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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

Dear Secretary Sebelius,

This letter represents comments and recommendations from the American Health Information Management Association (AHIMA) in response to the notice of proposed rulemaking published in the *Federal Register* Wednesday, September 14, 2011 to amend the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations [76FR56712].

AHIMA is a not-for-profit professional association representing more than 63,000 health information management (HIM) professionals who work throughout the healthcare industry. AHIMA's HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, reporting, and utilizing data vital for patient care, while making it accessible to healthcare providers and appropriate researchers when it is needed most. We respectfully submit our comments as our members are and will continue to be active participants in the implementation, maintenance, and compliance of this program.

If AHIMA can provide further information or if there are any questions regarding our recommendations, please contact me at (202) 659-9440 or [allison.viola@ahima.org](mailto:allison.viola@ahima.org), or Dan Rode, vice president, advocacy and policy, at (202) 659-9440 or [dan.rode@ahima.org](mailto:dan.rode@ahima.org).

Sincerely,

A handwritten signature in cursive script that reads "Allison Viola". The signature is written in black ink on a light-colored background.

Allison Viola, MBA, RHIA  
Director, Federal Relations

cc: Dan Rode, MBA, CHPS, FHFMA, Vice President, Advocacy and Policy

Impact on Patient Access to Laboratory Results

It is important to note that many situations where laboratory tests are requested will not be covered under the proposed rules. If the current proposal maintained in the final rule, Health and Human Services should educate consumers and identify more clearly the limited amount of information that will be available directly from laboratories as well as the potential misunderstandings that can occur if tests results are not fully understood (see below).

Context of Laboratory Results

AHIMA fully embraces patient access to their health information to support engagement and participation in the care they receive from providers; however we are concerned about providing direct access to test reports without having contextual knowledge of the results.

With regard to direct access to test reports, we believe there are many problematic issues. There may be too many situations in which a patient will receive test results that show a false positive or a false negative as in the case of a HIV or pregnancy test. There are situations where a test result may be out of the 'normal' range but for an individual that may be normal based on other medical conditions. The patient not fully understanding the context of the test results may make a potentially unstable situation worse and take action as a result of the report findings without the benefit of provider involvement. One way to limit the concern for understanding and patient safety would be to require laboratories to also provide information regarding the potential context of the result and urge individuals to discuss the results with their provider. This will be an additional burden on the laboratory since the purpose of the tests may not be known, or a number of test may be requested at the same time for a number of different reasons.

In order to provide safe healthcare to the patient, we encourage CMS/CDC/OCR to continue to use providers to help interpret test results of the health information, this will enable patients to ask questions and understand the information through a qualified professional. We believe this conversation between patient and provider will further enhance engagement of the patient and provider relationship. The need for this conversation however also requires CMS to recognize the need to cover the providers time for such conversations.

Most important, we strongly encourage CMS to leverage regulations currently in place to enable patient access to their health information. The Meaningful Use incentive program, HIPAA, and HITECH allow patient access to their health information and therefore, by amending CLIA our members believe this serves as a redundant activity and adds to the administrative burden of managing additional regulation. We suggest CMS modify the meaningful use program to identify an objective that would address this functionality.

AHIMA recommends that CMS provides additional clarity around the process in which patients will receive their test results. We also request information regarding test exclusions or whether minors will have access to their information. Further clarification should be provided in relation to who may receive the test results when there are legal conservators for patients.

In closing, this new regulation has the potential for placing several burdens on the healthcare entity. They will need to not only train staff but to monitor and keep staff apprised of all new state and federal regulations relating to the disclosure of protected health information; the burden to be able to address questions relating to the test results and lastly be potentially responsible for any adverse outcome associated with disclosing results that have significant impact on an individual's health.