

May 7, 2012

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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 Disability Rights Education and Defense Fund (DREDF) appreciates the 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). DREDF is a leading national law and policy center that works to advance the civil and human rights of people with disabilities through legal advocacy, training, education, and public policy and legislative development. We are committed to eliminating barriers and increasing access to effective healthcare for people with disabilities and eliminating long-overlooked health disparities that affect the length and quality of their lives.

The incentive program offers an important opportunity to reduce health disparities and improve health and healthcare equity for people with disabilities 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. In this context, reducing health disparities among people with disabilities is a focus of Healthy People 2020 and is specifically articulated in the Affordable Care Act (ACA). We strongly support the prominence of the goal to reduce health disparities articulated by the incentive program. However, we are concerned that the meaningful use requirements as proposed are inadequate to achieve this outcome for people with disabilities. We are at a critical juncture for ensuring that public investments in health information technology (IT) results in the reduction and elimination of health disparities among people with disabilities. The Stage 2 criteria therefore must reflect a more robust use of health IT to increase health equity for this large population. According to the U.S. Census Bureau, of the 291.1 million people in the population in 2005, 54.4 million (18.7 percent) had some level of disability, and 35.0 million (12.0 percent) had a severe disability. Rates of disability also increase with age. By 2030, estimates suggest that the number of people aged 65 years and older will rise to 69.4 million from 34.7 million in 2000.<sup>1</sup>

Our comments and recommendations focus on the following areas of particular concern to people with disabilities.

- Enforcing federal civil rights laws
- Requiring robust demographic data collection and use
- Disability status as a mandatory integral component of data collection
- Use of demographic data
- Building linkages with existing health disparity strategies

#### **I. Enforcing federal civil rights laws**

##### **Federal civil rights laws and EHR incentive payments**

We are very concerned by language regarding federal civil rights laws in both the final rules for Stage 1 and the proposed rules for Stage 2. In both instances, detailed below, the rules fail to acknowledge that EHR incentive payments constitute federal financial assistance and thus recipients are obligated to comply with Title VI, § 504, the Americans with Disabilities Act (ADA), and ACA § 1557, which bar discrimination on the grounds prohibited under the aforementioned laws as well as Title IX of the Education Amendments of 1972 and the Age Discrimination Act of 1975. In addition, incentive recipients are independently receiving federal funds as Medicare<sup>2</sup> and Medicaid providers and thus also subject to Title VI, Section 504, ADA, and ACA § 1557.<sup>3</sup>

Specifically, we were greatly dismayed – 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.” 75 Fed. Reg. at 44341 (July 28, 2010).

While the Health Information Technology for Economic and Clinical Health Act (HITECH Act) may not have granted this authority, pre-existing federal civil rights laws addressing the dissemination of federal financial assistance obligate incentive recipients to comply with civil rights requirements. The incentives themselves constitute federal financial assistance and thus are subject to these federal civil rights laws, which OCR enforces. Moreover, CMS itself, as a federal entity, is of course also subject to the “federally conducted” regulations of Section 504.<sup>4</sup>

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

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

This is misleading. *All* providers covered by these rules are required to provide people with disabilities with equal access to programs and services, including to medical records, since coverage by these rules is predicated upon receipt of federal funds as mandated by § 504. Other applicable law includes the ADA and/or ACA § 1557. Accordingly, information in the EHR should be accessible to individuals with diverse disabilities. For example, the EHR must be compatible with screen readers and patients must be notified that the EHR is available in a preferred alternative format upon request, at no additional cost to the patient. Alternative digital formats may include, but are not limited to 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]), or Waveform Audio File Format

(WAVE or WAV, Media Player). If individuals with disabilities cannot access the EHR, the information contained in the EHR must be made available in other alternative non-electronic formats such as Braille and large font. Similarly, all providers covered by these rules must ensure that patients receive information in languages that they can understand, including American Sign Language, written or spoken languages needed by Limited English Proficient (LEP) individuals, or alternative accessible formats that meet the access needs of individuals with intellectual disabilities, learning disabilities, and other disabilities that impair reading comprehension.

CMS and ONC have an affirmative responsibility to educate EHR incentive recipients to comply with their § 504, ADA, and ACA § 1557 obligations and specify that incentive payments do constitute federal financial assistance. CMS and ONC should rescind the statement quoted above in the Stage 1 final rule. They should also clarify the statement quoted above that is contained in the proposed Stage 2 rule regarding recipients' obligations under § 504, ADA and ACA § 1557 and indicate that incentive payments constitute federal financial assistance under § 504 and other applicable non-discrimination laws.

Similarly, § 504 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, hard of hearing or who have other hearing impairments. Thus, incentive recipients must also provide Sign Language interpreters or other augmentative or auxiliary communication assistance to comply with § 504.

#### **Recommendations:**

- **Clearly state in final rules that EHR incentive payments constitute federal financial assistance and thus all recipients are obligated to comply with to § 504, ADA, and ACA § 1557 as well as other applicable non-discrimination laws.**
- **Require EHR incentive payment recipients to provide Sign Language Interpreters or other augmentative or auxiliary communication assistance to comply with § 504, ADA and ACA § 1557**

#### **II. Requiring robust demographic data collection and use**

Demographic data collection is foundational to advancing health equity in general and is especially important for people with disabilities, therefore we support the use of high thresholds for these criteria, as discussed below. At the same time, we believe

providers also must be required to collect specific information related to people with disabilities that bears directly on the relationship between impairment, use of assistive technology, and known barriers to receiving care such as inaccessible diagnostic and exam equipment, lack of accommodations required for effective communication, and inflexible policies and procedures that result in exclusion from care. Moreover, we think that EPs, eligible hospitals, and CAHs must be required to use these data to monitor and remedy certain known causal links associated with health disparities among people with disabilities. (See Recommendations on disability status data collection standards below.)

### **Demographic data collection thresholds**

In Stage 1 of meaningful use, EPs, eligible hospitals, and critical access hospitals 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 support this increase because 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.

### **Recommendations:**

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

### **III. Disability status as a mandatory integral component of the data collection**

CMS & ONC propose the following objectives:

- Proposed EP Objective: Record the following demographics: Preferred language, gender, race and ethnicity, and date of birth.
- Proposed Eligible Hospital/CAH Objective: Record the following demographics: Preferred language, gender, race and ethnicity, date of birth, and date and preliminary cause of death in the event of mortality in the eligible hospital... 77 Fed. Reg. at 13711 (March 7, 2012)

We are perplexed and concerned that CMS omitted disability status from the objectives, and instead is soliciting comments on "the burden and ability of including disability status as part of data collection for [these] objective[s]." Both federal legislation and federal research have called for identifying disability status as a preliminary step in

understanding the causes of health disparities among people with disabilities. The ACA acknowledged the need to end health disparities among people with disabilities by including disability in Section 4302, which calls for 1) mandatory collection of data on race, ethnicity, sex, primary language, and disability status for applicants, recipients, or participants of any federally conducted or supported health care or public health program, activity or survey; and 2) requires that any reporting requirement imposed for purposes of measuring quality under any ongoing or federally conducted or supported health care or public health program, activity, or survey includes requirements for the collection of data on individuals receiving health care items or services under such programs activities by race, ethnicity, sex, primary language, and disability status. These statutory directives unequivocally require broad collection of disability status data and run counter to the decision to omit disability status from the abovementioned objectives.

Healthy People 2020 made it clear that "throughout the next decade, Healthy People 2020 will assess health disparities in the U.S. population by tracking rates of illness, death, chronic conditions, behaviors, and other types of outcomes in relation to demographic factors including disability status."<sup>5</sup> Moreover, three Surgeon's General reports,<sup>6</sup> a comprehensive report by the National Council on Disability (NCD),<sup>7</sup> and the recent report entitled "Ensuring Health Equity for Minority Persons with Disabilities" produced by the HHS Office of Minority Health in 2011 all acknowledge the significant health disparities people with disabilities face and recommend steps, including data collection, that must be taken to begin addressing underlying causes.<sup>8</sup> Finally, in light of available data regarding disability health disparities, HHS is completing a draft action plan to reduce disability health disparities due to be released in 2012, thus further reinforcing the urgency and importance of disability status data collection.<sup>9</sup>

### **Disability status data collection**

CMS has stated in the NPRM, "We believe that the recording of disability status for certain patients can improve care coordination, and so we are considering making the recording of disability status an option for providers. We seek comment on the burden incorporating such an option would impose on EHR vendors, as well as the burden that collection of this data might impose on EPs, eligible hospitals, and CAHs. In addition, we request public comment on (1) how to define the concept "disability status" in this context; and (2) whether the option to collect disability status for patients should be captured under the objective to record demographics, or if another objective would be more appropriate."<sup>10</sup>

As a matter of law and policy, we are surprised and troubled that CMS is merely "considering" recording disability status as an "option" and asks for comments on any

"burden" it might cause. As previously discussed, significant federal research as well as the ACA laid the factual and legal foundation for disability status data collection. We therefore strongly support recording disability status as a component of the demographic data collection requirements. Collection of this data must be considered a part of the demographic data collection criterion.

### **Burden on EHR vendors of collecting disability data**

It is difficult to accurately distinguish the burden on EHR vendors of requiring and incorporating disability data collection from the burden of incorporating new data collection criteria for any other demographic group. In light of the fact that new HIT infrastructures are being created, we question why disability would be omitted when existing law and policy call for collection of demographic data on disability status and when people with disabilities are known to experience significant health and healthcare disparities.

The presence of the question of burden strongly suggests that people with disabilities as compared with other demographic groups have not attained sufficient status or importance to warrant the effort required to create the electronic capability that is necessary to collect and report disability status. We therefore strongly urge CMS to focus on how to best phase in inclusion of disability status questions as ERH Phase 2 moves forward. At no time in the future will it be easier than it is now to fully include measurement of disability status. In fact, as the EHR vendors roll out the digital infrastructures required to collect data for meaningful use, there should be no question of excluding disability status, not only because the data is urgently needed, but also because inserting new data collection categories later will only become more and more difficult and expensive. Moreover, the increasing propensity of people to acquire impairments as they age, the increasing likelihood of adults with various disabilities to live longer lives, and the mutability of disability status in general are all factors that argue for the flexibility and real-time capacity of EHRs as the ideal format for capturing disability status for both demographic and care coordination purposes.

### **Burden on providers of collecting disability data**

Limited data on disability status and also on related, but more granular information on accommodations that people with specific impairments and functional limitations require to access effective and appropriate care makes it difficult to advance and embed policies and procedures that would address systemic deficiencies and improve the quality of healthcare people with disabilities receive. ***The Electronic Health Record***

***Incentive Program is the first opportunity to require standardized, granular disability status data collection at the provider level, the point where this data is most readily available and important from both a clinical and population standpoint. The importance of this opportunity for people with disabilities cannot be overstated.***

By offering EPs, eligible hospitals, and CAHs financial incentives for demographic data collection, CMS and ONC have made the assumption that providers are generally willing to record this electronic data in exchange for additional compensation. Thus, participating providers will find it necessary to train staff on the use of the new information collection systems and phase in use of the systems in accordance with federal agency timelines. Accordingly, we see no valid reason why recording disability status will be any more or less burdensome than recording new information for any other demographic group. Moreover, providing appropriate clinical care for people with disabilities often is predicated on the availability of this information, which up to now, has not been systematically collected by EPs, eligible hospitals, or CAHs. Finally, we note that, particularly in urban areas, providers often align themselves with larger entities such as physician groups and managed care organizations for various administrative, financial, and regulatory reasons. These overarching organizations, many of which are also subject to data collection standards imposed by state or ACA-related requirements pertaining to Medicaid expansion or the creation of Health Benefit Exchanges, can be expected to assist individual providers with developing data collection procedures, software, and policies at the provider level.

### **Recommendations on defining disability status and collection standards**

The six disability status questions contained in the American Community Survey (ACS)<sup>11</sup> 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 data standard for disability status in the HHS/Office of Minority Health survey standards issued pursuant to the ACA.

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. Meaningful use data collection provides a window through which one can collect detailed data regarding the quality of care of individuals and populations of people with disabilities.



Unless this additional data collection step is taken, quality measures that comprise required elements of care will never be applied, recorded, or reported for certain people with disabilities, thus excluding them from the effort to reduce health disparities and consigning them to continued invisibility both as individuals and as a population. For example, while recording a patient's weight is a required element of care according to many quality measures, non-ambulatory people who use mobility devices, such as wheelchairs, are almost never weighed because most healthcare providers will not proactively acquire or use accessible weight scales. Until information is uniformly collected on the frequency, or infrequency, with which non-ambulatory patients who use wheelchairs are being weighed, no baseline will exist that will inform needed remedial steps and thus no action can or will be taken to address this most basic healthcare disparity. Non-ambulatory people who use mobility devices could fall consistently outside of the 80 percent of unique patients for whom demographic data is required in Stage 2, and the links between the impairment, patient accommodation needs, and the data collection failure will never be brought to light or remedied.

Therefore, we strongly recommend that the following additional questions be added, which will help capture individuals with disabilities who may otherwise not be recognized by the six ACS questions, and formalize the collection of information that is necessary in any good patient history so that quality care can be provided in a manner that meets the functional needs of individuals 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, bi-polar 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. All information should be provided voluntarily.

#### **Recommendations:**

- **Require the collection of disability status data using the ACS questions on disability**
- **Collect self-reported diagnostic/impairment-related information and information related to use of assistive technology to supplement the ACS 6**
- **Collect self-reported information about the physical and communication accommodations patients with disabilities require in healthcare settings**

#### **IV. Use of demographic data**

Demographic data are of limited value if they are not used to address differences in care quality. If demographic data is collected without a clear purpose, it may result in mistrust among patients and lack of buy-in on the part of providers. Therefore, we strongly urge CMS to require that demographic data be used to improve care for all populations, including people with disabilities, 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, and in the case of people with disabilities, by the additional variables of self-reported diagnosis, use of assistive technology, and by required accommodations will reveal specific disparities in care among provider's patient populations and help providers create strategies to reduce and eliminate disparities. In ambulatory settings, the use of National Quality Forum-endorsed "disparities-sensitive" measures should be recorded and stratified, at a minimum.

We recommend that stratified quality data be reported at the population level on the CMS public reporting websites for hospitals and physician practices (and where possible, by practice- or provider-level). This also will serve to make the general public

more aware of disparities in their area, and could help communities identify and target disparities through health and social policies.

To protect patient privacy in situations where publically reported demographic or quality data in small populations or local areas may be individually identifiable, CMS should accompany public reporting requirements with rigorous privacy and security requirements.

### **Recommendations:**

- **Require that providers stratify clinical quality measures by demographic data, and for people with disabilities, by the additional variables of self-reported diagnosis, use of assistive technology, and by required accommodations**
- **Report stratified quality data at the population level on the CMS public reporting websites for hospitals and physician practices (and where possible, by practice- or provider-level).**
- **Accompany public reporting requirements with rigorous privacy and security requirements.**

### **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, then sub-populations could be compared 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. For example, weight measurement could be determined for wheelchair users as compared with people who do not use wheelchairs. Eventually, CMS should aim to be able to report lists by multiple demographic variables (for example, differences between people who have intellectual disabilities and those who do not, or women with and without disabilities) to better understand and address health disparities.

### **Recommendation:**

- **Link the “generate lists of patients” criterion to the requirement to collect demographic data by requiring providers to stratify such lists by demographics and by the additional variables of self-reported diagnosis,**

**use of assistive technology, and by required accommodations for people with disabilities**

**V. 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 disease and illness 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 for people with disabilities by ignoring the preferences and needs of the patient, not addressing access barriers, allowing provider biases, and ignoring barriers in provider and patient communication.<sup>12</sup> 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 identify health disparities among people with disabilities and promote national and local health disparity prevention strategies and public health initiatives.

Finally, we urge HHS to align the incentive programs to the upcoming HHS Action Plan to Reduce Disability Health Disparities. CMS and ONC also should align its upcoming HHS Health IT Plan to End Health Disparities with the HHS efforts to reduce disability disparities.

Thank you for the opportunity to comment on these proposed rules.

Sincerely,



Susan R. Henderson  
Executive Director

## Endnotes

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<sup>1</sup> J. Waldrop and S. M. Stern, Disability Status: 2000—Census 2000 Brief (Washington, DC: U.S. Bureau of the Census).

<sup>2</sup> 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 think all Medicare providers must provide language services.

<sup>3</sup> Section 1557 expressly extended the protections of Title VI, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and § 504 to “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 and ONC 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.

<sup>4</sup> See 28 C.F.R. Pt. 39, Editorial Note, Section 39.102 Application.

<sup>5</sup> Healthy People 2010, Objectives for Improving Health, Disability, and Secondary Conditions.  
<http://healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=9>

<sup>6</sup> US Department of Health and Human Services (DHHS), Office of the Surgeon General. The Surgeon General's call to action to improve the health and wellness of persons with disabilities. Washington, DC: DHHS, Office of the Surgeon General; 2005. Available at <http://www.ncbi.nlm.nih.gov/books/n/ctadisabil/pdf/>;  
US Department of Health and Human Services. Mental health: culture, race, and ethnicity. A supplement to Mental health: A report of the surgeon general. Rockville, MD: US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Centre for Mental Health Services; 2001. Available from <http://137.187.25.243/library/mentalhealth/cre/default.asp>;  
Office of the Surgeon General (US); National Institute of Child Health and Human Development (US); Centers for Disease Control and Prevention (US). Closing the Gap: A National Blueprint to Improve the Health of Persons with Mental Retardation: Report of the Surgeon General's Conference on Health Disparities and Mental Retardation. Washington (DC): US Department of Health and Human Services; 2002. Available from <http://www.ncbi.nlm.nih.gov/books/NBK44346/>

<sup>7</sup> National Council on Disabilities (NCD). The Current State of Health Care for People with Disabilities. Washington (DC): 2009.

<http://www.ncd.gov/publications/2009/Sept302009>

<sup>8</sup> Office of Minority Health (OMH). Ensuring Health Equity for Minority Persons with Disabilities. Washington (DC): U.S. Department of Health and Human Services; 2011. Available from

<http://minorityhealth.hhs.gov/Assets/pdf/Checked/1/ACMHHealthDisparitiesReport.pdf>

<sup>9</sup> Personal communication with Gloria Krahn, Director, Division of Human Development and Disability (DHDD), National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC). April 2012.

<sup>10</sup> 77 Fed. Reg. at 13712 (March 7, 2012)

<sup>11</sup> American Community Survey 2011 disability questions can be accessed at

<http://www.census.gov/acs/www/Downloads/QbyQfact/disability.pdf>

<sup>12</sup> National Council on Disabilities (NCD). 2009.