programs: Reform of Requirements for Long-term Care Facilities. Facility Assessment and Competency-Based Approach. Available at: <https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf> Accessed September 1, 2019.

⁷ Centers for Disease Control and Prevention. Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings – Recommendations of the Healthcare Infection Control Practices Advisory Committee. March 15, 2017. Available at: <https://www.cdc.gov/hicpac/pdf/core-practices.pdf> Accessed September 1, 2019.

⁸ Association for Professionals in Infection Control and Epidemiology. Comments in reference to *CMS-3260-P, Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities*. Available at: http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/LTC_COP_Comments_-_Final_9-10-15.pdf Accessed September 1, 2019.

⁹ Morrison J. Development of a resource model for infection prevention and control programs in acute, long term, and home care settings: conference proceedings of the Infection Prevention and Control Alliance. *Am J Infect Control*, 32 (2004), pp. 2–6.