

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Call for Comments on the Existing National Standards for the Culturally and Linguistically Appropriate Services in Health Care**

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of Minority Health.

ACTION: Notice.

SUMMARY: The HHS Office of Minority Health (OMH) announces the launch of an enhancement initiative of the existing National Standards for Culturally and Linguistically Appropriate Services in Health Care (CLAS Standards). The public comment period will begin September 20, 2010 and conclude December 31, 2010. During this time three regional meetings on the standards will be held throughout the country. Individuals and organizations are encouraged to submit their comments on the 14 standards and their current application and use. The enhanced national standards, as revised in accordance with public comment and subject matter expertise, will be published for review in spring of 2011 with the final versions being published in fall of 2011.

DATES: The initial comment and submission period is September 20 through December 31, 2010.

ADDRESSES: (1) Electronically through the public comment site <http://clashenhancements.thinkculturalhealth.org>.

(2) By mail, comments postmarked no later than December 31, 2010, can be submitted to: CLAS Standards c/o HHS Office of Minority Health, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852. Comments sent by courier will be accepted until 5 p.m. EST on December 31.

(3) Individuals may register for one of the regional meetings by using the online registration form at <http://clashenhancements.thinkculturalhealth.org>. To request a registration form by mail, write to CLAS Standards Enhancement Initiative meeting, c/o SRA International, Inc., 6003 Executive Blvd, Suite 400, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Guadalupe Pacheco, Office of Minority Health, 1101 Wootton Parkway, Suite 600, Rockville, MD 20852, Attn: CLAS, Telephone: (240) 453-6174; Fax: (240) 453-2883; E-mail: Guadalupe.Pacheco@hhs.gov.

Background: To help achieve its mission of "improving the health of racial and ethnic minority populations

through the development of effective health policies and programs that help to eliminate disparities in health," the OMH published the National Standards for Culturally and Linguistically Appropriate Services in Health Care (CLAS Standards) in 2001. The CLAS Standards were developed on the basis of an analytical review of key laws, regulations, contracts, and standards used by Federal and State agencies and other national organizations, with input from a national advisory committee of policymakers, health care providers, and researchers. Open public hearings were held to obtain input from communities throughout the nation. The CLAS Standards represent the first national standards for cultural competence in health care and offer comprehensive guidance on what constitutes culturally competent service delivery. They consist of 14 guidelines, recommendations, and mandates that serve to inform, guide, and facilitate implementation of culturally and linguistically appropriate services in health care. The CLAS Standards are organized by three themes: Culturally Competent Care, Language Access Services, and Organizational Supports. They recognize that culture and language are central to the delivery of health services.

Disparities in health care have been documented in a number of groundbreaking reports: Findings of the Supplement to Mental Health: A Report of the Surgeon General (CMHS, 2001a) reveal that "racial and ethnic minorities bear a greater burden from unmet mental health needs and thus suffer a greater loss to their overall health and productivity." Findings from the 2000 Surgeon General's Report Oral Health in America: A Report of the Surgeon General indicated significant disparities "between racial and socioeconomic groups in regards to oral health and ensuing overall health issues" (DHHS, 2000). The 2003 report from the Institute of Medicine, Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare (Smedley, Stith & Nelson, 2003), and its supplementary paper contributions such as Racial and Ethnic Disparities in Diagnosis and Treatment: A Review of the Evidence and a Consideration of Causes (Geiger, 2003) and The Civil Rights Dimension of Racial and Ethnic Disparities in Health Status (Perez, 2003), brought to the forefront that minorities receive lower quality health care even when socioeconomic and access-related factors are controlled. The report also showed that bias, stereotyping, prejudice, and clinical

uncertainty may contribute to racial and ethnic disparities in health care (Smedley *et al.*, 2003).

A significant body of research released since the 2003 IOM report corroborates these findings. The National Healthcare Disparities Report prepared by the Agency for Healthcare Research and Quality states that "although varying in magnitude by condition and population, disparities are observed in almost all aspects of health care" (The Agency for Healthcare Research and Quality, 2006). Inspired by the CLAS Standards, national organizations including the American Medical Association (AMA), American Association of Medical Colleges (AAMC), the Joint Commission, the National Committee for Quality Assurance (NCQA), the National Quality Forum (NQF) and others have released standards to help support the provision of culturally and linguistically appropriate care. Many of these standards promote the education and training of health care providers in culturally appropriate care.

Increasingly, national experts are looking to cultural competency training as a means to reduce disparities in health care. Evidence suggests that the most effective cultural competence training helps providers develop new knowledge, skills, and attitudes in order to effectively treat minority and immigrant populations (Smedley *et al.*, 2003). The concepts of cultural and linguistic competency as well as health disparities are featured prominently in the health care reform legislation enacted and signed by President Barack Obama in March 2010. References to the concepts of cultural and linguistic competency illustrate how pervasive and important the constructs have become.

Public comment period: It has been nearly ten years since the release of the landmark report regarding the CLAS Standards. In the report, the HHS, OMH provided the framework for all health care organizations to establish services and policies to best serve our increasingly diverse communities. In the decade following the release of the CLAS Standards, the field of cultural and linguistic competency has seen tremendous growth. It has evolved from a fledgling concept to a recognized intervention in the quest for health equity. The field of cultural and linguistic competency is dynamic and as such requires routine enhancement and nurturing. With this in mind, HHS, OMH has begun to revisit the National CLAS Standards.

The OMH has determined that the appropriate next step is for the CLAS

Standards to undergo a national process of public comment that will result in a broader awareness of HHS interest in CLAS, significant input from stakeholder groups on the existing CLAS Standards, as well as a final revision of the CLAS Standards and accompanying commentary supported by the expertise of a National Project Advisory Committee. The final revisions will be published in the **Federal Register** as recommended national standards for adoption or adaptation by stakeholder organizations and agencies.

The publication of the CLAS Standards in the **Federal Register**, and publicizing the availability of the complete report with commentary on the Internet and through local, regional, and national organizations will facilitate reaching as wide an audience of stakeholders as possible. This period of dissemination and awareness-raising will include three regional meetings to gather and solicit detailed input from interested individuals and organizations that will complement and enhance the public comments received by OMH through electronic and written means.

Individuals and organizations desiring to provide input on the standards are encouraged to send comments during the public comment period which is from September 20 through December 31, 2010. Individuals mailing comments are requested to include the following information: Name, position, organization, mail, and e-mail addresses and to identify specifically those portions of their comments that pertain to: The wording or the content of individual standards, the purpose of the standards and/or the intended audience for the national standards.

Dates and locations of the meetings are as follows:

Baltimore, Maryland, Friday, October 22, 2010, The Hyatt Regency, 300 Light Street, Baltimore, MD 21202.

San Francisco, California, Thursday, November 4, 2010, The Stanford Court, A Renaissance Hotel, 905 California Street, San Francisco, CA 94108.

Chicago, Illinois, Monday, November 15, 2010, The James Hotel, 55 East Ontario Street, Chicago, IL 60611-2727.

All meetings will convene at 9 a.m. and conclude at 3 p.m. On-site registration will be available starting at 7:30 a.m.

Information about the CLAS Standards Enhancement Initiative is available electronically at <http://classenhancements.thinkculturalhealth.org>.

Dated: September 2, 2010.

Garth N. Graham,

Deputy Assistant Secretary for Minority Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on Draft Tier 2 Strategies/Modules for Inclusion in the "HHS Action Plan to Prevent Healthcare-Associated Infections"

AGENCY: Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Healthcare Quality.

ACTION: Notice.

SUMMARY: The Office of Healthcare Quality is soliciting public comment on three new strategies or modules of the "HHS Action Plan to Prevent Healthcare-Associated Infections." To further the HHS mission to protect the health and well-being of the nation, the HHS Steering Committee for the Prevention of Healthcare-Associated Infections has developed draft comprehensive strategies for preventing and reducing healthcare-associated infections in ambulatory surgical centers and end-stage renal disease facilities, as well as a strategy to increase influenza vaccination coverage among healthcare personnel. These Tier 2 modules build upon and are to be included in the existing "HHS Action Plan to Prevent Healthcare-Associated Infections" that focuses on reducing hospital-acquired infections (Tier 1).

DATES: Comments on the draft Tier 2 modules should be received no later than 5 p.m. on October 11, 2010.

ADDRESSES: The draft Tier 2 modules can be found at <http://www.hhs.gov/ophs/initiatives/hai/actionplan/index.html#tier2>. Comments are preferred electronically and may be addressed to OHQ@hhs.gov. Written responses should be addressed to the Department of Health and Human Services, 200 Independence Ave, SW., Room 719B, Washington, DC 20201, Attention: Draft Tier 2 Modules.

FOR FURTHER INFORMATION CONTACT: Danielle Doughman, (202) 690-6476 or OHQ@hhs.gov.

SUPPLEMENTARY INFORMATION

I. Background

Healthcare-associated infections are among the leading causes of morbidity and mortality in the United States and the most common type of adverse event

in the field of healthcare today. They are defined as localized or systemic adverse events, resulting from the presence of an infectious agent or toxin, occurring to a patient in a healthcare setting. An epidemiologic study by the Centers for Disease Control and Prevention (CDC) revealed that the subset of HAIs with hospital-onset accounted for 1.7 million infections annually and were associated with 99,000 deaths in 2002. The fiscal cost is steep as well. Healthcare-associated infections contribute to an additional \$28 to \$33 billion dollars in healthcare expenditures annually.

For these reasons, the prevention and reduction of healthcare-associated infections is a top priority for the U.S. Department of Health and Human Services (HHS). Multiple agencies within HHS have been working to reduce the incidence and prevalence of healthcare-associated infections for decades. To further efforts, the HHS Steering Committee for the Prevention of Healthcare-Associated Infections was established in July 2008 and charged with developing a comprehensive strategy to progress toward the elimination of healthcare-associated infections.

In 2009, the Steering Committee issued the initial version of the "HHS Action Plan to Prevent Healthcare-Associated Infections." The initial strategy (Tier 1) focused on the prevention of infections in the acute care hospital setting and includes a prioritized research agenda; an integrated information systems strategy; policy options for linking payment incentives or disincentives to quality of care and enhancing regulatory oversight of hospitals; and a national messaging plan to raise awareness of HAIs among the general public, providers, and other stakeholder groups. The Action Plan also delineates specific measures and five-year goals to focus efforts and track national progress in reducing the most prevalent infections. In addition, the plan intended to enhance collaboration with non-government stakeholders and partners at the national, regional, state, and local levels to strengthen coordination and impact of efforts.

Recognizing the need to coordinate prevention efforts across healthcare facilities, HHS began to transition into the second phase (Tier 2) of the Action Plan in late 2009. Tier 2 expands efforts outside of the acute care setting into outpatient facilities (e.g., ambulatory surgical centers, end-stage renal disease facilities). The healthcare and public health communities are increasingly challenged to identify, respond to, and prevent healthcare-associated infections across the continuum of settings where