

**SHEA**  
The Society for Healthcare  
Epidemiology of America

**Board of  
Trustees 2011**

**President**

Steven M. Gordon, MD  
Cleveland Clinic Foundation

**President-Elect**

Jan E. Patterson, MD, MS  
University of Texas Health Science Center  
at San Antonio

**Vice-President**

John A. Jernigan, MD, MS  
Centers for Disease Control and Prevention and  
Emory University School of Medicine

**Secretary**

Sara E. Cosgrove, MD, MS  
Johns Hopkins University School of Medicine

**Treasurer**

Louise M. Dembry, MD, MS, MBA  
Yale University School of Medicine

**Past President**

Neil O. Fishman, MD  
University of Pennsylvania School of Medicine

**Councilors**

Anthony D. Harris, MD, MPH  
University of Maryland School of Medicine

Susan S. Huang, MD, MPH  
University of California Irvine School of Medicine

Keith S. Kaye, MD, MPH  
Wayne State University School of Medicine

Lisa L. Maragakis, MD, MPH  
Johns Hopkins University School of Medicine

**International Councilor**

Stephan Harbarth, MD, MS  
Geneva University Hospitals and Faculty of Medicine

**Executive Director**

Jennifer L. Bright, MPA

December 21, 2011

Marilyn Tavenner  
Acting Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW, Room 445-G  
Washington, DC 20201

**Re: CM42 CFR Parts 482 and 485, Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation; proposed rule**

Dear Ms. Tavenner:

The Society for Healthcare Epidemiology of America (SHEA) wishes to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide input into its proposed rule "Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation".

SHEA is a professional society representing more than 2,000 physicians and other healthcare professionals around the world with expertise in healthcare epidemiology and infection prevention and control. SHEA's mission is to prevent and control healthcare-associated infections and advance the field of healthcare epidemiology. The Society leads this field by promoting science and research and providing high-quality education and training in epidemiologic methods and prevention strategies. SHEA upholds the value and critical contributions of healthcare epidemiology to improving patient care and healthcare worker safety in all healthcare settings.

We are very pleased that CMS continues to demonstrate its commitment to reducing unnecessary regulatory burden and cost for hospitals and critical access hospital (CAHs). Our comments primarily reflect the views of our members who oversee infection prevention and control (IPC) programs in hospitals and CAHs as

they have a vested interest in the effective use of infection prevention practices that are evidence-based and produce positive outcomes. We will address the proposed elimination of the infection control log requirement, the use of standing orders as it relates to immunizations as well as the Physical Environment Life Safety Codes with impact on (IPC) programs and practice.

### **Nursing Services (§ 482.23)**

SHEA supports the use of standing orders specifically as it relates to the improvement of immunization rates. SHEA members have long advocated for the importance of vaccination to prevent the acquisition and transmission of contagious diseases.<sup>1</sup> Our members also participate in developing mechanisms by which to deliver vaccine to patients in order to avoid a “missed opportunity” for patient vaccination. The use of standing orders has been beneficial.<sup>2-5</sup> The ability to expand standing orders into this arena will certainly provide positive patient outcomes and improve vaccination rates. CMS is to be commended for the inclusion of “improving immunization rates,” as an area identified by the standing order literature.

**SHEA recommendation:** Support the expansion of standing orders for immunization

### **Infection Control (§482.42)**

The regulatory requirement placed on IPC programs in recent years has escalated. SHEA supports and appreciates the CMS recommendation to eliminate the requirement for an infection control log as a Condition of Participation (COP). Newer methodologies have enhanced the ability to provide useful surveillance processes that are real-time, targeted and based on the epidemiology of the area being monitored.<sup>4</sup> This elimination of the “log” will enhance the flexibility that Hospital Epidemiologists (HE) and Infection Preventionists (IPs) need to utilize such tools to identify, prevent, control, investigate, and report infections and communicable diseases in patients and hospital personnel. We agree that the separate infection control log was unnecessary, redundant and burdensome, and its elimination will further support our use of the right data that drive real-time decisions to keep our patients and staff safe.

**SHEA Recommendation:** Support elimination of the “infection control log” as described in rule §482.42

### **Physical Environment (§482.41) *Comment requested by CMS***

Adopting the latest edition of the Life Safety Code (2012 LSC) has the potential to save hospitals billions of dollars, and SHEA urges CMS to strongly consider this. SHEA is closely aligned with the American Society for Healthcare Engineering of the American Hospital Association (ASHE/AHA), and together they recognized the key relationship between the physical environment and the prevention and control of healthcare-associated infections (HAIs). As will be seen, the adoption of the 2012 LSC is critical to effect needed changes given its significant impact on other codes that affect IPC programs, broad patient

safety needs, and related costs and savings.

**Impact of codes:** The use of outdated Life Safety codes siphons significant resources away from patient care. We applaud CMS in recognizing the importance of the 2012 LSC, now that it was adopted in September 2011, along with the National Fire Protection Association (NFPA) 99 and other key codes related to the 2012 LSC. We wish to add our support as well to all such agencies that stand ready to assist CMS in starting the rule making process. CMS's adoption of the 2012 LSC will have a major impact on patients and their care in multiple ways including HAI reduction.

### **The cost of outdated codes**

- The 2000 LSC references more than 50 other technical codes and standards. When the 2000 edition was written, these reference codes were current. Reference standards have been updated over the years, with some having undergone major changes. Yet hospitals must use reference codes from as far back as 1995 because they are mandated by the 2000 LSC. Permitting hospitals to comply with the latest 2012 version would save facilities significant amounts of money by using *more cost effective materials and installation methods not permitted by the older codes*.
- **Using old codes is problematic given the speed of advances in safety and technology** over recent years. For example, the widespread adoption of non-smoking policies plus other code advancements, have led to great progress in lowering the number of hospital fires. Old codes do not reflect the technical advances behind these trends, resulting in more construction and *increased maintenance costs of outdated systems*.
- **New hospitals are built to comply with up-to-date codes**, such as the 2012 *International Building Code* (IBC) used by most local municipalities and code officials to regulate the design and construction of healthcare facilities. Ninety eight percent of U.S. jurisdictions use the IBC.<sup>7</sup> When hospitals undergo opening surveys, however, they must use the 2000 LSC, adding *costs of wasted equipment, re-design and more construction*.
- **New codes conflict with old costly codes.** Hospitals spend more than \$4 billion a year and suffer lengthy delays in bringing new and updated spaces online because of conflicting codes and standards, overregulation, unjustified code enforcement, and misinterpretations. Current estimates of annual health care construction range from *\$40 billion to \$60 billion; savings of 6 to 10 percent could be realized while maintaining the same levels of safety*.<sup>6-12</sup>

**The 2012 edition of the Life Safety Code is more closely aligned with the International Codes** published by the International Code Council, including the 2012 IBC. As noted, the IBC is adopted and enforced by the vast majority of state and local agencies. Adopting the 2012 LSC will save hospitals money and time because they will have to deal with *fewer instances of conflicting codes*.

**Increased patient safety, reduced HAI risk, with newer codes** The 2012 LSC is superior to the LSC 2000 because it permits:

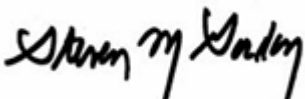
- **Placement of alcohol-based hand rubs (ABHR) dispensers in corridors and patient rooms.** The 2000 edition permitted this through an amendment that was recognized by CMS but *not by all local jurisdictions*. The 2000 edition said hand rubs could not be “adjacent” to electrical outlets, leading to citations due to conflicting interpretations. Other issues relate to the amount of ABHR that can be stored on hospital units per smoke zone so that more dispensers can be made available than now permitted. These improvements are clarified in the 2012 edition.
- **Lower range of relative humidity (RH) in the OR and similar controlled areas.** ASHE, ASHRAE, and NFPA passed and published changes that permit the lower range of 20% RH (down from 30% RH) in controlled, short-term spaces such as operating rooms. These updated documents became effective as of September 2011. The changes were accomplished through collaboration with additional groups including SHEA, AORN, APIC, NIH and more. SHEA members have done investigative work with others that proves there is no increased HAI risk and in fact the lower humidity is an advantage.<sup>6-12</sup> CMS however, has two different COPs on RH, which reference LSC 2000 and a defunct version of NFPA 99.

There were many joint requests sent to CMS for a Survey & Certification letter that would remove the requirement of 30% or 35% RH after approval of the 2012 codes. These included summaries of HAI and fire risks and more investigations are included in the annotated scientific publications. However, CMS continues to cite hospitals for the 1 or 2 days of the year when hospitals cannot maintain low RH values (30% or 35%), as they are obliged to enforce LSC 2000, which in turn references an outdated NFPA 99, as noted earlier. *Starting the federal rule-making and comment process for 2012 LSC is critical to realize savings of millions of dollars just for equipment purchased for these few days. This equipment is then turned off for the remainder of the year. In addition, the efforts and time expended by hospital personnel could be used in implementing more updated scientific interventions in the healthcare environment.*

**SHEA Recommendation:** SHEA strongly recommends adoption of the 2012 LSC and further, urges the federal notice-comment-rulemaking process be expedited

In conclusion, SHEA appreciates CMS’ thoughtful approach to recognizing existing redundancies in the COP’s and simplifying or eliminating the unnecessary burden currently placed on our healthcare system. We support the elimination of the infection control log, the use of standing orders to improve immunizations and the adoption of the 2012 LSC as soon as possible. Finally, we appreciate the opportunity to express our comments to the CMS proposed rule for Reform of Hospital and Critical Assess Hospital Conditions of Participation.

Sincerely,



Steven Gordon, MD  
President

1. Talbot T., Babcock H., Caplan A., Cotton D., Maragakis L., Poland G., et al. Revised SHEA Position Paper: Influenza Vaccination of Healthcare Personnel. *Infect Control and Hosp Epidemiol* 2010; 31(10):987-995 Available at: <http://www.mc.vanderbilt.edu/documents/infectioncontrol/files/2010%20Revised%20SHEA%20PP%20HCW%20Fluvax%20FINAL.pdf> Accessed November 2011.
2. Babcock H., Gemeinhart N., Jones M., Dunagan C., Woeltje K. Mandatory Influenza Vaccination of Health Care Workers: Translating Policy to Practice. *Clin Infect Dis* 2010; 50:459–464
3. Karanfil L. 1, Bahner J., Hovatter J., Thomas W. Championing Patient Safety through Mandatory Influenza Vaccination for All Healthcare Personnel and Affiliated Physicians. *Infect Control Hosp Epidemiol* 2011; 32(4).
4. Rakita R., Hagar B., Crome P., Lammert J. Mandatory Influenza Vaccination of Healthcare Workers: A 5-Year Study. *Infect Control Hosp Epidemiol* 2010; 31(9)
5. Wroten K, Piper J, Couch K. Improving influenza vaccination rates among adults in acute care using a standing order form by exception. *AJIC: Am J Infect Control*. June 2005. 33(5): e148.
6. ANSI/ASHRAE/ASHE. Addendum to American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. ASHRAE/ASHE Standard 170-2008. Ventilation of Health Care Facilities.2010; 1-4. Atlanta Available at: <http://www.fgiguilines.org/2010guidelines.html>. Accessed November 2011.
7. ASHE. Briefing for CMS: Reduced design criteria for relative humidity levels for short-term patient care areas. September 2010; and April 19, 2011; 1-29 American Society for Healthcare Engineering of the American Hospital Association. Available at: <http://www.ashe.org/advocacy/research/> or [http://www.ashe.org/advocacy/research/pdfs/briefing\\_cms\\_humidity-04-19-2011.pdf](http://www.ashe.org/advocacy/research/pdfs/briefing_cms_humidity-04-19-2011.pdf). Accessed November, 19, 2011 [Note: This document includes many articles referenced in the text but difficult to access.]
8. Bartley J, Olmsted RN. Behind the change in the ASHRAE/ASHE Standard 170 Engineered Systems 2; 2011: 26-29. Available: <http://www.esmagazine.com/publications/3/editions/1180>. Accessed November 2011.
9. Bartley J, Olmsted RN. Examining the evidence: SHEA and AORN endorse a change in the ASHRAE/ASHE design standard for relative humidity in the OR and other spaces. *Prevention Strategist*. Autumn 2010; 18-19. Available from APIC upon request.
10. Memarzadeh, F. White paper. Literature review of the effect of temperature and humidity on viruses. 2010: 1-23. Edited by SHEA members Bartley J and Olmsted RN. Available from SHEA upon request. [Also in ASHE Briefing: <http://www.ashe.org/advocacy/research/> or [http://www.ashe.org/advocacy/research/pdfs/briefing\\_cms\\_humidity-04-19-2011.pdf](http://www.ashe.org/advocacy/research/pdfs/briefing_cms_humidity-04-19-2011.pdf). Accessed November 2011.
11. Memarzadeh, F. The Environment of care and health care-associated infections: an engineering perspective. Facility Guidelines Institute and the American Society for Health care Engineering of the American Hospital Association. 2011: 1-80. Edited by SHEA members Bartley J and Olmsted R. Available from [http://www.ashe.org/resources/management\\_monographs/](http://www.ashe.org/resources/management_monographs/). Accessed November 2011.
12. Rosenberg J, Jackson M. White Paper: Developed and written for ASHRAE: Infectious disease risk from low humidity. American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. 2008 1-6. Available in the ASHE Briefing: <http://www.ashe.org/advocacy/research/> or [http://www.ashe.org/advocacy/research/pdfs/briefing\\_cms\\_humidity-04-19-2011.pdf](http://www.ashe.org/advocacy/research/pdfs/briefing_cms_humidity-04-19-2011.pdf).