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NEW RULES ON DIRECT PATIENT ACCESS TO LABORATORY TEST REPORTS

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A recent federal rule (the "Rule") was finalized amending provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to require clinical laboratories covered under CLIA to make available to patients, upon request, completed test reports. The Rule also amends the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to grant individuals the right to access such reports directly from laboratories without the ordering provider's approval.

Prior to the amendments, a CLIA laboratory could only disclose laboratory test results to three categories of individuals or entities: (1) an "authorized person," (2) the person responsible for using the test results in the treatment context, and (3) the laboratory that initially requested the test. In Texas and other states that did not allow individuals to access their own test results, patients were required to receive their test results through their health care providers. The Rule amends the CLIA regulations and gives an individual (or the individual's personal representative) the right to access, upon request, to the individual's completed test. HIPAA covered entities have until October 6, 2014 to comply with the Rule.

I. THINGS TO KNOW ABOUT THE NEW RULE:

1. The Rule Preempts State Laws Prohibiting Release of Test Reports.

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CHANNELVIEW HUSBAND AND WIFE SURVIVE BREAST CANCER TOGETHER

Juan and Nora Marroquin of Channelview have shared a lot in their 35 years of marriage, including successfully raising two children. However, their knack for sharing goes well beyond the usual—as both have survived breast cancer.

First diagnosed with a cancerous lesion above his left eye in 2012, Juan told his doctor of a suspicious lump around his right breast. Tests later confirmed it, too, was cancer.

Less than a year later after performing a breast self-exam, Nora noticed a suspicious lump in her right breast, which was cancer.

Both were diagnosed and treated at Harris Health System's facilities—Ben Taub Hospital, Lyndon B. Johnson Hospital and Smith Clinic. As if sharing the same cancer diagnosis wasn't enough, both have in common the same date for surgeries—June 20. Juan had his back-to-back surgeries to remove cancerous cells from his forehead and breast in 2012. Exactly a year later, Nora also had surgery to remove cancerous cells from her breast.

Juan and Nora Marroquin

"What are the chances? We thought what a big coincidence," Nora recalls. "We want 2014 to be without any kind of incident."

Juan says, "Maybe we'll win the lottery this time." Nora quickly replies, "We've already won it—we're alive and well."

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The Rule and the CLIA, and HIPAA amendments it finalizes, preempt a number of state laws that prohibit laboratories from releasing test reports directly to individuals or individuals without their ordering provider's approval. Now, under the HIPAA Privacy Rule, all HIPAA-covered laboratories (including primary laboratories, reference laboratories, and hospital laboratories) are required to provide test results upon patient requests, and may provide the results directly to the requesting patients.

2. Who May Access Laboratory Results.

The Rule gives an individual, or the individual's personal representative, the right to request access to their protected health information (PHI) directly from HIPAA-covered laboratories and these laboratories may not require these individuals to make such requests through their providers.

3. Patient Authentication Requirements.

The identity of patients requesting information from laboratories and their authority to request such information must be verified by the laboratory prior to releasing any information. The laboratory may verify a person's authority by asking for documentation such as a health care power of attorney, general power of attorney, durable power of attorney that includes the power to make health care decisions, proof of legal guardianship, or, in the case of a parent, information that establishes the relationship of the person to the minor individual.

4. Transmitting PHI to Another Entity.

Under the Rule, HIPAA-covered laboratories will be required to abide by an individual's request to have the laboratory transmit the copy of the individual's PHI to another person or entity designated by the individual.

5. Deadline for Responding to Information Requests.

Generally, laboratories will be required to provide individuals with access to their laboratory test reports within thirty (30) days of the request. In instances when retrieving records may take longer than thirty (30) days, laboratories may request one thirty (30) day extension as long as the laboratory provides the reason for the delay in writing to the requesting individual.

6. Interpreting Lab Reports.

The Rule does not require laboratories to interpret test results for patients. Patients merely have the right to inspect and receive a copy of their completed test reports and other individually identifiable health information maintained in a designated record set by a HIPAA-covered laboratory.

7. Charges for Producing PHI.

A HIPAA-covered laboratory may charge an individual a reasonable, cost-based fee that includes only the cost of: (1) labor for copying the requested PHI, (2) supplies for creating the paper copy or electronic media; (3) postage, when the individual has requested the copy be mailed and (4) preparation of an explanation or summary of the PHI, if agreed to by the individual.

8. Revising Notices of Privacy Practices.

HIPAA-covered laboratories must revise their privacy practices by October 6, 2014 to inform individuals of their right to access their own test results directly from the laboratory and must include a brief description of how the patient can exercise this right.

II. CONCLUSION.

The newly enacted Rule gives patients greater access to their laboratory records so that these patients may begin taking more active roles in managing their health care. However, the Rule imposes additional regulatory obligations upon HIPAA-covered laboratories. These HIPAA-covered laboratories should begin taking affirmative steps to ensure that they are in compliance with the amended CLIA regulations and Privacy Rules before October 6, 2014, the compliance date of the Rule. ▼