

New Final Rule by CMS (Centers for Medicare & Medicaid Services) Allows Patients Direct Access to Test Results

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On Feb. 3, 2014, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Office for Civil Rights jointly released a final rule allowing patients (or persons designated by the patient) direct access to the results of laboratory tests. The rule amends regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and the **Health Insurance Portability and Accountability Act** (HIPAA) of 1996, both of which restrict patient access to lab results.

While patients can continue to access their laboratory test reports from their practitioners, this new regulation provides patients with the option of obtaining results directly from the laboratory performing the tests. The rule amends CLIA regulations to allow laboratories to give a patient, or the patient's representative, access to the patient's completed laboratory test reports upon request.

In addition to providing direct access to laboratory test results under CLIA, this rule eliminates the exception under HIPAA to an individual's right to access his or her protected health information when it is held by a CLIA-certified or CLIA-exempt laboratory. Under HIPAA, patients, or patient representatives, can access patient protected health information, including an electronic copy, with limited exceptions. Previously, information held by CLIA-certified or CLIA-exempt laboratories was exempt from the requirement that individuals be allowed access to their protected health information.

Scheduled to take effect April 7, any state laws contrary to this final rule will be preempted.

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