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PROPOSED AMENDEMENT TO RULES GOVERNING PATIENTS' ACCESS TO CLIA TEST REPORTS PATIENTS

On **Wednesday, September 14,** the Department of Health and Human Services ("HHS") issued a notice of proposed rulemaking (the "NPRM") to amend the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") Regulations and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") Privacy Rule to obligate HIPAA-covered laboratories[1] to provide patients with direct access to test reports upon request. This marks a significant departure from the current regulatory scheme, which defers to state law regarding a patient's right of access to laboratory test reports.

Specifically, HHS proposed to amend the CLIA Regulations to specify that, upon request, a laboratory *may* provide a patient with access to completed test reports as long as such reports can be identified as belonging to the patient. Additionally, HHS proposed to amend the HIPAA Privacy Rule to provide individuals the *right* to receive their test reports directly from laboratories by removing the exceptions for CLIA-certified laboratories and CLIA-exempt laboratories from the provision of the Privacy Rule that provides individuals with the right of access to their protected health information ("PHI"). Accordingly, HHS cautioned in the NPRM that while the proposed revisions to the CLIA Regulations provide that a laboratory *may* provide an individual with access to completed test reports upon a patient's request, the term "may" must be read in concert with the proposed revision to the Privacy Rule which removes the exception for CLIA-covered or exempt entities, thereby requiring all covered entity laboratories to provide patients with direct access to test reports.

The NPRM explains the genesis of the proposed changes to the CLIA Regulations and the HIPAA Privacy Rule. In short, the Health Information Technology ("HIT") Policy Committee[2]

[1] Under the HIPAA Privacy Rule, a laboratory, as a health care provider, is only a covered entity if it conducts electronic transactions (e.g., electronic submission of health care claims). The list of HIPAA transactions applicable to providers are: health care claims or equivalent encounter information; coordination of benefits; health care claim status; eligibility for a health plan; referral certification and authorization. If a laboratory conducts a single one of the foregoing transactions electronically, it becomes a covered entity subject to the HIPAA Privacy Rule in connection with all protected health information that it creates or maintains.

[2] The HIT Policy Committee is the federal advisory committee born out of the Health Information Technology for Economic and Clinical Health ("HITECH") Act. The HIT Policy Committee has broad representation from major health care constituencies and provides recommendations to the Office of the National Coordinator for Health Information Technology ("ONC") on issues relating to the implementation of an interoperable, nationwide health information infrastructure. Among its efforts, the HIT Policy Committee has sought to identify barriers to the adoption and use of health information technology.

determined that the CLIA regulations are perceived by some stakeholders[3] as imposing barriers to the exchange of health information. The HIT Policy Committee therefore recommended that the provisions of the HIPAA Privacy Rule that exempt laboratories from HIPAA be removed. Based upon this recommendation, and the determination that direct patient access to laboratory test reports would support the commitments and goals of the Secretary of HHS and the CMS Administrator regarding the widespread adoption of EHRs by 2014, the CLIA staff joined efforts with the ONC, and the CMS Office of E-Health Standards and Services to craft the NPRM.

Proposed Changes to CLIA Regulations

- Expands the right of access to test reports[4] by adding language to specify that upon a patient's request, the laboratory *may* provide access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient.[5]

- Retains existing provisions that provide for release of test reports to "authorized persons" and, if applicable, the individuals (or their personal representative) responsible for using the test reports and, in the case of reference laboratories, the lab that initially requested the test.

- Notably, the proposed amendments to the CLIA Regulations are silent regarding the mechanism by which patient requests should be permitted, processed or responded to by laboratories. The NPRM explains that this latitude is intentional in order to allow patients and their personal representatives' access to patient test reports in accordance with the requirements of the HIPAA Privacy Rule.

- The NPRM should not be interpreted to discourage anonymous testing. The NPRM specifically advises that covered entity laboratories must satisfy the verification requirement of § 164.514(h) before providing an individual with access. Accordingly, where a covered entity laboratory receives a test order with only an anonymous identifier and is unable to identify the individual who is the subject of the test report, the laboratory is under no obligation to provide access.

Proposed Changes to HIPAA Privacy Rule

- Removes exceptions for CLIA-certified and CLIA-exempt laboratories from the provision that provides individuals with the right of access to their protected health information. Accordingly, HIPAA covered entities that are laboratories subject to CLIA or that are CLIA-exempt laboratories (as the term is defined at 42 C.F.R. § 493.2) would have the same obligations as other types of covered health care providers to provide individuals with access to their protected health information in accordance with 45 C.F.R. § 164.524.[6]

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[3] These stakeholders included large- and medium-sized laboratories, some public health laboratories, electronic health record system vendors, health policy experts, health information exchange organizations and healthcare providers.

[4] The regulatory requirements pertaining to laboratory test reports are set forth in 42 C.F.R. § 493.1291. As noted in the NPRM, currently, under § 493.1291(f), the CLIA Regulations limit a laboratory's disclosure of test results to three categories of individuals: (i) the "authorized person," (ii) the person responsible for using the test results in the treatment context, and, (iii) in the case of reference laboratories, the referring laboratory. The CLIA Regulations define "authorized person" as the individual authorized under state law to order or receive test results, or both. See 42 C.F.R. § 493.2. Accordingly, at present in those states that do not provide for individual access to test results, an individual must receive his or her results through the ordering provider.

[5] To accomplish this, the proposed changes would revise § 493.1292(f) and add § 493.1292(l) to the CLIA Regulations.

[6] To accomplish this, the proposed regulatory changes would revise 45 C.F.R. §§ 164.524(a)(1)(i) and (ii) and remove § 164.524(a)(1)(iii).

- By removing the exception for CLIA-certified and CLIA-exempt laboratories from the HIPAA Privacy Rule, covered entity laboratories would be required to have HIPAA compliant policies and procedures in place, including policies and procedures addressing the receipt, processing and response to requests for access. Notably, because the regulations implementing the HITECH Act's changes are not yet finalized, HIPAA covered laboratories will be required to continue to comply with the provisions of the HIPAA Privacy Rule concerning form of access provided and fees as they exist currently and as they are ultimately modified by the final rule implementing the HITECH Act.

Anticipated Effect

The CLIA amendments to the HIPAA Privacy Rule propose to preempt state law in those states that currently maintain laws that prohibit a laboratory from releasing a test report directly to the patient or that prohibit the release without the ordering provider's consent. HHS concludes in the NPRM that the proposed amendments, if finalized, would impact only those 39 states and territories where state law does not permit the laboratory to provide test reports directly to the patient. According to HHS, for those laboratories in the remaining 16 states and territories where the laboratory is currently allowed to provide the test report to the patient either directly or after provider approval, there is no impact based on the proposed amendments.

As some readers may know, clinicians have mixed views on this issue, and some maintain that diagnostic test results are best delivered through the patient's physician who can review, interpret and explain, as needed, the impact of such results to the patient. It may be worth noting, however, that while the CLIA amendments might remove legal barriers to a patient gaining access to such lab results, the CLIA amendments remain silent as to the *process*, including *timeframes*, pursuant to which a patient must be afforded such access. Therefore, presumably, a covered entity would continue to be required to respond to patient's access request within the 30 day timeframes allowed under HIPAA, unless applicable state law requires a shorter timeframe for response, or unless a provider is aiming to meet the much shorter timeframes (i.e., 3 business days) under Meaningful Use for affording a patient with access to his/her diagnostic tests.

If finalized, HIPAA-covered laboratories would be required to comply with revised § 164.524 no later than 180 days after the effective date of the final regulation (240 days after publication). A full copy of the proposed amendments to the CLIA Regulations and HIPAA Privacy Rule can be located at http://www.gpo.gov/fdsys/pkg/FR-2011-09-14/pdf/2011-23525.pdf.

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