

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-11-CLIA

DATE: February 7, 2014

TO: State Survey Agency Directors

FROM: Thomas Hamilton, Director
Survey and Certification Group

SUBJECT: Publication of Final Rule “**Clinical Laboratory Improvement Amendments (CLIA) Program and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule; Patients’ Access to Test Reports**”

Memorandum Summary

- **Goal:** To support the commitment of the Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), and the Office of Civil Rights (OCR) that patients should have access to their personal health information, including access to their laboratory test reports.
- **Notice of Final Rule:** CMS-2319-F was published in the Federal Register on February 6, 2014.
- **CLIA regulations:** The regulations at §493.1291(f) have been revised by replacing the phrase “individual responsible” with “persons responsible.” A new regulation has been added at §493.1291(l) to specify that, upon a request by a patient (or the patient’s personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory’s authentication process, can be identified as belonging to that patient.
- **HIPAA Privacy Rule:** The rule was amended at 45 CFR §164.524 to remove the exceptions that relate to CLIA and affect an individual’s right of access. This change preempts any contrary provisions of State law.

Background

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) were enacted by Congress to establish quality standards for certain laboratory testing. These standards ensure the accuracy, reliability and timeliness of patient test results, regardless of where the test is performed.

CLIA covers all phases of laboratory testing, including the reporting of test results. The CLIA-based limitations that govern to whom a laboratory may issue a test report are a concern in the current climate of health care reform. These limitations may affect one of the primary goals of health care reform, that of patients having control over their personal health information.

CLIA previously limited a laboratory's disclosure of test results to three categories of individuals: "authorized persons," the individual responsible for using the test results, and the laboratory that initially requested the test. Authorized person is defined in 42 CFR §493.2 as "an individual authorized under State law to order tests or receive test results, or both." In States that did not provide for an individual (or their personal representative) to have direct access to their test results, the individual (or personal representative) had to request and receive test results through the ordering provider.

The HIPAA Privacy Rule provided for the establishment of national standards to protect the privacy and security of personal health information and previously included exceptions related to CLIA and CLIA-exempt laboratories. These exceptions were: right of access under §164.524 of the Privacy Rule did not apply to protected health information maintained by a covered entity that is either subject to CLIA to the extent the provision of access to the individual would be prohibited by law, or exempt from CLIA. These exceptions have been removed from the Privacy Rule as the changes to the CLIA regulations do not warrant inclusion of these exceptions.

CLIA Regulatory Changes

The following changes have been made to the CLIA regulations at §493.1291 Standard: Test report:

- §493.1291(f) revised to read "Except as provided in §493.1291(l), test results must be released only to authorized persons and, if applicable, the persons responsible for using the test results and the laboratory that initially requested the test."
- A new regulation added as §493.1291(l) stating "Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient."

HIPAA Regulatory Change

Concurrent with the changes to the CLIA regulations, OCR has:

- Amended the Privacy Rule at 45 CFR §164.524 to remove the exceptions that relate to CLIA and affect an individual's right of access.

Summary

Because CMS has amended the CLIA regulations at §493.1291 to allow CLIA-certified laboratories to provide patients with direct access to their test reports, there is no longer a need for the exceptions for CLIA and CLIA-exempt laboratories found at §164.524 of the HIPAA Privacy Rule. The change to §164.524 preempts any contrary provisions of State law and aligns the changes to the Privacy Rule and CLIA regulations with the Department's goal of improving individual's access to their health information. However, with respect to a State law pertaining to an individual's right to access his or her protected health information, a State law is more stringent than the Privacy Rule if the State law "permits greater rights of access or amendment, as applicable" (§160.202).

The final rule can be downloaded at: <http://www.gpo.gov/fdsys/pkg/FR-2014-02-06/pdf/2014-02280.pdf>

For questions related to this memorandum, please contact Karen Dyer (karen.dyer@cms.hhs.gov) or Daniel Cajigas (daniel.cajigas@cms.hhs.gov) at 410-786-3531.

Attachment

- FAQ list for assistance with understanding the changes to CLIA and the HIPAA Privacy Rule.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Frequently Asked Questions
CMS-2319-P: Patients' Access to Test Reports

1. What are the changes to the CLIA regulations at 43 CFR §493.1291?

The rule includes the following changes to the CLIA regulations at 43 CFR §493.1291:

43 CFR§493.1291(f) has been amended as follows: Except as provided in §493.1291(l), test results must be released only to authorized persons, and, if applicable, the persons responsible for using the test results and the laboratory that initially requested the test.

A new provision has been added as §493.1291(l) that reads: Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient.

2. From whom can patients access or receive their laboratory test reports under CLIA/HIPAA?

Patients will be able to request and receive their test reports directly from any laboratory that is a HIPAA covered entity. A laboratory is a covered entity if it conducts one or more covered transactions electronically. Covered transactions include transmitting health care claims or equivalent encounter information to a health plan, requesting prior authorization from a health plan, or sending an eligibility inquiry to a health plan to confirm a patient's coverage under the plan.

Laboratories that do not conduct any of these or other HIPAA standard transactions electronically are not subject to the HIPAA Privacy Rule (45 CFR Parts 160 and 164, subparts A and E).

Patients can continue to request and receive their test reports through their health care provider or by being specified by the ordering provider as an additional recipient on the laboratory test requisition.

3. What do the changes to the CLIA regulations at §493.1291 mean for laboratories?

The changes to §493.1291 allow an individual or an individual's personal representative to receive completed test reports directly from the laboratories upon request. Laboratories will need to identify the test reports as belonging to the individual by using their authentication processes.

4. What do the changes to the HIPAA Privacy Rule at §164.524 mean for CLIA laboratories?

The rule removed the exceptions to an individual's right of access for CLIA and CLIA-exempt laboratories currently found in the HIPAA Privacy Rule. As a result, HIPAA

covered entities that are laboratories subject to CLIA have the same obligations as other types of covered health care providers with respect to providing individuals with access to their protected health information.

5. **Since laboratories vary greatly in terms of how they interact with individuals that request access to their laboratory test reports, is there any flexibility in how requests for access to test reports can be submitted, processed and responded to by laboratories?**

This rule provides laboratories with flexibility as to how to set up systems to receive, process, and respond to access requests. These processes must comply with the requirements for access in 45 CFR § 164.524 of the HIPAA Privacy Rule, which addresses HIPAA-covered laboratories

6. **Do the changes to CLIA and the HIPAA Privacy Rule affect State laws?**

The HIPAA Privacy Rule previously included a set of exceptions related to CLIA. The right of access under §164.524 of the HIPAA Privacy Rule did not apply to protected health information maintained by a covered entity that was: subject to CLIA to the extent the provision of access to the individual would be prohibited by law, or exempt from CLIA. These exceptions were included in the HIPAA Privacy Rule to avoid a conflict with the CLIA requirements that limited patient access to test reports.

Under this rule, CMS has amended the CLIA regulations to allow CLIA-certified laboratories that are HIPAA covered entities to provide patients with direct access to their test reports. Thus, there is no longer a need for the exceptions at §164.524 for CLIA and CLIA-exempt laboratories.

Because the exceptions have been removed, §164.524 of the HIPAA Privacy Rule will preempt any contrary provisions of State law. A provision of State law is “contrary” to a provision of the HIPAA Rules if a covered entity would find it impossible to comply with both the state and federal requirements; or the provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Social Security Act or section 254 of Pub.L.104-191, as applicable.

Pursuant to section 264(c)(2) of HIPAA, the HIPAA Privacy Rule included an exception from this general preemption if “the provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.” However, with respect to a State law pertaining to an individual’s right to access his or her protected health information, a State law is more stringent than the Privacy Rule if the State law “permits greater rights of access or amendment, as applicable” (§160.202).

A number of States have 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.

The changes to §164.524 preempt any contrary State laws that prohibit the HIPAA-covered laboratory from directly providing access to the individual.

7. **Must a laboratory have an electronic health record (EHR) system, patient portal or be a part of a health information exchange (HIE) to meet this new requirement for patient access to test results?**

A laboratory does not need to have an EHR system, patient portal or be a part of an HIE to meet the requirement for patient access to test results. However, we would anticipate that as EHRs, portals and HIEs become more commonplace, laboratories will develop processes to handle patient requests via these systems.

8. **There are concerns regarding the laboratory giving individuals their laboratory test reports without the individual having the benefit of health care provider interpretation. Patients will not necessarily have the contextual knowledge to read and understand the reports they receive. Laboratories feel they may be required to interpret test reports for patients.**

This rule does not diminish the role of the health care provider in interpreting the laboratory test reports for his/her patient in the context of the patient's medical condition. We expect that individuals will continue to obtain their test reports and the interpretation of those test reports from their health care provider.

Laboratories are required to provide individuals with access to their completed test reports. **The rule does not require laboratories to interpret test reports.** Laboratories can refer an individual back to their health care provider for this information.

9. **Who can have access to an individual's sensitive laboratory test reports? An individual may not want a parent, spouse, partner or other person to see their test reports.**

An individual has generally been granted an absolute right to access his or her own completed laboratory test reports when those reports are held by a HIPAA-covered laboratory. The only persons other than the individual that have a right to access such test reports directly from a HIPAA-covered laboratory are those persons who qualify as a person designated by the individual in accordance with the HIPAA Privacy Rule at §164.524(c)(3)(ii) or a "personal representative" of the individual. For the purposes of the Privacy Rule, a "personal representative" is defined at 45 CFR § 164.502(g) and, in certain contexts, includes a person who has authority under applicable law to make health care decisions for the individual. Such authority is generally determined under state law. HIPAA-covered laboratories are required under 45 CFR § 164.514(h) of the Privacy Rule to verify both the identity and authority of the person requesting an individual's protected health information.

10. **Will laboratories be permitted to charge individuals who request copies of test reports a fee for providing access?**

As provided by the HIPAA Privacy Rule in 45 CFR § 164.524, HIPAA-covered laboratories can charge individuals a reasonable, cost-based fee that includes only the cost of labor and supplies for creating the paper or electronic copy; postage, if the results are mailed; and if requested, the preparation of an explanation or summary of the individual's protected health information. HIPAA-covered laboratories can't charge fees to reflect the costs they incur in searching for and retrieving the information related to the individual's request.

11. **Do the new rules have any impact on the Medicare and Medicaid EHR Incentive Program meaningful use program?**

Under meaningful use, many EHR systems include patient portals which allow patients direct access to their health information, including laboratory results. In addition, state, local, regional, and payer-based health information exchanges (HIEs) allow providers, including laboratories, to securely share patient information both between providers and, in some cases, with patients.

If a laboratory shares a patient's lab results with a provider's EHR through an HIE, or directly, that information can be incorporated automatically into the patient record and, usually with physician approval, made available on the PHR or sent to a patient's secure email address. Providers (or PHR systems automatically) may also send patients email notifications that there is new data available in the PHR/portal, reminding them to log in and review their lab results.

These technologies not only facilitate patient access to lab information, but can make it easier for lab providers to share that information securely and at little or no cost.