



UPDATE Health Law Pulse

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HHS Releases Final Rule on Direct Patient Access to Test Results

On February 6, 2014, the Department of Health and Human Services Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention, and Office for Civil Rights (collectively, the Departments) jointly published a [final rule](#) to provide patients with greater access to certain health information (the Final Rule). The Final Rule amends the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to permit CLIA-regulated laboratories to disclose test results to patients. It also makes a corresponding amendment to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule regulations to require laboratories subject to HIPAA to disclose test reports to patients (or their personal representatives) upon request. The purpose of the Final Rule is to enable patients to become more actively involved in their health care by removing barriers to accessing their health information.

CLIA

CLIA regulations are national quality standards for all phases of laboratory testing, including reporting test results. CLIA currently restricts disclosure of a patient's laboratory test results to laboratories that initially requested the test, individuals responsible for using the test results for treatment, and individuals authorized by the state to order or receive such test results. Some states, however, do not permit patients to directly access their own laboratory test results. The Final Rule amends the CLIA regulations to allow CLIA-certified laboratories to provide, upon request, test results directly to a patient, a person designated by the patient or, upon the request of a patient's personal representative, to such a representative.

HIPAA

HIPAA protects the privacy and security of protected health information (PHI). In general, the HIPAA privacy rule permits an individual to obtain a copy of his or her PHI maintained by or for a covered entity in a designated record set. Although HIPAA provides patients and their representatives with a general right to access the patient's PHI held by a covered entity, there are exemptions that pertain to laboratories. Specifically, patients and their representatives have no right to directly access PHI held by covered entities that are exempt from CLIA regulations, or held by a covered entity that is subject to CLIA if the law otherwise prohibits such disclosure. As a result, patients may not have direct access to completed laboratory test results held by HIPAA-covered laboratories. The Final Rule broadens patients' right to access PHI by eliminating the CLIA exceptions. Under the Final Rule, HIPAA-covered laboratories, like other covered health care providers, are required to provide, upon request, completed test reports and other information maintained in a designated record set to patients and their personal representatives in accordance with the right-to-access provisions of the HIPAA privacy rule. This right of access includes information created prior to the effective date of the Final Rule. State laws that prohibit direct access to test results are preempted by the Final Rule's amendments to the HIPAA privacy rule. The Final Rule does not require HIPAA-covered laboratories to *interpret* the results for the patient. Laboratories may instruct the patient to contact the ordering or treating physician with any questions.

The Departments believe that providing greater access to information such as laboratory test results will allow individuals to better manage their health and take proactive measures to prevent and control disease.

The Final Rule becomes effective on April 7, 2014. For HIPAA-covered laboratories, the compliance date

is October 6, 2014.

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