Law Changes Patient Access to Clinical Lab Reports

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The US Department of Health and Human Services (HHS) continues to look for avenues to allow greater patient access to their own health information so that they may be more active in their healthcare management. HHS recently created final rules that remove the Clinical Laboratory Improvement Amendments (CLIA) regulatory barriers and HIPAA exceptions for CLIA-certified laboratories and CLIA-exempt laboratories as a way to expand patient ability to view and participate in their own care. CLIA prohibits the release of laboratory test results directly to the patient. A patient can only receive results directly from the ordering provider.

New Final Rule Now Effective

On April 7, 2014 a HHS final rule, "CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports" became effective. The rule has a mandatory implementation date of October 6, 2014 and impacts two federal rule sets, with implications for both CLIA-certified and CLIA-exempt laboratories. This final rule amends the CLIA regulations for patient or authorized personal representative access to their laboratory test reports directly from clinical laboratories subject to CLIA. The final rule leaves in place the existing CLIA language requiring the release of lab reports only to authorized persons and, if applicable, to the persons responsible for using them or to the laboratory that initially requested the test.

In addition to the CLIA regulation amendment, the final rule amends the HIPAA Privacy Rule to provide individuals (patients) and their designees the right to access and direct where to send copies of their protected health information (PHI), such as lab reports directly from the lab that performed the test. Since this amendment applies to labs subject to HIPAA, most clinical laboratories in the United States will need to comply. Clinical laboratories that are not subject to HIPAA will not be under any federal obligation to provide access or copies directly to individuals, but they will be permitted to do so under federal law.

Many Hospital Labs Already Compliant

At present many clinical labs are located within or as a part of organizations such as hospitals or surgery centers that also provide care other than laboratory services and are typically operated with more formal HIM processes that routinely perform release of information (ROI). Hospitals can continue to require requests for copies to come in through the HIM department, whether via a portal or other HIPAA compliant mechanisms already in place. These organizations will not see a change in their ROI operations, although they should update their HIPAA and CLIA compliance program documentation and Notice of Privacy Practices (NPP) to reflect the update.

For clinical laboratories that do not already have a formal record request or copy policies and procedures in place, care must be taken to get them implemented by the October 6, 2014 compliance deadline. The ROI requirements and best practices necessary for safely and securely managing patient record requests can be confusing due to their complex nature. AHIMA has made its HIM Body of Knowledge tools available to assist in the management of ROI processes.

A New Line of Service

HIPAA rules place emphasis on individuals receiving access to, and copies of, their PHI. An important means to reduce liability is to avoid barriers in the provision of these services. Instead, healthcare organizations must be open and make it easy for the patient to request and have their copies delivered. For example, laboratory administrators should make sure a patient has the means to make a records request through a web portal. This also applies to a patient's representative. It seems likely that the Office for Civil Rights (OCR) would find that kind of service provision a favorable factor in an investigation or audit.

State Law Adds Complexity

Although the new final rule preempts many state laws regarding the provision of copies of PHI from clinical laboratories directly to individuals, there are complications. For example, record copy fees may be set by the state. Clinical laboratories within each state will have to balance which state laws may be preempted from those that are not as they define their processes for ROI and the fees that are allowed to be charged. Under the HIPAA Privacy Rule, state laws can set medical record copy fees that are considered reasonable and can be implemented, as long as they do not include fees forbidden by HIPAA.

How HIPAA is Impacted

The removal of the clinical laboratory exception in HIPAA aligns clinical laboratories with the requirements other covered entities are subject to within HIPAA for record disclosure. Although the typical individual request will be for access or copies of laboratory test results, the rules that now apply to laboratories allow for the requests to be subject to the HIPAA designated record set (DRS) rules. A clinical laboratory's DRS probably includes a more expansive scope of information than only laboratory test results. The DRS might include billing and insurance information depending upon the definition created by each organization. Each clinical laboratory implementing ROI to satisfy the access and copy rules should evaluate and document their designated record sets as a part of their policy creation.

Under the final rule clinical laboratories will have the same HIPAA-required 30-day response limit requirement. Under HIPAA, a request must be responded to within 30 days of receiving the request. There is a specific exception granted if the test results take longer than 30 days to generate due to laboratory processing. As long as HIPAA-based access processes such as patient notification are followed, these requests do not have to be fulfilled. The comments within the rules assert that 30 days is enough time for the ordering physician to receive the results and review them with the patient prior to the laboratory distributing the copies. Laboratories are specifically not required to interpret the results of their tests for the requestor.

As with all HIPAA requests, proper requestor identification and care in the disclosure process is required. The risk of liability is higher for organizations that provide access to and disclosure of PHI due to both HIPAA and state breach laws. This also means that breach determination policies and procedures must be up-to-date and operational in order to keep organizational liability as low as possible. As with all the HIPAA rules, there is no exception for mental health or other highly sensitive patient health information (i.e., sexually transmitted diseases) access or disclosure.

Currently, under the HIPAA Omnibus Final Rule, the right to access applies to the delivery of copies to the individual or their designated recipient in both paper and electronic formats. Clinical laboratory records in both paper and electronic formats are now equally subject to HIPAA access and disclosure requirements.

E-mailing lab results is allowed as stated in HIPAA, but must be encrypted for transit and at rest in order to be considered within the breach safe harbor. However, e-mail does not have to be encrypted if the patient wishes to receive it in an unencrypted form and the lab (or other department managing the disclosure) informs the patient of the risks. Whether or not to encrypt e-mail is always an issue that requires careful consideration, though it is strongly recommended.

Notice of Privacy Practices Must Be Updated

Covered entities are required to provide individuals with details about how to access and get copies of their PHI through the Notice of Privacy Practices (NPP) document. Impacted covered entities that have the CLIA exception language within their NPP must be updated. This rule has modified the HIPAA Omnibus Final Rule required date for a NPP update; both the CLIA Amendment and Final Rule changes have to occur by October 6, 2014. They can be modified together and only once as long as it is completed by this date. CLIA laboratories need to provide patients access to and copies of their NPP in the same manner as all other entities subject to HIPAA. If the clinical lab has a website, it should also post a copy of their NPP.

With the deadline for the new CLIA regulatory amendment and removal of the HIPAA exception occuring October 6, laboratories should have already begun to perform gap analyses to identify areas that need to be addressed and implement the necessary policies, procedures, and forms.

Reference

US Department of Health and Human Services. "CLIA Program and HIPAA Privacy Rule; Patients' Access to Reports." *Federal Register* 79, no. 25 (February 6, 2014): 7289-7316. https://federalregister.gov/a/2014-02280.

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