CALIFORNIA HOSPITAL ASSOCIATION
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November 14, 2011

Donald M. Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Submitted electronically via www.regulations.gov

Subject: CMS–2319–P, CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports; (Vol. 76, No.178), September 14, 2011.

Dear Dr. Berwick:

On behalf of the California Hospital Association (CHA) and our nearly 400 hospital and health system members, we are pleased to submit comments on the Centers for Medicare & Medicaid Services' (CMS) Centers for Disease Control and Prevention, and Office for Civil Rights' proposed rule regarding patients' access to laboratory test reports.

The proposed rule would amend the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to specify that, upon a patient's request, the laboratory may provide access to completed laboratory test reports that, using the laboratory's authentication process, can be identified as belonging to that patient. In addition, the proposed rule would eliminate the current exception in the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) Privacy Rule limiting patients' right to access their completed laboratory test reports directly from a HIPAA-covered entity that also is a CLIA-covered laboratory.

Further, the proposed rule acknowledges that 20 states, including California have laws that prohibit a laboratory from releasing a test report directly to the patient or prohibit the release without the ordering provider's consent. The proposed rule states that these state laws would be preempted.

CHA supports the proposed regulatory changes that promote patient access to health information. Further, we applaud the agencies for putting forward federal preemption as a cornerstone of the proposed rule. This will bring further harmonization of federal and state laws across the nation and ensure, regardless of where a patient lives, access to personal health information is protected.

As CMS and other agencies proceed with implementation, we would like to point out some of the operational challenges for hospitals that, if not adequately addressed in the final rule, may add additional costs and administrative burden or put hospitals in an untenable position with patients.

Of particular concern to hospitals is the sharing test results with the patients and the immediate next step. When patients receive the copy of a completed laboratory test report, they likely will have questions about interpretation and what are appropriate clinical next steps. The lab providing a copy of the report cannot provide the clinical context or interpretation of findings that is generally provided by the ordering physician, and will need to refer the individuals back to their physician. **It is important that the agencies provide education to patients to ensure they understand the difference between the right to ask for a copy of a completed laboratory test report, which the proposed rule would enable, verses an interpretation of the results, which is appropriately left to the ordering and/or treating physician**.

Second, hospitals currently have processes in place through their health information management departments for authenticating patient identity and fulfilling requests for information. **CHA urges CMS to clarify that the processes currently in place for regular requests for information are robust and sufficient, and there is no need to create an additional process that will be cumbersome and outside the normal customary practices undertaken by hospitals on a daily basis. Further, we ask that CMS clarify that one option in fulfilling such a request is that the information can be shared through an electronic portal that may be affiliated with the electronic health record, in addition to other means.**

Third, there are several related regulations still pending that must be harmonized with this proposed rule. CHA urges CMS to look closely at the comments in response to the Health Information Technology for Economic and Clinical Health Act (HITECH) rule regarding provision of an electronic copy of records held in electronic form, as well as the HIPAA Privacy, Security, and Enforcement Rules that have yet to be finalized, to ensure common policy across all areas of regulation.

Finally, CHA is in agreement with many of the comments put forward by the American Hospital Association with regard to the complexities this proposed regulation presents to reference labs and urges CMS to consider these comments in its final rule.

We appreciate the opportunity to provide our comments. If you have any questions, please contact me at akeefe@calhospital.org or 202-488-4688.

Sincerely,

/s/

Alyssa Keefe
Vice President Federal Regulatory Affairs