CLIA Program and HIPAA Privacy Rule; Patients’ Access to Test Reports

Summary of Final Rule

[CMS-2319-F]

I. Introduction

On February 3, 2014, the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the Office for Civil Rights (OCR), hereafter referred to as the collaborating offices, jointly placed on public display a final rule under which patients could gain direct access to laboratory test reports, upon their request. This necessitates changes to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. This final rule is published in the February 6, 2014 issue of the Federal Register (79 FR 7290-7316).

The related proposed rule was published in the September 14, 2011 issue of the Federal Register. The collaborating offices say they received 160 timely comments. The final rule adopts the proposed changes to both the CLIA regulations and the HIPAA Privacy Rule, with minor clarifications and conforming changes.

The final rule is effective April 7, 2014. However, HIPAA covered entities must comply with the Privacy Rule changes adopted in the final rule by October 6, 2014 (240 days after the date of publication in the Federal Register), which includes the need to make revisions to their notices of privacy practices.¹

II. Background

CLIA regulations (§493.1291(f)) have limited a laboratory’s disclosure of laboratory test results to three categories of individuals: the “authorized person” (defined as the individual authorized under State law to order or receive test results, or both), the person responsible for using the test results in the treatment context, and, in the case of reference laboratories, the referring laboratory.

Further, under the HIPAA Privacy Rule, an individual’s right of access to his or her protected health information has not applied to test reports at CLIA and CLIA-exempt laboratories. In the proposed rule, the collaborating offices asserted that “the provision of direct patient access to laboratory test reports would support the commitments and goals of the Secretary of [Health and Human Services] HHS and the CMS Administrator regarding the widespread adoption of [electronic health records] EHRs by 2014.”

¹ The collaborating offices emphasize that the final rule does not alter the requirements for what makes a laboratory a HIPAA covered entity.
III. Provisions of the Final Regulation

The final rule revises the CLIA regulations to specify that, upon request by a patient (or the patient’s personal representative), the laboratory may provide access to completed test reports that, using the laboratory’s authentication processes, can be identified as belonging to the patient. More specifically, the regulation text reads as follows:²

§493.1291 Standard: Test report.

(f) 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.

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(l) 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.

Note that while the regulation text uses the word “may,” the collaborating offices emphasize that the accompanying change to the HIPAA Privacy Rule will mean that covered entity laboratories (that is, those laboratories conducting HIPAA transactions, such as health care claim status or eligibility for a health plan, electronically) will be required to provide patients with access to test reports. In effect, this change to the HIPAA Privacy Rule removes the existing exception to an individual’s right of access to his or her protected health information noted above. All of this means that CLIA-certified laboratories that are not HIPAA covered entities will not be required to provide patients with direct access to laboratory reports but would be free to do so.

IV. Analysis of and Responses to Public Comments

A. Right of Direct Access to Laboratory Test Reports (79 FR 7292)

The collaborating agencies acknowledge that a number of providers and laboratories expressed concerns about giving individuals a way to receive laboratory test reports without the benefit of provider interpretation and without contextual knowledge that may be necessary to properly read and understand the reports. However, they note that a number of studies have found that

² The regulatory text in the final rule differs from that in the proposed rule but is not materially different in its result.
physician practices failed to inform patients of abnormal test results about 7 percent of the time. Further, they expect that patients will continue to obtain test results and advice about what those results mean through their ordering or treating physician. They also agree with commenters who believe that the final rule will further encourage ordering and treating providers to more proactively discuss with patients the range of possible test results and what the results may mean for the particular patient before or at the time the test is ordered.

Also, since the Privacy Rule will generally allow laboratories up to 30 days to provide requested test reports (with a possible further extension of 30 days), the collaborating offices argue that in cases where an individual requests access to a completed test report, 30 days will generally be sufficient to allow the ordering or treating provider to receive the test report in advance of the patient, communicate the result to the patient, and counsel the patient as necessary with regard to the result. While not acknowledged, this could place laboratories in the unenviable position of having to decide whether to hold some or all requested test reports for the full 30 days in order to provide an adequate amount of time for this physician intervention to take place.

In response to comments, the collaborating offices clarify that the final rule does not require that laboratories interpret test results for patients. They also reject comments arguing that HIPAA-covered laboratories should be permitted, but not required, to provide individuals with access to their test reports, in part because a rule that only permitted access would not preempt those state laws that prohibit direct access. They also reject comments asking that the rule not apply to hospital reference laboratories, arguing that applying the access requirements as broadly and uniformly as possible best furthers the Department’s goal of increasing direct individual access rights to health information. However, the collaborating offices add that they expect most individuals will continue to request access to their health information from their treating provider or the referring laboratory, and not from the reference laboratory itself.

B. Scope of Information to Which an Individual Has Access (79 FR 7294)

The collaborating offices acknowledge that a number of commenters indicated that the rule should apply only to tests administered after the final rule is published or becomes effective but reject these comments. They add that in cases where retrieving records that have been archived may take longer than 30 days from the individual’s request, a covered laboratory may request one 30-day extension if it provides the reason for the delay in writing to the requesting individual. They also clarify that the final rule does not impose any new record retention requirements for laboratory test reports, but does apply for as long as the laboratory maintains the information, even in those cases where the information is maintained beyond the applicable record retention requirements.
The final rule notes that to the extent an individual requests access to all of his or her protected health information, a HIPAA-covered laboratory is required to provide access to all of the protected health information in the entire designated record set, which could include such items as completed test reports, test orders, ordering provider information, billing information, and insurance information. However, the collaborating offices say they do not expect many individuals will request access to all of the protected health information about the individual that the laboratory may hold. They also clarify that they do not consider test reports to be part of the designated record set until they are “complete” (that is, “when all results associated with an ordered test are finalized and ready for release”). Thus, if an individual is informed that a requested test report will take more than 30 days to complete and persists in requesting the test report, the individual would only have the right to obtain the protected health information in the designated record set at the time the request is fulfilled, “which may not include a particular test report because it is not yet complete.”

In response to commenters concerned about providing direct access to “sensitive” test reports, including genetic, cancer, pregnancy, sexually-transmitted disease, and mental health test results, the collaborating offices say that the only exception to direct access would be for cases where a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person, and the individual is provided a right to have the denial of access reviewed by an unaffiliated health care professional. They also agree with commenters who stated that categorizing laboratory testing into “sensitive” and “non-sensitive” categories would be a subjective endeavor that would not necessarily result in policies that are in patients’ best interest. However, once again, the collaborating offices note that the 30 day time-frame (plus one 30-day extension) provides laboratories with sufficient time to ensure treating or ordering physicians receive test reports before the patient does, which will allow them to counsel the patient with respect to the test result.

In response to comments, the collaborating offices note that:

- CLIA does not apply to test results that are only used for epidemiological studies or reported in the aggregate without patient identifiers;
- CLIA regulations are not applicable to an employer or entity that performs substance abuse testing strictly for the purpose of employment screening where the test results are merely used to determine compliance with conditions of employment, as opposed to counseling or some other form of treatment (but an individual might nonetheless have a right to access protected health information, including the results of alcohol or drug tests, from a HIPAA-covered laboratory);
- Food, environmental, or other test reports that do not identify or relate to an individual are not protected health information for purposes of the HIPAA Privacy Rule; and
- CLIA regulations do not cover radiologic testing or assessments (but these tests and assessments have always been subject to an individual’s right of access under the HIPAA Privacy Rule to the extent they are maintained by a hospital or other HIPAA covered entity).

C. Access by Personal Representatives and Designated Third Parties (79 FR 7297)

The final rule notes that with respect to adult individuals, the only persons that have a right to access an individual’s test reports directly from a HIPAA covered entity (other than the individual) are those persons who qualify as a personal representative of the individual, which generally means a person who has authority under applicable law to make health care decisions for the individual. Since the Privacy Rule will require HIPAA-covered laboratories to verify both the identity and authority of the person requesting access to an individual’s protected health information, the final rule adds that such laboratories may need to obtain documentation, such as a written health care power of attorney or, general power of attorney or durable power of attorney that includes the power to make health care decisions, or other evidence of the person’s authority to act as a personal representative.

With respect to an unemancipated minor, the final rule says that a parent is the personal representative of the minor in most cases. However, the final rule adds that there are limited exceptions in the HIPAA Privacy Rule to the parent being a personal representative of his or her minor child, which generally apply in circumstances where minors are able to obtain specified health care services without parental consent, with the Privacy Rule deferring to state or other applicable laws that expressly address the ability of the parent to obtain health information about the minor child.

The final rule also notes that §164.502(g)(5) of the Privacy Rule allows a covered entity to elect not to treat a person as the personal representative of an individual if the covered entity has a reasonable belief that the individual has been or may be subjected to domestic violence, abuse, or neglect by the person, and the covered entity, in the exercise of professional judgment, decides that it is not in the best interests of the individual to treat the person as the individual’s personal representative.

In response to comments, the final rule also clarifies that, in certain circumstances, an individual’s access right includes the right to have test reports shared with others who do not have independent access rights. Thus, upon the compliance date of the final rule, HIPAA-covered laboratories will be required to abide by an individual’s request to have the laboratory transmit a copy of the individual’s protected health information to another person or entity designated by the individual. In this regard, the final rule notes that the Privacy Rule requires that such requests must be in writing, signed by the individual, clearly identify the
designated person or entity, and provide information regarding where to send the copy of the protected health information.

The final rule also rejects comments seeking exemption for organ procurement organization laboratories that perform tests on decedent tissue and blood.

**D. Requests for and Provision of Access** *(79 FR 7299)*

As originally proposed, the final rule allows flexibility in how requests for access to laboratory test reports may be submitted, processed, and responded to by laboratories. The final rule also notes that where a HIPAA-covered laboratory can continue to comply with both the HIPAA Privacy Rule and state law, it must frame its policies and procedures in a way that complies with both laws. The final rule emphasizes that the HIPAA Privacy Rule does not preempt more stringent state laws, even if contrary to the Privacy Rule (with “more stringent” meaning that the state law provides greater rights of access, such as access to test reports within a shorter timeframe).

In response to comments, the collaborating offices say that laboratories that operate as part of a larger legal entity that is a hospital or that are part of an affiliated covered entity or organized health care arrangement with a hospital may continue to utilize the hospital’s already established mechanisms for providing access to individuals requesting their laboratory test reports, provided that the established mechanisms are compliant with the access provisions of the HIPAA Privacy Rule. The final rule also makes clear that laboratories may not require individuals to make requests through their providers.

With respect to the time frame for providing access, the final rule rejects comments requesting a defined delay or lag time, such as 48 or 72 hours, between when a laboratory provides a test report to a treating provider and when the laboratory provides the test report to the patient, and also rejects comments recommending that completion of the test report be used as the trigger for beginning the 30-day period for response. The final rule adds that in cases where the end of the initial 30-day period after an individual’s request for access to a test report is approaching and, due to the nature of the test, the laboratory is just completing the test report, the laboratory may delay providing access to the individual to ensure the completed test report is provided first to the individual’s provider, so long as the delay is not more than 30 days and the individual is informed in writing of the reason for the delay and the date by which the laboratory will provide the individual with access.

**E. Allowable Fees for Copying** *(79 FR 7300)*

The final rule makes clear that a HIPAA-covered laboratory may charge an individual a reasonable, cost-based fee that includes only the cost of: (1) labor for copying the protected health information requested by the individual, whether in
paper or electronic form; (2) supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media; (3) postage, when the individual has requested a copy be mailed; and (4) preparation of an explanation or summary of the protected health information, if agreed to by the individual. In contrast, such laboratory may not charge fees to reflect the costs it incurs in searching for and retrieving the information, or for costs associated with verification, documentation, liability insurance, maintaining systems, and other similar activities.

**F. Form and Format of Access (79 FR 7301)**

In response to comments, the final rule emphasizes that the Privacy Rule does not require that a HIPAA-covered laboratory have the capability to produce a copy of a completed test report in whatever electronic format or manner the individual requests. However, where an individual requests an electronic copy of test reports that a HIPAA-covered laboratory maintains only on paper, the laboratory must provide the individual with the type of electronic copy requested if it is readily producible electronically and in the format requested. On the other hand, if, for example, a laboratory could provide a scanned PDF version of the report but not the requested Word version, it could offer the PDF version. However, if the individual declines to accept the PDF version, or if the laboratory is not able to readily produce a PDF version of the test reports, the laboratory may provide the individual with hard copies of the reports, such as photocopies of the original reports.

The final rule also notes that the HIPAA Privacy Rule does not require covered entities to maintain patient portals (for accessing protected health information, including laboratory test reports). In response to a comment, it also states that providing an individual with an electronic copy of a test report in a proprietary format that will require the purchase or acquisition of proprietary software would not satisfy the applicable access requirements.

With respect to information security issues, the final rule notes that in e-mailing copies of test reports to individuals, HIPAA-covered laboratories must comply with the HIPAA Security Rule, which, among other things, requires implementation of technical security measures to guard against unauthorized access to electronic protected health information. Nonetheless, the final rule makes clear that a HIPAA-covered laboratory is permitted to send an individual copies of test reports via unencrypted e-mail, if it advised the individual of the risks associated with unencrypted e-mail and the individual persists in wanting the information sent in that manner. The final rule also notes that a HIPAA-covered laboratory is not responsible for any unauthorized access that may occur while protected health information is in transit using the means requested by the individual, nor for safeguarding the information once it is delivered to the individual.
G. Content of Test Report, Educational Materials, and Standard Statements
(79 FR 7302)

The final rule makes clear that laboratories are not required to interpret test reports for individuals, but that they may nonetheless provide additional educational or explanatory materials.

The final rule rejects comments recommending that laboratory test reports provided to individuals be accompanied by a standard statement explaining the limitations of the laboratory data alone in confirming or ruling out a diagnosis, explaining that the laboratory results are subject to a physician’s interpretation, and encouraging the individual to discuss the results with his or her physician, and by contact information for the physician who ordered the tests. However, once again, the collaborating offices say laboratories that wish to include such a standard statement are free to do so.

H. Verification of Identity and Authentication (79 FR 7303)

In response to commenters worried about the challenges laboratories would face in verifying an individual’s identify (because they often have no direct interaction with the individual and any contact information they receive from a health care provider can be incomplete or incorrect), the final rule notes that the Privacy Rule requires reasonable steps to verify an individual’s identity but leaves the type and manner of the verification to the discretion and professional judgment of the covered entity. It adds that a HIPAA-covered laboratory may not impose unreasonable verification measures as a means to avoid having to provide an individual with access to laboratory test reports.

I. Informing Individuals of Their New Right of Access (79 FR 7303)

In response to comments, the collaborating offices says they encourage, but do not require, treating health care providers to inform individuals of their right to receive test reports directly from HIPAA-covered laboratories. Similarly, they encourage, but do not require, providers to supply the individual with the name of the laboratory to which the specimen is being or had been sent and the other information necessary for the individual to request access from the laboratory.

On the other hand, the final rule will require HIPAA-covered laboratories to revise their notices of privacy practices to inform individuals of their new access right to laboratory test reports, include a brief description of how to exercise this right, and remove any statements to the contrary. This must be done by the compliance date of the final rule. The final rule reminds readers of a September 19, 2013 announcement that HHS was exercising its enforcement discretion to allow CLIA laboratories (including CLIA-exempt laboratories) that are HIPAA-covered entities to modify their notices of privacy practices by the compliance date of this final rule to comply with both a January 25, 2013 final rule and this
final rule. This obviated the need for such laboratories to modify their notices of privacy practices twice.

J. Preemption (79 FR 7304)

The proposed rule acknowledged that 20 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 final rule confirms that these laws will be preempted. However, the collaborating offices clarify that the final rule applies only to laboratories; thus, state laws that place requirements on other types of health care providers, such as those requiring a provider to discuss with and counsel a patient on HIV test results, are not preempted by the final rule. In addition, the collaborating offices note that the final rule does not impose any requirement or establish any permission in regard to a laboratory initiating contact with an individual for purposes of communicating test results.

K. Compliance Date (79 FR 7304)

As noted earlier, HIPAA-covered laboratories will have a total of 240 days after publication of the final rule to come into compliance with the changes made to the HIPAA Privacy Rule, and the collaborating offices decline to provide additional time as requested by a number of commenters.

L. Other Comments (79 FR 7305)

In response to miscellaneous comments, the collaborating offices:

- Note that a covered entity may not withhold or suspend an individual’s right under the HIPAA Privacy Rule to access his or her protected health information because the individual has not paid the covered entity for the health care services provided; and
- Decline to impose a requirement that laboratories notify the ordering provider when a patient has received, or will receive, copies of test reports directly from the laboratory.

V. Collection of Information Requirements (79 FR 7305)

The collaborating offices note that they did not receive any Paperwork Reduction Act (PRA)-related comments in response to the September 2011 proposed rule. Thus, the final rule essentially reiterates information provided in the proposed rule.

In terms of burden, the final rule focuses on the 22,816 laboratories that the collaborating offices believe will be most affected, either because they are located in 26 states or territories where there is no law regarding who can receive test reports or in 13 states or territories where reports can only go to the provider. The collaborating offices say this is because laboratories in such jurisdictions will
most likely not have procedures in place and will have to develop mechanisms for handling patient requests for laboratory test reports and providing such access. The final rule also lists the States and territories believed to fall into two other categories: allows test reports to patient (9 jurisdictions) and allows test reports to patient with provider approval (7 jurisdictions). The final rule assumes that Certificate of Waiver laboratories and Certificate of Provider-Performed Microscopy (PPM) laboratories will not be impacted by the changes adopted in the final rule (because tests are usually performed in these sites during a patient’s visit and a physician or health practitioner would presumably inform the patient of the results during the visit).

The final rule assumes each impacted laboratory will incur a one-time burden of 2 to 9 hours to identify the applicable legal obligations and to develop the processes and procedures for handling patient requests for access to test reports. Assuming that this task would fall to a management level employee (paid at $50.06 per hour), this translates into an estimated cost of about $100 to $450 per laboratory. The final rule further assumes that between 0.05 percent and 0.50 percent of patients will request direct access to their test reports, and that each request will require a total of 10 to 30 minutes to handle. Assuming that the handling of test report requests will be assigned to a clerical level employee (paid at $30.09 per hour), this translates into an estimated cost of about $5 to $15 per requested report.

The final rule also assumes that a total of 33,087 laboratories in the states and territories that are affected by the HIPAA notice provisions will need to revise their notices of privacy practices. These laboratories are located in states having no state law on direct access to laboratory test reports, a state law that provides test reports only to the provider, or a state law that permits test reports to go to patients only with provider approval. The burden involved in revising the notices of privacy practices was taken into account in a January 25, 2013 final rule (since HHS is allowing a single revision in the notices of privacy practices to comply with both the 2013 final rule and this one).

Comments regarding these issues may be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS-2319-F, Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov.

**VI. Regulatory Impact Analysis** (79 FR 7310)

The final rule is designated a “significant regulatory action” although not economically significant (because the overall cost impact on affected laboratories is estimated at less than $100 million for 2013). The impact analysis essentially tracks the analysis described above with respect to information collection burden. The total estimated financial impact on laboratories is between $3 million and $63 million for 2013, and between about $0.9 million and $60.9 million per year in
subsequent years (2014 through 2017, undiscounted, base year: 2013 $), when the only costs believed relevant are those relating to the handling of report requests.\(^3\)

The Secretary has determined that the final rule does not have a significant impact on the operations of a substantial number of small rural hospitals. Further, options for regulatory relief of small businesses were determined not to be feasible. The collaborating offices do not anticipate the final rule will impose an unfunded mandate on states, tribal governments, or the private sector of more than $142 million annually or impose substantial direct compliance costs on state and local governments. Further, they do not believe the changes to the CLIA regulations will have a substantial direct effect on state and local governments, preempt state law, or otherwise have a Federalism implication. Though the changes to the Privacy Rule will preempt a number of state laws, the collaborating offices view this preemption to be consistent with the preemption provision of the HIPAA statute.

The final rule estimates that the annual number of patient requests for direct access to laboratory test reports could range from 175,646 to 3,512,921.

The final rule also acknowledges that there could be some impact on the offices of healthcare providers. For example, if a patient does not know where the provider sent the laboratory test, the provider may need to provide laboratory contact information, which the collaborating offices assume would take “as little as 30 seconds.” In any event, the final rule goes on to say that “since the provider may need to provide an interpretation of the test results, the provider may give the patient a copy of the test report rather than referring the patient to the laboratory for the information.”

In terms of benefits, the final rule does not attempt to quantify them but identifies the following: (1) reducing the chance of the patient not being informed of a laboratory test result; (2) reducing the number of patients who fail to seek appropriate medical care; (3) benefiting health care providers by reducing their workload in providing laboratory test reports; (4) increasing patient participation in treatment programs, such as those that involve monitoring of chronic diseases; and (5) increasing the ability of patients to identify and treat health risks sooner and more effectively.

\(^3\) These estimates are obviously out of date since the final rule is being published and will be effective in 2014, not 2013. They were presumably prepared with the expectation that the final rule would be published and take effect in 2013.