

Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 10, 2006.

A. Federal Reserve Bank of Chicago (Patrick M. Wilder, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Jay Elliot Bell*, Chicago, Illinois; to acquire voting shares of Rochester State Bankshares, Inc., Rochester, Illinois, and thereby indirectly acquire voting shares of Rochester State Bank, Rochester, Illinois.

Board of Governors of the Federal Reserve System, December 20, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E5-7762 Filed 12-22-05; 8:45 am]

BILLING CODE 6210-01-S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the

standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center Web site at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 17, 2006.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *Harbor Bank Group, Inc.*, Charleston, South Carolina; to become a bank holding company by acquiring 100 percent of the voting shares of Harbor National Bank, Charleston, South Carolina (in organization).

B. Federal Reserve Bank of Kansas City (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *First Community Bancshares, Inc.*, Overland Park, Kansas; to acquire 100 percent of the voting shares of Corning Investment Company, Inc., Centralia, Kansas, and thereby indirectly acquire The Farmers State Bank of Corning, Corning, Kansas.

C. Federal Reserve Bank of San Francisco (Tracy Basinger, Director, Regional and Community Bank Group) 101 Market Street, San Francisco, California 94105-1579:

1. *Wells Fargo and Company*, San Francisco, California; to acquire 100 percent of the voting shares of Martinus Corporation, Rogers, Minnesota, and thereby indirectly acquire State Bank of Rogers, Rogers, Minnesota.

Board of Governors of the Federal Reserve System, December 19, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E5-7730 Filed 12-22-05; 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 Web site 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, 2006.

A. Federal Reserve Bank of Chicago (Patrick M. Wilder, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Iowa State Bank Holding Company*, Des Moines, Iowa; for prior approval to hold real estate for the purpose of economic development pursuant to Section 225.28(b)(12)(i) of Regulation Y.

Board of Governors of the Federal Reserve System, December 19, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E5-7731 Filed 12-22-05; 8:45 am]

BILLING CODE 6210-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[CMS-0015-N]

RIN 0938-ZA62

Consolidated Health Informatics (CHI) Initiative; Health Care and Vocabulary Standards for Use in Federal Health Information Technology Systems

AGENCY: Office of the Secretary (OS), HHS.

ACTION: Notice.

SUMMARY: This notice identifies the 20 messaging and vocabulary standards adopted for use in Federal government health information technology systems. The first set of 5 standards was adopted on March 21, 2003. The second set of 15 standards was adopted on May 6, 2004, thus completing the initial portfolio of

the Consolidated Health Informatics (CHI) initiative.

FOR FURTHER INFORMATION CONTACT:
Cheryl Ford, (410) 786-7415.

SUPPLEMENTARY INFORMATION:

I. Background

The Consolidated Health Informatics (CHI) initiative began in October 2001 as one of 24 E-Government initiatives included in the President's Management Agenda (PMA). The CHI initiative is a collaborative effort to adopt Federal government-wide health information interoperability standards to be implemented by Federal agencies in order to enable the Federal government to exchange electronic health information.

On May 6, 2004, the Secretary of the Department of Health and Human Services (HHS) announced the adoption by HHS, the Department of Defense, the Department of Veterans Affairs, the Office of Management and Budget, and other participating Federal partners of 15 healthcare messaging and vocabulary standards recommended by the CHI initiative (<http://www.hhs.gov/news/press/2004pres/20040506.html>). The adoption of these standards supplemented the first 5 standards adopted on March 21, 2003 (<http://www.hhs.gov/news/press/2003pres/20030321a.html>), thereby completing the initial CHI portfolio.

The portfolio of 20 adopted standards will be used by all Federal agencies in implementing new, and to the extent possible, in modifying existing health information technology systems, as well as related business processes.

II. CHI Adopted Standards

As a result of work completed in furtherance of CHI, the 20 clinical standards that have been adopted for use by all Federal agencies as they develop and implement new information technology systems are as follows:

1. Laboratory Results Names. Standard: Logical Observation Identifiers Names and Codes (LOINC®).
2. Messaging Standards. Includes: Scheduling, medical record/image management, patient administration, observation reporting, financial management, public health notification, and patient care. Standard: Health Level Seven® (HL7®) Version 2.3 and greater.
3. Messaging Standards. Includes: Retail pharmacy transactions. Standard: National Council for Prescription Drug Programs (NCPDP) SCRIPT®.
4. Messaging Standards. Includes: Device-device connectivity. Standard: Institute of Electrical and Electronics Engineers, Inc.™ 1073.

5. Messaging Standards. Includes: Image information to workstations. Standard: Digital Imaging and Communications in Medicine® (DICOM®).

6. Demographics. Standard: HL7® Version 2.4 and greater.

7. Lab Result Contents. Standard: Systematized Nomenclature of Medicine Clinical Terms® (SNOMED CT®).

8. Units of Measure. Standard: HL7® Version 2.X+.

9. Immunizations. Standard: HL7® Version 2.3.1, specifically the Vaccines Administered (CVX) and Manufacturers of Vaccines (MVX) external code sets maintained by the Centers for Disease Control and Prevention's (CDC) National Immunization Program (NIP).

10. Medications. Standards: Federal Drug Terminologies: (Sub-domain: Standard Adopted):

- *Active Ingredient:* FDA Established Names & Unique Ingredient Identifier (UNII) codes.
- *Manufactured Dosage Form:* FDA/CDER Data Standards Manual.
- *Drug Product:* FDA's National Drug Codes (NDC).
- *Medication Package:* FDA Standards Manual.
- *Label Section Headers:* LOINC® Clinical Structured Product Labeling (SPL).

• *Special Populations:* HL7 Version 2.4 and greater.

• *Drug Classifications:* The Department of Veterans Affairs' National Drug File Reference Terminology (NDF-RT) for mechanism of action and physiologic effect.

• *Clinical Drug:* the National Library of Medicine's RxNorm.

11. Interventions/Procedures (Part A): Lab Test Order Names. Standard: LOINC®.

12. Interventions/Procedures (Part B): Non-laboratory. Standard: SNOMED CT®.

13. Anatomy. Standards: SNOMED CT® and the National Cancer Institute's (NCI) Thesaurus.

14. Diagnosis/Problem Lists. Standard: SNOMED CT®.

15. Nursing. Standard: SNOMED CT®.

16. Financial/Payment. Standard: HIPAA Transactions and Code Sets.

17. Genes. Standard: Human Genome Nomenclature.

18. Clinical Encounters. Standard: HL7® Version 2.4 and greater.

19. Text-Based Reports. Standards: HL7® and Clinical Document Architecture (CDA) Version 1.0-2000 Chemicals.

20. Chemicals. Standard: Environmental Protection Agency's Substance Registry System.

Specific details of these CHI standards can be obtained from the domain-

specific full reports available for download at: <http://www.hhs.gov/healthit/chi.html>.

III. Collection of Information Requirements

This notice does not impose information collection and recordkeeping requirements regulated by the Paperwork Reduction Act of 1995; that is, it does not require obtaining facts or opinions or answers to questions by or for a Federal agency. Consequently, it need not be reviewed by the Office of Management and Budget under 44 U.S.C. 35.

IV. Impact Statement

We have chosen to explain the impact we foresee this notice having on the public as follows: There are indirect impacts for Federal contractors or potential contractors who may be involved in health information technology design, development, or evaluation. The Federal government will require all future health information technology system acquisitions to be based on CHI standards when applicable, whether system development occurs within the Agency or through the use of contractor services.

Authority: The E-Government Act of 2002 (Pub. L. 107-347) (H.R. 2458)

Dated: September 13, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 25, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05-24289 Filed 12-22-05; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10170]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, NHLBI Patient-Oriented Research and Career Enhancement Award for Stem Cell Research.

Date: December 21, 2007.

Time: 9 a.m. to 11 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, 7192, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mark Roltsch, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892-7924, 301-435-0287, roltschm@nhlbi.nih.gov.

This notice is being published less than 15 days prior to meeting due to the timing limitations imposed by the review and funding cycle.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: December 10, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-6053 Filed 12-14-07; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Additional Consolidated Health Information (CHI) Health Information Technology Standards

AGENCY: Federal Health Architecture (FHA), Office of the National Coordinator for Health Information Technology (ONC).

ACTION: Notice: Additional Consolidated Health Informatics (CHI) Health Information Technology Standards.

SUMMARY: This notice identifies three (3) additional Consolidated Health Informatics (CHI) messaging and vocabulary standards (Multimedia, Allergy, and Disability and Assessments) adopted for use in Federal government health information technology systems. This work supplements the work to further the adoption of the first set of 5 standards adopted on March 21, 2003 and second set of 15 standards adopted on May 6, 2004, as published in the December 23, 2005 *Federal Register* (70 FR 76287).

The CHI initiative began in October 2001 as one of 24 E-Government initiatives included in the President's Management Agenda (PMA). The CHI collaborative worked to adopt Federal government-wide health information interoperability standards to be implemented by Federal agencies in order to enable the Federal government to exchange electronic health information. By publication of this document, we are informing the public of the adoption of three new CHI standards, Multimedia, Allergy and Disability and Assessment (adoption reports available at: <http://www.hhs.gov/healthit/chiinitiative.html>).

CHI Adopted Standards

As a result of work completed in furtherance of CHI, the three new domain areas and associated clinical standards that have been adopted are noted in the individual standards adoption reports found at <http://www.hhs.gov/healthit/chiinitiative.html> and are summarized below:

1. *Multimedia Messaging Standard:*
 - National Electrical Manufacturer's Association (NEMA) Digital Imaging and Communications in Medicine (DICOMSM) 2004 Standard and higher.

2. *Allergy Messaging and Vocabulary Standard:*

- Health Level Seven (HL7[®]) HL7[®] 2.4 and higher messaging standard allergy information segments.
- College of American Pathologists (CAP) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT[®]) for allergy type, severity and reaction codes.
- National Library of Medicine (NLM) RxNorm for brand name allergen code.
- Food and Drug Administration (FDA) Unique Ingredient Identifier (UNII) codes for ingredient name allergen code.
- Department of Veteran Affairs (VA) National Drug File-Reference Terminology (NDF-RT) for drug class allergen code.
- 3. *Disability and Assessments:*
 - Regenstrief Institute, Inc LOINC[®] (Logical Observation Identifiers Names and Codes[®]) representation and codes for questions and answers on federally-required assessment forms;
 - CHI-endorsed semantic vocabulary matches linked with the LOINC[®] assessment questions and answers; and
 - HL7[®] v2.4 and higher messaging standard and the HL7[®] CDA (Clinical Document Architecture (CDA)) for exchanging standardized federally-required assessment content.

SUPPLEMENTARY INFORMATION: In 2006, the CHI initiative was transitioned to the Federal Health Architecture (FHA) under the Office of the National Coordinator for Health IT (ONC). Currently, the CHI standards are being coordinated with the public/private processes of Healthcare Information Technology Standards Panel (HITSP).

HITSP serves as a cooperative partnership between the public and private sectors for the purpose of achieving a widely accepted and useful set of standards specifically to enable and support widespread interoperability among healthcare software systems, as they will interact in a local, regional, and nationwide health information network.

CHI endorsement has been identified as one of the HITSP standards adoption criteria employed to adopt standards for the HITSP Interoperability Specifications. The HITSP Interoperability Specifications are developed to advance the national agenda for secure, interoperable health information systems. (Notice of Availability, 72 FR. 9339 (March 1, 2007).

Collection of Information Requirements

This notice does not impose information collection and recordkeeping requirements subject to

review the paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

Impact Statement

We foresee this notice having the following indirect effects upon the public: This notice will result in indirect impacts for Federal contractors or potential contractors who may be involved in health information technology design, development, or evaluation. The Federal government will require all future federal health information acquisitions to be based on CHI standards when applicable and as permitted by law, whether system development occurs within the Agency or through use of contractor services.

FOR FURTHER INFORMATION CONTACT: Vish Sankaran—(202) 205–2761.

Authority: The E-Government Act of 2002 (Pub. L. 107–347) (H.R. 2458).

Dated: December 7, 2007.

Robert M. Kolodner,

National Coordinator for Health Information Technology, Office of the National Coordinator for Health Information Technology.

[FR Doc. 07–6058 Filed 12–14–07; 8:45 am]

BILLING CODE 4150–45–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health; Decision To Evaluate a Petition To Designate a Class of Employees at the Pantex Plant, Amarillo, TX, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees at the Pantex Plant, Amarillo, Texas, to be included in the Special Exposure Cohort under the Energy Employees

Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Pantex Plant.

Location: Amarillo, Texas.

Job Titles and/or Job Duties:

Production workers, technicians, including radiography, guards, physical plant, maintenance, administrative and support staff, contractors, and Atomic Energy Commission staff.

Period of Employment: January 1, 1950 through December 31, 1991.

FOR FURTHER INFORMATION CONTACT:

Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to OCAS@CDC.GOV.

Dated: December 10, 2007.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. E7–24427 Filed 12–14–07; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30–Day–08–0338]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–4766 or send an e-mail to omb@cdc.gov. Send written

comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S.—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The oral use of smokeless tobacco (SLT) products represents a significant health risk which can cause cancer and a number of non-cancerous oral conditions, and can lead to nicotine addiction and dependence. Furthermore, SLT use is not a safe substitute for cigarette smoking. The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 *et seq.*, P. L. 99–252) requires each person who manufactures, packages, or imports smokeless tobacco (SLT) to provide the Secretary of Health and Human Services (HHS) with a list of ingredients added to tobacco in the manufacture of smokeless tobacco products. This legislation also authorizes HHS to undertake research, and submit an annual report to Congress (as deemed appropriate) discussing the health effects of these ingredients in smokeless tobacco products. HHS has delegated responsibility for the implementation of this Act to CDC’s Office on Smoking and Health (OSH). Respondents report the required information to CDC once per year according to Tobacco Ingredient and Nicotine Reporting instructions posted on the OSH Web site. Changes effective with this reinstatement relate to the redesign of the OSH Web site. There are no costs to respondents other than their time. The total estimated annualized burden hours are 18,843.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Smokeless Tobacco Manufacturers, Packagers, and Importers	11	1	1,713



U.S. Department of Health and Human Services Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status

October 2011

This guidance is available on the Internet at:
<http://aspe.hhs.gov/datacncl/standards/ACA/4302>

[Printer friendly version in PDF format](#) (10 pages)
[Free PDF reader](#)

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I. Purpose and Background

Purpose

The purpose of this guidance is to promulgate a set of uniform data collection standards for inclusion in surveys conducted or sponsored by HHS as required by Section 4302 of the Affordable Care Act.

Background

HHS reports, dating back to the landmark 1985 Secretary's Task Force on Black and Minority Health, emphasize the importance of timely and reliable data to assist in identifying racial and ethnic health disparities, in understanding the causes and correlates of disparities, and in monitoring progress in reducing them. HHS has a long commitment to developing such data, best exemplified by the 1997 HHS Data Inclusion policy, which required the collection of uniform standard data on race and ethnicity in all HHS-sponsored data collection activities.

Data improvement efforts enhance the ability of the public health and healthcare systems to identify and track disparities in health and health care, understand their correlates and consequences, and facilitate greater accountability for reducing them. However, the lack of standards related to data collection on vulnerable population subgroups remains a challenge for adequately collecting, reporting, and tracking data on health disparities.

Overview of Section 4302 of the Affordable Care Act

The Affordable Care Act (ACA) includes several provisions aimed at eliminating health disparities in America. Section 4302 (Understanding health disparities: data collection and analysis) of the ACA focuses on the standardization, collection, analysis, and reporting of health disparities data. While data alone will not reduce disparities, it can be foundational to our efforts to understand the causes, design effective responses, and evaluate our progress.

Section 4302 requires the Secretary of DHHS to establish data collection standards for race, ethnicity, sex, primary language, and disability status. The law requires that, once established, these data collection standards be used, to the extent practicable, in all national

population health surveys. In response to this statutory requirement, this implementation guidance outlines the new minimum data collection standards for race, ethnicity, sex, primary language and disability status for implementation in HHS, along with a description of the data standards development process, the rationale for each data standard, and instructions for their implementation.

II. Data Standards Development Process

Under the auspices of the ACA Prevention Implementation Workgroup and the Section 4302 Implementation Subgroup, the HHS Data Council was asked to recommend data standards for race, ethnicity, sex, primary language and disability status to support the implementation of Section 4302 of the Affordable Care Act. The HHS Data Council is the principal, senior internal Departmental forum and advisory body to the Secretary on health and human services data policy and coordinates HHS data collection and analysis activities. A special workgroup within the Data Council, the Section 4302 Standards Workgroup, was formed to lead this task. The Workgroup included representatives from HHS, the Office of Management and Budget (OMB), and the Census Bureau. The Workgroup examined current federal data collection standards, adequacy of prior testing, and quality of the data produced in prior surveys; consulted with statistical agencies and programs; reviewed OMB data collection standards and the Institute of Medicine (IOM) Report *Race, Ethnicity, and Language Data Collection: Standardization for Health Care Quality Improvement*, and built on its members' experience with collecting and analyzing demographic data.¹¹

The following criteria guided development for data standards for each of the five required variables:

1. Data standards would be evidence-based and demonstrated to have worked well in practice for national survey data collection.
2. Data standards would be framed as minimum data standards, with agencies permitted to include as many additional questions on these topics as desired as long as the minimum standard is included. Agencies would also be permitted to include additional response categories for data standards with as much additional detail and granularity as desired, provided that the additional detail could be aggregated back to the minimum standard and the sample design and sample size support estimates at that level of granularity.
3. The data standards would comply at a minimum, with any standards already mandated by OMB.
4. Data standards are for person-level data collected in population-based health surveys, where subjects either self-report information or a knowledgeable proxy provides information about the subject or responds for all persons in a household.

A draft set of data collection standards were developed, subjected to several levels of internal review, and then published for public comment. This policy guidance reflects the final set of data collection standards and supporting guidance for implementation.

III. Data Collection Standards and Rationale for Selection

A. Race and Ethnicity

The starting point for the race and ethnicity data collection standards is OMB's current government-wide standard, issued in 1997 after a comprehensive public engagement process and extensive field testing. The principles underlying these government-wide standards are described below. The justifications for these principles are described by OMB in detail at http://www.whitehouse.gov/omb/fedreg_1997standards/.

- Self-identification is the preferred means of obtaining information about an individual's race and ethnicity, except in instances where observer identification is more practical. The surveyor should not tell an individual who he or she is, or specify how an individual should classify himself or herself.
- To provide flexibility and ensure data quality, separate questions for race and ethnicity should be used wherever feasible. Specifically, when self-reporting or other self-identification approaches are used, ethnicity is asked first, and then race. The standard acknowledges that this standard might not work in other contexts (e.g., administrative records.)
- The specified race and ethnicity categories provide a minimum set of categories except when the collection involves a sample of such size that the data on the smaller categories would be unreliable, or when the collection effort focuses on a specific racial or ethnic group.
 - The OMB minimum categories for race are: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White.
 - The OMB minimum categories for ethnicity are: Hispanic or Latino and Not Hispanic or Latino.
- When self-reporting or other self-identification approaches are used, respondents who wish to identify their multi-racial heritage may choose more than one race; there is no "multi-racial" category.
- OMB encourages additional granularity where it is supported by sample size and as long as the additional detail can be aggregated back to the minimum standard set of race and ethnicity categories.
- Any other variation will have to be specifically authorized by the OMB through the information collection clearance process. In those cases where the data collection is not subject to the information collection clearance process, a direct request for a variance should be made to OMB.

The categories for HHS data standards for race and ethnicity are based on the disaggregation of the OMB standard used in the American Community Survey (ACS) and the 2000 and 2010 Decennial Census. The data standard for race and ethnicity is listed below. Race and ethnicity data collection applies to survey participants of all ages.

Ethnicity Data Standard
Are you Hispanic, Latino/a, or Spanish Origin?
(One or more categories may be selected)

Categories	Notes
a. ____ No, not of Hispanic, Latino/a, or Spanish origin	These categories roll-up to the Hispanic or Latino category of the OMB standard
b. ____ Yes, Mexican, Mexican American, Chicano/a	
c. ____ Yes, Puerto Rican	
d. ____ Yes, Cuban	
e. ____ Yes, Another Hispanic, Latino/a or Spanish origin	

Race Data Standard

What is your race?

(One or more categories may be selected)

Categories	Notes
a. <input type="checkbox"/> <i>White</i>	These categories are part of the current OMB standard
b. <input type="checkbox"/> <i>Black or African American</i>	
c. <input type="checkbox"/> <i>American Indian or Alaska Native</i>	
d. <input type="checkbox"/> <i>Asian Indian</i>	These categories roll-up to the Asian category of the OMB standard
e. <input type="checkbox"/> <i>Chinese</i>	
f. <input type="checkbox"/> <i>Filipino</i>	
g. <input type="checkbox"/> <i>Japanese</i>	
h. <input type="checkbox"/> <i>Korean</i>	
i. <input type="checkbox"/> <i>Vietnamese</i>	
j. <input type="checkbox"/> <i>Other Asian</i>	These categories roll-up to the Native Hawaiian or Other Pacific Islander category of the OMB standard
k. <input type="checkbox"/> <i>Native Hawaiian</i>	
l. <input type="checkbox"/> <i>Guamanian or Chamorro</i>	
m. <input type="checkbox"/> <i>Samoan</i>	
n. <input type="checkbox"/> <i>Other Pacific Islander</i>	

Rationale for Race and Ethnicity Data Standard

As a result of the 1997 HHS data inclusion policy, the basic OMB standard is already included in most HHS data collection initiatives. The new HHS data standards for race and ethnicity include additional granularity, but all categories roll-up to the OMB standard. However, because additional granularity in the race and ethnicity categories is important for documenting and tracking health disparities, large federal surveys such as the National Health Interview Survey (NHIS), Current Population Survey (CPS), and the ACS have implemented such a more granular strategy, particularly for Hispanic and Asian subpopulations.

Accordingly, the new data standards for race and ethnicity are a slightly modified version of the ACS and Decennial Census questions. These items provide additional granularity for Hispanic (four additional categories) and Asian subpopulations (7 additional categories) beyond the OMB minimum standard categories. The race and ethnicity categories for the ACS and recent Decennial Census have been tested and structured to increase response rates, validity, and reliability.^[iii] The more detailed ACS and recent Decennial Census race categories roll up to the OMB standard five categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. As with OMB standards, respondents are also instructed to mark all categories that apply (i.e. they may be able to select more than one racial category). The ACS and Decennial Census ethnicity categories roll up to the OMB standard categories: Hispanic or Latino and Not Hispanic or Latino.^[iii, iv] Respondents are also able to select more than one ethnicity category. The recommended standard is in conformance with the methods, logistics, practices and limitations of HHS major surveys, where population estimates are the goal.

HHS agencies may request permission from OMB during the Paperwork Reduction Act clearance process to add a write-in option of "other" to interviewer-administered surveys. This respondent-specified race must then be coded by the agency to the OMB and HHS standards before results are publically reported.

B. Sex

The data standard for sex is male and female. Sex data collection applies to survey participants of all ages.

Sex Data Standard

What is your sex?

- a. *Male*
- b. *Female*

Rationale for Sex Data Standard

For the purpose of this report, the category of sex was defined as biologic sex. Sexual orientation and gender identity were considered as separate concepts. The Department has developed a data progression plan for collecting sexual orientation data and has conducted gender identity data collection listening sessions.

C. Primary Language

The standard for primary language is a measure of English proficiency. The recommended question is based on that used on the ACS. The question applies to survey participants aged five years and above.

Data Standard for Primary Language

How well do you speak English? (5 years old or older)

- a. *Very well*
- b. *Well*
- c. *Not well*

d. _____ Not at all

The primary language data standard represents a minimum standard and the question and answer categories cannot be changed. Additional questions on language may be added to any survey as long as the minimum standard is included.

Optional Granularity

For agencies that wish to collect data on the specific language spoken, the Data Council recommends collecting data on language spoken at home. The recommended survey items are used in the ACS (see below). Collecting this additional information would be optional and at the discretion of the agency, if information on specific language was desired.

1. Do you speak a language other than English at home? (5 years old or older)

- a. _____ Yes
b. _____ No

For persons speaking a language other than English (answering yes to the question above):

2. What is this language? (5 years old or older)

- a. _____ Spanish
b. _____ Other Language (Identify)

For agencies that desire to collect information on specific languages beyond Spanish, and have sufficient sample sizes to support such estimates, HHS would publish on the HHS website a list of the ten most prevalent languages spoken in the U.S., as reported by ACS. These would roll up to the "Other Language" category, and provide technical notes to assist in coding. Spanish as a category is reported about 60 percent of the time in the ACS.[LV](#)

Rationale for Primary Language Data Standard

The survey item selected for the minimum standard is based on the ACS, which assesses both English proficiency and language spoken other than English, and has been collected by the Census Bureau since 1980.

For statistical, planning, analytical and research purposes, disparities have been associated with English language proficiency rather than specific language spoken. For clinical purposes relating to an individual, specific language and proficiency would both be needed. This recommendation is consistent with language recommendations from the Institute of Medicine report *Race, Ethnicity, and Language Data Collection: Standardization for Health Care Quality Improvement*.

Several HHS surveys currently collect data on language or English proficiency primarily in the preliminary screening phase of in person or telephone interview surveys for administrative purposes in surveys, to determine how or in what language the interview would be administered. It is not the intent of this standard to disrupt those screening practices.

D. Disability Status

The six item set of questions used on ACS and other major surveys to gauge disability is the data standard for survey questions on disability. Note the age thresholds for survey participants for the different disability questions.

Data Standard for Disability Status**1. Are you deaf or do you have serious difficulty hearing?**

- a. _____ Yes
b. _____ No

2. Are you blind or do you have serious difficulty seeing, even when wearing glasses?

- a. _____ Yes
b. _____ No

3. Because of a physical, mental, or emotional condition, do you have serious difficulty concentrating, remembering, or making decisions? (5 years old or older)

- a. _____ Yes
b. _____ No

4. Do you have serious difficulty walking or climbing stairs? (5 years old or older)

- a. _____ Yes
b. _____ No

5. Do you have difficulty dressing or bathing? (5 years old or older)

- a. _____ Yes
b. _____ No

6. Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping? (15 years old or older)

- a. _____ Yes
b. _____ No

The six-item disability standard represents a minimum standard and the questions and answer categories cannot be changed. Additional questions on disability may be added to any survey as long as the minimum standard is included. If the ACS changes the disability questions in the future, HHS will revisit the standard and modify as necessary.

Rationale for Disability Data Standard

The six item set of questions used on the ACS and other major surveys to measure disability was developed by a federal interagency committee and reflects the change in how disability is conceptualized consistent with the International Classification of Functioning, Disability, and Health. The question set defines disability from a functional perspective and was developed so that disparities between the 'disabled' and 'nondisabled' population can be monitored. The question set went through several rounds of cognitive and field testing and has been adopted in many federal data collection systems. OMB has encouraged the use of this question set by other federal agencies conducting similar population studies due to the extensive testing used in the development of these measures, including the findings that alternative measures did not test as well. Cognitive testing of these questions revealed that the six questions must be used as a set to

assure a meaningful measure of disability.^[vii]

IV. Implementation Guidance

A. Inclusion of Data on Race, Ethnicity, Sex, Primary Language and Disability Status: The minimum data standards described herein on race, ethnicity, sex, primary language, and disability status must be included in all population health surveys conducted or sponsored by HHS.

B. Collecting and Reporting Data on Race, Ethnicity, Sex, Primary Language and Disability Status: Data on race, ethnicity, sex, primary language, and disability status must be collected, analyzed, and reported in an objective, accurate, and useful manner. Both the collection and reporting of the data must be sensitive to constituent concerns about potential misuse or abuse. Only those demographic categories for race, ethnicity, sex, primary language and disability status, with adequate sample sizes to provide statistically reliable data, should be reported. Information on the validity and reliability of the data should be included, whenever possible, to enable the readers to judge the credibility of the findings.

C. Data Collection and Reporting Activities Covered by this Policy: This policy applies to population-based health surveys conducted or sponsored by HHS, in which respondents either self-report information or a knowledgeable proxy provides information about the person or responds for all persons in a household.

For purposes of this guidance, the terms "agency conducted or sponsored" are defined as in the Paperwork Reduction Act (PRA) implementing regulations (5 C.F.R. §1320.3(d)) and would generally include any data collection that would require OMB PRA approval.^[viii] A federal agency is considered to "conduct or sponsor" a collection of information if the agency collects the information, causes another agency to collect the information, contracts or enters into a cooperative agreement with a person to collect the information, or requires a person to provide information to another person, or in similar ways causes another agency, contractor, partner in a cooperative agreement, or person to obtain, solicit, or require the disclosure to third parties or the public of information by or for an agency. Collection of information through investigator initiated grants are generally not subject to OMB review or to this policy, except if 1) the grant recipient is conducting the data collection at the specific request of the agency or 2) the terms and conditions of the grant require specific approval by the agency of the data collection procedures (5 C.F.R. §1320.3(d)).

D. Data Standards Represent Minimum not Maximum: The data standards described herein represent minimum standards and are not intended to limit the collection of needed data. Agencies desiring more granularity or additional data are permitted and encouraged to collect additional data as needed as long as: the minimum standard is included; in the case of race and ethnicity the data can be aggregated up to the minimum standard, and the sample size supports those estimates. For the disability data standard, although survey questions and answer categories included in the standard cannot be changed, additional disability questions may be included.

E. Implementation Schedule: Beginning with the effective date of this guidance, HHS agencies are required to include the data collection standards in all HHS conducted or sponsored person-level data collected in population-based health surveys, where subjects either self-report information or a knowledgeable proxy provides information about the subject or responds for all persons in a household. Implementation will be carried out in accordance with normal agency planning, budgeting and data collection cycles. Any new survey must include the standards, and current surveys must incorporate the data standards no later than the time of the next major revision.

V. Exemptions from Policy

Exemptions to this inclusion policy for data on race, ethnicity, sex, primary language, and disability status for HHS sponsored data collection activities are as follows:

1. When a data collection activity of an HHS Agency, component, or HHS-funded program is directed to one or a limited number of categories of a specific demographic variable (e.g., women), only that specific demographic variable would be excluded, but other standards would still be required. For example, if a survey specifically focuses on women, it is not necessary to collect data on sex, but data collection for race, ethnicity, primary language, and disability status is required. Similarly, an Indian Health Service survey focusing only on American Indians would not be required to include the full race data standard, but would have to include the standards for ethnicity, sex, primary language and disability status.
2. When consultation with the Agency statistician determines that the data on categories for any particular demographic group- race, ethnicity, sex, primary language, or disability status- are considered statistically unreliable, then such demographic groups should not be reported separately unless accompanied by the appropriate caveats.
3. Special exemptions may be granted on a case-by-case basis by the HHS Secretary or a designee.

VI. Effective Date of Policy: (Effective upon Secretary's signature)

VII. Related Policies

Office of Management and Budget government-wide race and ethnicity data collection standards, originally issued in 1997. http://www.whitehouse.gov/omb/fedreg_1997standards/.

HHS Inclusion Policy for Race and Ethnicity <http://aspe.hhs.gov/datacncl/inclusn.htm>

Endnotes

i. IOM (Institute of Medicine). 2009. *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement*. Washington, DC: The National Academies Press.

ii. Alberti, N. (2006) *The 2005 National Census Test: Analysis of the Race and Ethnicity Questions*. Final Report, 2005 National Census Test Analysis. U.S. Census Bureau

iii. Office of Management and Budget. (1997a) *Recommendation from the Interagency Committee for the Review of the Racial and Ethnic Standards to the Office of Management and Budget Concerning Changes to the Standards for Classification of Federal Data on Race and Ethnicity*, Federal Register: 62: 36873-36946, July 9.

iv. Office of Management and Budget. (1997b) *Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity*, Federal Register: 62: No.210, October 30.

v. Shin, Hyon B. and R. Kominski. (2010). *Language Use in the United States: 2007*, American Community Survey Reports, ACS-12. U.S. Census Bureau, Washington, DC.

vi. Brault, M. S. Stern, D. Raglin. (2007). *Evaluation Report Covering Disability*, American Community Survey Content Test Report P.4. U.S. Census Bureau, Washington, DC.

vii. Controlling Paperwork Burdens on the Public. Code of Federal Regulations. 5 CFR Section 1320.

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