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November 10, 2011

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

Re: CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports; RIN
0938–AQ38

Dear Administrator Berwick:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to submit the following comments in response to the proposed rule to amend the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to specify that, upon a patient's request, the laboratory may provide a patient direct access to completed test reports using an authentication process to identify the patient. In addition, the proposed rule would amend the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to provide individuals the right to receive their test reports directly from laboratories by removing the exceptions for CLIA-certified laboratories and CLIA-exempt laboratories from the provision that provides individuals with the right of access to their protected health information (PHI). This proposed rule would also preempt any contrary provisions of state law.

The AMA supports patients having the right to request a copy of their completed test report from the laboratory. The rule should make it clear that the report will be on final test results. The laboratory should also be required to notify the ordering physician when known, and also provide a copy of the completed test report to the ordering physician at the same time as the patient, preferably sooner, so that the physician and the patient can discuss the report. Lab reports should also contain standard language emphasizing both the limitations of the lab data alone in confirming or ruling out a diagnosis, and the importance of the patient discussing their lab results with their physician. The ordering physician's contact information should also be included in the report. A critical part of the lab testing and results process is physician-patient communications. Lab test results often contain a lot of

information that is confusing or unanticipated (e.g., confusion over medical terminology that describes results of their diagnostic tests) that may cause patients undue anxiety as they await to hear from their physician to interpret the results. For example, a patient reviewing his/her lab test results may be overwhelmed by a number of possible abnormalities until they are explained by his/her physician. It is also important to understand that in some cases what a patient might think is a normal test result may not be the case. For example, a patient with heart disease seeing what s/he considers to be a normal reading on the lab test report might decide to cancel future appointment(s) with his/her physician, which should be kept because the reading may actually be high for the patient's individual circumstance. The communication between a physician and patient is especially critical when a patient receives a sensitive lab report such as test results on HIV. Physicians are in the best position to discuss sensitive lab test results with their patient given the physician's knowledge of the patient, on how the patient will accept information, and of the impact on the patient when s/he receives this information. **Physician-patient communications are critical for providing and improving care and for patient outcomes.**

This proposed rule would preempt any contrary state laws that prohibit laboratories from directly providing the individual with access to his/her laboratory test results. According to the proposed rule, the laws of twenty-six states and territories are silent with respect to who is authorized to receive laboratory test reports. Laws in seven states, the District of Columbia, and Puerto Rico already allow the laboratory to release test reports directly to the patient. The remaining states have laws that may contradict the proposed HIPAA rule on direct patient access to lab test results. States with contradictory laws should have an opportunity to consider whether their laws should be modified to conform with the proposed HIPAA requirement to allow patients to request their test results directly from a laboratory. **We therefore, strongly urge CMS to allow ample time for states with contrary laws to review their laws and consider conforming their laws with the proposed changes to the CLIA and HIPAA regulations.**

A patient's lab test results must be protected from unauthorized disclosures and uses. We agree that in cases where the laboratory receives a request for access from an individual but can not verify that the requesting individual is the subject of the test report, that the laboratory be under no obligation to provide access to the report. **Adequate privacy and security measures should be considered as part of the laboratory's authentication process to protect patients' lab test results from inappropriate disclosures or uses.**

A number of HIPAA regulations have been issued in the past two years based on requirements specified in the "Health Information Technology for Economic and Clinical Health Act (HITECH) of the "American Recovery and Reinvestment Act of 2009" (ARRA-Pub. L. 111-5). In addition, HIPAA covered entities must also comply with the upcoming HIPAA Version 5010 and ICD-10 compliance deadlines. **We strongly urge CMS to implement reasonable, sequenced compliance deadlines that factor in the significant amount of financial, operational, and technological resources it will take for HIPAA-**

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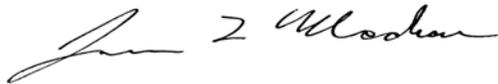
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covered entities and other affected parties to fully comply with all of these new HIPAA requirements.

The AMA is a strong advocate for promoting health literacy education. A patient's ability to obtain, process, and understand health information and services is necessary in order to make appropriate health decisions. **We strongly recommend that CMS work with physicians and other stakeholders on patient education and outreach efforts so that patients who have received their test results directly from the laboratory understand and know how to use the information and how important it is to discuss their lab test report with their physicians.**

We appreciate the opportunity to provide our comments and welcome the opportunity to discuss with you further our recommendations. Please contact Mari Savickis at (202) 789-7414 or mari.savickis@ama-assn.org if you have any questions or concerns.

Sincerely,

A handwritten signature in cursive script, appearing to read "James L. Madara".

James L. Madara, MD