HealthInformation & the Law

Myth Busters

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MYTH: Patients must always wait and get their clinical lab test results back from their provider only.

FACT: Under recent changes to CLIA and HIPAA regulations, labs are now permitted, and sometimes required, to provide completed lab test results directly to patients.

Waiting on lab test results has always been a point of frustration for patients because, in most cases, the results had to be delivered to the patient by the medical provider. This required extra time, cost, and sometimes another in-person appointment with the provider just to receive the test results themselves.

But in the era of health reform comes a movement to empower patients to become more involved in their healthcare, which requires access to more information (including one's own lab test results) without the provider acting as an intermediary. To this end, HHS has recently updated the regulations implementing both HIPAA and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to allow labs to release test results directly to patients or their authorized representatives. This represents a major shift in the rules regarding the release of lab test results by enabling patients to access their own information.

Before the revised regulations, labs covered under CLIA (over 200,000 of them) were only permitted to disclose test results 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. Although state laws vary on the issue, this framework over the years has forced most patients to get their test results only from their doctor, including results such as cholesterol levels and the like. Now, labs will be allowed to disclose test results upon request directly to the patient, the patient's personal representative, or a person designated by the patient (once verified by the lab). However, this new pathway is limited by state law – that is, in states that affirmatively restrict direct patient access of lab test results, the CLIA lab must still follow state law. But in states without such restrictions, the lab is now free to disclose the test results directly to the patient or patient representative.

On the other hand, if the lab is also a covered entity under HIPAA and thus subject to the Privacy Rule, the lab *must* disclose test results directly to the patient or patient's representative upon request.

While these new regulations ease access to the lab test results themselves, nothing in the new rules requires the lab to interpret the results for the patient or to provide the patient with any guidance on what to do next (such as discuss the results with your provider). The labs, however, can choose to provide such information to the patients with the release of the test results themselves.

For More Information:

- <u>Learn</u> about state and federal laws related to privacy.
- <u>Read</u> our overview of HIPAA and related resources.

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