



News Release

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HHS strengthens patients' right to access lab test reports

As part of an ongoing effort to empower patients to be informed partners with their health care providers, the Department of Health and Human Services (HHS) has taken action to give patients or a person designated by the patient a means of direct access to the patient's completed laboratory test reports.

"The right to access personal health information is a cornerstone of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule," said Secretary Kathleen Sebelius. "Information like lab results can empower patients to track their health progress, make decisions with their health care professionals, and adhere to important treatment plans."

The final rule announced today amends the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to allow laboratories to give a patient, or a person designated by the patient, his or her "personal representative," access to the patient's completed test reports on the patient's or patient's personal representative's request. At the same time, the final rule eliminates the exception under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule 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. While patients can continue to get access to their laboratory test reports from their doctors, these changes give patients a new option to obtain their test reports directly from the laboratory while maintaining strong protections for patients' privacy.

The final rule is issued jointly by three agencies within HHS: the Centers for Medicare & Medicaid Services (CMS), which is generally responsible for laboratory regulation under CLIA, the Centers for Disease Control and Prevention (CDC), which provides scientific and technical advice to CMS related to CLIA, and the Office for Civil Rights (OCR), which is responsible for enforcing the HIPAA Privacy Rule.

Under the HIPAA Privacy Rule, patients, patient's designees and patient's personal representatives can see or be given a copy of the patient's protected health information, including an electronic copy, with limited exceptions. In doing so, the patient or the personal representative may have to put their request in writing and pay for the cost of copying, mailing, or electronic media on which the information is provided, such as a CD or flash drive. In most cases, copies must be given to the patient within 30 days of his or her request.