



January 15, 2016

Ms. Jennifer Park, Senior Advisor
Office of the U.S. Chief Statistician
Office of Information and Regulatory Affairs
Office of Management and Budget
9th Floor
1800 G Street, NW
Washington, DC 20503

DELIVERED ELECTRONICALLY

RE: OMB-2016-0008, Proposals from the Federal Interagency Working Group for Revision of the Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, 82 F.R. 12242 (Mar 1, 2017)

Dear Ms. Park:

On behalf of the American Clinical Laboratory Association, I respectfully submit the following comments regarding March 1, 2017 Proposals from the Federal Interagency Working Group for Revision of the Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (OMB-2016-0008, 82 F.R. 12242).

ACLA is a trade association representing the nation's leading providers of clinical laboratory services, including regional and national laboratories. Its diverse membership includes a broad array of clinical laboratories: large national independent labs, reference labs, esoteric labs, hospital labs, and nursing home labs. As discussed further below, ACLA respectfully requests that OMB not change the minimum set of Race and Ethnicity values represented in Table 1, without additional research and concurrence of the federal agencies dealing with the health care industry information technology.

Discussion

US based Laboratories currently use the OMB values represented in Table 1 in their nationally installed base. Revisions to the OMB standards for data on race and ethnicity may require laboratories to make changes to data collection forms (provider requisition/order forms), computer programs, thousands of interfaces with provider electronic health record (EHR) systems, and other related materials for laboratory information systems. These costs may be considerable, depending on the magnitude of revision. Since laboratory result reference ranges may be reported based on the patient's race or ethnicity, changing the values these laboratory results are based upon could have unintended consequences, and potentially impact the patient's safety. In addition, this data is often used for historical trending by many healthcare entities including laboratories, EHR system vendors, and even research facilities. Applying this change

would have negative impact to trending patient laboratory results across the patient healthcare record.

The values in OMB Table 1 were added to the [Health Level Seven](#) (HL7) standard for health care information exchange in 1999 by the Centers for Disease Control (CDC). HL7 standards are [referenced](#) in the Health and Human Services/ Meaningful Use program and also referenced in the Office of National Coordinator (ONC) sponsored laboratory result implementation guide¹ named for Meaningful Use Stage 2 and also referenced in ONC's [2014 Edition](#) required for certification of EHR systems.

Additionally, CDC developed an expanded set of race and ethnicity codes [CDC Race and Ethnicity Code Set Version 1.0 ([CDCREC](#))] for more granular clinical classification of race and ethnicity; this expanded set may be used for clinical purposes. These expanded codes roll up to the OMB "minimum set" categories in Table 1, thus revising them could have a negative impact that ripples through the health care information technology industry. The expanded CDC Race and Ethnicity Code Set Version 1.0 is additionally referenced by ONC's [2015 Edition](#) Standard [Common Clinical Data Set](#) which EHR systems must implement by 2018 in order to achieve certification by ONC, using [certification](#) tools developed by the National Institute of Standards and Technology (NIST).

Recommendation

ACLA respectfully requests that OMB not change the minimum set of Race and Ethnicity values represented in Table 1, without additional research and concurrence of the federal agencies dealing with the health care industry information technology, including:

- Centers for Disease Control (CDC) - CDC Race and Ethnicity Code Set Version 1.0, public health, surveillance
- Centers for Medicare and Medicaid Services (CMS) – Meaningful Use, Medicare Access and CHIP Reauthorization Act (MACRA) Advancing Care Information
- Office of National Coordinator (ONC) – EHR Certification and standards for Meaningful Use, Medicare Access and CHIP Reauthorization Act (MACRA) Advancing Care Information
- National Institute of Standards and Technology (NIST) – Certification tools for EHR certification in collaboration with ONC

If it is necessary to change the OMB Table 1 values (below), the new values must be map-able to existing values so that health IT systems may recognize both values (old and new) without disturbing existing functionality. We suggest that a master list be published in the National Library of Medicine (NLM) Value Set Authority Center (VSAC) to be adopted across the various standards bodies. We also don't recommend combining Ethnicity and Race values due to the potential clinical impact.

¹ HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Result Interface, Release 1 – US Realm

Table 1. Current Separate Questions Format

ETHNICITY	Hispanic or Latino
	Not Hispanic or Latino
RACE	American Indian or Alaska Native
	Asian
	Black or African American
	Native Hawaiian or Other Pacific Islander
	White

ACLA appreciates the opportunity to submit these comments. Additional background is included in the attached addendum. If additional information or background would be helpful, please do not hesitate to reach out to me at tsparkman@acla.com.

Sincerely,



Thomas B. Sparkman
Vice President

ATTACHMENT: ADDENDUM

ADDENDUM

Background (information only)

The current values in the OMB table below are in the HL7 Version 2 (V2), Chapter 3 Patient Administration standard, with codes values assigned by CDC, and also referenced in the US Lab Implementation Guides.

ACLA agreed to submit a general comment suggesting the minimum OMB categories be retained for backward compatibility since they have been a part of the HL7 Version 2 healthcare standards since 2004, and are referenced by the laboratory implementation guides developed under sponsorship of ONC Standards & Interoperability Framework, thus we believe that agencies should not issue contradictory requirements.

Additionally, CDC developed an expanded set of race and ethnicity codes [CDC Race and Ethnicity Code Set (CDCREC)]. These codes roll up to the OMB “minimum set” categories in Table 1 below. The expanded set is also referenced in the ONC electronic directory of service (eDOS) for electronic exchange of lab test compendium. Changes to the “minimum set” values could present unnecessary issues and complications. The expanded CDC vocabulary is also referenced in the ONC sponsored lab implementation guides.

OMB Values	From HL7 V2.4 published November 2000																																
<p>Table 1. Current Separate Questions Format</p> <table><tr><td>ETHNICITY</td><td>Hispanic or Latino</td></tr><tr><td></td><td>Not Hispanic or Latino</td></tr><tr><td rowspan="5">RACE</td><td>American Indian or Alaska Native</td></tr><tr><td>Asian</td></tr><tr><td>Black or African American</td></tr><tr><td>Native Hawaiian or Other Pacific Islander</td></tr><tr><td>White</td></tr></table>	ETHNICITY	Hispanic or Latino		Not Hispanic or Latino	RACE	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Other Pacific Islander	White	<p>User-defined Table 0189 - Ethnic group</p> <table><tr><th>Value</th><th>Description</th></tr><tr><td>H</td><td>Hispanic or Latino</td></tr><tr><td>N</td><td>Not Hispanic or Latino</td></tr><tr><td>U</td><td>Unknown</td></tr></table> <p>User-defined Table 0005 - Race</p> <table><tr><th>Value</th><th>Description</th></tr><tr><td>1002-5</td><td>American Indian or Alaska Native</td></tr><tr><td>2028-9</td><td>Asian</td></tr><tr><td>2054-5</td><td>Black or African American</td></tr><tr><td>2076-8</td><td>Native Hawaiian or Other Pacific Islander</td></tr><tr><td>2106-3</td><td>White</td></tr><tr><td>2131-1</td><td>Other Race</td></tr></table>	Value	Description	H	Hispanic or Latino	N	Not Hispanic or Latino	U	Unknown	Value	Description	1002-5	American Indian or Alaska Native	2028-9	Asian	2054-5	Black or African American	2076-8	Native Hawaiian or Other Pacific Islander	2106-3	White	2131-1	Other Race
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