Shelbyville, Inc., Shelbyville, Kentucky; to acquire 100 percent of the voting shares of Dupont State Bank, Dupont, Indiana.

Board of Governors of the Federal Reserve System, December 19, 2000.

Robert deV. Frierson

Associate Secretary of the Board.

[FR Doc. 00–32748 Filed 12–21–00; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 16, 2001.

A. Federal Reserve Bank of Minneapolis (Karen L. Grandstrand, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480–2171:

1. Glacier Bancorp, Inc., Kalispell, Montana; to merge with WesterFed Financial Corporation, Missoula, Montana, and thereby indirectly acquire Western Security Bank, Missoula, Montana and thereby engage in controlling, owning, and operating a savings association pursuant to § 225.28(b)(4) of Regulation Y.

Board of Governors of the Federal Reserve System, December 18, 2000.

Robert deV. Frierson

Associate Secretary of the Board.

[FR Doc. 00–32632 Filed 12–21–00; 8:45 am]

BILLING CODE 6210–01–S

HARRY S. TRUMAN SCHOLARSHIP FOUNDATION

Harry S. Truman Scholarship 2001 Competition

AGENCY: Harry S. Truman Scholarship Foundation.

ACTION: Notice of closing for nominations from eligible institutions of higher education.

SUMMARY: Notice is hereby given that, pursuant to the authority contianed in the Harry S. Truman Memorial Scholarship Act, Pub. L. 93–642 (20 U.S.C. 2001), nominations are being accepted from eligible institutions of higher education for 2001 Truman Scholarships. Procedures are prescribed at 45 CFR 1801.

In order to be assured consideration, all documentation in support of nominations must be received by the Truman Scholarship Foundation, 712 Jackson Place, NW, Washington, DC 20006 no later than January 29, 2001 from participating institutions.

Dated: December 18, 2000.

Louis H. Blair,

Executive Secretary.

[FR Doc. 00–32639 Filed 12–21–00; 8:45 am]

BILLING CODE 6820–AD–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Minority Health; National Standards on Culturally and Linguistically Appropriate Services (CLAS) in Health Care

AGENCY: HHS/OS/Office of Public Health and Science, Office of Minority Health, DHDS.

ACTION: Final report.

SUMMARY: The HHS Office of Minority Health announces the publication of final national standards on culturally and linguistically appropriate services (CLAS) in health care, following a 120-day comment period on draft standards in 2000 and revisions to the standards. The CLAS standards, with a brief background summary of the development and comment process, are printed below.

FOR FURTHER INFORMATION CONTACT: Guadalupe Pacheco, Office of Minority Health, 5515 Security Lane, Suite 1000, Rockville, MD 20852, Attn: CLAS; Office Telephone: (301) 443–5084, FAX: (301) 594–0767, E-Mail: gpacheco@osophs.dhhs.gov. The standards, the public comments from the regional meetings, and a complete report on the project can be found online at [www.omhrc.gov/CLAS].

SUPPLEMENTARY INFORMATION:

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—Background
—Public Comment Period and Regional Informational Meetings
—National Project Advisory Committee (NPAC)
—Analysis and Response to Public Comments on the CLAS Standards
—National Standards for Culturally and Linguistically Appropriate Services in Health Care

Background

Cultural and linguistic competence is the ability of health care providers and health care organizations to understand and respond effectively to the cultural and linguistic needs brought by patients to the health care encounter. As health providers begin to treat a more diverse clientele as a result of demographic shifts and changes in insurance program participation, interest is increasing in culturally and linguistically appropriate services that lead to improved outcomes, efficiency, and satisfaction. The provision of culturally and linguistically appropriate services is in the interest of providers, policymakers, accreditation and credentialing agencies, purchasers, patients, advocates, educators and the general health care community.

Many health care providers do not have clear guidance on how to prepare for, or respond to, culturally sensitive situations. Until now, no comprehensive nationally recognized standards of cultural and linguistic competence in health care service delivery have been developed. Instead, Federal health agencies, State policymakers, and national organizations have independently developed their own standards and practices. Some have developed definitions of cultural competence while others mandate providing language services to limited English proficient (LEP) speakers. Some specify collection of language, race, and ethnicity data. Many approaches attempt to be comprehensive, while others target only a specific issue, geographic area, or subfield of health care such as mental health. The result is a wide spectrum of ideas about what constitutes culturally appropriate health services, including significant

differences with respect to target population, scope, and quality of services. Although limited in their jurisdiction, many excellent policies do exist, and the increasing numbers of model programs and practices demonstrate that culturally competent health services are viable, beneficial, and important to health care consumers.

In 1997, the U.S. Department of Health and Human Services' (HHS) Office of Minority Health (OMH) asked Resources for Cross Cultural Health Care and the Center for the Advancement of Health to review and compare existing cultural and linguistic competence standards and measures in a national context, propose draft national standard language where appropriate, assess the information or research needed to relate these guidelines to outcomes, and develop an agenda for future work in this area. Assuring Cultural Competence in Health Care: Recommendations for National Standards and an Outcomes-Focused Research Agenda was the result of this request, with a two-part report submitted to OMH in May 1999.

The first part of the 1999 report contained draft national standards for culturally and linguistically appropriate services in health care. Based on an analytical review of key laws, regulations, contracts, and standards currently in use by Federal and State agencies and other national organizations, these draft standards were developed with input from a national project advisory committee of policymakers, health care providers, and researchers. Each standard was accompanied by a discussion that addressed the proposed guideline's relationship to existing laws and standards, and offered recommendations for implementation and oversight to providers, policymakers, and advocates.

Public Comment Period and Regional Informational Meetings

The Office of Minority Health determined that the appropriate next step for the draft CLAS standards was to undergo a national process of public comment that would result in a broader awareness of HHS interest in CLAS in health care, significant input from stakeholder groups on the draft standards, and a final revision of the standards and accompanying commentary supported by the expertise of a National Project Advisory Committee.

The draft CLAS standards were published in the **Federal Register** on December 15, 1999 (Volume 64, Number 240, pages 70042–70044), and the full report was made available for review online at [www.omhrc.gov/CLAS]. Individuals and organizations desiring to comment on the standards were encouraged to read the standards and full report, and to send comments during the public comment period, which ran from January 1 to April 30, 2000. During this period, written comments sent by e-mail and regular mail were received from 104 individuals and organizations.

Individuals also had the opportunity to participate in one of three regional meetings on the CLAS standards. The purpose of these one-day meetings was to present information on the standards' development process, and for participants to discuss and provide feedback on issues related to the standards themselves or their implementation. Meetings were publicized in the **Federal Register** notice, on the website, and in letters mailed to more than 3,000 stakeholders. The meetings were held on January 21, 2000, in San Francisco, California; March 10, 2000, in Baltimore, Maryland; and April 7, 2000, in Chicago, Illinois. More than 309 individuals, representing themselves or their organizations, participated in the three meetings. All sessions of each meeting were audiotaped and transcribed for inclusion in the analysis of public comments.

Following the closure of the public comment period on April 30, 2000, the project team (consisting of staff members of OMH, IQ Solutions, Inc., and its subcontractor Resources for Cross Cultural Health Care) implemented the following steps to analyze the public comments on the CLAS standards received through the three regional meetings, mail, and e-mail.

The public comments received from all sources were organized according to the following categories (the numbers used to identify the standards pertain to the numbering system of the draft standards. The standards have been reordered in the final revision):

- General Comments (made on the overall report).
- Diverse and Culturally Competent Staff (Standards 1, 4, and 5).
- Consumer and Community Input (Standard 3).
- Bilingual/Interpreter Services (Standards 6, 7, and 9).
- Translated Written Materials (Standard 8).
- The Culturally Competent Organization (Standards 2 and 13).
- Data Collection and Performance Evaluation (Standards 10, 11, 12, and 14).

Within these categories, comments were organized by individual standards and within standards by major identified themes. Staff reviewed the compilations of comments to identify issues and controversies for each standard, and the original comments were organized topically for each standard and for the General Comments. The project team then conducted a series of meetings to discuss comments on topically grouped sets of standards. Deliberations on the CLAS Standards addressed the following set of questions:

- Is there a powerful consensus from public comments to change the standard in any way? If so, what are the issues?
- Are there any meaningful secondary issues that are so compelling or sensible that they need to be considered in terms of changes to the standard?
- Are there any other issues that should be addressed (e.g., controversies raised by the standard) by the CLAS Standards National Project Advisory Committee (NPAC)?

Deliberations on the general comments addressed the following set of questions:

- What are the major themes or issues related to the previous process of developing the standards, and how should these issues be addressed in the final CLAS standards report?
- What are major themes related to contextual issues, and how should these themes be addressed in the final CLAS standards report?
- What are major issues related to the subsequent standards development process, and how should these themes be addressed?

National Project Advisory Committee

Based on the discussions related to these questions, the project team prepared a deliberation report for the NPAC that included an analysis of comments on the general comments and each standard. Each analysis:

- Makes recommendations for changes to the standards when clearly indicated by a consensus in either public comments or project team deliberations;
- Identifies key themes, issues, and controversies; and
- Provides rationales for changes or controversies that the NPAC is being asked to consider.

The CLAS Standards National Project Advisory Committee was composed of 27 individuals representing State and Federal agencies, health care organizations, health care professionals, consumers, unions, and health care accrediting agencies. A complete list of NPAC members is available at [www.omhrc.gov/CLAS]. The NPAC

met with the project team in Washington, DC, on July 21–22, 2000. Together, the group:

- Considered the recommendations proposed in the deliberation report and either concurred on the suggested changes to the standard or offered an alternative approach to responding to public comments on the issues;
- Examined key issues for which recommendations were not presented in the analysis (due to a lack of clear consensus) and, when possible, recommended changes to the standards that were responsive to public comments;
- Identified and addressed other issues not raised in the deliberation report; and
- Made recommendations for next steps.

Following the meeting the project team revised the standards based on the public comments and the deliberations of the NPAC, whose members were given the opportunity to review and comment on subsequent revisions. No formal consensus was obtained from the NPAC after the meeting, although most comments were integrated into the final standards by the project team, and the NPAC was given the opportunity to review and comment on the final revisions. The final revisions are now being published in the **Federal Register** as recommended national standards for adoption or adaptation by stakeholder organizations and agencies.

The project team will also produce a comprehensive final report documenting all phases of the project and discussing issues related to the standards in depth. This report will be available in early January 2000 online at [www.omhrc.gov/CLAS] and in hard copy by request to: Guadalupe Pacheco, Office of Minority Health, 5515 Security Lane, Suite 1000, Rockville, MD 20852, Attn: CLAS; Office: Telephone (301) 443–5084, FAX: (301) 594–0767, E-Mail: gpacheco@osophs.dhhs.gov.

Analysis and Response to Public Comments on the CLAS Standards

In response to publication in the **Federal Register** of the CLAS Standards on December 15, 1999, OMH received public comments from 413 individuals or organizations, along with comments from the NPAC. Comments were received from a broad range of stakeholders, including hospitals, community-based clinics, managed care organizations, home health agencies, and other types of health care organizations; physicians, nurses, and other providers; professional associations; state health departments; government and other purchasers of health care; accreditation and credentialing agencies; patient advocates and advocacy groups; policymakers; and educators. We present comments and responses generally in the order in which the issues appeared in the recommended CLAS Standards.

General Comments

The comments called for more specificity regarding terms such as culture and competence. Two comments affirmed the choice of definition used by the report; there were other votes for and against culturally sensitive/effective/appropriate/competent. Culturally and linguistically appropriate services (CLAS) was retained as the overall descriptor for the package of activities described by standards. Cultural competence remains the mainstream term for this area, and will be used within standards and defined in the glossary. The NPAC generally agreed with the continued use of the definition of cultural and linguistic competence from the original report.

Comments suggested that the scope of the project include other consumer groups/issues such as the poor, homeless, disabled, gender, socioeconomic status, HIV, gay, bisexual, transgender, immigrants, American Indians, different ages, countercultures, cultures within cultures, individuals within cultures. In the discussion for this section, the final report on the CLAS standards will articulate an inclusive definition of culture that promotes a broad understanding of the whole person. The report will note that every aspect of culture does not need to be addressed in each standard in order for them to apply to different groups, although we will emphasize the original focus on racial, ethnic, and linguistic issues.

Comments asked that the standards be more precise and directive and include more discussion in the standards themselves. To provide added details without encumbering the language of the standards, the format for presenting the revised CLAS standard was revised to continue using concise language for the standard itself and incorporate wordsmithing changes that enhance the clarity of each standard. Additional clarification of key issues or requirements are provided in a brief commentary accompanying the standard. It is our intent that the commentary will not be separated from the standard in executive summaries or other abbreviations of the full report. We also moved many important points from the discussion section of each standard in the original report into the commentary and will include more examples of models and implementation practices in the discussion section of the final report. However, much of the research on and verification of this information should be conducted within the context of the anticipated pilot tests of the standards by health care organizations. Suggestions also were made for reorganizing the standards by topic area; the revised standards reflect this reorganization, with three main categories (culturally competent care, language assistance, and organizational supports for cultural competence).

Comments raised concerns about too much emphasis on foreign language issues, and it was suggested that they be broadened to include other communication issues. The policies from which the standards were derived are much more specific on the issue of language than culture, and this reflects the current abstract nature of cultural competence and the clear mandates that exist on language issues. We have tried to strengthen the commentary and discussions on cultural competence generally, separate the general cultural competence and language issues into different categories, and call for more work on developing national standards for cultural competence training and other aspects of cultural competence.

Comments raised questions about several implementation issues, including the cost burden and the applicability of the CLAS standards to different kinds of health care organizations (*e.g.,* community clinics/community-based organizations (CBOs), mono-ethnic or ''already'' culturally competent providers, with extensive ethnic diversity/little diversity, rural providers, home health care agencies). Although the comments raise valid issues, we cannot address cost implications and the implementation nuances according to organization type within the scope of this project. Follow-up projects to pilot test implementation of the CLAS standards and address such issues are planned.

Commenters suggested that additional groups might have participated in the development and comment process, including: health care providers, practicing clinicians, CBOs, community health centers, consumer groups, ethnic organizations, grassroots advocacy groups, Indian reservations, tribal organizations, primary consumers, direct service personnel, Native Americans, Asians, and people who don't speak English. They also suggested that the outreach/public comment process could have been more inclusive by using more participatory

approaches to getting information, offering interpreters, doing a better job of informing people about the process, and targeting certain audiences. The final report will detail the public comment process used and its limitations. For example, alternative methods to get input, such as focus groups, ethnic media advertising, were constrained by resource limitations. We used recommendations from public meetings and developed a matrix to assist with our analysis and inclusion of different stakeholder groups in the NPAC. We attempted to recruit representatives from key groups and added additional stakeholders to the NPAC who provided community- and patient-based perspectives.

Comments indicated that many people are not aware of existing laws that addressed issues raised by the CLAS standards, and some standards can be strengthened on the basis of Federal legislation. The commentary of the revised standards identifies the relationship between each standard and any existing Federal laws or regulations. Input from the NPAC was used to identify relevant Federal requirements.

Comments raised concerns about whether the recommended CLAS standards should be guidelines, standards, or mandates. Overall, there was a broad continuum of support for and opposition to different conceptualizations of the standards. Fifty comments supported the standards as mandates, with another 37 expressing endorsement, support for their adoption, agreement with the intent, and other general expressions of praise. Thirty-four comments expressed some level of concern about seeing the standards as national standards or requirements. Some prefer the standards as guidelines, and others disliked them in any format. Among the reasons for their concern or opposition include: The potential costs/burden of implementation; the standards are too broad, too narrow, or too prescriptive; and the lack of research evidence to support the CLAS activities. These issues were raised in the pre-NPAC analytical report and discussed by the committee. The NPAC offered up a consensus on three types of standards of varying stringency: mandates, guidelines, and recommendations. The revised CLAS standards are identified according to these types.

Several comments were raised about elevating the issues of racism, bias, discrimination, and the issues of gender, social class, and socioeconomic status more directly into the standards. Unconscious and conscious referral bias and its impact on health disparities was emphasized, as well as a tension between recognizing the needs of newcomers vs. English-speaking individuals who may still not be respectfully treated in health care. The revised preamble highlights bias and discrimination issues, and the final report will further discuss these issues.

Preamble

Public comments offered a variety of suggestions on how to revise the preamble to the CLAS standards. The principal themes focused on describing the purpose and desired outcomes of the standards, elucidating the standards' overarching principles, and providing definitions to key terms. Other comments suggested that the preamble should include a list of stakeholders and specifically address issues such as bias, ethics and confidentiality, and access. We have revised the preamble to provide both a visionary and practical foundation for understanding the CLAS standards while focusing on a principal theme rather than the array of issues identified. We also have added explanations of the three types of standards (mandates, guidelines, and recommendations), definitions of key concepts used in the standards, and a list of intended stakeholders.

Standard 1

Public comments took issue with the overall language of the standard, questioning whether its vague language will render it difficult to implement and enforce. Various comments cited the lack of operationally defined and measurable requirements, recommended that the standard be moved to the preamble or combined with Standard 5, and suggested ways that the standard could be strengthened. The revised standard, along with the accompanying Commentary, is intended to encompass the spirit and overall purpose of the CLAS standards as well as the details that can help organizations ''actualize'' and ''operationalize'' the requirements of Standard 1. As suggested in public comments and by the NPAC, portions of the discussion in the CLAS standards report have been incorporated into the standard's Commentary, including actions organizations can take to support culturally competent encounters. The intent of the standard is more fully explicated in the discussion section of the final report.

Public comments focused on the term ''attitudes'' or the phrase ''attitudes, behaviors, knowledge, and skills'' of staff. The lack of definitions and measures for these terms was cited as an obstacle to implementing Standard 1. The revised standard deletes this phrase and focuses instead on concrete actions as reflected in the commentary.

Comments requested that the CLAS standards address the issue of traditional health practices. The response to these comments was to include a reference to traditional health practices in the Commentary to Standard 1. The Commentary cites ''being familiar with and respectful of various traditional healing systems and beliefs and, where appropriate, integrating these approaches into treatment plans.'' The discussion section for this standard in the final report will include additional information and examples.

NPAC members emphasized the need to define ''respectful,'' ''effective,'' ''understandable,'' and ''culturally competent'' care. The revised standard calls more explicitly for ''care that is provided in a manner compatible with [patients'/consumers'] cultural health beliefs and practices and preferred language'' rather than merely culturally competent care. This language was recommended by a NPAC member and supported by the committee. The definition and assessment of cultural competence are discussed more fully in the final report. Further explanation of the other terms provided in the Commentary as well as the discussion section of the final report.

Standard 2

One comment pointed out that ''diverse staff'' and ''culturally competent staff'' are two distinct concepts that have been combined in a single standard. The conceptual issues raised by combining in one standard two distinct notions about the staff of a culturally competent organization were addressed by separating the two different notions. With the deletion of ''culturally competent,'' Standard 2 now focuses on the need for a diverse staff that reflects the racial/ethnic and cultural profile of the communities being served and is primarily concerned with strategies for staff recruitment and retention. Standard 3 now focuses on the need for cultural competence in that staff and addresses issues related to education and training.

Comments raised concerns about the definition of diverse staff in Standard 2. With additional input from the NPAC, the standard now defines a diverse staff within the standard as one that is ''representative of the demographic characteristics of the service area.'' The standard's accompanying Commentary provides numerous examples of the types of staff members who should reflect the communities' diversity.

Comments criticized the use of the phrase ''administrative, clinical, and support staff'' in the original draft standard. Although comments differ in their suggested approach, they expressed a consensus that the standard needs to be inclusive of all position levels in an organization. The revised standard substitutes ''at all levels of the organization'' for ''administrative, clinical, and support staff.'' The commentary accompanying the standard provides more detailed information about the various position levels and types of staff members that are included in this specification.

Public comments recommended making Standard 2 more inclusive by deleting the words ''racial and ethnic.'' The phrase was considered too limiting a descriptor of communities and not synonymous with culture or diversity. The term was deleted to encompass all cultural groups in the communities being served.

Public comments indicate that use of the term ''qualified'' staff within Standard 3 is controversial. Another issue is that the term ''qualified'' raises questions about its definition, including the different levels of qualification that might be required for various types of staff. NPAC input was sought on whether the term ''qualified'' should be included within the standard and, if it was to be included, how it should be defined in the Commentary. However, no consensus among the group was reached. One member urged that the issue be addressed in the final report if not in the commentary.

Standard 3

Public comments focused on the nature of the organization's responsibility in arranging for ongoing education and training. Interpretations differed on whether the original terminology, ''arrange for,'' implies that the organization itself should conduct in-service training or should be responsible merely for making arrangements and paying for the training to be offered (possibly outside of the organization) to staff members. Substitution of the term ''ensure,'' along with an explanation in the Commentary of the intent of the standard, clarifies the role of the health care organization.

Comments questioned whether specific types of staff members should be specified in Standard 3. Comments addressed the need to define who should be included in the various staff categories and to include all position levels in an organization. Similar comments were made about Standard 2, and a similar approach was used to revise Standard 3 with the substitution of ''staff at all levels and across all disciplines'' for ''administrative, clinical, and support staff.''

More than 50 public comments on Standard 3 dealt with ways to offer more explicit guidance on cultural competency education and training. Comments emphasized the need to develop a standard or measures for cultural competency training; offered recommendations on the process of cultural competency education and training as well as specific topics that should be included in cultural competency trainings. Despite the preponderance of comments related to providing greater specificity about the conduct and evaluation of cultural competency education and training, the fact remains that there is no consensus on the definition of cultural competency or what constitutes a culturally competent health professional. Moreover, there are no standard curricula or universally accepted certification or credentialing for cultural competence and no standardized measures for evaluating the effectiveness of cultural competency trainings. Given the lack of certainty or consensus in this area, we sought NPAC advice on whether Standard 3 or its accompanying Commentary should be more prescriptive about the content and process of cultural competency education and training. The Commentary reflects suggestions by NPAC members.

Standards 4 and 5

Comments raised questions about the relationship between standards 4, 5, and 6. The project team originally decided to combine standards 4 and 5 as a complete articulation of the healthcare organization's responsibility to advertise, offer, and provide language services as stipulated in Title VI of the Civil Rights Act of 1964. However, the NPAC thought that the obligation to provide verbal and written notices was sufficiently important to warrant its own standard. Thus, Standard 4 now addresses the organization's obligation to offer and provide language assistance services, and standard 5 addresses the obligation to provide verbal and written notices of patients'/consumers' rights to such services.

Public comments emphasized the need to clarify the link between Standards 4 and 5 and Title VI of the Civil Rights Act of 1964. The link between these standards and Title VI and VII is explicitly highlighted in the Commentary, and organizations are referred to the August 30, 2000 Office for Civil Rights (OCR) guidance on Title VI with respect to LEP individuals [www.hhs.gov/ocr/lep]. Because of this reference, language in the standard and commentary for standards 4–7 was changed to reflect requirements of terminology in the guidance. For example, the term ''language assistance services,'' taken from the OCR guidance, was chosen as a generic term for bilingual interpreter services, and written materials in other languages.

A reference to the needs of patience/consumers speaking American Sign Language (ASL) was made in the commentary in response to public comments.

Standard 6

Comments indicated confusion related to the abilities and responsibilities of bilingual staff who do not function as interpreters. Abilities and responsibilities of bilingual staff who communicate directly with patients/consumers are now specified in a paragraph in the commentary. NPAC comments were incorporated into descriptions of what constitutes the competence of these staff members as well as of interpreters. The abilities and responsibilities of interpreter staff are similarly addressed. The commentary now also addresses the need for assuring competence, and the requirements of Title VI with respect to assuring competence.

Numerous public comments and the NPAC raised issues related to the use of family and friends as interpreters. The wording in the standard about family and friends was revised, and additional details are provided in the commentary.

Standard 7

Comments suggested the deletion of the term ''translated'' and raised concerns about the advisability of merely translating materials versus creating original documents in non-English languages. The new standard no longer uses the term ''translated.''

The term ''signage'' was cited in comments for being too vague and needing clarification. Public comments were addressed by including guidance in the commentary on the types of signage that should be translated. The NPAC suggested that signage in Standard 7 should not include the posted notices already addressed in Standard 5. The language of the standard was further refined to reflect NPAC input, and in the commentary, other types of notices (e.g., regarding patients rights) have been added to examples of way-finding signage.

Comments cited the term ''commonly used'' as being too ''broad'' or ''unclear.'' One concern is that the term could be interpreted as requiring

translation of every document, however insignificant or large. Other comments raised questions about what constituted ''patient education materials and other materials.'' These comments have been addressed by deleting the term ''commonly used'' and using the broader term ''patient-related materials'' instead of patient education materials. ''Patient-related materials'' encompasses alternative formats (see below) as well as various forms, notifications, and health prevention and promotion materials. The standard's commentary refers organizations to the OCR guidance for examples of the types of documents that may be important to translate.

The term ''predominant language groups'' was commonly cited in public comments, many of which were concerned about the vagueness of the term. However, suggestions for defining the term varied. Public comments have been addressed by revising the language of the standard and including the clarification of requirements in the accompanying commentary. The term ''commonly encountered,'' as suggested in one comment, addresses the need for organizations and providers to assess needs in their particular service areas. It also is consistent with language in OCR Title VI policy guidance, which refers to ''regularly encountered'' language groups. Because there is existing policy guidance on the Federal mandate for translated materials, the standard's commentary refers to that document for guidance in determining for which language groups materials should be translated.

There was a general consensus among commenters that materials should be consistent with a patient's culture and literacy level. Comments emphasized that literal translation of patient information is not sufficient. Signage and materials also must use culturally appropriate images and take into account people's acculturation levels, medical beliefs, and practice systems. The inappropriately high reading level for forms and health education materials in English was cited often, and this problem is compounded when materials with inappropriate reading levels are translated. The need for consistency with a patient's culture and literacy levels was addressed in the discussion section of the original CLAS standards report. In response to public comments, the wording of the standard itself has been revised to include ''easily understood.'' The new terminology mirrors that used in the first article in the Consumer Bill of Rights and Responsibilities, which states that ''Consumers have the right to receive accurate, *easily understood* information * * *'' The term is intended to emphasize the need to help ensure the patient's comprehension of information, a requirement that goes beyond mere literal translation. For further emphasis on this issue, the accompanying commentary for the standard specifies that signage and patient information should be responsive not only to language differences but also to patients' cultures and literacy levels.

Comments called attention to the need for alternative formats to address the needs of people with sensory, developmental, and/or cognitive impairments and persons whose languages lack a written version. Public comments have been addressed by including in the standard's commentary a reference to the need to develop alternative materials as a detail of the standard's requirements. Deletion of the word ''written'' also addresses the issue raised in comments of providing information for people who are illiterate or whose language has no written form.

Public comments addressed issues concerning the appropriate translation process. In response to such comments, the commentary accompanying the standard now specifies three important aspects of the translation process: use of a trained translator, back translation and/or review by a target audience group, and periodic updates.

Comments expressed concern that standard 7 could be interpreted as a way to replace oral interpretation with translated written materials. Rather than address this important concern by complicating the language of the standard itself, specific reference to the continued importance of oral interpretation is contained in the commentary accompanying the standard.

Standard 8

Comments suggested that a rationale for the standard should be provided. Language from comments and the original report articulate the central nature of this standard, which is now stated in the first paragraph of the commentary.

Comments observed that the word ''have'' in the original standard lacked the power to convey the critical importance of the activities described in this standard. The response to these comments was to replace ''have'' with ''develop, implement, and promote.''

Many comments spoke to the need for integrating CLAS into the mission and activities of the organization. This concept is now articulated in the commentary.

Nearly half of the comments on Standard 8 addressed the issue of internal and external accountability for cultural competence in an organization. Some comments identified a bottom-up or line-staff approach to initiating cultural competence activities, although most comments recognized the need for top management support for cultural competence to assure accountability and longevity, and shared responsibility for implementation throughout the organization. This issue is now raised in the commentary.

One comment directly addressed the need to involve communities and patient/consumers in the development of an organization's management strategy on cultural competence. This issue is now mentioned in the commentary, with a reference to Standard 12, which more fully explores the role of community involvement.

In accordance with suggestions from the NPAC, ''management strategy'' has been changed to ''strategic plan.''

Standard 9

Comments pointed out the need to identify the purpose and use of the data collection activities called for in the CLAS standards. These comments have been addressed by describing the purpose of organizational self-assessment at the beginning of the standard's commentary. The role of initial and ongoing organizational self-assessment is described in more detail in the discussion section of the final report.

The NPAC was divided on whether to classify Standard 9 as a guideline or recommendation. The two aspects of the standard—conducting an initial and ongoing self-assessment and integrating measures of cultural and linguistic competence into existing quality improvement activities—were supported by different levels of evidence. Self-assessment was considered by some committee members to be a prerequisite for developing the strategic plan called for in Standard 8. Consequently, this aspect of the standard has been identified as a guideline. Many public comments and NPAC members emphasized the importance of taking organizational self-assessment to another level by assessing the impact of CLAS services on patient care, access, satisfaction, and health outcomes. Because the current evidence base does not support a guideline to link organizational self-assessment with the impact of CLAS on patients, building such links is a recommendation of this standard.

Comments raised issues about the use of patient surveys in organizational self-

assessments. Concerns were expressed about the need for the surveys to be culturally and linguistically appropriate, to be suitable for measuring patient acceptance or compliance, and to be jointly designed with the appropriate patient population. Comments also pointed out the difficulties in identifying valid patient surveys that can be used across cultures and the possibility that a qualitative approach might be more appropriate than patient surveys for finding out how serious organizations are about implementing the CLAS standards. The response to these comments is to include in the commentary a statement that patient/consumer and other community surveys are an important component of organizational self-assessment of cultural and linguistic competence, but they should not constitute the only self-assessment tool. The commentary also notes that these surveys should be culturally and linguistically appropriate. The final report will contain a discussion on patient satisfaction surveys.

Organizational self-assessment appears to be an issue for which many commenters sought clarification. Comments called for more specificity in Standard 9, made suggestions about the processes and components of self-assessment, addressed self-assessment tools, and discussed the need for and appropriateness of indicators and measures of organizational competence in CLAS. Although the general consensus of these comments was that the standard should be more prescriptive regarding the organizational self-assessment, no preferred process, tool, or measures emerged. This situation is mirrored in the field, where there also is a lack of consensus about what constitutes valid tools and measures for organizational cultural competence. Given the lack of information and consensus, we requested NPAC input on what specific details, if any, should be provided to help organizations implement the standard. Input from NPAC members and other experts contributed to a discussion in the final report that will provide examples of ways that some organizations are linking self-assessment with CLAS impact.

Standard 10

Public comments focused on how the standard should describe the data collected on language. Clarification was requested on what was meant by ''primary spoken language,'' and several comments cited the need to address both written and spoken languages. Comments suggested using the term ''preferred'' language. The term ''preferred'' has the advantage of implying that the patient/consumer, rather than the organization's staff, makes the decision about which language is noted in the management information system (MIS) and patient record. The response to the public comments is to use the term ''preferred language'' as well as both spoken and written languages in the standard. The commentary describes what is meant by ''preferred'' and ''written'' language.

One public comment raised the important issue of the potential for variations in data, depending on when they are collected. This comment recognizes that there may be multiple points of entry (e.g., physician's office, pharmacy, and enrollment office) into a health care organization and that information may not be routinely shared across the various service components. To address this issue, the commentary calls for data to be collected at the patient's/consumer's first point of contact with the health care organization and be collected in health records and integrated into the organization's MIS. This requirement is designed to ensure consistency and continuity of information across appropriate service components of the organization.

Public comments emphasized the importance of explaining the purpose of data collection, particularly to populations that may fear negative reprisals for providing personal information. To respond to this important concern, the commentary accompanying the standard lists five purposes for the collection of data on race/ethnicity and language.

More public comments addressed the issue of race/ethnicity data than any other topic related to this standard. Comments focused on how these data should be collected, including the need to collect information on subpopulations and to standardize race/ethnicity data, recommended systems for classifying race and ethnicity, and the importance of self-identified race/ethnicity. To respond to these concerns, the standard's commentary recommends using the standard procedures and racial/ethnic categories specified in the Office of Management and Budget (OMB) standards for maintaining , collecting, and presenting Federal data on race and ethnicity (revision to OMB directive #15) and adapted in the U.S. Census 2000. In keeping with the OMB requirements and Census 2000, the commentary calls for organizations to allow individuals to select more than one race/ethnic category. The commentary also encourages organizations to enhance their information on subpopulations by collecting additional identifiers such as country of origin.

Comments and NPAC members suggested that data on language be inclusive of diverse dialects or languages such as American Sign Language (ASL). The response to these comments is to specify in the commentary that data collected on language should include dialects and ASL.

Public comments raised the issue of special data collection considerations that should be made in certain cases involving minor children. The response to these comments is to include in the commentary a statement calling for the collection and documentation of information about the preferred language and interpretation needs of non-English-speaking parents of an English-speaking minor child. NPAC input helped modify this statement.

Comments raised concerns about the confidentiality and privacy of individual data collected on language and race/ethnicity. In addition to clarifying the purpose of such data collection, the commentary for Standard 10 requires that health care organizations maintain all patient data according to the highest standard of confidentiality and privacy. In response to NPAC concerns, organizations also are asked to inform patients/consumers about the purposes of data collection and to emphasize that the data will not be used for discriminatory purposes. Additionally, the commentary states that no patient/consumer should be required to provide data on race, ethnicity, or language or be denied care or services if he or she chooses not to provide such information.

Standard 11

Comments cited a lack of clarity in the draft of Standard 11, but no consensus emerged on how to reframe the standard. Our deliberations on how to rewrite Standard 11 centered first on its purpose, which is now stated at the beginning of the commentary. Based on this identified goal, we have honed the focus of the standard on the maintenance of two tools for helping organizations understand their communities (i.e., a demographic, cultural, and epidemiological profile of the community, and a needs assessment) and on the use to which this information should be put (i.e., to plan for and implement responsive services). Additional details provided in the commentary are intended to further clarify the language of the standard.

Public comments suggested that the aggregate data collected under the terms of Standard 11 should be updated regularly. Two comments specifically suggested annual updates. Because many characteristics of a community change over time, it is important that health care organizations ensure that information on their community is up to date. However, some organizations might consider an annual update too burdensome. To address this issue without being too prescriptive, the revised standard requires organizations to maintain a current profile of the community and needs assessment, and the commentary calls for organizations to obtain baseline data and update it regularly.

Comments and the NPAC discussed various methods and information sources that could be used to maintain the profile and the needs assessment. To respond to these comments, the commentary calls for health care organizations to use a variety of methods and information sources and presents examples of each.

Comments suggested that both qualitative and quantitative methods should be used to collect information on the community. These comments have been addressed by calling for the use of qualitative and quantitative methods in the standard's commentary.

Comments emphasized the need to involve the community in data collection efforts. This issue is addressed by including in the standard's commentary the reminder that health care organizations should involve the community in the design and implementation of the community profile and needs assessment in accordance with Standard 12.

At the request of the NPAC, the commentary includes a statement that organizations should not use the collected data for discriminatory purposes.

Standard 12

Many comments focused on wordsmithing changes to the language of the draft standard. The standard has been streamlined, although the major thrust is the same. As rewritten, the standard is intended to be directive, but not prescriptive. The commentary provides a rationale for the standard, examples that elucidate key words, and examples of the types of activities in which communities might become involved.

Comments suggested that both informal and formal mechanisms should be used to facilitate community and patient/consumer involvement. This language has been added to the standard, along with examples of such mechanisms in the commentary.

Comments suggested using a stronger term than ''involvement.'' At the suggestion of the NPAC, the standard was revised to recommend ''participatory, collaborative partnerships'' to strengthen the standard.

The NPAC did not achieve consensus on whether Standard 12 should be a guideline or recommendation. Although a summary chart developed by the NPAC at the committee meeting listed Standard 12 under guidelines, some individual members voiced a minority opinion that it should be a recommendation. Given the overwhelming number of public comments about the critical role of community in CLAS, in the final report, this standard is listed as a guideline.

Standard 13

Comments noted the ambiguity of certain terms used in the standard. The standard was rewritten based on several suggestions provided by commenters. ''Develop structures and procedures to address'' was replaced with ''provide a process to identify, prevent, and resolve,'' and additional details of staff and patient complaints were included in the commentary.

In response to public comments, language was included in the commentary that recognizes that many existing legal requirements cover some of the issues raised in the standard.

NPAC members recommended that staff issues be separated from patient/consumer issues because there are many mechanisms (e.g., EEO, labor grievance processes) within organizations to work with staff-staff problems. The revised standard focuses on conflict and grievance resolution processes for patients/consumers and does not refer to staff issues.

NPAC members expressed concerns that the draft standard did not provide a sufficient link with existing organizational mechanisms for patient complaint/grievance processes. Although it was suggested that complaint processes for cross-cultural issues should be integrated with existing mechanisms rather than be separate parallel systems, it was agreed that the key was that the process be culturally competent and include culturally competent staff. The revise standard calls for organizations to ensure that conflict and grievance resolution processes are culturally and linguistically sensitive and capable of identifying, preventing, and resolving cross-cultural conflicts or complaints by patients/consumers, rather than develop structures and procedures to address cross-cultural issues.

Standard 14

The requirement in Standard 14 did not appear in any of the source documents for the original CLAS standards report. However, its inclusion as a CLAS standard was recommended and approved by the National Advisory Committee that met in July 1998. The original intent of the standard was to address the accountability of health care organizations to their patients/consumers and communities by calling for organizations to publish an annual report. However, opinions expressed in the public comments differed on the need for this standard as well as on the nature of the report and the extent to which its preparation should involve the community. A major issue was believed to be the fear that the standard would become a mandated process that would be used by Federal agencies as a monitoring tool. The general consensus of comments is that the standard must be more specific if it is to have any meaning.

Given the level of uncertainty about the report's intended purpose and lack of specificity in the draft standard, the NPAC was requested to provide input on the purpose of the annual report and on any details that should be added to the standard or commentary to help organizations implement this standard. The revised standard reflects the NPAC's consensus that the standard should be a recommendation rather than a guideline and that organizations should be encouraged not to make an annual report but rather to regularly make available to the public information about their progress in implementing the CLAS standards. The commentary explains the potential purposes of the standard and provides examples of ways that organizations could report this information.

After consideration of the comments received and further analysis of specific issues, the revised CLAS Standards are presented below.

National Standards for Culturally and Linguistically Appropriate Services in Health Care

Preamble

The following national standards issued by the U.S. Department of Health and Human Services' (HHS) Office of Minority Health (OMH) respond to the need to ensure that all people entering the health care system receive equitable and effective treatment in a culturally and linguistically appropriate manner. These standards for culturally and

linguistically appropriate services (CLAS) are proposed as a means to correct inequities that currently exist in the provision of health services and to make these services more responsive to the individual needs of all patients/consumers. The standards are intended to be inclusive of all cultures and not limited to any particular population group or sets of groups; however, they are especially designed to address the needs of racial, ethnic, and linguistic population groups that experience unequal access to health services. Ultimately, the aim of the standards is to contribute to the elimination of racial and ethnic health disparities and to improve the health of all Americans.

The CLAS standards are primarily directed at health care organizations; however, individual providers are also encouraged to use the standards to make their practices more culturally and linguistically accessible. The principles and activities of culturally and linguistically appropriate services should be integrated throughout an organization and undertaken in partnership with the communities being served.

The 14 standards are organized by themes: Culturally Competent Care (Standards 1–3), Language Access Services (Standards 4–7), and Organizational Supports for Cultural Competence (Standards 8–14). Within this framework, there are three types of standards of varying stringency: mandates, guidelines, and recommendations as follows:

CLAS mandates are current Federal requirements for all recipients of Federal funds (Standards 4, 5, 6, and 7).

CLAS guidelines are activities recommended by OMH for adoption as mandates by Federal, State, and national accrediting agencies (Standards 1, 2, 3, 8, 9, 10, 11, 12, and 13).

CLAS recommendations are suggested by OMH for voluntary adoption by health care organizations (Standard 14).

The standards are also intended for use by:

—Policymakers, to draft consistent and comprehensive laws, regulations, and contract language. This audience would include Federal, State and local legislators, administrative and oversight staff, and program managers

—Accreditation and credentialing agencies, to assess and compare providers who say they offer culturally competent services and to assure quality for diverse populations. This audience would include the Joint Commission on Accreditation of Healthcare Organizations, the National Committee for Quality Assurance, professional organizations such as the American Medical Association and American Nurses Association, and quality review organizations such as peer review organizations

—Purchasers, to advocate for the needs of ethnic consumers of health benefits, and leverage responses from insurers and health plans. This audience would include government and employer purchasers of health benefits, including labor unions

—Patients, to understand their right to receive accessible and appropriate health care services, and to evaluate whether providers can offer them

—Advocates, to promote quality health care for diverse populations and to assess and monitor care being delivered by providers. The potential audience is wide, including legal services and consumer education/protection agencies; local and national ethnic, immigrant, and other community-focused organizations; and local and national nonprofit organizations that address health care issues.

—Educators, to incorporate cultural and linguistic competence into their curricula and to raise awareness about the impact of culture and language on health care delivery. This audience would include educators from health care professions and training institutions, as well as educators from legal and social services professions

—The health care community in general, to debate and assess the applicability and adoption of culturally and linguistically appropriate health services into standard health care practice

The CLAS standards employ key concepts that are defined as follows:

CLAS standards: The collective set of CLAS mandates, guidelines, and recommendations issued by the HHS Office of Minority Health intended to inform, guide, and facilitate required and recommended practices related to culturally and linguistically appropriate health services.

Culture: ''The thoughts, communications, actions, customs, beliefs, values, and institutions of racial, ethnic, religious, or social groups. Culture defines how health care information is received, how rights and protections are exercised, what is considered to be a health problem, how symptoms and concerns about the problem are expressed, who should provide treatment for the problem, and what type of treatment should be given. In sum, because health care is a cultural construct, arising from beliefs about the nature of disease and the human body, cultural issues are actually central in the delivery of health services treatment and preventive interventions. By understanding, valuing, and incorporating the cultural differences of America's diverse population and examining one's own health-related values and beliefs, health care organizations, practitioners, and others can support a health care system that responds appropriately to, and directly serves the unique needs of populations whose cultures may be different from the prevailing culture'' (Katz, Michael. Personal communication, November 1998).

Cultural and linguistic competence: ''Cultural and linguistic competence is a set of congruent behaviors, attitudes, and policies that come together in a system, agency, or among professionals that enables effective work in cross-cultural situations. 'Culture' refers to integrated patterns of human behavior that include the language, thoughts, communications, actions, customs, beliefs, values, and institutions of racial, ethnic, religious, or social groups. 'Competence' implies having the capacity to function effectively as an individual and an organization within the context of the cultural beliefs, behaviors, and needs presented by consumers and their communities'' (Based on Cross, T., Bazron, B., Dennis, K., & Isaacs, M., (1989). Towards A Culturally Competent System of Care Volume I. Washington, DC: Georgetown University Child Development Center, CASSP Technical Assistance Center)

Culturally and linguistically appropriate services: Health care services that are respectful of and responsive to cultural and linguistic needs.

Health care organizations: Any public or private institution involved in any aspect of delivering health care services.

Patients/consumers: Individuals, including accompanying family members, guardians, or companions, seeking physical or mental health care services, or other health-related services.

Staff: Individuals employed directly by a health care organization, as well as those subcontracted or affiliated with the organization.

1. Health Care Organizations Should Ensure That Patients/Consumers Receive From All Staff Members Effective, Understandable, and Respectful Care That Is Provided in a Manner Compatible With Their Cultural Health Beliefs and Practices and Preferred Language

This standard constitutes the fundamental requirement on which all activities specified in the other CLAS standards are based. Its intent is to ensure that all patients/consumers receiving health care services experience culturally and linguistically competent encounters with an organization's staff. The standard is relevant not only to staff, who ultimately are responsible for the kinds of interactions they have with patients, but also to their organizations, which must provide the managers, policies, and systems that support the realities of culturally competent encounters.

Respectful care includes taking into consideration the values, preferences, and expressed needs of the patient/consumer. Understandable care involves communicating in the preferred language of patients/consumers and ensuring that they understand all clinical and administrative information. Effective care results in positive outcomes for patients/consumers, including satisfaction; appropriate preventive services, diagnosis, and treatment; adherence; and improved health status.

Cultural competence includes being able to recognize and respond to health-related beliefs and cultural values, disease incidence and prevalence, and treatment efficacy. Examples of culturally competent care include striving to overcome cultural, language, and communications barriers; providing an environment in which patients/consumers from diverse cultural backgrounds feel comfortable discussing their cultural health beliefs and practices in the context of negotiating treatment options; using community workers as a check on the effectiveness of communication and care; encouraging patients/consumers to express their spiritual beliefs and cultural practices; and being familiar with and respectful of various traditional healing systems and beliefs and, where appropriate, integrating these approaches into treatment plans. When individuals need additional assistance, it may be appropriate to involve a patient advocate, case manager, or ombudsperson with special expertise in cross-cultural issues.

Ways to operationalize this standard include implementing all the other CLAS standards. For example, in accordance with Standard 3, ensure that staff and other personnel receive cross-cultural education and training, and that their skills in providing culturally competent care are assessed through testing, direct observation, and monitoring of patient/consumer satisfaction with individual staff/personnel encounters. Assessment of staff and other personnel could also be done in the context of regular staff performance reviews or other evaluations that could be included in the organizational self-assessment called for in Standard 9. Health care organizations should provide patients/consumers with information regarding existing laws and policies prohibiting disrespectful or discriminatory treatment or marketing/enrollment practices.

2. Health Care Organizations Should Implement Strategies To Recruit, Retain, and Promote at All Levels of the Organization a Diverse Staff and Leadership That Are Representative of the Demographic Characteristics of the Service Area

The diversity of an organization's staff is a necessary, but not sufficient, condition for providing culturally and linguistically appropriate health care services. Although hiring bilingual and individuals from different cultures does not in itself ensure that the staff is culturally competent and sensitive, this practice is a critical component to the delivery of relevant and effective services for all patients/consumers. Diverse staff is defined in the standard as being representative of the diverse demographic population of the service area and includes the leadership of the organization as well as its governing boards, clinicians, and administrative personnel. Building staff that adequately mirrors the diversity of the patient/consumer population should be based on continual assessment of staff demographics (collected as part of organizational self-assessment in accordance with Standard 9) as well as demographic data from the community maintained in accordance with Standard 11. Staff refers not only to personnel employed by the health care organization but also its subcontracted and affiliated personnel.

Staff diversity at all levels of an organization can play an important role in considering the needs of patients/consumers from various cultural and linguistic backgrounds in the decisions and structures of the organization. Examples of the types of staff members whose backgrounds should reflect the community's diversity include clinical staff such as doctors, nurses, and allied health professionals; support staff such as receptionists; administrative staff such as individuals in the billing department; clergy and lay volunteers; and high-level decisionmakers such as senior managers, corporate executives, and governing bodies such as boards of directors.

Acknowledging the practical difficulties in achieving full racial, ethnic, and cultural parity within the workforce, this standard emphasizes commitment and a good-faith effort rather than specific outcomes. It focuses not on numerical goals or quotas, but rather on the continuing efforts of an organization to design, implement, and evaluate strategies for recruiting and retaining a diverse staff as well as continual quality evaluation of improvements in this area. The goal of staff diversity should be incorporated into organizations' mission statements, strategic plans, and goals. Organizations should use proactive strategies, such as incentives, mentoring programs, and partnerships with local schools and employment programs, to build diverse workforce capacity. Organizations should encourage the retention of diverse staff by fostering a culture of responsiveness toward the ideas and challenges that a culturally diverse staff offers.

3. Health Care Organizations Should Ensure That Staff at All Levels and Across All Disciplines Receive Ongoing Education and Training in Culturally and Linguistically Appropriate Service Delivery

Hiring a diverse staff does not automatically guarantee the provision of culturally competent care. Staff education and training are also crucial to ensuring CLAS delivery because all staff will interact with patients/consumers representing different countries of origin, acculturation levels, and social and economic standing. Staff refers not only to personnel employed by the health care organization but also its subcontracted and affiliated personnel.

Health care organizations should either verify that staff at all levels and in all disciplines participate in ongoing CME-or CEU-accredited education or other training in CLAS delivery, or arrange for such education and training to be made available to staff. This training should be based on sound educational (*i.e.,* adult learning) principles, include pre- and post-training assessments, and be conducted by appropriately qualified individuals. Training objectives should be tailored for relevance to the particular functions

of the trainees and the needs of the specific populations served, and over time should include the following topics:

- Effects of differences in the cultures of staff and patients/consumers on clinical and other workforce encounters, including effects of the culture of American medicine and clinical training;
- Elements of effective communication among staff and patients/consumers of different cultures and different languages, including how to work with interpreters and telephone language services;
- Strategies and techniques for the resolution of racial, ethnic, or cultural conflicts between staff and patients/consumers;
- Health care organizations' written language access policies and procedures, including how to access interpreters and translated written materials;
- The applicable provisions of:

(1) Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, 45 C.F.R. 80.1 *et seq.* (including Office for Civil Rights Guidance on Title VI of the Civil Rights Act of 1964, with respect to services for (LEP) individuals (65 FR 52762–52774, August 30, 2000).

- Health care organizations' complaint/grievance procedures;
- Effects of cultural differences on health promotion and disease prevention, diagnosis and treatment, and supportive, rehabilitative, and end-of-life care;
- Impact of poverty and socioeconomic status, race and racism, ethnicity, and sociocultural factors on access to care, service utilization, quality of care, and health outcomes;
- Differences in the clinical management of preventable and chronic diseases and conditions indicated by differences in the race or ethnicity of patients/consumers; and
- Effects of cultural differences among patients/consumers and staff upon health outcomes, patient satisfaction, and clinical management of preventable and chronic diseases and conditions.

Organizations that conduct the trainings should involve community representatives in the development of CLAS education and training programs, in accordance with Standard 12.

4. Health Care Organizations Must Offer and Provide Language Assistance Services, Including Bilingual Staff and Interpreter Services, at No Cost to Each Patient/Consumer With Limited English Proficiency at All Points of Contact, in a Timely Manner During All Hours of Operation

Standards 4, 5, 6, and 7 are based on Title VI of the Civil Rights Act of 1964 (Title VI) with respect to services for limited English proficient (LEP) individuals. Title VI requires all entities receiving Federal financial assistance, including health care organizations, take steps to ensure that LEP persons have meaningful access to the health services that they provide. The key to providing meaningful access for LEP persons is to ensure effective communication between the entity and the LEP person. For complete details on compliance with these requirements, consult the HHS guidance on Title VI with respect to services for (LEP) individuals (65 FR 52762–52774, August 30, 2000) at [www.hhs.gov/ocr/lep].

Language services, as described below, must be made available to each individual with limited English proficiency who seeks services, regardless of the size of the individual's language group in that community. Such an individual cannot speak, read, or understand the English language at a level that permits him or her to interact effectively with clinical or nonclinical staff at a health care organization. (Patients needing services in American Sign Language would also be covered by this standard, although other Federal laws and regulations apply and should be consulted separately.)

Language services include, as a first preference, the availability of bilingual staff who can communicate directly with patients/consumers in their preferred language. When such staff members are not available, face-to-face interpretation provided by trained staff, or contract or volunteer interpreters, is the next preference. Telephone interpreter services should be used as a supplemental system when an interpreter is needed instantly, or when services are needed in an unusual or infrequently encountered language. The competence and qualifications of individuals providing language services are discussed in Standard 6.

5. Health Care Organizations Must Provide to Patients/Consumers in Their Preferred Language Both Verbal Offers and Written Notices Informing Them of Their Right To Receive Language Assistance Services

LEP individuals should be informed—in a language they can understand—that they have the right to free language services and that such services are readily available. At all points of contact, health care organizations should also distribute written notices with this information and post translated signage. Health care organizations should explicitly inquire about the preferred language of each patient/consumer and record this information in all records. The preferred language of each patient/consumer is the language in which he or she feels most comfortable in a clinical or nonclinical encounter.

Some successful methods of informing patients/consumers about language assistance services include: (a) using language identification or ''I speak * * *'' cards; (b) posting and maintaining signs in regularly encountered languages at all points of entry; (c) creating uniform procedures for timely and effective telephone communication between staff and LEP persons; and (d) including statements about the services available and the right to free language assistance services in appropriate non-English languages in brochures, booklets, outreach materials, and other materials that are routinely distributed to the public.

6. Health Care Organizations Must Assure the Competence of Language Assistance Provided to Limited English Proficient Patients/Consumers by Interpreters and Bilingual Staff. Family and Friends Should Not Be Used To Provide Interpretation Services (Except on Request by the Patient/Consumer)

Accurate and effective communication between patients/consumers and clinicians is the most essential component of the health care encounter. Patients/consumers cannot fully utilize or negotiate other important services if they cannot communicate with the nonclinical staff of health care organizations. When language barriers exist, relying on staff who are not fully bilingual or lack interpreter training frequently leads to misunderstanding, dissatisfaction, omission of vital information, misdiagnoses, inappropriate treatment, and lack of compliance. It is insufficient for health care organizations to use any apparently bilingual—person for delivering language services'they must assess and

ensure the training and competency of individuals who deliver such services.

Bilingual clinicians and other staff who communicate directly with patients/consumers in their preferred language must demonstrate a command of both English and the target language that includes knowledge and facility with the terms and concepts relevant to the type of encounter. Ideally, this should be verified by formal testing. Research has shown that individuals with exposure to a second language, even those raised in bilingual homes, frequently overestimate their ability to communicate in that language, and make errors that could affect complete and accurate communication and comprehension.

Prospective and working interpreters must demonstrate a similar level of bilingual proficiency. Health care organizations should verify the completion of, or arrange for, formal training in the techniques, ethics, and cross-cultural issues related to medical interpreting (a minimum of 40 hours is recommended by the National Council on Interpretation in Health Care). Interpreters must be assessed for their ability to convey information accurately in both languages before they are allowed to interpret in a health care setting.

In order to ensure complete, accurate, impartial, and confidential communication, family, friends or other individuals, should not be required, suggested, or used as interpreters. However, a patient/consumer may choose to use a family member or friend as an interpreter after being informed of the availability of free interpreter services unless the effectiveness of services is compromised or the LEP person's confidentiality is violated. The health care organization's staff should suggest that a trained interpreter be present during the encounter to ensure accurate interpretation and should document the offer and declination in the LEP person's file. Minor children should never be used as interpreters, nor be allowed to interpret for their parents when they are the patients/consumers.

7. Health Care Organizations Must Make Available Easily Understood Patient-Related Materials and Post Signage in the Languages of the Commonly Encountered Groups and/or Groups Represented in the Service Area

An effective language assistance program ensures that written materials routinely provided in English to applicants, patients/consumers, and the public are available in commonly encountered languages other than English. It is important to translate materials that are essential to patients/consumers accessing and making educated decisions about health care. Examples of relevant patient-related materials include applications, consent forms, and medical or treatment instructions; however, health care organizations should consult OCR guidance on Title VI for more information on what the Office considers to be ''vital'' documents that are particularly important to ensure translation (65 FR 52762–52774, August 30, 2000) at [www.hhs.gov/ocr/lep].

Commonly encountered languages are languages that are used by a significant number or percentage of the population in the service area. Consult the OCR guidance for guidelines regarding the LEP language groups for which translated written materials should be provided. Persons in language groups that do not fall within these guidelines should be notified of their right to receive oral translation of written materials.

Signage in commonly encountered languages should provide notices of a variety of patient rights, the availability of conflict and grievance resolution processes, and directions to facility services. Way-finding signage should identify or label the location of specific services (e.g., admissions, pediatrics, emergency room). Written notices about patient/consumer rights to receive language assistance services are discussed in Standard 5.

Materials in commonly encountered languages should be responsive to the cultures as well as the levels of literacy of patients/consumers. Organizations should provide notice of the availability of oral translation of written materials to LEP individuals who cannot read or who speak nonwritten languages. Materials in alternative formats should be developed for these individuals as well as for people with sensory, developmental, and/or cognitive impairments.

The obligation to provide meaningful access is not limited to written translations. Oral communication often is a necessary part of the exchange of information, and written materials should never be used as substitutes for oral interpreters. A health care organization that limits its language services to the provision of written materials may not be allowing LEP persons equal access to programs and services available to persons who speak English.

Organizations should develop policies and procedures to ensure development of quality non-English signage and patient-related materials that are appropriate for their target audiences. At a minimum, the translation process should include translation by a trained individual, back translation and/or review by target audience groups, and periodic updates.

It is important to note that in some circumstances verbatim translation may not accurately or appropriately convey the substance of what is contained in materials written in English. Additionally, health care organizations should be aware of and comply with existing State or local nondiscrimination laws that are not superceded by Federal requirements.

8. Health Care Organizations Should Develop, Implement, and Promote a Written Strategic Plan That Outlines Clear Goals, Policies, Operational Plans, and Management Accountability/Oversight Mechanisms To Provide Culturally and Linguistically Appropriate Services

Successful implementation of the CLAS standards depends on an organization's ability to target attention and resources on the needs of culturally diverse populations. The purpose of strategic planning is to help the organization define and structure activities, policy development, and goal setting relevant to culturally and linguistically appropriate services. It also allows the agency to identify, monitor, and evaluate system features that may warrant implementing new policies or programs consistent with the overall mission.

The attainment of cultural competence depends on the willingness of the organization to learn and adapt values that are explicitly articulated in its guiding mission. A sound strategic plan for CLAS is integrally tied to the organization's mission, operating principles, and service focus. Accountability for CLAS activities must reside at the highest levels of leadership including the governing body of the organization. Without the strategic plan, the organization may be at a disadvantage to identify and prioritize patient/consumer service need priorities.

Designated personnel or departments should have authority to implement CLAS-specific activities as well as to monitor the responsiveness of the whole organization to the cultural and linguistic needs of patients/consumers.

Consistent with Standard 12, the strategic plan should be developed with the participation of consumers, community, and staff who can convey the needs and concerns of all communities and all parts of the organization affected by the strategy.

And, consistent with Standards 9, 10, and 11, the results of data gathering and self-assessment processes should inform the development and refinement of goals, plans, and policies.

9. Health Care Organizations Should Conduct Initial and Ongoing Organizational Self-Assessments of CLAS-Related Activities and Are Encouraged To Integrate Cultural and Linguistic Competence-Related Measures Into Their Internal Audits, Performance Improvement Programs, Patient Satisfaction Assessments, and Outcomes-Based Evaluations

Ideally, these self-assessments should address all the activities called for in the 14 CLAS standards. Initial self-assessment, including an inventory of organizational policies, practices, and procedures, is a prerequisite to developing and implementing the strategic plan called for in Standard 8. Ongoing self-assessment is necessary to determine the degree to which the organization has made progress in implementing all the CLAS standards. The purpose of ongoing organizational self-assessment is to obtain baseline and updated information that can be used to define service needs, identify opportunities for improvement, develop action plans, and design programs and activities. The self-assessment should focus on the capacities, strengths, and weaknesses of the organization in meeting the CLAS standards.

Integrating cultural and linguistic competence-related measures into existing quality improvement activities will also help institutionalize a focus on CLAS within the organization. Linking CLAS-related measures with routine quality and outcome efforts may help build the evidence base regarding the impact of CLAS interventions on access, patient satisfaction, quality, and clinical outcomes.

Patient/consumer and community surveys and other methods of obtaining input are important components of organizational quality improvement activities. But they should not constitute the only method of assessing quality with respect to CLAS. When used, such surveys should be culturally and linguistically appropriate.

10. Health Care Organizations Should Ensure That Data on the Individual Patient's/Consumer's Race, Ethnicity, and Spoken and Written Language Are Collected in Health Records, Integrated Into the Organization's Management Information Systems, and Periodically Updated

The purposes of collecting information on race, ethnicity, and language are to:

- Adequately identify population groups within a service area;
- Ensure appropriate monitoring of patient/consumer needs, utilization, quality of care, and outcome patterns;
- Prioritize allocation of organizational resources;
- Improve service planning to enhance access and coordination of care; and
- Assure that health care services are provided equitably.

Collection of data on self-identified race/ethnicity should adhere to the standard procedures and racial and ethnic categories specified in the Office of Management and Budget's most current policy directive and adapted in the U.S. Census 2000. To improve the accuracy and reliability of race and ethnic identifier data, health care organizations should adapt intake and registration procedures to facilitate patient/consumer self-identification and avoid use of observational/visual assessment methods whenever possible. Individuals should be allowed to indicate all racial and ethnic categories that apply. Health care organizations can enhance their information on subpopulation differences by collecting additional identifiers such as self-identified country of origin, which provides information relevant to patient/consumer care that is unobtainable from other identifiers.

The purpose of collecting information on language is to enable staff to identify the preferred mode of spoken and written communication that a patient/consumer is most comfortable using in a health care encounter. Language data also can help organizations develop language services that facilitate LEP patients/consumers receiving care in a timely manner. To improve the accuracy and reliability of language data, health care organizations should adapt procedures to document patient/consumer preferred spoken and written language. Written language refers to the patient/consumer preference for receiving health-related materials. Data collected on language should include dialects and American Sign Language.

For health encounters that involve or require the presence of a legal parent or guardian who does not speak English (e.g., when the patient/consumer is a minor or severely disabled), the management information system record and chart should document the language not only of the patient/consumer but also of the accompanying adult(s).

Health care organizations should collect data from patients/consumers at the first point of contact using personnel who are trained to be culturally competent in the data collection process. Health care organizations should inform patients/consumers about the purposes (as stated above) of collecting data on race, ethnicity, and language, and should emphasize that such data are confidential and will not be used for discriminatory purposes. No patient/consumer should be required to provide race, ethnicity, or language information, nor be denied care or services if he or she chooses not to provide such information. All patient/consumer data should be maintained according to the highest standards of ethics, confidentiality, and privacy, and should not be used for discriminatory purposes.

11. Health Care Organizations Should Maintain a Current Demographic, Cultural, and Epidemiological Profile of the Community as Well as a Needs Assessment to Accurately Plan for and Implement Services That Respond to the Cultural and Linguistic Characteristics of the Service Area

The purpose of this standard is to ensure that health care organizations obtain a variety of baseline data and update the data regularly to better understand their communities, and to accurately plan for and implement services that respond to the cultural and linguistic characteristics of the service area.

Health care organizations should regularly use a variety of methods and information sources to maintain data on racial and ethnic groups in the service area. It is important that health care organizations go beyond their own data, such as marketing, enrollment, and termination figures, which may provide an incomplete portrait of the potential patient/consumer population, many of whom may not be aware of or use the organization's services. A more useful and in-depth approach would use data sources such as census figures and/or adjustments, voter registration data, school enrollment profiles, county and State health status reports, and data from community agencies and organizations. Both quantitative and qualitative methods should be used to determine cultural factors related to

patient/consumer needs, attitudes, behaviors, health practices, and concerns about using health care services as well as the surrounding community's resources, assets, and needs related to CLAS. Methods could include epidemiological and ethnographic profiles as well as focus groups, interviews, and surveys conducted in the appropriate languages spoken by the patient/consumer population. Health care organizations should not use the collected data for discriminatory purposes.

In accordance with Standard 12, health care organizations should involve the community in the design and implementation of the community profile and needs assessment.

12. Health Care Organizations Should Develop Participatory, Collaborative Partnerships With Communities and Utilize a Variety of Formal and Informal Mechanisms to Facilitate Community and Patient/Consumer Involvement in Designing and Implementing CLAS—Related Activities

The culturally competent organization views responsive service delivery to a community as a collaborative process that is informed and influenced by community interests, expertise, and needs. Services that are designed and improved with attention to community needs and desires are more likely to be used by patients/consumers, thus leading to more acceptable, responsive, efficient, and effective care. As described below, this standard addresses two levels of consumer/patient and community involvement that are not token in nature, but involve working with the community in a mutual exchange of expertise that will help shape the direction and practices of the health care organization.

Patients/consumers and community representatives should be actively consulted and involved in a broad range of service design and delivery activities. In addition to providing input on the planning and implementation of CLAS activities, they should be solicited for input on broad organizational policies, evaluation mechanisms, marketing and communication strategies, staff training programs, and so forth. There are many formal and informal mechanisms available for this, including participation in governing boards, community advisory committees, ad hoc advisory groups, and community meetings as well as informal conversations, interviews, and focus groups.

Health care organizations should also collaborate and consult with community-based organizations, providers, and leaders for the purposes of partnering on outreach, building provider networks, providing service referrals, and enhancing public relations with the community being served.

Related to Standard 11, health care organizations should involve relevant community groups and patients/consumers in the implementation of the community profile and needs assessment.

13. Health Care Organizations Should Ensure That Conflict and Grievance Resolution Processes Are Culturally and Linguistically Sensitive and Capable of Identifying, Preventing, and Resolving Cross-Cultural Conflicts or Complaints by Patients/Consumers

This standard requires health care organizations to anticipate and be responsive to the inevitable cross-cultural differences that arise between patients/consumers and the organization and its staff. Ideally, this responsiveness may be achieved by integrating cultural sensitivity and staff diversity into existing complaint and grievance procedures as well as into policies, programs, offices or committees charged with responsibility for patient relations, and legal or ethical issues. When these existing structures are inadequate, new approaches may need to be developed. Patients/consumers who bring racial, cultural, religious, or linguistic differences to the health care setting are particularly vulnerable to experiencing situations where those differences are not accommodated or respected by the health care institution or its staff. These situations may range from differences related to informed consent and advanced directives, to difficulty in accessing services or denial of services, to outright discriminatory treatment. Health care organizations should ensure that all staff members are trained to recognize and prevent these potential conflicts, and that patients are informed about and have access to complaint and grievance procedures that cover all aspects of their interaction with the organization. In anticipation of patients/consumers who are not comfortable with expressing or acting on their own concerns, the organization should have informal and formal procedures such as focus groups, staff-peer observation, and medical record review to identify and address potential conflicts.

Among the steps health care organizations can take to fulfill this standard are: providing cultural competence training to staff who handle complaints and grievances or other legal or ethical conflict issues; providing notice in other languages about the right of each patient/consumer to file a complaint or grievance; providing the contact name and number of the individual responsible for disposition of a grievance; and offering ombudsperson services. Health care organizations should include oversight and monitoring of these culturally or linguistically related complaints/grievances as part of the overall quality assurance program for the institution.

14. Health Care Organizations Are Encouraged to Regularly Make Available to the Public Information About Their Progress and Successful Innovations in Implementing the CLAS Standards and To Provide Public Notice in Their Communities About the Availability of This Information

Sharing information with the public about a health care organization's efforts to implement the CLAS standards can serve many purposes. It is a way for the organization to communicate to communities and patients/consumers about its efforts and accomplishments in meeting the CLAS standards. It can help institutionalize the CLAS standards by prompting the organization to regularly focus on the extent to which it has implemented each standard. It also can be a mechanism for organizations to learn from each other about new ideas and successful approaches to implementing CLAS.

Health care organizations can exercise considerable latitude in both the information they make available and the means by which they report it to the public. For example, organizations can describe specific organizational changes or new programs that have been instituted in response to the standards, CLAS-related interventions or initiatives undertaken, and/or accomplishments made in meeting the needs of diverse populations. Organizations that wish to provide more in-depth information can report on the data collected about the populations and communities served in accordance with Standard 11 and the self-assessment results gathered from Standard 9. Organizations should not report scores or use data from self-assessment tools that have not been validated. However, as standard self-assessment instruments and performance measures are developed and validated, additional information gathered by using these tools could be made available to the public.

Health care organizations can use a variety of methods to communicate or report information about progress in implementing the CLAS standards, including publication of stand-alone documents focused specifically on cultural and linguistic competence or

inclusion of CLAS components within existing organizational reports and documents. Other channels for sharing this information include the organization's member publications; newsletters targeting the communities being served; presentations at conferences; newspaper articles; television, radio, and other broadcast media; and postings on Web sites.

The complete report, along with supporting material, is available online at www.OMHRC.gov/clas.

Dated: December 15, 2000.

Nathan Stinson, Jr.,

Deputy Assistant Secretary for Minority Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control And Prevention

[60Day–01–12]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506 (c)(2)(A) of the Paperwork reduction Act of 1995, the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Applying Schema Matching to Latex Allergy Prevention -NEW- National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention.

This project is a 3-year study that will investigate whether application of schema correspondence theory will increase the effectiveness of NIOSH natural rubber latex (NRL) allergy information brochures. Allergy to NRL has been identified as a significant health risk among workers using latex gloves. NRL allergy may involve the skin (redness, hives, or itching) and/or the respiratory track (runny nose, itchy eyes, sneezing, asthma). Reactions to NRL range from mild to severe enough to require medical attention. In rare instances, anaphylaxis (shock) can occur. A number of studies suggest prevalence of NRL sensitization among healthcare workers ranging from 5–12%. Non-healthcare workers are also at risk for NRL allergy. Prevalence rates of up to 7% for antibodies to NRL allergy have been reported among the general population.

In 1997, NIOSH published Alert: Preventing allergic reactions to natural rubber latex in the workplace. Despite the importance of such NIOSH recommendations, it is unclear how relevant this information is perceived to be by workers. Contemporary models of persuasion consider message relevance to be crucial in determining whether a message will be carefully thought about. Schema correspondence theory proposes that increasing the number of elements in a health and safety message that members of an occupational group can identify with should increase its relevance to that group. Messages are more effective, when individuals can think about themselves as they are presented with the information.

Message development and occupational group selection for this project will be guided by Holland's Career Typology Theory. This theory postulates that both individuals and occupations may be described in terms of six primary work personality types, each of which is characterized by a distinctive clustering of work-related interests, values and activities. One occupational group from each of the six primary Holland types will be targeted in this study. These groups are: police officers, veterinary assistants, hairstylists, childcare workers, and food service workers. Occupational group specific information, such as work-related interests, values, and activities, will be combined with NRL allergy information to produce brochures tailored for each of the six groups. The effectiveness of the tailored NRL brochures developed by this study will be compared with a ''generic'', untailored NRL brochure, with the existing NIOSH NRL allergy brochure, Latex Allergy: A Prevention Guide, and with a NRL allergy brochure currently under development by another NIOSH research project.

In a Pretesting Phase, workers will assess statements that will be used to develop the study brochures. These brochures will be assessed in a small scale Pilot Study using samples from each of the six occupational groups. The tailored brochures will be finalized and assessed in a full scale Field Study using samples from each of the six occupational groups. Participants will be asked to read the brochures that have been tailored for their occupational group and then to complete attitude and behavior surveys immediately, and at one and three month follow ups.

This study will contribute significantly to the knowledge concerning the application of schema matching theory to occupational safety and health information. In addition, this study will also provide valuable information regarding the effectiveness of text-based occupational safety and health interventions over time. If proven successful, schema matching could be used by NIOSH to increase the effectiveness of a wide range of occupational safety and health communications. Based on an average hourly wage of $10.00 among all occupational groups combined, the total annual cost to respondents is $16,225. This is a 3-year study.

Phase	Number of respondents	Number of responses per respondent	Average time burden (hours) per response	Total burden (hours)
Pretesting	180	1	2.0	360