November 14, 2011

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2319-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: File Code CMS-2319-P, CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports

To Whom It May Concern:

IEEE USA strongly supports the proposed rule changes to allow patient access to laboratory test results. These changes remove the anomaly associated with laboratory results, giving patients the same rights to this information as they have to the rest of their information under the Health Insurance Portability and Accountability Act (HIPAA).

However, while the propose changes are consistent with the stated goal of “widespread adoption of Electronic Health Records (EHRs) by 2014,” they are not sufficient in themselves to significantly increase the likelihood of consistently incorporating laboratory information in EHRs. A standard, secure, electronic process is required for patients to obtain laboratory reports that can be easily incorporated into a patient’s EHR. This process should include a digital signature to provide assurance that the lab information has not been modified.

While there are many ways a standard process could be established, it might simplify the process if the patient’s request for lab data were included with the provider’s original request for the lab tests. The use of Nationwide Health Information Network (NwHIN) Direct to allow secure e-mail of the test results to both the provider and the patient (or the patient’s designee) may provide a very low cost approach to appropriate distribution of the lab information consistent with the modified rules. Finally, while the patient’s right to the lab information should be the same as with other HIPAA protected information, the patient may wish to receive the information together with an explanation of the information by the provider, and the process should accommodate such a preference.

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If we can be of further assistance, please contact Deborah Rudolph in our Washington office at (202) 530-8332 or email at d.rudolph@ieee.org.

Sincerely,

Ronald G. Jensen
IEEE-USA President

RGJ/DR:bc