eHEALTH INITIATIVE
Real Solutions. Better Health.

November 14, 2011

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445-G
Washington, DC 20201

Re: CMS-2319-P, NPRM amending CLIA Program and HIPAA Privacy Rule

Submitted via http://www.regulations.gov

Dear Dr. Berwick,

eHealth Initiative appreciates the opportunity to comment on the proposed rulemaking amending the Clinical Laboratory Information Act (CLIA) and the HIPAA Privacy Rule to facilitate patient access to their laboratory results.

eHealth Initiative (eHI) is an independent, non-profit, multi-stakeholder organization. Its mission is to drive improvements in the quality, safety and efficiency of healthcare through information and information technology (IT). eHI advocates for the use of health information technology (HIT) that is practical, sustainable and addresses stakeholder needs, particularly those of patients. The comments below were developed through our multi-stakeholder consensus process.

eHI applauds your efforts to remove one of the hurdles faced by individuals and the care team seeking to facilitate health information exchange seeking to become partners with their care team in maintaining their health and wellness. An individual's access to their protected health information (PHI) was facilitated by the HIPAA regulation in 2002, yet exceptions limited an individual's ability to obtain lab results upon request. eHI supports the NPRM proposal to remove the exception to the HIPAA Privacy Rule for CLIA-covered entities, and to clarify that federal regulation will pre-empt contrary state law and fill a void in state law regarding

818 Connecticut Avenue NW Suite 500 Washington, D.C. 20006
Tel: 202.624-3270 Fax: 202.429.5553
www.ehealthinitiative.org

direct patient access to lab results. The NPRM brings an appropriate alignment of regulations to support patient access to protected health information.

We also are encouraged that this NPRM, while facilitating patient's access to their laboratory results upon request, also will advance the goal of exchange of clinical information among a care team. Laboratory results can constitute up to 70 percent of a clinical record, and patient receipt of the results can open opportunities for bi-directional access to information that improves coordination among the members of a patient's care team.

eHI offers several recommendations to address areas where we believe greater clarity would support alignment with other regulatory initiatives and benefit the patient and the patient's care team:

Sequence the Final Rule on Lab Results and HITECH HIPAA Privacy Final Rule

At this time, the HITECH HIPAA Privacy Final Rule has not been published. It is unknown when that final rule will be published and how it will differ from the proposed rule. This NPRM, CMS-2319-P, links the disclosure requirements to HIPAA Privacy rule. The HITECH HIPAA Privacy final rule is anticipated to include changes to the form required for PHI report, and the charge that may be assessed for the production of the report. Providers, vendors and the public at large will be placed at a disadvantage if the NPRM amending CLIA and HIPAA Privacy is made final in advance of the HITECH HIPAA Privacy final rule. Such an event could result in two sets of compliance requirements within a limited period of time. We recommend that the publication of the final rule amending CLIA and HIPAA Privacy be conditioned on the prior publication of the HITECH HIPAA Privacy final rule. Without appropriate sequencing of these two regulations, two sets of administrative requirements may exist, creating unnecessary compliance complexity in procedures and processes.

Engaging Patients with Information and Education

A discussion about lab results by the patient and their care team is the preferred scenario, as it places the lab results within the larger context of the patient's health and wellness. In many instances today, the patient will not know which laboratory was the recipient of the lab specimen and conducted the testing. In order to facilitate patient ability to request their lab results, eHI offers several recommendations:

1. HHS should address how the patient can learn the identity of the laboratory to which the request for lab results should be directed, and how the laboratory can provide to the patient the contact information of the ordering and treating clinician(s), when that information is known.

2. HHS should encourage ongoing collaboration and cooperation among ordering clinicians and laboratories in the use of best practices for the conveyance of the appropriate clinical context of the lab results. The increasing availability of bi-directional exchange and the increasing complexity of diagnostic tests will provide increasing opportunities for laboratory physicians to be members of the patient's care team.

New Relationship Between Laboratories and Patients Brings New Challenges

The NPRM will facilitate the relationship for laboratories with patients, and we have previously lauded the benefits that are derived from this regulatory change. CLIA-covered laboratories, previously exempt from HIPAA requirements to disclose protected health information to patients upon request, will have a direct relationships with patients for the first time. Authentication of the patient is one challenge that these laboratories will face, as previously the sole relationship existed between the laboratory and the clinician ordering the test. Small hospitals, particularly Critical Access Hospitals (CAHs) or hospitals in rural areas, and independent laboratories may face financial constraints that make the compliance with the NPRM requirements challenging.

The NPRM seeks comment on best practices for direct provision of patients' laboratory results. eHI recommends that HHS provide non-binding guidance in the final rule of this NPRM that is specifically directed to the laboratories that will have a new, direct relationship with patients. eHI further recommends that the non-binding guidance include a framework on what labs must do to meet the requirements of the NPRM, including the development and testing of systems needed to operationalize the responses to patient requests for lab results, and a realistic assessment of the timeframes for compliance.

Accuracy of the Estimate of the Information Collection Burden

The NPRM requests comment on the accuracy of the estimate of the information collection burden and implementation costs. As noted earlier, eHI recommends that HHS sequence the publication of the final version of this NPRM to a date after

the publication of the HITECH HIPAA Privacy final rule. Absent this sequence, the estimates of cost associated with implementation could be significantly higher than anticipated, as the laboratories would be compelled to comply with current HIPAA Privacy requirements and subsequently modified HIPAA Privacy requirements.

Although it is valid to attempt to estimate the burden associated with compliance, in accordance with regulatory review requirements, this effort should be balanced with the reality of the transformation underway in healthcare. Existing federal policies and concurrent market forces are accelerating healthcare delivery and payment redesign, an expansion of health information exchange, and increased consumer empowerment via education and technology applications. The result of this activity may drive greater demand that can be estimated accurately today. In response to a request for a specific comment on the accuracy of the estimate of the information collection burden, eHI urges HHS to assess the estimated information collection burden over time, as the infrastructure for information exchange and patient demand for information is expected to increase over time. Based on this assessment, we suggest that HHS look for revisions in the final regulation or in sub-regulatory guidance.

eHI appreciates the opportunity to comment on the NPRM amending CLIA and the HIPAA Privacy Rule. We believe the NPRM is an important addition to the regulatory reform needed to advance the development of safe, high-quality, coordinated, patient-centered care that recognizes individuals and their family caregivers as members of the patient's care team. If you have any questions, please contact me at Jennifer.Covich@ehealthinitiative.org.

Sincerely,

Jennifer Covich Bordenick
Chief Executive Officer
eHealth Initiative