



October 4, 2011

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

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) appreciates the opportunity to comment on the September 14, 2011 proposed rule, which would amend the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) regulation and the Health Insurance Portability and Accountability (HIPAA) privacy standards to allow patients to request and receive their test reports directly from a clinical laboratory. We support your efforts to empower patients by encouraging them to obtain and understand their personal health data.

Accessing Test Results

The proposed rule states that “Upon a patient’s request, the laboratory may provide access to completed tests reports that, using the laboratory’s authentication process, can be identified as belonging to the patient.” The explanatory text further elaborates that the change in the HIPAA privacy rule would, in fact, require laboratories to provide this data. AACC agrees that patients should have greater access to their test results so that they can take a more active role in managing their health.

AACC is concerned, however, that providing laboratory test results without context may have limited value for some consumers, while unnecessarily alarming others. Most laboratory test reports only provide a numeric value along with a reference range for the each result. AACC recommends that patients be encouraged to consult with their physician before making any health-related decisions based on their test results.

Processing Patient Requests

In the explanatory comments, CMS states that laboratories can determine for themselves the process “by which patient requests for access would be submitted, processed, or responded to by the laboratories.” AACC supports this approach. We believe all health care providers providing tests results should have the flexibility to develop a process that allows them to fulfill the request expeditiously, but without interrupting their operations.

The privacy rule also “permits covered entities to charge a reasonable, cost-based fee to provide individuals with copies of their protected health information. The fee may include only the cost of copying (including supplies and labor) and postage, if the patient requests that the copy be mailed.” AACC recommends that health care providers also be allowed to recoup costs

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associated with retrieving the results, if the information has been stored elsewhere and is not readily available. Currently, the HIPAA rule does not permit providers to include the “costs associated with searching for and retrieving the requested information.”

Promoting Consumer Understanding

AACC urges CMS to educate consumers about the value of laboratory testing and its importance to maintaining and improving their health. We recommend that the agency encourage health care providers and patients alike to utilize consumer websites, such as Laboratory Tests Online <http://labtestsonline.org/>, which explain the reasons tests are ordered and what the results may mean. Greater use of these free websites can ‘empower’ patients as they seek to play a more active role in managing their personal care.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC’s members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (314) 362-0194, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in cursive script that reads "Ann M. Gronowski".

Ann M. Gronowski, PhD
President, AACC