



David C. Harlow

Chair, Public Policy Committee

c/o The Harlow Group LLC

31 Olde Field Road

Newton MA 02459

Phone: 617.965.9732

Email: david@harlowgroup.net

May 4, 2012

Farzad Mostashari, MD, National Coordinator
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: 2014 Edition EHR Standards and Certification Criteria Proposed Rule
Hubert H. Humphrey Building
Suite 729D
200 Independence Ave. SW
Washington, DC 20201

Re: Health Information Technology; Implementation Specifications, and Certification Criteria:
Electronic Health Record Technology, 2014 Edition (Docket ID HHS-OS-2012-0004)

Dear Dr. Mostashari:

The Society for Participatory Medicine applauds the work done to date in focusing on patient engagement in the proposed Stage 2 Meaningful Use regulations and the proposed Health IT Standards regulations. It is our hope that the final requirements will be even stronger and more focused in this regard than the current drafts.

As set forth in greater detail below, we have a number of comments that we believe will improve the regulations and their use as a lever to improve patient experience, patient engagement, patient care and, ultimately, patient outcomes.

We would like to highlight two in particular:

We favor improving the likelihood that patients will access their data by allowing for some **automation of the process of accessing and downloading patient data**, using existing technologies that protect patient privacy and security.

We also favor **immediate patient access to information** in the patient's electronic health record - unless the patient has elected otherwise.

The overarching principle with respect to patient access to electronic health record data running through the entire meaningful use regulation and the health IT standards regulation should be:

"Nothing about me without me."¹

The Society for Participatory Medicine has individual and institutional members nationwide and has a governing board comprised of both clinicians and patients. It was founded to study and promote participatory medicine, which we define as being centered on networked patients shifting from being mere passengers to responsible drivers of their health, and providers who encourage and value them as full partners. For further background on the Society and its activities, we invite you to see the Society's website (<http://participatorymedicine.org>), its online journal, The Journal of Participatory Medicine (<http://jopm.org>) and its blog, e-patients.net (<http://e-patients.net>).

On behalf of its patient, provider and advocate members, the Society proposes adjusting the draft regulations in a number of specific ways, in order to bring clinicians and patients closer together, to promote greater patient engagement and to achieve greater patient-centeredness, which are keystones of the federal government's health care policies.

45 CFR § 170.202(a) Transport standards - Directed exchange

We strongly support this proposal and suggest that patients should have access to the same documents (CCDA, transition of care records, Digital Imaging and Communications in Medicine (DICOM), links to imaging) as physicians and institutional providers. Not every patient will want such access, but patients and their family members or other designees should have the ability to review this information in real time -- in order to serve as an additional check on accuracy, and in order to promote the broader goals of patient-centeredness.

45 CFR § 170.202(a)(1) and (2) Transmit care summary to third party.

We recommend that "transmit to third party" also support widely available and secure protocols, such as the OAuth protocol, to enable secure delegation by the patient to access of his or her downloadable documents. This will enable the patient to avoid inconvenience, delay and errors by providing to third parties limited access to the same information the patient can view and download.

45 CFR § 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

To the extent that these standards and specifications relate to communication of information to patients, they should accommodate widely available and secure protocols, such as OAuth. For example, a patient's designee could use OAuth to download a "Blue Button"-type file of that patient's medical records.

45 CFR § 170.314(a) (12) - Imaging. "Electronically indicate to a user the availability of a patient's images and/or narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable immediate electronic access to such images and narrative interpretations."

We recommend that, in order to ensure immediate access, certified EHR technology (CEHRT) provide stream-capable hyperlinks to images that can be viewed in a typical web browser without the delay related to use of DICOM file transfer and without the requirement to install additional software beyond the standard web browser itself. These links should be secure and accessible not only to clinicians, as the proposed rule would have it, but to patients and patients' agents as well.

¹ Valerie Billingham, Through the Patient's Eyes, Salzburg Seminar, Session 356, 1998

45 CFR § 170.314(a)(16) "Objective: Use Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient. Measure: Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all office visits by the Eligible Provider. More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS21 or 23) are provided patient-specific education resources identified by Certified EHR Technology."

We strongly suggest that the patient educational material needs to be provided digitally and free of charge, actually delivered and not simply identified via a search function within the EHR. The educational material should also be free of any advertising and produced either without sponsorship by parties with conflicts, or with full editorial control vested in the authors, not the sponsors. The source of the material, and any sponsorship, will be fully disclosed.

45 CFR § 170.314(b)(2) -- Create and transmit summary care record

We recommend that instances of sending summary care records to a patient's PHR via Direct Project protocols be included in the 10% measure. Direct will give patients the ability to easily share their visit summaries with their care team.

45 CFR § 170.314(b)(3) -- Electronic prescriptions

We recommend that there be a way for patients to review e-prescriptions and participate in medication reconciliations with both their doctors and pharmacists via the patient portal. Prescriptions transmitted electronically will provide additional protections to patients with the ability to compare/confirm drug formularies and will eliminate paper waste and legibility issues.

* * *

In closing, we would like to stress the importance of making the data available to patients in a way that would also enable the patient's automated agents to access the data on their behalf, therefore making it much more likely that more patients would access EHR data online. The manual steps required in many PHR environments are in part responsible for the limited adoption of these potentially valuable tools. It is also worth noting that security and privacy are significantly enhanced using a separate access path (such as OAuth) for the patient's automated agents so that the patient is not forced to share his or her password with the agent.

Thank you for the opportunity to share our perspective. Should you or your staff require any additional information, please do not hesitate to contact us.

Sincerely,



Danny Z. Sands, MD
President
dzsands@cisco.com



David Harlow, JD MPH
Chair, Public Policy Committee
david@harlowgroup.net