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## Part II

### Department of Health and Human Services

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42 CFR Part 493

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45 CFR Part 164

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

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 493

#### Office of the Secretary

#### 45 CFR Part 164

[CMS-2319-F]

RIN 0938-AQ38

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

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS; Centers for Disease Control and Prevention (CDC), HHS; Office for Civil Rights (OCR), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to specify that, upon the request of a patient (or the patient's personal representative), laboratories subject to CLIA may provide the patient, the patient's personal representative, or a person designated by the patient, as applicable, with copies of completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient. Subject to conforming amendments, the final rule retains the existing provisions that require release of test reports only to authorized persons and, if applicable, to the persons responsible for using the test reports and to the laboratory that initially requested the test. In addition, this final rule amends the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to provide individuals (or their personal representatives) with the right to access test reports directly from laboratories subject to HIPAA (and to direct that copies of those test reports be transmitted to persons or entities designated by the individual) by removing the exceptions for CLIA-certified laboratories and CLIA-exempt laboratories from the provision that provides individuals with the right of access to their protected health information. These changes to the CLIA regulations and the HIPAA Privacy Rule provide individuals with a greater ability to access their health information, empowering them to take a more active role in managing their health and health care.

**DATES:** *Effective Date:* These regulations are effective on April 7, 2014.

HIPAA covered entities must comply with the applicable requirements of this final rule by October 6, 2014.

#### FOR FURTHER INFORMATION CONTACT:

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*For HIPAA Privacy Rule:* Andra Wicks, OCR, (202) 205-2292.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

##### A. CLIA Statute and Regulations

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the implementing regulations established nationwide quality standards to ensure the accuracy, reliability and timeliness of clinical laboratories' test results. The standards vary based on the complexity of the laboratory test method; that is, the more complicated the test method, the more stringent the requirements for the laboratory.

The CLIA regulations established three categories of testing based on complexity level. In increasing order of complexity, these categories are waived, moderate complexity (which includes the subcategory of provider-performed microscopy (PPM)), and high complexity. Laboratories must hold a CLIA certificate for the most complex form of CLIA-regulated testing that they perform.

The CLIA regulations cover all phases of laboratory testing, including the reporting of test results. The CLIA regulatory limitations that govern to whom a laboratory may issue a test report have become a point of concern. The requirements for a laboratory test report are set forth in 42 CFR 493.1291.

Under the current CLIA regulations at § 493.1291(f), a CLIA laboratory may only disclose laboratory test results to three categories of individuals or entities: The "authorized person," the person responsible for using the test results in the treatment context, and the laboratory that initially requested the test. "Authorized person" is defined in § 493.2 as the individual authorized under state law to order or receive test results, or both. In states that do not allow individuals to access their own test results, the individuals must receive their test results through their health care providers.

Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (The Recovery Act), which was enacted on February 17, 2009, incorporated the Health Information Technology for Economic and Clinical Health (HITECH) Act. The HITECH Act created a Federal advisory committee known as the

Health Information Technology (HIT) Policy Committee. The HIT Policy Committee has broad representation from major health care constituencies and provides recommendations to the Department's Office of the National Coordinator for Health Information Technology (ONC) on issues relating to the implementation of an interoperable, nationwide health information infrastructure. The HIT Policy Committee has sought to identify barriers to the adoption and use of health information technology. According to the HIT Policy Committee, some stakeholders perceive the CLIA regulations as imposing barriers to the exchange of health information. These stakeholders include large and medium sized laboratories, public health laboratories, electronic health record (EHR) system vendors, health policy experts, health information exchange organizations (HIOs), and health care providers who believe that the individual's access to his or her own records is impeded, preventing patients from having a more active role in their personal health care decisions.

We believe these concerns, as well as the advent of certain health reform concepts (for example, personalized medicine, an individual's active involvement in his or her own health care, and the Department's work toward the widespread adoption of EHRs), call for revisiting barriers or challenges to individuals' gaining access to their health information.

The Centers for Medicare & Medicaid Services (CMS) worked with ONC, the Centers for Disease Control and Prevention (CDC), and the Office for Civil Rights (OCR) to propose changes to the CLIA regulations and to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to remove barriers to an individual's direct access to his or her own test reports from laboratories. See *CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports*, 76 Fed. Reg. 56712, September 14, 2011. The Department believes that this right is crucial to provide individuals with vital information to empower them to better manage their health and take action to prevent and control disease. In addition, removing barriers in this area supports the commitments and goals of the Secretary of the Department of Health and Human Services (the Department) and the Administrator of CMS regarding personalized medicine, an individual's active involvement in his or her own health care, and the widespread adoption of EHRs by 2014.

### B. HIPAA Statute and Privacy Rule

The Health Insurance Portability and Accountability Act of 1996, Title II, subtitle F—Administrative Simplification, Public Law 104–191, 110 Stat., 2021, provided for the establishment of national standards to protect the privacy and security of certain individually identifiable health information. The Administrative Simplification provisions of HIPAA and their implementing regulations apply to three types of entities, which are known as “covered entities”: Health care providers who conduct covered health care transactions electronically, health plans, and health care clearinghouses.

A laboratory, as a health care provider, is only a covered entity if it conducts one or more covered transactions electronically, such as transmitting health care claims or equivalent encounter information to a health plan, requesting prior authorization from a health plan for a health care item or service it wishes to provide to an individual with coverage under the plan, or sending an eligibility inquiry to a health plan to confirm an individual's coverage under that plan.

If a laboratory does not conduct any of these or the other HIPAA standard transactions electronically (either because it does not conduct the transactions at all or because it does so via paper), then the laboratory is not subject to the HIPAA Privacy Rule (45 CFR Part 160 and Part 164, subparts A and E). Any laboratory that conducts a single electronic transaction for which there is a HIPAA standard under the HIPAA Transactions and Code Sets Rule becomes a covered entity and is subject to the Privacy Rule with respect to all protected health information that it creates or maintains (that is, the application of the Privacy Rule is not limited to the individuals or records associated with an electronic transaction). This final rule does not alter the requirements for what makes a laboratory a HIPAA covered entity.

The Privacy Rule at § 164.524 provides individuals with a general right of access to inspect and obtain a copy of protected health information about the individual in a designated record set maintained by or for a covered entity. A “designated record set” is defined at 45 CFR § 164.501 as a group of records maintained by or for a covered entity that is comprised of: The medical records and billing records about individuals maintained by or for a covered health care provider; the enrollment, payment, claims adjudication, and case or medical management record systems maintained

by or for a health plan; or other records that are used, in whole or in part, by or for the covered entity to make decisions about individuals.

The term “record” means “any item, collection, or grouping of information that includes protected health information and is maintained, collected, used or disseminated by or for a covered entity.” Laboratory test reports that are maintained by or for a laboratory that is a covered entity are part of a designated record set.

The HIPAA Privacy Rule requires a HIPAA covered entity to provide the individual with a copy of the information in his or her designated record set in the form and format requested by the individual, if a copy in that form and format is readily producible. Where the information in the designated record set is maintained electronically, and the individual requests an electronic copy of the information, the covered entity must provide the individual with access to the information in the requested electronic form and format, if it is readily producible in that form and format. When it is not readily producible in the electronic form and format requested, then the covered entity must provide the copy in an alternative readable electronic format as agreed to by the covered entity and the individual (see § 164.524(c)(2)(ii)).

The right of access under § 164.524 extends not only to individuals, but also to individuals' personal representatives, who generally are persons authorized under applicable law to make health care decisions for the individual. The rules governing who may act as a personal representative under the Privacy Rule are set forth at § 164.502(g). Additionally, under § 164.524(c)(3)(ii), if requested by an individual who is exercising his or her right of access, a covered entity must transmit the copy of protected health information directly to another person or entity designated by the individual.

However, while individuals (and personal representatives) generally have the right to inspect and obtain a copy of their protected health information in a designated record set, the current Privacy Rule includes a set of exceptions related to CLIA. Specifically, the right of access under § 164.524 of the Privacy Rule does not apply to: Protected health information maintained by a covered entity that is— (1) subject to CLIA to the extent the provision of access to the individual would be prohibited by law; or (2) exempt from CLIA. These exceptions, found at § 164.524(a)(1)(iii)(A) and (B) of the Privacy Rule, cover test reports

and other protected health information only at CLIA and CLIA-exempt laboratories. The individual has a right to access this information when held by any other type of covered entity (for example, a hospital or treating physician).

These exceptions were included in the Privacy Rule because the Department wanted to avoid a conflict with the CLIA regulatory requirements that limited patient access to test reports (65 FR 82485, December 28, 2000). However, because CMS proposed to amend the CLIA regulations to allow CLIA-certified laboratories to provide patients with direct access to their test reports, the Department simultaneously proposed to remove the exceptions for CLIA and CLIA-exempt laboratories from the right of access at § 164.524 so that HIPAA-covered laboratories would be required by HIPAA to provide individuals, upon request, with access to their completed test reports.

## II. Summary of the Proposed Changes to the CLIA Regulations (§ 493.1291)

On September 14, 2011, we published a proposed rule in the **Federal Register** entitled, “Patients' Access to Test Reports” (76 FR 56712) that, if finalized, would amend § 493.1291 of the CLIA regulations. Specifically, we proposed to add at 42 CFR 493.1291(l) to specify that, upon a patient's request (or upon the request of the patient's personal representative), the laboratory may provide a patient with access to his or her completed test reports that, using the laboratory's authentication processes, can be identified as belonging to that patient. While we proposed to use the word “may,” we highlighted the importance of reading the proposed amendments to the CLIA regulations in concert with the proposed changes to the HIPAA Privacy Rule (discussed below), which would require covered entity laboratories to provide patients with access to test reports. We did not propose to specify in the CLIA regulations the mechanism by which patient requests for access would be submitted, processed, or responded to by the laboratories. In providing this latitude, we intended to allow patients and their personal representatives access to patient test reports in accordance with the requirements of the HIPAA Privacy Rule. Subject to conforming amendments, we proposed to retain the existing requirements at § 493.1291(f) that otherwise limit the release of test reports to authorized persons and, if applicable, the individuals (or their personal representatives) responsible for using

the test reports and the laboratory that initially requested the test.

### III. Summary of the Proposed Changes to the HIPAA Privacy Rule (§ 164.524)

The Department also proposed to amend the HIPAA Privacy Rule at 45 CFR 164.524(a)(1)(iii)(A) and (B) to remove the exceptions to an individual's right of access that relate to CLIA and CLIA-exempt laboratories to align the Privacy Rule with CMS' proposed changes to the CLIA regulations and the Department's goal of improving individuals' access to their health information.

Under the proposal, HIPAA covered entities that are laboratories subject to CLIA, as well as those that are exempt from CLIA, would have the same obligations as other types of covered health care providers with respect to providing individuals (or their personal representatives) with access to their protected health information in accordance with § 164.524.

Consistent with the proposed change to the CLIA regulatory requirements, which would allow a laboratory to provide patients and their personal representatives with direct access to completed test reports when the laboratory can authenticate that the test report pertains to the patient, we also clarified that CLIA and CLIA-exempt laboratories that are HIPAA covered entities would have to satisfy the verification requirement of § 164.514(h) of the Privacy Rule before providing an individual with access. We recognized that a laboratory could receive a test order with only an anonymous identifier and be unable to identify the individual who is the subject of the test report. We noted that it was not our intent to discourage anonymous testing. As we discussed in the proposed rule, a laboratory that received a request for access from an individual where the laboratory could not authenticate that the requesting individual is the subject of a test report would be under no obligation to provide access.

The proposed rule also explained that the changes to the HIPAA Privacy Rule would result in the preemption of a number of state laws that prohibit a laboratory from releasing a test report directly to the individual or that prohibit the release without the ordering provider's consent because the state laws now would be contrary to the access provision of the HIPAA Privacy Rule mandating direct access by the individual.

Finally, we explained that it was our intent that HIPAA-covered laboratories would be required to comply with the revised individual access requirements

of the Privacy Rule by no later than 180 days after the effective date of any final rule. The effective date of the final rule would be 60 days after publication in the **Federal Register**, so laboratories subject to HIPAA would have a total of 240 days after publication of the final rule to come into compliance.

### IV. Provisions of the Final Regulations

This final rule adopts the proposed changes to both the CLIA regulations and the HIPAA Privacy Rule, with minor clarifications and conforming changes, which are explained below in the relevant responses to comments. These modifications broaden individuals' rights to access their protected health information directly from laboratories subject to HIPAA. In addition, the changes remove federal barriers to direct access for laboratories not subject to HIPAA. With respect to the CLIA regulations, this final rule allows laboratories subject to CLIA, upon the request of a patient (or the patient's personal representative) to provide access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient. The final rule also clarifies that laboratories subject to CLIA may provide a copy of the patient's test reports to a person or entity designated by the patient to receive such reports in accordance with the HIPAA Privacy Rule at § 164.524(c)(3)(ii). Subject to certain conforming amendments, this final rule retains the CLIA regulatory provision that requires the release of test reports only to authorized persons, to the persons responsible for using the test reports, and to the laboratory that initially requested the test. These CLIA regulatory modifications take effect 60 days after publication of this final rule in the **Federal Register**.

With respect to the Privacy Rule, the final rule removes the exceptions to an individual's right of access at § 164.524(a)(1)(iii) related to CLIA and CLIA-exempt laboratories. Thus, as of the compliance date of this final rule, HIPAA-covered laboratories will be required to provide an individual (or the individual's personal representative) with access, upon request, to the individual's completed test reports (and other information maintained in a designated record set) in accordance with the provisions of § 164.524 of the Privacy Rule. The compliance date of this rule is October 6, 2014.

The Department's rationale for adopting the proposed provisions in this final rule, along with further clarifications and interpretations of the

provisions, is explained below in the responses to the public comments.

### V. Analysis of and Responses to Public Comments

In response to the September 2011 proposed rule, we received over 160 timely public comments on various issues related to the rule. Interested parties that submitted comments included health care consumers and patient advocacy organizations; laboratories, hospitals, and other health care providers and their associations; information technology organizations; governmental organizations, and others. We have analyzed these comments and determined that it is appropriate to finalize the provisions as set forth in the proposed rule. The comments we received on these provisions and our responses are set forth below.

#### A. Right of Direct Access to Laboratory Test Reports

*Comment:* 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. For example, commenters expressed concern that patients might receive and act upon results that appear to be abnormal (showing false positives or false negatives, or results that are out of the normal range for the general population) but may be normal for that particular patient due to his or her medical conditions. Commenters also requested that the Department clarify that the laboratories themselves would not be required to interpret test reports for individuals.

Other commenters stated that the proposed rule was redundant, and would add significant burden without a commensurate benefit to individuals, as existing HIPAA and HITECH Act (§ 13405(e)) laws already provide individuals with a comprehensive right to access their protected health information, including test reports, through their physicians. Further, some commenters stated that the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs,<sup>1</sup> which include criteria to ensure that certain laboratory test reports become standardized elements in a certified EHR, are a better mechanism than the proposed rule to ensure more timely access to all health information. The

<sup>1</sup> See <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html>.

commenters also stated that the information provided to individuals through the Medicare and Medicaid EHR Incentive Programs' requirements will be in a more consistent, more user-friendly, and more interoperable format than that obtained directly from a laboratory. Furthermore, commenters stated that many providers have already invested significant dollars and resources in secure patient portals to provide for individual access to health information directly from these providers.

In contrast, other commenters, including certain laboratories, consumers, and consumer advocates, generally supported expanding an individual's right of access to include receiving test reports directly from laboratories. These commenters stated that providing individuals with the ability to access their laboratory test reports directly from laboratories would provide individuals with an increased ability to play a more active role in their health care and have more informed conversations with their health care providers, resulting in better health outcomes. Some commenters also thought that the proposals would remove barriers to the electronic exchange of individually identifiable health information.

Further, in response to concerns regarding instances in which patients might misunderstand or become distressed over the results of laboratory tests due to the lack of treating provider interpretation or counseling, some commenters stated that they would not anticipate that many patients will request direct access to any test reports that they do not feel prepared to review on their own. Rather, the commenters indicated that the proposals would encourage doctors to more proactively discuss the range of possible results and the consequences of each before tests are ordered. One laboratory noted that, in its experience, many patients do not request access to their test results until they have spoken to a physician about them. Some commenters challenged what they termed to be a "paternalistic" notion that patients are unable to understand their health data without physician explanation. These commenters stated that if patients want additional information from, or consultation with, their physicians, they will follow up with their physicians directly.

**Response:** We appreciate all of the comments that we received with regard to the right of individuals to access their laboratory test reports directly from laboratories. We agree with those commenters who stated that the rule is

necessary to ensure patients have better and more complete access to their health information, which will enable patients to be more proactive and more informed with regard to their health care. However, we disagree with those commenters who argued that the rule would be redundant. While individuals do have a right of access to their health information under the HIPAA Privacy Rule, there may be circumstances when an ordering or treating provider is not subject to the HIPAA Privacy Rule (for example, because the provider does not bill health plans electronically) and, thus, is not required to provide an individual with access to his or her health information. Further, some studies have found that physician practices failed to inform patients of abnormal test results about seven percent of the time, resulting in a substantial number of patients not being informed by their providers of clinically significant tests results. *See Casalino LP, Dunham D, Chin MH, et al. Frequency of Failure To Inform Patients of Clinically Significant Outpatient Test Results, Arch Intern Med., June 22, 2009, 169 (12): 1123–1129.* The rule strengthens individuals' current ability to have access to completed test reports by ensuring they are able to access them directly from HIPAA-covered laboratories.

Finally comments regarding the provision of access through the mechanisms established by EHR Incentive Programs failed to recognize the voluntary nature of the programs or the fact that the programs' requirements do not pertain to laboratories.

Furthermore, the rule does not diminish the investment health care providers have made to provide individuals with access to their health information through patient portals, as those portals provide patients with access to a much broader range of health information than just test results. The rule provides an additional avenue for an individual to obtain test reports directly from laboratories, which we expect will reduce the chances of patients not being informed of laboratory test results and potentially reduce the numbers of patients who fail to seek appropriate care. We also agree with commenters that increased patient access to laboratory test reports, which can then be shared with the patient's other providers, will help reduce unnecessary and duplicative testing.

With respect to those comments concerned about patients receiving test reports without the benefit of provider interpretation, we emphasize that this rule does not alter the role of the ordering or treating provider in

reporting and explaining test results to patients. We expect that patients will continue to obtain test results and advice about what those test results mean, through their ordering or treating providers. Further, as noted above, for those individuals who do or will request access to test reports from a laboratory, it was the experience of one large laboratory that many patients do not request access to their test reports from a laboratory until they have spoken with their physicians. We expect this trend to continue to generally be the case. We also agree with commenters that the 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.

Further, under the HIPAA Privacy Rule, in most cases, laboratories will be required to provide individuals with access to their laboratory test reports within 30 days of the request (see § 164.524(b)(2)(i)). As discussed more fully below, in cases where an individual requests access to completed test reports, we believe 30 days will generally be sufficient to allow the ordering or treating provider to receive the test report in advance of the patient's receipt of the report, and to communicate the result to the patient, and counsel the patient as necessary with regard to the result.

Finally, we clarify that this final rule does not require that laboratories 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. Laboratories may continue to refer patients with questions about the test results back to their ordering or treating providers.

**Comment:** Some commenters indicated they would support changes to the regulations, which would permit, but not require, laboratories to provide individuals with access to their completed test reports. One commenter stated that the proposed rule was unclear as to whether laboratories will have the discretion to provide access, or whether they will be required to provide access, to individuals who request their test reports. Other commenters were concerned about the differential application of the rule to HIPAA-covered versus non-HIPAA-covered laboratories, stating that this construct will create confusion and frustration among patients who may expect to be able to access their test reports from any

laboratory and who may not understand the distinction among laboratories based on HIPAA covered entity status.

*Response:* Laboratories that are HIPAA covered entities are required by this final rule to provide, upon request by an individual or the individual's personal representative, access to the protected health information about the individual maintained in a designated record set in accordance with the HIPAA Privacy Rule at § 164.524. CLIA laboratories that are not subject to HIPAA will have discretion to provide patients with direct access to their laboratory test reports, subject to any applicable state laws that may constrain access.

We do not believe it is appropriate to only permit rather than require HIPAA-covered laboratories to provide individuals with access to their test reports. This may not significantly expand individuals' ability to access their health information, as some laboratories not currently providing individuals with direct access to their test reports might choose not to begin providing direct access. Further, in a number of states, state law prohibits laboratories from providing individuals with direct access to their test reports. If the HIPAA Privacy Rule merely permitted access, it would not preempt those state laws that prohibit direct access, because a permissive federal requirement is not contrary to a prohibitive state law (see § 160.202). As of the effective date of this final rule, the CLIA regulations will expressly permit the disclosure of test reports to the individual. The combination of the change in the HIPAA Privacy Rule, combined with the change to the CLIA regulations, will result in HIPAA-covered laboratories being required to disclose test reports to patients, in most cases, within 30 days of a request.

*Comment:* A few commenters stated that the rule should only apply to the primary laboratory to which the specimen was submitted, as opposed to reference laboratories that may perform some or all of the testing. These commenters stated that reference laboratories have no relationship with the individual and have either limited or inadequate information about the individual to enable the laboratory to provide individuals with access. A few commenters indicated that, while applying the rule to hospital laboratories with respect to the test reports of the hospital's own patients may not be a significant challenge, applying the rule to hospital laboratories in their role as reference laboratories for other providers, such as community physicians and other

laboratories, would raise significant operational challenges.

In contrast, one laboratory commenter recommended that no laboratories be exempt from the individual access requirements, stressing the importance of uniform application of the rule and a patient's ability to access his or her test report from whatever laboratory performed the test.

*Response:* We appreciate the commenters' concerns regarding laboratory contact with individuals; however, we do not agree that limited information about the individual who is the subject of a test report is a sufficient reason to exempt reference laboratories from the access requirements of the HIPAA Privacy Rule. We believe 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. To the extent that reference laboratories are covered entities under HIPAA, they will be required, upon the compliance date of this rule, to provide individuals with access to test reports in compliance with § 164.524 of the Privacy Rule. Reference laboratories that are not subject to HIPAA will not be under any federal obligation to provide access, but they will be permitted to do so under Federal law. However, we expect that, in most cases, individuals will continue to request access to their health information either from their treating provider, or from the referring laboratories. This expectation is based on our understanding that many, if not most, individuals will not be aware of the identity of the reference laboratory, or may not know that a reference laboratory is conducting all or part of the ordered tests. Therefore, we do not expect reference laboratories to encounter many individual requests for access. Furthermore, in the limited circumstances where a patient may request access to test reports from a laboratory acting as a reference laboratory with respect to that patient, the reference laboratory need only provide the individual with the requested access to the extent the laboratory can authenticate the test report as belonging to that patient. The same applies for hospital laboratories that also act as reference laboratories. Finally, we do not believe that there will be significant operational issues for hospital laboratories as hospitals already have policies and procedures in place to comply with the existing HIPAA Privacy Rule access provisions and the hospital laboratories can use these policies and procedures for purposes of this rule.

#### *B. Scope of Information to Which an Individual Has Access*

*Comment:* A number of commenters indicated that the rule should apply only to tests administered after the final rule is published or becomes effective. These commenters expressed concern with laboratories having to retrieve copies of old test reports that have been archived and may exist offsite. For example, commenters stated that many laboratories have archived test reports that exist on paper or on backup tapes, and that it would be costly and burdensome to retrieve and transfer the archived test reports to other suitable media to transmit to an individual.

A few commenters asked that the rule not require laboratories to provide test reports that have been kept beyond the retention date(s) required in the CLIA regulations. One commenter indicated that the rule should specify a timeframe after a test report is first generated beyond which an individual would not have a right to access the test report directly from the laboratory.

*Response:* While we appreciate the commenters' concerns, as with any other HIPAA covered entity, under this final rule, an individual has a right to access information about the individual in one or more designated record sets maintained by a HIPAA-covered laboratory, for as long as the information is maintained by the laboratory (see § 164.524(a)(1)). This right extends to test reports and other information about the individual in a designated record set maintained offsite, archived, or created before the publication or effective date of this final rule. We do not agree that information created before the effective date of this final rule should be exempt from the access requirement. The reasons for granting individuals access to health information pertaining to them do not vary with the date the information was created. 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. See the Privacy Rule requirements for timely action on access requests at § 164.524(b)(2).

We also clarify that this final rule does not impose any new record retention requirements for laboratory test reports. These obligations are established under CLIA and other applicable Federal and state laws. See, for example, 42 CFR § 493.1105. Rather, it provides an individual with a right to access protected health information in the designated record set of a HIPAA-

covered laboratory for as long as the laboratory maintains the information (even in those cases where the information is maintained beyond applicable record retention requirements).

*Comment:* Some commenters supported the language in the proposed rule at § 493.1291(l) that limited patients' access to "completed" test reports. Other commenters felt that additional guidance was needed as to what information qualified as a "completed" test report. For example, one commenter asked whether a test report is considered "completed" (and subject to the right of access) each time a component of a multi-step test is completed or only when all aspects of the ordered test are completed and recorded in a finalized report that is ready for issuance. The commenter also asked, in circumstances where a single order involves a test to be performed multiple times over a period of time, whether the report is considered complete each time the test is performed or only after the entire series of tests is performed. This commenter suggested that the test report should be considered "complete," and subject to the right of access, only when all of the test results are final.

*Response:* Under the HIPAA Privacy Rule at § 164.524(a)(1), an individual has a general right to access the protected health information about the individual in a designated record set maintained by a covered entity or its business associate. As described above, laboratory test reports maintained by or for a laboratory that is a HIPAA covered entity fall within the definition of "designated record set." However, test reports may be only part of a designated record set that a HIPAA-covered laboratory holds. 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. This could include, for example, completed test reports, test orders, ordering provider information, billing information, and insurance information.

While an individual may have a right to all of this information, we do not expect that many individuals will request access to all of the protected health information about the individual that the laboratory may hold in a designated record set. Rather, we expect that most individuals will request access to test reports of discrete laboratory tests that they know were ordered by their providers. In these cases, the Privacy Rule requires a

HIPAA-covered laboratory to provide the individual with a copy of or access to only the specific information requested by the individual.

Further, a HIPAA-covered laboratory is required to provide an individual with access only to that information that it actually maintains about the individual in a designated record set at the time the request for access is fulfilled. For purposes of this final rule, we clarify that we do not consider test reports to be part of the designated record set until they are "complete." To maintain consistency with CLIA, we consider a test report to be complete when all results associated with an ordered test are finalized and ready for release.

If an individual requests access to a particular test report, we expect that the HIPAA Privacy Rule's time allowance of 30 days from the request to provide access will be sufficient in most cases to provide the individual with access to the completed test report as we expect many requests for access will be made days after the order has been placed by the physician or even after the patient has discussed a particular result with his or her physician. In those limited cases where 30 days may not be sufficient to complete the test report, due to the nature of the tests to be performed, and the laboratory knows this at the time the individual requests access, we expect a covered entity laboratory to explain this circumstance to the individual. Upon informing individuals when they request access that the test report they are seeking will take longer than 30 days to complete, the individuals are likely to be willing to withdraw or hold their request until a later time to ensure that they get access to what they want or need. If an individual chooses not to withdraw his or her request for access, the individual will then have a right only 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. If a laboratory determines, after it has accepted a request, that the requested test will take more than 30 days to analyze and complete, it may notify the individual in writing within the initial 30-day period of the need and specific reason for the delay in providing access to the completed test result and the date by which the laboratory will complete its action on the request, in accordance with § 164.524(b)(2)(iii) of the HIPAA Privacy Rule. We note, however, that the HIPAA Privacy Rule allows only one extension on an access request. In the rare circumstance where 60 days is not

sufficient to provide the individual with access to a completed test report, the covered laboratory must provide the individual with only the existing protected health information that is part of the designated record set within that time (for example, other completed test reports or test requisitions), which would then not include the test report requested by the individual, because the test report is not yet complete.

In general, we expect the initial 30-day period allowed by the Privacy Rule to provide sufficient time to provide individuals with access to completed test reports. However, we acknowledge there may be rare circumstances when it would not be, and we expect covered laboratories to communicate and work with individuals concerning these limitations.

*Comment:* Some providers and laboratories objected to individuals having direct access to laboratory test reports they characterize as "sensitive," including genetic, cancer, pregnancy, sexually-transmitted disease, and mental health test results. Commenters stated there are tests for which it is acceptable to release results to the patient without physician involvement (for example, cholesterol test results) and there are tests for which it is not (for example, cancer or HIV test results). One commenter stated, for example, that under California law, before the disclosure of HIV test results, the physician has a duty to discuss what the results may mean and offer the patient appropriate education and psychological counseling. Some commenters recommended giving ordering and treating providers ample discretion to determine when it is in the patient's best interest to receive test reports without the benefit of a physician's interpretation. Others recommended that laboratories be permitted to identify tests or categories of tests that may only be released to the physician and to limit an individual's direct access to the reports.

In contrast, some commenters stated that all test reports should be treated equally, providing several reasons, including: Patients today are much better informed and have access to interpretative information on laboratory results from many sources, including the internet; given the timeframes allowed for providing access under the HIPAA Privacy Rule, it is likely that the ordering or treating provider will receive results well before the patient and will have adequate time to discuss the result and what it means in terms of the patient's health care with the patient; and trying to identify which tests are sensitive is subjective and not

necessarily in the best interest of the patient.

*Response:* Under the HIPAA Privacy Rule, an individual generally has a broad right of access to any or all of his or her health information maintained in a designated record set. In this final rule, we extend that broad right to the laboratory setting. With a very limited exception, covered entities may not deny an individual access to his or her health information based on the information's sensitive nature or potential for causing distress to the individual. The limited exception is 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 (see § 164.524(a)(3)(i)).

As we discuss elsewhere in this final rule, we do not believe that this rule will eliminate or interfere with the role or obligation of the treating or ordering provider to report and counsel patients on laboratory test results. The rule provides ample time to ensure providers receive sensitive test reports before the patient and to allow providers to counsel individuals on the test reports. In addition, as indicated above, we believe the rule will further encourage providers, at the time the test is ordered, to counsel patients on the potential outcomes of a test and what they may mean for the patient, given his or her medical history.

Finally, we 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 the patient's best interest. This endeavor also would result in a lack of uniformity across states and laboratories with respect to the types of information to which an individual has access under the rule. This outcome would be too complex and burdensome for laboratories to administer and confusing for individuals attempting to exercise their rights.

*Comment:* A few commenters, while in general support of the proposed rule, raised specific concerns about providing laboratory test reports directly to certain mental health patients (for example, those who may be suffering from medical conditions such as paranoia). These commenters were concerned that direct access to laboratory test reports without any involvement of the treatment team could have a very

negative impact on the mental health of these patients. Some commenters asked that the current provision in the HIPAA Privacy Rule allowing the denial of access to protected health information when the access is reasonably likely to endanger the life or physical safety of the individual or another person also apply to access made available under this final rule. They suggested that this would allow providers to determine when prior provider review and approval would be required before the release of given laboratory test reports to mentally ill patients.

*Response:* We believe the existing exceptions to access in the Privacy Rule appropriately balance an individual's right to access his or her health information with other considerations, such as the potential for harm. Therefore, we decline to provide a specific exception to the right of access for mental health patients. A laboratory is subject to the same requirements under the HIPAA Privacy Rule as other covered entities to generally provide all individuals with access to their health information. As previously discussed, we believe 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's receipt of the test report, which will allow them to counsel the patient with respect to the test result.

As noted above, the HIPAA Privacy Rule at § 164.524(a)(3)(i) provides that a covered entity may deny access to an individual if a "licensed health care professional" has determined, in the exercise of professional judgment, that the access requested by the individual is reasonably likely to endanger the life or physical safety of the individual or another person. However, this is a limited exception to an individual's right of access and applies only with respect to endangerment of the life or physical safety of the individual or another person; thus, concerns about psychological or emotional harm are not sufficient to justify denial of access. Furthermore, a HIPAA-covered laboratory that wishes to deny access to the individual based on a determination by a licensed health care professional must provide the individual with an opportunity to have the denial reviewed by a licensed health care professional who is designated by the laboratory to act as a reviewing official and who did not participate in the original decision to deny. The HIPAA-covered laboratory must promptly refer a request for review to the reviewing official, who must determine, within a reasonable amount of time, whether or not to deny the

access requested. See § 164.524(d). The laboratory would then be required to provide or deny access in accordance with the determination of the reviewing official (see § 164.524(a)(4)).

*Comment:* Two commenters requested clarification on whether the expanded right of individual access would apply to food or environmental test reports maintained by a laboratory, that are the result, for example, of testing done after an outbreak of disease, and that may be linked to particular patients. A public health laboratory requested clarification on how this rule applies to public health surveillance or outbreak test reports. One commenter requested clarification as to whether individuals would have a right to employment-related test results, such as testing for drug and alcohol use. Finally, another commenter asked that patient access to laboratory results be expanded to include the results of radiologic assessments.

*Response:* This final rule is intended to remove barriers in the HIPAA Privacy and CLIA regulations to individual access to test reports maintained by laboratories subject to or exempt from CLIA. If the samples tested are not of the human body, the entity conducting the testing is not subject to CLIA for purposes of that testing or those test results. Furthermore, if the testing is not for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings, that testing and those test results are also not subject to CLIA. Some outbreak and surveillance activities may involve testing samples from humans and thus be subject to CLIA if individual patient-specific test results are reported to ordering providers. However, CLIA does not apply to test results that are only used for epidemiological studies or reported in the aggregate without patient identifiers.

As for employment-related testing, the CLIA regulations are not applicable to an employer or entity that performs substance abuse testing strictly for the purpose of employment screening where test results are merely used to determine compliance with conditions of employment, as opposed to counseling or some other form of treatment. Substance abuse testing as part of a treatment program is covered by CLIA.

Even if CLIA does not apply to the conduct of certain types of laboratory tests, HIPAA may still apply to require access to certain test reports to the extent the laboratory is a HIPAA covered entity and the information to

which an individual is requesting access is protected health information under HIPAA. Individuals have a right to access test reports in designated record sets held by or for HIPAA-covered laboratories that constitute protected health information under the HIPAA Privacy Rule—that is, those reports that relate to the past, present, or future physical or mental health or condition of an individual or the provision of health care to an individual (which would include testing for the presence of alcohol or drugs) and that identify the individual, or with respect to which there is a reasonable basis to believe that information in the test report can be used to identify the individual. See the definitions of “individually identifiable health information” and “protected health information” at § 160.103. 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.

Although the CLIA regulations do not cover radiologic testing or assessments, 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*

*Comment:* Several commenters raised concerns regarding access to an individual’s sensitive laboratory test reports, such as those concerning reproductive health, by the individual’s parents, spouse, partner, or other persons, when the individual may not want these persons to see the test report.

*Response:* We understand commenters’ concerns and provide the following guidance to HIPAA-covered laboratories regarding how the Privacy Rule ensures that only persons with appropriate authority are provided access. 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 are those persons who qualify as a personal representative of the individual. A personal representative for purposes of the Privacy Rule generally is a person who has authority under applicable law to make health care decisions for the individual (see § 164.502(g)). Before providing access to a person other than the individual who is requesting access, a HIPAA-covered laboratory is required under § 164.514(h) of the Privacy Rule to verify both the identity and authority of the person to have access to the individual’s protected health information. In order to conduct the

required verification, a covered laboratory may need to obtain documentation that the person requesting access to the individual’s protected health information qualifies as the individual’s personal representative, for example, by having the person present 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, in most cases, a parent is the personal representative of the minor, because the parent usually has the authority under state law to make health care decisions about his or her minor child. However, 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 under state or other laws, or standards of professional practice. Additional information on these circumstances is available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/personalreps.html>.

Regardless, however, of whether a parent is the personal representative of a minor child, the Privacy Rule defers to state or other applicable laws that expressly address the ability of the parent to obtain health information about the minor child. In doing so, the Privacy Rule permits a covered entity to provide the parent with access to a minor child’s protected health information when and to the extent it is permitted or required by state or other laws (including relevant case law). Likewise, the Privacy Rule prohibits a covered entity from providing a parent with access to a minor child’s protected health information, when and to the extent it is prohibited under state or other laws (including relevant case law). If state or other applicable law is silent concerning parental access to the minor’s protected health information, and a parent is not the personal representative of a minor child based on one of the exceptional circumstances described above, a covered entity has discretion to provide or deny the parent access to the minor’s health information, if doing so is consistent with state or other applicable law, and provided the decision is made by a licensed health care professional in the exercise of professional judgment. For example, where a minor is able under state law to consent and obtain

treatment for a reproductive health care service that involves laboratory testing, and the state law is otherwise silent on parental access to a minor’s protected health information, a testing laboratory that has received a parent’s request for access to this test report of the minor child may wish to take into account any instructions of the treating medical professional in determining whether to grant or deny access to the parent of the minor.

In general, we expect personal representatives will continue to obtain access to individuals’ health information through the individual’s treating providers, with whom many personal representatives will already have established a relationship and be known to the provider. Therefore, we do not expect HIPAA-covered laboratories will receive many requests from persons requesting access as a personal representative of the individual.

With respect to laboratories that are not HIPAA covered entities, the changes to the CLIA regulations in this final rule merely permit, not require, the disclosure of completed test reports to an individual’s personal representative. Thus, laboratories not subject to HIPAA should exercise their judgment in providing access to personal representatives, while taking into account any other applicable federal or state laws.

*Comment:* A few commenters asked how a laboratory should determine whether a person requesting access to another individual’s completed test reports has the appropriate legal authority to act on behalf of the individual, and, by virtue of that authority, is a personal representative for the individual. Commenters indicated that the laboratory test order from the ordering provider does not include this information. These commenters also expressed concern about the costs to determine whether a particular person had authority to access an individual’s laboratory test reports.

*Response:* As indicated above, a HIPAA-covered laboratory is required to verify the identity and authority of any person requesting access to laboratory test reports as a personal representative of an individual. Depending on the circumstances, a HIPAA-covered laboratory could verify a person’s authority by asking for documentation of a health care power of attorney, or general power or 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. A HIPAA-covered laboratory may also contact the treating provider to inquire whether the treating provider can provide documentation of the person's status as a personal representative of the individual.

We address the costs that a HIPAA-covered laboratory may incur in the verification process, in section VII below. We note here as we did above, however, that we do not anticipate HIPAA-covered laboratories will receive many requests from persons requesting access as a personal representative of the individual. Thus, we do not expect HIPAA-covered laboratories will incur significant costs for verification of such persons. Several clinical laboratory commenters indicated that most patients or personal representatives do not know what laboratory conducted the laboratory tests. Based on these comments, we expect personal representatives, like individuals themselves, generally will continue to obtain access to the individuals' health information through the individuals' treating providers, with whom many personal representatives will already have established a relationship for the purposes of obtaining access.

*Comment:* One commenter requested that the same requirements for denying access to protected health information by a personal representative in cases where access may cause substantial harm to the individual (for example, in cases of spousal abuse) should also be available when personal representatives request direct access to an individual's test reports from laboratories.

*Response:* As described above, the Privacy Rule's access and personal representative provisions apply in the same manner to HIPAA-covered laboratories as to other types of covered entities. Section 164.524(a)(3)(iii) of the Privacy Rule permits a covered entity to deny a personal representative access to an individual's protected health information when a licensed health care professional has determined, in the exercise of professional judgment, that providing access to the personal representative is reasonably likely to cause substantial harm to the individual or another person. Thus, a HIPAA-covered laboratory may deny a personal representative access to an individual's protected health information under this provision when the laboratory has received and documented the requisite determination from a licensed health care professional that granting access to the personal representative is reasonably likely to cause substantial harm to the individual or another person. As was described above with respect to individuals denied access to

their own records because of concerns of endangerment, the personal representative retains the right to have the denial reviewed by another licensed health care professional who is designated by the HIPAA-covered laboratory to act as a reviewing official and who did not participate in the original decision to deny. A laboratory denying access must inform the personal representative of this right and have the ability to have the denial reviewed in accordance with these requirements.

We also note 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. We do not anticipate that this provision will frequently apply in the circumstances where a personal representative is requesting direct access to an individual's test report maintained by a HIPAA-covered laboratory, as most laboratories will not have the requisite relationship with the individual that will enable them to make this type of assessment. However, there may be situations where a HIPAA-covered laboratory is made aware of the dangers by a treating provider or the individual. The HIPAA-covered laboratory should consider this information in the exercise of its own professional judgment.

*Comment:* One commenter stated that it was unclear from the proposed rule whether a patient's access right would include the right to have the test reports shared with others who do not have independent access rights. This commenter urged the Department to amend the CLIA regulations to clarify that the laboratory may provide access to the patient, his or her personal representative, or any other party designated by the patient or his or her personal representative.

*Response:* We clarify 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. In addition to access by personal representatives, the HITECH Act strengthened an individual's right of electronic access, which included giving individuals the right to direct that a covered entity transmit an electronic copy of the individual's protected health information directly to another

person or entity designated by the individual (see, section 13405(e) of the HITECH Act). The regulations that implemented these statutory provisions were published as part of the HIPAA Privacy Rule on January 25, 2013, and became effective on March 26, 2013. While Section 13405(e) of the HITECH Act is applicable to electronic copies, the Department also used its general authority under sections 262 and 264 of HIPAA to implement this right uniformly regardless of whether the access requested is for an electronic or a paper copy of the individual's protected health information. Thus, upon the compliance date of this final 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 protected health information to another person or entity designated by the individual. The Privacy Rule requires that such requests must be made 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. See § 164.524(c)(3)(ii) and the preamble to the final HITECH rule (78 FR 5566) for more information.

With respect to the changes to the CLIA regulations, the CLIA regulatory text as written in this rule will be sufficient to allow a laboratory to, upon the request of a patient (or their personal representative, if applicable), provide a copy of the patient's test report to a person or entity designated by the individual in accordance with the HIPAA Privacy Rule.

*Comment:* One commenter requested that organ procurement organization laboratories that perform tests on decedent tissue and blood be exempted from the rule altogether, since the outcome of these tests would not be of meaningful value to the personal representatives of decedents, and in the case of blood tests, could cause undue concern given the frequency of false positive results.

*Response:* We appreciate that Organ Procurement Organization laboratories operate under different circumstances than clinical laboratories. However, we do not believe there should be an exemption for these laboratories. Laboratories that are covered entities under HIPAA are required to provide individuals (or their personal representatives) with access to protected health information, including that of decedents (see § 164.524). We do not believe the concerns raised by the commenter justify removing a personal representative's right to access the protected health information of a

decendent at an Organ Procurement Organization laboratory that is a covered entity. However, we do not expect many Organ Procurement Organization laboratories will be HIPAA covered entities unless they also provide clinical or other laboratory services that involve reimbursement by health plans. Further, we emphasize that a HIPAA-covered laboratory is only required to provide an individual (or personal representative) with access when they receive a request for access, which we do not expect to be a very frequent occurrence in the context of testing for organ procurement purposes.

#### *D. Requests for and Provision of Access*

##### 1. HIPAA Access Processes

*Comment:* Several commenters supported allowing flexibility in how requests for access may be submitted, processed, and responded to by laboratories. Commenters indicated a flexible approach was important since laboratories vary greatly in terms of how they interact with patients, if at all, and flexibility would allow laboratories to implement processes that would not disrupt operations. One commenter stated that some state laws may affect the processes that laboratories may put in place and urged that the Department clarify that the authority for specifying the processes for handling requests for access lies with the laboratories rather than the states. Another commenter expressed concern with the rule not spelling out the mechanisms by which patient requests for access would be submitted, processed, or responded to by laboratories. The commenter suggested that the final rule should require some type of written record, such as a signature on an office form, and verification of the identity of the person requesting the records.

*Response:* We agree with the commenters that flexibility in how laboratories receive and respond to access requests is important given the varied circumstances of each laboratory. This final rule provides laboratories with flexibility as to how to set up systems to receive, process, and respond to requests for access by individuals, so long as these processes comply with the timing and other requirements for access in § 164.524 of the HIPAA Privacy Rule where HIPAA-covered laboratories are concerned. For example, some laboratories that interact directly with individuals may give individuals the option to request a copy of their completed test reports when the individuals are physically present at the laboratory for specimen collection.

With regard to state laws, it is unclear from the comments how exactly these laws impact laboratory processes. The HIPAA Privacy Rule only preempts contrary provisions of state law. Thus, 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. Further, the HIPAA Privacy Rule does not preempt more stringent state laws, even if contrary to the Privacy Rule. In the context of individuals' rights to access their health information, "more stringent" means that the state law provides greater rights of access. Therefore, a HIPAA-covered laboratory must continue to abide by state laws that provide the individual with a greater right of access. For example, if a state law requires individual access to test reports within a shorter timeframe than the Privacy Rule requires, access must be provided within that shorter timeframe. Finally, as noted above and discussed more fully below, while the HIPAA Privacy Rule provides some flexibility to HIPAA-covered laboratories in how their access processes are developed, it does have specific requirements for verification of identity and authority of the individual requesting access, as well as timeliness and the form of access provided, among other requirements, that must be followed in providing access to individuals. With respect to the form of the individual's request, the Privacy Rule does permit covered entities to require that individuals make requests for access in writing (see § 164.524(b)(1)).

*Comment:* Some commenters asked for clarification as to whether hospital laboratories may continue to rely on existing hospital HIPAA access processes, which may have been implemented through their health information management departments, to provide individuals with access to their test reports, rather than having to create an additional process outside the normal customary practices followed by hospitals to comply with the access requirements of the HIPAA Privacy Rule. A few commenters specifically noted that some hospitals have patient portals in place to provide individuals with access to their protected health information, including laboratory results.

*Response:* 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 (see the definition of "organized health care arrangement" in the HIPAA Rules at

§ 160.103, and the provisions for affiliated covered entities at § 164.105(b)), may continue to utilize the hospital's already established mechanisms for providing access to individuals requesting their test reports from the hospital laboratories, provided that the established mechanisms are compliant with the access provisions of the HIPAA Privacy Rule. This includes providing individuals with access to their test reports through a patient portal to the extent the individuals have agreed to receive access in this manner. However, laboratories that are not part of a hospital need to establish their own process for providing individuals with direct access to their protected health information in accordance with the Privacy Rule, even if the laboratories' test reports are otherwise available to an individual through an unaffiliated treating hospital or provider's patient portal or other access mechanism.

*Comment:* One commenter asked whether a patient will be expected to make a request for access from the laboratory to test reports at the time the patient is in the treating provider's office, or whether patients have a right to contact the laboratory directly for access. Another commenter asked whether, with regard to the referral of specimens from one laboratory to another, a patient will need to request access to the test reports of both laboratories or just request access from one of the laboratories to obtain all of the test results.

*Response:* Under this final rule, individuals have a right to make requests for access to their protected health information directly to HIPAA-covered laboratories. Laboratories may not require individuals to make requests through their providers. While laboratories cannot require individuals to submit requests for access to protected health information maintained by the laboratories through their treating providers, individuals may do so if that is one avenue the laboratory uses to receive requests for access from individuals. Laboratories, however, may require that individuals make access requests directly to the laboratory.

With respect to laboratories that refer specimens to another laboratory, an individual has a right to access his or her protected health information maintained in a designated record set at either laboratory. However, where one laboratory refers only one part of a test to another laboratory, the individual may need to request access from the referring laboratory to obtain access to a complete set of test results. As explained above, a HIPAA-covered laboratory is required to provide an

individual with access only to that protected health information maintained by the laboratory in its designated record sets.

## 2. Time Frame for Providing Access

*Comment:* Some commenters were concerned that the required 30-day timeframe in the HIPAA Privacy Rule for providing an individual with access to laboratory test reports may not be sufficient to ensure that a provider receives the report before the patient. The commenters believe this is particularly problematic in the case of “sensitive” test results. One commenter suggested that laboratories should have the option of using up to two 30-day extensions when a licensed health care professional has determined, in the exercise of professional judgment, that the ordering provider should have additional time to receive and review the test report before the patient is provided access. Another commenter stated that the rule should not require laboratories to release a test report to a patient before a treating provider, except in emergency circumstances. Other commenters suggested that there should be 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.

In contrast, other commenters were against providing a defined delay between when the provider and the patient could obtain the test report. Some commenters stated that the Privacy Rule’s 30-day timeframe for providing access affords ample opportunity for a provider to receive a test report and consult with the patient before the patient receives the test report he or she requested directly from the laboratory. For example, one commenter suggested that the 30-day period provides laboratories with sufficient flexibility to release routine test results within a few days, while delaying the results of more sensitive tests to allow more time for consultation between the provider and the patient.

*Response:* We believe 30-days is generally sufficient time to allow a treating provider to receive a test report in advance of the patient’s receipt of the report and to communicate the result to and counsel the patient as necessary with regard to the result. Specifically, requests to a laboratory for access may be made some time after the provider has ordered the test or even after the provider has received the completed test report. In cases where the end of the initial 30-day period after an individual’s request for access 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 no 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. However, laboratories may have only one extension (see § 164.524(b)(2)(iii)). Since we believe the timeframes provided in the HIPAA Privacy Rule generally are sufficient to enable laboratories to provide test reports to ordering providers before patients, we decline to specify a specific lag time or to allow an additional 30-day extension beyond the one 30-day extension currently permitted.

*Comment:* A few commenters expressed concern that the 30-day period (and one 30-day extension) for providing access may not be sufficient for all laboratory test reports to be completed. One commenter suggested that the 30-day period to provide the individual with a copy of the test report should begin from the time of the individual’s request for access, or test completion, whichever is later.

*Response:* We understand the commenters’ concerns; however, we do not believe it is necessary to establish the completion of the test report as the trigger for the beginning of the 30-day period if the completion of the test report is later than the individual’s request for access, or to otherwise create a timeliness requirement for laboratories that is different than the requirement for other types of covered entities. As discussed above in the section on “Scope of Information to Which an Individual Has Access,” the Privacy Rule provides sufficient flexibility in most cases to enable laboratories to provide individuals with access to the completed test reports they request. In those rare cases where a test report is not completed, and therefore is not available, within the HIPAA timeframe for responding to requests and the individual is not willing to withdraw his or her request so that he or she will receive a completed test report, the Privacy Rule requires only that the laboratory provide access to the existing protected health information in its designated record set(s) about the individual, which would not include the completed test report requested. We believe that uniformity of the timeliness requirement in the Privacy Rule for all covered entities, including laboratories, is important to ensure consumer

understanding and covered entity compliance.

## E. Allowable Fees for Copying

*Comment:* Several commenters stated that laboratories should be permitted to charge individuals that request a copy of one or more test reports an additional fee along with the current fee permitted by the HIPAA Privacy Rule. A number of commenters were specifically concerned with the costs of retrieving archived test reports, which may only be available on paper or limited media, and transferring them to a suitable medium for distribution to the patient. A few commenters suggested that a laboratory should be able to recoup the full costs of providing reports to the individual, including costs associated with retrieval of the information, copying, verification, documentation, liability insurance, and other administrative costs.

In contrast, a number of commenters stated that individuals should not encounter any additional fee to receive copies of test reports from laboratories, other than the costs associated with completing the tests.

*Response:* We appreciate the comments on this issue. The fee provisions in the Privacy Rule are carefully balanced to reduce costs to covered entities while at the same time avoid being an impediment to individuals’ ability to receive copies of their protected health information. Therefore, we decline to expand the fees that may be charged to individuals or to disallow any fees that are currently provided for under the HIPAA Privacy Rule. HIPAA-covered laboratories must comply with the same fee limitations at § 164.524(c)(4) of the Privacy Rule as other HIPAA covered entities in providing individuals with copies of their health information. This means 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 the copy be mailed; and (4) preparation of an explanation or summary of the protected health information, if agreed to by the individual. HIPAA-covered laboratories may not charge fees to reflect the costs they incur in searching for and retrieving the information that is the subject of the individual’s request. Further, fees for costs associated with verification, documentation, liability

insurance, maintaining systems, and other similar activities are not permissible fees under this provision.

*Comment:* One commenter asked for a more definitive framework of what is an appropriate fee.

*Response:* We are unable to provide a more definitive framework of what is an appropriate fee, given that costs will vary depending on a number of circumstances, such as the form of the copy requested (paper versus electronic), the amount of information to be included in the copy, and whether the individual has requested the copy to be placed on electronic media or mailed. Covered entities may take into account all of these factors in determining what is a reasonable, cost-based fee. However, we consider fees expressly permitted under state law for copying and postage to be reasonable (as long as they do not include amounts associated with fees not provided for under the HIPAA Privacy Rule, such as the fees for the cost of search and retrieval or other costs).

#### F. Form and Format of Access

*Comment:* Some commenters stated that HIPAA-covered laboratories should be able to limit the types of electronic formats in which patients could receive copies of their completed test reports, and that the format provided should not be controlled solely by patient preference. These commenters were concerned with requiring laboratories to have the capability to convert test reports to all types of universal formats (for example, Microsoft (MS) Word, MS Excel, or Portable Document Format (PDF)). One commenter stated it is not practicable to reproduce all of the data of the official report into some formats, such as MS Excel. A few commenters expressed concern that HIPAA-covered laboratories will be required to invest in new technology to allow for patient portals into laboratory systems so that patients can view their test reports online. Certain commenters were specifically concerned about the resources involved with having to convert final laboratory reports that exist only on paper to PDF or other electronic format.

Other commenters advocated for the use of patient portals and personal health records (PHRs) to deliver test reports to patients in a readable and secure manner. One commenter stated that the rule should ensure laboratories are not allowed to provide test reports exclusively through proprietary formats that require expensive proprietary software to view, interpret, or process the results. Finally, one commenter

asked who makes the determination about which format is acceptable.

*Response:* 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. Rather, the Privacy Rule requires a covered entity to provide the individual with a copy of the requested information in the form and format requested by the individual, if a copy in that form or format is readily producible. With respect to protected health information maintained by the covered entity only in paper form, the Privacy Rule requires the covered entity to provide the individual with a copy of the protected health information in the form and format requested by the individual, if it is readily producible. If not, the copy must be either a readable hard copy or in another form or format as agreed to by the covered entity and the individual (see § 164.524(c)(2)(i)). Thus, where an individual requests an electronic copy of test reports that a HIPAA-covered laboratory maintains only on paper, the laboratory is required to provide the individual with the type of electronic copy requested if it is readily producible electronically and in the format requested. For example, a HIPAA-covered laboratory maintaining the requested test reports on paper may be able to readily produce a scanned PDF version of the report but not the requested Word version. In this case, the laboratory may provide the individual with the PDF version if the individual agrees to accept the PDF version. 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.

However, when the protected health information to which the individual seeks access is maintained electronically by the covered entity and the individual requests an electronic copy of the information, the Privacy Rule requires the covered entity to provide the individual with access to the information in the requested electronic form and format if it is readily producible in that form and format. When it is not readily producible in the electronic form and format requested, then the covered entity must provide the copy in an alternative readable electronic format as agreed to by the covered entity and the individual (see § 164.524(c)(2)(ii)). In short, this means that any HIPAA-covered laboratory that maintains

protected health information about an individual in one or more designated record sets electronically must have the capability to provide the individual with some form of electronic copy of the individual's protected health information. For example, this would include providing the individual with an electronic copy of the protected health information in the format of MS Word or Excel, text, HTML, or text-based PDF. In addition, we encourage laboratories to make available to individuals, upon request, an electronic copy of their protected health information in machine-readable formats (such as in HL7), which will enable individuals to use their protected health information in electronic health information tools, such as PHRs, if they choose.

We agree with the commenters that individuals should not have an unlimited choice in the form of electronic copy they will receive. The Privacy Rule allows a covered laboratory to make some other agreement with individuals as an alternative means to provide a readable electronic copy to the individual where the covered laboratory is not able to readily provide the form of electronic copy requested. If an individual requests a form of electronic copy that the HIPAA-covered laboratory is unable to produce, the laboratory must offer the individual other electronic formats that are available on its systems. If the individual declines to accept any of the electronic formats that are readily producible by the HIPAA-covered laboratory, the laboratory must provide a hard copy as an option to fulfill the access request. We remain neutral on the type of technology that covered entities may adopt. We note that a PDF is a widely recognized format that would satisfy the electronic access requirement if it is the individual's requested format or if the individual agrees to accept a PDF instead of the individual's requested format. Alternatively, there may be circumstances where an individual prefers a simple text or rich text file and the laboratory is able to accommodate this preference. In this case, a hard copy of the individual's protected health information would not satisfy the electronic access requirement. However, a hard copy may be provided if the individual decides not to accept any of the electronic formats offered by the covered entity.

For example, if a HIPAA-covered laboratory receives a request from an individual to have access to test reports through a web-based portal, but the only readily producible version of the

protected health information by the laboratory is in PDF, the Privacy Rule requires the laboratory to provide the individual with the PDF copy of the protected health information, if the individual agrees to receive it in that form. If the individual declines to receive the PDF copy, the laboratory may provide the individual with a hard copy of the information.

Further, while we encourage laboratories to offer patients the ability to access their test reports through patient portals maintained by the laboratories, the HIPAA Privacy Rule does not require covered entities to have this capability. We recognize that what is available in a readable electronic form and format will vary by system and technological capabilities will improve over time. Therefore, the Privacy Rule allows covered entities the flexibility to provide individuals with electronic copies of protected health information that are currently readily producible and available on their various systems. A HIPAA-covered laboratory is not required to purchase new software or systems in order to accommodate an electronic copy request for a specific form that is not readily producible by the laboratory at the time of the request, provided the laboratory is able to provide some form of electronic copy. We note that providing the individual with an electronic copy of a test report in a proprietary format that will require the purchase or acquisition by the individual of proprietary software to view the report would not satisfy these access requirements.

*Comment:* A few commenters suggested that any electronic copies provided to individuals should include a digital signature to provide assurance that test results had not been modified.

*Response:* HIPAA-covered laboratories may include digital signatures on electronic copies of test reports given to individuals, provided the electronic copy is still in a format that has either been requested by the individual or is an alternative that has been agreed to by the individual and the laboratory.

*Comment:* Some commenters were concerned about the ability of laboratories to transmit electronic copies of test reports to individuals in a secure manner, and asked for guidance on how test reports should be transmitted to patients. A few commenters were concerned with transmitting test reports to patients via unencrypted email. One commenter expressed concern about being found responsible for a breach if a HIPAA-covered laboratory sent test reports in an unsecure manner after a specific

request by the individual to send them in that manner. Other commenters suggested that any method of transmitting test reports to individuals should be acceptable, whether it be by mail, email, transmission to a PHR or patient portal, or other method.

*Response:* How a test report is transmitted to an individual will vary depending on the circumstances and the request of the individual. In cases where an individual is in close proximity of the laboratory, the individual may wish to come and pick up the test report from the laboratory directly; however, the individual is not required to do so. Individuals also have a right under the Privacy Rule to have either the paper or electronic (for example, on compact disk) copies of their protected health information mailed to them, and HIPAA-covered laboratories may charge an individual for postage in cases where the individual has asked that the copy be mailed. In sending the copy to an individual, covered laboratories are required to reasonably safeguard the information (see § 164.530(c)). This may include ensuring the packaging is securely sealed and that none of the information from the test reports is visible from the outside of the package.

Individuals also may request that a laboratory email an electronic copy of a test report. In emailing copies of test reports to individuals, HIPAA-covered laboratories are required to comply with the HIPAA Security Rule, which, among other requirements, requires implementation of technical security measures to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network (see § 164.312(e)). As a security measure, the Security Rule requires encryption when transmitting electronic protected health information where it is reasonable and appropriate to encrypt the information. In general, encryption is a reasonable and appropriate measure to safeguard email transmissions. However, we have found that there may be instances when an individual may not want to receive his or her protected health information in an encrypted format or may be unable to access the information when encrypted. In these cases, a HIPAA-covered laboratory is permitted to send the individual copies of the test reports via unencrypted email, if it advises the individual of the risks associated with unencrypted email, and, after doing so, the individual still wishes to receive his or her protected health information via unencrypted email. 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. Further, a HIPAA-covered laboratory is not responsible for safeguarding protected health information once it is delivered to the individual.

Finally, as mentioned above, we encourage laboratories to offer individuals access to their test reports and other health information through secure patient portals or PHRs. However, use of this method is not required.

*Comment:* One commenter asked if CMS has the regulatory authority to establish minimum requirements for the provision of electronic test results to patients in a structured format or at least to suggest guidance to laboratories if the test results are to be provided in an electronic format.

*Response:* CMS does not have current plans to establish regulations that would impose minimum requirements for the provision of electronic results in a structured format, but could examine these options going forward. Furthermore, CLIA guidance on electronic formats was provided as part of the March 2010 revision to the CLIA State Operations Manual Appendix C—Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services (see, CMS Ref: S&C–10–12–CLIA).<sup>2</sup>

#### *G. Content of Test Report, Educational Materials, and Standard Statements*

*Comment:* A few commenters requested further guidance on what the test report that is provided to an individual should look like. Commenters noted that the laboratory coding schema on the official test report sent to the provider may need further interpretation and context before it would be useful to the patient. These commenters expressed concern with the resources and information system development that would be needed to provide a more understandable test report to the individual. Other commenters stated that the report furnished to the individual should be the “official” report furnished to the ordering provider rather than one that is reworded and redesigned in an effort to meet the needs of the individual. Otherwise, they noted, there could be inadvertent inconsistencies or inaccuracies when one compared the “official” report to the patient-centric report.

<sup>2</sup> <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter10-12.pdf>.

In addition, some commenters suggested that laboratories should provide brief explanations or patient-specific educational materials on the tests reported, including reference ranges, so that the individual can interpret the information (for example, similar to a pharmacy's provision of the package insert for prescription drugs).

*Response:* As discussed above, the final rule does not require laboratories to interpret test reports for individuals. An individual has a right to receive a copy of the information about the individual maintained by or on behalf of a HIPAA-covered laboratory in a designated record set, which may include the official test report that is also provided to the individual's provider. However, while not required, a laboratory may also provide additional educational or explanatory materials regarding the test results to individuals if it chooses to do so.

*Comment:* A number of commenters suggested that the information provided to individuals should include 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 providing the contact information of the physician who ordered the tests.

*Response:* As we explain above, this final rule does not supplant the treatment conversation a health care provider has with a patient about the patient's test results. We expect that individuals will continue to obtain test results through their treating or ordering providers, and even when individuals request access to test reports directly from laboratories, we believe that, in most cases, these individuals will have had conversations with their treating providers about their test results before receiving access. Therefore, we do not believe a regulatory requirement for a standard statement is warranted. However, laboratories that wish to include one with test reports are free to do so.

#### H. Verification of Identity and Authentication

*Comment:* Some commenters stated that many laboratories would have challenges with verifying an individual's identity 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. One commenter indicated that these limitations would necessitate that an

individual make a request for a test report in person. These commenters requested guidance or sample authentication practices for verifying an individual's identity upon receiving a request, whether in person, by phone, fax, or other means. One commenter suggested that the Department should provide guidance on the appropriate assurance levels for identity proofing and authentication, as defined by the National Institute of Standards and Technology (NIST) (Publication 800-63).

*Response:* Under § 164.514(h) of the Privacy Rule, a covered entity is required to take reasonable steps to verify the identity of the individual making a request for access. The rule does not mandate any particular form of verification (such as obtaining a copy of a driver's license), but rather leaves the type and manner of the verification to the discretion and professional judgment of the covered entity. Further, covered entities may rely on industry standards in developing reasonable verification processes. The type of verification may also vary depending on how the individual is to receive access, the form of the request, and whether the covered entity is requiring that all requests for access be made in writing, as permitted by § 164.524(b)(1), or permitting oral requests for access. For example, in those cases where an individual requests to pick up a copy of a test report directly from a laboratory, the laboratory may require that some form of photo identification be provided before the individual receives a copy. When a HIPAA-covered laboratory requires that a request for a copy of the test report be made on its own supplied form (whether by fax, email, or otherwise), the laboratory could request basic information on the form (date of birth, provider's name, date specimen was collected, etc.) to verify that the person requesting access is the individual who is the subject of the test report. Similarly, if a laboratory allows an individual to verbally request access over the phone, the laboratory can, at that time, request the information needed to verify the person is the subject individual. For those laboratories using patient portals to provide access, those portals should already be set up with appropriate authentication controls, as required by § 164.312(d) of the HIPAA Security Rule, to ensure that the person seeking access is the one claimed. However, we do not prescribe specific levels of authentication.

We understand that, in many cases, a laboratory may not have extensive contact or other information about an

individual. However, the rule makes clear that a laboratory is only required to provide an individual with access to test reports that can be identified as belonging to the individual who has requested access, based on the laboratory's authentication processes. Thus, when a laboratory is able to authenticate a test report as belonging to a particular patient, that laboratory will have at least some basic information about the patient, such as name, date of birth, date specimen was collected, etc., that can also be used to verify the identity of a person requesting access to that test report. When a laboratory believes a provider may have supplied incorrect information for a patient, which prevents the laboratory from properly verifying the individual, the laboratory may contact the provider to see if correct information is available.

While the Privacy Rule requires verification of the identity of the person requesting access, a HIPAA-covered laboratory may not impose unreasonable verification measures on an individual as a means to avoid having to provide the individual with access. For example, a HIPAA-covered laboratory may not require an individual who wants a copy of his or her test reports mailed to his or her home address to physically come to the laboratory to request access and provide proof of identity in person.

#### I. Informing Individuals of Their New Right of Access

*Comment:* A few commenters stated that providers should be required to inform or notify individuals of their right to receive test reports directly from laboratories, and to provide the information necessary for individuals to request test reports from the appropriate clinical laboratories. One commenter suggested this information could be included in the provider's notice of privacy practices. Another commenter asked if this final rule would require HIPAA-covered laboratories to revise their notices of privacy practices to include a statement regarding an individual's right to receive test results directly from the laboratory.

*Response:* We encourage, but do not require, treating health care providers to inform individuals of their right to receive test reports directly from HIPAA-covered laboratories. We believe requiring providers to do so would create an unwarranted burden on providers. However, whenever providers send a specimen(s) to the laboratory, as opposed to the individual going to the laboratory himself or herself to provide the testing sample, we encourage providers to supply the individual with the name of the

laboratory to which the specimen is being or has been sent and the other information necessary for the individual to request access from the laboratory.

With respect to HIPAA notices of privacy practices, a covered entity is required to promptly revise its notice whenever there is a material change to any of its privacy practices, including those pertaining to individuals' rights to access their protected health information (see § 164.520(b)(3) of the Privacy Rule). This final rule provides individuals with a right to access their protected health information directly from HIPAA-covered laboratories. A change in an individual's access rights constitutes a material change to the privacy practices of HIPAA-covered laboratories. Thus, by the compliance date of this final rule, HIPAA-covered laboratories must revise their notices to inform individuals of this right and to include a brief description of how to exercise this right, and must remove any statements to the contrary (see § 164.520(b)(1)(iv)(C)). Further, HIPAA-covered laboratories must make the revised notice available as required by § 164.520(c). We do not require that other covered health care providers, such as ordering providers, revise their notices of privacy practices to inform individuals of their right to access protected health information directly from laboratories.

The Department recognizes that HIPAA-covered laboratories are already required by the modifications to the HIPAA Rules that were published on January 25, 2013 (78 FR 5566) to revise their notices by September 23, 2013. To avoid HIPAA-covered laboratories having to modify their notices twice within the same year to comply with both the January 25, 2013, final rule and this rule, the Department announced on September 19, 2013, that it was exercising its enforcement discretion to allow CLIA laboratories (including CLIA-exempt laboratories) that are HIPAA covered entities to take until the compliance date of this final rule, October 6, 2014, to revise their notices to reflect both sets of modifications. See <http://www.hhs.gov/ocr/privacy/hipaa/enforcement/clia-labs.html>. Thus, CLIA and CLIA-exempt laboratories that are HIPAA covered entities need only update their notices once to comply with both rules.

#### J. Preemption

*Comment:* A number of commenters supported the rule's general preemption of contrary state laws, stating that it would bring further harmonization of federal and state laws and ensure, regardless of where an individual lives,

that he or she has access to laboratory test reports. Other commenters requested clarification with respect to preemption, asking whether state laws that require more timely access to test reports than the Privacy Rule or that would limit the types of identification a laboratory could ask an individual to present to verify identity would continue to stand. One commenter stated that the final rule should preempt state laws that restrict laboratory-initiated contact with patients for purposes of communicating laboratory results. This commenter stated that there can be compelling medical reasons for laboratories to initiate contact. Another commenter stated that the rule should not preempt state laws that require the provider to discuss the results and provide psychological counseling along with disclosure of HIV test results.

*Response:* We agree with commenters that preemption of certain contrary state law is necessary to ensure that individuals' access rights under the Privacy Rule are strengthened. A number of states have laws that prohibit a laboratory from releasing a test report directly to the individual or that prohibit the release without the ordering provider's consent. Upon the effective date of this final rule, the Privacy Rule preempts these laws and HIPAA-covered laboratories should begin to come into compliance.

With respect to those commenters requesting clarification on HIPAA preemption, we note that HIPAA preempts only state laws that are contrary to the Privacy Rule. "Contrary" generally means a covered entity would find it impossible to comply with both the state and HIPAA requirements. In certain cases, a contrary state law is not preempted, such as where a state law is more stringent than the Privacy Rule. "More stringent" means, with respect to individuals' access rights, that the state law provides greater rights of access to individuals (see, 45 CFR Part 160, Subpart B). A state law that requires a laboratory to provide an individual with more timely access to test reports is not contrary to the Privacy Rule and thus, is not preempted. Similarly, a state law that limits the types of identification a laboratory can ask an individual to produce is not contrary to the Privacy Rule, provided the laboratory is still able to verify the identity of the person requesting access as required by § 164.514(h). HIPAA-covered laboratories should be able to comply with both sets of requirements in providing individuals with access to their test reports. Further, we clarify that this final rule applies only to

laboratories. 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 this final rule. Finally, the trigger for the access obligations under the Privacy Rule is a request from an individual or the individual's personal representative. This 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

*Comment:* A number of commenters advocated for a longer time period for HIPAA-covered laboratories to come into compliance than the proposed 180-day compliance period. Commenters suggested a variety of different compliance dates, including one year and beyond. Some commenters raised specific concerns with respect to laboratories that do not currently provide individuals with access to test reports, since the laboratories would need to develop all new policies, protocols, and mechanisms for receiving and responding to requests for access to test reports.

Other commenters asked that the Department wait to finalize the rule until after the HITECH Act changes to the Privacy Rule become final so that HIPAA-covered laboratories would need to develop only one set of policies, protocols, and procedures one time, to comply with the Privacy Rule's access provisions. A few commenters requested that the Department implement reasonable, sequenced compliance deadlines for all related regulations under the HITECH Act and HIPAA, such as changes to the Privacy Rule, EHR Incentive Programs' requirements, and the implementation of HIPAA Version 5010 and ICD-10. Commenters stated that sequenced deadlines would better take into account the significant amount of financial, operational, and technological resources needed to fully comply with all of these new requirements.

*Response:* While we appreciate the commenters' concerns regarding the compliance date, we decline to extend the 180-day compliance period for this final rule. We believe 180 days will provide HIPAA-covered laboratories with sufficient time to become prepared to provide individuals who request them with copies of test reports and will also ensure that individuals are afforded and able to benefit from this new right in a timely manner after the rule's issuance. Thus, HIPAA-covered laboratories are required to comply with

the individual access provisions of the Privacy Rule by no later than 180 days after the effective date of the final rule. The effective date of the final rule is 60 days after publication in the **Federal Register**; therefore, laboratories have a total of 240 days after publication of this final rule to come into compliance. Moreover, in a number of cases, laboratories that operate in states that allow an individual to receive test reports directly from the laboratories will already have policies for providing individuals with access to test reports, which can then be modified as needed to be consistent with Privacy Rule requirements. The HITECH Act enhancements to an individual's right of access under the Privacy Rule were finalized and incorporated into the Privacy Rule on March 26, 2013. Thus, in implementing this rule and the HITECH Act changes, HIPAA-covered laboratories need only develop one set of policies. Finally, while we understand that overlapping compliance deadlines for different rules may be burdensome to entities that are subject to all of the rules, we do not believe it is feasible to completely sequence regulatory deadlines and still realize in a timely manner the benefits and protections the new requirements are intended to provide.

#### L. Other Comments

*Comment:* Commenters asked whether a laboratory could be subject to penalties for charging more than the reasonable cost-based fee allowed by the Privacy Rule, for failing to comply with an individual's request for completed test reports within the appropriate time period, or for failing to comply with an individual's request altogether.

*Response:* HIPAA-covered laboratories that fail to comply with the Privacy Rule's access provisions are subject to an enforcement action for noncompliance by the Department, which may include the imposition of civil money penalties. More information about HIPAA enforcement is available on the OCR Web site at: <http://www.hhs.gov/ocr/privacy/hipaa/enforcement/index.html>.

*Comment:* A few commenters suggested that the rule increases burden on individuals, by making them first call their provider's office to learn the name of the laboratory producing the test report and then making them call the laboratory for a copy of the test report, instead of just having them contact the provider's office for the test results.

*Response:* We do not agree that this final rule increases the burden on individuals. As previously discussed in

detail above, the rule does not supplant the role of the treating provider in discussing test results with a patient or an individual's right under the HIPAA Privacy Rule to access protected health information about the individual maintained by the provider, including laboratory test results. The rule merely provides an additional avenue for individuals to obtain copies of their test reports by allowing individuals to obtain their test reports directly from the laboratories.

*Comment:* One commenter stated that certain third-party payers and insurers do not allow laboratories to bill a patient any amount in addition to what is paid to the laboratory for testing services by that third-party payer or insurer. The commenter contended that this prohibition would prevent a laboratory from charging an individual a cost-based fee for providing a copy of the test report.

*Response:* First, we note that charging an individual a fee for access is optional and not required under the Privacy Rule. Second, the billing restriction described by the commenter is likely tied to the costs associated with the provision of health care services, and not to a laboratory's ability to charge an individual for reasonable costs associated with providing the individual access to his or her protected health information. It has not been our experience that covered health care providers subject to similar billing restrictions have been unable to charge individuals reasonable cost-based fees for access to their records.

*Comment:* One commenter asked, when a patient fails to compensate the laboratory for services provided, whether a laboratory may withhold future test results from the patient until payment is made.

*Response:* 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.

*Comment:* One commenter stated that laboratories should not be required to provide test reports in a patient's preferred language.

*Response:* A covered entity's obligations under civil rights or other laws to ensure equal access to health care for individuals, including requirements for when certain documents must be translated, are not diminished or disturbed by this rule.

*Comment:* A few commenters suggested that laboratories should be required to notify the ordering provider when a patient has received, or will

receive, copies of test reports directly from the laboratory.

*Response:* We do not believe this requirement is warranted. As discussed above, this rule does not change the ability of an ordering provider to receive test reports and discuss them with the patient. However, a laboratory that wishes to provide notification to a provider that an individual will receive a copy of a test report directly may do so.

*Comment:* One commenter stated that, by deferring to state law, the CLIA regulations impede disclosures of test reports to other HIPAA covered entities and business associates for purposes that are otherwise permitted by HIPAA. This commenter stated that the list of persons authorized to receive the reports should be expanded to include HIPAA covered entities and business associates. This commenter believes that the expansion of the list will eliminate barriers to legitimate disclosures to these entities, such as for treatment or quality improvement purposes.

*Response:* The CLIA regulations at § 493.1291(f) state that test results must be released only to authorized persons and, if applicable, to the persons responsible for using the test results, and to the laboratory that initially requested the test. "Responsible for using" would cover those HIPAA covered entities that are in a treatment relationship with the individual. CLIA also defines "authorized person" as an individual authorized under state law to order tests or receive test results, or both. State law can expand the list of entities that can be considered "authorized" persons under CLIA.

## VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the

affected public, including automated collection techniques.

In our September 14, 2011 proposed rule (76 FR 56712), we solicited public comment on each of these issues, as required by section 3506(c)(2)(A) of the PRA. We did not receive any PRA-related comments.

Except as provided in § 493.1291(l), test reports must be released only to authorized persons and, if applicable, the individuals (or their personal representatives) responsible for using the test reports and, to the laboratory that initially requested the test. Under § 493.1291(l), the laboratory may, upon

request by the patient (or the patient's personal representative), provide access to the patient's test reports that the laboratory can identify as belonging to that patient. The CLIA regulations do not require that CLIA-certified laboratories provide this access—rather, these laboratories are allowed to provide for access. However, the accompanying changes to the HIPAA Privacy Rule in this final rule require that CLIA-certified laboratories that are HIPAA covered entities provide individuals with access in accordance with the Privacy Rule. The CLIA-certified laboratories that are covered entities under HIPAA will need

to ensure that their practices conform to CLIA and HIPAA requirements.

We have prepared the Paperwork Reduction Act and the Regulatory Impact Analysis (RIA) that represents the costs and benefits of the final rule based on an analysis of identified variables and data sources needed for this change. We identified known data elements (Table 1) and made assumptions on elements where a source could not be identified (Table 2). Our assumptions are based on internal discussions and consultation with laboratories representative of the industry.

TABLE 1—SUMMARY OF KNOWN DATA ELEMENTS

| Variable                                                                                                           | Data element  | Source                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------|---------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| States/territories where laboratories, as listed in Table 3, are impacted by the new individual access provisions. | 39            | Determination of this finding is based on two reports as listed here:<br>1. <i>Privacy and Security Solutions for Interoperable Health Information Exchange, Releasing Clinical Laboratory Test Results; Report on Survey of State Laws</i> prepared by Joy Pritts, JD, for the Agency for Health care Research and Quality and Office of the National Coordinator August 2009; RIT Project Number 0209825.000.015.100 (Accessed July 15, 2010).<br>2. <i>Electronic Release of Clinical Laboratory Results: A Review of State and Federal Policy</i> , prepared by Kitty Purington, JD, for the California Health care Foundations January 2010 (Accessed July 15, 2010). |
| Laboratories, as listed in Table 6, impacted by the new individual access provisions.                              | 22,816        | Data from CLIA Online Survey Certification and Reporting database (OSCAR) database accessed August 27, 2012.<br>Includes Certificate of Compliance and Certificate of Accreditation in the 39 states impacted by the patient access provisions.                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Test results in laboratories, as listed in Table 6, impacted by the new individual access provisions.              | 7,025,841,649 | Data from OSCAR database accessed August 27, 2012<br>Includes Certificate of Compliance and Certificate of Accreditation in the 39 states impacted by the patient access provisions.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| States/territories, as noted in Table 7, where the HIPAA Privacy Rule will pre-empt State Law <sup>1</sup> .       | 46            | Determination of this finding is based on two reports as listed here:<br>1. <i>Privacy and Security Solutions for Interoperable Health Information Exchange, Releasing Clinical Laboratory Test Results; Report on Survey of State Laws</i> prepared by Joy Pritts, JD, for the Agency for Health care Research and Quality and Office of the National Coordinator August 2009; RIT Project Number 0209825.000.015.100 (accessed July 15, 2010).<br>2. <i>Electronic Release of Clinical Laboratory Results: A Review of State and Federal Policy</i> prepared by Kitty Purington, JD, for the California Health care Foundations January 2010 (Accessed July 15, 2010).   |
| Laboratories, as indicated in Table 7, required to update their HIPAA notices of privacy practices.                | 33,807        | Data from OSCAR database accessed August 27, 2012<br>Includes Certificate of Compliance and Certificate of Accreditation in the 27 states impacted by the HIPAA provisions to update the notices of privacy practice.                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Hourly salary of clerical level employee to process requests for test reports.                                     | \$30.09       | 2013 salary/wages and benefits—use 2012 salary/wages and benefits obtained from the U.S. Bureau of Labor Statistics, Economic News Release, March 2012 U.S.—Total employer costs per hour worked for employee compensation: Civilian workers; Occupational Group: Service-providing at <a href="http://www.bls.gov/news.release/ecec.t01.htm">http://www.bls.gov/news.release/ecec.t01.htm</a> and adjusts annually by 2.78 percent to reflect an average increase in total compensation costs from 2007–2011.                                                                                                                                                             |
| Hourly salary of management level employee to determine policy.                                                    | \$50.06       | 2013 salary/wages and benefits—use 2012 salary/wages and benefits obtained from the U.S. Bureau of Labor Statistics, Economic News Release, March 2012 U.S.—Total employer costs per hour worked for employee compensation: Civilian workers; Occupational Group: Service-providing at <a href="http://www.bls.gov/news.release/ecec.t01.htm">http://www.bls.gov/news.release/ecec.t01.htm</a> and adjusts annually by 2.78 percent to reflect an average increase in total compensation costs from 2007–2011.                                                                                                                                                             |

1. Note that there may be circumstances where a laboratory is able to comply with both HIPAA and the state law.

TABLE 2—SUMMARY OF ASSUMPTIONS

| Variable                                               | Low                   | High             |
|--------------------------------------------------------|-----------------------|------------------|
| Number of test results per test report .....           | 10 test results ..... | 20 test results. |
| Percentage of patients requesting test report .....    | 0.05% .....           | 0.50%.           |
| Time required to process request for test report ..... | 10 minutes .....      | 30 minutes.      |

We determined that the impacted CLIA-certified laboratories can be broken down into four categories: Laboratories in states and territories where there is no law regarding who can receive test reports (N=26), laboratories in states and territories where test reports can only be given to the provider (N=13), laboratories in states and territories that allow test reports to go directly to the patient through some

means or mechanism (N=9), and laboratories in states and territories that allow the test reports to go to the patient with provider approval (N=7). Of these four categories, we believe that laboratories in the 39 states and territories where there is either no law regarding receipt of test reports or where reports can only go to the provider are affected by the individual access provisions contained in this rulemaking

(see Table 3 for a list of states and territories by category). Laboratories in the remaining categories would most likely have existing procedures in place to respond to patient requests for test reports, whereas the laboratories in the first two categories would most likely not have procedures in place and would have to develop mechanisms for handling these requests and providing access.

TABLE 3—IMPACT ON LABORATORIES OF NEW INDIVIDUAL ACCESS PROVISIONS

| Impacts laboratories                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                             | Does not impact laboratories                                                                                                    |                                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| No State law                                                                                                                                                                                                                                                                                                                             | Allows test reports only to provider                                                                                                                        | Allows test reports to patient                                                                                                  | Allows test reports to patient with provider approval                                     |
| Alabama<br>Alaska<br>Arizona<br>Colorado<br>Guam<br>Idaho<br>Indiana<br>Iowa<br>Kentucky<br>Louisiana<br>Minnesota<br>Mississippi<br>Montana<br>Nebraska<br>New Mexico<br>North Carolina<br>North Dakota<br>Northern Mariana Islands<br>Ohio<br>Oklahoma<br>South Carolina<br>South Dakota<br>Texas<br>Utah<br>Vermont<br>Virgin Islands | Arkansas<br>Georgia<br>Hawaii<br>Illinois<br>Kansas<br>Maine<br>Missouri<br>Pennsylvania<br>Rhode Island<br>Tennessee<br>Washington<br>Wisconsin<br>Wyoming | Delaware<br>District of Columbia<br>Maryland<br>New Hampshire<br>New Jersey<br>Nevada<br>Oregon<br>Puerto Rico<br>West Virginia | California<br>Connecticut<br>Florida<br>Massachusetts<br>Michigan<br>New York<br>Virginia |

In addition to the impact from the access provisions, laboratories both in the 39 states and territories where there is either no law regarding receipt of test reports or where reports can only go to the provider, as well as in the 7 states and territories that currently allow test reports to go to the patient only with provider approval, will be affected by the requirement to update HIPAA notices of privacy practices as a result

of this final rule (see Table 4 for a list of states and territories by category). Even if laboratories in the 7 states and territories that currently allow test reports to go to the patient with provider approval have processes in place to provide test reports to patients, their notices of privacy practices may now contain inaccurate statements about how individuals can obtain copies of their test reports, given that this final

rule preempts these state laws. Therefore, by the compliance date of this rule, the laboratories in the 46 states and territories identified in Table 4 will need to revise their notices to inform individuals of their right to obtain reports directly from the laboratory, provide a brief description of how to exercise this right, and must remove any statements to the contrary (see § 164.520(b)(1)(iv)(C)).

TABLE 4—IMPACT ON LABORATORIES OF HIPAA PRIVACY RULE REQUIREMENT TO REVISE THEIR NOTICES OF PRIVACY PRACTICES

| Impacts laboratories                                      |                                                              |                                                                               | Does not impact laboratories                                                          |
|-----------------------------------------------------------|--------------------------------------------------------------|-------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| No State law                                              | Allows test reports only to provider                         | Allows test reports to patient with provider approval                         | Allows test reports to patient                                                        |
| Alabama<br>Alaska<br>Arizona<br>Colorado<br>Guam<br>Idaho | Arkansas<br>Georgia<br>Hawaii<br>Illinois<br>Kansas<br>Maine | California<br>Connecticut<br>Florida<br>Massachusetts<br>Michigan<br>New York | Delaware<br>District of Columbia<br>Maryland<br>New Hampshire<br>New Jersey<br>Nevada |

TABLE 4—IMPACT ON LABORATORIES OF HIPAA PRIVACY RULE REQUIREMENT TO REVISE THEIR NOTICES OF PRIVACY PRACTICES—Continued

| Impacts laboratories                                                                                                                                                                                                                                                        |                                                                                             |                                                       | Does not impact laboratories           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|-------------------------------------------------------|----------------------------------------|
| No State law                                                                                                                                                                                                                                                                | Allows test reports only to provider                                                        | Allows test reports to patient with provider approval | Allows test reports to patient         |
| Indiana<br>Iowa<br>Kentucky<br>Louisiana<br>Minnesota<br>Mississippi<br>Montana<br>Nebraska<br>New Mexico<br>North Carolina<br>North Dakota<br>Northern Mariana Islands<br>Ohio<br>Oklahoma<br>South Carolina<br>South Dakota<br>Texas<br>Utah<br>Vermont<br>Virgin Islands | Missouri<br>Pennsylvania<br>Rhode Island<br>Tennessee<br>Washington<br>Wisconsin<br>Wyoming | Virginia                                              | Oregon<br>Puerto Rico<br>West Virginia |

The CMS Online Survey, Certification, and Reporting (OSCAR) database indicates that there are a total of 234,756 laboratories which provide approximately 12.8 billion tests annually (see Table 5) in the United States. We assume Certificate of Waiver laboratories and Certificate of PPM laboratories would not be impacted because the tests are usually performed in these sites during a patient's visit. We

assume that the physician or health practitioner would inform the patient of those results during the visit, and we anticipate that the patient would ask that person with whom they interacted as opposed to the laboratory, if they have reason to seek copies of the test report in the future. In the 39 states and territories that are impacted by the patient access provision, there are

22,816 laboratories that perform over 7 billion tests annually (see Table 6).

However, we recognize that some laboratories included in these estimates may not be covered entities under HIPAA (because they do not conduct covered health care transactions electronically, for example, filing electronic claims for payment) and, therefore, would not be required to provide direct individual access.

TABLE 5—ALL U.S. LABORATORY TESTING SUBJECT TO CLIA

| CLIA certificate type                                    | Number of laboratories | Number of tests |
|----------------------------------------------------------|------------------------|-----------------|
| Certificate of Compliance .....                          | 20,470                 | 3,122,772,023   |
| Certificate of Accreditation .....                       | 16,829                 | 8,998,058,524   |
| Certificate of Waiver .....                              | 158,996                | 477,094,700     |
| Certificate of Provider Performed Microscopy (PPM) ..... | 38,461                 | 207,777,472     |
| Totals .....                                             | 234,756                | 12,805,702,719  |

TABLE 6—NUMBER OF LABORATORIES IMPACTED BY NEW INDIVIDUAL ACCESS PROVISIONS

| State or territory | Number of laboratories | Number of tests |
|--------------------|------------------------|-----------------|
| Alaska .....       | 103                    | 10,688,466      |
| Alabama .....      | 868                    | 252,267,262     |
| Arkansas .....     | 540                    | 74,686,910      |
| Arizona .....      | 581                    | 195,731,588     |
| Colorado .....     | 499                    | 138,847,079     |
| Georgia .....      | 1,190                  | 217,997,888     |
| Guam .....         | 13                     | 2,500,654       |
| Hawaii .....       | 117                    | 36,918,267      |
| Idaho .....        | 230                    | 33,092,465      |
| Illinois .....     | 1,053                  | 1,852,543,312   |
| Indiana .....      | 621                    | 190,732,493     |
| Iowa .....         | 548                    | 82,389,916      |
| Kansas .....       | 438                    | 240,744,893     |
| Kentucky .....     | 710                    | 133,586,267     |

TABLE 6—NUMBER OF LABORATORIES IMPACTED BY NEW INDIVIDUAL ACCESS PROVISIONS—Continued

| State or territory             | Number of laboratories | Number of tests |
|--------------------------------|------------------------|-----------------|
| Louisiana .....                | 677                    | 135,050,184     |
| Maine .....                    | 140                    | 36,150,552      |
| Minnesota .....                | 832                    | 165,066,668     |
| Mississippi .....              | 523                    | 45,808,928      |
| Missouri .....                 | 683                    | 192,145,580     |
| Montana .....                  | 961                    | 300,480,983     |
| Nebraska .....                 | 317                    | 33,103,996      |
| New Mexico .....               | 189                    | 44,642,110      |
| North Carolina .....           | 673                    | 48,771,993      |
| North Dakota .....             | 177                    | 49,833,112      |
| Northern Mariana Islands ..... | 181                    | 56,185,878      |
| Ohio .....                     | 634                    | 163,151,403     |
| Oklahoma .....                 | 485                    | 111,005,884     |
| Pennsylvania .....             | 747                    | 87,776,132      |
| Rhode Island .....             | 477                    | 91,657,444      |
| South Carolina .....           | 453                    | 38,185,190      |
| South Dakota .....             | 469                    | 171,638,497     |
| Tennessee .....                | 2,626                  | 949,935,182     |
| Texas .....                    | 1,594                  | 155,118,958     |
| Utah .....                     | 705                    | 256,856,757     |
| Vermont .....                  | 245                    | 174,974,043     |
| Virgin Islands .....           | 45                     | 11,413,475      |
| Washington .....               | 936                    | 167,818,742     |
| Wisconsin .....                | 482                    | 73,457,876      |
| Wyoming .....                  | 54                     | 2,884,622       |
| Total .....                    | 22,816                 | 7,025,841,649   |

In addition to complying with the individual access requirements, 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 to reflect the right of individuals to obtain test reports directly from laboratories (see Table 7). However, as stated above, we recognize that some laboratories included in these estimates may not be covered entities under HIPAA and, therefore, would not be required to provide direct individual access and would not be required to revise any notices.

TABLE 7—NUMBER OF LABORATORIES IMPACTED BY THE HIPAA PRIVACY RULE REQUIREMENT TO REVISE THEIR NOTICES OF PRIVACY PRACTICES

| State             | Number of laboratories |
|-------------------|------------------------|
| Alaska .....      | 103                    |
| Alabama .....     | 868                    |
| Arkansas .....    | 540                    |
| Arizona .....     | 581                    |
| California .....  | 2,919                  |
| Colorado .....    | 499                    |
| Connecticut ..... | 379                    |
| Florida .....     | 2,462                  |
| Georgia .....     | 1,190                  |
| Guam .....        | 13                     |
| Hawaii .....      | 117                    |
| Idaho .....       | 230                    |

TABLE 7—NUMBER OF LABORATORIES IMPACTED BY THE HIPAA PRIVACY RULE REQUIREMENT TO REVISE THEIR NOTICES OF PRIVACY PRACTICES—Continued

| State                       | Number of laboratories |
|-----------------------------|------------------------|
| Illinois .....              | 1,053                  |
| Indiana .....               | 621                    |
| Iowa .....                  | 548                    |
| Kansas .....                | 438                    |
| Kentucky .....              | 710                    |
| Louisiana .....             | 677                    |
| Massachusetts .....         | 693                    |
| Maine .....                 | 140                    |
| Michigan .....              | 926                    |
| Minnesota .....             | 832                    |
| Mississippi .....           | 523                    |
| Missouri .....              | 683                    |
| Montana .....               | 961                    |
| Nebraska .....              | 317                    |
| New Mexico .....            | 189                    |
| New York .....              | 2,425                  |
| North Carolina .....        | 673                    |
| North Dakota .....          | 177                    |
| Northern Mariana Islands .. | 181                    |
| Ohio .....                  | 634                    |
| Oklahoma .....              | 485                    |
| Pennsylvania .....          | 747                    |
| Rhode Island .....          | 477                    |
| South Carolina .....        | 453                    |
| South Dakota .....          | 469                    |
| Tennessee .....             | 2,626                  |
| Texas .....                 | 1,594                  |
| Utah .....                  | 705                    |
| Vermont .....               | 245                    |
| Virgin Islands .....        | 45                     |
| Virginia .....              | 467                    |

TABLE 7—NUMBER OF LABORATORIES IMPACTED BY THE HIPAA PRIVACY RULE REQUIREMENT TO REVISE THEIR NOTICES OF PRIVACY PRACTICES—Continued

| State            | Number of laboratories |
|------------------|------------------------|
| Washington ..... | 936                    |
| Wisconsin .....  | 482                    |
| Wyoming .....    | 54                     |
| Totals .....     | 33,087                 |

*A. Information Collection Requests (ICRs) Regarding the Development of Process To Provide Patient Access to Test Reports (§ 493.1291)*

Under § 493.1291(l), we assume that the development of the mechanisms to provide patient access to laboratory test reports will be a one-time burden and that each laboratory will develop its own unique policies and procedures to address patient access or adopt mechanisms/procedures developed by consultants or associations representing laboratories. We assume 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. While we provide a range of burden estimates in this final rule, for purposes of OMB review and approval we will submit burden estimates based

on 9 hours. We also assume an hourly rate for a management-level employee to be \$50.06 (see Table 1).

The range of costs for laboratories to develop the necessary processes and procedures for handling patient requests is:

(2 hours × \$50.06 per hour × 22,816 laboratories) = \$2,284,338

(9 hours × \$50.06 per hour × 22,816 laboratories) = \$10,279,521

Since this is a one-time burden, the average annual cost over the 3-year OMB approval period, which is the period between approval and renewal of the information collection by OMB, will range between \$761,446 and \$3,426,507.

The ongoing burden associated with responding to test report requests is dependent upon the total number of test reports that exist in affected laboratories, the percent of the results that would be requested, and the cost of producing these reports for those individuals who ask for direct access.

Laboratory test reports are commonly understood to contain multiple test results with many laboratory tests being ordered as panels of tests. Each laboratory may have its own unique test

report panels which may contain anywhere from 1 to 20 individual test results.

Using a range of 10 to 20 test results in a test report, we estimated the annual number of test reports that may be requested to be:

(7,025,841,649 tests per year/20 tests per report) = 351,292,082 test reports/year

(7,025,841,649 tests per year/10 tests per report) = 702,584,165 test reports/year

We are unaware of any data that would provide a reasonable estimate for the number of patients who would request test reports from laboratories if they are available. We solicited public comments on this issue but did not receive any to inform our estimates. Therefore, we assume a range of 1 in 2,000 patients (0.05 percent) to 1 in 200 patients (0.50 percent) will request direct access to his or her test report.

Using these figures, the range of the number of patient requests per year will be:

(351,292,082 test reports per year × .0005) = 175,646 patient requests per year

(702,584,165 test reports per year × .005) = 3,512,921 patient requests per year

The processing of a patient request for a test report generally covers steps from actual receipt of the patient's request to the delivery of the report and documentation of the delivery. Requests for laboratory results are usually handled by non-managerial or clerical staff. Due to the lack of data that indicates the amount of time it takes for staff to process a test report request, we assume a range of 10 minutes (0.17 hours) to 30 minutes (0.5 hours) to handle a request from start to finish.

We then multiplied this range by the range of the anticipated number of patient requests to obtain the total annual burden hours:

(175,646 patient requests per year × 0.17 hours) = 29,860

(3,512,921 patient request per year × 0.5 hours) = 1,756,461

We then multiplied this range by the hourly rate of \$30.09 for a clerical-level employee (see Table 1) to develop the total labor cost of reporting:

29,860 (total annual burden hours) × \$30.09 = \$898,487

1,756,461 (total annual burden hours) × \$30.09 = \$52,851,911

TABLE 8—SUMMARY OF ANNUAL REQUIREMENTS AND BURDEN ESTIMATES

| Regulation section(s) | OMB Control No. | Respondents | Responses | Burden per response (hours) | Total annual burden (hours) | Hourly labor cost of reporting (\$) | Total labor cost of reporting (\$) | Total capital/maintenance costs (\$) | Total cost (\$) |
|-----------------------|-----------------|-------------|-----------|-----------------------------|-----------------------------|-------------------------------------|------------------------------------|--------------------------------------|-----------------|
| 42 CFR 493.1291 ....  | 0938—New        | 22,816      | 22,816    | 9                           | 205,344                     | 50.06                               | 10,279,521                         | 0                                    | 10,279,521      |
| 42 CFR 493.1291 ....  | 0938—New        | 3,512,921   | 3,512,921 | .5                          | 1,756,461                   | 30.09                               | 52,851,911                         | 0                                    | 52,851,911      |
| Total .....           | .....           | 3,535,737   | 3,535,737 | .....                       | 1,961,804                   | .....                               | 63,131,432                         | .....                                | 63,131,432      |

We will exercise our enforcement discretion to allow HIPAA-covered laboratories to revise their notices only once to reflect the changes to privacy practices of these entities both resulting from this rule, as well as the final rule published on January 25, 2013, modifying the HIPAA Rules, which became effective on March 26, 2013 (78 FR 5566). Since we accounted for the overall burden to covered health care providers, including laboratories, of revising notices in the burden statement accompanying the January 25, 2013, final rule (78 FR 5669), we do not include estimates of any additional burden in this rule.

If you comment on these information collection and recordkeeping requirements, please submit your comments 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](mailto:OIRA_submission@omb.eop.gov).

## VII. Regulatory Impact Analysis

### A. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated a “significant regulatory action” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Laboratories regulated under CLIA that do not currently provide patients with an opportunity to receive, upon request, a copy of their laboratory test report (defined in CLIA § 493.1291) are affected by this final rule. According to the CMS OSCAR database accessed on August 27, 2012, there are 234,756

laboratories in the United States that are subject to CLIA. OSCAR is a data network maintained by CMS in cooperation with the state surveying agencies and accrediting organizations that provides a compilation of all the data elements collected during inspection surveys conducted at laboratories. Of the total CLIA-certified laboratories identified in the OSCAR database, we believe approximately 90 percent of these would not be impacted by the individual access provisions because they perform testing either under a Certificate of Waiver or Certificate of Provider Performed Microscopy (PPM) or they are located in states that already allow the laboratory to provide patient access to test reports, either directly or with provider approval. Removing the step in which the provider grants permission to the laboratory should not pose an additional impact on the laboratory, as we believe these laboratories already have processes in place to provide patients access to test reports once that permission is received.

We expect that 22,816 laboratories located in the 39 states and territories identified in Table 3 as having no state law or a state law that provides test reports only to the provider will be impacted by the individual access provisions in this final rule. In addition, we expect that 33,087 laboratories located in the 46 states and territories identified in Table 4 as having no state law, 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, will be affected by the HIPAA requirement to update their notices of privacy practices. We believe that this final rule does not constitute an economically significant rule because we estimate the range of overall annual costs that would be expended by the affected laboratories would be less than \$100 million for 2013.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we assume that the great majority of medical laboratories are small entities, either by virtue of being nonprofit organizations or by meeting the SBA definition of a small business by having revenues of less than \$13.5 million in any 1 year. We believe at least 83 percent of medical laboratories qualify as small entities based on their nonprofit status as reported in the American Hospital Association Fast Fact Sheet updated June 24, 2010 ([http://www.aha.org/aha/resource-](http://www.aha.org/aha/resource-center/Statistics-and-Studies/Fast_Facts_Nov_11_2009.pdf)

[center/Statistics-and-Studies/Fast\\_Facts\\_Nov\\_11\\_2009.pdf](http://www.aha.org/aha/resource-center/Statistics-and-Studies/Fast_Facts_Nov_11_2009.pdf)).

Other options for regulatory relief of small businesses, as discussed in section E of this final rule, were determined not to be feasible and therefore these options were not analyzed for this final rule. We believe any alternative to allowing the laboratory to provide patient access to test reports would be counterproductive to the Department's efforts to provide patient-centered health care. We are unaware of any instances in which the changes included in this final rule would affect health care entities operated by small government jurisdictions.

Section 1102(b) of the Social Security Act also requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not expect this final rule would have a significant impact on small rural hospitals. The final rule applies only to laboratories. If a small rural hospital operates a laboratory, we anticipate compliance with this final rule will require minimal effort as we expect that the hospital already has procedures in place for responding to individual access requests for hospital records under the HIPAA Privacy Rule. We believe that these existing policies and procedures should be easy to translate for use in direct access requests to hospital-operated laboratories. Therefore, the Secretary has determined that this final rule does not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately \$142 million. We do not anticipate this final rule will impose an unfunded mandate on states, tribal governments, or the private sector of more than \$142 million annually. Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirements and costs on state and

local governments, preempts state law, or otherwise has Federalism implications.

The changes to the CLIA regulations at § 493.1291 will not have a substantial direct effect on state and local governments, preempt state law, or otherwise have a Federalism implication and there is no change in the distribution of power and responsibilities among the various levels of government.

The Federalism implications of the Privacy Rule were assessed as required by Executive Order 13132 and published as part of the preamble to the final rule on December 28, 2000 (65 FR 82462, 82797). Regarding preemption, though the changes to the Privacy Rule will preempt a number of state laws (see Table 4), this preemption of state law is consistent with the preemption provision of the HIPAA statute. The preamble to the final Privacy Rule explains that the HIPAA statute dictates the relationship between state law and Privacy Rule requirements, and the rule's preemption provisions do not raise Federalism issues.

We do not believe that this rule will impose substantial direct compliance costs on state and local governments. We do not believe that a significant number of laboratories affected by these proposals are operated by state or local governments. Therefore, the modifications in these areas will not cause additional costs to state and local governments.

In considering the principles in and requirements of Executive Order 13132, the Department has determined that the modifications to the Privacy Rule will not significantly affect the rights, roles and responsibilities of the states.

#### *B. Anticipated Effects*

The current CLIA regulations and related laws of the states and territories pose potential barriers to the laboratory exchange of health care information (test reports) directly with the patient. These regulatory changes will amend § 493.1291(f) and add § 493.1291(l) to the CLIA regulations and also amend § 164.524 of the Privacy Rule. These changes are being made in support of the Department's efforts toward achieving patient-centered and health IT-enabled health care and would allow patients direct access to their laboratory test reports from a laboratory.

The changes providing for individual access will impact laboratories in 39 states and territories (Table 3) where state law does not permit the laboratory to provide test reports directly to the patient. These changes do not impact the laboratories in the remaining 16

states and territories where the laboratory is allowed to provide the test report to the patient either directly or after provider approval. However, laboratories in 46 states and territories (Table 4) where state law does not permit the laboratory to provide test reports directly to the patient or permits direct access only after provider approval, will be impacted by the requirement to update their HIPAA notice of privacy practices to reflect individuals' new access rights under this final rule.

### C. Costs

Although data are not available to calculate the estimated costs and benefits that will result from these changes, we are providing an analysis of the potential impact based upon available information and certain assumptions. These regulatory changes are anticipated to have the following associated costs and benefits:

- The impacted laboratories may require additional resources to ensure patients receive test reports when requested.
- Patients will benefit from having direct access to their laboratory test results. (See section D below).

#### 1. Quantifiable Impacts

Laboratories that are issued a CLIA Certificate of Compliance or Certificate of Accreditation in the 39 states and territories identified in Table 3 will be required to provide patients with a copy of their test report upon request. The OSCAR database includes 22,816 laboratories in the 39 states and territories that will be impacted and the corresponding number of annual tests in these laboratories is approximately 7 billion as shown in Table 6. Data are not available for estimating the number of test results reported per test report. However, the majority of test reports contain multiple test results. Tests are frequently ordered as panels of individual tests. For example, according to 2008 CMS reimbursement data, three of the four most frequently ordered tests in the Medicare outpatient setting are panels of multiple individual tests,

some of which may contain up to 20 tests. As part of a medical encounter, frequently more than one panel is ordered per patient, and a test report could contain a large number of individual test results. Therefore, for the purposes of this analysis, an assumed range of 10 to 20 is used to represent the average number of test results per test report. Applying this range to the total number of annual tests (7,025,841,649) from Table 6, the estimated number of total annual test reports ranges from a low of 351,292,082 to a high of 702,584,165.

For the purposes of this analysis, we assume that many patients will still prefer to obtain their laboratory result information from their health care provider, who will also be able to provide interpretation of the test results, and thus an assumed range of from 1 in 2,000 (0.05 percent) to 1 in 200 (0.50 percent) is used to represent the proportion of test reports requested. Applying this range to the number of estimated annual test reports (351,292,082 to 702,584,165) yields an estimated annual number patient requests ranging from 175,646 to 3,512,921.

Processing a request for a test report, either manually or electronically, will require completion of the following steps: (1) Receipt of the request from the individual; (2) authentication of the identification of the individual; (3) retrieval of test reports; (4) verification of how and where the individual wants the test report to be delivered and provision of the report by mail, fax, email or other electronic means; and (5) documentation of test report issuance. We estimate the total time to process each test report request to be in the range of 10 minutes (0.17 hours) to 30 minutes (0.5 hours). This estimate for a range of total time includes estimates for a range of time for each of the five steps listed above. The time needed to complete each step is dependent on the capabilities of the laboratory, such as whether manual or automated processes are available, and the desired method of communication of test reports to the

individual patient as listed in step four. We multiplied the range for the number of patient requests, 175,646 to 3,512,921 by 0.17 hours and 0.5 hours to determine the total number of hours for processing the test reports to be in the range of 29,860 and 1,756,461. The estimated annual cost to process all test report requests in 2013 ranges from \$898,487 to \$52,851,911.

The analysis also assumed each of the estimated 22,816 laboratories to be impacted by individual access provisions of this rule (Table 6) will need to develop and implement a policy and process to receive and respond to patient requests as discussed above. To estimate the initial, one-time development cost, it is assumed to require laboratory management staff time ranging from a low of 2 hours to a high of 9 hours per laboratory. To convert the number of hours to an estimated cost per laboratory, we applied the rate of \$50.06 (see Table 1) to the assumed 2 to 9 hour time range yields an estimated cost per laboratory ranging from \$100.12 to \$450.54, which when applied to the estimated 22,816 laboratories impacted results in a total estimated one-time development cost ranging from \$2,284,338 to \$10,279,521.

Table 9 shows the total estimated range of annual costs for the change in undiscounted 2013 dollars and discounted at 3 percent and 7 percent to translate expected benefits or costs in any given future year into present value terms. To calculate the total estimated costs in 2013, we added the cost to develop the necessary policies and processes (which would only be applicable in the first year) and the cost of responding to test report requests. These costs total between \$3 million and \$63 million for 2013 to provide patients with access to their laboratory test reports. As subsequent years will only entail the costs associated with processing requests, we simply took the 2013 values for the cost of responding to test reports and applied the same inflation factor used in Table 1 for the hourly rate calculations. The resulting values can be found in Table 9.

TABLE 9—TOTAL ESTIMATED ANNUAL COSTS OF PATIENT TEST REPORT REQUESTS

[Policy development and processing for the patient access]

|            | Undiscounted<br>(Base year: 2013 \$) |              | Discounted<br>at 3% |              | Discounted<br>at 7% |              |
|------------|--------------------------------------|--------------|---------------------|--------------|---------------------|--------------|
|            | Low                                  | High         | Low                 | High         | Low                 | High         |
| 2013 ..... | \$3,182,819                          | \$63,131,432 | \$3,090,115         | \$61,292,652 | \$2,974,597         | \$59,001,338 |
| 2014 ..... | 932,243                              | 55,934,563   | 878,728             | 52,723,690   | 814,257             | 48,855,414   |
| 2015 ..... | 959,045                              | 57,542,682   | 877,662             | 52,659,705   | 782,866             | 46,971,969   |
| 2016 ..... | 986,617                              | 59,197,034   | 876,597             | 52,595,798   | 752,686             | 45,161,134   |

TABLE 9—TOTAL ESTIMATED ANNUAL COSTS OF PATIENT TEST REPORT REQUESTS—Continued

[Policy development and processing for the patient access]

|            | Undiscounted<br>(Base year: 2013 \$) |            | Discounted<br>at 3% |            | Discounted<br>at 7% |            |
|------------|--------------------------------------|------------|---------------------|------------|---------------------|------------|
|            | Low                                  | High       | Low                 | High       | Low                 | High       |
| 2017 ..... | 1,014,982                            | 60,898,949 | 875,533             | 52,531,968 | 723,668             | 43,420,109 |

Laboratories will be able to offset some of these costs pursuant to § 164.524(c)(4) of the HIPAA Privacy Rule, which permits covered entities to impose on the individual a reasonable, cost-based fee for providing access to their health information, including the cost of supplies for and labor of copying the requested information.

As we explain above, with respect to notices of privacy practices, we are exercising our enforcement discretion to allow HIPAA-covered laboratories to revise their notices only once to reflect the changes to privacy practices of these entities both resulting from this rule, as well as the final rule published on January 25, 2013, modifying the HIPAA Rules, which became effective on March 26, 2013 (78 FR 5669). Since we accounted for the overall costs to covered health care providers, including laboratories, of revising and reprinting notices in the impact statement accompanying the January 25, 2013, final rule (78 FR 5669), we do not include here any estimates of additional costs to revise and print notices.

Therefore, we estimate the cost to provide patients with access to their laboratory test reports is estimated to be between \$3 million and \$63 million for 2013.

## 2. Non-Quantifiable Impacts

The burden in this final rule would be primarily on laboratories to provide the laboratory test reports when requested by the patient; however, there may be some non-quantifiable impacts on the health care provider's office. If the patient does not know where the provider sent the test request, the provider may need to provide laboratory contact information to the patient so he or she may request the test report. We assume that notification of the laboratory name and contact information could be provided in as little as 30 seconds; however there are no data to confirm this, and we did not receive comments on the issue. We also note 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. The time cost to patients of new interactions with laboratories is a further impact of the rule that has not been quantified.

### D. Benefits

Although we cannot quantify the impact on patients, we believe that it will be positive in light of findings from studies that focused on patient receipt of test results from the provider. We found several studies where greater than 90 percent of patients stated they preferred being notified of all test results, both normal and abnormal (1. Baldwin DM, Quintela J, Duclos C, et al. Patient Preferences for Notification of Normal Laboratory Test Results: A Report from the ASIPS Collaborative. *BMC Fam Practice* 2005; 6:11; 2. Boohaver EA, Ward RE, Uman JE et al. Patient Notification and Follow-up of Abnormal Test Results. *Arch Intern Med* 1996; 327–331; 3. Grimes GC, Reis MD, Gokul B, et al. Patient Preferences and Physician Practices for Laboratory Test Result Notification. *JABFM* 2009;22:6:670–676; and 4. Meza JP and Webster DS. Patient Preferences for Laboratory Test Result Notification. *Am J Manag Care* 2000; 6:1297–300). These same studies reported, for both the health care provider and patient, the preferred method for receiving normal test results was the U.S. mail, and direct phone contact from the provider was the preferred method for abnormal test results. These preferences may have changed in the last 5 years given the increase in the use of electronic communications. Advantages reported in these studies for the patient having direct access to the test report include reduced workload for the health care provider's office, reduced chance of a patient not being informed of a laboratory test result, and reduced numbers of patients who fail to seek appropriate medical care. Additionally, we expect significant benefits to flow to patients as a result of increased access to their laboratory test results.

Commenters to this final rule describe

these benefits as including increased patient participation in treatment programs, such as those that involve monitoring of chronic diseases, and the ability of patients to identify and treat health risks sooner and more effectively.

### E. Alternatives Considered

The changes to the CLIA regulations and the HIPAA Privacy Rule are in support of the Department's efforts toward achieving patient-centered health care. Several alternatives were considered before selecting the approach in this final rule to provide access to laboratory test reports upon a patient's request. One alternative would have been to leave the regulations as written without making any changes. However, this option would leave in place the restrictions on patients' direct access to their laboratory test results and would therefore impede the goal of promoting patient-centered health care. Another alternative would have been to revise the definition of "authorized person" under CLIA to specifically include a patient as an authorized person. This alternative was not considered feasible because the definition of "authorized person" in the CLIA regulations also permits individuals to order tests, and it defers to state law for authorization. A last alternative considered would have been to require the laboratory to automatically provide each test report directly to each patient rather than the permissive approach to provide patients access to their reports upon request. However, this alternative would have had the potential of significantly increasing the cost for laboratories since 100 percent of the 350 million to 703 million test reports issued annually would need to be provided to the patients.

### F. Accounting Statement and Table

We have prepared the following accounting statement showing the classification of the expenditures associated with the provisions of this final rule.

| Category                                                 | Primary estimate | Minimum estimate | Maximum estimate | Source citation (RIA, preamble, etc.)        |
|----------------------------------------------------------|------------------|------------------|------------------|----------------------------------------------|
| <b>BENEFITS:</b>                                         |                  |                  |                  |                                              |
| Monetized benefits .....                                 | n/a              | n/a              | n/a              | RIA Section C2                               |
| Annualized qualified, but unmonetized, benefits .....    | n/a              | n/a              | n/a              | RIA Section C2                               |
| (Unqualified benefits) .....                             | n/a              | n/a              | n/a              | RIA Section C2                               |
| <b>COSTS:</b>                                            |                  |                  |                  |                                              |
| Monetized costs (2012 \$):                               |                  |                  |                  |                                              |
| Patient access provisions 2013 .....                     | n/a              | \$3,182,819      | \$63,131,432     | RIA Sec C1 (Table 7)                         |
| Patient access provisions 2014 .....                     | n/a              | \$932,243        | \$55,934,563     | RIA Sec C1 (Table 7)                         |
| Patient access provisions 2015 .....                     | n/a              | \$959,045        | \$57,542,682     | RIA Sec C1 (Table 7)                         |
| Patient access provisions 2016 .....                     | n/a              | \$986,617        | \$59,197,034     | RIA Sec C1 (Table 7)                         |
| Patient access provisions 2017 .....                     | n/a              | \$1,014,982      | \$60,898,949     | RIA Sec C1 (Table 7)                         |
| Annualized quantified, but unmonetized, benefits .....   | n/a              | n/a              | n/a              |                                              |
| Qualitative (unquantified) costs .....                   | n/a              | n/a              | n/a              | RIA Section C2                               |
| <b>TRANSFERS:</b>                                        |                  |                  |                  |                                              |
| Annualized monetized transfers: "on budget" .....        | n/a              | n/a              | n/a              |                                              |
| From whom to whom? .....                                 | n/a              | n/a              | n/a              |                                              |
| Annualized monetized transfers: "off-budget" .....       | n/a              | n/a              | n/a              |                                              |
| From whom to whom? .....                                 | n/a              | n/a              | n/a              |                                              |
| <i>Category .....</i>                                    | <i>Effects</i>   |                  |                  | <i>Source Citation (RIA, preamble, etc.)</i> |
| Effects on State, local, and/or tribal governments ..... | n/a              | n/a              | n/a              | RIA Sec A (Table 4)                          |
| Effects on small businesses .....                        | n/a              | n/a              | n/a              | RIA Section A                                |
| Effects on wages .....                                   | n/a              | n/a              | n/a              |                                              |
| Effects on growth .....                                  | n/a              | n/a              | n/a              |                                              |

### G. Conclusion

We estimated the cost to laboratories to provide patients with a copy of their test reports upon request and determined it would cost between \$3 million and \$63 million in 2013. These costs will diminish in subsequent years. In addition laboratory provision of test reports to patients may provide information that could benefit the patient by reducing the chance of the patient not being informed of a laboratory test result, reducing the number of patients lost to follow-up, and benefiting health care providers by reducing their workload in providing laboratory test reports. Finally, as we explain above, to avoid HIPAA-covered laboratories having to modify their notices twice within the same year to comply with both the January 25, 2013, final rule and this rule, we will exercise our enforcement discretion to allow CLIA laboratories (including CLIA-exempt laboratories) that are HIPAA covered entities to take until the compliance date of this final rule to revise their notices to reflect both sets of modifications. See <http://www.hhs.gov/ocr/privacy/hipaa/enforcement/clia-labs.html>. Therefore, CLIA and CLIA-exempt laboratories that are HIPAA covered entities need only update their notices once to comply with both rules.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

### VIII. Analysis of and Responses to Public Comments on the Paperwork Reduction and Regulatory Impact Analysis

We have provided an analysis of the potential impact of this final rule, based upon available information and certain assumptions. We have prepared the Paperwork Reduction Act and the Regulatory Impact Analysis representing the costs and benefits of the final rule based on analysis of identified variables and data sources needed for this change. We requested that commenters provide any additional data that would assist us in the analysis of the potential impact of this regulation on CLIA certified laboratories but we did not receive any additional data.

Therefore, based on our analysis and assessment of the overall annual costs to the laboratories affected by this final rule, we are finalizing the provisions as set forth in the proposed rule. The comments we received on this provision and our responses are set forth below.

*Comment:* We received several comments from organizations and individuals suggesting the implementation and operations cost estimate provided in the regulatory impact analysis (that is, for the laboratory to receive the request, authenticate the requestor is allowed to have access to the test report, process the request and provide the test report) was too low. Some suggested there were other factors that were not considered in the proposed rule's RIA, such as costs for training staff to provide the reports

in a compliant manner, verification that the information was received, and for providing an explanation or summary of results, which may require higher level staff than those at a clerical level. Some recommended we review the anticipated cost structure and contact several laboratories to request best estimates. One organization recommended that we permit laboratories to charge a standard fee between \$10 to \$15 per test report issued to cover overall administrative costs, which would be in addition to the actual cost of the supplies used to provide the test report to the patient or personal representative or, if applicable, a third party designated by the individual.

*Response:* Our cost estimate was based on assumptions from internal discussions and consultation with two laboratories that provide test reports directly to patients. Although the proposed rule solicited comments and additional data from laboratories that already provide test reports directly to the patient, we did not receive any data to support adjusting the estimates provided in the proposed rule; therefore, we are not adjusting those estimates in this final rule and acknowledge that they may not reflect costs for every laboratory setting. We appreciate the commenter's suggestion about staff training costs; however we believe that there is no need to include additional costs for training staff to provide the reports in a HIPAA Privacy Rule compliant manner since training

cost was part of our original estimate for developing and implementing a policy and process.

In addition, the HIPAA Privacy Rule permits covered entities to charge a reasonable cost-based fee to provide individuals with copies of their protected health information. The fee may include only the cost of copying (including supplies and labor) and postage, if the individual requests that the copy be mailed. If the individual (or individual's personal representative) has agreed to receive a summary or explanation of his or her protected health information, the covered entity may also charge a reasonable, cost-based fee for preparation of the summary or explanation. The fee may not include costs associated with searching for and retrieving the requested information, nor does the HIPAA Privacy Rule permit charging a standard fee; therefore, this final rule does not permit laboratories to charge these fees. The fees permitted to be charged to individuals under the HIPAA Privacy Rule are discussed more fully above in section VII.

*Comment:* We received a few comments that smaller, rural hospitals, particularly Critical Access Hospitals (CAHs), may face financial constraints that would make compliance with this requirement challenging.

*Response:* The impacts discussed in the preamble affect only those laboratories that currently do not provide patients with access to their health information. Since most hospitals are HIPAA covered entities, they are required already to provide individuals with access to the protected health information in their designated record sets, including laboratory test results, in accordance with § 164.524 of the HIPAA Privacy Rule. As discussed above, laboratories that operate as part of a legal entity that is a hospital or that are part of an affiliated covered entity or organized health care arrangement with the hospital (see the definition of "organized health care arrangement" in the HIPAA Rules at § 160.103, and the provisions for affiliated covered entities at § 164.105(b)), may continue to utilize the hospital's already established mechanisms for providing access to the individuals requesting their test reports from the hospital laboratories, provided that the established mechanisms are compliant with the access provisions of the HIPAA Privacy Rule.

*Comment:* Several commenters asked why we used test volume data that was self-reported rather than validated Part B claims or actual claims. Other commenters asked why we did not analyze the cost of providing access to completed test reports to Medicare fee-

for-service beneficiaries in states that already allow laboratories to provide a copy of test results to the patient.

*Response:* We used data from the CMS OSCAR database for our estimates. The OSCAR database is not limited to Medicare-reimbursed tests only, but also includes testing totals for laboratory tests reimbursed by private payers and those that are not reimbursed. Test volume is self-reported by laboratories and validated by CMS surveyors during laboratory inspections. This data is more accurate for estimating the impact of these changes. We requested comments from laboratories that are currently providing test reports to the patient. We did not receive any comments that would support adjusting the estimates provided in the proposed rule; therefore, we conclude that these estimates are sufficiently accurate and have retained those estimates in this final rule.

*Comment:* We received several comments disagreeing with the time estimate of 2 to 9 hours for laboratories to identify the applicable legal obligations and develop processes or procedures to handle the patient requests for access to test reports. One commenter stated that his institution had reported spending several hours in meetings between administration, laboratory management, and legal counsel examining procedural options and the risks of each procedure. Other commenters stated that it would not be possible for the information technology/data privacy teams to meet this requirement in the allotted timeframe for implementation. Several commenters suggested some laboratories may need to develop policies related to sensitive issues, such as minors and parent/guardian access or release of the results of drug testing that might have an impact on the laboratory's liability insurance costs. Other comments stated that the policy development would not be a one-time charge since laboratories would need to monitor all new state and federal regulations related to the disclosure of protected health information.

*Response:* Our cost estimate was based on assumptions from internal discussions and consultation with two laboratories that provide test reports directly to patients. Although the proposed rule solicited comments and additional data from laboratories that already provide test reports directly to the patient, we did not receive any data to support adjusting the estimates provided in the proposed rule. We acknowledge that these estimates may not reflect costs for every laboratory setting. However, in the absence of data

to support changing our estimate, we are not adjusting those estimates in this final rule. Laboratories may be able to learn from those in the 16 states that allow the laboratory to provide a copy of the test results to the patient and from larger reference laboratories that have already developed policies to accommodate requests received from patients that receive testing in these 16 states. The HHS Office for Civil Rights, which administers and enforces the HIPAA Privacy Rule, provides guidance on its Web site and through other sources on many compliance issues, including regarding disclosure of information on minors. See <http://www.hhs.gov/ocr/privacy/> for more information. This may be a new requirement for laboratories, but other HIPAA covered entities have, for quite some time, followed the requirements in § 164.524 of the HIPAA Privacy Rule when providing protected health information.

*Comment:* We received comments from organizations that supported the proposed change, but noted it would be impossible to know how many individuals would request their test reports. Other comments suggested the laboratory could receive a barrage of requests. One comment said our estimates of 0.05 percent to 0.5 percent of patients requesting their test report from the laboratory falls short of what is needed to meet the Department's goal of patient engagement to ensure the provider receives and acts on the test results. The commenters suggested that under the health care transformation that is taking place, the patient could be provided a digitally signed copy of the laboratory report in his or her electronic patient health record (EHR) at the same time and in the same format as the laboratory report provided electronically to the requesting health care provider's electronic health record. Patients would only need to give the requesting provider the repository identifier for their personally controlled health record for inclusion with the laboratory test order.

*Response:* We agree that it is difficult to know how many individuals will request their test report from covered entity laboratories. However, we received several comments indicating that the preferred method for a patient to receive laboratory test results is the same procedure as currently practiced; that is, the health care provider's office notifies the patient of the results on the same day the results are received from the laboratory. This procedure allows the patient to ask the health care provider's office for interpretation of the laboratory test report in concert with

results of other procedures, as well as provides an opportunity to discuss any needed treatment or follow-up. Allowing patients to request and receive laboratory test reports directly from the laboratory will provide an additional route for them to receive the test report. However, this will not replace the current procedure. If the ordering physician does not contact the patient with critical or significant laboratory test results, patients may prompt the physician's office to find and act on the test results. The rate of apparent failures to inform or document informing the patient of abnormal test results ranges from 0 percent to 26.2 percent [Casalino LP, Dunham D, Chin MH, et al. Frequency of Failure to Inform Patients of Clinically Significant Outpatient Test Results. *Arch Intern Med.* 2009; 169(12):1123–1129]. When patients have their laboratory test results, they are more likely to ask appropriate questions of their health care provider and more fully participate in making better decisions that lead to better care. The regulations promulgated pursuant to the HITECH Act, particularly for Meaningful Use and Certification of EHRs, encourage patient access to comprehensive patient data through robust patient-centered health information exchange. Technology is currently being tested to allow patients the ability to retrieve personal health data directly from secured health records. We agree with the comment about electronic health records in that a request for access for protected health information to either the health care provider or the laboratory may be replaced with this technology as it becomes more readily available.

#### List of Subjects

##### 42 CFR Part 493

Administrative practice and procedure, Grant programs—health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

##### 45 CFR Part 164

Administrative practice and procedure, Computer technology, Electronic information system, Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Hospitals, Medicaid, Medical research, Medicare, Privacy, Reporting and recordkeeping requirements, Security.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 493 as set forth below:

#### PART 493—LABORATORY REQUIREMENTS

- 1. The authority citation for part 493 continues to read as follows:

**Authority:** Section 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)).

#### Subpart K—Quality System for Nonwaived Testing

- 2. Section 493.1291 is amended by—  
■ A. Revising paragraph (f).

- B. Adding a new paragraph (l).

The revision and addition read as follows:

##### § 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.

\* \* \* \* \*

(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.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR Subtitle A, Subchapter C, part 164, as set forth below:

#### PART 164—SECURITY AND PRIVACY

- 1. The authority citation for part 164 continues to read as follows:

**Authority:** 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2(note)); and secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279.

- 2. Section 164.524 is amended by revising paragraphs (a)(1)(i) and (ii) and removing paragraph (a)(1)(iii) to read as follows:

##### § 164.524 Access of individuals to protected health information.

(a) \* \* \*

(1) \* \* \*

(i) Psychotherapy notes; and

(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

\* \* \* \* \*

Dated: August 16, 2013.

**Thomas R. Frieden,**

*Director, Centers for Disease Control and Prevention, Administrator, Agency for Toxic Substances and Disease Registry.*

Dated: August 19, 2013.

**Marilyn Tavenner,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: August 19, 2013.

**Leon Rodriguez,**

*Director, Office for Civil Rights.*

Dated: August 27, 2013.

**Kathleen Sebelius,**

*Secretary, Department of Health and Human Services.*

**Editorial Note:** This document was received at the Office of the Federal Register on January 30, 2014.

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