February 4, 2014

On February 3, 2014, the federal government (the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Office for Civil Rights) announced the issuance of a final federal rule providing patients (or a personal/legal representative acting on behalf of the patient) with the right to access completed laboratory test reports directly from laboratories which are required to comply with the Health Insurance Portability and Accountability Act of 1996 and its regulations (a "HIPAA-covered laboratory"). The rule was first proposed in 2011. This new rule is significant in that it allows patients and/or their legal representative direct access to the results of laboratory diagnostic testing – access that, until now, was only allowed in a few states.

While some states in the country previously passed legislation that required laboratories to provide patients with direct access to these reports -- many states prohibited direct access. New York State, in an apparent compromise between the two extremes, took an alternative approach. The current state regulation (found at 10 NYCRR 58-1.8) provides that laboratory test results cannot be reported directly to the patient unless authorization is first provided by the physician, his or her agent, or other person authorized by law to use the results in the conduct of his or her official duties. The new rule will supersede all conflicting state laws, including New York's law.

The new rule amends the federal Clinical Laboratory Improvement Amendments of 1988 ("CLIA") to permit this direct access and it also eliminates the exception under the HIPAA Privacy Rule which denies an individual the right to access his or her protected health information when it is held by a CLIA-certified or CLIA-exempt laboratory.

The new rule will not affect a patient's ability to obtain the laboratory test reports and results directly from his or her physician or other direct treatment health care provider. In fact, many patients may still want to obtain the test reports and results directly from their physicians or other providers as the new rule does not require that laboratories interpret test results for patients. Patients merely have the right to inspect and receive a copy of their completed test reports from the HIPAA-covered laboratory.

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The rule notes that HIPAA-covered laboratories will be required to disclose test reports to patients within thirty (30) days of a request. Since most New York health care providers have to disclose records in less than thirty (30) days under New York Public Health Law Section 18 and other applicable laws, it is possible that such shorter time frames will apply to HIPAA-covered laboratories in the future as well.

The rule, which will be published in the Federal Register on February 6, 2014, also provides that there are an estimated 22,816 laboratories which will be impacted by the individual access provisions of the rule. These laboratories will all need to develop and implement a policy and process to receive and respond to patient requests. HIPAA-covered laboratories will have a total of 240 days after publication (in October, 2014) of the final rule to come into compliance.

If you have any questions about any of these new developments, please contact any attorney of our Firm at 585-730-4773.

This Legal Briefing is intended for general informational and educational purposes only and should not be considered legal advice or counsel. The substance of this Legal Briefing is not intended to cover all legal issues or developments regarding the matter. Please consult with an attorney to ascertain how these new developments may relate to you or your business.

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