

**RACIAL, ETHNIC AND PRIMARY LANGUAGE DATA  
COLLECTION: AN ASSESSMENT OF FEDERAL  
POLICIES, PRACTICES AND PERCEPTIONS**

**VOLUME 2**

**THE CURRENT FEDERAL LANDSCAPE IN HEALTH CARE REGARDING  
THE COLLECTION AND REPORTING OF DATA ON RACE, ETHNICITY AND  
PRIMARY LANGUAGE: A SURVEY OF THE LAWS, REGULATIONS,  
POLICIES, PRACTICES AND DATA COLLECTION VEHICLES**

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ON RACE, ETHNICITY AND PRIMARY LANGUAGE:  
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## I. EXECUTIVE SUMMARY

The collection and reporting of data on race, ethnicity and primary language encompasses a wide array of policies and practices which influence why, how and when data is collected, reported and used. The collection of individualized data, including race and ethnicity, across federally supported health programs is essential to identify, measure, and eventually eliminate health disparities. This data is also vital to developing and implementing effective prevention, intervention, and treatment programs; developing meaningful standards to analyze the efficacy of data collection activities to ensure nondiscrimination; facilitating the provision of culturally and linguistically appropriate health care; and identifying and tracking similarities and differences in performance and quality of care in various geographic, cultural and ethnic communities.

Pursuant to a grant from the Commonwealth Fund, through a subcontract from the Summit Health Institute for Research and Education (SHIRE), the National Health Law Program conducted this survey of the statutes, regulations, policies and procedures of federal agencies to identify when they call for the collection and reporting of data on race, ethnicity and primary language. Examination of whether such activities actually occur is beyond the scope of this survey.

The principal focus of this volume is on the health programs within HHS, but information on other federal agencies' health programs is provided as a framework for reference and discussion. HHS has demonstrated considerable accomplishments in supporting data collection and reporting to reduce health disparities and provide quality, non-discriminatory care to the individuals and families it serves. HHS' broad inclusion policy requires the collection of racial and ethnic data in all data collection activities it undertakes or sponsors. HHS has also issued guidance on providing language assistance to individuals with limited English proficiency by recipients of federal financial assistance, and developed culturally and linguistically appropriate services standards.<sup>i</sup> Recently proposed regulations implementing Medicaid managed care and promulgated regulations governing the State Children's Health Insurance Program (SCHIP) continue this exemplary emphasis on obtaining quality, reliable data.

Title VI of the Civil Rights Act of 1964 is considered the broadest mandate the federal government has to require collection and/or reporting of data on race, ethnicity

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<sup>i</sup> See HHS, Office for Civil Rights, *Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency*, 65 Fed. Reg. 52762 (August 30, 2000) (this guidance implements Executive Order No. 13166, *Improving Access to Services for Persons with Limited English Proficiency* (August 11, 2000)). See also Office of Minority Health, Office of Public Health and Science, *National Standards on Culturally and Linguistically Appropriate Services in Health Care*, 65 Fed. Reg. 80865 (December 22, 2000).

and primary language. Title VI prohibits intentional discrimination on the basis of race or national origin in the provision of any services that are at all supported with federal funds. Title VI is a valuable tool not only to redress past discrimination, but also to monitor ongoing practices. It provides a legal foundation for the collection of racial, ethnic and primary language data by and from recipients of federal financial assistance even when an explicit statutory requirement to collect this data does not exist.

The research for this survey found no statutes that expressly prohibit collection of racial, ethnic or primary language data. Rather, this volume identifies over 80 program-specific statutes that require reporting or collection of data -- most require data collection generally, a few directly address racial and ethnic data and none mention primary language data. For HHS programs that provide *health care services* (e.g. Medicaid, SCHIP, Medicare), three statutes require collection and/or reporting of racial and/or ethnic data and two more require collection of “demographic” or enrollee “characteristics”, which presumably includes race and/or ethnicity. The three statutes that *explicitly* mention race and ethnicity require:

- grantees of the Maternal and Child Health (MCH) Services Block Grant to provide an annual report including, by racial and ethnic group, the number of deliveries in a state per year and the number of women who were provided prenatal, delivery or postpartum care under MCH or Medicaid;
- the Substance Abuse and Mental Health Services Administration (SAMHSA) to evaluate mental health services by conducting surveys that include data on race and ethnicity; and
- grantees of SAMHSA providing services to children of substance abusers to collect data on the ethnicity of the children served.

The two statutes that *implicitly* include racial and ethnic data in other data collection and/or reporting require:

- states to report of the characteristics of children and families served by the State Children’s Health Insurance Program (SCHIP); and
- grantees to report demographic data of individuals served through Ryan White Care Act programs.

For agencies that conduct *clinical research or surveillance of diseases*, five statutes address racial and/or ethnic data collection and/or reporting. All except one relate to health surveillance programs operated by the Centers for Disease Control and Prevention: two require collecting racial and ethnic data (birth defects/developmental disabilities and lead poisoning) and two require demographic data (cancer and infertility/sexually transmitted diseases). One statute requires the National Institutes of Health to operate a national database system and clearinghouse on women’s health research that includes either ethnic or racial data.



In addition to statutory provisions, five sets of federal regulations require racial and ethnic data collection and/or reporting – four in health services and one in research. The *health services* regulations require:

- states to provide Medicaid managed care organizations and primary health plans with the race, ethnicity and primary language of enrollees;<sup>ii</sup>
- states operating SCHIP programs to report enrollees' race and ethnicity quarterly;
- inclusion of identification and social data in patient records in the End-Stage Renal Disease program; and
- states to provide, if available, racial and ethnic data for the target population for prevention activities funded through SAMHSA.

In the research arena, the Food and Drug Administration requires applications for approvals of new drugs to include an analysis of the drug's effect on different demographic groups.

As many statutes delegate decisions on what data to collect to the agency, an analysis of statutory and regulatory authority for data collection and reporting does not present the entire picture. This volume identifies over 100 data collection vehicles, databases, instruments and surveys that collect data on race, ethnicity and/or primary language. Most of this collection arises from internal Department and/or agency policies determining that collection and reporting of this information is necessary and beneficial. For example, HHS' inclusion policy requires the collection of racial and ethnic data in all data collection activities it undertakes or sponsors. The National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Agency for Healthcare Research and Quality (AHRQ) have policies requiring the inclusion of minorities in clinical trials and research, and annual reporting requirements to document inclusion. It is evident that these agencies have found reporting to be of benefit to their mission and ability to assess their effectiveness in improving the health of the nation.

Unlike NIH, CDC, and AHRQ, SAMHSA uses a mechanism that merely encourages grantees to report race and ethnicity data; and less than 1/3 have voluntarily complied. While SAMHSA itself must statutorily include race and ethnicity in surveys it conducts, SAMSHA grantees (except those providing services to children of substance abusers) do not have mandatory reporting requirements.

In addition to analyzing the collection and reporting of racial and ethnic data, this survey also examines collection and reporting of primary language information. No statutes require collection and reporting of primary language data. Two sets of regulations – Medicaid managed care and SCHIP -- address this data. The SCHIP final regulations, published in January 2001, required states to report enrollee's primary language annually. In an interim final rule released in July 2001, this reporting

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<sup>ii</sup> This requirement was included in a proposed rule.

requirement was deleted. Proposed Medicaid managed care regulations require states to provide enrollee's primary language data to managed care organizations upon enrollment.

The recent inclusion of race, ethnicity and primary language reporting provisions in the Medicaid managed care regulations demonstrate HHS' continued commitment to collecting this data across all of its agencies, programs and activities. Despite the fact that not requiring the reporting of race and ethnicity data in recently established data standards implementing the Health Insurance Portability and Accountability Act represents a lost opportunity, HHS intends to include reporting of race and ethnicity in future revisions to those standards. The key to obtaining support for the collection and reporting of data lies in documenting the need for and benefits of the data and how it relates to improving the health of the nation, ensuring the health of the workforce, and capitalizing on the investment in human capital for present and future generations.

While this volume is a survey of all the relevant statutes, regulations, policies, practices and data collection activities of the federal health programs, it should not be considered by itself. When coupled with its companion volume, which examines what data is collected in practice, the study findings confirm the need to collect race, ethnicity and primary language data comprehensively and reliably. This data is important to identify, measure and track health status to ultimately reduce or eliminate racial and ethnic disparities in health care; to ensure non-discrimination; to monitor performance and quality of care; to ensure culturally and linguistically appropriate health care; and to implement effective prevention and intervention programs.

## II. INTRODUCTION

This volume provides the framework and authority for the collection of racial, ethnic and primary language data by federal health programs. To obtain the information, the National Health Law Program, pursuant to a grant from the Commonwealth Fund and a contract with the Summit Health Institute for Research and Education (SHIRE), conducted a survey of the statutes, regulations, policies, practices and data collection instruments applicable to all federal health programs.<sup>1</sup> This volume sets forth the results of that survey and outlines the circumstances under which racial, ethnic and primary language data are currently collected by or reported to federal health programs.

### A. Organization

This volume first provides a general overview of federal laws and policies applicable to the collection and/or reporting of data on race, ethnicity and primary language. This volume is then divided into two main parts – health programs operated or administered by the Department of Health and Human Services (HHS) and other federal health programs. The principal focus of this volume is on the health programs within HHS;<sup>2</sup> the information on other federal agencies is provided primarily as a framework for reference and discussion. The other federal agencies included in this volume which administer health programs are: the Department of Defense (overseeing health programs for active duty and retired members of the uniformed services, their families, and survivors); the Department of Labor (overseeing employer-sponsored programs through the Employee Retirement Income Security Act); the Department of Veterans Affairs (administering health programs for veterans); and, the Office of Personnel Management (overseeing the Federal Employee Health Benefit Plans).

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<sup>1</sup> The methodology for this survey focused on researching applicable statutes and regulations using both commercial and non-commercial search engines: Westlaw, Lexis, the Cornell University Legal Information Institute's compilation of the United States Code (U.S.C.), and the Government Printing Office's compilation of the Code of Federal Regulations (C.F.R.) and the Federal Register (Fed. Reg.). Policies and practices were obtained by researching materials available on the World Wide Web, including agency guidances, policy manuals, letters, and transmittals. Additional information was obtained through conversations with agency staff and relevant non-governmental organizations. Data collection requests submitted to the Office of Management and Budget, agency publications and communication with designated collection officers identified data collection vehicles and racial and ethnic data fields. Information was also supplied through interviews conducted by SHIRE.

<sup>2</sup> HHS maintains a directory, available to the public, that includes its major funded and maintained data collection systems for both health and social services. *See HHS Directory of Health and Human Services Data Resources*, <http://aspe.hhs.gov/datacncl/datadir/introduc.htm>.

Within the section on HHS, the Department's activities are broken down into three categories: development of policy, provision of services, and research activities. The first category covers broad HHS policies, including those established by the Office for Civil Rights, Office of Minority Health, the Surgeon General and the Assistant Secretary for Planning and Evaluation. The agencies providing services include the Centers for Medicare and Medicaid Services, Health Resources Services Administration, Indian Health Service, and the Substance Abuse and Mental Health Services Administration. Research activities are undertaken by the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).

A distinction in the collection of data – both as to quantity and quality – arises between service providers and researchers. Since researchers are trained to collect data, collecting racial and ethnic data is a logical outgrowth of their everyday work. Research data is often more comprehensive and reliable than that collected by service providers whose *raison d'être* is to provide services rather than collect and report data. Many more researchers than service providers understand the need for and reap an immediate benefit from collecting, reporting and analyzing this data. Another reason providers may avoid collecting data is a concern that the data they collect might demonstrate violations of Title VI's non-discrimination requirements (*see* Part III.B).

For each Department, agency or sub-agency, the information provided is organized as follows: a brief statement of the Department or agency's purpose and/or mission; statutes and regulations; policies and practices; and data collection vehicles (*i.e.*, instruments, surveys, databases, and aggregated databases). The information in each of these sub-sections will include the following:

**Statutes and Regulations:** Outlines relevant federal statutes and regulations that address data collection. These provisions include:

- mandatory direct data collection– a direct requirement to collect racial, ethnic and/or primary language data;
- mandatory indirect data collection – a direct requirement to collect data generally, but not specifically racial, ethnic and/or primary language data (which the agency may nonetheless authorize);
- mandatory direct data report – requires agencies or grantees to report racial, ethnic and/or primary language data, which implicitly requires collecting that data;
- mandatory indirect data report – requires agencies or grantees to report data generally, but not specifically racial, ethnic and/or primary language data (which the agency may nonetheless authorize);
- permissive indirect data report – permits but does not require agencies or grantees to report data generally or racial, ethnic and/or primary language data specifically; and

- encouragement of data collection and/or reporting – does not mandate agencies or grantees to collect or report data on race, ethnicity and/or primary language, but encourages it.

**Policies and Practices:** Outlines current policies and practices regarding data collection, including program manuals, Department and agency transmittals, letters to state health officials, and any other available information.

**Data Collection Vehicles:** Provides information on data collection instruments (surveys, reports, forms), databases and aggregated databases.<sup>3</sup> Some databases include information compiled from other sources.<sup>4</sup>

Data collection and reporting requirements may include four types:

- individualized data on individuals within a certain program (*e.g.* collecting the race of each member enrolled in a health plan);
- aggregate data (combined/massed individualized data on a group; *e.g.* reporting data on the total number of African-Americans enrolled in a health plan);
- sampled data or data concerning a specific targeted population (*e.g.* collecting data on 10% of all enrollees or all individuals with diabetes within a health plan); or
- targeted data (individual or aggregate data on a targeted subset) (*e.g.* collecting data on all those diagnosed with a particular disease).

The most comprehensive data collection exists when individualized data is collected for all individuals within a certain program. For example, the Medicare Enrollment Database includes information on all Medicare enrollees. Often, while a provider or health plan may *collect* individualized data, they only are required to *report* aggregated data to a state or federal agency. Aggregated data provide a comprehensive overview but limit analysis beyond the information provided. For example, recently released State Children’s Health Insurance Program regulations require states to provide quarterly reports on the race and ethnicity of all applicants and enrollees. The report provides aggregated data for identified sub-sets of the population, but would not allow analysis within further sub-sets.

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<sup>3</sup> Information on the data collection activities of non-HHS federal agencies was acquired from the World Wide Web and conversations with agency staff. To identify the data collection instruments and databases of HHS, we also utilized the Directory of Health and Human Services Data Resources (*see* fn. 2). Because data collection activities are initiated and revised frequently, changes in the *status quo* reported here will almost certainly exist by the time this survey is published.

<sup>4</sup> Because race and ethnicity categories vary, often dramatically, from agency to agency as well as from instrument to instrument, this section provides a listing of the actual categories used.

Survey data are used to draw conclusions about the broader population. For example, the Medicare Health Outcomes Survey obtains information from a subset of Medicare recipients in an effort to determine general attributes of all Medicare recipients. In some instances, surveys may over-sample for minorities to ensure a statistically reliable sample size exists. Generally, individualized data are more comprehensive but survey data may be more statistically reliable since HHS has direct oversight of the actions of contractors conducting surveys but only indirect control of the actions of thousands of providers who collect and report individualized data. Within this volume, we have divided data collection vehicles into two parts – survey data and individualized data.

## **B. Other Issues to Consider**

This volume documents a significant number of existing data collection policies and practices. However, much of the data is collected through limited research or surveys rather than individualized data on all program participants. While research and survey data are certainly valuable, they are of more limited utility because they are not comprehensive. The collection of individualized data across the federal health programs is essential to identifying and eliminating health disparities; developing and implementing effective prevention, intervention, and treatment programs; developing meaningful standards to analyze the efficacy of data collection activities to ensure nondiscrimination; facilitating the provision of culturally and linguistically appropriate health care; and identifying and tracking similarities and differences in performance and quality of care in various geographic, cultural and ethnic communities.

The purpose of this survey, however, is to describe written policies and practices that address the reporting and/or collection of racial, ethnic and primary language data. It is beyond the scope of this volume to analyze how and to what extent the reporting and/or collection that is supposed to occur actually does occur. For example, the Medicaid Act requires states to submit reports to the Centers for Medicare and Medicaid Services, including any information CMS deems necessary. By including fields for race and ethnicity of enrollees on these reporting forms, CMS has made a policy decision that this reporting is desirable. But the inclusion of the fields does not mean that they are used. To the extent we have obtained information on how a particular policy or practice is implemented or enforced, that information is included.

Another issue that affects the validity of data is how the data are collected – self-reported (usually obtained during face-to-face interviews or telephone surveys) or designated by a third party (medical provider, survey administrator, intake worker). Self-reported data are the most reliable since individuals designate their race and/or ethnicity themselves. Third parties may misidentify an individual's race and/or ethnicity if the identification is based solely on visual cues and not on information provided by the individual. Also, individuals who would self-identify as multi-racial may be undercounted if a third party reports the data. In addition, the existence of multiple third party sources may cause inconsistency in reporting. Yet self-reporting is not always possible if data are collected indirectly. Most obviously, race reported on death certificates is based

on observation rather than self-reporting. Thus, in determining whether data are consistent and comparable across programs, an evaluation of how the data are collected and reported is imperative. Self-reporting is the more appropriate mechanism for research data. For providers or health plans that report encounter or claims data, self-reported data is not necessarily feasible. For example, the Medicaid managed care regulations require states to notify managed care organizations (MCOs) of enrollees' race, ethnicity and primary language, but does not require providers or MCOs to collect or independently verify this data. On the other hand, at the state or federal level, race and ethnicity data gathered upon enrollment may be linked with claims and encounter data to correlate with the race and ethnicity of the individual

While much focus has been placed on racial and ethnic disparities in health care and the need for the collection of data for these and other reasons, the same attention has not been paid to disparities arising from individuals with limited English proficiency. This survey documents many requirements addressing the collection of racial and ethnic data but very few for primary language, although recent developments should increase the focus on this important issue.<sup>5</sup>

Finally, a lack of consistency continues to exist regarding the collection and/or reporting data for Hispanics/Latinos. Initially, Hispanic/Latino was considered a "race" for data collection purposes. While Hispanic/Latino is now considered an ethnicity, some agencies have not yet implemented these changes. In addition, the Office of Management and Budget (*see* Part III.A.) requires federal agencies to utilize separate questions on race and ethnicity if individuals are self-reporting information, but allow one question for reporting by third parties. Until all agencies come into compliance with the OMB standards, different practices regarding the reporting and collection of regarding the Hispanic/Latino community will continue to exist.

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<sup>5</sup> *See* Executive Order No. 13166, *Improving Access to Services for Persons with Limited English Proficiency* (August 11, 2000), Department of Justice Memorandum, <http://www.usdoj.gov/crt/spectop.html> (October 26, 2001), and releases by HHS Office for Civil Rights, (*see* Part IV.B.1.a.), by the HHS Office of Minority Health (*see* Part IV.B.1.b.), and the Centers for Medicare and Medicaid Services (*see* Part IV.C.1.). Pursuant to the Department of Justice Memorandum, the Office for Civil Rights' release may be amended.

### **III. OVERVIEW: FEDERAL STATUTES, REGULATIONS, POLICIES AND PRACTICES OF GENERAL APPLICABILITY**

In addition to provisions governing individual departments or agencies, a number of statutes, regulations, policies and practices apply to all federal departments and agencies. This section outlines these general provisions.

#### **A. Office of Management and Budget**

The Office of Management and Budget (OMB) operates within the Executive Office of the President. One role of OMB is to oversee and coordinate the Administration's information and regulatory policies. In this role, OMB evaluates all federal data collection activity requests, analyzing them for compliance with the Administrative Procedures Act, the Paperwork Reduction Act and OMB's Standards for the Collection of Federal Data on Race and Ethnicity. Each of these is outlined below.

##### **1. The Administrative Procedures Act**

The Administrative Procedures Act (APA) provides the general authority and requirements for the implementation of federal rules.<sup>6</sup> It requires each agency to publish in the Federal Register its:

- rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and content of all papers, reports, or examinations;
- substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and
- each amendment, revision, or repeal of the foregoing.<sup>7</sup>

Thus prior to the imposition of an obligation on all or some part of the general public, except in limited emergency circumstances, an agency must promulgate a rule pursuant to the APA rulemaking procedures, which include allowing notice and comment by the public.<sup>8</sup>

##### **2. The Paperwork Reduction Act of 1995**

The Paperwork Reduction Act (PRA) applies the procedures set out in the APA to the data collection activities of the federal government. The purposes of the PRA include minimizing the paperwork burden resulting from such collection activities; improving the

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<sup>6</sup> See 5 U.S.C. § 550 *et seq.*, and particularly § 551.

<sup>7</sup> 5 U.S.C. § 552.

<sup>8</sup> 5 U.S.C. § 553.



quality and use of federal information to strengthen decisionmaking, accountability, and openness in government and society; and minimizing the cost to the federal government of the creation, collection, maintenance, use, dissemination, and disposition of information.<sup>9</sup>

While the PRA provides general authority to establish performance standards and data collection and reporting requirements that measure compliance with those standards, it also places limits on the collection of data. An agency may not require collection of data unless it has conducted the required review, evaluated any public comments received, submitted certification to OMB, and published notice in the Federal Register. Further, the agency must demonstrate that the collection will not impose an undue burden on small businesses, local governments or other small entities.<sup>10</sup>

To obtain OMB approval of a collection of information, an agency must demonstrate that it has taken every reasonable step to ensure that the proposed collection of information is the least burdensome necessary for the agency to comply with legal requirements and achieve program objectives; is not duplicative of information otherwise accessible to the agency; and has practical utility.<sup>11</sup> The agency must also seek to minimize the cost to itself of collecting, processing, and using the information, but not by shifting disproportionate costs or burdens onto the public. To the extent that OMB determines that all or any portion of a collection of information is unnecessary, the agency may not engage in that collection.

### **3. Standards for the Classification of Federal Data on Race and Ethnicity**

To ensure uniformity and comparability of data in collections by multiple federal agencies, OMB has promulgated standards governing the collection of racial and ethnic data. OMB's standards, initiated over 20 years ago with subsequent modifications, provide a common language to promote uniformity and comparability for data on race and ethnicity throughout the federal government. The standards outline permissible racial and ethnic categories to be used by federal agencies when collecting data through administrative forms, surveys, or research. OMB revised these standards in part based on concerns raised after the 1990 census that the standards were under-inclusive. In 1997, OMB published Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (OMB Standards<sup>12</sup>) which require a minimum of five race categories:

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<sup>9</sup> 44 U.S.C. § 3501.

<sup>10</sup> 44 U.S.C. § 3507, *see also* 5 C.F.R. Part 1320.

<sup>11</sup> 5 C.F.R. § 1320.5.

<sup>12</sup> 62 Fed. Reg. 58782 (October 30, 1997). Many federal agencies still refer to these standards as "OMB Directive No. 15," a version of the Standards issued when OMB was part of the Department of Commerce. The current Standards are not, however, a directive. For a history of the OMB Standards and a survey of literature on racial disparities in health care, *see* Matt Ayotte, Britt Peterson, and Anthea Wang, *Racial*

American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White.<sup>13</sup> Regarding ethnic categories, a minimum of two must be included: Hispanic or Latino, and Not Hispanic or Latino.

When self-identification is used (such as in a survey of recipients), the revised standards specify that individuals should have the opportunity to select more than one category of race (*e.g.* African-American *and* White). In addition, OMB requires that two separate questions should be asked – what is your race *and* what is your ethnicity? When self-identification is not feasible or appropriate, a combined race/ethnicity question may be used – what is your race/ethnicity? The single question answers should include Hispanic as an option, co-equal with the other categories. If the combined question is used, OMB suggests attempting to allow the designation of ethnicity and race or multiple races, but providing only one option is acceptable.<sup>14</sup>

All new data collection instruments must use the new standards.<sup>15</sup> For existing data collections, agencies have until January 1, 2003 to implement the new standards. *It is important to note, however, that the OMB Standards do not mandate the collection of racial and ethnic data; they merely provide uniform standards to be used when these data are collected.*

On March 9, 2000, OMB issued guidance on the aggregation and allocation of data on race for civil rights monitoring and enforcement.<sup>16</sup> This guidance reiterates the requirements of the revised standards.

**Aggregation:** when agencies mass data from multiple smaller categories into a broader category (*e.g.* Filipino, Japanese, and Chinese all aggregate into the OMB Standard category of Asian or Pacific Islander), the agency should utilize:

- the five single race categories mandated by the revised standards;
- the four double race combinations most frequently reported;<sup>17</sup>

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*Disparities in Health Care*, Kaiser Family Foundation Publication No. 1526, <http://www.kff.org> (December 6, 2000).

<sup>13</sup> *Id.*

<sup>14</sup> *Id.* at 58786.

<sup>15</sup> The 2000 Census, required to conform to the OMB Standards, provided 63 categories of racial data. The Census included 15 separate categories of race, allowed for multi-racial selections, and permitted self-identification of specific races or sub-groups of the Asian or Pacific Islander race not included in the list provided. Five ethnicity choices were available, including further delineation within a general category of “other Hispanic/Spanish/Latino.” See U.S. Census 2000 Questionnaire, <http://www.census.gov/dmd/www/pdf/d-61b.pdf>.

<sup>16</sup> *Guidance on Aggregation and Allocation of Data on Race for Use in Civil Rights Monitoring and Enforcement*, OMB Bulletin No. 00-02, <http://www.whitehouse.gov/OMB/bulletins/b00-02.html>.

- any multiple race combination that comprises more than 1% of the population in interest,<sup>18</sup> and
- a balance category for responses not included in the above.

**Allocation:** when determining how to identify an individual who reports more than one race, the agency should:

- not allocate data from the five single race categories (*e.g.* for individuals who identify as African-American, no allocation is necessary);
- for responses combining one minority race and white, allocate the response to the minority race (*e.g.* an individual who identifies as African American and White would be allocated as African American); and
- for responses including two minority races, allocate the response in one of two ways based on the type of enforcement action (*e.g.* an individual identifies as African American and Hispanic but alleges discrimination due to Hispanic origin, allocate as Hispanic).<sup>19</sup>

Use of these standards for the collection of racial and ethnic data are designed to allow data to be compared and contrasted among agencies and across programs within agencies.

On January 16, 2001, OMB published Provisional Guidance on the Implementation of the 1997 Standards for Federal Data on Race and Ethnicity.<sup>20</sup> This report provides guidance to federal agencies on collecting, tabulating and using data, and building bridges to compare data collected under the OMB standards.

Since the OMB standards will not cover all data collection instruments until 2003, it will be some time before standardization of collections is achieved. Thus, the information provided throughout this volume is the product of current collection practices. For example, many data collections included in this volume do not have separate race and ethnicity questions.

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<sup>17</sup> These are: American Indian or Alaska Native and White, Asian and White, Black or African American and White, American Indian or Alaska Native and Black or African American.

<sup>18</sup> Agencies must use Census 2000 data to determine when a multiple race category meets the 1% threshold for the relevant jurisdiction.

<sup>19</sup> If the enforcement action is based on a complaint, the agency should allocate to the race that the complainant alleges the discrimination was based on. If the enforcement action requires assessing disparate impact or discriminatory patterns, the agency should analyze the patterns based on alternative allocations to each of the minority groups.

<sup>20</sup> 66 Fed. Reg. 3829, January 16, 2001. The full report is available at [http://www.whitehouse.gov/omb/inforeg/r&e\\_guidance2000update.pdf](http://www.whitehouse.gov/omb/inforeg/r&e_guidance2000update.pdf).

## **B. Title VI of the Civil Rights Act of 1964**

Title VI of the Civil Rights Act of 1964 (Title VI), one of the primary federal anti-discrimination laws, prohibits discrimination on the basis of race or national origin in the provision of any services that are at all supported with federal funds. Title VI is a valuable tool not only to redress past discrimination, but also to monitor ongoing practices. It provides a legal foundation for the collection of racial, ethnic and primary language data from recipients of federal financial assistance even when a specific statutory requirement to collect this data does not exist. Title VI states:

No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.<sup>21</sup>

This protection generally extends to all programs and activities of any entity receiving federal financial assistance, whether or not the particular program at issue has itself received or benefited from those funds.<sup>22</sup> Title VI applies to state agencies and other recipients of federal funds, but not to federal agencies.<sup>23</sup>

The Department of Justice (DOJ) regulations implementing Title VI require each federal agency to provide for the collection of data and information from applicants for and recipients of federal assistance sufficient to permit effective enforcement of Title VI.<sup>24</sup> While these regulations are generally applicable to all federal agencies, each agency must also publish guidelines for each of its programs as appropriate to provide detailed information on the requirements of Title VI. These agency-specific regulations should describe:

- the nature of Title VI coverage;
- the methods of enforcement;
- examples of prohibited practices in the context of the particular type of program;
- required or suggested remedial action; and
- the nature of requirements relating to covered employment, data collection, complaints and public information.<sup>25</sup>

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<sup>21</sup> 42 U.S.C. § 2000d.

<sup>22</sup> 42 U.S.C. § 2000d-4a. In certain limited circumstances, all of an entity's programs or activities will not be required to comply.

<sup>23</sup> See 42 U.S.C. § 2000d-4a, definition of "program or activity."

<sup>24</sup> 28 C.F.R. § 42.406(a). This does not apply if the collection is determined by a federal agency to be inappropriate or inapplicable. HHS' regulations implementing Title VI, however, do not require the collection of this data. See IV.A.1.

<sup>25</sup> 28 C.F.R. § 42.404(a).

Since the language a person speaks has been determined to represent a proxy for national origin,<sup>26</sup> Title VI also impacts agencies' policies and practices with regard to the collection of primary language data. Recognizing the unique problems individuals with limited English proficiency (LEP) face in accessing federal programs, President Clinton issued an Executive Order in August of 2000, requiring each federal agency to develop a plan for improving LEP individuals' access to and participation in its programs and activities.<sup>27</sup> This was followed by guidance from both DOJ<sup>28</sup> and HHS.<sup>29</sup> DOJ's guidance required all other federal agencies to publish guidance implementing the Executive Order by December 11, 2000. The Executive Order was reaffirmed by President Bush.<sup>30</sup>

The Executive Order and HHS' subsequent LEP guidance do not explicitly discuss data collection. To monitor compliance effectively, however, agencies can require recipients of federal funds to collect primary language data under the same rationale that Title VI provides for the collection of racial and ethnic data. For example, HHS' guidance suggests that intake workers should record an individual's primary language in his/her record so that staff can identify the client's language assistance needs.

### C. The Consumer Bill of Rights and Responsibilities

In 1997, President Clinton convened the Advisory Committee on Consumer Protection and Quality in Health Care. Its mission was to advise the President on

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<sup>26</sup> See, e.g. *Garcia v. Gloor*, 618 F.2d 264 (5<sup>th</sup> Cir. 1980), *cert denied*, 449 U.S. 1113 (1981); *Gutierrez v. Municipal Court of S.E. Judicial District*, 838 F.2d 1031, 1039 (9<sup>th</sup> Cir. 1988), *vacated as moot*, 490 U.S. 1016 (1989).

<sup>27</sup> Executive Order No. 13166, *Improving Access to Services for Persons with Limited English Proficiency* (August 11, 2000). One noteworthy aspect of this Executive Order is that it requires *federal agencies* to develop a system by which LEP individuals can meaningfully access their services. This is the first time that the mandates of Title VI have been extended to the federal agencies themselves. The guidance does not, however, directly require collection and reporting of primary language data.

<sup>28</sup> Department of Justice, *Enforcement of Title VI of the Civil Rights Act of 1964: National Origin Discrimination against Persons with Limited English Proficiency, Policy Guidance*, 65 Fed. Reg. 50123 (August 16, 2000). The Guidance emphasizes that it does not create any new obligations but only clarifies existing Title VI responsibilities.

<sup>29</sup> HHS, Office for Civil Rights, *Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency*, 65 Fed. Reg. 52762 (August 30, 2000). Like the DOJ Guidance, this Guidance does not create any new obligations but only clarifies existing Title VI responsibilities of recipients of federal financial assistance through HHS.

<sup>30</sup> See Department of Justice, *Memorandum: Executive Order 13166 (Improving Access to Services for Persons with Limited English Proficiency)* (October 26, 2001), <http://www.usdoj.gov/crt/spectop.html>. By February 2001, each Department must review and re-publish its guidance pursuant to clarifications made by this Memorandum.

changes occurring in the health care system, recommend measures to promote and assure health care quality and value, and protect consumers and workers in the health care system.

As part of its responsibilities, this committee developed a Consumer Bill of Rights and Responsibilities (CBRR), also known as the Patients' Bill of Rights.<sup>31</sup> It provides that consumers must not be discriminated against in the delivery of health care services based on their race, ethnicity, or national origin. In addition, the CBRR prohibits such discrimination in both the marketing and enrollment practices of health care providers.<sup>32</sup>

On February 20, 1998, President Clinton issued an Executive Memorandum requiring all federal agencies to ensure that health plans overseen or administered by them comply with the Consumer Bill of Rights and Responsibilities.<sup>33</sup> The Executive Memorandum directed further actions to ensure that all federal employee health benefits plans, Medicare, Medicaid, the military health system, and the veterans health administration comply with certain provisions of the CBRR. While private plans are not subject to the CBRR, the Department of Labor was required to implement regulations to strengthen provisions regarding dissemination of materials to plan participants and internal appeals procedures to be consistent with the CBRR.<sup>34</sup> Meanwhile, Congress continues to debate enactment of a legislative patients' bill of rights.

While the CBRR on its own does not require data collection, it provides additional authority for monitoring nondiscrimination and ensuring compliance with federal civil rights laws.

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<sup>31</sup> Appendix A: Consumer Bill of Rights and Responsibilities, Executive Summary at 1, <http://www.hipaanet.com/cbrr.htm> (hereinafter Appendix A). See also <http://www.consumer.gov/qualityhealth/rights.htm>. Congress is considering whether to enact a statutory Patients Bill of Rights to protect all enrollees in health maintenance organizations.

<sup>32</sup> Appendix A, Chapter Five: Respect and Nondiscrimination, at 56.

<sup>33</sup> *Memorandum on Federal Agency Compliance With the Patient Bill of Rights* (February 20, 1998), <http://www.hcqualitycommission.gov/press/potusmmo.html>. This Memorandum was based in part on a report to the Vice President, *Progress Report in Implementing the Patient's Bill of Rights*. The HHS compliance report is available at <http://aspe.hhs.gov/health/vpreport.htm>.

<sup>34</sup> See Department of Labor, *Employee Retirement Income Security Act of 1974; Rules and Regulations for Administration and Enforcement; Claims Procedure; Final Rule*, 65 Fed. Reg. 70246 (November 21, 2000).

#### D. The Health Insurance Portability and Accountability Act<sup>35</sup>

In stark contrast to the nondiscrimination requirements of Title VI and the CBRR, which encourage the collection of racial and ethnic data, the implementation of the Health Insurance Portability and Accountability Act (HIPAA)<sup>36</sup> erects new hurdles to the consistent and uniform collection of this data. Congress passed HIPAA in 1996 to improve the efficiency and effectiveness of the health care system “by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.”<sup>37</sup> One of the primary goals of HIPAA was to provide a single format for electronic transmission of health care claims.<sup>38</sup>

HIPAA applies to health plans,<sup>39</sup> health care clearinghouses,<sup>40</sup> and health care providers.<sup>41</sup> HHS must establish standards for certain transactions regarding the

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<sup>35</sup> The brief description of HIPAA included here is intended to explain the provisions relevant to the collection of racial and ethnic data. For more information on the many other aspects of HIPAA, see <http://aspe.hhs.gov/admnsimp/index.htm> or <http://www.hhs.gov/ocr/hipaa/>. One consumer advocacy resource is the Health Privacy Project, part of the Institute for Health Care Research and Policy, Georgetown University, <http://www.healthprivacy.org/>.

<sup>36</sup> 42 U.S.C. § 1171 *et seq.*

<sup>37</sup> Health Insurance Portability and Accountability Act of 1996, P.L. 104-191 § 261 (August 21, 1996). This section is not codified.

<sup>38</sup> Currently, approximately 400 different formats exist for electronic health claims. The goal of adopting a single standard is to allow faster, more cost-effective processing of transactions. See, e.g., HHS Office of the Secretary and Centers for Medicare and Medicaid Services, *Health Insurance Reform: Standards for Electronic Transactions; Announcement of Designated Standard Maintenance Organizations; Final Rule and Notice*, 65 Fed. Reg. 50312 (August 17, 2000) (hereafter HIPAA Standards Regulations).

<sup>39</sup> Health plans include: a group health plan as defined in the Public Health Service Act (PHSA) if the plan has 50 or more participants or is administered by an entity other than the employer who established and maintains the plan; a health insurance issuer as defined in the PHSA; a health maintenance organization as defined in the PHSA; Part A or Part B of Medicare and Medicare supplemental policies; Medicaid; a long-term care policy, including most nursing home fixed indemnity policies; an employee welfare benefit plan covering two or more employers; the health care program for active military personnel and the Civilian Health and Medical Program of the Uniformed Services; the veterans health care program; the Indian Health Service program; and the Federal Employees Health Benefit Plan. 42 U.S.C. § 1171(5).

<sup>40</sup> Health care clearinghouses are defined as public or private entities that process or facilitate the processing of nonstandard data elements of health information into standard data elements. 42 U.S.C. § 1320d, Social Security Act (SSA) § 1171.

<sup>41</sup> Health care providers are defined as including providers of services (hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation

electronic transmission of health information.<sup>42</sup> In adopting the standards, HHS must establish code sets (discrete identifiers) for appropriate data elements (categories of information).<sup>43</sup> In this context, “race and ethnicity” is a data element that contains a discreet identifier for each racial or ethnic possibility (*e.g.*, H for Hispanic). Those identifiers, taken together, constitute the code set.

Unfortunately, HHS was not given ultimate authority over the content of the standards. While HHS must adopt the standards,<sup>44</sup> HIPAA instructs HHS to work from standards developed by a “standard setting organization,”<sup>45</sup> and affords the agency only limited authority to adopt modifications.<sup>46</sup>

On August 17, 2000, HHS promulgated regulations that designated the standards for HIPAA-related transactions.<sup>47</sup> Within each standard, code sets are designated as “required,” “situational” or “not used.”<sup>48</sup> In the standards for health care claims, the code set for race and ethnicity is currently designated as “not used.”<sup>49</sup>

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facilities, home health agencies, hospice programs, or for limited purposes regarding services provided in a teaching facility, a fund), providers of medical or other health services (defined in 42 U.S.C. § 1395x(s), SSA § 1861) and any other person furnishing health care services or supplies.

<sup>42</sup> 42 U.S.C. § 1320d-1, § 1320d-2(a), SSA § 1172, § 1173. These transactions are: health claims or equivalent encounter information; health claims attachments; enrollment and disenrollment in a health plan; eligibility for a health plan; health care payment and remittance advice; health plan premium payments; first report of injury; health claim status; and referral certification and authorization

<sup>43</sup> 42 U.S.C. § 1320d-2(c), SSA § 1173. Compliance with these standards is required within 24 months after adoption/establishment although smaller health plans (as determined by HHS) have 36 months. 42 U.S.C. § 1320d-4, SSA § 1175.

<sup>44</sup> 42 U.S.C. § 1320d-2, SSA § 1173.

<sup>45</sup> A “standard setting organization” must be accredited by the American National Standards Institute that develops standards for information transactions, data elements, or any other standard necessary to or facilitating the implementation of HIPAA. 42 U.S.C. 1320d(8), SSA § 1171.

<sup>46</sup> 42 U.S.C. § 1320d-1, SSA § 1172.

<sup>47</sup> HIPAA Standards Regulations at 50371 *et seq.*

<sup>48</sup> *See, e.g., National Electronic Data Interchange Transaction Set Implementation Guide: Benefit Enrollment and Maintenance*, ASC X12N 834 (May 1999 with annotations from November 1999 and February 2000), [http://hipaa.wpc-edi.com/HIPAA\\_40.asp](http://hipaa.wpc-edi.com/HIPAA_40.asp).

<sup>49</sup> ASC X12N 837, X092 (Health Care Eligibility Benefit Inquiry and Response to Inquiry), X093 (Health Care Claim Status Request and Response to Status Request), X094 (Health Care Services Request for Review/Response to Request for Review), X096 (Institutional), X097 (Dental), X098 (Professional). *See, e.g.* X098 at 124-5, 164-5, 342-3. This is also the case for the Health Care Eligibility Benefit Inquiry and Response standards. ASC X12N 270/271 at 83-4, 124-5, 210-11, & 287-88.



In the standards for Benefit Enrollment and Maintenance, the code set for race and ethnicity is currently designated as “situational”, which means it need only be transmitted “when such transmission is required under the insurance contract between the sponsor and payer and allowed by federal and state regulations.”<sup>50</sup> While it is unclear how many contracts would require this, it is clear that such reporting of racial and ethnic data will be far from universal.

If race and ethnicity information is transmitted, the approved HIPAA categories are: Not Provided, Asian or Pacific Islander, Black, Caucasian, Hispanic, American Indian or Alaskan Native, Black (Non-Hispanic), and White (Non-Hispanic).<sup>51</sup> This code set is not compliant with the recognized OMB standards,<sup>52</sup> although HHS is working with the standards development organization in an attempt to change this.<sup>53</sup>

Prior to promulgation of the regulations, those at HHS drafting the regulations and members of the HHS Data Council<sup>54</sup> recognized that the Benefit Enrollment and Maintenance transaction set would be the most favorable vehicle for transmitting racial and ethnic data. Thus, HHS worked with the standards development organization to change its designation of the race or ethnicity code set from “not used” to “situational.” The modification of standards is assigned to “designated standard maintenance organizations” (DSMOs).

Currently, HHS has six DSMOs.<sup>55</sup> Since the current focus is on decreasing burdens on providers adapting to HIPAA and eliminating code sets not directly related to the claims process, however, it is unlikely that changes to improve the collection of racial and ethnic data will occur.<sup>56</sup> HHS is developing a Health Care Reporting Guide which, while based on the current standards, will also address information collections not covered by HIPAA but necessary for other reporting requirements. Both HHS and individual states can request additional information outside of the HIPAA reporting requirements.

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<sup>50</sup> ASC X12N 834, Member Demographics, at 70-72.

<sup>51</sup> *Id.*

<sup>52</sup> See Part III.A.3.

<sup>53</sup> Document prepared for the HHS Data Council, *Collecting Racial and Ethnic Data and HIPAA Standard Transactions* (August 18, 1999).

<sup>54</sup> See Part IV.A.2.a.

<sup>55</sup> 45 C.F.R. § 162.910. These are: Accredited Standards Committee X12 (developers of the current standards), Health Level 7 (addressing clinical and administrative data), the National Council for Prescription Drug Programs, the American Dental Association’s Dental Content Committee, the National Uniform Billing Committee and the National Uniform Claims Committee. For more information on changes to the standards, see <http://www.hipaa-dsmo.org/crs/>.

<sup>56</sup> *Id.*

However, an additional hurdle to obtaining information through this standard exists. The enrollment and disenrollment transaction was designed primarily for the use of sponsors, who are not required to abide by HIPAA. Thus, even if racial and ethnic data were designated as “required,” a widespread increase of the collection of racial and ethnic data would not necessarily occur, since sponsors could avoid compliance without repercussions.

While the regulations adopting the standards do not require the reporting of racial and ethnic data, they do include, at the behest of the HHS Data Council, statements regarding HHS’ intent to work towards broader collection of racial and ethnic data in the future. The regulations identify four purposes for which the collection of this data is critical:

- to measure racial and ethnic disparities in type, report, and appropriateness of care received;
- to focus efforts in areas, populations and health plans where evidence of disparities based on race and national origin exist;
- to monitor progress towards eliminating disparities in health and health care; and
- to monitor and enforce statutes and regulations that prohibit discrimination on the basis of race and national origin.<sup>57</sup>

The regulations encourage the health care industry to reach consensus on an approach to enhance the collection of demographic data. HHS stated its intention to work with the industry for future revisions of the standards to allow collection of this data. HHS also stated that it would continue to participate in the process and plans to explore approaches for promoting and facilitating the voluntary collection of high quality demographic data.<sup>58</sup>

Many states have had separate data collecting requirements addressing race and ethnicity. The drawback to this reporting is the likelihood of non-uniform formats, especially for state-level data collection. Further, if collection remains outside of the normal stream of data collection, it is likely to impose a greater burden on providers.<sup>59</sup> And seeking to capitalize on the opportunities standardization provides, many states anticipate becoming HIPAA compliant and no longer requesting additional information.<sup>60</sup> While the enrollment standard at least allows the situational collecting of race and ethnicity data, this information may be unavailable to many states for a number of reasons, including: lack of access to enrollment files, lack of relationships with entities

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<sup>57</sup> HIPAA Standards Regulations at 50388.

<sup>58</sup> *Id.*

<sup>59</sup> Testimony of Dr. Anne Elixhauser, AHRQ, to the National Committee on Vital and Health Statistics, June 24, 1999, <http://www.ncvhs.hhs.gov/990624tr.htm#hipaa>.

<sup>60</sup> *Id.*

over which states do not have jurisdiction (such as ERISA plans), need for patient identifiers to link the data, and the lack of data on the uninsured or self-insured.

Unless and until the claims standards are amended to *require* the submission of racial and ethnic data, HIPAA will represent, at best, a squandered opportunity for evaluating the existence and magnitude of disparities in health care through the collection of racial and ethnic data across federal programs. At worst, it could, in the quest for uniformity, ultimately result in the demise of current beneficial data collection activities.

## **E. Conclusion**

While no overarching federal statutes specifically require the collection of racial and ethnic data, the nondiscrimination mandates of Title VI and the Consumer Bill of Rights and Responsibilities provide strong justifications for doing so. Both Title VI and the CBRR represent foundations on which the collection and/or reporting of racial, ethnic and primary language data may be erected. Compounding this disconnect, the standards adopted to implement HIPAA act to deter the collection of racial and ethnic data. The next sections of this volume examine, Department-by-Department and sometimes agency-by-agency, provisions relating to the collection of racial, ethnic and primary language data.

## **IV. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

The Department of Health and Human Services oversees a large number of federal health programs as well as research activities. As part of the overall goals of the Department, HHS strives to address racial and ethnic disparities in health, ensure that members of all racial and ethnic groups are provided appropriate levels of health and social services, and assure nondiscriminatory access to health care and other HHS funded or directly-operated services.

This section will first outline general statutes, regulations, policies, and practices applicable to all HHS agencies. It will then provide detailed information for each relevant agency within HHS.

### **A. General Framework**

#### **1. Statutory and Regulatory Authority**

Entities receiving federal financial assistance through HHS must abide by the requirements of Title VI of the Civil Rights Act of 1964.<sup>61</sup> The HHS regulations issued to implement Title VI provide a basis for collecting racial, ethnic and primary language data.

Under these regulations, every application for federal financial assistance shall, as a condition of its approval, include an assurance that the program will be conducted or the facility operated in compliance with all requirements of Title VI.<sup>62</sup> The relevant HHS official overseeing administration of the program must specify the form of the assurance required and the extent to which the assurances are required from subgrantees, contractors and subcontractors, transferees, successors in interests, and other participants in the program. State agencies applying for or receiving federal financial assistance to operate programs through HHS must provide the same assurances. Further, states must adopt methods of administration for the program that give reasonable assurance that the applicant and all recipients of federal financial assistance under the program will comply with all the requirements imposed by Title VI.<sup>63</sup>

In addition to the required assurances, all recipients must keep records and submit compliance reports “in such form and containing such information” as the responsible HHS official determines necessary to ascertain whether the recipient is complying with

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<sup>61</sup> See Section III.B.

<sup>62</sup> 45 C.F.R. § 80.4(a).

<sup>63</sup> 45 C.F.R. § 80.4(b).

the regulations.<sup>64</sup> According to an example included in the regulations, recipients should have racial and ethnic data showing the extent to which members of minority groups are beneficiaries of and participants in the federally assisted programs.<sup>65</sup> In cases of subcontracting or subgranting, these secondary recipients must submit compliance reports to the primary recipient to allow it to carry out its obligations under the regulations. The Title VI regulations do not specifically address collection of primary language data but collection can be justified by the need to monitor compliance with the Act's national origin nondiscrimination requirements.

Regarding all health-related research grants made by HHS (except those administered by the Agency for Healthcare Research and Quality, *see* Part IV.D.1), the agency may impose additional conditions prior to or at the time of any award when necessary to assure or protect advancement of the project, the interest of public health, or the conservation of grant funds.<sup>66</sup>

Finally, all agencies within the Public Health Service must submit biennial reports to the Office of Minority Health summarizing their minority health activities.<sup>67</sup>

## **2. Policies and Practices**

HHS has a number of specific policies relating to the collection of racial and ethnic data, including the Policy Statement on Inclusion of Race and Ethnicity in HHS Data Collection Activities, the HHS Initiative to Eliminate Racial and Ethnic Disparities in Health, and Culturally and Linguistically Appropriate Services standards. Each of these, along with a description of the HHS Data Council, is discussed below.

### **a. HHS Data Council**

In 1995, HHS Secretary Donna Shalala created the HHS Data Council to coordinate all of the Department's health and non-health data collection and analysis activities. The mission of the Data Council is to implement a data collection strategy and coordinate HHS activities, data standards and related data and privacy policy activities.<sup>68</sup>

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<sup>64</sup> 45 C.F.R. § 80.6(b). While HHS must monitor compliance with Title VI, whether to collect data is left to the discretion of HHS. *See Madison-Hughes v. Shalala*, 80 F.3d 1121, 1124-5 (6<sup>th</sup> Cir. 1996).

<sup>65</sup> While it would be difficult to imagine demonstrating compliance without data, these regulations do not actually require data collection. Thus, these regulations do not comport with DOJ's Title VI regulations, which specifically require data collection. *See* III.B.

<sup>66</sup> 42 C.F.R. § 52.8, § 52.9.

<sup>67</sup> 42 U.S.C. § 300u-6(f)(2).

<sup>68</sup> These responsibilities include: developing an agency-wide data collection strategy, including coordination and consolidation of surveys; working with HHS' program and policy makers, the National Center on Vital and Health Statistics (NCHVS), the research

The Data Council has a number of subgroups, including a Working Group on Racial and Ethnic Data. In December 1999, this Working Group, in conjunction with the Data Work Group for the HHS Initiative to Eliminate Racial and Ethnic Disparities in Health, issued a report with recommendations to improve the collection and use of racial and ethnic data.<sup>69</sup> The overarching recommendations were to:

- develop a 10-20 year strategic plan for national surveys (e.g. the National Health Interview Survey) that includes a schedule for periodic targeting of racial and ethnic groups;
- ensure that standards developed in response to HIPAA include racial and ethnic identifiers;<sup>70</sup>
- address racial and ethnic data gaps for measurable objectives<sup>71</sup> for Healthy People 2010;
- expand or establish new registries for certain chronic conditions targeted in the eliminating disparities initiative;
- explore the feasibility of collecting sufficiently large sample sizes in each state for each racial and ethnic group that comprises a significant proportion of the state;
- support extramural and intramural analyses of existing data for and related to racial and ethnic groups;
- develop aggressive public use data release programs to promote wider analysis of minority health data;

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community, states, the private sector, and others so that data collected by HHS will meet the needs of all users and be easily accessible; working towards consensus in data standards and privacy; serving as HHS' liaison to and contact point for the NCVHS to determine its focus, obtain issue specific reports, monitor its work, and make recommendations for membership and rechartering; responding to data standards and privacy issues presented by NCVHS and others; overseeing surveys and general statistical analysis; and implementing the Vice President's charge to lead an interagency effort in four areas of information system policy: data standards, privacy, telemedicine, and enhanced health information. See <http://aspe.hhs.gov/datacncl/index.htm>.

<sup>69</sup> *HHS Plan to Improve the Collection and Use of Racial and Ethnic Data*, HHS Data Council Working Group on Racial and Ethnic Data (December, 1999), <http://aspe.hhs.gov/datacncl/racerpt/index.htm>.

<sup>70</sup> The HIPAA standards ultimately adopted by HHS do not in fact require the reporting of race and ethnicity. See Part III.D.

<sup>71</sup> "Measurable objectives" provide direction for action by using a baseline to represent the starting point for moving toward the desired end. The baselines use valid and reliable data derived from currently established, nationally representative data systems. An example of a measurable objective is increasing the proportion of individuals with health insurance; the baseline is 83% with a goal of 100%. See *Healthy People 2010 Volumes I and II, Reader's Guide*,

<http://www.health.gov/healthypeople/document/html/volume1/readersguide.htm>.

- publish periodic national reports on the health of racial and ethnic groups compared to all races and white populations;
- develop an initiative to train health personnel in areas such as completing records, statistics, survey research, and epidemiology to improve the comprehensiveness and reliability of racial and ethnic data; and
- disseminate relevant racial and ethnic findings to the communities where the data were collected.

The report also provides more specific recommendations grouped into four categories: data collection, data analysis and interpretation, data dissemination and use, and data research and maintenance. As a follow-up to this report, HHS will be developing a detailed implementation plan and an oversight or coordinating entity.

In addition to drafting this report, the Working Group also compiled a Directory of HHS' Health and Human Services Data Resources.<sup>72</sup> This Directory includes data resources with current utility or those with a potential for use by a variety of audiences, including recurring surveys and disease registries either maintained or sponsored by HHS.

The work of the Data Council is crucial to ensuring that data collection is uniform and comparable across all of HHS' programs. The implementation of HHS' Inclusion Policy, discussed in the next section, is in turn crucial to ensuring that data are collected.

#### **b. Policy Statement on Inclusion of Race and Ethnicity in HHS Data Collection Activities**

In 1997, HHS issued a policy to include race and ethnicity in all HHS data collection activities. This inclusion policy, based in part on similar policies issued by the National Institutes of Health and the Centers for Disease Control and Prevention, specifies the minimum standard categories of racial and ethnic groups<sup>73</sup> that should be collected and reported in covered HHS data systems.<sup>74</sup>

HHS developed its inclusion policy after a review of its data systems found that some systems did not collect the data, some collected but did not report the data, and racial and ethnic categories were inconsistent among various HHS agencies. The

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<sup>72</sup> The full directory is available at <http://aspe.hhs.gov/datacncl/datadir/introduc.htm>. Information is provided on each data resource including the categories of race and/or ethnicity collected, information on the status of collection and accessing the data, and a contact person.

<sup>73</sup> The policy adopts the standards specified in the OMB Standards (and its future revisions). See Part III.A.3.; 62 Fed. Reg. 58782 (October 30, 1997).

<sup>74</sup> *Policy Statement on Inclusion of Race and Ethnicity in DHHS Data Collection Activities* (October 27, 1997), (hereinafter Policy Statement), <http://aspe.os.dhhs.gov/datacncl/inclusn.htm>.

available data reflected disparities in health conditions among minorities, but that major omissions of racial and ethnic data existed which made it difficult to address specific health and social services needs. HHS' policy outlines six specific needs:

- for consistent, reliable racial and ethnic data to develop and implement effective prevention, intervention, treatment and other needed health programs, policies, and services;
- for standardized and reliable racial and ethnic data across its agencies when necessary for HHS to make a coordinated response to major health and social services issues;
- to develop meaningful criteria and standards to improve its ability to determine and analyze the efficacy of HHS data collection activities for ensuring nondiscrimination;
- to provide uniform guidance to all HHS programs regarding data used to help determine compliance with Title VI;
- for data which are not collected despite the relevance of the subject matter to HHS goals; and
- for improved and consistent collection and reporting of health and social services data on racial and ethnic groups because of the omission of this data, and the need to address specific health and social services needs of minority populations.

In addition to mandating the collection of data, HHS also specifies the level at which reporting should occur.<sup>75</sup> Whenever possible, the collection and reporting of racial and ethnic data should occur at the level of the providing organization and program beneficiary to be useful in determining compliance with Title VI. The information should be collected either directly from the providing entity or beneficiary, or collected through the use and/or matching of existing administrative data sets.<sup>76</sup> *The collection and reporting of the data must be sensitive to racial and ethnic communities' concerns about the use, or potential misuse, of the data.* HHS states that it will not use the data in a way that would stigmatize certain populations or suggest a biological or genetic connection based on nongenetic studies when race and ethnicity are actually surrogates for other risk factors.

The policy also specifies which data collection activities it covers. The policy thus applies to:

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<sup>75</sup> While the inclusion policy is framed as "mandatory," the policy is not always followed in practice. This may be due to a lack of knowledge of the policy's requirements, a broader interpretation of its exceptions, a lack of enforcement, or all of the above.

<sup>76</sup> An example of using or matching data sets is the Centers for Medicare and Medicaid Services' use of data maintained by the Social Security Administration to ascertain the race and ethnicity of Medicare beneficiaries.



- statistical data collections (*e.g.*, vital statistics, disease registries, and other research and survey data such as those collected in national health status surveys, longitudinal research surveys, and studies of access, utilization, and financing of health and social services);
- administrative records (*e.g.*, those used for research, general program administration, contracts and grants reporting, and assessing civil rights compliance);
- research, evaluation and other study projects;
- applications, grants, and contract proposals that collect data from the public; and
- reporting systems for civil rights compliance required under Title VI.

The policy does not apply to:

- data collection activities directed to one or a limited number of minority racial or ethnic groups;<sup>77</sup>
- services or programs exempted because they are directed, by federal law, to one or a limited number of minority racial or ethnic groups and would include only those groups;
- data collection activities that, upon consultation with an HHS statistician, would produce statistically unreliable data on particular racial or ethnic groups;<sup>78</sup>
- data collection and reporting for activities that are not health or human services program administrative, research, survey, or services reporting or assessment;<sup>79</sup>
- data from activities not sponsored or funded by HHS but used by HHS for regulatory, research or other purposes;
- U.S. commonwealths, trusts, and territories and other areas where the Bureau of Census does not use the OMB Standards' categories; and
- special exemptions granted on a case-by-case basis by HHS.<sup>80</sup>

Overall, HHS' policy extends further than the OMB Standards since it purports to mandate the collection of racial and ethnic data throughout all of HHS' data collection practices.

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<sup>77</sup> These activities do not have to collect using the minimum categories specified by OMB but should collect and report data on subgroups within the targeted minority group.

<sup>78</sup> This data should not be reported separately unless accompanied by appropriate caveats.

<sup>79</sup> These collections may be subject to other reporting requirements such as employment activities covered by the Office for Personnel Management (*see* Part V.C.).

<sup>80</sup> Policy Statement, *supra* note 72 at 5.

**c. HHS Initiative to Eliminate Racial and Ethnic Disparities in Health**

In 1998, after President Clinton introduced the President's Initiative on Race,<sup>81</sup> HHS implemented its own Initiative to Eliminate Racial and Ethnic Disparities in Health.<sup>82</sup> The Initiative seeks to eliminate racial and ethnic disparities in six areas by 2010 and hence parallels the focus of Healthy People 2010.<sup>83</sup> When HHS workgroups were formed to report on the health problems in these areas, they had difficulty finding relevant, complete and accurate data.

The Initiative was formed in part as a response to those difficulties, and seeks to encourage research; expand and improve programs that provide quality health services, reduce poverty and afford children safe and healthy environments; and expand prevention efforts. Toward these ends, HHS will:

- examine its current programs to assure that they focus on opportunities to eliminate health disparities and fully maximize the best scientific and community derived knowledge about delivering effective clinical and preventive services;
- identify gaps in knowledge and develop research agendas to address them;
- recommend new programs or modifications of existing programs where appropriate; and
- provide a national framework for public and private sector collaborations to eliminate health disparities through the Healthy People 2010 campaign.<sup>84</sup>

While the Initiative only indirectly addresses data collection, its goal of eliminating disparities in health care illustrates why the collection of racial, ethnic and primary language data is so important. Without collecting data on race and ethnicity on a

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<sup>81</sup> See *One America in the 21st Century: Forging a New Future*, Final Report by the Advisory Board to the President's Initiative on Race, September 18, 1998, <http://www.multiracial.com/government/PIR.pdf>.

<sup>82</sup> See <http://www.raceandhealth.hhs.gov/>.

<sup>83</sup> These six areas are: infant mortality, cancer screening and management, cardiovascular disease, prevention of diabetes complications, HIV/AIDS, and child and adult immunization. According to HHS, these areas were selected because they reflect areas of disparity that are known to affect multiple racial and ethnic minority groups at all life stages and because data was likely to be available. For more information on Healthy People 2010, see <http://www.health.gov/healthypeople/default.htm>.

<sup>84</sup> See *Eliminating Racial and Ethnic Disparities in Health, Overview, The Department's Action Plan*, <http://www.raceandhealth.hhs.gov/sidebar/sbinitOver.htm>.

consistent, ongoing basis, researchers cannot evaluate whether and to what extent disparities persist.

#### **d. Culturally and Linguistically Appropriate Services Standards**

A recent development regarding data collection was the publication of Culturally and Linguistically Appropriate Services (CLAS) standards for health care.<sup>85</sup> The CLAS standards seek to provide guidance on how to prepare for and respond to culturally sensitive situations. The standards are divided into three categories: mandates, guidelines,<sup>86</sup> and recommendations. Included in CLAS is one guideline which states that health care organizations should ensure that data on a patient's or 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.<sup>87</sup> The CLAS standards identify the OMB Standards as providing appropriate categories. In addition, these standards encourage self-identification by patients or consumers rather than observation methods by staff. Not only do the standards recommend noting the primary language of the patient/consumer, they also recognize that the language of a parent or guardian should be noted for patients/consumers who are minors. If, as HHS has suggested, this standard were adopted as a mandate, the collection of primary language, racial and ethnic data would dramatically increase.

To assist with implementation of the CLAS standards, the George Washington University Center for Health Services Research has developed purchasing specifications for cultural competence in the delivery of services. While specifically addressing only Medicaid managed care, many of the specifications may be adapted for use by other state purchasers and Medicare.<sup>88</sup> (*See* Part IV.C.1.d.ii.)

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<sup>85</sup> Office of Minority Health, Office of Public Health and Science, *National Standards on Culturally and Linguistically Appropriate Services in Health Care*, 65 Fed. Reg. 80865 (December 22, 2000). The complete report and other supplementary materials to these standards are available at <http://www.OMHRC.gov/clas>.

<sup>86</sup> "Guidelines" are activities that the CLAS standards recommend should be adopted as mandates by federal, state and national accrediting agencies. *Id.* at 80873.

<sup>87</sup> *Id.* at 80877, Standard 10. The explanation to Standard 10 provides five purposes for the collection of this information: to adequately identify population groups within a service area; to ensure appropriate monitoring of patient/consumer needs, utilization, quality of care and outcome patterns; to prioritize allocation of organizational resources; to improve service planning to enhance access and coordination of care; and to assure that health care services are provided equitably. *Id.*

<sup>88</sup> George Washington University Center for Health Services Research and Policy, *Optional Purchasing Specifications: Cultural Competence in the Delivery of Services Through Medicaid Managed Care*, (Final Review Draft, January 5, 2001).

### **3. Conclusion**

In general, HHS policies encourage and support the widespread collection of racial, ethnic and primary language data, with the notable exception of HIPAA transactions. While these policies apply to all of HHS' programs, each separate agency and program often has statutes, regulations, policies, practices and data collections relevant to its own mission and authority. The following sections examine these specific provisions.

#### **B. Agencies Developing Policy**

##### **1. Office of the Secretary**

The Office of the Secretary encompasses a number of the HHS' policy-setting divisions. Within the Office of the Secretary, four entities impact how the Department collects racial, ethnic and primary language data. While these entities generally do not oversee specific data collection vehicles, their work impacts HHS' data collection policies and practices. These four, discussed in detail below, are the Office for Civil Rights (OCR), the Office of Minority Health (OMH), the Office of the Surgeon General, and the Assistant Secretary for Planning and Evaluation (ASPE).

##### **a. Office for Civil Rights**

The Office for Civil Rights (OCR) assists in carrying out HHS' overall mission of improving the health and well-being of all people affected by HHS programs through both prevention and the elimination of unlawful discrimination. The mission of OCR is to ensure that people have equal access to all HHS programs.

##### **i. Statutory and Regulatory Authority**

As related to the collection of racial, ethnic and primary language data, OCR's primary responsibility arises from its duty to enforce Title VI of the Civil Rights Act of 1964.

OCR also has direct responsibility for overseeing compliance of programs receiving funding through the Hill-Burton Act,<sup>89</sup> which authorized assistance for construction and renovation of public and other nonprofit medical facilities.<sup>90</sup> The Hill-Burton community service assurance requirement mandates that recipients of Hill-Burton funds make services available to persons residing in the facility's service area without discrimination on the basis of race, color, national origin, creed, or any other ground

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<sup>89</sup> 42 U.S.C. § 291 *et seq.*

<sup>90</sup> While no new projects are funded under the Hill-Burton Act, the community service assurance requirement continues indefinitely for projects that received funds. *See* 42 C.F.R. § 124.603.

unrelated to the individual's need for the service or the availability of the needed service in the facility.<sup>91</sup> In addition, recipients must report information prescribed by HHS to determine their compliance with the requirement to provide a designated level of uncompensated care to individuals unable to pay.<sup>92</sup>

## **ii. Policies and Practices**

OCR does not have any independent policies and practices separate from those of HHS.

On January 19, 2001, OCR issued a joint letter with the Surgeon General clarifying that the collection and analysis of racial and ethnic data by health plans and providers is not prohibited under federal law.<sup>93</sup> This letter outlines how the collection of racial and ethnic data may be useful to:

- focus prevention, health education and treatment efforts for specific demographic groups on health conditions prevalent in those groups;
- identify and track similarities and differences in quality of care among various geographic, cultural and ethnic groups, and evaluate programs and health plan performance;
- facilitate the provision of culturally and linguistically appropriate health care;
- understand etiologic processes and identify points of intervention; and
- analyze compliance with title VI and identify potential Title VI problems before they arise.

## **iii. Data Collection Vehicles**

Under the Community Service Assurance Reporting System (CSARS), OCR obtains information from facilities that received funding under the Hill-Burton Act. Not only do these facilities report data on the races of individuals served, they further subdivide that data by type of payor (*i.e.*, Medicaid, Medicare, self-pay, etc.). CSARS also collects information about facilities' ability to communicate with persons of limited English proficiency (LEP).

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<sup>91</sup> 42 U.S.C. §§ 300s(6), 300s-6; 42 C.F.R. §§ 124.9, 124.603.

<sup>92</sup> 42 C.F.R. §§ 124.501, 124.503, 124.509, 124.605.

<sup>93</sup> Letter from Thomas E. Perez, Director, Office for Civil Rights, and David Satcher, Assistant Secretary for Health and Surgeon General (January 19, 2001). This letter, referred to as the "Aetna letter", was sent to 30 interested parties, was written in response to questions from Aetna U.S. Healthcare to the Office for Civil Rights regarding parameters for racial and ethnic data collection.

Data Collection Instrument	Racial Categories	Ethnic Categories
CSARS	American Indian or Alaskan Native; Asian or Pacific Islander; Hispanic; <sup>94</sup> Not of Hispanic Origin (broken down into Black and White)	N/A

**b. Office of Minority Health**

The mission of the Office of Minority Health (OMH) is to improve the health of racial and ethnic populations through the development of effective health policies and programs that seek to eliminate disparities in health.

**i. Statutory and Regulatory Authority**

Under its statutory mandate, OMH must develop mechanisms to support better information dissemination, education, prevention and service delivery to individuals from disadvantaged backgrounds, including racial or ethnic minorities. In addition, OMH must ensure that the National Center for Health Statistics collects data on the health status of minority groups, defined as American Indians (including Alaska Natives, Eskimos and Aleuts), Asian Americans and Pacific Islanders, Blacks, and Hispanics. With respect to individuals with limited English proficiency (LEP), OMH must work to increase the access of individuals to primary health services.<sup>95</sup> Because of its mandate, OMH has an impact on the collection of racial, ethnic and primary language data throughout HHS.

In the Health Professions Education Partnership Act of 1998,<sup>96</sup> Congress established an Advisory Committee on Minority Health. On December 28, 2000, Secretary Donna Shalala announced the appointment of 12 members to this new committee.<sup>97</sup> The committee will advise HHS on methods of improving the health of racial and ethnic minority populations and on the development of goals and program activities within HHS. Until the Advisory Committee establishes an agenda, however, its impact on HHS policies and practices remains unknown.

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<sup>94</sup> While the OMB Standards designate “Hispanic” as an ethnicity and not a race, agencies have until 2002 to change data instruments to reflect the new standards. Thus, many data collection instruments in this volume will include Hispanic as a category of race. In addition, when self-reported data is infeasible or inappropriate, agencies may use one combined race/ethnicity category. *See* Part III.A.3.

<sup>95</sup> *See* 42 U.S.C. § 300u-6.

<sup>96</sup> *Id.*

<sup>97</sup> *See* <http://www.hhs.gov/news/press/2000pres/20001228.html>.

As part of the Minority Health and Health Disparities Research and Education Act of 2000, the National Academy of Sciences<sup>98</sup> must review the data collection systems and practices of HHS and its programs or activities. This study must identify the data needed to support efforts to evaluate the effects of socioeconomic status, race and ethnicity on access to and disparities in health care; examine the effectiveness of current data collection systems and practices; make recommendations for ensuring the collection of reliable and complete racial and ethnic information; and project the costs of implementing the recommendations.<sup>99</sup>

OMH must submit a biennial report to Congress which includes the reports submitted by each Public Health Service agency and evaluates the extent to which OMH's activities have been effective in improving the health of racial and ethnic minority groups.<sup>100</sup>

## **ii. Policies and Practices**

OMH does not have any independent policies and practices separate from HHS. OMH serves as co-chair of the HHS Data Council Working Group on Racial and Ethnic Data and serves on the Subcommittee on Populations of the National Committee on Vital and Health Statistics.

## **iii. Data Collection Vehicles**

OMH does not independently oversee any data collection. OMH has contracted with the National Health Law Program to conduct a survey of the racial, ethnic and primary language data collection and reporting statutes, regulations, policies and practices of the 50 states and District of Columbia.<sup>101</sup>

## **c. Office of the Surgeon General**

The mission of the Surgeon General is to protect and advance the health of the nation through educating the public; advocating for effective disease prevention and health promotion activities; articulating scientifically based health policy analysis and advice to the President and HHS on the full range of critical public health, medical, and health system issues; and providing leadership in promoting special HHS health initiatives. For example, the Surgeon General provides particular leadership on the HHS

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<sup>98</sup> See <http://www4.nationalacademies.org/nas/nashome.nsf> for information about the National Academy of Sciences.

<sup>99</sup> 42 U.S.C. § 741; *see also* Minority Health and Health Disparities Research and Education Act of 2000 § 301.

<sup>100</sup> 42 U.S.C. § 300u-6(f)(1).

<sup>101</sup> A preliminary report was completed in Spring 2001 and is available from the National Health Law Program, (202)-289-7661. The final report is contemplated for completion in the summer of 2002.

Initiative on Racial and Ethnic Disparities, as well as with respect to Healthy People 2010.

**i. Statutory and Regulatory Authority**

The Surgeon General has no specific statutory or regulatory authority relating to the collection of racial and ethnic data or data collection.

**ii. Policies and Practices**

The Surgeon General does not have any independent policies and practices separate from HHS.

On January 19, 2001, the Surgeon General released a letter jointly with the Office for Civil Rights regarding the collection of racial and ethnic data.<sup>102</sup>

**iii. Data Collection Vehicles**

The Surgeon General does not independently oversee any data collection.

**d. Assistant Secretary for Planning and Evaluation**

The Assistant Secretary for Planning and Evaluation (ASPE) is the principal advisor to the Secretary of HHS on policy development. ASPE is responsible for major activities in the areas of policy coordination, legislation development, strategic planning, policy research and evaluation, and economic analysis. ASPE also co-chairs the HHS Data Council.<sup>103</sup>

**i. Statutory and Regulatory Authority**

ASPE has no specific statutory or regulatory authority relating to the collection of racial and ethnic data or data collection generally.

**ii. Policies and Practices**

ASPE does not have any independent policies and practices separate from HHS.

**iii. Data Collection Vehicles**

While ASPE does not independently oversee any data collection, in May 2000, it released an assessment of the major federal data sets for analyses of Hispanic, Asian or

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<sup>102</sup> See note 92.

<sup>103</sup> See Part IV.A.2.a.



Pacific Islander subgroups and Native Americans. This report, including an Inventory of Selected Existing Federal Databases, identifies barriers to developing data and options for improving the capacity to obtain statistically reliable data about these populations.<sup>104</sup>

### **C. Agencies Providing or Administering Health Care Services**

A number of agencies within HHS either directly provide health care services or contract for the provision of services. While HHS' data collection inclusion policy applies to these agencies, the resulting collection of racial, ethnic and primary language data has not yielded consistently comprehensive or statistically reliable information, due partly to a lack of enforcement of data collection requirements on grantees. The reliability of the data varies across each agency.

#### **1. Centers for Medicare and Medicaid Services**

The Centers for Medicare and Medicaid Services (CMS, formerly known as the Health Care Financing Administration or HCFA) oversees the largest health programs within HHS: Medicaid, the State Children's Health Insurance Program (SCHIP) and Medicare. Medicaid and Medicare alone benefit approximately 75 million Americans. CMS oversees SCHIP in conjunction with the Health Resources and Services Administration (HRSA). SCHIP current has approximately 3.3 million enrollees and is expected to cover approximately 10 million children.

For the purposes of this report, each program will be addressed separately. Since both Medicaid and SCHIP are joint federal-state programs, CMS has authorized the states to make many of the decisions about data collection. Although CMS generally oversees the states' data collection activities which are conducted pursuant to its requirements, it is beyond the scope of this volume to address individual state data collection policies.<sup>105</sup>

##### **a. Statutory and Regulatory Authority**

HHS has broad authorization to publish necessary rules and regulations, not inconsistent with the relevant statutory provisions, to ensure the efficient administration of the Medicaid, Medicare and SCHIP programs.<sup>106</sup>

One statutory provision applies to both Medicaid and Medicare. Regarding extended care, post-hospital extended care, and home health care, HHS must implement

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<sup>104</sup> Joseph Waksberg, Daniel Levine and David Marker, *Assessment of Major Federal Data Sets for Analyses of Hispanic and Asian or Pacific Islander Subgroups and Native Americans: Inventory of Selected Existing Federal Databases*, prepared by Westat on behalf of ASPE (May, 2000), <http://aspe.hhs.gov/hsp/minority-db00/task2/index.htm>.

<sup>105</sup> The National Health Law Program will complete a preliminary report on this topic in Spring 2001, pursuant to a contract with OMH. See Part IV.B.1.b.iii.

<sup>106</sup> 42 U.S.C. § 1302, Social Security Act (SSA) § 1102.

automated data collection so that the information is more easily accessible.<sup>107</sup> Each Medicaid and Medicare patient must receive a standardized comprehensive patient-specific assessment to evaluate the necessity for home health services.<sup>108</sup> This data is reported through the OASIS (Outcome and Assessment Information Set).<sup>109</sup> Home health agencies (HHAs) must electronically transmit OASIS data to the state which prepares data for retrieval by a central repository established by CMS.<sup>110</sup> OASIS does not collect racial, ethnic or primary language data.

#### **b. Policies and Practices**

Each separate program has its own policies and practices, discussed below.

#### **c. Medicaid**

The Medicaid program is a joint federal-state program that provides health care to certain low-income individuals who are within a statutorily prescribed eligibility category and meet eligibility requirements.

##### **i. Statutory and Regulatory Authority**

The Medicaid program has a general requirement that states report data, but it does not specifically require racial, ethnic and primary language data. States must provide reports in the form and containing such information as CMS requires.<sup>111</sup> A state's plan must provide that the state agency will submit all reports required by CMS and follow CMS's instructions with regard to the form and content of the reports.<sup>112</sup> Further, state agencies must retain information specified by CMS as necessary for reporting and accountability.<sup>113</sup>

In addition to these reporting requirements, states must also maintain sufficient patient encounter data to identify the physician who delivers services to patients.<sup>114</sup> Waivers granted to states under section 1115 and section 1915 of the Medicaid Act are

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<sup>107</sup> 42 U.S.C. § 1395hh(c)(3), SSA § 1871.

<sup>108</sup> 42 C.F.R. § 484.55. Individuals needing other extended care services must also receive a standardized comprehensive assessment, but the particular assessment tools differ by the type of service the patient requires.

<sup>109</sup> This fulfills provisions of the Balanced Budget Act (BBA) of 1997 which requires automation for prospective payment to home health agencies.

<sup>110</sup> See <http://www.hcfa.gov/medicaid/oasis/hhview.htm>.

<sup>111</sup> 42 U.S.C. § 1396a(a)(5), SSA § 1902.

<sup>112</sup> 42 C.F.R. § 431.16.

<sup>113</sup> 42 C.F.R. § 431.17(b)(2).

<sup>114</sup> 42 U.S.C. § 1396b(m)(2)(A)(xi), SSA § 1903. This provision has been interpreted to require the collection of encounter data *and* information sufficient to identify providers, rather than requiring the encounter data as a way to identify the provider.

also covered by data collection requirements.<sup>115</sup> And the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program requires reports about the number of children provided screenings.<sup>116</sup>

The Balanced Budget Act of 1997 (BBA) required states to participate in the Medicaid Statistical Information System (MSIS).<sup>117</sup> MSIS is an electronic system through which states submit person-specific eligibility and claims data. MSIS substitutes for a hard copy report, CMS Form 2082, Statistical Report on Medical Care: Eligibles, Recipients and Services.

## ii. Policies and Practices

The State Operations Manual embodies many of CMS's policies for the Medicaid program. It reiterates the requirements to abide by Title VI and generally outlines data requirements, but does not provide specific data elements for collection.<sup>118</sup> In addition, the state agency must establish and maintain basic records and prepare operating reports to reflect essential administrative data.<sup>119</sup>

CMS may obtain racial and ethnic information on “dual-eligible” individuals – those eligible for both Medicare and Medicaid – from the Social Security Administration's (SSA) database pursuant to established links between Medicare and SSA's systems.<sup>120</sup> This group, comprised of approximately three to five million

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<sup>115</sup> 42 U.S.C. § 1315, SSA § 1115; 42 U.S.C. § 1396n(c), (d), SSA § 1915.

<sup>116</sup> 42 U.S.C. § 1396a(a)(43), SSA § 1902. For more information on EPSDT, *see* <http://www.hcfa.gov/medicaid/epsdthm.htm>.

<sup>117</sup> 42 U.S.C. § 1396b(r), SSA § 1903(r); *see also* Dear State Medicaid Director letter (Sept. 15, 1997), <http://www.hcfa.gov/medicaid/bbamsis.htm>.

<sup>118</sup> State Operations Manual at 1008, 8005, <http://www.hcfa.gov/pubforms/progman.htm>.

<sup>119</sup> *Id.* at 4003.1.

<sup>120</sup> When SSA was part of HHS, the Medicare and Social Security data systems were designed to allow information sharing between those programs. The continuation of this link allows CMS to access SSA databases for information on Medicare enrollees. SSA maintains the Numerical Identification File (NUMIDENT), an administrative file that contains the information collected when an individual applies for a Social Security card (or replacement) or requests a change of name or other correction. The NUMIDENT also contains death information. The categories used are: Asian, Asian-American or Pacific Islander; Hispanic; Black (Not Hispanic); North American Indian or Alaskan Native; White (Not Hispanic). Contrary to the OMB Standards, which require two questions for self-reported data (one on race, one on ethnicity), the SSA does not provide separate racial and ethnic categories and does not allow for the designation of more than one race. *See* SSA Form SS-5, Application for a Social Security Card. The Enumeration at Birth program, which assigns Social Security Numbers to newborns in the hospital at the time of birth, does not collect racial and ethnic data.

Medicaid beneficiaries, includes individuals over 65, persons with disabilities, and individuals eligible for the treatment of End Stage Renal Disease.

**iii. Data Collection Vehicles**

Although able to require data collection under its authority to implement the program as well as to monitor Title VI compliance, CMS has primarily left decisions regarding data collection to the states. Many states maintain State Medicaid Research Files (SMRFs).<sup>121</sup> The SMRFs may contain enrollment data including race and ethnicity. Since the categories within a state’s SMRF are not established by CMS (and need not conform to the OMB Standards), states’ data are often not comparable because they use different categories. The result is that data are less comprehensive and comparable than if CMS adopted a national system for data collection.

CMS maintains two primary claims databases for Medicaid – one for MSIS and one containing data from the hard-copy CMS Form 2082. While both the MSIS and CMS Form 2082 include fields for race and ethnicity of enrollees, the information gathered from states has been unreliable and inconsistent. Since these forms are primarily for claims reporting, the Secretary of HHS or the White House has historically overruled any attempts by CMS to sanction states who fail to report racial and ethnic data of enrollees.<sup>122</sup>

In addition, Medicaid home health agencies must submit data through OASIS for individuals assessed for home health services.<sup>123</sup>

**Data Collection/Reporting Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
CMS Form 2082, Statistical Report on Medical Care: Eligibles, Recipients, Payments and Services	White; Black/African American; American Indian/Alaskan Native; Asian; Hispanic/Latino; Native Hawaiian/Other	N/A

<sup>121</sup> Patrick Minor, National Center for Primary Care, Morehouse School of Medicine, *Accessing and Analyzing Medicaid Data: Common Problems and Questions*, presentation at Academy for Health Services Research and Health Policy, Fall Seminars in Health Services Research Methods: Using Federal and State Databases (November 1, 2000). Only 60% of states have SMRFs available. *Id.*

<sup>122</sup> See, e.g. National Committee on Vital and Health Statistics, Subcommittee on Population Specific Issues, *Medicaid Managed Care Data Collection and Reporting (Final Report)*, prepared with the assistance of the George Washington University Medical Center School of Public Health and Health Services, Center for Health Services Research and Policy, at ii (December, 1999).

<sup>123</sup> See 42 C.F.R. § 484.55.

	Pacific Islander	
MSIS (Medicaid Statistical Information System)	White; Black/African American; American Indian/Alaskan Native; Asian; Hispanic/Latino; Native Hawaiian/Other Pacific Islander	N/A
OASIS (Outcome and Assessment Information Set)	American Indian or Alaska Native; Asian; Black or African-American; Hispanic or Latino; Native Hawaiian or Pacific Islander; White; Unknown	N/A

**Survey Activities:**

While primarily used in managed care, HEDIS may be used to evaluate fee-for-service providers either through a requirement of a state Medicaid agency or through an independent accrediting organization.

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
HEDIS Consumer Survey <sup>124</sup> (Health Plan Employer Data and Information Set)	American Indian/Alaska Native; Asian; Black/African-American; Hispanic/Latino; Native Hawaiian/Other Pacific Islander; White; Other	N/A

**d. Medicaid Managed Care**

Medicaid managed care organizations (MCOs) have reporting requirements in addition to those generally required by Medicaid.

**i. Statutory and Regulatory Authority**

Managed care in the Medicaid program initially began as demonstration projects under Section 1115 and later as waivers under Section 1915(b) of the Social Security Act. In 1997, as part of the Balanced Budget Act, Congress gave states the authority to implement managed care without waivers from CMS.<sup>125</sup> If a state contracts with MCOs

<sup>124</sup> The HEDIS Consumer survey is one part of the HEDIS instrument, *see* Part IV.C.1.d.iii.

<sup>125</sup> *See* 42 U.S.C. § 1396u-2, SSA § 1932.

to serve its Medicaid population, the state must develop and implement a quality assessment and improvement strategy for the MCOs.<sup>126</sup>

All MCO and prepaid health plan (PHP) contracts must include assurances that the MCO/PHP will not discriminate in enrollment on the basis of race, color or national origin.<sup>127</sup> According to recently proposed Medicaid managed care regulations, states must provide the race, ethnicity and primary language of all enrollees to the MCO/PHP at the time of enrollment.<sup>128</sup> While the states must have this data available to provide it to the MCO/PHP, the regulation does not explicitly require the reporting of this information to CMS.

## **ii. Policies and Practices**

States have the option of using the Quality Improvement System for Managed Care (QISMC) standards and guidelines to outline MCOs requirements regarding quality measurement, improvement, and the delivery of health care and enrollee services. While these standards do not require collection of race, ethnicity and primary language data, standards regarding cultural competency support the collection of this data

In consultation with the Health Resources Services Administration and CMS, the George Washington University Center for Health Services Research and Policy has drafted optional purchasing specifications for cultural competence in the delivery of services.<sup>129</sup> One of the specifications addresses data collection and reporting and is intended to supplement provisions of general applicability in a purchasing document related to data collection and reporting. It also builds on the CLAS standards.<sup>130</sup>

## **iii. Data Collection Vehicles**

CMS has left primary responsibility for determining what data are collected and/or reported to the states.

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<sup>126</sup> 42 U.S.C. § 1396u-2(c), SSA § 1932.

<sup>127</sup> 42 C.F.R. § 438.6(d)(4). While these regulations were finalized on January 19, 2001, the Bush Administration stayed their effective date three times. Nonetheless, in a proposed rule published in August 2001, CMS included the same provisions. *Proposed* 42 C.F.R. § 438.6(d)(4), 66 Fed. Reg. at 43661 (August 20, 2001).

<sup>128</sup> 42 C.F.R. § 438.204(b)(1)(iii). *See fn. 127* for the history of this regulation. In the proposed rule published in August 2001, CMS also included these provisions. *Proposed* 42 C.F.R. § 438.204(b)(2), 66 Fed. Reg. at 43668 (August 20, 2001).

<sup>129</sup> George Washington University Center for Health Services Research and Policy, *Optional Purchasing Specifications: Cultural Competence in the Delivery of Services Through Medicaid Managed Care*, (Final Review Draft, January 5, 2001).

<sup>130</sup> *Id.* at § 107. *See* Part IV.A.2.d.

In Medicaid Managed Care, states may require MCOs to comply with HEDIS (Health Plan Employer Data and Information Set) requirements.<sup>131</sup> HEDIS was developed by CMS in collaboration with the National Committee for Quality Assurance (NCQA) and the American Public Human Services Association. HEDIS is a standardized quality performance measurement system adapted for use by state Medicaid agencies.<sup>132</sup> MCOs must submit two types of data – plan information (which does not provide enrollees’ race, ethnicity or primary language data) and results of a consumer survey (which does include the race and ethnicity of survey participants).

In addition to HEDIS, states may use a version of the Consumer Assessment of Health Plan Study (CAHPS) produced by AHRQ that includes measures specifically designed for use by state agencies.<sup>133</sup>

**Data Collection/Reporting Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
HEDIS Plan Information	White; Asian American; American Indian; Eskimo; Aleut; Chinese; Filipino; Hawaiian; Korean; Vietnamese; Japanese; Asian Indian; Samoan; Guamanian; Other Asian or Pacific Islander; Other; Mixed Race; No Reply <sup>134</sup>	Hispanic; Non-Hispanic

**Survey Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
HEDIS Consumer Survey	American Indian/Alaska Native; Asian; Black/African-American; Hispanic/Latino; Native Hawaiian/Pacific Islander; White; Other	N/A

<sup>131</sup> See <http://www.hcfa.gov/quality/10b.htm>.

<sup>132</sup> NCQA, working with CMS, has developed a guide for states regarding quality improvement in managed care. NCQA, *Health Care Quality Improvement Studies in Managed Care Settings: Design and Assessment – A Guide for State Medicaid Agencies*, <http://www.ncqa.org/>.

<sup>133</sup> See AHRQ, Part IV.D.1.

<sup>134</sup> Information provided by the National Committee for Quality Assurance Technical Advice Line from the HEDIS Technical Manual, Vol. II, 202-955-1701.

**e. State Children’s Health Insurance Program**

The State Children’s Health Insurance Program (SCHIP) is a limited federal-state health program designed to cover state-defined populations of low-income children and families who are ineligible for Medicaid.

**i. Statutory and Regulatory Authority**

SCHIP, enacted in 1997, is codified in Title XXI of the Social Security Act.<sup>135</sup> SCHIP requires that a state’s child health plan include an assurance that the state will collect data, maintain records and furnish reports to HHS as necessary to monitor program administration and compliance, and to evaluate and compare the effectiveness of state plans.<sup>136</sup> Additionally, a state must submit to HHS a description and analysis of the effectiveness of elements of the state plan, including the characteristics of the children and families assisted.<sup>137</sup>

In the final SCHIP regulations, states must report quarterly on enrollees’ race and ethnicity.<sup>138</sup> The regulations require usage of the OMB Standards.<sup>139</sup>

**ii. Policies and Practices**

SCHIP programs are covered by HHS’ inclusion policy

**iii. Data Collection Vehicles**

States may report SCHIP enrollee data to CMS through the Statistical Enrollment Data System.<sup>140</sup> CMS plans to develop an option for states to provide SCHIP claims data through existing statistical reporting systems such as MSIS.<sup>141</sup>

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<sup>135</sup> See 42 U.S.C. § 1397aa *et seq.*

<sup>136</sup> 42 U.S.C. § 1397gg(b), SSA § 2107.

<sup>137</sup> 42 U.S.C. § 1397hh(b)(1)(B), SSA § 2108.

<sup>138</sup> 42 C.F.R. § 457.740(a)(3)(ii). These regulations deleted a requirement to report the primary language of enrollees that was included in regulations finalized in January, 2001. The Bush Administration delayed the effective date of these regulations and published an interim final rule in July 2001, which maintained the race and ethnicity reporting requirement. For the earlier requirement on reporting primary language, *see* 42 C.F.R. § 457.750(b)(7), 66 Fed. Reg. 2684 (January 11, 2001).

<sup>139</sup> See <http://www.hcfa.gov/regs/hcfa2006fc/hcfa2006fc.htm>, Provisions of the Proposed Rule and Discussion of Public Comments, Subpart G, at 558.

<sup>140</sup> Dear State Health Official Letter, (Sept. 13, 2000), <http://www.hcfa.gov/init/ch91300.htm>.

<sup>141</sup> See Part IV.C.1.c.i.



## **f. Medicare**

While also administered by CMS, Medicare differs from both Medicaid and SCHIP because it is not a joint federal-state partnership. Thus, CMS has sole authority to determine data collection practices.

### **i. Statutory and Regulatory Authority**

CMS has general authority to prescribe regulations necessary to administer Medicare.<sup>142</sup> In addition, Medicare providers must release data with respect to patients, as may be necessary, as part of peer reviews of the utilization and quality of services.<sup>143</sup>

Medicare claims must be filed on a form prescribed by CMS in accordance with CMS instructions.<sup>144</sup>

### **ii. Policies and Practices**

CMS obtains racial and ethnic data about Medicare enrollees from data available through the Social Security Administration.<sup>145</sup>

### **iii. Data Collection Vehicles**

CMS has established a number of Medicare databases that include information on both Medicare fee-for-service (FFS) and Medicare managed care (Medicare Plus Choice or M+C). The Enrollment DataBase is CMS's basic database for Medicare beneficiaries. Surveys conducted by CMS, such as the Current Beneficiary Survey, provide the means to assess utilization of services by Medicare beneficiaries, using the Enrollment DataBase. The Medicare data files consistently assign race categories in the enrollment and utilization files because the utilization files derive their information from the master enrollment file at the time the claim is processed.<sup>146</sup>

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<sup>142</sup> 42 U.S.C. § 1395hh, SSA § 1871. This operates in addition to HHS' general authority to issue regulations for the operation of programs under the Social Security Act. *See* 42 U.S.C. § 1302, Social Security Act (SSA) § 1102.

<sup>143</sup> 42 U.S.C. § 1395cc, SSA § 1866.

<sup>144</sup> 42 C.F.R. § 424.32.

<sup>145</sup> When SSA was part of HHS, the Medicare and Social Security data systems were designed to allow information sharing between those programs. The continuation of this link allows CMS to access SSA databases for information on Medicare enrollees. *See* note 119.

<sup>146</sup> Marshall McBean, *Using Medicare Data for Health Services Research: Demographic and Clinical Information*, presentation at Academy for Health Services Research and Health Policy, Fall Seminars in Health Services Research (November 1, 2000).

CMS must implement a nationwide survey of health care experiences and consumer satisfaction among beneficiaries enrolled in the original Medicare FFS program.<sup>147</sup> CMS must provide information on “plan quality and performance indicators for beneficiaries under the [Medicare managed care] plan[s], and how they compare to such indicators under the original Medicare fee-for-service program, including information on Medicare enrollee satisfaction.”<sup>148</sup>

**Data Collection/Reporting Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Enrollment DataBase <sup>149</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black (non-Hispanic); White (Non-Hispanic); Hispanic; Other	N/A
National Claims History 100% Nearline File <sup>150</sup>	Asian/Pacific Islander; Hispanic; Black (non-Hispanic); American Indian/Alaskan Native; White (Non-Hispanic); Other; Unknown	N/A
National Claims History Standard Analytical Files (SAF) <sup>151</sup>	Asian/Pacific Islander; Hispanic; Black (non-Hispanic); American Indian/Alaskan Native; White (Non-Hispanic); Other; Unknown	N/A
Health Insurance Skeleton Eligibility Write-Off File (HISKEW) <sup>152</sup>	Asian/Pacific Islander; Hispanic; Black (non-Hispanic); American Indian/Alaskan Native; White (Non-Hispanic); Other; Unknown	N/A
Medicare Current Beneficiary Survey	American Indian/Alaskan Native; Asian/Pacific	Hispanic; Not of Hispanic Origin; Don't Know;

<sup>147</sup> See Medicare+Choice, Part IV.C.1.g.i. for citations.

<sup>148</sup> 42 C.F.R. § 422.64(c)(10).

<sup>149</sup> The Enrollment DataBase contains Medicare beneficiary enrollment information.

<sup>150</sup> This file houses all processed institutional and physician/supplier claims data.

<sup>151</sup> SAF provides final action claims level files developed from the Medicare National Claims History Database.

<sup>152</sup> HISKEW contains data for all beneficiaries ever enrolled in Medicare with a subset of data elements from the Enrollment DataBase quarterly.

(MCBS) <sup>153</sup>	Islander; Black; White; Other; Don't Know; Refused Specification; Not Ascertained	Refused Specification; Not Ascertained
Medicare Provider Analysis and Review File (MEDPAR) <sup>154</sup>	Asian/Pacific Islander; Hispanic; Black (non-Hispanic); American Indian/Alaskan Native; White (non-Hispanic); Other; Unknown	N/A

**Survey Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Medicare Health Outcomes Survey (HOS) <sup>155</sup>	American Indian/Alaska Native; Asian; Black or African-American; Hispanic or Latino; Native Hawaiian/Pacific Islander; White; Unknown	N/A
CAHPS – Fee-for-Service Survey <sup>156</sup>	White; Black/African American; Asian; Native Hawaiian/Pacific Islander; American Indian/Alaskan Native	Hispanic or Latino Origin or descent

**g. Medicare Plus Choice**

In 1997, through enactment of the Balanced Budget Act, Congress authorized the Medicare Plus Choice (M+C) program to allow managed care organizations to serve Medicare enrollees.<sup>157</sup>

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<sup>153</sup> MCBS provides a representative sample specific to benefits received and costs.

<sup>154</sup> MEDPAR contains inpatient hospital and Skilled Nursing Facility final action stay records.

<sup>155</sup> The HOS, formerly named the Health of Seniors Survey, is a recent HEDIS measure that allows comparison of changes in self-reported health status for mental and physical health. For more information see <http://www.hcfa.gov/quality/3e.htm>.

<sup>156</sup> CMS initially undertook the CAHPS survey only for M+C enrollees but, to allow comparison with Medicare FFS enrollees (required by the Balanced Budget Act), CMS extended the CAHPS survey to the latter.

<sup>157</sup> See 42 U.S.C. § 1395w-21, SSA § 1851 *et seq.*

## **i. Statutory and Regulatory Authority**

CMS must provide information on plan quality and performance indicators (including enrollee satisfaction) for M+C, and how those compare to indicators under the original Medicare FFS program.<sup>158</sup> The managed care organizations must have arrangements for an ongoing quality assurance program for health care services.<sup>159</sup> The M+C regulations reiterate these requirements.<sup>160</sup>

In addition, each M+C organization must submit to CMS all data necessary to characterize the context and purposes of each encounter between enrollees and providers, suppliers, physicians or other practitioners. On dates established by CMS, M+C organizations must begin submitting data on all inpatient hospital discharges, physician, outpatient hospital, skilled nursing facility, and home health agencies, and all other data CMS deems necessary.<sup>161</sup> To the extent CMS requires, the data must also account for services covered under the Medicare FFS program, for Medicare covered services for which Medicare is not the primary payor, or for other additional or supplemental benefits the M+C organization provides. And, when appropriate, M+C encounter data must conform to the requirements for equivalent data submitted by Medicare FFS providers and to all relevant national standards.<sup>162</sup>

Contracts between CMS and M+C organizations must include an agreement to comply with all the applicable requirements and conditions, including operating a quality assurance and performance improvement program, complying with the reporting requirements and submitting encounter data.<sup>163</sup> M+C organizations must also have an effective procedure to report statistics and other information required.<sup>164</sup>

In December 2000, the Benefits Improvement Protection Act (BIPA) was enacted.<sup>165</sup> As part of BIPA, each M+C organization, private M+C fee-for-service plan, and non-network Medical Savings Account (MSA) plan<sup>166</sup> must have, as part of their quality assurance program, a special focus on racial and ethnic minorities.<sup>167</sup> There is no

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<sup>158</sup> 42 U.S.C. § 1395w-22(d)(2)(A), (4)(D), SSA § 1852.

<sup>159</sup> 42 U.S.C. § 1395w-22(e), SSA § 1852.

<sup>160</sup> 42 C.F.R. §§ 422.64(c)(10), 422.152, 422.154.

<sup>161</sup> 42 U.S.C. § 1395w-23(a)(3)(B), SSA § 1853; 42 C.F.R. § 422.257(a), (b).

<sup>162</sup> 42 C.F.R. § 422.257(c)(2). CMS recognizes that while establishing an encounter data system may be the most effective means of meeting the requirements, an M+C organization may use any methods or procedures to collect quality data.

<sup>163</sup> 42 U.S.C. § 1395mm(i)(3)(D), (k)(4)(B), SSA § 1876; 42 C.F.R. § 422.502(a)(5), (8).

<sup>164</sup> 42 C.F.R. § 422.516(a)(6).

<sup>165</sup> P.L. No. 106-554 (Dec. 21, 2000).

<sup>166</sup> These plans are defined in 42 U.S.C. § 1395w-28(a), SSA § 1859.

<sup>167</sup> P.L. 106-554 § 616(a); *see also* 42 U.S.C. § 1395w-22(e), SSA § 1852. Each element of the quality assurance plan must have this focus. For all three types of organizations

specific requirement to collect racial, ethnic or primary language data. Every two years HHS must submit a report to Congress on how the quality assurance programs focus on racial and ethnic minorities.<sup>168</sup>

The M+C regulations require that M+C organizations ensure services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.<sup>169</sup> Current data collection activities do not, however, require information on primary language.

## ii. Policies and Practices

In May 1999, CMS issued an Operational Policy Letter to clarify when M+C organizations may collect racial and ethnic data.<sup>170</sup> CMS allows M+C organizations to collect data before, during and after enrollment.<sup>171</sup> Information may only be requested from enrollees on a voluntary basis and may not be used for pre-selection or eligibility determinations. CMS suggests that M+C organizations use the OMB Standards to promote the usefulness of the data for analysis. Finally, the letter includes rationales for collecting data:

- to reach out to specific demographic groups for prevention, health education and treatment efforts for diseases prevalent in these groups;
- to facilitate the provision of culturally and linguistically appropriate care; and

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these elements are: health outcomes; high volume and high risk services and the care of acute and chronic care conditions; continuity and coordination of care; and, consumer satisfaction. In addition, M+C organizations must include methods for: detection of under- and over-utilization of services; establishing or altering practice parameters after identifying areas for improvement; and ensuring the availability of quality and outcome measures that facilitate beneficiary comparison and choice of health care options.

<sup>168</sup> This report must include: a description of the means by which such programs focus on racial and ethnic minorities; an evaluation of the impact of such programs on eliminating health disparities and improving health outcomes, continuity and coordination of care, management of chronic conditions, and consumer satisfaction; and recommendations on ways to reduce clinical outcome disparities among racial and ethnic minorities. *Id.* § 616(b).

<sup>169</sup> 42 C.F.R. § 422.112(a)(9).

<sup>170</sup> Operational Policy Letter No. 99.093, Clarification of Policy Regarding the Collection of Information on Race and Ethnicity, <http://www.hcfa.gov/medicare/opl093.htm> (May 3, 1999).

<sup>171</sup> An initial letter stated that M+C organizations could only collect racial and ethnic data after enrollment.

- to track similarities and differences in plan performance in various geographic, cultural and ethnic communities.

CMS requires all M+C plans to report on performance measures using HEDIS and to participate in independently administered CAHPS surveys.<sup>172</sup>

M+C organizations must comply with the Quality Improvement System for Managed Care (QISMC) standards and guidelines. Every two years, CMS assesses M+C plans' compliance with QISMC standards regarding quality measurement, improvement, and the delivery of health care and enrollee services. While not requiring the collection of race, ethnicity and primary language data, QISMC includes cultural competency standards that support the collection of this data. As part of QISMC, each M+C organization must undertake a quality assessment and performance improvement (QAPI) project. For 2003, the CMS-defined national QAPI projects require improved quality of care either for clinical health care disparities or culturally and linguistically appropriate services.<sup>173</sup>

### iii. Data Collection Vehicles

#### Data Collection/Reporting Activities:

Data Collection Instrument	Racial Categories	Ethnic Categories
HEDIS Plan Information	White; Asian American; American Indian; Eskimo; Aleut; Chinese; Filipino; Hawaiian; Korean; Vietnamese; Japanese; Asian Indian; Samoan; Guamanian; Other Asian or Pacific Islander; Other; Mixed Race; No Reply <sup>174</sup>	Hispanic; Non-Hispanic

<sup>172</sup> OPL No. 47 (revised), Medicare Managed Care (April 14, 1997), <http://www.hcfa.gov/medicare/opl047.htm>.

<sup>173</sup> OPL No. 2001.133, Letter to M+C Organizations and Regional Offices, Medicare+Choice Organizations' (M+CO) National Quality Assessment and Performance Improvement (QAPI) for the Years 2002 and 2003, July 16, 2001, <http://www.hcfa.gov/medicare/index.htm>. This letter supersedes a letter to M+C Organizations and Regional Offices, dated January 18, 2001, which had designated these as national objectives for 2002 (this letter is available from NHeLP).

<sup>174</sup> Information provided by the National Committee for Quality Assurance Technical Advice Line.

**Survey Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
CAHPS–Medicare Satisfaction Survey <sup>175</sup>	White; Black/African American; Asian; Native Hawaiian/Pacific Islander; American Indian/Alaskan Native	Hispanic or Latino Origin or descent
HEDIS Consumer Survey <sup>176</sup>	American Indian/Alaska Native; Asian; Black/African-American; Hispanic/Latino; Native Hawaiian/Pacific Islander; White; Other	N/A

**h. Medicare End Stage Renal Disease Program**

The Medicare program also provides health coverage to individuals eligible for treatment of End Stage Renal Disease (ESRD).

**i. Statutory and Regulatory Authority**

HHS must establish a national registry and coordinate data reported by network organizations, transplant centers, and other sources on all ESRD patients.<sup>177</sup>

Through the ESRD program, certain reporting requirements exist.<sup>178</sup> Hospitals providing renal transplantation services must submit an annual report to CMS on utilization rates.<sup>179</sup> As a condition for ESRD suppliers<sup>180</sup> of transplantation services to be covered by Medicare, the suppliers must furnish data and information to HHS in the manner specified.<sup>181</sup> Specifically regarding ESRD facilities, the governing body of the ESRD facility must maintain and submit records and reports required by CMS.<sup>182</sup>

<sup>175</sup> CAHPS -- Medicare collects and reports objective information to help consumers and purchasers choose and assess managed care plans.

<sup>176</sup> The HEDIS Consumer Survey uses the same instrument as the Health Outcomes Survey used in fee-for-services Medicare.

<sup>177</sup> 42 U.S.C. § 1395rr(c)(7), SSA § 1881 .

<sup>178</sup> 42 U.S.C. § 1395rr(c)(2)(F), (H), SSA § 1881.

<sup>179</sup> 42 C.F.R. § 405.2123.

<sup>180</sup> Suppliers include ESRD facilities, laboratories performing histocompatibility testing, and organ procurement organizations.

<sup>181</sup> 42 C.F.R. § 405.2133.

<sup>182</sup> 42 C.F.R. § 405.2136(c)(3)(v).

Medical records maintained by ESRD facilities must contain identification and social data.<sup>183</sup>

**ii. Policies and Practices**

CMS, in collaboration with NIH and CDC, is developing a core data set of information to be collected on all ESRD patients and/or facilities.<sup>184</sup>

**iii. Data Collection Vehicles**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
End Stage Renal Disease (ESRD) Program Management and Medical Information System <sup>185</sup>	American Indian/Alaskan Native; Asian; Pacific Islander; Mid-East/Arabian; Indian Sub-Continent; Black; White; Other or Multiracial; Unknown	Hispanic: Mexican; Hispanic: Other; Non-Hispanic

**2. Health Resources and Services Administration**

The Health Resources and Services Administration (HRSA) directs national health programs that improve the nation’s health by assuring equitable access to comprehensive, quality health care. HRSA supports a nationwide network of 643 community and migrant health centers, and 144 primary care programs for the homeless and residents of public housing, serving 8.1 million individuals each year. HRSA specifically works to improve and extend life for people living with HIV/AIDS, to provide primary health care to medically under-served people, and to serve women and children through state programs.

**a. Statutory and Regulatory Authority**

The specific authorities are provided within each bureau.

**b. Policies and Practices**

HRSA’s activities are centered on the goal of assuring 100% access to health care with no health disparities. HRSA has identified four long-range strategies to accomplish this goal. Within the strategy for eliminating health disparities, one sub-strategy focuses on enhancing data collection. Without data collection and analysis, HRSA cannot delineate specific populations and sub-populations that suffer from health disparities.

<sup>183</sup> 42 C.F.R. § 405.2139(a).

<sup>184</sup> See, National ESRD Core Data Set Initiative, National ESRD Health Information Agreement Concept Description, <http://www.hcfa.gov/quality/301.htm>.

<sup>185</sup> This system includes medical and demographic information.



HRSA intends to work throughout HHS to coordinate data collection activities for targeted population groups.<sup>186</sup>

**c. Data Collection**

HRSA itself oversees the Area Resource File (ARF), which includes county specific health resource information. ARF incorporates information on health facilities, health professions, measures of resource scarcity, health status, economic activity and socioeconomic environmental characteristics. The ARF is derived from over 50 existing data source files and records (e.g., NCHS’ mortality and natality records). The data collection activities of HRSA’s bureaus are listed within those specific sections.

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Area Resource File (ARF)	Varies	Varies

**d. Bureau of Primary Health Care**

The mission of the Bureau of Primary Health Care (BPHC) is to increase access to comprehensive primary and preventive health care and to improve the health status of under-served and vulnerable populations. BPHC oversees both community and migrant health centers, programs funded to serve migrant and seasonal agricultural workers, the homeless, and residents of public housing. BPHC grantees must serve populations that are “under-served”, whether because of difficulty paying for services, language or cultural differences, or insufficient health professionals and/or resources in the community.

BPHC operates the Minority and Women’s Health program to promote activities that reduce disparities in the health status of racial and ethnic minorities as well as women. The program seeks to stimulate collaborative partnerships to ensure coordinated health care that responds to an individual’s cultural and linguistic needs. This program established a Primary Health Care Component of the National Center for Cultural Competence to provide knowledge development and information exchange between BPHC and its funded programs. The Cultural Competency Program of BPHC seeks to demonstrate that culturally and linguistically competent practices increase access to services and reduce disparities in the health status of ethnic, racial and cultural populations.<sup>187</sup>

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<sup>186</sup> See HRSA, *The Access Agency Strategic Plan FY 2000*, available through <http://www.ask.hrsa.gov:80/detail.cfm?id=HRS00122>.

<sup>187</sup> The goals of this program include: promoting knowledge development, dissemination, exchange and application between BPHC-funded programs at national, regional, state and community levels; identifying and disseminating best practices; encouraging linkages between the BPHC, field offices, primary care agencies and primary care organizations; providing training, technical assistance, consultation,

### **i. Statutory and Regulatory Authority**

Each community and migrant health center overseen by BPHC must develop an effective procedure for reporting statistics and other information relating to the patterns of use of its services; the availability, accessibility, and acceptability of its services; and other matters relating to operation.<sup>188</sup> For centers that serve a substantial proportion of individuals of limited English-speaking ability, the center must, to the extent practicable, make arrangements to provide services in the most appropriate language and cultural context.<sup>189</sup>

The BPHC's regulations for community and migrant health centers specifically call attention to the requirement to abide by the nondiscrimination requirements of Title VI.<sup>190</sup> In addition, health centers must maintain systems that enable the center to provide statistics and other information reasonably required by BPHC regarding the center's patterns of utilization and the availability, accessibility, and acceptability of its services.<sup>191</sup>

BPHC also operates the Native Hawaiian Health Care Program, authorized by the Native Hawaiian Health Care Act of 1988.<sup>192</sup> This Act authorized the establishment of health promotion, disease prevention and primary care services for Native Hawaiians and persons of Hawaiian ancestry. The Program advocates for, initiates, and maintains culturally appropriate strategic actions aimed at improving the physical, mental and spiritual health of Native Hawaiians.

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information and written policy briefings; and developing and distributing fact sheets on current topics of interest in cultural and linguistic competence.

<sup>188</sup> 42 U.S.C. § 254b(j)(3)(I).

<sup>189</sup> 42 U.S.C. § 254b(j)(3)(K). In addition, each center must identify an individual on its staff who is fluent in both that language and in English and whose responsibilities shall include providing guidance to individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences.

<sup>190</sup> 42 C.F.R. § 51c.109.

<sup>191</sup> 42 C.F.R. § 51c.303(j).

<sup>192</sup> P.L. 100-579, *codified at* 42 U.S.C. § 11703. Grantees serving any population of Native Hawaiians of whom a substantial portion have a limited ability to speak English, must demonstrate the ability to provide health services through individuals who are able to communicate in the language and cultural context most appropriate. Grantees must designate at least one individual, fluent in both English and the appropriate language, for this purpose.

## ii. Policies and Practices

BPHC's policies are included in its Uniform Data Set (UDS) Manual that explains data collection requirements for BPHC funded programs.<sup>193</sup> In addition to requiring information on race and ethnicity, the UDS requires collection of the percentage of users needing interpretation, bilingual or Sign Language services.<sup>194</sup>

BPHC Policy Information Notice 98-23 articulates expectations for all BPHC programs. While many of these address the operations of BPHC funded clinical programs, the expectations recognize that BPHC grantees serve culturally and linguistically diverse populations, and that all funded programs are expected to provide services which are appropriately culturally and linguistically diverse.<sup>195</sup> As additional guidance, BPHC has published a guide on how to provide culturally competent primary care services.<sup>196</sup>

## iii. Data Collection Vehicles

### Data Collection/Reporting Activities:

Data Collection Instrument	Racial Categories	Ethnic Categories
Uniform Data Set <sup>197</sup>	White; Black; Hispanic; Asian/Pacific Islander; American Indian/ Alaskan Native; Unreported or Unknown	N/A

<sup>193</sup> The UDS Manual is available at <http://bphc.hrsa.gov:80/news/docs/UDS2000MANUAL.pdf>.

<sup>194</sup> *Id.* at 27. The Manual explains that the primary language data required is the percentage of users who are best served in a language other than English, or with sign language. Centers must account for those users who were served by a bilingual provider and those who may have brought their own interpreter. Grantees may report estimated data if the health center does not maintain actual data in its management information system; wherever possible, the estimate should be based on a sample. *Id.* at 24.

<sup>195</sup> BPHC Policy Information Notice No. 98-23, *Health Center Program Expectations* (August 17, 1998), <http://bphc.hrsa.gov:80/ogm/Pin98-23%20HC%20Prog%20Expectations.pdf>.

<sup>196</sup> See *Cultural Competence: A Journey*, <http://bphc.hrsa.gov/culturalcompetence/default.htm>.

<sup>197</sup> The UDS collects uniformly defined information on patient characteristics and clinical conditions for major BPHC grant programs.

**Survey Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Community Health Center and National Health Service Corps User/Visit Survey <sup>198</sup>	White; Black/African-American; Native American; Alaska Native; Native Hawaiian; Guamanian; Samoan; Other Pacific Islander; Asian (Indian); Chinese; Japanese; Korean; Vietnamese; Filipino; Other Asian	Hispanic or Latino (specify Puerto Rican; Cuban/Cuban-American; Other Hispanic/Latino Caribbean; Mexican/Mexican-American; Central or South American; Other Latin American; Other Spanish American); Non-Hispanic or Latino

**e. HIV/AIDS Bureau**

The HIV/AIDS Bureau of HRSA develops programs that focus on the most important issues in HIV/AIDS, including managed care, HIV/AIDS drugs, treatment adherence, data and evaluation, measuring outcomes, and reaching the most vulnerable populations.

**i. Statutory and Regulatory Authority**

The Ryan White Care Act<sup>199</sup> authorizes programs administered by the HIV/AIDS Bureau. For emergency relief grants,<sup>200</sup> and HIV Care Grants,<sup>201</sup> an application must include the number of individuals to be served and their demographic data.<sup>202</sup> For grants providing early intervention services, applicants must submit the number of individuals to whom the applicant provides services and their epidemiological and demographic data.<sup>203</sup>

**ii. Policies and Practices**

The HIV/AIDS Bureau does not have any policies or practices independent of the general HHS policies and practices.

<sup>198</sup> This survey collects in-depth information about the process and outcomes of care for users of community health centers and the National Health Service Corps.

<sup>199</sup> The Ryan White Care Act of 1990, as amended by the Ryan White Care Act of 1996, P.L. 104-146, 42 U.S.C. § 2601 *et seq.*

<sup>200</sup> Emergency relief grants are defined in 42 U.S.C. § 2604(b).

<sup>201</sup> HIV Care Grants are defined in 42 U.S.C. § 2612.

<sup>202</sup> 42 U.S.C. §§ 2605(b), 2617(b).

<sup>203</sup> 42 U.S.C. § 2664(a)(2)(A), (B).

**iii. Data Collection Vehicles**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Dental Reimbursement Program–HIV/AIDS <sup>204</sup>	White; Black; Hispanic; Asian/Pacific Islander; American Indian; Missing/Unknown	N/A
Ryan White CARE Act Administrative Report <sup>205</sup>	White; Black; Hispanic; Asian/Pacific Islander; American Indian; Missing/Unknown	N/A
Ryan White CARE Act – Cross-Title Data Report Form (CTDR) <sup>206</sup>	OMB Standards	OMB Standards

**f. Maternal and Child Health Bureau**

The Maternal and Child Health Bureau (MCHB) has primary responsibility for promoting and improving the health of the nation’s mothers and children.

**i. Statutory and Regulatory Authority**

The Maternal and Child Health (MCH) Services Block Grant program has three components: formula block grants to states, Special Projects of Regional and National Significance (SPRANS) and Community Integrated Service Systems (CISS) grants. All MCH grants have an annual reporting requirement including, by racial and ethnic group, the number of deliveries in a state per year and the number of women who were provided prenatal, delivery or postpartum care under MCH or Medicaid.<sup>207</sup>

In addition, each state must submit an annual report to HHS which includes, by racial and ethnic group, the rate of infant mortality and low-birth-weight births; the total number of deliveries in the State and deliveries by pregnant women provided prenatal, delivery or postpartum care or entitled to benefits under Medicaid; and the total number of infants under one year and those provided benefits under the MCH grants, Medicaid or SCHIP.<sup>208</sup> HHS must submit a report to Congress including this information.<sup>209</sup>

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<sup>204</sup> This survey provides information on patient demographics, distribution of dental procedures, HIV related activities, and use of reimbursement award.

<sup>205</sup> These administrative reports collect provider information, demographics, and client service information.

<sup>206</sup> Beginning in 2002, the CTDR will replace the Administrative Report, allowing grantees to provide aggregate data on all Ryan White CARE Act activities rather than delineating data by funding category.

<sup>207</sup> 42 U.S.C. § 706.

<sup>208</sup> 42 U.S.C. § 706(a)(2)(B)(i), (C)(i), (ii).

Recipients must abide by HHS' Title VI regulations<sup>210</sup> and provide information on an annual basis as determined by HHS.<sup>211</sup>

**ii. Policies and Practices**

The Maternal and Child Health Bureau does not have any policies or practices independent of the general HHS policies and practices.

**iii. Data Collection Vehicles**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Block Grant Accountability <sup>212</sup>	White; Black; American Indian; Asian/Pacific Islander; Other/Unknown	Total Non-Hispanic; Total Hispanic (Mexican, Cuban, Puerto Rican, Central and South American; Other/Unknown)

**g. Office of Special Projects – Division of Transplantation**

The mission of the Office of Special Projects, Division of Transplantation is to provide oversight of the Organ Procurement and Transplantation Network (OPTN), the Scientific Registry of Transplant Recipients (SRTR), and the National Marrow Donor Program (NMDP) contracts; national coordination of organ donation activities, and the funding of grants and special initiatives to study ways to increase donation; and technical assistance to Organ Procurement Organizations (OPOs) and other transplant-related entities.

**i. Statutory and Regulatory Authority**

The National Organ Transplant Act requires the Organ Procurement and Transplantation Network to collect, analyze, and publish data concerning organ donation and transplants; and carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation, including but not limited to projects to examine and attempt to increase transplantation among populations with special needs, including racial or ethnic minorities.<sup>213</sup>

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<sup>209</sup> 42 U.S.C. § 706(a)(3).

<sup>210</sup> 42 C.F.R. § 51a.7.

<sup>211</sup> 42 C.F.R. § 51a.8.

<sup>212</sup> This database collects information on State's needs, priorities, program activities, performance measures and outcomes to be compiled and compared with information from other States. The data are used to generate reports to Congress.

<sup>213</sup> 42 U.S.C. § 274(b)(2)(I), (b)(2)(N).

BPHC must develop and maintain a scientific registry of the recipients of organ transplants. The scientific registry must include information about patients and transplant procedures as deemed necessary for an ongoing evaluation of the scientific and clinical status of organ transplantation.<sup>214</sup> The statute does not elucidate specific data collection requirements regarding race and ethnicity.

The regulations similarly require reporting sufficient to determine the effectiveness of the organ donation, procurement and transplantation system, but do not specifically address racial and ethnic data.<sup>215</sup>

**ii. Policies and Practices**

The Special Projects Office does not have any policies or practices independent of the general HHS policies and practices.

**iii. Data Collection Vehicles**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Organ Transplantation Scientific Registry <sup>216</sup>	White; Black; American Indian/Alaskan Native; Asian; Pacific Islander; Mid-East/Arabian; Indian Sub-Continent	Hispanic (Mexican); Hispanic (Other); Non-Hispanic

**3. Indian Health Service**

The Indian Health Service (IHS) is responsible for providing federal health services to American Indians and Alaska Natives. The IHS is the principal federal health care provider and health advocate for Indian people. Its goal is to assure that comprehensive, culturally acceptable personal and public health services are available and accessible to American Indian and Alaska Native populations. The IHS currently provides services to approximately 1.5 million American Indians and Alaska Natives who belong to more than 550 federally recognized tribes in 35 states.

**a. Statutory and Regulatory Authority**

The IHS operates pursuant to a federal trust responsibility.<sup>217</sup> Because of the sovereign status of federally recognized tribes vis-à-vis the federal government, the IHS

<sup>214</sup> 42 U.S.C. § 274a.

<sup>215</sup> 42 C.F.R. § 121.11(b).

<sup>216</sup> This database collects information on cadaveric and living donor characteristics, survival rates, waiting lists and organ disposition.

may not impose mandatory reporting requirements unless required by statute. Thus each Indian tribe or tribal organization negotiates with IHS regarding the type and frequency of data report(s).<sup>218</sup>

The IHS must submit annual reports to Congress on the current health status and resource deficiencies for each tribe or service unit.<sup>219</sup>

IHS must establish epidemiology centers and, in consultation with CDC and Indian tribes, sets of data for uniformly defining health status.<sup>220</sup> These data sets must impose a minimal reporting burden.<sup>221</sup> The uniform data set serves as the target for IHS and the Indian tribes or tribal organizations during individual negotiations on program data reporting requirements.<sup>222</sup> Tribes are not, however, required to use the data sets developed.

For health services to Native Americans living in urban areas, IHS provides services through grantees that must provide annual reports, including information requested by IHS or HHS.<sup>223</sup>

HHS, acting through IHS, must also establish an automated management information system for IHS that includes a patient care information system for each area served by IHS.<sup>224</sup>

#### **b. Policies and Practices**

IHS does not have any published policies and practices regarding data collection. Because IHS serves only American Indians and Alaska Natives, however, the HHS inclusion policy has a different focus. Rather than have separate racial and ethnic categories, IHS databases include fields for tribal designations.

IHS operates a Patient Registration-System (PRS), the official means for collecting, identifying, and recording patient demographic and eligibility information.<sup>225</sup>

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<sup>217</sup> 25 U.S.C. § 1661.

<sup>218</sup> 25 C.F.R. § 900.65.

<sup>219</sup> 25 U.S.C. § 1621.

<sup>220</sup> 25 U.S.C. § 1621m.

<sup>221</sup> 25 C.F.R. § 900.67.

<sup>222</sup> 25 C.F.R. § 900.68. On January 22, 1992, the Core Data Set Requirements were finalized by IHS. 56 Fed. Reg. 2642 (January 22, 1992); updated in 1993 (57 Fed. Reg. at 42588, September 15, 1992) and 1994 (59 Fed. Reg. at 3252; January 20, 1994). *See also* Indian Health Manual, Part 2, Chapter 6 at 2-6.2C(2)(d), <http://www.ihs.gov/PublicInfo/Publications/IHSManual/index.asp>.

<sup>223</sup> 25 U.S.C. § 1657.

<sup>224</sup> 25 U.S.C. § 1662.



The Indian Health Manual (IHM) establishes the policies, procedures, responsibilities, and program elements for the PRS. The Manual notes that the collection of demographic data provides the ability to examine the demographic characteristics of patients, facility by facility, thereby supporting resource allocation and other planning needs involving patient care systems and health service delivery programs.<sup>226</sup>

All individuals must be registered in the PRS prior to receiving IHS health care services.<sup>227</sup> Required fields include Tribe of Membership/Tribe Codes<sup>228</sup> and Indian Blood Quantum.<sup>229</sup> The information in the PRS is used for compiling national statistics.<sup>230</sup>

**c. Data Collection Vehicles**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
American Indian and Alaska Linked Birth/Infant Death Record Database <sup>231</sup>	American Indian; Alaska Native	N/A
American Indian and Alaska Native Mortality Database <sup>232</sup>	American Indian; Alaska Native	N/A
American Indian and Alaskan Native Natality Database <sup>233</sup>	American Indian; Alaska Native	N/A
Indian Health Service	American Indian; Alaska	N/A

<sup>225</sup> Indian Health Manual (IHM), Part 2, Services to Indians and Others, Chapter 6 – Patient Registration, 2-6.1.

<sup>226</sup> *Id.* at 2-6.1A(2)(b).

<sup>227</sup> *Id.* at Part 3, Professional Services, Chapter 3 – Medical Records, 3-3.12; 3-3.12F(6)a.

<sup>228</sup> The PRS includes a list of recognized tribes. IHM, Part 2, Chapter 6, at 2-6.5(C)(6). The complete listing of tribe codes is in the User Guide/Standard Code Book Tables (Vol. II.), May 24, 1991. *Id.* at 2-6.5C(5).

<sup>229</sup> According to the IHM, “[t]he actual blood quantum fraction of the patient must be entered into the PRS as verified with BIA documents. Since membership in a tribe is important to eligibility for contract health services [defined in IHM Part 2, Chapter 3], a notation regarding verified blood quantum will be made in the Patient Registration System. (Making an entry in this PRS field is required to continue in the database as it is presently structured).” *Id.* at Part 2, Chapter 6, at 2-6.5.C(7).

<sup>230</sup> *Id.* at 2-6.6(A).

<sup>231</sup> This infant mortality database contains information from the National Center for Health Statistics, Vital Statistics System (NCHS VSS), based on its vital statistics collections from the states.

<sup>232</sup> This mortality database contains information from the NCHS VSS.

<sup>233</sup> The natality database contains information from the NCHS VSS.

Ambulatory Patient Care System <sup>234</sup>	Native; Tribal Affiliation	
Indian Health Service Dental Services Reporting System <sup>235</sup>	American Indian; Alaska Native; Tribal Affiliation	N/A
Indian Health Service Inpatient Care System <sup>236</sup>	American Indian; Alaska Native; Tribal Affiliation	N/A
Indian Health Service Patient Registration System <sup>237</sup>	American Indian; Alaska Native; Tribal Affiliation	N/A
Indian Health Service Population Estimates and Projections <sup>238</sup>	American Indian; Alaska Native	N/A

#### 4. Substance Abuse and Mental Health Services Administration

The mission of the Substance Abuse and Mental Health Services Administration (SAMHSA) is to improve the quality and availability of prevention, treatment, and rehabilitation services to reduce illness, death, disability, and cost to society resulting from substance abuse and mental illnesses.

##### a. Statutory and Regulatory Authority

SAMHSA must collect data on the incidence and prevalence of the various forms of mental illness and substance abuse, both nationally and in major metropolitan areas selected by SAMHSA.<sup>239</sup> With respect to substance abuse data, SAMHSA's Administrator must ensure that demographic data are collected on individuals receiving treatment.<sup>240</sup> In addition, SAMHSA must conduct surveys on substance abuse issues.<sup>241</sup>

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<sup>234</sup> This system collects diagnostic data on individuals receiving ambulatory medical care provided or funded by IHS.

<sup>235</sup> This system collects dental services information on individuals receiving dental care provided or funded by IHS.

<sup>236</sup> The Inpatient Care System collects diagnostic data on individuals receiving inpatient care provided or funded by IHS.

<sup>237</sup> This system collects demographic data on individuals receiving health care provided or funded by HIS.

<sup>238</sup> This database estimates and projects counts of the American Indian and Alaska Native population eligible for Indian Health Service services.

<sup>239</sup> 42 U.S.C. § 290aa-4.

<sup>240</sup> 42 U.S.C. § 290aa-4(c)(1)(D).

<sup>241</sup> 42 U.S.C. § 290aa-4(b)(2).

SAMHSA must also, after consultation with the states and appropriate national organizations, develop uniform criteria for the collection of data.<sup>242</sup>

SAMHSA has an associate administrator for women's services charged with assuring that the unique needs of minority women – including Native American, Hispanic, African-American and Asian -- are addressed within SAMHSA's activities. SAMHSA must also improve the collection of data on women's health, including developing standards for all programs funded by SAMHSA so that data are, to the extent practicable, collected and reported using common reporting formats, linkages and definitions.<sup>243</sup>

SAMHSA administers the Substance Abuse Treatment and Prevention Block Grant. Funding agreements must require states to submit reports containing information SAMHSA designates (after consultation with the states).<sup>244</sup> States must provide a "needs assessment" which identifies the specific risk factors the grant funds will address. For prevention and treatment activities funded through the Alcohol and Drug Abuse and Mental Health Services Block Grant, however, SAMHSA already requires the race and/or ethnicity of the target population, if available.<sup>245</sup>

In evaluating mental health services, SAMHSA must conduct surveys which include data on race and ethnicity.<sup>246</sup> SAMHSA may also make grants for services to children of substance abusers. These grants specifically require data collection, including the ethnicity of the children.<sup>247</sup>

#### **b. Policies and Practices**

SAMHSA has a voluntary reporting initiative, the Treatment and Outcome Performance Pilot Study (TOPPS).<sup>248</sup> The purpose is to assist state agencies to respond to questions about the performance and functioning of substance abuse treatment programs. TOPPS is developing a standardized approach to measure the performance of SAMHSA block grant-funded programs and the treatment outcomes of clients.<sup>249</sup> Thus, when applying for funds under the block grant, states may report on certain categories and prevention methods. To date, fewer than 20 states have chosen to participate in this voluntary reporting.

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<sup>242</sup> 42 U.S.C. § 290aa-4(c).

<sup>243</sup> 42 U.S.C. § 290aa(f).

<sup>244</sup> 42 U.S.C. § 300x-52.

<sup>245</sup> 45 C.F.R. § 96.133.

<sup>246</sup> 42 U.S.C. § 290bb-31(b)(14).

<sup>247</sup> 42 U.S.C. § 280d(n). This statute differs from most others by specifying ethnicity without also referring to race. Usually if only one term is used, it is race.

<sup>248</sup> See Center for Substance Abuse Treatment, *Knowledge Development and Application (KDA)*, SAMHSA Programs in Brief, <http://www.samhsa.gov/>.

<sup>249</sup> *Id.*

**c. Data Collection Vehicles**

SAMHSA maintains seven different databases. The paramount one is the Drug and Alcohol Services Information System, which is the primary source of national data on substance abuse treatment. The other SAMSHA databases are listed below.

**Data Collection/Reporting Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Drug and Alcohol Services Information System (DASIS) <sup>250</sup>	White; Black; Asian or Pacific Islander; American Indian or Alaska Native; Don't Know; Other	Puerto Rican; Mexican; Cuban; Other Hispanic; Not of Hispanic Origin
TOPPS – Treatment Outcomes <sup>251</sup>	White; Black; Native Hawaiian/Other Pacific Islander; Asian; American Indian/Alaska Native	Hispanic or Latino; Non-Hispanic or Latino
TOPPS – Prevention Measures <sup>252</sup>	White; Black; Hispanic; Native Hawaiian/Pacific Islander; Asian; American Indian/Alaska Native	N/A
Inventory of Mental Health Organizations and General	American Indian/Alaskan Native; Asian/Pacific	Hispanic; Non-Hispanic; Unknown

<sup>250</sup> DASIS has three components: the Inventory of Substance Abuse Treatment Services (I-SATS; a listing of all known public and private substance abuse treatment facilities [before 2000, I-SATS was known as the National Master Facility Inventory]); the National Survey of Substance Abuse Treatment Services (N-SSATS; an annual survey of all facilities in I-SATS, collecting information on location, characteristics, services offered and utilization [before 2000, N-SSATS was known as the Uniform Facility Data Set (UFDS)]); and the Treatment Episode Data Set (TEDS; a compilation of data on the demographic and substance abuse characteristics of those admitted to substance abuse treatment).

<sup>251</sup> TOPPS treatment outcomes are: all primary clients, employment status, living status (measuring percentage of homelessness), criminal activity (measuring percent change in arrests), and alcohol and drug use (separated into alcohol use, marijuana use, cocaine use, amphetamine use, and opiate use). See Uniform Application for Substance Abuse and Treatment Block Grants, Section IV-A, <http://www.samhsa.gov/centers/csat/csat.html>.

<sup>252</sup> TOPPS prevention measures are: 30-day substance use, age of initiation of substance use, intention/expectation to use, perception of risk/harm of substance use, and attitudes about substance use. See Uniform Application for Substance Abuse and Treatment Block Grants, Section IV-B, <http://www.samhsa.gov/centers/csat/csat.html>.

Hospital Mental Health Services <sup>253</sup>	Islander; Black; White; Unknown	
Inventory of Mental Health Services in State Adult Correctional Facilities <sup>254</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black; White; Unknown	Hispanic; Not of Hispanic Origin; Ethnicity Unknown
Drug Abuse Warning Network (DAWN) <sup>255</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black (Non-Hispanic); White (Non-Hispanic); Hispanic; Other; Unknown	N/A
Services Research Outcome Study <sup>256</sup>	Hispanic (specify: Mexican/Mexican-American/Chicano, Puerto Rican, Cuban, Other Spanish or Hispanic); American Indian; Alaskan Native; Asian/Pacific Islander; Black/African American; White; Other	N/A

**Survey Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Center for Mental Health Services Client/Patient Sample Survey <sup>257</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black; White; Unknown	Hispanic (specify: Mexican/Mexican-American, Puerto Rican, Cuban, Other Hispanic, Hispanic but type unknown); Non-Hispanic; Unknown

<sup>253</sup> This inventory provides a complete enumeration of all specialty mental health organizations and psychiatric services of non-federal general hospitals in the U.S.

<sup>254</sup> This inventory was conducted on a one-time basis to describe inmates receiving each of the mental health services in each prison surveyed. Data collection is complete.

<sup>255</sup> DAWN collects data to identify substances associated with drug-related episodes and deaths, to monitor trends in drug use, to detect new drugs of abuse, and to assess hazards associated with drug use.

<sup>256</sup> This study was conducted as a follow-up of persons admitted for abuse treatment in 1989-1990 to obtain a picture of clients' status 5 years following a treatment episode. Data collection is complete.

Alcohol and Drug Services Survey <sup>258</sup>	<b>Aggregate Facility-Level Data:</b> American Indian/Alaskan Native; Asian/Pacific Islander; Black, Not Hispanic; White, Not Hispanic; Hispanic; Other <b>Client-Level Data:</b> American Indian; Alaskan Native; Asian/Pacific Islander; Black; White	Hispanic; Not of Hispanic Origin; Unknown
National Household Survey on Drug Abuse <sup>259</sup>	White; Black/African American; American Indian/Alaska Native; Asian/Pacific Islander; Other (specify)	Hispanic or Spanish Origin or Descent; Not of Hispanic or Spanish Origin or Descent

#### **D. Agencies Conducting or Overseeing Research**

As a subset of their broader missions, four agencies within HHS conduct or oversee clinical research involving human subjects. Because racial and ethnic data is collected as part of this research, this survey includes information on these research activities. These agencies are the Agency for Healthcare Research and Quality (AHRQ, formerly the Agency for Health Care Policy and Research), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA).

The CDC and NIH have specific policies that require the inclusion of minorities in clinical research, except in limited circumstances. AHRQ and FDA research projects abide by the NIH inclusion policy.

##### **1. Agency for Healthcare Research and Quality**

The Agency for Healthcare Research and Quality (AHRQ) supports cross-cutting research on health care systems, health care quality, cost issues and effectiveness of

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<sup>257</sup> This survey collects general-purpose statistics on the sociodemographic, clinical, and service use characteristics of clients served in the inpatient, outpatient and partial care programs of mental health.

<sup>258</sup> This survey obtains information on substance abuse treatment facilities and clients to supplement current information and analyze the outcomes of treatment.

<sup>259</sup> This survey provides reliable estimates of the prevalence of substance use, consequences of that use, and patterns of substance use.

medical treatments. AHRQ conducts and supports research and evaluations and supports demonstration projects. These projects include healthcare for priority populations, including minorities. AHRQ also conducts policy research which analyzes racial and ethnic data obtained from a variety of sources, including federal databases.

AHRQ, in collaboration with the NIH's Office of Research on Minority Health and National Cancer Institute, recently launched funding for a new research initiative to improve knowledge of the factors underlying ethnic and racial inequities in health care. The program, called EXCEED (Excellence Centers to Eliminate Ethnic/Racial Disparities), begins this year.<sup>260</sup>

AHRQ has also awarded exploratory grants to support planning efforts by primary care practice-based research networks (PBRNs). These PBRNs will engage in research with over 5,000 primary care providers and nearly 7 million patients in a variety of primary care settings. The grants support the development of a PBRN plan to enhance the network's capacity to collect and analyze primary care data, study the health care of minority and underserved populations, and translate new research findings into practice. After the planning phase, AHRQ will fund primary care research in key areas such as patient safety and reducing health care disparities.<sup>261</sup>

#### **a. Statutory and Regulatory Authority**

AHRQ's responsibilities include enhancing the quality, appropriateness, and effectiveness of, and access to, health services.<sup>262</sup> AHRQ accomplishes this by establishing a broad base of scientific research and through the promotion of improvements in clinic and health systems practices. Along with its general mandate, AHRQ also must focus its resources specifically on minorities.<sup>263</sup>

The Benefits Improvement and Protections Act of 2000 specifically addressed actions HHS must take to reduce racial and ethnic disparities in cancer screening and treatment.<sup>264</sup> Presumably AHRQ will be the agency within HHS designated to address these responsibilities. HHS must submit a report to Congress describing these projects and evaluating them for: cost-effectiveness; quality of the health care services provided

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<sup>260</sup> See <http://www.ahrq.gov/research/nov00/1100ra33.htm> for information on the grantees.

<sup>261</sup> See <http://www.ahrq.gov/news/press/pr2000/pbrnspr.htm>.

<sup>262</sup> 42 U.S.C. § 299(b).

<sup>263</sup> 42 U.S.C. § 299(c)(1)(B)(ii).

<sup>264</sup> P.L. 106-554 § 122. HHS must develop at least nine demonstration projects to examine: reducing disparities in early detection and treatment; improving clinical outcomes; eliminating disparities in the utilization of screening services; and, ensuring cultural competency and language access. Two projects are required for each of the following groups: American Indians, including Alaska Natives, Eskimos, and Aleuts; Asian Americans and Pacific Islanders; Blacks; and Hispanics.

to target individuals under the demonstration projects; beneficiary and health care provider satisfaction; and other information HHS determines to be appropriate.

AHRQ must also undertake research on racial and ethnic disparities pursuant to the Minority Health and Health Disparities Research and Education Act of 2000. This research includes identifying populations for whom there is a significant disparity in the quality, outcomes, cost or use of health care services, or in access to and satisfaction with these services as compared to the general population. AHRQ must also conduct and support research and demonstration projects on specific issues.<sup>265</sup>

AHRQ grants and contracts mandate compliance with HHS' Title VI regulations.<sup>266</sup> AHRQ may also impose additional conditions to assure or protect advancement of the project, the interest of public health, or the conservation of grant funds.<sup>267</sup> Pursuant to this authority, AHRQ could require grantees and contractors to collect racial and ethnic data.

#### **b. Policies and Practices**

It is AHRQ policy to include minority groups in all AHRQ-supported research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.<sup>268</sup> To the extent possible, AHRQ requires adherence to the NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research.<sup>269</sup> Grant applicants must provide assurances that they will abide by these policies.<sup>270</sup>

#### **c. Data Collection Vehicles**

AHRQ undertakes three primary surveys: the Medical Expenditure Panel Survey (MEPS), the Healthcare Cost and Utilization Project (HCUP), and the HIV Cost and Services Utilization Survey (HCSUS).

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<sup>265</sup> 42 U.S.C. § 903.

<sup>266</sup> 42 C.F.R. § 67.19.

<sup>267</sup> 42 C.F.R. § 67.22.

<sup>268</sup> *See, e.g.* AHRQ Small Research Grant Program, PA NUMBER: PAR-01-040, (January 2, 2001), <http://grants.nih.gov/grants/guide/pa-files/PAR-01-040.html>; AHRQ Health Services Research, PA NUMBER: PA-00-111 (June 22, 2000), <http://grants.nih.gov/grants/guide/pa-files/PA-00-111.html>.

<sup>269</sup> *See* Part IV.D.3.b.

<sup>270</sup> *See* Application for a Public Health Service Grant, PHS 398, at 29, <http://www.nih.gov/grants/forms.htm>. An Application for Continuation of a Public Health Service Grant must also provide these assurances. PHS 2590.



<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
MEPS – HC, NHC <sup>271</sup>	American Indian; Aleut; Asian; Black; White; Other	Hispanic; Non-Hispanic
HCUP <sup>272</sup>	White; Black; Hispanic; Asian/Pacific Islander; Native American; Other	N/A
HCSUS <sup>273</sup>	White/Caucasian; Black/African American; Hispanic/Latino; American Indian/Alaskan Native; Asian/Pacific Islander	N/A

AHRQ was also the primary force behind development of the Consumer Assessment of Health Plans Study (CAHPS), initially created to collect objective information to help consumers and purchasers assess managed care plans. Medicaid, Medicare, the Department of Defense and independent accrediting organizations have all utilized tailored versions of CAHPS to evaluate private insurers.

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
CAHPS	White; Black/African American; Asian; Native Hawaiian/Pacific Islander; American Indian/Alaskan Native; Aleut; Asian; Black; White; Other	Hispanic or Latino Origin or descent

## 2. Centers for Disease Control and Prevention

<sup>271</sup> MEPS incorporates four component surveys, only two of which include consumer information: the Household Component (HC) and the Nursing Home Component (NHC). The Household Component is a nationally representative survey of the U.S. civilian population to assess medical expenditures. See <http://www.meps.ahrq.gov/>.

<sup>272</sup> HCUP comprises a “family of administrative longitudinal databases” including hospital discharge databases and a national sample of discharges from community hospitals. HCUP has two primary components: the Nationwide Inpatient Sample (NIS, containing inpatient data from a national sample of 1,000 hospitals) and the State Inpatient Databases (SID, covering inpatient care in community hospitals of 22 States, representing more than 50% of all hospital discharges). See <http://www.ahrq.gov/data/hcup/>.

<sup>273</sup> HCSUS collects information on people receiving care for HIV to examine the costs of care, utilization of services, access to care, quality of care, quality of life, unmet needs for medical and non-medical services, social support, satisfaction with medical care, and knowledge of HIV therapies. See <http://www.ahrq.gov/data/hcsusix.htm>.

The Centers for Disease Control and Prevention (CDC) promote health and quality of life by preventing and controlling disease, injury and disability.<sup>274</sup> The CDC provides a system of health surveillance to monitor and prevent the outbreak of diseases. With the assistance of states and other partners, CDC maintains national health statistics and supports research into disease and injury prevention.

CDC employs a wide range of strategies to ensure progress against disease, disability and premature death. One of these strategies, public health surveillance, provides information to monitor the health of the public, identify public health problems and priorities, take public health action to prevent further illness, and evaluate the effectiveness of these actions.

#### **a. Statutory and Regulatory Authority**

Most of the CDC's data collection activities arise from requirements to establish surveillance systems or registries for specific diseases. These systems focus not on a general population of individuals within a health program such as Medicaid, but rather on those individuals suffering from a specific disease.

The CDC's general authority arises from the mandate to "conduct. . .and promote the coordination of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man. . ." <sup>275</sup> It is this provision that authorizes CDC's data collection activities.

In 1993, Congress authorized the CDC to implement a pilot sentinel disease surveillance system<sup>276</sup> to determine the applicability of and the difficulties associated with the implementation of the sentinel disease concept for identifying the relationship between the occupation of household members and the incidence of subsequent conditions or diseases in other members of the household.

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<sup>274</sup> This survey does not include information about the Agency for Toxic Substances and Disease Registries (ATSDR), a subset of CDC, which addresses the effect of hazardous substances in the environment on the public health. While ATSDR maintains registries of these events, they are not directly related to the provision or monitoring of health. *See* <http://www.atsdr.cdc.gov/>.

<sup>275</sup> 42 U.S.C. § 241.

<sup>276</sup> P.L. 103-43, § 1910 (June 10, 1993). This section has not been codified in the U.S.C. A sentinel surveillance system monitors a rate of occurrence of specific conditions or disease rates in a specific cohort, geographic area, or population group to assess and estimate the change in health trends in larger population. *See* The Online Medical Dictionary, <http://www.graylab.ac.uk/cgi-bin/omd?action=Home&query>.

### **i. Mandatory Data Collection Requirements**

A number of statutes specifically require the collection of racial and ethnic data. Regarding birth defects and developmental disabilities, the CDC must collect and analyze data by racial and ethnic group, including Hispanics, non-Hispanic whites, Blacks, Native Americans, Asian Americans, and Pacific Islanders.<sup>277</sup> The CDC must prepare a biennial report to Congress that contains information specific to various racial and ethnic groups. The CDC must also directly or indirectly collect data on the incidence and prevalence of lead poisoning in infants and children, including their racial and ethnic status.<sup>278</sup>

### **ii. Surveillance Systems**

In addition to mandatory data collections, the CDC operates a number of surveillance systems pursuant to its general mandate.<sup>279</sup> In addition, specific requirements for surveillance include:

- juvenile diabetes, including the incidence and prevalence, and a national database for such data;<sup>280</sup> and
- asthma, including compiling and reporting the prevalence, severity, and to the extent practicable, mortality of asthma and the quality of asthma management.<sup>281</sup>

### **iii. Contracts for States or Others to Collect Data**

In some situations, the CDC does not directly collect data but contracts with states to establish registries or collect data. While not all require racial and ethnic data pursuant to statutory requirements, all do collect this data. These registries include:

- cancer registries, including demographic data and other elements determined necessary, about each case of cancer;<sup>282</sup>
- the National Bone Marrow Donor Registry, which carries out a program to recruit bone marrow donors, including increasing the representation of

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<sup>277</sup> 42 U.S.C. § 247b-4(b)(1)(A). The CDC must collect data from birth certificates, death certificates, hospital records, and other appropriate sources; and must encourage States to establish or improve programs for the collection and analysis of epidemiological data on birth defects.

<sup>278</sup> 42 U.S.C. § 274b-3(b)(3).

<sup>279</sup> 42 U.S.C. § 242k(l). *See* Part IV.D.2.e. for a discussion of the statutory authority of the National Center for Health Statistics, a subset of CDC, authorizing collection of information on the incidence of various acute and chronic illnesses and infant and maternal morbidity and mortality.

<sup>280</sup> 42 U.S.C. § 247b-9.

<sup>281</sup> 42 U.S.C. § 247b-10.

<sup>282</sup> 42 U.S.C. § 280e(a)(1).

racial and ethnic minority groups and identifying groups that are underrepresented;<sup>283</sup>

- National Bone Marrow Donor scientific registry for patients who have been recipients of a transplant of bone marrow from a biologically unrelated donor;<sup>284</sup>
- autism and pervasive developmental disabilities;<sup>285</sup> and,
- traumatic brain injury registry (which can be administered either by CDC directly or through arrangements with academic institutions).<sup>286</sup>

CDC may also make grants to address infertility and sexually transmitted diseases.<sup>287</sup> Applicants must agree to submit a report that includes the demographic characteristics of individuals served.

## **b. Policies and Practices**

### **i. Surveillance Activities**

CDC does not yet have an integrated surveillance system to capture all the information required to monitor the public health. Rather, because of different information requirements, multiple, distinct users and different collaborative partners, CDC maintains multiple data sources. The National Disease Surveillance Program currently includes surveillance of 19 separate reportable diseases.<sup>288</sup>

In 1993, CDC's Steering Committee on Public Health Information and Surveillance System Development convened to begin implementing integrated public health information and surveillance systems through the National Electronic Disease Surveillance System (NEDSS). When completed, NEDSS will electronically integrate

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<sup>283</sup> 42 U.S.C. § 274k(b)(2), (c)(1). The statute also includes people of mixed ancestry in this category. HRSA's Special Projects Office oversees these activities. *See* Part IV.C.2.g.

<sup>284</sup> 42 U.S.C. § 274l. The scientific registry must include information about patients, transplant procedures, and other information appropriate to conduct an ongoing evaluation of the scientific and clinical status of transplantation. Annual reports concerning patient outcomes are required for each transplant center.

<sup>285</sup> 42 U.S.C. § 247b-4b(a)(1). The grants are available to public or nonprofit private entities (including health departments and political subdivisions of states, universities and other educational entities).

<sup>286</sup> 42 U.S.C. § 280b-1c.

<sup>287</sup> 42 U.S.C. § 247c-1.

<sup>288</sup> These diseases include: bacterial meningitis, dengue, hantavirus, HIV/AIDS, Idiopathic CD4+T-lymphocytopenia, Kawasaki syndrome, Legionellosis, lyme disease, tick-born Rickettsial Disease, toxic shock syndrome, toxocariasis, trichinosis, typhoid fever, and viral hepatitis. *See* CDC Proposed Data Collection, 66 Fed. Reg. 1682 (January 9, 2001).

and link a wide variety of surveillance activities, and will facilitate more accurate and timely reporting of disease information to CDC and state and local health departments. CDC established the Health Information and Surveillance Systems Board (HISSB) to provide an ongoing framework for integration of public health information systems. The Board develops and adopts standards for core variables and other data elements, including race and ethnicity.

As part of the effort to integrate its surveillance systems, CDC has developed standard code sets, including one for race and ethnicity. The main purpose of the code set is “to facilitate the use of federal standards for classifying data on race and ethnicity when these data are exchanged, stored, retrieved, or analyzed in electronic form.”<sup>289</sup> These standards provide two primary categories for ethnicity – Hispanic or Latino and Not Hispanic or Latino – and six primary categories for race – American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; and White.<sup>290</sup> CDC allows a combined format for race and ethnicity when race is reported by a third party, but recommends using ‘Hispanic and one or more races’ and ‘More than one race’ for self-reporting situations. Data element categories may be expanded into more detail as long as they remain capable of being collapsed into the standards.

## ii. CDC Research Activities

Regarding research it undertakes or sponsors, the CDC has its own inclusion policy that was, along with NIH’s inclusion policy, the basis for the broader HHS inclusion policy. This policy requires racial and ethnic minorities to be included in research conducted by CDC staff,<sup>291</sup> as well as in external research projects,<sup>292</sup> unless a clear and compelling rationale and justification establish that inclusion is not appropriate or feasible.<sup>293</sup> This policy differs from that of HHS in that CDC’s policy addresses the inclusion of racial and ethnic minorities in clinical research and human trials, while HHS’ policy addresses collection of racial and ethnic data as an adjunct to the delivery of services.

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<sup>289</sup> Common Data Elements, Implementation Guide Version 2.4, [www.cdc.gov/data/index.htm](http://www.cdc.gov/data/index.htm).

<sup>290</sup> *Id.* In addition to the two ethnic and six racial categories, the Common Data Elements include breakouts into specific ethnic and racial groups. For example, if someone indicates American Indian or Alaskan Native, the individual’s tribe is also collected. CDC’s Race and Ethnicity Code Set Version 1.0 includes 35 pages of these breakouts of race and ethnicity.

<sup>291</sup> CDC Manual Guide, General Administration CDC-80, *Inclusion of Women and Racial and Ethnic Minorities in Research* (hereafter CDC Research Inclusion Policy) (February 16, 1996).

<sup>292</sup> CDC, *Policy on the Inclusion of Women and Racial Minorities for Externally Awarded Research*, 60 Fed. Reg. 47947 (September 15, 1995).

<sup>293</sup> CDC Research Inclusion Policy at 5.

**c. Data Collection Vehicles**

**i. Surveillance Systems**

The CDC operates the following surveillance systems, all of which collect data on race and ethnicity:

- National Disease Surveillance Program Case Report;
- Sexually Transmitted Disease (STD) Surveillance System<sup>294</sup> and STD Morbidity Surveillance System;
- National Surveillance of Dialysis-Associated Diseases;
- Cholera and Vibrio Illness Investigation Report Form;
- National Childhood Blood Lead Surveillance System;
- National Surveillance for Hospital Health Care;
- Sentinel Surveillance for Chronic Liver Disease;
- Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers;
- National Program of Cancer Registries – Cancer Surveillance System;
- Surveillance and Evaluation of Plasma Donors for HIV and HCV;
- Public Health Infrastructure Surveillance and Performance Monitoring Network; and
- AIDS Prevention and Surveillance Project Reports.

Some surveillance systems have multiple data collection instruments or databases. For example, the following table provides an example of the surveillance system for cancer and the multiple reporting systems for HIV/AIDS.

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Surveillance Systems	OMB standards <sup>295</sup>	OMB standards <sup>296</sup>
Cancer Surveillance System	White; Black; American Indian/Aleutian/Eskimo; Chinese; Japanese; Filipino; Hawaiian; Korean; Asian Indian/Pakistani; Vietnamese; Laotian; Hmong; Kampuchean;	Non-Spanish/Non-Hispanic; Mexican (includes Chicano); Puerto Rican; Cuban; South or Central American (except Brazil); Other Spanish (includes European); Spanish, NOS;

<sup>294</sup> This system collects monthly aggregate data on cases of primary, secondary and early latent syphilis in 7 cities.

<sup>295</sup> According to CDC staff, all of their collections utilize the OMB standards although, depending on the surveillance or survey, certain race or ethnicity categories may be further delineated. Telephone conversation with Anne O’Connor, Assistant Reports Clearance Officer, Office of Program Planning and Evaluation, Centers for Disease Control and Prevention (January 10, 2001).

<sup>296</sup> *Id.*

	Thai; Micronesian; Chamorran; Guamanian; Polynesian; Tahitian; Samoan; Tongan; Melanesian; Fiji Islander; New Guinean; Other Asian (including Asian, NOS and Oriental); Pacific Islander, NOS; Other; Unknown	Hispanic, NOS (i.e., there is evidence other than surname or maiden name that the person is Hispanic, but he/she cannot be assigned to any of the preceding categories); Spanish (surname only) (only evidence of person's Hispanic origin is surname or maiden name); Unknown
HIV/AIDS Reporting System <sup>297</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black (Non-Hispanic); White (Non-Hispanic); Hispanic	N/A
HIV Epidemiology Research Study <sup>298</sup>	Native American; Asian; Black/African American; White; Hispanic/Latino; Other	N/A
HIV Seroprevalence Among Intravenous Drug Users Entering Treatment Programs <sup>299</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black; White; Other	Hispanic (Mexican-American, Puerto Rican, Cuban); Not of Hispanic Origin
HIV Seroprevalence in Sexually Transmitted Disease Clinics <sup>300</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black; White; Other	Hispanic (Mexican-American, Puerto Rican, Cuban); Not of Hispanic Origin
HIV Seroprevalence Survey of Childbearing Women <sup>301</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black; White; Other	Hispanic (Mexican-American, Puerto Rican, Cuban); Not of Hispanic Origin
HIV Serosurvey in Selected Tuberculosis Clinics <sup>302</sup>	American Indian/Alaskan Native; Asian/Pacific	N/A

<sup>297</sup> This reporting system monitors the total number of reported cases from public, private, and government reporting facilities.

<sup>298</sup> This study provides the effects of HIV on the physical, emotional, and social health of American women.

<sup>299</sup> This database monitors HIV seroprevalence in intravenous drug users entering treatment.

<sup>300</sup> This collection provides baseline HIV seroprevalence, monitors trends over time, and determines risk factors for HIV infection.

<sup>301</sup> This survey determines the prevalence of HIV infection among women delivering live infants and provides information about their trends.

	Islander; Black (Non-Hispanic); White (Non-Hispanic); Hispanic	
Pediatric Spectrum of HIV Disease <sup>303</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black; White; Other	Hispanic (country of birth recorded); Not of Hispanic Origin
Supplement to HIV/AIDS Surveillance <sup>304</sup>	American Indian/Alaskan Native; Asian/Pacific Islander (Asian: Chinese, Filipino, Japanese, Korean, Asian Indian, Vietnamese, Laotian, Thai, Cambodian, Pakistani, Indonesian, Hmong, Burmese Bangladesh, Sri Lankan, Malayan, Okinawan, Other Asian [specify], Unspecified/Pacific Islander: Hawaiian, Samoan, Tongan, Tahitian, Guamanian Islander, Northern Mariana, Palauan, Fijian, Other Pacific Islander [specify], Unspecified); Black; White; Other	Hispanic (Mexican, Puerto Rican, Cuban, Central American, South American, Dominican Republic, Spanish, and Portuguese); Not of Hispanic Origin

**ii. Other Data Collection Vehicles**

The CDC maintains a number of databases in addition to the surveillance systems.<sup>305</sup> According to the CDC, these collections utilize OMB standards for race and ethnicity.<sup>306</sup> Yet certain surveys that were included in the HHS Directory of Data

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<sup>302</sup> This database determines the prevalence of HIV infection of tuberculosis patients.

<sup>303</sup> This project, enrolling infected children in 8 different locations, characterizes and follows trends regarding pediatric HIV.

<sup>304</sup> This supplement obtains increased descriptive information on persons reported with HIV/AIDS and is conducted in 12 states.

<sup>305</sup> The agency is also responsible for a number of health surveys, but these are overseen by one of its sub-agencies, the National Center for Health Statistics. *See* Part IV.D.2.e.

<sup>306</sup> Telephone conversation with Anne O'Connor, Assistant Reports Clearance Officer, Office of Program Planning and Evaluation, Centers for Disease Control and Prevention (January 10, 2001).



Resources provided additional categories for race and ethnicity. Information from the Directory is included as available.

**Data Collection/Reporting Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Adult Spectrum of Disease (ASD) <sup>307</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black (Non-Hispanic); White (Non-Hispanic); Hispanic	N/A
Annual and Weekly MMWR <sup>308</sup> Reporting Series	OMB standards	OMB standards
National Birth Defects Prevention Study	OMB standards	OMB standards
National Nosocomial Infections Study	OMB standards	OMB standards
Follow-Up Study of Children with Developmental Disabilities	OMB standards	OMB standards

**Survey Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Survey Component of CDC's Prevention of HIV Infection in Youth at Risk	OMB standards	OMB standards
Youth Risk Behavior Surveys	OMB standards	OMB standards
Survey Measuring HIV/STD Risk Behavior	OMB standards	OMB standards
National AIDS Hotline Survey of Callers	OMB standards	OMB standards
Young Men's Survey <sup>309</sup>	American Indian/Alaskan Native; Asian/Asian American; Black/African American; Hispanic/Latino/Chicano; Native Hawaiian/Other Pacific Islander; White	N/A

<sup>307</sup> ASD characterizes HIV patients at various stages who received medical care at selected inpatient and outpatient facilities in targeted areas

<sup>308</sup> MMWR is the Morbidity and Mortality Weekly Report.

**d. Associate Director for Minority Health**

The overall goal of the Office of the Associate Director for Minority Health at CDC is to close the health gap by enhancing the overall health of the American public. Its philosophy is that minority health initiatives must be operational in all of the centers, institutes, offices, and programs at CDC to be effective. In addition, where appropriate, these initiatives must be transferred to state and local government and nongovernmental agencies and organizations.

The Office focuses on encouraging minority health activities within CDC and facilitating the development of minority health programs in state and local health departments, local community-based organizations, and national, civic, social, religious, and voluntary organizations. It also seeks to maximize health services and resources available to minority populations.

While the Office does not oversee any specific data collection vehicles, it impacts the overall CDC policies and practices regarding data collection.

**e. National Center for Health Statistics**

An entity within CDC, the National Center for Health Statistics (NCHS), is the government's principal vital and health statistics agency. Its mission is to provide statistical information to guide actions and policies to improve the health of the American people.

**i. Statutory and Regulatory Authority**

The NCHS must collect and analyze adequate health data specific to particular ethnic and racial populations, including data collected under national health surveys.<sup>310</sup> NCHS must collect statistics on:

- the extent and nature of illness and disability of the population of the U.S. (or of any subgroups), including life expectancy, the incidence of various acute and chronic illnesses, and infant and maternal morbidity and mortality;
- the impact of illness and disability of the population on the economy of the U.S. and on other aspects of the well-being of its population or of subgroups;
- environmental, social, and other health hazards;

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<sup>309</sup> This survey supports a category of surveys that assess HIV-1 seroprevalence, risk behaviors, and psychosocial factors associated with risk behaviors among young men who have sex with men and attend public venues.

<sup>310</sup> 42 U.S.C. § 242k(b).

- determinants of health; and
- utilization of health care, including utilization of ambulatory health services by specialty and type of practice of the health professionals providing such services, and services of hospitals, extended care facilities, home health agencies, and other institutions.<sup>311</sup>

In addition, NCHS provides grants to conduct special surveys or studies, to analyze data and for research on improving methods for developing statistics on ethnic and racial populations and subpopulations.<sup>312</sup>

NCHS is also mandated to undertake an annual collection of vital statistics data from the records of births, deaths, marriages, and divorces in registration areas.<sup>313</sup> NCHS must encourage states and other registration areas to obtain detailed data on ethnic and racial populations, including subpopulations of Hispanics, Asian Americans, and Pacific Islanders that have significant representation in the area.<sup>314</sup> To obtain uniformity in the registration and collection of mortality, morbidity, and other health data, NCHS must distribute suitable and necessary forms for the collection and compilation of such data.<sup>315</sup> Thus, all vital statistics information should include the same categories for race and ethnicity and be comparable across states and registration areas.

NCHS must also undertake annual data collection concerning the general health, illness, and disability status of the civilian non-institutionalized population. Specific topics to be addressed, on an annual or periodic basis, include the incidence of illness and accidental injuries, the prevalence of chronic diseases and impairments, disability, physician visits, hospitalizations, and the relationship between demographic and socioeconomic characteristics and health characteristics.<sup>316</sup>

NCHS is responsible for coordinating its health statistical and epidemiological activities<sup>317</sup> by:

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<sup>311</sup> 42 U.S.C. § 242k(l).

<sup>312</sup> 42 U.S.C. § 242k(m). NCHS must undertake and support research, demonstrations, and evaluations regarding new or improved methods for obtaining current data, and may undertake and support epidemiological research, demonstrations, and evaluations on the matters referred to in the bullets above.

<sup>313</sup> The data shall be obtained only from and restricted to records of the states and municipalities as NCHS determines possess records affording satisfactory data in necessary detail and form.

<sup>314</sup> 42 U.S.C. § 242k(h)(1). This section authorizes the collections undertaken through the National Vital Statistics System.

<sup>315</sup> 42 U.S.C. § 242k(g).

<sup>316</sup> 42 U.S.C. § 242k(h)(2). This section authorizes the NCHS surveys.

<sup>317</sup> 42 U.S.C. § 242b(c). This includes all health services research, evaluations, and demonstrations, health statistical and epidemiological activities, and research, evaluations, and demonstrations concerning the assessment of health care technology

- establishing standardized means for the collection of health information and statistics under laws administered by HHS;
- developing and maintaining the minimum sets of data needed on a continuing basis to fulfill NCHS' collection requirements; and
- establishing standards to assure the quality of health statistical and epidemiological data collection, processing, and analysis.<sup>318</sup>

NCHS also oversees the Cooperative Health Statistics System (CHSS).<sup>319</sup> Through this system, NCHS is responsible for coordinating the activities of federal agencies involved in the design and implementation of the System; undertaking and supporting research, development, demonstrations, and evaluations respecting the System; making grants to and entering into contracts with state and local health agencies to assist them in meeting the costs of data collection and other activities carried out under the System; and reviewing the statistical activities of HHS to assure that they are consistent with the System.<sup>320</sup>

## ii. Policies and Practices

NCHS does not have any independent policies and practices separate from HHS and CDC.

## iii. Data Collection Vehicles

The NCHS oversees eight different surveys as well as the National Vital Statistics System which is separately authorized by statute. Some of the health surveys over-sample for specific racial or ethnic groups to obtain more detailed data than the OMB standards. One example is the National Health and Nutrition Examination Survey (NHANES), which over-samples for Mexican-Americans.

### **Data Collection/Reporting Activities:**

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undertaken and supported through units of HHS. To the maximum extent feasible, such coordination must be carried out through AHRQ and NCHS.

<sup>318</sup> 42 U.S.C. § 242k(i). NCHS must also review HHS proposed collections and collection renewals for conformance with the minimum sets of data and standards. If any collection does not conform, NCHS must take action to assure conformance within 90 days after the review is complete.

<sup>319</sup> The CHSS emphasizes a “bottom-up” process of national data collection through which data is collected once, initially processed by the states, and submitted to the federal level in a machine-readable form.

<sup>320</sup> 42 U.S.C. § 242k(e).

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
National Vital Statistics System <sup>321</sup>	White; Black; American Indian; Chinese; Japanese; Hawaiian; Filipino; Other Asian/Pacific Islander <sup>322</sup>	Mexican; Puerto Rican; Cuban; Central or South American; Other; Unknown Hispanic <sup>323</sup>
Early Childhood Longitudinal Study – Birth Cohort <sup>324</sup>	White; Black or African American; American Indian or Alaska Native (specify tribe); Asian Indian; Chinese; Filipino; Japanese; Korean; Vietnamese; Other Asian (collect specific group name); Native Hawaiian; Guamanian or Chamorro; Samoan; Other Pacific Islander (collect specific group name); and Other (specify)	Hispanic Origin (Mexican, Mexican American or Chicano; Puerto Rican; Cuban; Other Spanish/Hispanic/Latino [specify]); Not of Hispanic Origin

**Survey Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
National Health and Nutrition Examination Survey (NHANES) <sup>325</sup>	OMB standards	Mexican/Mexican American; Other Latin American or Other Spanish; Not of Hispanic Origin
National Health Care Survey (NHCS) <sup>326</sup>	OMB standards	OMB standards

<sup>321</sup> NVSS is responsible for the Nation's official vital statistics. These are provided through state-operated registration systems of births, deaths, marriages, divorces, and fetal deaths. Additional programs related to NVSS include the Linked Birth and Infant Death Data Set, the National Maternal and Infant Health Survey, the National Mortality Followback Survey, the National Survey of Family Growth, and the National Death Index. All of these include the same racial and ethnic categories as NVSS.

<sup>322</sup> For natality and mortality statistics, selected states also include Asian Indian, Korean, Samoan, Vietnamese, and Guamanian. See CDC, National Vital Statistics System - Fetal Death Statistics, <http://www.hhs.gov/progorg/asp/minority/mincdc49.htm>.

<sup>323</sup> *Id.* According to the CDC, not quite all areas currently report Hispanic origin data for fetal birth statistics.

<sup>324</sup> This study, undertaken in collaboration with the Department of Education, examines early childhood health and diseases; access to health care and insurance; the relationship between health and learning and educational development; maternal depression and family health; the father's participation in childrearing; and child care arrangements.

<sup>325</sup> NHANES collects information about the health and diet of people in the U.S.

National Health Interview Survey (NHIS) <sup>327</sup> and NHIS on Disability (NHIS-D) <sup>328</sup>	White; Black/African American; Native (American); Alaska Native; Native Hawaiian; Guamanian; Samoan; Other Pacific Islander; Asian Indian; Chinese; Filipino; Japanese; Korean; Vietnamese; Other Asian; Some other race; Refused; Don't Know <sup>329</sup>	Puerto Rican; Cuban/Cuban American; Dominican (Republic); Mexican; Mexican American; Central or South American; Other Latin American; Other Hispanic/Latino; Refused; Don't Know <sup>330</sup>
Second Supplement on Aging (SOAII), <sup>331</sup> Second Longitudinal Study of Aging (LSOAII) <sup>332</sup>	White; Black; Indian (American); Eskimo; Aleut; Chinese; Filipino; Hawaiian; Korean; Vietnamese; Japanese; Asian Indian; Samoan; Guamanian; Other Asian or Pacific Islander; Other Race; Multiple Race; Unknown	Multiple Hispanic; Puerto Rican; Cuban; Mexican; Mexican-American; Chicano; Other Latin American; Other Spanish; Spanish, Don't Know type; Unknown if Spanish origin; Not Spanish origin
National Immunization	OMB standards	OMB standards

<sup>326</sup> NCHS incorporates a number of existing surveys: the National Hospital Discharge Survey, the National Ambulatory Medical Care Survey, the National Nursing Home Survey, the National Health Provider Inventory (formerly the National Master Facility Inventory), the National Survey of Ambulatory Surgery, the National Hospital Ambulatory Medical Care Survey, the National Home and Hospice Care Survey and the National Employer Health Insurance Survey.

<sup>327</sup> NHIS is the principal source of information on the health of the civilian non-institutionalized population. The NHIS also has a central role in the ongoing integration of household surveys in HHS. Two major HHS national household surveys are already linked to NHIS, the National Survey of Family Growth and the AHRQ's MEPS.

<sup>328</sup> NHIS-D collects data that is used to understand disability, to develop public health policy, to produce simple prevalence estimates of selected health conditions, and to provide descriptive baseline statistics on the effects of disabilities.

<sup>329</sup> These categories are included in the April 11, 2000, revision to NHIS.

<sup>330</sup> *Id.*

<sup>331</sup> SOAII, conducted as a supplement to the NHIS in 1984 and 1994, allows the examination of individual's functional status, living arrangements, use of hospitals and nursing homes, and death rates. Data collection is complete.

<sup>332</sup> LSOAII, conducted as a supplement to the NHIS from 1984-1990, allows the examination of changes in functional status, chronic conditions, and comorbidity; causes and consequences of such changes; living arrangements and social supports; health care coverage and utilization; and death rates. Data collection is complete.

Survey, Survey of Families with Young Children (SFYC), and the Survey of Children with Special Health Care Needs <sup>333</sup>		
National Survey of Family Growth <sup>334</sup>	OMB standards	Spanish/Hispanic Origin – Puerto Rican, Cuban, Mexican, Other (specify); Not of Spanish/Hispanic Origin
State and Local Area Integrated Telephone Survey (SLAITS) <sup>335</sup>	OMB standards	OMB standards

### 3. National Institutes of Health

The National Institutes of Health (NIH), with 17 separate institutes, is the world’s premier medical research organization. NIH supports 35,000 research projects nationwide. The goal of research conducted at NIH is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability. NIH conducts and supports research in its own laboratories and at other facilities.

#### a. Statutory and Regulatory Authority

NIH’s research institutes must include minorities in clinical research and conduct outreach to improve participation.<sup>336</sup> These requirements are waived if appropriate with respect to the health of the subject, the purpose of the research or approved by NIH.<sup>337</sup>

In addition to requiring the participation of minorities, NIH must maintain a national data system and clearinghouse of research focused on women’s health, incorporating information on subject eligibility criteria, including ethnicity *or* race.<sup>338</sup>

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<sup>333</sup> These surveys collect information on the immunization coverage and health care of children across the United States.

<sup>334</sup> NSFG collects data on factors affecting pregnancy and women's health.

<sup>335</sup> SLAITS provides state-based estimates that vary by the questionnaire module being used. These modules include: health insurance coverage; health care utilization and barriers; performance partnership initiatives; the impact of welfare-related reform and the State Children’s Health Insurance Program; and children with special health care needs.

<sup>336</sup> 42 U.S.C. § 289a-2(a)(1)(B).

<sup>337</sup> 42 U.S.C. § 298a-2(b).

<sup>338</sup> 42 U.S.C. § 287d-1. Requiring ethnicity *or* race differs from most statutes, which require either race only or race *and* ethnicity.

NIH must also operate a data bank of information on clinical trials for drugs for serious or life-threatening conditions, although race and/or ethnicity is not specified in the statute as required.<sup>339</sup>

Congress also required NIH to establish guidelines that address:

- when including minorities is inappropriate;
- how researchers can ensure sufficiently valid analysis of whether the variables studied affect minorities differently than other subjects of the trial; and
- how to operate outreach programs to recruit minorities to participate in clinical research.<sup>340</sup>

NIH's policy requires a research plan to describe the proposed study population in terms of racial and ethnic groups and to describe the proposed outreach efforts to recruit minorities.<sup>341</sup> The guidelines also reiterate use of the OMB Standards as basic guidance, cognizant of distinctions based on cultural heritage.<sup>342</sup> Finally, the guidelines require annual reporting on the enrollment of subjects, including their race and ethnicity.<sup>343</sup> In August 2000, NIH released updated guidelines for advanced clinical trials, providing further guidance on planning, conducting, and reporting the analysis of racial and ethnic differences in the intervention effect being studied.<sup>344</sup>

NIH regulations require grantees to abide by these guidelines as well as the Title VI nondiscrimination requirements.<sup>345</sup> Applicants for both initial and ongoing grants must provide assurances and certifications in their grant applications that they will abide

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<sup>339</sup> 42 U.S.C. § 282(j).

<sup>340</sup> 42 U.S.C. § 289a-2(d)(1). Cost is not a permissible consideration in determining inclusion in clinical trials. 42 U.S.C. § 282a-2(d)(2). Inclusion in clinical trials is not required if substantial scientific data demonstrates no significant differences between the effects the variables to be studied have on minorities and those who will be included in the trial. In other clinical research, cost is not a permissible consideration unless the data that would be obtained is obtainable through other means of comparable quality.

<sup>341</sup> 59 Fed. Reg. at 14508, 14509, III.A (March 28, 1994). The revised guidelines ensure that minorities and their subpopulations are included in all human subject research, and disallow cost as a reason for exclusion and initiate programs for outreach efforts to recruit minorities. See <http://grants.nih.gov/grants/guide/1994/94.03.18/index.html>.

<sup>342</sup> *Id.* at 14511, V.D.

<sup>343</sup> *Id.* at 14509, III.C.

<sup>344</sup> This relates to Phase III clinical trials. The updated guidelines are available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html>.

<sup>345</sup> 42 C.F.R. §§ 52.8, 52a.8. In addition, NIH may impose any other conditions necessary to assure the carrying out of the purposes of the award, the interests of public health, or the conservation of grant funds. 42 C.F.R. §§ 52.9, 52a.9.



by civil rights requirements, follow the NIH Guidelines and provide both an initial and annual report on research participants, by race and ethnicity.<sup>346</sup>

The NIH Revitalization Act established the Office of Research on Minority Health.<sup>347</sup> In December 2000, the enactment of the Minority Health and Health Disparities Research and Education Act effectively upgraded this office, establishing the National Center on Minority Health and Health Disparities.<sup>348</sup> This Center will conduct and support research on minority health conditions.

### **b. Policies and Practices**

Prior to the establishment of HHS' inclusion policy, NIH had its own.<sup>349</sup> While this policy ultimately was promulgated as a regulation (see above), NIH continues to develop policies regarding the inclusion of minorities in its research activities. While not directly addressing data collection, NIH's five-year strategic research plan delineates specific racial and ethnic minority populations – African Americans, Asians, Pacific Islanders, Hispanics, Native Americans, and Alaska Natives – for attention in research, research infrastructure, and public information and community outreach.<sup>350</sup> Each NIH Center and Institute has its own mission-specific strategic plan.<sup>351</sup>

To measure compliance with statutory and regulatory policies regarding the inclusion of minorities, NIH's Tracking and Inclusion Committee compiles and publishes data from a computerized tracking system.<sup>352</sup>

### **c. Data Collection Vehicles**

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<sup>346</sup> U.S. Department of Health and Human Services, Application for a Public Health Service Application (PHS 398), at 9-10, Application for Continuation of a Public Health Service Grant, (PHS 2590), at 6, <http://grants.nih.gov/grants/forms.htm>.

<sup>347</sup> 42 U.S.C. § 283b.

<sup>348</sup> P.L. 106-525 (October 22, 2000). Within NIH, a “center” has more authority with regard to policy development than does an “office.” Further discussion of this bill and its possible implications for the collection of racial and ethnic data are discussed in the other volume of this report.

<sup>349</sup> NIH guidelines date back to 1989, when NIH issued a Memorandum on Inclusion. Since NIH's policy is consistent with that of HHS, it continues without revision.

<sup>350</sup> *NIH Strategic Research Plan to Reduce and Ultimately Eliminate Health Disparities FY 2002-2006, draft*, (October 6, 2000), <http://healthdisparities.nih.gov/working/institutes.html>.

<sup>351</sup> These plans are available at <http://healthdisparities.nih.gov/working/institutes.html>.

<sup>352</sup> This system includes aggregate data reported annually by researchers engaged in NIH-funded activities. See NIH, *Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research: Comprehensive Report*, at 3, <http://www4.od.nih.gov/orwh>.

NIH requires all grant recipients to provide annual inclusion reports, specifying the race and ethnicity of clinical trial participants. The following databases provide issue-specific information on certain NIH activities in addition to the data collected on annual inclusion reports.

**Survey Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
Public Use Data on Cancer Incidence and Survival from the Surveillance, Epidemiology and End Results (SEER) Program of the National Cancer Institute <sup>353</sup>	Black; White; American Indian/Aleutian/Eskimo; Chinese; Japanese; Filipino; Hawaiian; Korean; Asian Indian; Pakistani; Vietnamese; Laotian; Hmong; Kampuchean; Pacific Islander (Chamorroan, Tahitian, Samoan, Tongan, Fiji Islander, New Guinean); Thai	Hispanic; Non-Hispanic
Arteriosclerosis Risk in Communities Study <sup>354</sup>	White; Black; Asian/Pacific Islander; Native American; Hispanic	N/A
Cardiovascular Health Study <sup>355</sup>	White; Black; American Indian/Alaskan Native; Asian/Pacific Islander	N/A
Coronary Artery Risk Development in Young Adults <sup>356</sup>	White; Black; American Indian/Alaskan Native; Asian/Pacific Islander; Hispanic	N/A
Established Populations for Epidemiologic Studies for the Elderly <sup>357</sup>	White (Non-Hispanic); Black (Non-Hispanic); Asian/Pacific Islander; Aleutian/Eskimo/American Indian; Hispanic; Other	N/A

<sup>353</sup> This system collected, analyzed and disseminated data useful in addressing the prevention, diagnosis, treatment, incidence and survival rate of cancer. Data collection is complete.

<sup>354</sup> This is a prospective epidemiologic study of cardiovascular disease in middle-aged persons in four US communities.

<sup>355</sup> This prospective epidemiologic study of cardiovascular disease collects data on older persons in four US communities.

<sup>356</sup> This is a prospective epidemiologic study of young adults in four US communities.

National Institute of Mental Health Epidemiologic Catchment Area Program <sup>358</sup>	American Indian; Alaskan Native; Asian; Pacific Islander; Black (Not Hispanic); Hispanic; White (Not Hispanic); Other/Unknown	N/A
National Longitudinal Study of Adolescent Health <sup>359</sup>	Hispanic, all races; African American, Non-Hispanic; Asian, Non-Hispanic; Native American, Non-Hispanic; Other, Non-Hispanic; White, Non-Hispanic	N/A

**Survey Activities:**

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
National Longitudinal Alcohol Epidemiologic Survey <sup>360</sup>	White; Black; American Indian/Eskimo/Aleut; Asian/Pacific Islander; Other	58 categories
Current Population Survey - Nativity Supplement <sup>361</sup>	N/A	N/A
National Survey of Adolescent Males <sup>362</sup>	Black; White; American Indian or Alaska Native; Asian or Pacific Indian; Other	Hispanic or Hispanic Origin; if yes – Mexican/Mexican-American/Chicano; Cuban/Cubano; Puerto Rican; Other Latin American/Hispanic/Latino/Hispanic Descent

<sup>357</sup> These studies provide research for a broad range of studies in representative samples of community-dwelling persons age 65 and older.

<sup>358</sup> This collaborative research project assessed the prevalence of mental and addictive disorders, and estimated the usage of different sectors of the service system. Data collection is complete.

<sup>359</sup> This is a congressionally mandated study on adolescent health focusing on the social context of health related behaviors.

<sup>360</sup> This survey provided comprehensive information on amounts and patterns of alcohol consumption and problems associated with alcohol. Data collection is complete.

<sup>361</sup> This provided data to measure changes in the labor force. Data collection is complete.

<sup>362</sup> This survey examined factors affecting young men’s risk of becoming infected with HIV, STDs, or of becoming a parent (over-sampled for Blacks and Hispanics). The

New Immigrant Survey - A Pilot Study <sup>363</sup>	Unknown <sup>364</sup>	Unknown
Health Information National Trends Survey (HINTS) <sup>365</sup> (proposed)	OMB Standards <sup>366</sup>	OMB Standards
National Epidemiologic Survey on Alcohol and Related Conditions <sup>367</sup>	OMB Standards	OMB Standards

#### 4. Food and Drug Administration

The Food and Drug Administration (FDA) promotes and protects the public health by helping safe and effective products reach the market in a timely way. The FDA also monitors products for continued safety after they are in use.

##### a. Statutory and Regulatory Authority

The FDA, in consultation with the Director of NIH and representatives of the drug manufacturing industry, must review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials.<sup>368</sup>

FDA's regulations require applications for approval of new drugs to include analyses of effectiveness and safety data for important demographic subgroups, including

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survey also requests language spoken at home; first language spoken as a child; country of birth; and date of arrival in U.S. This survey has been incorporated into the National Survey of Family Growth. Further information is available from the Urban Institute, Population Studies Center, (202) 833-7200.

<sup>363</sup> This survey will evaluate methods of tracking newly arrived immigrants over time.

<sup>364</sup> This instrument is under development but researchers anticipate including questions regarding country of origin, race and ethnicity, modeled after the categories used in the 2000 Census. For more information, contact James Smith, Senior Economist, RAND, 310-393-0411 x6925.

<sup>365</sup> HINTS is a new survey to provide nationally representative, population-based standardized data on health knowledge and health information, focusing on cancer communication practices and cancer knowledge.

<sup>366</sup> The HINTS survey is still being developed, but NIH anticipates including both race and ethnicity questions utilizing the OMB standards.

<sup>367</sup> The purpose of this study is to determine the incidence and prevalence of alcohol use disorders in a representative sample of the U.S. population.

<sup>368</sup> The Food and Drug Administration Modernization Act of 1997 § 115, Clinical Investigations, 21 U.S.C. § 355(b)(1).

racial subgroups.<sup>369</sup> The FDA may refuse to approve a new drug that does not analyze safety and efficacy information appropriately by gender.<sup>370</sup> In addition, enrollment of subjects into clinical studies for investigational new drugs (INDs) should be tabulated by race in annual reports.<sup>371</sup> The FDA offers guidelines to assist applicants in presenting the clinical and statistical data required as part of an application.<sup>372</sup>

The FDA must undertake periodic surveys of the needs, interest, attitudes, knowledge and behavior of the American public regarding health and health care.<sup>373</sup>

#### **b. Policies and Practices**

The Food and Drug Administration Modernization Act (FDAMA) Women and Minorities Working Group found that specific guidance on the inclusion of minorities in its clinical trials was unnecessary. While the FDA had restricted women with childbearing potential from participating in clinical trials, the FDA never had a regulatory barrier to the inclusion of minorities in clinical trials. Thus, FDA's guidance was drafted specifically to address gender inclusion but articulates the expectation that all appropriate demographic subgroups should be included in product development.<sup>374</sup> The Working Group notes that the inclusion of this statement only in the Gender Guideline conceivably might diminish its impact on minority recruitment.<sup>375</sup> It appears that Congress wanted additional guidance, since it required a review and possible development of guidance in 1997, four years after the Gender Guidelines were published.

#### **c. Data Collection Vehicles**

The FDA has undertaken five different surveys, outlined below. Only two, the National Survey of Prescription Drug Information and the Health and Diet Survey, remain active collections.

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<sup>369</sup> 21 C.F.R. § 314.50(d)(5)(v). The regulations require data on a drug's effectiveness by racial subgroup, with identification of any modifications of dose or dose interval needed for specific subgroups.

<sup>370</sup> Final Rule on Investigational New Drug Applications and New Drug Applications, (1988).

<sup>371</sup> 21 C.F.R. § 312.33(a)(2). Requiring tabulation of the total number of subjects initially planned for inclusion in the study and the number entered into the study through the date of the report.

<sup>372</sup> Center for Drug Evaluation and Research, Food and Drug Administration, Guideline for the Format and Content of the Clinical and Statistical Sections of an Application (July, 1998), <http://www.fda.gov/cder/guidance/statnda.pdf>.

<sup>373</sup> 42 U.S.C. § 300u-1.

<sup>374</sup> See FDA, *Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs*, 58 Fed. Reg. 39406 (July 22, 1993).

<sup>375</sup> *FDAMA Women and Minorities Working Group Report*, (July 20, 1998), at 7, <http://www.fda.gov/cder/guidance/women.pdf>.

<b>Data Collection Instrument</b>	<b>Racial Categories</b>	<b>Ethnic Categories</b>
National Surveys of Prescription Drug Information Provided to Patients (1994, 1996) <sup>376</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black, Not of Hispanic Origin; White, Not of Hispanic Origin; Hispanic; Other	N/A
Consumer Survey of Cosmetic Usage Patterns <sup>377</sup>	Asian/Pacific Islander; Black; Native American; White; Other; Hispanic; Not of Hispanic Origin; Refused Specification; Don't Know	N/A
Food Label Use and Nutrition Education Survey <sup>378</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black; White; Hispanic; Not of Hispanic Origin	N/A
Health and Diet Survey <sup>379</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black; White; Hispanic; Not of Hispanic Origin	N/A
Weight Loss Practices Survey <sup>380</sup>	American Indian/Alaskan Native; Asian/Pacific Islander; Black; White; Other; Hispanic; Not of Hispanic Origin	N/A

<sup>376</sup> These surveys collected prescription drug information to assess the amount and type of information being received by pharmacists, physicians, and other sources.

<sup>377</sup> This collection surveyed information to conduct scientific risk assessment before human injury occurs. This was a single-time data collection.

<sup>378</sup> This survey established a baseline on consumer uses of food labels to provide an understanding of label use in diet management. This data collection is complete, but selected questions will be incorporated in future Health and Diet Surveys.

<sup>379</sup> This survey collected information to monitor public awareness, knowledge, attitudes, and reported behavior related to food and nutrition.

<sup>380</sup> This survey provided detailed information from telephone surveys about types and combinations of weight loss practices in the general public. This was a one-time collection and is complete.

## V. OTHER AGENCIES

While the principal focus of this volume is on the health programs within HHS, information on other federal agencies can provide a framework for reference and discussion. This section includes information on other federal agencies that administer health programs: the Department of Defense (overseeing health programs for active duty and retired members of the uniformed services, their families, and survivors); the Department of Labor (overseeing employer-sponsored programs through the Employee Retirement Income Security Act); the Department of Veterans Affairs (administering health programs for veterans); and, the Office of Personnel Management (overseeing the Federal Employee Health Benefit Plans).

### A. Department of Defense

The Department of Defense (DOD) operates the Military Health System (MHS) for all active duty and retired members of the uniformed services, their families, and survivors – approximately nine million individuals worldwide. The MHS, previously known as CHAMPUS,<sup>381</sup> currently operates as TRICARE. TRICARE brings together the health care resources of the Army, Navy and Air Force and supplements them with networks of civilian health care professionals to provide better access and high quality service while maintaining the capability to support military operations.

#### 1. Statutory and Regulatory Authority

The statutes and regulations implementing the MHS do not address data collection but authorize DOD to prescribe administrative regulations.<sup>382</sup> The implementing regulations allow for the collection of utilization data as needed for carrying out MHS programs and missions.<sup>383</sup>

In the National Defense Authorization Act of FY 1993, Congress required implementation of a National Claims Processing System for the MHS, requiring that, to the maximum extent practicable, the system conform to the Medicare claims system.<sup>384</sup> The implementation of this requirement is discussed below.

Congress also requires an annual beneficiary survey to determine the availability of health care services, the types of services received, the facilities in which services were provided, the familiarity with services and facilities available, the health of individuals in

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<sup>381</sup> CHAMPUS is the acronym for the Civilian Health and Medical Program of the Uniformed Services.

<sup>382</sup> 10 U.S.C. Part 55, 32 C.F.R. § 199.1

<sup>383</sup> 32 C.F.R. § 199.1(c)(8).

<sup>384</sup> National Defense Authorization Act FY 1993, P.L. 102-484 § 711 (October 23, 1992), *codified at* 10 U.S.C. § 1106.

the MHS, the level of satisfaction with the MHS and the quality of care provided, and any other matters deemed appropriate.<sup>385</sup>

DOD's general regulations require compliance with Title VI for recipients of federal financial assistance, which would include non-DOD health care providers contracting with TRICARE.<sup>386</sup>

## 2. Policies and Practices

The TRICARE information system, called the Defense Enrollment Eligibility Reporting System (DEERS) (also called the National Enrollment Database [NED]), includes information about all TRICARE recipients.<sup>387</sup> DEERS is primarily an eligibility system with information on enrollment. Treatment records are compiled by health care providers.<sup>388</sup>

Two MHS manuals address the requirements for TRICARE data. TRICARE's Program Management Plan<sup>389</sup> provides uniform responsibilities and standards for implementation, operation, and maintenance of a central beneficiary enrollment process and repository for beneficiary information. The Automated Data Processing (ADP) Manual defines the contractor's responsibilities related to the automated collection and transmission of relevant data between the contractor, the TRICARE Management Activity (TMA), and DEERS.

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<sup>385</sup> 10 U.S.C. § 1071.

<sup>386</sup> See 32 C.F.R Part 195. DOD regulations require each applicant for federal financial assistance to include assurances of compliance with Title VI and to keep racial and ethnic data showing the extent to which members of minority groups are beneficiaries of federally assisted programs. 32 C.F.R. §§ 195.6, 195.7.

<sup>387</sup> Centralization of TRICARE enrollment information into DEERS will incorporate enrollment programs, enrollment dates, and fees. See Defense Manpower Data Center, *Defense Enrollment Eligibility Reporting System/Military Health System (DEERS)/(MHS): Technical Specifications for the TRICARE National Enrollment Database (NED) Solution*, prepared for the Office of the Undersecretary of Defense (Personnel and Readiness) and Defense Manpower Data Center, version 9, at 3 (November 3, 2000), (hereafter DMDC Technical Specifications) <http://www.dmdc.osd.mil/deers/>.

<sup>388</sup> DMDC Technical Specifications at 3. The Composite Health Care System is the data system for military treatment facilities, and includes computerized patient records. Non-military providers do not maintain computerized records accessible through CHCS.

<sup>389</sup> TRICARE 6010.52-M, <http://www.tricare.osd.mil/TRICAREManuals/adp.htm>.



### 3. Data Collection Vehicles

The data dictionary for NED does not require the collection of racial or ethnic data.<sup>390</sup> Rather, demographic information on military personnel contained in DEERS is obtained from each service’s personnel records and from the Realtime Automated Personnel Identification System (RAPIDS) for dependents and retirees.<sup>391</sup>

Active duty personnel generally receive care at military treatment facilities (MTFs). Dependents of active duty personnel, retirees, and others eligible for treatment through the MHS may receive care either at an MTF or a non-MTF. Depending on the source of treatment, different data collection activities are required.

For military treatment facilities, patients must register in the Composite Health Care System. CHCS is linked to DEERS so that certain information from DEERS is accessible, although not race or ethnicity. CHCS thus collects race and ethnicity at the time of registration but this information is not transferred to DEERS.<sup>392</sup> Information from patients receiving care at non-MTFs is contained in separate data systems that may not be accessible through DEERS.<sup>393</sup>

#### Data Collection/Reporting Activities:

Data Collection Instrument	Racial Categories	Ethnic Categories
CHCS <sup>394</sup>	White; Asian-Pacific Islander; Black; Western Hemisphere Indian; Other; Unknown	Hispanic; Southeast Asian; Filipino; Other Asian/Pacific Islander; Other; Unknown

#### Survey Activities:

Data Collection Instrument	Racial Categories	Ethnic Categories
Health Care Survey of DOD Beneficiaries <sup>395</sup>	American Indian or Alaska Native; Asian; Black or African American; Hispanic or Latino; Native Hawaiian	N/A

<sup>390</sup> DMDC Technical Specifications, *Data Dictionary for the TRICARE National Enrollment Database*, <http://www.dmdc.osd.mil/deers/>.

<sup>391</sup> RAPIDS collects information when individuals apply for military identification cards. Telephone conversation with George Bodie, DEERS/RAPIDS Program Office, DMDC, 703-696-6771.

<sup>392</sup> Telephone Conversation with Julie Clark, Project Officer, Clinical Information Technology, Office of the Secretary of Defense, 703-681-7130 x 4720.

<sup>393</sup> It is beyond the scope of this survey to evaluate non-federal databases.

<sup>394</sup> CHCS includes information from all military treatment facilities, including both in-patient and out-patient treatment.

	or other Pacific Islander; White	
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## **B. Department of Veterans Affairs, Veterans Health Administration**

The mission of the Department of Veterans Affairs' Veterans Health Administration (VHA) is to serve the needs of America's veterans by providing primary care, specialized care, and related medical and social support services. The VHA operates the Veterans Healthcare System (VHS) to meet this mission.

### **1. Statutory and Regulatory Authority**

The VHA must operate an annual patient enrollment system.<sup>396</sup> The purpose of this system is to ensure quality care is provided in a timely manner. VHS may not provide hospital care or medical services unless an individual enrolls in the patient enrollment system.<sup>397</sup> This system, discussed below, does collect racial and ethnic data of enrollees. The VHA has authority to prescribe all rules and regulations necessary or appropriate to administer the VHS.<sup>398</sup>

The VHA must also establish and conduct a comprehensive quality assurance program.<sup>399</sup> As part of this requirement, VHA must compare mortality and morbidity rates between VHA and prevailing national standards, and analyze deviations with regard to characteristics of respective patient populations and other factors VHA considers appropriate.<sup>400</sup> This requirement may provide part of the basis for collecting racial and ethnic data on VHA enrollees.

In addition to operating the VHS, the VHA also undertakes medical research to contribute to the nation's knowledge about disease and disability. This includes biomedical research, mental illness research, prosthetic and other rehabilitative research and health-care-services research. There is a particular emphasis on research into spinal-cord and other injuries leading to paralysis of the lower extremities, and injuries and illnesses particularly related to military service.<sup>401</sup> VHA must ensure, whenever possible

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<sup>395</sup> This survey is based on the CAHPS survey designed by AHRQ (*see* Part IV.D.1.c.).

<sup>396</sup> 38 U.S.C. § 1705.

<sup>397</sup> 38 U.S.C. § 1705(c) and 38 C.F.R. § 17.36. For limited exceptions to these requirements, *see* 38 C.F.R. § 17.37.

<sup>398</sup> 38 U.S.C. § 1705(b). Treatment through VHS is not available to all veterans. Rather, priorities are established based on whether an individual's disability is service-connected, the rating of the disability, the need for on-going care, and the need for assistance to defray the costs of care. *See also* 38 U.S.C. § 501 regarding VA's general authority to promulgate regulations.

<sup>399</sup> 38 U.S.C. § 7311.

<sup>400</sup> 38 U.S.C. § 7311(c)(2)(A), (B).

<sup>401</sup> 38 U.S.C. § 7303(a).

and appropriate, that veterans who are members of minority groups are included as subjects in its research.<sup>402</sup> When minorities are included in research, VHA must ensure that the design and execution of the research project can provide a valid analysis of whether the variables tested affect members of minority groups differently than other subjects.<sup>403</sup> Because of these requirements, VHA research projects collect data on the race and ethnicity of participants.

The VA Title VI regulations suggest that recipients maintain records on race or ethnicity to demonstrate compliance.<sup>404</sup> These regulations also require assurances of compliance with Title VI in applications for federal financial assistance.<sup>405</sup>

While VHA has administered a patient survey pursuant to statutory authority, that authority was repealed.<sup>406</sup> VA must also collect data on participation and provision of services.<sup>407</sup>

## 2. Policies and Practices

Despite the repeal of the statute, VHS conducts patient satisfaction surveys pursuant to an executive order requiring agencies to conduct surveys to determine the kinds of services its customers need, as well as levels of satisfaction with existing services.<sup>408</sup>

While the application for enrollment in VHA and CHAMP-VA<sup>409</sup> includes questions about gender and religion, it does not ask for race and/or ethnicity.<sup>410</sup>

VHA policy applies Title VI not just to recipients of federal financial assistance but also to the internal programs of the VHA itself.<sup>411</sup>

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<sup>402</sup> 38 U.S.C. § 7303(c)(1)(B).

<sup>403</sup> 38 U.S.C. § 7303(c)(2).

<sup>404</sup> 38 C.F.R. § 18.6.

<sup>405</sup> 38 C.F.R. § 18.4.

<sup>406</sup> 38 U.S.C. § 219, 38 U.S.C. § 3305.

<sup>407</sup> 38 U.S.C. § 527.

<sup>408</sup> Executive Order 12862, Setting Customer Service Standards (September 11, 1993).

*See also*, VHA Directive 99-032, *Office of Management and Budget Approval of Customer Satisfaction Surveys* (July 15, 1999),

<http://www.va.gov/publ/direc/health/direct/199032.htm>.

<sup>409</sup> CHAMP-VA is a managed care program similar to DOD's CHAMPUS.

<sup>410</sup> *See* Form 10-10EZ, Part I – General Information,

<https://www.1010ez.med.va.gov/sec/vha/1010ez/SelectorPage.asp#select>.

<sup>411</sup> VHA DIRECTIVE 99-043, *Nondiscrimination in Federally-Conducted and Federally-Assisted (External) Programs* (September 23, 1999),

<http://www.va.gov/publ/direc/health/direct/199043c1.htm>.

### 3. Data Collection Vehicles

The VHS maintains the Veterans Health Administration Information Systems and Technology Architecture (VISTA), a computerized medical information system that covers almost all aspects of health care and health status. Part of VISTA is the National Patient Care Database (NPCD),<sup>412</sup> which contains information on each episode of care provided by the VA health care system and includes a patient's race and ethnicity.

Data Collection Instrument	Racial Categories	Ethnic Categories
NPCD <sup>413</sup>	Hispanic, Black; Hispanic, White; American Indian; Black; Asian; White; Unknown; Other	N/A

#### Survey Activities:

Data Collection Instrument	Racial Categories	Ethnic Categories
National Survey of Veterans <sup>414</sup>	White; Black or African-American; American Indian or Alaska Native; Asian, Native Hawaiian or Other Pacific Islander; Don't Know; Refused	Spanish/Hispanic/Latino
Census of Enrollment <sup>415</sup>	American Indian or Alaska Native; Asian; Black or African-American; Spanish/Hispanic/Latino; Native Hawaiian or Other Pacific Islander; White	N/A <sup>416</sup>

<sup>412</sup> The NPCD integrated four prior VHS databases including the Outpatient Care File (OCF) and the Patient Treatment File (PTF, for inpatient data).

<sup>413</sup> Information was obtained from the NPCD's PTF dataset, [http://www.virec.research.med.va.gov/DATABASES/NPCD/NPC\\_PTF\\_RESGUIDE.PDF](http://www.virec.research.med.va.gov/DATABASES/NPCD/NPC_PTF_RESGUIDE.PDF), and from the OCF dataset, [http://www.virec.research.med.va.gov/DATABASES/NPCD/NPC\\_OPC\\_RESGUIDE.PDF](http://www.virec.research.med.va.gov/DATABASES/NPCD/NPC_OPC_RESGUIDE.PDF).

<sup>414</sup> The National Survey of Veterans, addressing all services provided by the Department of Veterans Affairs, is conducted every 5-7 years; it was previously known as the Survey of Veterans.

<sup>415</sup> The Census was conducted twice, focusing on functional status measurement and additional modules, including patient satisfaction. Telephone conversation with Charles Humble, National Performance Data Feedback Center, 919-993-3035 (Mar. 26, 2001).

<sup>416</sup> The VHS tested two formats for collecting race and ethnicity data – one question (providing both race and ethnicity categories and allowing multiple designations); and

Patient Satisfaction Surveys <sup>417</sup>	N/A <sup>418</sup>	N/A
Outpatient Care Satisfaction Survey <sup>419</sup>	American Indian or Alaska Native; Asian; Black or African-American; Spanish/Hispanic/Latino; Native Hawaiian or Other Pacific Islander; White	N/A

### C. Office of Personnel Management

The Office of Personnel Management (OPM) is the federal government’s human resources agency. OPM manages the largest employer-sponsored health insurance program in the world, the Federal Employee Health Benefit Program (FEBHP), which covers all federal employees and their dependents.<sup>420</sup> FEBHP covers almost 9 million individuals.<sup>421</sup> FEBHP offers enrollment in a wide variety of government-approved health programs.

#### 1. Statutory and Regulatory Authority

OPM prescribes federal civilian personnel standards regarding data collection.<sup>422</sup> Each federal agency must report federal personnel information to OPM.<sup>423</sup> So while each

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two questions (one for race and one for ethnicity). Since the one question format produced more comprehensive data, the VHS uses one combined question rather than the OMB Standards.

<sup>417</sup> This includes the Inpatient Satisfaction Survey; Outpatient Care Satisfaction Survey; Gulf War Satisfaction Survey; Prosthetics Satisfaction Survey; Spinal Cord Injury Satisfaction Survey; and Home Based Primary Care Satisfaction Survey.

<sup>418</sup> Information on a patient’s race and ethnicity is obtained from NPCD.

<sup>419</sup> Since NPCD’s outpatient data collection has not captured race as comprehensively as its other patient data collections, the outpatient care satisfaction survey will begin collecting race data this year. Use of a combined race/ethnicity question was adopted after testing completed for the Census of Enrollment, *see* note 415.

<sup>420</sup> The authorization for FEBHP is contained at 5 U.S.C. Part 89; regulations are at 5 C.F.R. Part 890. The definition of employees is found in 5 U.S.C. § 8901.

<sup>421</sup> Federal Employee Health Benefits Program Facts, [http://www.opm.gov/insure/health/fehb\\_facts/index.htm](http://www.opm.gov/insure/health/fehb_facts/index.htm).

<sup>422</sup> 5 U.S.C. § 2951; 5 C.F.R. § 7.2.

<sup>423</sup> This includes both competitive and excepted service employees, and those who are permanent, career, career-conditional, indefinite, temporary, emergency or subject to contract.

FEHBP plan or provider is not required to collect data, it is available through OPM’s personnel files.

## 2. Policies and Practices

OPM’s Operating Manual contains standards for the Central Personnel Data File (CPDF). The objectives of these standards are to facilitate the use of federal civilian personnel data and to avoid unnecessary duplication and incompatibility in the collection, processing and dissemination of such data.<sup>424</sup> The CPDF tracks the race or national origin of individuals, as well as the individual’s health plan. OPM’s Guide to Personnel Data Standards does not provide race or national origin categories. It does specify that employees of mixed race or national origin should be identified using the race or national origin with which they most closely associate themselves.<sup>425</sup> This would not allow multiple selections as required by OMB’s Guidelines.

## 3. Data Collection Vehicles

Data Collection Instrument	Racial Categories	Ethnic Categories
CPDF	American Indian/Alaskan Native; Asian/Pacific Islander; Black, not of Hispanic Origin; Hispanic; White, not of Hispanic Origin; Asian Indian; Chinese; Filipino; Guamanian; Hawaiian; Japanese; Korean; Samoan; Vietnamese; All Other Asian/Pacific Islander; Not Hispanic in Puerto Rico <sup>426</sup>	N/A

<sup>424</sup> *Operating Manual: The Guide to the Central Personnel Data File*, (through Update 3, June, 1999), <http://www.opm.gov/feddata/html/datastan.htm>. The CPDF covers all federal civilian employees of the Executive Branch except those in: the CIA; Defense Intelligence Agency; Federal Reserve System – Board of Governors; National Imagery and Mapping Agency; National Security Agency; Office of the Vice President; Postal Rate Commission; Tennessee Valley Authority; U.S. Postal Service; White House Office; commissioned officers in the Departments of Commerce, HHS and EPA; employees of the Judicial Branch; non-appropriated fund personnel and non-U.S. citizens in foreign countries.

<sup>425</sup> *Id.*

<sup>426</sup> *The Guide to Personnel Data Standards*, (Update 11, 3/00). Certain codes are for use only in certain areas. For example, the codes Hawaiian, Japanese, Korean, Samoan, Vietnamese, All Other Asian/Pacific Islander are only used in Hawaii. *Id.*

## D. Department of Labor

The Department of Labor (DOL) is charged with preparing the American workforce for new and better jobs, and ensuring the adequacy of America's workplaces. It is responsible for the administration and enforcement of over 180 federal statutes including protecting workers' wages, health and safety, promoting equal employment opportunity, and administering job training.

### 1. Statutory and Regulatory Authority

DOL oversees employer-sponsored health insurance programs pursuant to the Employee Retirement Income Security Act (ERISA). ERISA covers most private sector employee benefit plans that are voluntarily established and maintained by an employer, an employee organization, or jointly by one or more employers and an employee organization. ERISA sets uniform minimum standards to assure that employee benefit plans operate in a fair and financially sound manner. Administrators of ERISA plans must file an annual report containing financial and other information concerning the operation of the plan.<sup>427</sup> Since the role of the DOL in overseeing ERISA plans is primarily to protect against fraud rather than to monitor the quality of care, the annual report does not report enrollee-specific information.<sup>428</sup>

DOL does have its own Title VI implementing regulations, but these do not affect ERISA plans since these plans do not receive federal financial assistance.<sup>429</sup>

In addition to overseeing ERISA plans, DOL coordinates various collections of information, coordinated through the Current Population Survey, authorized by Congress.<sup>430</sup>

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<sup>427</sup> Plans with fewer than 100 participants must file at least every third year, with an abbreviated report in the two intervening years. Plan administrators must furnish participants and beneficiaries with a summary of the information in the annual report. See <http://www.dol.gov/dol/pwba/public/pubs/forms/formmain.htm>.

<sup>428</sup> For additional information on the scope of DOL's authority in administering and enforcing ERISA, see, *Progress in Implementing the Patient's Bill of Rights through the Department of Labor*, <http://www.dol.gov/dol/pwba/public/pubs/rept1198.htm>. While this addresses implementation of the CBRR (see Part III.C.), the same limitations exist with regard to Title VI.

<sup>429</sup> See 29 C.F.R. § 31.5. DOL's Title VI regulations require each recipient to keep compliance reports sufficient to ascertain compliance with Title VI nondiscrimination requirements. The regulations specify that recipients should have data on race and ethnicity showing the extent to which members of minority groups are beneficiaries of federally assisted programs.

<sup>430</sup> The CPS is authorized by 13 U.S.C. § 182 and 29 U.S.C. §§ 1-9. In addition, portions of the survey in any month may be authorized by one of the following: 7 U.S.C. §§ 1621,

## 2. Policies and Practices

There are no specific policies regarding the collection of racial and ethnic data in the ERISA programs that DOL oversees.<sup>431</sup>

## 3. Data Collection Vehicles

Despite the fact that DOL does not have authority to collect racial and ethnic data from the health programs it oversees, DOL does collect reports of accidents and deaths in the workplace and conducts surveys regarding health issues.

### Data Collection/Reporting Activities:

Data Collection Instrument	Racial Categories	Ethnic Categories
Survey of Occupational Injuries and Illnesses <sup>432</sup>	White, Not of Hispanic Origin; Black, not of Hispanic Origin; Hispanic; Asian or Pacific Islander; American Indian, Aleut, Eskimo	N/A
Census of Fatal Occupational Injuries <sup>433</sup>	OMB Standards	OMB Standards

### Survey Activities:

Data Collection Instrument	Racial Categories	Ethnic Categories
Current Population Survey (CPS) <sup>434</sup>	White; Black; American Indian, Aleut or Eskimo; Asian or Pacific Islander; Other	German; Mexican; Italian; Puerto Rican; Irish; Cuban; French; Central or South American (Hispanic Countries); Polish; Other Hispanic; Russian; AfroAmerican (Black, Negro); English; Dutch; Scottish; Swedish; Mexican American; Hungarian; Chicano; Other

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1627; 38 U.S.C. § 219; P.L. 89-010; P.L. 92-318; and P.L. 93-380. See CPS Questionnaire, <http://www.bls.census.gov/cps/bquestons.htm>.

<sup>431</sup> DOL administers other labor-related programs for which data collection policies and practices exist but those are beyond the scope of this volume.

<sup>432</sup> This survey reports information on non-fatal work-related injuries and illnesses.

<sup>433</sup> This survey collects information on fatal work-related injuries and illnesses.



National Longitudinal Surveys <sup>435</sup> 1979 Cohort	Hispanic; Non-Hispanic Black; Non-Hispanic non-Black; child's race defined as the mother's	Black; Chinese; English; Filipino; French; German; Greek; Hawaiian/Pacific Islander; Indian American or Native American; Indian Asian; Irish; Italian; Japanese; Korean; Latino/Hispanic descent – Cuban, Chicano, Mexican; Mexican American; Puerto Rican; Other Latino/Hispano descent; Other Spanish descent; Polish; Portuguese; Russian; Scottish; Vietnamese; Welsh; Other specified; American; None
National Longitudinal Survey, 1997 Cohort <sup>436</sup>	White; Black/African-American; American Indian, Aleut, Eskimo; Asian/Pacific Islander; Other	Hispanic/Latino/Spanish Origin; Non-Hispanic/Latino/Spanish Origin

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<sup>434</sup> The CPS, conducted jointly by Bureau of the Census and Bureau of Labor Statistics, collects information monthly from 50,000 households on employment and unemployment, demographics, earnings, and more. The March supplement collects both demographic and health insurance information.

<sup>435</sup> These are a set of surveys designed to gather information at multiple points in time on the labor market experiences of six groups of men and women; including health conditions.

<sup>436</sup> The individuals in this cohort were between ages 12 and 16 in 1997. Additional information is available from NLS User Services, (614) 442-7366, or at <http://stats.bls.gov/nlshome.htm>.

## VI. OBSERVATIONS AND CONCLUSIONS

Despite widespread misconceptions by providers, insurers, the public and even federal agency staff, federal law does *not* prohibit the collection of racial, ethnic or primary language data. Indeed, the anti-discrimination mandate of Title VI offers a strong rationale for collecting this data. In addition, the collection of racial and ethnic data, and to a lesser extent primary language data, is often required by the policies and practices of the federal health programs. While several HHS policies clearly mandate the collecting and reporting of racial and ethnic data throughout its health services and research programs, actual practice appears to vary dramatically from program to program, and may occur much less frequently than the policies may suggest.

One indicator of whether practice is likely to mirror policy is whether a program is actually operated, or merely administered, by a federal agency. The Departments of Defense and Veterans' Affairs have the capability of linking enrollment databases to patient records/claims databases and have, to some degree, accomplished this. The Medicare program is perhaps the best example of the possibilities of linking this data, due in large part to the federal operation of this programs and the limited number of providers who participate. As evident in Medicare, it is much easier to collect data on a one-time basis at enrollment and link the information to claims data than it is to require providers to report data on an ongoing basis. For programs operated by federal agencies, the collection of comprehensive racial and ethnic data on enrollment is facilitated by the limited number of data collectors and the agency's direct oversight of the collection and reporting. In the Medicare program, both the federal control over enrollment and the established links between its computers and those of SSA form the basis for reasonably reliable racial and ethnic data about enrollees. Concerns exist, however, about the comprehensiveness, comparability and the future availability of this data due to SSA's use of non-standard categories of race and ethnicity and the fact that the forms used to assign Social Security Numbers at birth no longer collect racial and ethnic data.

When an agency merely administers or oversees a program, it has less control over enrollment or providers. The result is that data is less comprehensive and reliable. For example, in the Medicaid and SCHIP programs, the states design the enrollment forms and maintain the data, resulting in non-uniform collecting. CMS has not exercised its authority to require consistent data collection and reporting in the past. The provisions in the new Medicaid managed care and SCHIP regulations would, however, allow CMS to enforce collection requirements.

In addition to the distinction between operation and administration, another indicator of the likelihood of comprehensive, reliable data collection is whether the data comes from research or services programs. HHS' research activities have produced more comprehensive and statistically reliable data, presumably because researchers are trained to collect data and recognize its usefulness. Collection of racial and ethnic data in health services programs has been considerably less comprehensive than in the research arena.

Yet, whatever the flaws in the system for collecting and reporting racial and ethnic data, it remains light-years ahead of that used to gather data on primary language. Recognition of access and utilization limitations due to limited English proficiency has only recently begun to be highlighted. While Title VI has prevented national origin discrimination since 1964, only last year was guidance issued by the Department of Justice and HHS outlining requirements of federal fund recipients to provide translation and other services to individuals with limited English proficiency.

Since only five health services-related statutes and five research-related statutes require race or ethnicity data collection and/or reporting, the decision whether to require and then enforce such data collections represents a policy choice of the Department of Health and Human Services (HHS). Despite having a broad inclusion policy, the Department recently deviated from its declared course by not using its influence to require the reporting of this data in standards issued to comply with the Health Insurance Portability and Accountability Act. While HHS has stated its intent to amend the standards to require racial and ethnic data reporting, the absence of such a requirement in the promulgated standards represents an important and perhaps irretrievably lost opportunity since proposed changes to the standards have thus far focused on reducing reporting obligations, not adding to them. Unless and until the claims standards are amended to *require* the submission of racial and ethnic data, HIPAA will represent, at best, a squandered opportunity for evaluating the existence and magnitude of disparities in health care through the collection of racial and ethnic data across federal programs. At worst, it could, in the quest for uniformity, ultimately result in the demise of current beneficial data collection activities.

In sum, the collection of racial, ethnic and primary language data by federal agencies and recipients of federal funds is entirely permissible under federal law. It can be, and has been consistently argued by HHS, that such collections are necessary, to measure and address existing disparities in the delivery of health care; to develop and implement effective prevention, intervention, treatment and other health programs; to develop meaningful standards to analyze the efficacy of data collection activities to ensure nondiscrimination; to facilitate the provision of culturally and linguistically appropriate health care; and to identify and track similarities and differences in performance and quality of care in various geographic, cultural and ethnic communities. Adequate policy declarations, data collection instruments and mechanisms exist to accomplish this data collection. In short, the federal government possesses the tools to accomplish its stated goal of eliminating racial, ethnic and primary language disparities in the delivery of health care by the year 2010. What remains to be seen is whether the federal government retains and fully exercises the requisite will.