February 12, 2014

On Monday, February 3, 2014, the Department of Human Health Services (HHS) issued a final rule permitting, and in some cases requiring, laboratories subject to the Clinical Laboratory Improvement Amendments (CLIA) to provide patients and authorized designees direct access to patients’ completed laboratory test reports. The final rule is consistent with ongoing efforts of HHS to empower patients to be informed about their health care, to be actively involved in treatment decisions and to adhere to treatment plans.

Historically, CLIA required that laboratory tests be disclosed only to (1) an “authorized person,” which is the individual authorized under state law to order or receive the test results, (2) the person responsible for using the test results in the treatment context, and (3) the laboratory that initially requested the test. Patients in states not allowing direct access to laboratory test results had to receive results from their health care providers. Further, the Health Insurance Portability and Accountability Act (HIPAA) contained an exception to its Privacy Rule, specifying that the right of access to protected health information (PHI) did not apply to PHI maintained by a covered entity that was (1) subject to CLIA to the extent the provision of access to the individual would be prohibited by law, or (2) exempt from CLIA (the “HIPAA CLIA Exceptions”).

Although patients can continue to obtain their laboratory results from their health care providers, the final rule eliminates the HIPAA CLIA Exceptions and amends CLIA to allow laboratories to provide patients and their authorized designees direct access to the patient’s completed test reports provided that the laboratory can verify the reports belong to such patients. The final rule, however, does not allow laboratories to interpret test results for patients; thus, laboratories will continue to refer patients to their health care providers for that purpose. Additionally, the final rule permits lab test results to be withheld from patients under limited circumstances (e.g., endangerment situations).

Interestingly, not all states will be impacted by this final rule. States that currently permit test reports to be given to patients or that allow test reports to be given to patients upon the approval of their provider will not be impacted. States that have no current state law governing who may obtain lab test reports will need to comply, and the law in states where lab test results can only be reported to health care providers will be preempted by the final rule because the state law will now be contrary to direct access provisions of HIPAA.

In response to concerns that patients may receive test results without having first discussed them with their physicians, HHS notes that under HIPAA most laboratories will have 30 days to respond to a request for laboratory results, which should provide sufficient opportunity for the ordering or treating physician to obtain and discuss the results with patients. HHS also clarifies that HIPAA-covered laboratories may not require patients to make access requests through their health care providers. Finally, HHS clarifies that laboratories subject to HIPAA must disclose test results in response to requests while labs that are not subject to HIPAA have the discretion to do so, subject to any applicable state law.

The amendments to CLIA made by the final rule take effect on April 7, 2014 and the amendments to HIPAA deleting the CLIA Exceptions take effect on October 6, 2014. HHS notes in the final rule that, “by the
compliance date of this final rule, HIPAA-covered laboratories must revise their [notice of privacy practices] to inform individuals of this right, include a brief description of how to access this right and must remove any statements to the contrary.” Accordingly, laboratories subject to HIPAA should review their notices of privacy practices and related policies and procedures and make indicated changes. Additionally, laboratories should review their state’s requirements regarding the disclosure of laboratory test results to determine the impact of the final rule on that law. For assistance with these matters or questions regarding patient rights to access laboratory test results under CLIA or HIPAA, please contact any member of Honigman’s Health Care Department.