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Mr. Andrew M. Slavitt
Acting 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-3260-P, Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities.

Dear Mr. Slavitt:

The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide input into its proposed rule "Reform Requirements for Long-Term Care Facilities." 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.

We support the emphasis on person-centered, competency-based care. We realize that these regulatory changes may seem daunting, but in the same way that restraint and psychotropic reduction were viewed as impossible changes for long-term care facilities (LTCF) in 1989, we found that the regulatory expectations brought real change to the lives of residents, resident families, and staff who work in long-term care. Because of the extensive increase in requirements related to infection prevention, we encourage CMS to consider a 3-5 year phase-in period to allow facilities to come up to speed with all of the requirements and for the appropriate educational tools to be developed. The emphasis on infection prevention and control in long-term care is an emphasis whose time has come.

Transitions of Care (§483.15)

APIC notes that CMS is proposing to require not only that a transfer and discharge be documented in the clinical record, but that specific information, such as history of present illness, reason for transfer, and past medical/surgical history, be exchanged with the receiving provider or facility when the resident is transferred. APIC appreciates the desire to formalize the information that is being provided during care transitions, especially between facilities, as this is often the time when critical and valuable information is lost, which can create complications and adverse events for residents. APIC would like to note that while CMS does not intend to standardize these transfer documents, APIC believes it is critical that the following information be included in any recommended transitions of care communications: multidrug-resistant organism (MDRO) status; current or recent antibiotic use, indication and stop date; presence of indwelling devices; and current transmission-based precautions status. These communications will



facilitate implementation of timely and correct infection prevention and control interventions at the receiving facility.

Recommendation:

- APIC recommends that in order to facilitate proper infection prevention and control interventions at the receiving facility, the following information should be provided during transitions of care: MDRO status; current or recent antibiotic use, indication and stop date; presence of indwelling devices; and current transmission-based precautions status.

Pharmacy Services (§483.45)

APIC agrees having the pharmacist review residents' medical charts at admission and when antibiotic and antipsychotic medications are prescribed would not only assist the pharmacist in detecting irregularities related to these drugs, but also enhance or contribute to the goal of ensuring that these medications are used only when medically appropriate for the resident. We also share the belief that the pharmacist's review could contribute to CMS proposed requirements for infection control and antibiotic stewardship.

Recommendation:

- APIC supports the use of a consultant pharmacist to review the medical records for appropriate use of antimicrobial medication in an evidence-based activity and to monitor cumulative antibiotic use, use of specific antibiotics, as well as antibiotic cost and trends as part of the overall Quality Assurance and Performance Improvement (QAPI) process.

Food and Nutrition Services (§483.60)

APIC notes that CMS is proposing to require under §483.70 (b) and (c) that facilities be in compliance with applicable federal, state, and local laws; regulations and codes; professional standards; and other Department of Health and Human Services (HHS) regulations. We agree with CMS that such a requirement would include compliance with the food service recommendations of the U.S. Food and Drug Administration (FDA) model Food Code. APIC notes that all 50 states have adopted food codes patterned after the FDA food code.¹ Therefore, we support the use of the FDA Food Code as the standard for safe food preparation and service, and support CMS utilizing it as the standard for safe food service. APIC also would support a requirement to use the Hazard Analysis and Critical Control Points (HACCP) program for all skilled nursing facilities (SNFs) and nursing facilities (NFs), as it is a comprehensive, systemic approach to food safety that addresses biological, chemical and physical hazards that can cause food to be unsafe. The use of HACCP in these settings would provide an additional layer of protection to prevent foodborne illness outbreaks occurring among the vulnerable populations served in SNFs and NFs, regardless of size.

Recommendation:

- APIC supports the adoption of the FDA model Food Code for food preparation and service, and the use of the HACCP program in all SNFs and NFs to provide the best protection against foodborne illness among the vulnerable populations served in these facilities.

Administration (§483.70)

APIC notes that under §483.70(e) CMS proposes to establish a new requirement for an annual, comprehensive facility assessment. Infection preventionists have long used an annual risk assessment to help promote vigilance, develop goals, and improve practices to minimize risk and maximize safety. APIC



applauds the adoption of this new requirement, and believes it is critical that relevant infection control data be included in the annual assessment, including but not limited to the prevalence of MDROs and *Clostridium difficile*; the infection surveillance data for urinary, respiratory, skin/soft tissue, and gastrointestinal infections; outbreaks of infectious diseases (norovirus, influenza, scabies, etc.); antibiotic utilization data; and process-related data (hand hygiene, glove use, etc.). APIC supports the annual facility assessment implementation as this process will improve accountability, resident and staff safety, operational efficiency, and support continuous quality improvement efforts within SNFs and NFs.

Recommendations:

- APIC supports the adoption of the annual facility assessment.
- APIC encourages CMS to incorporate relevant infection control data into the annual facility assessment as this will help inform the plans, goals and interventions implemented by the Infection Prevention and Control Program.

Infection Control (§483.80)

Infection Prevention and Control Program (IPCP)

APIC recognizes that healthcare occurs across a continuum and long-term care facility residents should be afforded safe quality care. We appreciate CMS emphasis on creating a formal infection prevention program that requires facilities to have a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under an arrangement based upon its facility and resident assessments that is reviewed and updated annually. We support the requirement for an Infection Prevention and Control Program. An effective program would include a facility-specific risk assessment; multidisciplinary input; evidence-based policies and procedures; an approved surveillance plan that uses standardized definitions for the identification of healthcare-associated infections (HAIs); and regular reassessment. APIC would like to emphasize that HAI surveillance is an important component of the IPCP, and should utilize evidence-based standard surveillance definitions developed by the Centers for Disease Control and Prevention (CDC) to facilitate benchmarking across facilities.²

Recommendations:

- APIC supports the implementation of a comprehensive IPCP.
- APIC supports the adoption of standardized HAI surveillance definitions developed by the CDC.

Infection Prevention and Control Officer (IPCO)

APIC applauds CMS for designating an IPCO to oversee the IPCP. This role has traditionally been assigned to nurses who have other competing duties and who are often not specifically trained in infection prevention. We agree that infection prevention and control requires additional education and training, and that basic clinical programs such as nursing school are not adequate preparation for competent practice as the IPCO. Formal infection control training for an LTC IPCO must be based on the core competencies defined by APIC and the Certification Board of Infection Control and Epidemiology (CBIC) in order to maintain the high professional standards across the healthcare continuum. We also note that the standard accepted term for a person with this level of training is “infection preventionist” (IP), and we recommend that CMS use this term instead of IPCO in order to ensure consistency across the infection prevention community and understanding of the level of training required to qualify for this duty.



It is important that infection prevention and control education and training be either endorsed or developed by professional infection prevention and control organizations, public health departments, academic communities with public health or infection prevention and control expertise, or board-certified individuals with an understanding of the unique needs of the long-term care continuum.

APIC supports QAPI focus and the CMS proposal to require the IP to serve as a member of the facility's quality assessment and assurance (QAA) committee. QAPI principles, standards, and tools match the knowledge and skills needed for infection prevention and control, and will contribute to the development of a strong long-term care IPCP. It is also important to emphasize that the QAPI model requires careful consideration in order to prevent similar situations that have occurred with minimum data set (MDS) coordinators and acute care infection preventionists, where requirements for timely documentation and data submission may interfere with active involvement of the IP in person-centered care with the resident/patient and family. We support having the IP as an active participant of the QAA interdisciplinary team.

The responsibilities proposed for the IP would be new long-term care regulatory requirements, and therefore will require a reworking of staffing models to accommodate this change. As stated previously, many nurses currently serving in the infection control role in LTCFs fulfill numerous roles, such as director of nursing, staff development coordinator, or MDS coordinator, and are challenged to dedicate sufficient time to the infection prevention. APIC would like to note that currently the staff person responsible for infection prevention has been a clinician; however, other non-clinical personnel such as a medical technologist or those who have Master's degrees in public health or epidemiology can competently serve in this role. As such, it is not essential that a clinician serve in this role, exclusively.

While we believe that designating this as a defined role in regulation will help increase the prominence of this position, and thus dedicate more resources and man-hours to the role, we note that CMS is not proposing specific time requirements for the IPCO due to the diverse nature of the resident population and wide variance in the qualifications, training, and time needed by the IPCO at each facility. We also note that CMS provided cost estimates based upon an average of 15% of one full time equivalent (FTE) for compliance with IPCO requirements. APIC believes that CMS has significantly underestimated the time required to direct an effective IPCP. An average of 15% of an FTE is not sufficient. While APIC agrees that location-specific differences exist, 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. The following aspects may vary considerably depending upon the size of the facility, complexity of services performed and acuity of residents: surveillance activities including data entry and analysis; risk assessment; staff, contractor, volunteer and visitor training; antibiotic stewardship; and quality assessment and improvement efforts. Thus APIC believes that the cost estimate for infection prevention and control staffing needs to reflect the complex roles and responsibilities of the IP, as well as facility size and acuity of the residents/patients. A 100-bed facility with long-term dementia residents has entirely different infection prevention and control needs than a 100-bed post-acute care rehabilitation facility or a 500-bed SNF. Therefore, we suggest using a formula similar to a staffing model proposed by Health Canada of one IP/ 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.³ This model is valid and should be considered when developing the final rule.

Recommendations:

- APIC supports the designation of an IPCO, and requests that CMS use the term “infection preventionist” when referring to the person serving in this position, as this is the recognized term for a person who performs this function with the required level of education and training.
- Formal training required for the infection preventionist must be consistent with the APIC and CBIC core competencies and be endorsed or developed by professional infection prevention and control organizations such as APIC and the Society for Healthcare Epidemiology of America (SHEA), public health departments, academic communities with public health or infection prevention expertise, or board-certified infection preventionists or healthcare epidemiologists with an understanding of the unique needs of the long-term care continuum.
- APIC supports the IP as an active member of the QAA interdisciplinary team.
- APIC recommends that CMS utilize the annual facility assessment and other models to help determine appropriate FTE for infection prevention staffing.

Antibiotic stewardship

We note that CMS is also proposing to add an antibiotic stewardship program as part of the revamped regulations. APIC is very supportive of this measure, as antibiotics are used frequently and often inappropriately in this setting, creating the opportunity for adverse events and development of antibiotic resistant organisms. A successful antibiotic stewardship program requires a dedicated individual with authority to oversee antibiotic use. This individual should be a clinical pharmacist or medical director who works in coordination with the IPCO(s) in implementing the program. Of note, the vast majority of IPs do not have the knowledge and expertise to oversee an antibiotic stewardship program or develop antimicrobial use protocols. These responsibilities should be moved to either §483.30 Physician Services or §483.45 Pharmacy Services.

APIC agrees that antibiotic use protocols and monitoring antibiotic utilization are key facets of an antibiotic stewardship program, but physicians are often not on-site when symptoms arise and are reliant on nursing staff to provide the needed information to initiate antibiotics. Therefore, an antibiotic stewardship program must also standardize nurse-licensed independent provider (LIP) communication, improve nursing documentation, and provide education to front-line nursing staff and LIPs on when diagnostic testing is appropriate and needed, so that inappropriate testing, and thus prescribing, does not occur. Additionally, it is important that LIPs have local antimicrobial susceptibilities data (antibiograms) that can aid in appropriate prescribing. The IP must work with either the on-site lab or a referral lab to provide cumulative data on antimicrobial susceptibility in the form of a facility-specific antibiogram.^{4,5}

Recommendations:

- APIC supports including an antibiotic stewardship program in the LTC requirements, but we recommend that these responsibilities be moved to either §483.30 Physician Services or §483.45 Pharmacy Services.
- Oversight of the antibiotic stewardship program should be the responsibility of either a clinical pharmacist or medical director who works with the IPCP to implement the program.
- The antibiotic stewardship program should minimally include antibiotic use protocols, systems for monitoring antibiotic utilization, and follow antibiotic susceptibility patterns (antibiograms)



for the facility; however, it should also address nurse-LIP communication, nursing documentation, and provide staff and LIP education on when diagnostic testing is appropriate and needed.

- APIC recommends that IPs and staff nurses receive training in the risks and benefits of antibiotic use so that they have a better understanding of the importance of antimicrobial stewardship.

Education (\$483.95)

Education is a critical part of any multifaceted infection prevention and control program, and has been effective in LTC settings when combined with other measures.⁵ A properly trained IP must take an active role in developing and administering the new training requirements based on adult education principles as an important part of the competency-based staffing. Educational programs ideally need to be varied in approach, repeated regularly, combined with other measures, and made locally relevant. Examples might include combining didactic sessions with feedback on individual performance, or discussing how national guidelines for infection prevention apply to individual cases. Any education provided must be consistent with national guidelines from the CDC or professional organizations with expertise in infection prevention and healthcare epidemiology, including APIC, SHEA, or the Infectious Diseases Society of America (IDSA). APIC supports the training of staff in policies and procedures as they relate to infection prevention and control, but would suggest that training also be provided to volunteers and other individuals providing services in the facilities.

Recommendation:

- APIC supports training of staff and providers on policies and procedures as they relate to infection prevention and control. The education must be varied in its approach, repeated regularly, and based on national guidelines and recommendations from CDC and professional organizations such as APIC, SHEA, or IDSA.

APIC, infection preventionists, and epidemiologists have been innovators and leaders in developing systematic processes to improve the safety and the quality of care delivery for patients, residents, clients, and healthcare personnel. We believe that the focus on quality, safety, and infection prevention and control in the proposed rule can be well supported by the processes and educational offerings already available and under development by organizations such as APIC, SHEA and other public health organizations and academic communities. APIC commends CMS for continuing to advance infection prevention and control and healthcare quality to incorporate all settings of care. While we are encouraged by the extensive nature of these revised requirements, we would encourage CMS to consider a 3-5 year phase-in period to allow for facilities to come up to speed with all of the requirements and for the appropriate educational tools to be developed. We look forward to continuing to work with CMS, and to providing assistance to LTCFs as they prepare to implement these new requirements.

Sincerely,

A handwritten signature in black ink that reads "Mary Lou Manning". The signature is fluid and cursive.

Mary Lou Manning, PhD, CRNP, CIC, FAAN, FNAP
2015 APIC President

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- ¹ FDA, Real Progress in Food Code Adoption, 2013. Available at <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm108156.htm>. Accessed August 25, 2015.
- ² Stone ND, et al. Surveillance definitions of infections in long term care facilities: Revisiting the McGeer criteria. *Infect Control Hosp Epidemiol*, 33 (2012), pp. 965–977.
- ³ 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.
- ⁴ Smith PW, et al. Antibiotic stewardship programs in Long-term care facilities. *Ann Longterm Care*, 19 (2011). Available at <http://www.annalsoflongtermcare.com/article/antibiotic-stewardship-programs-long-term-care-facilities>. Accessed August 27, 2015.
- ⁵ Schwartz DN, et al. An educational intervention to improve antimicrobial use in a hospital-based long-term care facility. *J Am Geriatr Soc*. 2007;55(8):1236-1242.