



May 7, 2012

Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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U.S. Department of Health and Human Services
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RE: CMS-0044-P (Electronic Health Record Incentive Program—Stage 2 Proposed Rule), RIN 0991-AB82 (2014 Edition EHR Standards and Certification Criteria Proposed Rule)

Dear Acting Administrator Tavenner and National Coordinator Mostashari:

The undersigned member organizations and other supporters of The Leadership Conference on Civil and Human Rights appreciate this opportunity to provide comments in response to the proposed rules implementing Stage 2 of the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, including the standards and implementation specifications that certified EHR technology would need to include to support meaningful use as of 2014 (file codes CMS-0044-P and RIN 0991-AB82). The Leadership Conference is a coalition charged by its diverse membership of more than 200 national organizations to promote and protect the civil and human rights of all persons in the United States (U.S.). The Leadership Conference's Health Care Task Force is committed to eliminating health disparities and ensuring that all people in the United States can access quality, affordable health care, without discrimination.

The incentive program offers an important opportunity to reduce health disparities and improve equity in the U.S. health care system. Indeed, reducing disparities is included in the first of the "five pillars" of meaningful use health outcomes policy priorities. We strongly support the prominence given to this goal in the program's structure; however, we are concerned that the meaningful use requirements as proposed are inadequate to achieve this outcome. We are at a critical juncture for ensuring that public investments in health information technology (IT) result in the reduction and ultimate elimination of disparities. If the Stage 2 criteria do not reflect a more robust application of health IT to increasing health equity, the federal government is in jeopardy of creating greater disparities as the majority of Americans begin to see benefits from health IT implementation.

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In particular, we offer a number of recommendations in three key areas to enable the incentive program to meaningfully impact inequities in health and health care. An outline of our recommendations is below. This is followed by a narrative discussion of each recommendation in detail.

In summary, we recommend the following:

- I. The incentive programs should reinforce federal civil rights and health information privacy laws.
 - a. Federal civil rights laws and EHR incentive payments
 - i. Clearly state in final rules that because EHR incentive payments constitute federal financial assistance, all recipients are obligated to comply with Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act, the Americans with Disabilities Act (ADA), and Section 1557 of the Affordable Care Act (ACA).
 - ii. Require EHR incentive payment recipients to comply with the Department of Health and Human Services' (HHS's) "Limited English Proficiency (LEP) Guidance" and work with the Office of Civil Rights (OCR) to determine the most effective ways to educate EHR incentive payment recipients and assist them in complying with these laws.
 - iii. Require EHR incentive payment recipients to provide sign language interpreters or other augmentative or auxiliary assistance to comply with Section 504 of the Rehabilitation Act.
 - iv. Require discharge instructions and EHR-enabled patient-specific educational materials to be provided in the common primary languages, in compliance with Title VI of the Civil Rights Act of 1964, Section 1557 of the ACA, and HHS LEP Guidance.
 - b. Privacy protections in meaningful use
 - i. Disqualify providers fined for willful neglect of the Health Information Portability and Accountability Act (HIPAA) privacy and security regulations from eligibility for EHR incentive payments.
- II. The incentive program should require robust demographic data collection and use.
 - a. Demographic data collection thresholds
 - i. Maintain 80 percent threshold for demographic data collection measure.
 - ii. Maintain requirements that each demographic data element must be recorded (unless declined by the patient/member) in order to fulfill the criteria.
 - b. Race/ethnicity standards
 - i. Require providers to use more granular race/ethnicity data collection standards than the current Office of Management and Budget (OMB) Standards (preferably, using standards based on the 2009 Institute of Medicine (IOM) recommendations; if not, using, at a minimum, the HHS/Office of Minority Health (OMH) survey standards).
 - c. Language standards
 - i. Adopt the 2009 IOM recommendations as to how to ask for language data.
 - ii. Adopt the International Organization for Standardization (IOS) data set to classify language data and develop and adopt any additional standards before Stage 2 implementation in 2014.
 - d. Guidance on best practices for soliciting race/ethnicity and language data

- i. Direct providers to use recommendations from the Health Research & Educational Trust (HRET) Disparities Toolkit to explain to patients and families why race/ethnicity and language data is being collected and state that the information is confidential.
 - ii. Direct providers to *not say* that providers are collecting the information because, “(1) government agencies require it, or (2) it was needed to gain information to help hire and train staff.”
 - e. Disability status data collection
 - i. Require the collection of disability status data using the American Community Survey (ACS) questions on disability.
 - ii. Collect self-reported diagnostic/impairment related information and information related to use of assistive technology to supplement the six ACS questions.
 - iii. Collect information about the physical and communication accommodations patients with disabilities require in health care settings.
 - f. Sexual orientation and gender identity data collection
 - i. Commit to inclusion of sexual orientation and gender identity data collection requirements in Stage 3, applicable across all facilities and providers, with appropriate privacy protections.
 - ii. In anticipation of sexual orientation and gender identity data inclusion in Stage 3, issue sub-regulatory guidance and work with Regional Extension Centers (RECs) to inform providers about best practices for soliciting these demographic data from patients. This guidance should eventually be incorporated into the Stage 3 requirements themselves.
 - iii. Include nondiscrimination protections in meaningful use requirements that cover sexual orientation and gender identity.
 - g. Use of demographic data
 - i. Require that providers stratify clinical quality measures by demographic data.
 - ii. Link the “generate lists of patients” criterion to the requirement to collect demographic data by requiring providers to stratify such lists by demographics.
 - iii. Require EHR incentive payment recipients to provide information to patients in a language that they understand once language needs are recorded.
- III. The incentive program should build linkages with existing health disparity strategies.
 - a. Alignment with the *HHS Action Plan to Reduce Racial and Ethnic Health Disparities*
 - i. Require the recording of patient indicators for cardiovascular disease and the provision of appropriate patient education, treatment, patient-reminders for follow-up (in the patient’s preferred language), etc.
 - ii. Leverage upcoming *HHS Health IT Plan to End Health Disparities* to serve as additional support for mobile technologies, EHRs, and other systems to prevent and eliminate disparities.
 - iii. Reference *Action Plan* action step on implementing targeted activities to reduce disparities in flu vaccination as support for requiring eligible professionals (EPs) to record whether patients have been inoculated against the flu and issue patient reminders for flu vaccinations.
 - b. Coordination with local health department reporting requirements
 - i. Encourage local departments of health to use granular demographic data, in alignment with the standards used by providers.

- ii. Specify that clinical decision support rules should be able to be customized to include rules applicable to local or national public health initiatives.
- c. Alignment with Early Periodic Screening, Diagnosis, and Treatment (EPSDT)
 - i. Require certified EHR systems to have the capability to identify children under age 21 who are enrolled in Medicaid and alert providers to age, developmental, and condition appropriate screenings and treatments that correspond to the EPSDT benefit.
 - ii. Require certified EHR systems to have the ability to capture information and coding for well-child visits, EPSDT screening and treatment, consultations, and relevant pediatric databases in a manner that is extractable for uniform reporting to the state Medicaid agency.
 - iii. Work with state Medicaid programs to ensure the existence of state-level infrastructure to support the receipt and use of EHR information about EPSDT from all participating providers.

I. Reinforcing federal civil rights and health information privacy laws

a. Federal civil rights laws and EHR incentive payments

We are very concerned by the language regarding federal civil rights laws in both the final rule for Stage 1 and the proposed rule for Stage 2. In both instances, as detailed below, the rules fail to acknowledge that EHR incentive payments constitute federal financial assistance and thus recipients of meaningful use funds are obligated to comply with Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act, the Americans with Disabilities Act (ADA), and Section 1557 of the Affordable Care Act (ACA), which prohibits discrimination on the bases of race, color, national origin, sex, age, and disability. In addition, incentive recipients are independently receiving federal funds as Medicare¹ and Medicaid providers and thus subject to Title VI, Section 504, ADA, and Section 1557.²

Specifically, we were greatly troubled – both as a matter of law and policy – that CMS included the following statement in its response to a comment in the Stage 1 meaningful use final rules:

“We do not have the authority under the HITECH Act to require providers to actually communicate with the patient in his or her preferred language, and thus do not require EPs, eligible hospitals, and CAHs to do so in order to qualify as a meaningful EHR user as suggested by some commenters.”³

¹ As a matter of policy, Medicare Part B providers who only receive federal funding through Medicare Part B are exempt from Title VI. However, because the EHR incentive payments are in addition to Medicare Part B funding and because of the application of ACA § 1557, we believe all Medicare providers must comply with Title VI.

² Section 1557 prohibits discrimination on the bases of race, color, national origin, sex, age and disability in “any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title.” The nondiscrimination protections in these statutes thus apply to any financial assistance provided by CMS through the EHR incentive payment program both because recipients are federal fund recipients *and* because the EHR incentive program is administered by a federal agency.

³ 75 Fed. Reg. at 44341 (July 28, 2010).

While the Health Information Technology for Economic and Clinical Health Act (HITECH Act) may not have specifically granted this authority, pre-existing federal civil rights laws governing the dissemination of federal financial assistance obligate incentive recipients to comply with civil rights requirements. The incentives themselves constitute federal financial assistance and thus recipients are subject to these federal civil rights laws that OCR enforces.

In the proposed rules for Stage 2, we were similarly troubled to see CMS state:

“However, providers should be aware that while meaningful use is limited to the capabilities of CEHRT to provide online access there may be patients who cannot access their EHRs electronically because of their disability. Additionally, other health information may not be accessible. Providers who are covered by civil rights laws must provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.”⁴

This is misleading. *All* providers covered by these rules are required to provide people with disabilities with access to medical records, since coverage by these rules is predicated upon receipt of federal funds and access to health records is mandated by Section 504 of the Rehabilitation Act, ADA, and/or Section 1557 of the ACA. Accordingly, information in the EHR should be compatible with screen readers and available in a preferred alternative format upon request at no additional cost to the patient. Alternative formats may include, but are not limited to Braille, large font, and electronic formats such as Digital Accessible Information System (DAISY), e-text (rich text format, American Standard Code for Information Interchange (ASCII)), audio files (MPEG Audio Layer III (MP3), Waveform Audio File Format (WAVE or WAV), Media Player). Similarly, all providers covered by these rules should ensure that LEP patients can receive information in non-English languages.

We believe CMS and ONC have an affirmative responsibility to educate EHR incentive recipients to comply with their obligations under Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act, ADA, and Section 1557 of the ACA and to specify that incentive payments do constitute federal financial assistance. CMS and ONC should rescind the statement quoted above in the Stage 1 final rule, amend the statement in the Stage 2 rules, and clarify recipients’ obligations under Title VI, Section 504, ADA and Section 1557.

Under Title VI of the Civil Rights Act of 1964,⁵ no federal funds can be used in a discriminatory manner, whether intentionally, or, pursuant to federal regulations, through disparate impact. Title VI applies to all programs receiving federal financial assistance, including private entities. Congress has defined covered programs to include “an entire corporation . . . if assistance is extended to such corporation . . . or which is principally engaged in the business of providing education, health care . . .”⁶ Discrimination under Title VI has been determined to include preventing meaningful access to federally funded services for “national origin minorities” with LEP (Title VI prohibits discrimination on the basis of national origin). In 1974, the Supreme Court concluded that programs with a discriminatory impact against individuals based on their language are akin to those which discriminate based on national origin.⁷ Since EHR incentive recipients are receiving federal funds for meaningfully using certified EHRs, they are subject to

⁴ 77 Fed. Reg. at 13719 and 13730 (March 7, 2012).

⁵ See 42 U.S.C. § 2000d (2006).

⁶ See 42 U.S.C. § 2000d-4a (2006).

⁷ See *Lau v. Nichols*, 414 U.S. 563 (1974).

Title VI. Further, under Executive Order 13166, CMS and ONC should require that its federal fund recipients comply with HHS' "LEP Guidance" issued by OCR and work with OCR to determine the most effective ways to educate EHR incentive payment recipients and assist them in complying with these laws.⁸

Moreover, Section 1557 of the ACA prohibits discrimination based on sex, which necessarily includes discrimination based on gender identity and on nonconformity with sex stereotypes. In recent years, courts and federal agencies have consistently followed this understanding of the law. For example, the U.S. Equal Employment Opportunity Commission (EEOC) recently concluded that discrimination based on gender identity or transgender status is a form of sex discrimination under Title VII.⁹ In 2010, the Department of Education published a "Dear Colleague" letter explaining that Title IX's prohibition based on sex discrimination protects LGBT students from harassment based on their actual or perceived nonconformance with gender stereotypes.¹⁰ In addition, the Department of Housing and Urban Development announced in 2010 that it would treat "gender identity discrimination most often faced by transgender persons as gender discrimination under the Fair Housing Act."¹¹ Accordingly, under Section 1557 incentive recipients must ensure that their records systems are able to track the provision of all appropriate care to transgender individuals, and recipients may not discriminate against or refuse to serve any person, including LGBT persons, because of their gender identity or nonconformity with sex stereotypes. The Department of Health and Human Services also recognized the importance of addressing discrimination against LGBT people in health care recently when it included explicit prohibitions against gender identity and sexual orientation discrimination in final rules for state health insurance exchanges and qualified health plans.¹²

Similarly, Section 504 of the Rehabilitation Act prevents discrimination against otherwise qualified people with disabilities under any program or activity that receives federal funds. Similar to Title VI, federal fund recipients may not discriminate against people with disabilities, including those who are deaf or hard of hearing or have other hearing impairments. As one example, incentive recipients must also provide sign language interpreters or other augmentative or auxiliary assistance to their patients to comply with Section 504.

Recommendations:

- i. Clearly state in final rules that because EHR incentive payments constitute federal financial assistance all recipients are obligated to comply with Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act, ADA, and Section 1557 of the ACA.**

⁸ See Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition against National Origin Discrimination Affecting Limited English Proficient Persons (HHS LEP Guidance), available at <http://www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf>.

⁹ *Macy v. Holder*, E.E.O.C. Appeal No. 0120120821 (Apr. 23, 2012).

¹⁰ United States Department of Education, "Dear Colleague," (October 26, 2010), available at http://www2.ed.gov/about/offices/list/ocr/letters/colleague-201010_pg8.html.

¹¹ Memorandum from John Trasviña to FHEO Regional Directors, Assessing Complaints that Involve Sexual Orientation, Gender Identity, and Gender Expression (June 2010); U.S. Department of Housing and Urban Development, Ending Housing Discrimination Against Lesbian, Gay, Bisexual and Transgender Individuals and Their Families, (n.d.), available at http://portal.hud.gov/hudportal/HUD?src=/program_offices/fair_housing_equal_opp/LGBT_Housing_Discriminatio

¹²

Codified at 45 C.F.R. § 155.120(c)(2) and 45 C.F.R. § 156.200(e).

- ii. **Require EHR incentive payment recipients to comply with the HHS’s “LEP Guidance” and work with OCR to determine the most effective ways to educate EHR incentive payment recipients and assist them in complying with these laws.**
- iii. **Require EHR incentive payment recipients to provide sign language interpreters or other augmentative or auxiliary assistance to comply with Section 504 of the Rehabilitation Act.**

Incorporating language access requirements into meaningful use objectives

We strongly support the expectation for Stage 3 that electronic discharge instructions must be provided in the common primary languages. Given the current application of Title VI of the Civil Rights Act of 1964 and Section 1557 of the ACA to EHR incentive payment recipients, we believe that the Stage 2 regulations should also require that discharge instructions be provided in the common primary languages. We believe the same applies to the provision of EHR-enabled patient-specific educational materials. We encourage CMS and ONC to include requirement in the final rules to provide discharge instructions and EHR-enabled patient-specific educational materials in the common primary languages, in compliance with Title VI, Section 1557, and HHS LEP Guidance.

Recommendation:

- iv. **Require discharge instructions and EHR-enabled patient-specific educational materials to be provided in the common primary languages, in compliance with Title VI of the Civil Rights Act of 1964, Section 1557 of the ACA, and HHS LEP Guidance.**

b. Privacy protections in meaningful use

For patients to support the use of health IT, it is critical that their personal health information be protected. While the Stage 1 final rules and the proposed rules include some privacy protections, we are concerned that they do not go far enough to ensure that providers are using appropriate safeguards. We are further concerned by the apparent rationale for this treatment of privacy in the proposed rules indicated by CMS’ statement in the Stage 1 final rule that: “we do not see meaningful use as an appropriate regulatory tool to impose different, additional, and/or inconsistent privacy and security policy requirements from those policies already required by HIPAA.” (75 Fed. Reg. at 44369 (July 28, 2010).

We believe the EHR incentive program can and should be used as a tool to reinforce the protections provided under HIPAA. For instance, CMS should make compliance with state and federal privacy and security laws a meaningful use requirement. CMS should disqualify providers fined for willful neglect of HIPAA privacy and security regulations from eligibility for the EHR incentive payments.

Recommendation:

- i. **Disqualify providers fined for willful neglect of the HIPAA privacy and security regulations from eligibility for EHR incentive payments.**

II. Requiring robust demographic data collection and use

Demographic data collection is foundational to advancing health equity and we applaud CMS and ONC for taking preliminary steps to advance demographic data collection in Stage 1 and in the proposed criteria for Stage 2 of meaningful use. In particular, we support the use of high thresholds for this criteria and the contemplated expansion of the criteria to include demographic categories beyond race, ethnicity,

language, and gender (i.e. biological sex). At the same time, we believe providers must be required to collect more granular data than currently proposed and must be required to use these data to identify and address disparities.

a. Demographic data collection thresholds

In Stage 1 of meaningful use, providers (EPs, eligible hospitals, and critical access hospitals (CAHs)) must record demographic information for 50 percent of unique patients. In Stage 2, CMS proposes increasing this threshold to 80 percent of unique patients. We endorse this increase. We have heard, anecdotally, from many providers that a minimum threshold for reporting demographic data is helpful in constructing goals for data collection. Further, the higher threshold will allow for meaningful comparisons between patients, with reduced concern for sample bias. We encourage CMS to maintain the 80 percent threshold in the final rule.

We also strongly support the specification that the numerator represents “the number of patients in the denominator who have *all* the elements of demographics (or a specific notation if the patient declined to provide one or more elements or if recording an element is contrary to state law) recorded as structured data” (emphasis added). It is imperative that the requirement not be limited to only one demographic data element, but that all elements be recorded (unless declined by the patient/member) to fulfill the requirement. We also support the specification that patients must be able to decline to provide one or more elements.

Recommendations:

- i. Maintain 80 percent threshold for demographic data collection measure.**
- ii. Maintain requirements that each demographic data element must be recorded (unless declined by the patient/member) in order to fulfill the requirement.**

b. Race/ethnicity standards

In both the final rules for Stage 1 and the proposed rules for Stage 2, providers must, at a minimum, collect race/ethnicity data based on the 1997 Revised OMB Standards. Although we support the standard collection of race/ethnicity data, we believe strongly that the use of OMB standards moves us backward in being able to meaningfully identify groups with relevant disparities in care and outcomes and, therefore, urge CMS and ONC to use standards that collect more granular data.

There are five categories for race in current OMB Standards – American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White; and two categories for ethnicity – “Hispanic or Latino” and “Not Hispanic or Latino.” For culturally and linguistically diverse groups, such as Asian American subgroups, Native Hawaiians, and Pacific Islanders, and American Indians/Alaskan Natives, data collected using these standards have often been inadequate to identify salient health issues and inform appropriate policy or other interventions. Notably, IOM stated the following with regard to the OMB standards on race/ethnicity in the brief to the 2009 report *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement*:

“While analyses based on these categories can reveal important disparities in care, they are not always sufficiently descriptive to target interventions most effectively. More discrete population data are needed to identify opportunities for quality improvement and outreach without inefficiently targeting interventions to an entire broad race or Hispanic ethnicity category. The

OMB categories do not, for example, capture whether a Hispanic child has a Mexican or Cuban background, or whether an Asian adult is of Japanese or Vietnamese ancestry. These more granular ethnicity distinctions have revealed differentials in utilization of health care services and outcomes (for example, cancer or hypertension-related mortality) that were hidden by only using the OMB categories.”¹³

Meaningful use should enable providers to identify critical health and health care disparities that are masked under the OMB standards. Specifically, we believe CMS and ONC should adopt the recommendations from the 2009 IOM report for the standardized collection of more granular race/ethnicity data. To implement these recommendations, CMS and ONC should develop and make available nationally standardized lists for granular ethnicity categories – developing technical standards using the Centers for Disease Control and Prevention (CDC) code sets for race and ethnicity¹⁴ – and proposed strategies for aggregating granular ethnicity categories to the broader OMB race and Hispanic ethnicity categories. We believe the extra year provided by CMS before Stage 2 of this rule commences will provide sufficient time to develop these standards and to get input from relevant stakeholders on which elements to revise in the standards.

If CMS and ONC choose not to adopt the IOM recommendations for Stage 2, they must, at a bare minimum, require providers to use the HHS/OMH survey standards,¹⁵ released in October 2011, for race/ethnicity rather than the OMB standards. While the HHS/OMH standards are not as robust as may be necessary for local markets to define specific disparities and target appropriate interventions, they capture more granular data regarding Hispanic, Asian, and Native Hawaiian/Pacific Islander populations than the OMB standards and will at least facilitate alignment with national survey data to analyze trends in care. We are concerned that using any standards less robust than the newly-adopted HHS/OMH standards would undermine HHS’s effort to improve the quality and effectiveness of demographic data collection in federal health programs and activities, as called for by Section 4302 of the ACA.

Recommendations:

- i. Require providers to use more granular race/ethnicity data collection standards than the current OMB Standards (preferably, using standards based on the 2009 IOM recommendations; if not, using, at a minimum, the HHS/OMH survey standards).**

c. Language standards

We believe the collection and analysis of language data as part of meaningful use is critical to ensure that providers have information about their patients to plan and provide needed language services and can ensure that the services provided to LEP patients are not disparate from those provided English-speaking patients. The communication between patient and provider and the prevention of discrimination is

¹³ Institute of Medicine, *Report Brief: Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement*, (August 2009), available at <http://www.iom.edu/~media/Files/Report%20Files/2009/RaceEthnicityData/Race%20Ethnicity%20report%20brief%20FINAL%20for%20web.pdf>.

¹⁴ Available at <http://phinvads.cdc.gov/vads/ViewValueSet.action?id=66D34BBC-617F-DD11-B38D-00188B398520#>.

¹⁵ Available at <http://minorityhealth.hhs.gov/templates/content.aspx?ID=9227&lvl=2&lvlID=208>.

essential to ensuring that LEP individuals can benefit from access to health care services as equally as English-speaking individuals.

We applaud CMS and ONC for recognizing the importance of language access by requiring collection of language data as a component of meaningful use. However, it is equally important that CMS and ONC outline explicit requirements rather than broad generalities going forward to continue to increase the collection and use of these data by EHR users. We urge CMS and ONC to adopt the 2009 IOM recommendations as to how to ask for language data.

The IOM report prioritizes spoken language need for individuals with LEP. Specifically, the report proposes two questions to assess spoken language need: one assessing the respondent's ability to speak English, and the second to determine the spoken language preferred in a health care setting using a list of locally relevant response categories from a national standard list, which should include sign language. In addition, an open-ended option of "Other, please specify: ___" should be provided to capture spoken languages not listed as a response option.

While there is evidence that supports a high correlation between English-language proficiency in speaking, reading, and writing ability, differences in education level and health literacy can have an impact on an individual's reading comprehension. As such, the final rules for Stage 2 should support the recommendations of the IOM and also encourage the collection and reporting of written language preference, including Braille. It is also critical that the final rules specify that language data be self-reported. Providers must not attempt to identify a patient's language needs as that could result in the recording of mistaken or wrong information. Further, it is important that these data be updated, at least yearly, since language proficiency can advance.

The IOM report did not provide a code set to classify language data. We recommend a two-step process. As a first step, ONC should adopt and utilize the code set for collecting language data from ISO, as included in the proposed rule on certification standards. However, since the ISO data set is limited, we also recommend that ONC evaluate the need to add additional codes/categories and adopt any needed additional standards before implementation in 2014. We believe the extra year provided by CMS before Stage 2 commences will provide sufficient time to develop these standards and to get input from relevant stakeholders on which elements to revise in the standards.

Recommendations

- i. Adopt the 2009 IOM recommendations as to how to ask for language data.**
- ii. Adopt the IOS data set to classify language data and develop and adopt any additional standards before Stage 2 implementation in 2014.**

d. Guidance on best practices for soliciting race/ethnicity and language data

We recommend that CMS direct providers to utilize recommendations from the HRET Disparities Toolkit to explain why race/ethnicity and language data are being collected. HRET undertook a multi-year process to research, field test and identify the most effective ways to collect race, ethnicity and language data from patients. The recommended rationale is: "We want to make sure that all our patients get the best care possible. We would like you to tell us your racial/ethnic background so that we can review the treatment that all patients receive and make sure that everyone gets the highest quality of care."¹⁶

¹⁶See <http://www.hretdisparities.org/Howt-4176.php>.

In addition, it is important to state that the information is confidential. HRET's suggested languages states: "The only people who see this information are registration staff, administrators, and the people involved in quality improvement and oversight, and the confidentiality of what you say is protected by law." The importance of patients understanding the reason and benefits for collecting these data cannot be underestimated. Patients who understand are more willing to comply with the request. This will be a "win-win" for EHR incentive recipients and patients, as it will be easier for EHR incentive recipients to meet the 80 percent requirement and patients will benefit from providers having these data so they can effectively plan for needed language services.

Providers should also be explicitly directed to *not* say that providers are collecting the information because, "(1) government agencies require it, or (2) it was needed to gain information to help hire and train staff." These statements have shown less successful at improving patients' comfort level, particularly for nonwhites.¹⁷

Recommendations:

- i. Direct providers to use recommendations from the HRET Disparities Toolkit to explain to patients and families why race/ethnicity and language data is being collected and state that the information is confidential.**
- ii. Direct providers to *not* say that providers are collecting the information because, "(1) government agencies require it, or (2) it was needed to gain information to help hire and train staff."**

e. Disability status data collection

The proposed rules solicit comments on requiring providers to solicit and record disability status for patients. The ACA laid the foundation by acknowledging disability status as a bona fide demographic characteristic and mandating the collection of data on "disability status for applicants, recipients, or participants" by "any federally conducted or supported health care or public health program, activity or survey" under Section 4302. We therefore strongly support recording disability status as a component of the demographic data collection requirements.

The six disability status questions contained in the ACS should be a starting point for data collection about people with disabilities, since these questions have been widely tested and are in use in multiple government surveys. The ACS questions were also adopted as the initial standard for disability status in the HHS/OMH survey standards. However, the ACS questions collect only a portion of the demographic data required to fully represent the disability status and related needs of people with disabilities.

The ACS questions do not adequately measure some populations of people with disabilities and some significant traits that define disability for certain individuals. The meaningful use data collection requirements provide a window through which one can collect detailed data regarding the quality of care of individuals and populations of people with disabilities. The following additional questions will help capture individuals with disabilities who may otherwise not be recognized by the six ACS questions, and formalizes the collection of information that is necessary in any good patient history so that quality care

¹⁷ Baker et al. "Patients' attitudes toward health care providers collecting information about their race and ethnicity" *J Gen intern Med.* (2005), available at <http://www.ncbi.nlm.nih.gov/pubmed/16191134>.

can be provided in a manner that meets the functional needs of individual patients with disabilities and populations of people with disabilities:

1. “Do you have a primary diagnosis that relates to a physical, mental, emotional, learning, developmental, or other limitation or impairment that is not captured in the above six questions?” (For example, learning disability, autism, bipolar disorder, intellectual disability). Y/N
 - a. “If yes, please specify.”
2. “Do you use any type of assistive technology such as a wheelchair, crutches, hearing aids, electronic or manual communication device?” Y/N
 - a. “If yes, what device(s) do you use?”
3. “Do you require any physical accommodations such as transfer assistance, assistance positioning, and/or accessible examination equipment such as an exam table or weight scale?” Y/N
 - a. “If yes, what accommodations do you require?”
4. “Do you require assistance or accommodation to communicate?” Y/N
 - a. “If yes, what assistance or accommodation do you require (e.g., ASL interpreter, print materials in accessible formats such as large font or digital format, assistive listening device, additional time)?”

Information should be self-reported by the person with the disability. The person with the disability may choose to use the communication assistance of an accompanying guardian, personal assistant, family member, or friend. If the person with the disability is unable to self-report, a guardian, personal assistant, family member, or friend with appropriate knowledge may provide the information. In addition, as with other demographic data, patients must be able to decline to provide this information.

Collection of this data should be considered a part of the demographic data collection criterion. Doing so does not represent an additional burden to health care providers and health care institutions (i.e. hospitals, clinics, etc.), because they cannot provide appropriate care and services without it. Moreover, because the information is so critical to effective patient care it should be collected as soon as possible and in conjunction with the overall effort to collect disability status data on people with disabilities.

Recommendations:

- i. Require the collection of disability status data using the ACS questions on disability.**
- ii. Collect self-reported diagnostic/impairment related information and information related to use of assistive technology to supplement the six ACS questions.**
- iii. Collect information about the physical and communication accommodations patients with disabilities require in healthcare settings.**

f. Sexual orientation/gender identity data collection

We appreciate the request from CMS and ONC for comments on whether the recording of gender identity and/or sexual orientation should be included within the Stage 2 criteria. Specifically, CMS and ONC encouraged commenters to identify the benefits of including gender identity and sexual orientation electronic data collection and their applicability across providers.¹⁸

Collecting confidential gender identity and sexual orientation data is crucial to improving the quality and efficiency of the health care lesbian, gay, bisexual, and transgender (LGBT) people receive, and to

¹⁸ 77 Fed. Reg. 13698, 13712 (March 7, 2012).

addressing the significant health disparities that the LGBT population experiences. We strongly urge CMS and ONC to begin planning for the collection of gender identity and sexual orientation data as part of the demographic data required for meaningful use. As explained below, we believe these data should be required at Stage 3 of meaningful use and that CMS and ONC should begin laying the groundwork for their inclusion immediately.

Identifying and understanding LGBT health disparities

A growing body of knowledge demonstrates that the LGBT population faces significant health disparities and barriers to accessing health care coverage and services. According to the federal government's *Healthy People 2020* and two reports from IOM, LGBT people face higher health risks than the general population, and many of these risks are due to the stress of discrimination and unequal treatment.¹⁹ For instance, *Healthy People 2020* reports that lesbian and bisexual women are more likely to be overweight or obese, and gay men are at higher risk of human immunodeficiency virus (HIV) and other sexually transmitted diseases (STDs). Transgender people experience high rates of HIV/STDs, violence, and mental health concerns, and they are less likely to have health insurance than other people. HHS is working to address LGBT health disparities through initiatives that include establishing a nationally representative baseline for LGBT population health by improving survey research on the LGBT population.²⁰

However, in its 2011 report, *The Health of Lesbian, Gay, Bisexual, and Transgender People*, IOM found that LGBT health disparities remain poorly understood and made several recommendations related to improving data collection, with the goal of continuing to build a knowledge base that allows LGBT health disparities to be effectively identified, tracked, and addressed.²¹ Notably, recommendation #3 from the IOM states, "Data on sexual orientation and gender identity should be collected in electronic health records."²² The recommendation indicates that CMS and ONC should include the collection of these data in its meaningful use objectives for EHRs.

Benefits of including gender identity and sexual orientation in meaningful use objectives

Requiring data collection on gender identity and sexual orientation as part of meaningful use objectives will improve the quality and efficiency of LGBT patient care, leading to improved population-level health outcomes. Providers who collect these data will be better able to record accurate health histories and identify the specific health needs of LGBT patients. Patient-level quality and efficiency improvements will include recognizing patient representatives who are same-sex partners, providing the full scope of appropriate care for transgender people, and documenting comprehensive sexual and reproductive health histories.

Additionally, population-wide data on transgender health is essential to the development of rigorous scientific research that can help further advance the development of treatment protocols such as the

¹⁹ U.S. Department of Health and Human Services, *Healthy People 2020: Lesbian, Gay, Bisexual, and Transgender Health* (2010).

²⁰ U.S. Department of Health and Human Services, "LGBT Data Progression Plan" (2011), available at <http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlid=209>.

²¹ Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011).

²² *Id.* at 302-03.

Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People maintained by the World Professional Association for Transgender Health and the *Primary Care Protocol for Transgender Patient Care* from the Center of Excellence for Transgender Health at the University of California at San Francisco.²³ These improvements will help physicians and facilities provide higher quality and more cost-effective care, eventually contributing to improved population-wide health outcomes.

Requiring gender identity and sexual orientation data collection as a component of meaningful use will also provide a tool to track health disparities among the LGBT population. This information is critical to the creation of effective federal, state, and local health policies to combat these disparities. For example, for LGBT populations to be eligible for critical federal protections and services allocated to underserved or vulnerable groups, policymakers must be able to cite to a broad evidence base regarding the health and access disparities that affect the LGBT population. Collecting gender identity and sexual orientation data in EHRs will contribute to the continued building of that evidence base.

Finally, including gender identity and sexual orientation in meaningful use objectives will facilitate the evaluation of LGBT-inclusive nondiscrimination protections and cultural competency trainings on patient outcomes and satisfaction. Many facilities have such protections and trainings already in place, and the Joint Commission requires all facilities it accredits to abide by nondiscrimination standards that include sexual orientation and gender identity.²⁴

Recommendation for gender identity and sexual orientation data collection requirements in Stage 3

To facilitate implementation of IOM's 2011 recommendation that data on sexual orientation and gender identity be collected in EHRs, a number of stakeholders are working with IOM to hold a one-day workshop in June 2012 that will bring together a diverse group of experts and stakeholders to discuss current and future trends in this field.

Many health care facilities around the country, including hospitals, community health centers, and managed care organizations, are already recognizing LGBT individuals in their patient populations and implementing efforts to collect and safeguard important sexual orientation and gender identity data in their patient records systems. This workshop will offer facilities and providers across the country an opportunity to share the expertise they have developed about how to collect data on gender identity and sexual orientation in clinic settings.

While the workshop summary will not be finalized in time to contribute to the comment process for Stage 2, its findings will be disseminated to the Policy and Standards Committees at ONC as they undertake the development of Stage 3 meaningful use standards. These findings will also help develop concrete

²³ See J. Feldman, "Preventive Care of the Transgendered Patient: An Evidence-Based Approach," in *Principles of Transgender Medicine and Surgery* 33, 38 (R. Ettner, S. Monstrey, E. Eyler, eds, 2007); World Professional Association for Transgender Health, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* (2011), available at http://www.wpath.org/documents/Standards%20of%20Care_FullBook_1g-1.pdf; University of California, San Francisco, Center of Excellence for Transgender Health, *Primary Care Protocol for Transgender Patient Care* (2011), available at <http://transhealth.ucsf.edu/trans?page=protocol-00-00>.

²⁴ The Joint Commission, *Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the LGBT Community: A Field Guide* (2011), available at <http://www.jointcommission.org/assets/1/18/LGBTFieldGuide.pdf>.

recommendations for the collection of gender identity and sexual orientation data in EHRs, explore the applicability of these data across providers, and develop mechanisms to support providers and patients in the collection of these data. Therefore, we recommend that CMS and ONC commit to inclusion of sexual orientation and gender identity data collection in Stage 3.

Applicability across providers

Including gender identity and sexual orientation in the Stage 3 meaningful use objectives will help improve coordination of patient care across facilities and providers, including EPs, eligible hospitals, and CAHs. No other demographic requirements are limited or proposed to be limited by provider except the “date and preliminary cause of death in the event of mortality in the eligible hospital or CAH,” which are only proposed to be required by eligible hospitals and CAHs, but not EPs.²⁵ Sexual orientation and gender identity, like other demographics such as preferred language, gender, race/ethnicity, and age, are associated with particular health disparities and socially-determined risk factors. Including this information in EHRs, with appropriate privacy protections similar to those developed for other demographic data, will help improve individual care and generate more comprehensive national population-level data on the health of LGBT people.

Recommendation:

- i. Commit to inclusion of sexual orientation and gender identity data collection in Stage 3, applicable across all facilities and providers, with appropriate privacy protections.**

Best practices for soliciting demographic data

IOM, in its 2011 report on LGBT health, noted that the collection of meaningful data on gender identity and sexual orientation requires consideration of “possible discomfort on the part of health care workers with asking questions about sexual orientation and gender identity, a lack of knowledge by providers of how to elicit this information, and some hesitancy on the part of patients to disclose this information.”²⁶ Once steps to include gender identity and sexual orientation data collection in Stage 3 have begun, CMS should draw on the findings of the June 2012 IOM workshop report to issue sub-regulatory guidance and work with RECs to inform providers about best practices for soliciting these demographic data from patients. This guidance should eventually be incorporated into the Stage 3 requirements themselves. These steps will help ensure that the data are collected accurately, consistently, and respectfully.

Recommendation:

- ii. In anticipation of sexual orientation and gender identity data inclusion in Stage 3, issue sub-regulatory guidance and work with RECs to inform providers about best practices for soliciting these demographic data from patients. This guidance should be eventually be incorporated into the Stage 3 requirements themselves.**

Prohibiting discrimination on the basis of sexual orientation and gender identity

We urge CMS to follow the example of accrediting bodies such as the Joint Commission by including nondiscrimination protections in meaningful use requirements that cover sexual orientation and gender

²⁵77 Fed. Reg. 13698, 13711 (March 7, 2012).

²⁶Institute of Medicine, *supra* note 18, at 9, 303.

identity.²⁷ Such protections will help ensure that health care providers do not use information kept in EHRs to discriminate against LGBT people by refusing to provide certain services, for example, or by providing substandard care.

Recommendation:

- iii. Include nondiscrimination protections in meaningful use requirements that cover sexual orientation and gender identity.**

g. Use of demographic data

Demographic data are of limited value if they are not used to address differences in care quality. If demographic data are collected without a clear purpose, mistrust among patients and lack of buy-in on the part of providers may result. Therefore, we strongly urge CMS to require that demographic data be used to improve care for all populations and to reduce health disparities in a direct way.

Clinical quality measures

CMS should require that providers stratify clinical quality measures by demographic data. Monitoring quality metrics by demographic variables will reveal specific disparities in care among provider's patient populations and help providers create strategies to reduce and eliminate such disparities. In ambulatory settings, the use of National Quality Forum (NQF)-endorsed "disparities-sensitive" measures should be recorded and stratified, at a minimum. NQF has also expanded its work on disparities from ambulatory care measures with a project developing Healthcare Disparities and Cultural Competency Consensus Standards. The standards are currently undergoing public comment and should be finalized later this year. CMS should work to implement these standards upon NQF endorsement.

Recommendations:

- i. Require that providers stratify clinical quality measures by demographic data.**

Generating lists of patients

CMS should link the "generate lists of patients" criterion to the requirement to collect demographic data. These lists of patients could be stratified by demographics in order to quantify the prevalence of certain diagnoses in sub-populations of a specific patient population. These lists could be made even more useful by then comparing sub-populations on quality metrics, which would help identify the contributors to disparities in care in a particular practice, which in turn would enable the practice to devise strategies for eliminating the identified disparities. Eventually, CMS should aim to be able to report lists by multiple demographic variables (for example, differences between Spanish-speaking Hispanics vs. English-speaking Hispanics or women with and without disabilities) to better understand and address health disparities.

Recommendation:

- ii. Link the "generate lists of patients" criterion to the requirement to collect demographic data by requiring providers to stratify such lists by demographics.**

²⁷ The Joint Commission, *supra* note 21.

Providing language access

Collection of language data will have a dual purpose – allowing an analysis to identify any disparities and prevent discrimination, as discussed above, as well as service planning so that language services are in place for LEP patients. Almost 20 percent of the population speaks a language other than English at home. More than 24 million, or 8.7 percent of the population, speak English less than very well and should be considered LEP for health care purposes.²⁸ Numerous studies have documented the problems associated with a lack of language services, including one by the Institute of Medicine, which stated that:

“Language barriers may affect the delivery of adequate care through poor exchange of information, loss of important cultural information, misunderstanding of physician instruction, poor shared decision-making, or ethical compromises (e.g. difficulty obtaining informed consent). Linguistic difficulties may also result in decreased adherence with medication regimes, poor appointment attendance, and decreased satisfaction with services.” (Cites omitted.)²⁹

We believe the collection and analysis of language data as part of meaningful use is critical to ensure that providers have information about their patients to plan and provide needed language services and can ensure that the health care services provided to LEP patients are not disparate from those provided English-speaking patients. The communication between patient and provider and the prevention of discrimination is essential to ensuring that LEP individuals can benefit from access to healthcare services as meaningfully as English-speaking individuals.

Thus, we believe that once language needs are recorded, EHR incentive recipients must provide information to patients in a language that they understand. For example, patient reminders must be provided in the patient’s language when a language is noted. Again, this is a critical piece to ensure that we move beyond mere data collection to a meaningful use of this data that will ensure LEP patients have access to care and providers can meet the needs of LEP patients. It will also ensure these providers comply with existing civil rights laws as discussed above.

Recommendation:

- iii. Require EHR incentive payment recipients to provide information to patients in a language that they understand once language needs are recorded.**

III. Building linkages with existing health disparity strategies

The EHR incentive program should be seen as an additional opportunity to improve the health of the public, particularly those communities experiencing health disparities. Appropriate health care seeks to provide quality services to individuals throughout their life-spans, in order to prevent and treat illnesses, address disabilities, and to improve the physical and mental well-being of all individuals. Unfortunately, this care can be delivered in a way that contributes to health disparities by ignoring the preferences of the

²⁸ American Community Survey, 2006-2008, *Selected Social Characteristics in the United States: 2006-2008*; also American Community Survey, 2008, *Language Spoken at Home by Ability to Speak English for the Population 5 Years and Over*, Table B16001, available at <http://factfinder.census.gov>.

²⁹ Institute of Medicine, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health*, at 17 (2002).

patient, not addressing barriers in access, allowing provider biases, and ignoring barriers in provider and patient communication.³⁰

Accordingly, HHS has been a key partner in the nation's efforts to identify health disparities impacting local communities and propose solutions to improve the public's health. As part of this objective, meaningful use can be used to help promote national and local health disparity prevention strategies and public health initiatives. Moreover, for EPs who qualify for the Medicaid incentive payments, the proposed rules could also serve as a mechanism to assist providers in ensuring that children enrolled in Medicaid receive required timely services in the Early and Periodic Screening, Diagnosis and Treatment Services (EPSDT) program.³¹

a. Alignment with the *HHS Action Plan to Reduce Racial and Ethnic Health Disparities*

In 2011, HHS released an action plan to address health disparities impacting underserved communities. The *HHS Action Plan to Reduce Racial and Ethnic Health Disparities (Action Plan)* provides specific goals and strategies that HHS will pursue to reduce or eliminate disparities.³² The *Action Plan* includes integrated approaches, best practices, and evidence-based programs. One objective of the plan is to reduce disparities in the quality of care. In this objective, HHS has created an initiative to develop, implement, and evaluate interventions that range from quality of care improvement opportunities to potential reimbursement incentives for policy and health system changes. The final rules for Stage 2 should reflect this initiative by requiring the recording of patient indicators for cardiovascular disease and providing appropriate patient education, treatment, patient-reminders for follow-up (in the patient's preferred language), etc.

The *Action Plan* also includes an action step to improve outreach for and adoption of EHR technology to improve care through the REC program and other federal grant programs. The action step also refers to an upcoming *HHS Health Information Technology (HIT) Plan to End Health Disparities (HHS Health IT Plan)*, which will include best practices to improve care provided in underserved communities through technologies and such as telehealth, EHRs, personal health records (PHRs), and other clinical tools. The *HHS Health IT Plan* will also promote interagency collaborations (including ONC, CMS, OMH, the Office of the Assistant Secretary for Health, Health Resources and Services Administration (HRSA), and the National Institutes of Health). Although the *HHS Health IT Plan* has not been released to date, we anticipate that it could serve as additional support for mobile technologies, EHRs, and other systems to prevent and eliminate disparities.

In addition, the *Action Plan* contains a strategy to reduce disparities in population health by increasing the availability and effectiveness of community-based programs and policies. For example, HHS has created an action step to implement targeted activities to reduce disparities in flu vaccination. The initiative requires improving vaccination rates in racial and ethnic minority communities, by working with medical associations, pharmacies, and state and local health departments to increase the availability of flu vaccine

³⁰ U.S. Department of Health and Human Services, Agency for Health Care Research and Quality, 2010 *National Health Care Disparities Report* (March 2011), available at <http://www.ahrq.gov/qual/nhdr10/nhdr10.pdf>.

³¹ 42 U.S.C. §§ 1396a (a) (10)(A), 1396a (a) (43), 1396d (a) (4) (B), 1396d(r) (as added and amended by Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, §6403, 103 Stat 2106, 2262-64).

³² See generally U.S. Department of Health and Human Services, *HHS Action Plan to Reduce Racial and Ethnic Health Disparities*, available at http://minorityhealth.hhs.gov/npa/files/Plans/HHS/HHS_Plan_complete.pdf.

and communicate a common set of messages about the seriousness of flu and the safety of the vaccine. The Stage 2 criteria should reference this step as support for requiring EPs to record whether patients have been inoculated against the flu (particularly if they are elderly, and/or have chronic health conditions), and issue patient reminders for flu vaccinations.

Recommendations:

- i. Require the recording of patient indicators for cardiovascular disease and the provision of appropriate patient education, treatment, patient-reminders for follow-up (in the patient’s preferred language), etc.**
- ii. Leverage upcoming *HHS Health IT Plan to End Health Disparities* to serve as additional support for mobile technologies, EHRs, and other systems to prevent and eliminate disparities.**
- iii. Reference *Action Plan* action step on implementing targeted activities to reduce disparities in flu vaccination as support for requiring EPs to record whether patients have been inoculated against the flu and issue patient reminders for flu vaccinations.**

b. Coordination with local health department reporting requirements

Surveillance of existing disease and serious threats to the public’s health are the primary reason for the use of data collection among public health authorities. These efforts are important to prevent mortality, measure health trends, demonstrate the need for public health intervention programs and resources, monitor the effectiveness of prevention measures, identify high-risk groups, and develop studies about risk factors for disease causation or progression.³³

National, state, and local public health officials have different objectives for the collection of data. Local public health authorities are usually concerned with preventing and responding to immediate outbreaks of illnesses to prevent the spread of disease. State public health officials are typically focused on using studies to identify neighborhoods and counties that should be targeted for screenings and intervention. National authorities tend to focus on whether national health intervention strategies are effective and altering recommendations for treatment and screenings when appropriate.³⁴ The Stage 2 final rules should encourage local departments of health to use more granular demographic data in alignment with the standards used by providers.

The final rules should also enable providers to align their clinical assessments of patients (and corresponding treatment) with local public health and health initiatives that address health disparities. These initiatives and programs should include prevention and screening services for women’s health. For instance, the Public Health Advisory Committee to the California Department of Public Health recommended several health priority areas for the state in *Healthy California 2020*.³⁵ These priority areas included oral health, access to health care, mental health, and tobacco use/substance abuse. Similarly, Los Angeles County has been an active member of the Partnership to Eliminate Disparities in Infant

³³ Rebecca Meriweather, M.D., Office of Public Health, Louisiana Department of Health and Hospitals, New Orleans, LA, *Blueprint for a Public Health Surveillance System for the 21st Century*, available at <http://www.cste.org/pdffiles/Blueprint.pdf>.

³⁴ *Id.*

³⁵ Public Health Advisory Committee, California Department of Public Health, *Healthy California 2020* (Apr. 30, 2011), available at <http://cdph.ca.gov/services/boards/phac/Documents/PHAC-HP2020-Report-revision-one-3-4-11.pdf>.

Mortality Action Learning Collaborative.³⁶ The Collaborative focuses on eliminating racial inequities that contribute to infant mortality in urban areas of Los Angeles County. To support these initiatives through meaningful use, CMS and ONC should specify that clinical decision support rules should be able to be customized to include rules applicable to local or national public health initiatives.

Recommendations:

- i. Encourage local departments of health to use granular demographic data, in alignment with the standards used by providers.**
- ii. Specify that clinical decision support rules should be able to be customized to include rules applicable to local or national public health initiatives.**

c. Alignment with Early Periodic Screening, Diagnosis, and Treatment (EPSDT)

Low-income children are likely to have more exposure to factors that negatively impact their health status. Some of these factors include: greater exposure to environmental hazards, poor nutrition, fewer educational opportunities, and inadequate housing. Children living in poverty, especially children of color, are more likely than other children to experience ill health, including vision, hearing and speech problems, dental problems, elevated lead blood levels, behavioral problems, anemia, asthma, and pneumonia.³⁷

To address these health issues, early detection and comprehensive treatment and health education became the cornerstones of EPSDT that was added to the Medicaid Act in 1967. EPSDT entitles children and youth under age 21 to preventive care and treatment services. Medicaid extended coverage to more than one in four children in 2008 (27 percent) in the U.S. and more than half (51 percent) of children who lived in families whose incomes are below the federal poverty level.³⁸ As a result, EPSDT has the potential to significantly improve the health status of children if it is appropriately utilized.

EPSDT screening services

EPSDT covers four separate screening services: medical, vision, hearing, and dental. The medical screen must include at least these five components: a comprehensive health and developmental history; a comprehensive unclothed physical exam; immunizations (as determined by the Advisory Committee on Immunization Practices); laboratory testing when appropriate, including lead tests (required at 12 and 24 months of age and up to 72 months of age if there is no record of a previous test), and health education and anticipatory guidance.³⁹

³⁶ Los Angeles County, Partnership to Eliminate Disparities in Infant Mortality Action Learning Collaborative, *What is the Partnership to Eliminate Disparities in Infant Mortality Action Learning Collaborative?*, available at <http://www.publichealth.lacounty.gov/mch/reproductivehealth/pedim%20alc%20website.pdf>.

³⁷ Jane Perkins, National Health Law Program, *Medicaid Early and Periodic Screening, Diagnostic, and Treatment Fact-sheet* (Oct. 2008), available at <http://www.healthlaw.org/images/stories/epsdt/3-ESDPT08.pdf> [hereafter cited as Perkins, *Medicaid EPSDT*].

³⁸ *Id.* (citing See Kaiser Family Foundation, *Quick Takes-Medicaid/SCHIP*, available at <http://facts.kff.org/?CFID=34872150&CFTOKEN=20197859>).

³⁹ See Centers for Medicare & Medicaid Services, U.S. Dep't of Health & Human Services, *State Medicaid Manual* § 2700.4. Note: All five elements of the screen must occur if the examination is to be reported by the state on the Form CMS-416 as an EPSDT medical screen.

In addition, medical screens must be provided according to a “periodicity schedule.” The state establishes the periodicity schedule after consultation with recognized child health care medical organizations. Congress and CMS have suggested the periodicity schedule of the American Academy of Pediatrics (AAP).⁴⁰ However, a recommended periodicity schedule is HRSA’s Bright Futures, which emphasizes the prevention and health promotion needs of infants, children, and adolescents.⁴¹

States are also responsible for providing for periodic vision, hearing, and dental examinations, as well as diagnosis and treatment for vision, hearing, and dental problems. Vision services must include vision screens and diagnosis and treatment of vision defects, including eyeglasses.⁴² Dental services must include dental screens, relief of pain and infections, restoration of teeth, and maintenance of dental health.⁴³ Moreover, vision, hearing, and dental services must be provided according to their own separate periodicity schedules. The periodicity schedule for each type of screen must be determined by the state after consultation with recognized medical and dental organizations involved in child health care. An oral screening as part of a physical examination does not substitute for examination by a dental professional.⁴⁴

EPSDT also covers needed visits to health providers outside of the periodicity schedule to determine if a child has a condition that requires additional care. These visits are “interperiodic screens.”⁴⁵ Non-health providers (such as a parent or a teacher) can identify if there is a need for an interperiodic screen. In addition, “any encounter with a health care professional acting within the scope of practice is considered to be an interperiodic screen, whether or not the provider is participating in the Medicaid program at the time those screening services are furnished.”⁴⁶ In turn, this interperiodic visit qualifies a child for the treatment portion of the EPSDT benefit.

EPSDT Treatment Services

EPSDT requires state Medicaid agencies to “arrange for (directly or through referral to appropriate agencies, organizations, or individuals) corrective treatment.”⁴⁷ State Medicaid programs should affirmatively arrange for treatment, either directly or through appropriate referrals.⁴⁸

The Medicaid Act defines a comprehensive package of EPSDT benefits, and it sets forth the medical necessity standard that must be applied on an individual basis to determine each child’s needs. These services can include both the mandatory and optional services that are covered in the Medicaid program.⁴⁹

⁴⁰ Perkins, *Medicaid EPSDT*.

⁴¹ See generally HHS, Health Resources and Services Administration, Maternal and Child Health Bureau, *Bright Futures*, available at <http://www.brightfutures.org/>.

⁴² See 42 U.S.C. § 1396d(r)(2). See also *id.* at § 1396d(r)(4). Hearing services must include hearing screens and diagnosis and treatment for defects in hearing, including hearing aids.

⁴³ See *id.* at § 1396d(r)(3).

⁴⁴ See CMS, STATE MEDICAID MANUAL § 5123.G.

⁴⁵ Perkins, *Medicaid EPSDT*.

⁴⁶ See, e.g., Memorandum from Director, Health Care Financing Administration Medicaid Bureau, to Region III Administrator, Health Care Financing Administration (Apr. 12, 1991) (on file with Perkins, National Health Law Program).

⁴⁷ 42 U.S.C. § 1396a(a)(43)(C).

⁴⁸ Perkins, *Medicaid EPSDT*.

⁴⁹ 42 U.S.C. § 1396d(r)(5), 1396d(a). See generally Perkins, *Medicaid EPSDT*, p. 10 (lists EPSDT’s full scope of benefits).

EPSDT Reporting Requirements

States are required to report their EPSDT compliance to CMS by April 1 of each year on Form CMS-416 to demonstrate the state's attainment of participant and screening goals.⁵⁰ The form is a public document that can also indicate trends and projections to ensure that children are receiving quality health care.⁵¹

Supporting EPSDT through meaningful use

The EPSDT is a unique benefit that can improve the health of children living in poverty. Because EPSDT includes specific screening, treatment, and reporting requirements, the final rules should specify that certified EHR systems must be able to identify children under age 21 who are enrolled in Medicaid and alert providers to those age, developmental, and condition appropriate screenings and treatments that correspond to the EPSDT benefit. This capability will ensure that patients (and their parents/guardians) can be informed of these services and receive them in a timely fashion.

In addition, the final rules should provide that EHR systems should have the ability to capture information and coding for well-child visits, EPSDT screening and treatment, consultations, and relevant pediatric databases in a manner that is extractable for uniform reporting to the state Medicaid agency. Certified EHR systems should also facilitate reporting to the provider's managed care organization (MCO); however, the MCO should not be relied on as an intermediary between the provider and the state Medicaid agency for conveying this information. We also encourage CMS to work with state Medicaid programs to ensure the existence of state-level infrastructure to support the receipt and use of EHR information about EPSDT from all participating providers.

Recommendations:

- i. Require certified EHR systems to have the capability to identify children under age 21 who are enrolled in Medicaid and alert providers to age, developmental, and condition appropriate screenings and treatments that correspond to the EPSDT benefit.**
- ii. Require certified EHR systems to have the ability to capture information and coding for well-child visits, EPSDT screening and treatment, consultations, and relevant pediatric databases in a manner that is extractable for uniform reporting to the state Medicaid agency.**
- iii. Work with state Medicaid programs to ensure the existence of state-level infrastructure to support the receipt and use of EHR information about EPSDT from all participating providers.**

Conclusion

We greatly appreciate the opportunity to comment on the proposed rules. The EHR incentive program has significant potential to increase equity in our health care system. However, unless conscious efforts are made to take advantage of these opportunities, populations facing discrimination and health disparities may not see the full benefits of health IT and health information exchange. We hope the final rules will

⁵⁰ See HHS, CMS, *Form 416: Annual EPSDT Participation Report*, available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Downloads/Form-CMS-416-PDF.pdf>

⁵¹ Perkins, *Medicaid EPSDT*.

make the changes we have recommended in order to ensure meaningful use delivers on its promise to all populations. If you have any questions about these comments, please contact Leadership Conference Health Care Task Force Co-chairs Christine Monahan at the National Partnership for Women & Families (cmonahan@nationalpartnership.org) and Mara Youdelman at the National Health Law Program (youdelman@healthlaw.org).

Sincerely,

Asian & Pacific Islander American Health Forum
Asian Pacific American Legal Center, Member of Asian American Center for Advancing Justice
Association of Asian Pacific Community Health Organizations (AAPCHO)
Center for American Progress
Coalition for Disability Health Equity
Disability Policy Consortium
Disability Rights Education & Defense Fund
Florida Legal Services, Inc.
Human Rights Campaign
The Leadership Conference on Civil and Human Rights
Mental Health America
NAACP
National Center for Transgender Equality
National Council of Jewish Women
National Council of La Raza (NCLR)
National Gay and Lesbian Task Force
National Health Law Program
National Immigration Law Center
National Latina Institute for Reproductive Health
National Partnership for Women & Families
National Women's Law Center
Public Justice Center
SHIRE (Summit Health Institute for Research and Education), Inc.
Voices for America's Children