ACLA
AMERICAN CLINICAL LABORATORY ASSOCIATION

April 27, 2023

The Honorable Richard L. Revesz
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th St., NW
Washington, DC 20503

RE: Initial Proposals for Updating OMB's Race and Ethnicity Statistical Standards (OMB-2023-0001)

Dear Mr. Revesz,

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to provide comments on the proposals to update the 1997 Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) ("Proposals").[1] ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care.

ACLA appreciates the efforts of the Office of Management and Budget (OMB) Interagency Technical Working Group (Working Group) to review Federal statistical standards to ensure that they are keeping pace with changes in the population and evolving needs and uses for data. ACLA encourages the OMB to prioritize stakeholder engagement in the development of proposed standards and ensure that any proposed standards for race and ethnicity would be supported across all jurisdictions and would still result in discrete values for race and ethnicity.

A. General Considerations

ACLA recognizes that the OMB race and ethnicity data collection instrument is used broadly and by a wide array of governmental and private entities in a variety of ways, and laboratory testing is just one context in which the instrument may be used. However, we hope that OMB and the Working Group will consider how these updated demographic data categories may impact laboratories, the clinical testing services they provide, and the data they report.

ACLA members have an interest in the Proposals in part because an individual's race and/or ethnicity is relevant for determining the reference range or "normal range" for certain laboratory test results. For example, for alpha-fetoprotein testing, which is a common prenatal test used to screen for possible genetic problems and birth defects in a developing fetus, race is used to modify the median equation used to generate the multiples-of-median (MoM) (a factor of 1.1 is applied to generate the MoM) for the reference range, and a higher cutoff is used for Black women

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[1] 88 Fed. Reg. 5375 (Jan. 27, 2023).

when identifying patients whose pregnancies should be evaluated further (2.8 for Black mothers, 2.5 for all other races/ethnicities). These adjustments allow the "screen positive" rate to be equal across all races and ethnicities. Without the adjustments, the positive rate in Black mothers could be artificially higher, resulting in a potential increased number of unnecessary amniocentesis procedures.

In addition to the potential clinical implications of changes in these demographic data categorizations, there are also interoperability issues to consider, as communications between clinicians and laboratories, and between laboratories and public health authorities, could be affected.

B. Standardization of Race and Ethnicity Data

It is very important to ACLA members that race and ethnicity data be standardized to facilitate the efficient transmission and exchange of the data between entities. For example, information that a health care professional enters into an electronic health record (EHR) can be used to create a test order and transmit it to a laboratory using a laboratory information system (LIS) through an interface with the EHR. A lack of standardization can result in unnecessary reduplication of efforts, including health care professionals and laboratories having to re-enter information in an LIS to create a lab order.

The proposed revision to SPD 15 includes an "open-ended write-in field to collect details on racial and ethnic responses."[2] ACLA urges OMB to exclude write-in fields in a race and ethnicity data collection instrument. Open-ended write-in fields impede sharing information electronically between entities because of the high risk of error, such as an individual misspelling their ethnicity or using a name for a country that is not widely recognized. Standardized data values limit the types of errors that could prevent information from being exchanged efficiently between entities.

Each time the standards change, ACLA members and many other entities must reprogram interfaces to allow for exchange of electronic data. ACLA hopes that OMB will be thoughtful and deliberate as it finalizes its new policies regarding standards pertaining to race and ethnicity, given that certain other agencies are in the process of newly updating their own demographic standards and actually reference the OMB 1997 data collection standards for race and ethnicity data collection. The Office of the National Coordinator for Health Information Technology (ONC) uses United States Core Data for Interoperability (USCDI) v3 and is currently seeking feedback on its proposed USCDI v4. The draft USCDI v4 would ask for race and ethnicity separately, using the OMB 1997 data collection tool.[3] Similarly, the Centers for Disease Control and Prevention (CDC) recently released the CDC Race and Ethnicity 2022 Code System, which also is based on the 1997 standards.

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[2] 88 Fed. Reg. 5382.

[3] https://www.healthit.gov/isa/uscdi-data-class/patient-demographicsinformation#draft-uscdi-v4.

C. Collect Race and Ethnicity Information Using One Combined Question

The Working Group is proposing that SPD 15 move from the two separate questions format to a single combined question for self-reported race and ethnicity information collections. Among the challenges that would result from employing a new combined question design may take significant time and resources for some surveys and information collections to implement.

The combination of race and ethnicity as a single question/response would disable discrete data interoperability. It would also enable partial or incomplete responses. Additionally, efforts to support race and ethnicity values across different jurisdictions (federal, public health, states, etc.) would become significantly more challenging. ACLA recommends that any new proposed standards for race and ethnicity be supported across all jurisdictions and still result in discrete values for race and ethnicity.

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ACLA appreciates the opportunity to provide these comments on the initial proposals from the Federal Interagency Technical Working Group on Race and Ethnicity Standards for revising OMB's 1997 SPD 15. If you have any questions, please contact Joan Kegerize at jkegerize@acla.com.

Sincerely,

Susan Van Meter, President
American Clinical Laboratory Association