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Patients' Right to Access Lab Reports under New CLIA Regulations

In February 2014, the U.S. Department of Health and Human Services (HHS) announced significant changes to the regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the HIPAA Privacy Rule. The new regulations give patients a means of direct access to their own completed laboratory test reports, a move designed to empower patients with more information so they can take an active role in their healthcare.

The CLIA Amendments of 1988 set forth the uniform federal regulatory quality standards for clinical laboratory testing of humans, except for clinical trials and research. CLIA empowers HHS to set the rules for laboratory testing and to certify labs, which authorizes them to conduct tests on specimens derived from humans for the purpose of diagnosis, health assessments, or prevention or treatment of a disease or impairment. CLIA's main objective is to ensure the accuracy, reliability, and timeliness of lab test results regardless of where the test was performed. (Certain types of tests, such as tests approved by the FDA for home use, are granted waivers from many of the CLIA requirements.) The CLIA program, while operated by HHS, is funded through user fees remitted by over 200,000 laboratories.

Before the recent changes, labs subject to CLIA were permitted to disclose test results only to: (1) a person responsible for using the test results in the treatment context; (2) a referring laboratory that initially requested the test; or (3) an "authorized person," defined as an individual authorized under state law to receive test results. State laws vary on the definition of "authorized person," (and some are silent on the issue) and therefore, most patients have only been able to access laboratory test results through their health care provider. Under the new rule, CLIA labs will now be allowed to release test results directly to the patient, the patient's personal representative or a person designated by the patient (as long as the lab can verify this information). However, it is important to note that unless the lab is also a covered entity under HIPAA, the lab is permitted (but not required) to provide patients with access to test reports. In other words, CLIA labs not subject to HIPAA will remain subject to any state laws restricting direct patient access, but will be permitted to disclose results directly to patients in the absence of such state laws. CLIA labs that are covered entities under HIPAA now have the same obligations as other covered health care providers to provide individuals with access to their PHI, including laboratory test results.

There is no requirement in the final rule that the lab interpret the test results for the patient or include any advisories to discuss the results with a physician, but labs are free to include this information with the test results if they so choose.

For more information on state and federal laws related to privacy, see www.healthinfolaw.org/topics/63. For more information about HIPAA, see www.healthinfolaw.org/federal-law/HIPAA. Follow us on Twitter at **@HealthInfoLaw**