Releasing Test Results Directly to Patients

Toolkit Overview

Giving patients vital personal health information can empower their active participation in managing their health and health care

What high-level insight does this Toolkit provide?

The Toolkit will assist you in analyzing the potential impact on your practice of the new Final Rule amending the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) with respect to patient access to laboratory reports (the "rule"):

- Learn how to modify your existing policies to comply with the new rule
- Determine how to manage requests for laboratory test results, including suggested methods to authenticate a patient's identify and deliver reports
- Identify potential documentation needs
- Understand report format requirements
- Learn how to calculate allowable fees
- Assess workflow and opportunities

Please be aware that these changes to the law have important implications for laboratories and practices and liability may arise if the changes are not properly and timely implemented by practices. For example, failure to properly provide a patient with access to his/her protected health information may be a violation of the individual rights provisions of HIPAA. At the same time, providing such information to the wrong person due to authentication failures could result in a breach of protected health information under HIPAA, also creating liability. This Toolkit does not constitute legal advice. Each practice should consult its own legal counsel to ensure compliance with the applicable requirements of CLIA, HIPAA and other laws as it develops and implements policies and procedures under the Final Rule.

What does the Toolkit include?

1. **Toolkit Overview**

   This document.

2. Guide 1: Compliance Summary and Impact Analysis

What does this rule mean to your practice? What are you required to do? For some practices, this rule introduces new and unique challenges while others may simply need to modify elements of existing policies and procedures. Knowing the difference will keep your practice compliant.

This guide provides a brief summary of the rule's objectives, an analysis of required policy changes, and a rundown of key workflow and operational areas that may be impacted.

3. Guide 2: Managing the Process

It's very likely that your practice will receive requests for test results. Remaining compliant in your response to these requests is critical. This guide will address certain operational areas and suggest approaches with respect to:

- How patients will request information
- How to authenticate a patient's identity
- The scope of the information you must provide
- The time frame you have to respond
- How to deliver results to the patient

4. Guide 3: Opportunity Assessment and Frequently Asked Questions

With every challenge comes opportunity. Explore potential new ways for your practice to interface with patients and clinicians. Learn how other practices have leveraged this rule to increase their visibility and value to patients. The guide includes a FAQ addressing specific issues raised by other pathologists. Please keep in mind that you should consult your compliance professionals and legal counsel with respect to your policies and procedures governing your interactions with patients and physicians.

5. Resource and Reference Guide (Appendix 1)

This guide outlines a variety of resources that can help you to develop specific policies, procedures and staff training materials. This guide includes tables prepared by the U.S. Department of Health and Human Services (HHS) summarizing how all 50 states will be impacted by the new rule.

New federal rule gives patients right to access their laboratory reports directly from the lab

A new federal rule provides patients with the right to access their laboratory reports directly from the lab, preempting a number of state laws that prohibit or limit patients' access to these reports. The rule also creates other material changes to CLIA and HIPAA.

The final rule titled "*CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports*" was issued on February 6, 2014, by the Centers for Medicare and Medicaid Services (CMS) in conjunction with the HHS, Office for Civil Rights (OCR) and the Centers for Disease Control and Prevention (CDC).

The rule is effective April 7, 2014. On this date, certain state restrictions prohibiting patients' access to their test results became void, preempted by the new rule. Please note, however, that state laws that are *more stringent* than HIPAA will still apply. More stringent state laws, for example, may permit even greater rights of access to individuals than HIPAA, may require access in shorter timeframes than the rule, or may limit the types of identification that laboratories can seek to verify identity. In addition, state laws that place requirements on other types of health care providers are <u>not</u> preempted by the rule (e.g., laws requiring a provider to counsel patients on HIV results).

On October 6, 2014, all practices that **are HIPAA covered entities <u>must comply with the rule</u>.** Practices may voluntarily comply with the rule before the October deadline. Failure to comply with the rule's access provisions may subject your practice to an enforcement action by the OCR that may include civil monetary penalties. In addition, be mindful of the potential damage to a practice's reputation and relationships with other health care providers and patients as well.

Historically, some state laws have prohibited patient access to laboratory records while other states impose limitations on access or are completely silent on the matter. Appendix 1 of this Toolkit includes a categorized listing of states provided by HHS.[1] Regardless of your practice's location, modifications to your practice's policies and procedures related to CLIA, HIPAA and CAP inspections likely will be necessary.

[1] The CAP has not independently reviewed or confirmed the content of these state laws.

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Guide 1: Compliance and Impact Analysis

What does this new rule mean to your practice and what do you need to do?

For pathology laboratories producing a copy of a test report for a clinician is a rather simple process. Producing a report and releasing it to someone other than a clinician brings with it a host of compliance issues.

The final rule known as "CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports" ("the rule") expands patients' direct access to their protected health information to include laboratory test results. The rule specifically states that "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 the patient."[2]

CAP designed this guide to assist practices to understand the rule and its objectives and to help practices identify what potential modifications to practice policies and procedures may be necessary to remain compliant.

The Toolkit provides generalized information regarding suggested approaches for practices under the new rule. Consult with your compliance professionals and legal advisors to ensure your practice's complete compliance with this rule and other regulations.

This guide covers:

- Background about a patient's right to access protected health information
- Summary of the rule' s key provisions
- Actions a practice can take to comply with the rule

[2] 79 Fed. Reg. 7290 (Feb. 6, 2014).

Background

In the evolving health care landscape, engaging patients to participate in their health and health care is a foundational principal. Various health care reform initiatives, such as personalized health care and the widespread adoption of electronic medical records, have created a demand to modify the methods through which to access lab test reports. According to former Secretary of Health and Human Services Kathleen Sebelius, "The right to access personal health information is a cornerstone of the [HIPAA] Privacy Rule . . .[i]nformation like lab results can empower patients to track their health progress, make decisions with their health care professionals, and adhere to important treatment plans."[3]

The CLIA regulations establish nationwide quality standards to ensure the accuracy, reliability, and timeliness of clinical laboratory test results. These regulations cover all phases of laboratory testing, including the reporting of test results. Historically, CLIA mandated that "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."[4]

"Authorized person" is defined as "the individual authorized under state law to order or receive test results, or both."[5] Several states have prohibited patients from directly receiving test results from a laboratory; therefore, patients' only way to gain access was through health care providers. Other states have permitted patient access to results under certain conditions while some states had no regulations addressing the issue. For a complete listing of these states and their respective approach to patient access (as set forth by HHS in the rule), please refer to Appendix 1.[6]

Enacted in 1996, HIPAA created national standards to protect the privacy and security of certain individually identifiable health information. Practices and laboratories considered to be "covered entities," namely those practices and laboratories that engage in certain electronic transactions defined by HIPAA (see Appendix 1 for details regarding these types of electronic transactions) must abide by the HIPAA Privacy Rule. Among other things, the HIPAA Privacy Rule states that, subject to certain exceptions, a patient has "a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set."[7]

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[3] HHS Press Release, "HHS strengthens patients' right to access lab test reports," (Feb. 3, 2014).
[4] See 79 Fed. Reg. 7290.
[5] 42 C.F.R.§ 493.2.
[6] The CAP has not independently reviewed or confirmed the content of these state laws.
[7] 45 C.F.R. § 164.524. A "designated record set" is defined as a group of records maintained by or for a covered entity that is: (i) the medical records and billing records about individuals maintained by or for a covered health care provider; (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) used in whole or in part, by or for

The HIPAA Privacy Rule contains several exemptions to the right of access to a designated record set.[8] These exemptions previously included lab test reports. In other words, prior to the effective date of the rule, any pathology laboratory or practice that was a covered entity, whether subject to CLIA or exempt from CLIA, did not have an obligation to make test reports available to patients, unless state law dictated otherwise. If patients wished, they could access their lab test results from any other type of covered entity, such as a treating physician.

The CLIA and HIPAA regulations prior to these latest changes effectuated by the rule effectively precluded a patient's ability to access laboratory test reports directly from the lab, unless state laws permitted access. The lack of consistency among states posed significant barriers to the February 2009 Health Information Technology for Economic and Clinical Health Act (HITECH Act), which facilitates the widespread adoption of electronic health records and the interoperability of a nationwide health information infrastructure.

In consideration of the objective to "empower patients to track their health progress, make decisions with their health care professionals, and adhere to important treatment plans," the new rule was developed.[9] All practices and laboratories must comply with all applicable aspects of the rule by October 6, 2014.

Summary of the rule's key provisions

The outline below highlights certain requirements of the new rule. This Toolkit addresses these provisions and provides suggested operational and compliance actions for your practice to evaluate and modify. Your practice must:

1. Provide individuals or their personal representatives with access to their protected health information in designated record sets maintained by the practice upon request. These record sets include completed laboratory test results
2. Prepare to accept requests for test reports directly from patients or their personal representatives
3. Authenticate the identity of the patient or personal representative
4. Provide the test reports within 30 days of the date the patient makes the request[10]
5. Provide the completed test reports (or if incomplete, the other information available in the designated record set) in the form and format requested by the

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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. See 45 C.F.R. § 164.501.

[8] 45 C.F.R.§ 164.524.

[9] HHS Press Release, "HHS strengthens patients' right to access lab test reports", (Feb. 3, 2014).

[10] A one-time 30-day extension is available under certain circumstances.

patient or in an alternative method mutually agreed upon by the patient and the practice

6. With very limited exceptions, disclose test reports deemed to be "sensitive" such as tests for pregnancy or sexually transmitted diseases
7. Create a cost-based fee schedule for copying the report (optional)
8. Modify its Notice of Privacy Practices ("Notice") **by October 6, 2014**
9. Adapt to changes in the practice's CAP checklist as necessary

Operational impact analysis

The impact of the rule on a practice will vary according to its operational structure, and its historical experience with the provisions of the rule. It's likely that your practice will need to amend certain aspects of its standard operating procedures, checklists and related CLIA and HIPAA policies to ensure compliance.

CLIA

The CLIA policy manual maintained by your CLIA practice/laboratory may need amending to allow for patients to have access to their test results. Any existing policy language regarding to whom a report can be issued may need modification to reflect the following CLIA amendment:

"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 C.F.R.164.524(c)(3)(ii)[persons designated by the patient], as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient."[11]

Here's an example of how this amendment may integrate into your practice's CLIA policy:

"XYZ clinical laboratory" will disclose completed test results to only:

1. An authorized person responsible for using the test results in a treatment context. An authorized person is an individual under state law who is authorized to order or receive test results, or both.
2. The laboratory that initially requested the test.

[11] 42 C.F.R.§ 493.1291(l).

3. The patient or the patient's personal representative, upon request. The patient, and personal representative as applicable, must meet the authentication requirements as outlined in the policy.

Some practices have elected to create a policy governing the entire process including requests, authentication and delivery. Guide 2 contains an example of this approach. Consult with laboratory/practice compliance professionals and legal counsel in crafting policies reflecting changes due to the new rule.

HIPAA Privacy Rule

The new rule also makes changes to the HIPAA regulations. The impact of these changes reflects the CLIA amendment and eliminates the previous exemption applicable to CLIA-covered and CLIA-exempt labs, thereby allowing patients to obtain their test results directly from laboratories. Your practice's Notice must reflect these changes. By the October 6, 2014 compliance date, if you are a HIPAA-covered laboratory, you must revise your Notices to inform individuals of their new access right and include a brief description of how to access the right. You must also remove any contrary statements and must make the revised Notices available to patients.[12] Specifically, you should:

- Review your practice's Notice to ensure that individuals are informed of their right to access completed test results directly from the clinical laboratory
- Include a brief description of how individuals may access their results
- Ensure that any contradictory language is removed from the Notice

Appendix 1 of this Toolkit contains a summary of the Notice requirements along with sample templates provided by HHS and a number of references that your practice may use in complying with the various provisions.

Notices of HIPAA Privacy Practices MUST be updated to include this patient right of access by October 6, 2014.

CAP checklist

The April 21, 2014 version of the CAP checklist includes a minor revision (outlined below) addressing the rule's impact. Make appropriate amendments to your practice's policies. CAP will consider additional revisions to the 2015 checklist edition.

[12] See 45 C.F.R. §164.520(b)(3).

GEN.41304	Patient Data Accessibility	Phase II
	There is a documented protocol in place to ensure that patient data are accessible only to those ~~healthcare personnel~~ individuals who are authorized to review test results. *NOTE: Only those healthcare personnel authorized to review a patient's test results should have access to those results. Laboratories subject to US regulations must provide final test results to the patient or the patient's personal representative upon request.* REFERENCES 1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2014(Feb 6):7289 [42 C.F.R.493.1291(l)]	

General operational requirements

The rule may impact various practice operational areas. The outline below summarizes the requirements and areas of potential impact. The rule provides a practice with the latitude to develop policies and procedures to remain compliant and defers to the professional judgment of the practice and to industry standards. Practice leadership should work closely with its compliance manager and outside counsel as appropriate to develop policies and procedures. Refer to Guide 2, "Managing the Process," for additional information and suggestions on each of these operational areas.

1. Accepting requests for test results
2. Authenticating and verifying the identities of patients and patient representatives
3. Record keeping and retrieval
4. Determining the content and format of reports
5. Delivering reports within 30 days
6. Developing a fee schedule

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Guide 2: Managing the process and staying compliant

This guide provides insight into the various requirements imposed by the rule and the potential impact it may have on your workflow. This impact will vary according to your organizational structure. A practice must frame its policies and procedures to ensure compliance with both applicable federal and state laws.

If part of a larger health system or a hospital, your practice may continue to use established mechanisms, provided the health system or hospital complies with the HIPAA Privacy Rule. You may wish to consult with the health system/hospital's compliance officer and your own legal counsel to ensure that the policies contain the appropriate "access" language and that utilizing and relying on the hospital's policies allows your practice to fully meet your obligations under the rule.

Workflow Analysis

Evaluate each step in the workflow process to determine compliance. Some practices may need to amend their corresponding policies and procedures to reflect any workflow modifications. Some suggested approaches are below.

1. Accepting requests for test results

Practices must develop a mechanism permitting patients to make requests for their test results. Patients may request results from your practice in person, on the phone or electronically. As a risk management measure, some practices have established the management of requests as a supervisory-level responsibility or have focused only one or two employees on requests to ensure familiarity with policy requirements and consistent responses.

Practices may require individuals to make all requests for information (including those initiated by phone call) in writing, provided the individual is informed of the requirement (see item 2 below). One approach is to record the requests in the individual's file and in a separate log maintained by the practice for the purpose of cataloguing patient access requests. The information should contain

the patient's name, the date of the request, the date of the test, the referring physician, and the method by which the patient elects to receive the results. If the practice imposes a fee for fulfilling these requests, arrange for payment at the time of the request. Refer to Item 6 for fee schedule information.

Under the new rule, practices *may not require* that patients make their requests through other health care providers. A patient may elect to request their results from another provider, but practices must have the ability to accept requests directly from the patient.

2. Authentication and verification of patient identity

This aspect of compliance with the rule may be particularly challenging, as many pathology practices have typically had little or no direct contact with patients in the past. In addition, a provider who sends the patient for testing may provide incomplete or incorrect information to the practice, thereby creating barriers in the verification/authentication process. When a practice creates a verification process, it cannot impose unreasonable verification methods on patients, such as requiring them to physically come to the practice to make requests and provide identification. As a general matter, practices should avoid relying exclusively on information received from another provider in implementing their verification processes due to the potential for incomplete or incorrect information, although seeking information from providers may be part of the authentication process.

The HIPAA Privacy Rule does not dictate any specific methods a practice must use in the verification process. The rule does require that practices "take reasonable steps to verify the identity of the individual making a request for access."[13] Furthermore, the rule does not mandate any particular form of verification (i.e., driver's license) but rather leaves the development of this process to the discretion and professional judgment of the practice.

For example, some practices have created the following guidelines to govern this process;

- Patients must make requests in writing by completing a form developed by the practice. The form can request information only the patient knows, such as name, address, date of birth, treating physician's name, date specimen taken, type of specimen, insurance

[13] 79 Fed. Reg. at 7303; 45 C.F.R.§ 164.514(h).

company name, insurance numbers, and/or social security number (SSN) or last four digits of SSN. A practice can verify requests from the encounter or accession form provided by the treating physician.

Note: Practices may face some potential liability if their policy relies on information obtained from other providers (e.g., errors in information submitted by physician practices). It is understood that there are practical issues here, however, given the lab's/practice's lack of direct contact with patients, making such reliance is the only practical alternative in at least some instances. Note that Health and Human Services (HHS) did identify other providers as one possible method of obtaining information. Nonetheless, it is suggested laboratories avoid relying solely on other providers to meet the requirements of the rule.

- If a patient calls into the practice, a practice employee can complete the form for the patient's signature based on information provided by the patient over the phone, or the practice can e-mail or fax the blank form to the patient to complete.
- A patient on the practice's premises may complete the form and show a photo ID.

The new rule also allows a personal representative of the patient to have access to test reports. This provision may create a challenge for practices, as encounter forms or accession forms typically do not contain information about personal representatives. A practice must verify the identity and authority of the person making a request as a "personal representative." Practices may consider including the following items in the policy for the authentication of personal representatives;

- Documentation of a health care power of attorney
- Documentation of a general or durable power of attorney that includes the power to make health care decisions
- Proof of legal guardianship
- In the case of minors, information that establishes the relationship of the person to the minor individual. **Review appropriate state laws governing the rights of minors in a health care setting**

- Contacting the treating/referring physician to obtain documentation confirming an individual's status as a personal representative of the patient[14]

  Note: Reliance on legal documents, such as powers of attorney is likely preferable, but confirmation via treating providers may add some protection in instances where such legal documents may have been revoked, expired, etc. (e.g., there have seen instances of spouses undergoing divorces seeking access to the medical information of their soon-to-be-former spouse, something a treating provider may be more aware of than a laboratory).

The last provision of the rule requires the practice to abide by a patient's request to have the laboratory test results and related protected health information transmitted to another person or entity designated by the patient. The rule specifically **requires**:

- The patient to place the request in writing
- The patient to sign the request
- The request to clearly identify the person or entity who will receive the information
- Clearly stated information about where to send the health information[15]

Practices should take steps to ensure these specific requirements are in written policies that can be referred to when needed.

3. Record keeping

Documentation is a critical function in this process and properly maintaining records helps promote compliance. Practices must create methods to record requests (e.g., name of requestor, date, contact information, nature of request), mechanisms used to authenticate patient (or personal representative) identity, mechanisms to comply with required delivery dates of protected health information, mechanisms to ensure the proper format of delivery, and mechanisms to document and collect any associated costs. Include the original request form in the records (if applicable). Ensure records are retained for

[14] 79 Fed. Reg. at 7297.
[15] 79 Fed. Reg. at 7298; 45 C.F.R.§ 164.524(c)(3)(ii).

appropriate timeframes (e.g., HIPAA requires records be retained for six years and state laws may include other requirements).

4. Record retrieval and delivery

Once the request has been made, the practice will have up to 30 days *from the date of the request* (not the date of test completion) to deliver the test results, unless state law requires a shorter time frame. For example, if your state requires delivery in 10 days, you must comply with the 10-day rule.

If, for some reason, the practice cannot retrieve and deliver the requested report in the 30-day window, the practice is permitted *one* 30-day extension. The practice must notify the patient in writing of its inability to comply with the 30-day requirement, state why it is unable to comply, and provide a date when the results will be delivered. If, after the 30-day extension, the requested test report is still not complete, the practice must provide the patient with any part of the requested designated record set that is available, along with the reason for the delay of the information that is not available. Appendix 1 of this Toolkit contains a sample letter. Practices may wish to consult compliance professionals or legal counsel should difficulties arise with respect to timely response to access requests.

5. Delivery format

The rule states that a practice must provide the individual with a copy of the protected health information in the form and format requested by the individual, if the practice can readily produce a copy in that form or format. If the practice cannot deliver the results in the form and format requested by the individual, the practice can either deliver a readable hard copy or provide the information in another form and format mutually agreed upon by the requesting individual and the practice.

You may wish to evaluate the practice's laboratory information systems (LIS) to determine how they will produce and deliver requested reports and to make sure they will have the required information readily available when patients make requests. The rule does not require a practice to obtain additional infrastructure or to deliver reports in a defined format. Some practices provide the requesting individual choices when the request is made – for example, printed hard copies or electronic copies on a CD or thumb drive. Some practices scan the documents into a PDF format, which is widely accepted. In addition, a number of proprietary products enable practices to create "patient portals" for this purpose. You should evaluate such products to determine if they

have acceptable security measures built-in to ensure compliance. You should also consider ways to communicate to the applicable patient or patient representative that the test results are available on the portal (and provide contact information for a customer service or IT helpline to assist patients with portal use) and document that delivery of the requested results occurred through the standard patient portal process as appropriate (e.g., to ensure that timeliness and other requirements are met).

6. Development of a fee schedule

The HIPAA Privacy Rule contains a provision permitting practices to charge a "reasonable, cost-based fee" for the expenses incurred in complying with patient requests for access. This fee structure is designed to be fair to the practice while not impeding the patient's ability to receive protected health information. The allowable costs include:

- Labor for copying the information requested by the individual, whether in paper or electronic form
- Supplies for creating the paper copy or electronic media if the individual requests that the practice provide an electronic copy on portable media (CD or thumb drive).
- Postage, if the individual requests the practice to mail the information.
- Preparation of a summary or explanation of the information, if agreed to by the individual.[16]

Refer to Appendix 1 of this Toolkit for a sample worksheet to assist practices in calculating these costs.

The rule specifically excludes certain costs that a practice may incur. These include:

- Fees associated with the verification and authentication process
- Documentation expenses
- Liability insurance

[16] 79 Fed. Reg. at 7300.

- Acquiring and maintaining "systems," such as expenses associated with obtaining or updating computer systems or programs or creating a patient portal[17]

Creating a fixed fee (i.e. $5.00 per report) may not conform to the provisions of the rule. The practice's actual costs will depend on a number of factors, including, but not limited to, the amount of information included in the copy and the method by which the patient has elected to receive the information. Consult your state laws (if applicable) regarding the allowable fees for copying and postage. CMS considers those fees reasonable, as long as they are not associated with any costs listed in the exclusion list above.[18]

Assessing a charge for access and copying is an option and not a requirement under the rule. Note that a practice cannot deny a patient's right to obtain copies of their protected health information and test reports if they have failed cannot afford to pay the established fees for the underlying health care services provided.[19]

1. Content of test reports and protected health information

Historically, under HIPAA, patients have had the right to receive a copy of the information that a practice maintains about them in a "designated record set" (see footnote 7 for definition), with the exception of laboratory test reports. The rule removes this exception and includes completed test reports in the designated record set. When an individual makes a request, make an effort to identify exactly what the patient expects: a single test result performed on a specified date, or all records and results that the practice maintains? Clarifying these expectations with the patient will avoid misunderstandings and unnecessary re-work and enhance the patient's experience with your practice.

Test reports covered under the rule are defined as those that are "completed." Test results are considered complete when all results associated with an ordered test are finalized and ready for release.

The rule does not require that the practice create a different report format for patient delivery than what is used for providers. Some practices may have reports that contain a variety of graphs, photos or charts along with reference

[17] 79 Fed. Reg. at 7300-01.
[18] 79 Fed. Reg. at 7301.
[19] 79 Fed. Reg. at 7305.

ranges or other data points. A practice complies by simply supplying such reports to the patient if within the scope of the request.

Under the final rule, a practice is not required to provide an interpretation of the results or any other collateral information regarding the test, test procedures, normal values or any other clinical information. Some practices, however, use this additional explanatory or educational information as an opportunity to engage patients in discussions about the results of their medical conditions. Refer to Guide 3 of the Toolkit for additional information.

1.1 Sensitive reports

Some health care professionals characterize certain tests as being "sensitive." Likewise, some states provide heightened privacy protections for certain types of health information. These tests may pertain to, but are not limited to, sexually transmitted diseases, cancer, genetic and genomic analysis, pregnancy and mental health. Under the rule, *no test is exempt* from access by the patient. However, several exemptions granted through this rule may permit a practice to deny access. (See 7.2 and section 8 below)

1.2 Denial of access to certain "sensitive" reports in limited circumstances

As indicated above, all test results are subject to access by the patient. The only limitation regarding sensitive reports are in those limited 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."[20]

The rule identifies the determining factor as the endangerment of the life or physical safety of the patient or another person. Concerns about

[20] 79 Fed. Reg. at 7296; 45 C.F.R. § 164.524(a)(3)(i). Access may also be denied, subject to review, when the protected health information contains information about another person (other than a health care provider) and a licensed health care professional determines, in the exercise of professional judgment, that access to this information is reasonably likely to cause substantial harm to the other person and when the request for access is made by a personal representative and a licensed health care professional determines, in the exercise of professional judgment, that the provision of such access to such personal representative is reasonably likely to cause substantial harm to the individual or another person. 45 C.F.R. § 164.524(a)(3)(ii)&(iii).

emotional or psychological harm alone generally do not provide sufficient grounds for denying access.[21]

If a practice elects to deny access to an individual due to a determination made by a licensed health care professional, the practice must promptly provide the individual with an opportunity to have the denial reviewed by another health care professional designated by the practice. This person acts as a "reviewing official" and must not have been involved in the original denial. The reviewing official must determine within a reasonable amount of time whether to grant the patient access. The practice must then follow the reviewing official's decision.[22]

1.3 Types of exempt records

A patient has the right to access all records in the designated record set maintained by a practice with the exception of:

- Psychotherapy notes
- Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding[23]

2. Denial of access[24]

Under limited circumstances, a practice may deny a patient access to protected health information without the opportunity for review as detailed in Section 7.2 (above). These instances are:

- The records are exempt from access (Section 7.3 above)
- If the covered entity is a correctional institution or a practice acting under the direction of a correctional institution, it may deny, in whole or in part, an inmate's request to obtain protected health information if obtaining it would jeopardize the health, safety, security, custody, or rehabilitation of the individual or other inmates, or the safety of any officer, employee, or other person at the correctional facility or responsible for the transportation of the inmate
- A patient participating in a research project that includes treatment who has agreed to have access to protected health information denied while

[21] 79 Fed. Reg. at 7296.
[22] 79 Fed. Reg. at 7296; 45 C.F.R. § 164.524(a)(4).
[23] 45 C.F.R. §164.524(a).
[24] 45 C.F.R. §164.524.

participating in the research project. In these situations, patients are informed that right of access will be reinstated at the conclusion of their participation.

3. Record retention issue

The rule does not change any existing record retention regulations as established by CLIA or state laws. Therefore, all records in a "designated record set" maintained by a practice (at the time the request is made) are available to the patient upon request. These records may include those archived or maintained off-site and could include accession or encounter forms, test orders, ordering provider information, insurance information, and billing/ payment information. For this reason, clearly identify which records a patient desires at the time of request.

A practice may not use the cost of retrieving off-site or archived records as a factor in determining the charge to the patient.

4. Employment drug testing

CLIA regulations do not compel practices to release drug testing results to the patient, as employment-related testing is not a regulated activity under CLIA. Employment drug testing is defined as testing for the purposes of pre-employment/employment screening used merely to determine compliance with conditions of employment and not for counseling, treatment or diagnostic purposes. Note, however, that drug testing as part of a substance abuse treatment program **is** covered by CLIA and subject to the patient access rule, as these results may be used in the diagnosis, prevention or treatment of a disease or impairment.

If your practice conducts pre-employment or random employer-mandated drug testing and your practice is a HIPAA-covered entity, you may be required to release the results of those tests to the patient upon request, as these results are considered protected health information under the HIPAA Privacy Rule. [25]

[25] 45 C.F.R. §160.103

5. Patient notification of right of access

Notifying patients of their rights under the new rule may also be challenging. The rule encourages but does not require the treating health care provider to inform patients of their right to access their test results directly from a practice. Furthermore, the rule simply encourages the treating health care provider to supply the patient with the name and contact information of the practice/laboratory to which the specimen has been sent. Practices may use this aspect of the rule as an opportunity to work with providers who send patients to their laboratories to create a patient-friendly experience for those patients who wish to request protected health information. Refer to Guide 3 of this Toolkit for additional information.

HIPAA-covered practices must revise their Notices of Privacy Practices by the compliance date of **October 6, 2014** to inform patients of their right to access results directly from the practice and make these revised notices available to patients. Include a description of how to exercise these rights in such Notices. Ensure that you remove any contrary information as well. You should consult the HIPAA Privacy Rule for additional information regarding revisions to Notices.[26]

Post right-to-access information in a conspicuous place, especially if patients come to your facility to have specimens collected (i.e., a patient service center or "PSC"), In addition, PSC employees may wish to have patients sign the practice's or laboratory's amended Notice of Privacy Practices. Employees can explain patient access rights at that time and provide the patient with the option to obtain a copy of their test results.

No requirement in the rule compels nor prohibits your practice from notifying treating health care providers that their patients have made requests for test results. Some practices have used this kind of notification as an opportunity to contact and demonstrate high quality services to providers utilizing their laboratories for testing. Ensure that you comply with any other applicable requirements of HIPAA or other law in providing such notice.

[26] See 45 C.F.R. §164.520(b)(3).

Releasing Test Results Directly to Patients

This Toolkit does not constitute legal advice.

Guide 3: Opportunities and FAQs

Opportunities

"Hiding in plain sight"

Challenges often come with opportunities, some hidden and others in plain sight. While this new rule presents challenges to many practices, it also provides an opportunity to develop new and unique tools that could enhance patient access to their health information.

Many pathology practices have little or no contact with their patients, and some have only infrequent contact with clinicians. Complying with the rule provides practices with opportunities to enhance their exposure and demonstrate value to patients, increase communication with treating clinicians, and more actively participate in the patient care process.

This guide presents a variety of potential opportunities for your practice to explore. Before launching any new tactical initiatives, consult with your compliance professionals and legal counsel to ensure compliance with state and federal laws, particularly fraud and abuse laws that may place limits on your interactions with both patients and clinicians.

The Patient Request Process

The rule mandates that laboratories/practices provide protected health information and testing results to patients who request them. Managing the process of fulfilling these requests in a "patient- friendly" and educational manner will reflect well on your practice and provide an opportunity to strengthen the patient-pathologist relationship.

The process begins in the "pre-request" stage. The rule does not require clinicians to inform patients of their right of access to test results; clinicians are simply "encouraged" to do so. Your practice can choose to inform patients proactively by:

- Printing business cards with your practice's contact information, including phone number and e-mail address. On the reverse side, list your

authentication requirements for test result requests. Clinicians can make these cards available to all of their patients.

- Your practice can print educational brochures explaining the right of access rule and including contact information and information regarding the practice. You may wish to place these brochures in waiting areas. Ensure such brochures comply with state laws on advertising by health care entities.
- Practices should ensure that their strategies comply with all federal and state laws

Once a patient is aware of the right of access rule, your practice can create an easy way for the patient to obtain a test report. Your practice may wish to:

- Create a form authorizing your practice to release the test reports to the patient and make this form available to patients at their physician's office. This assumes the applicable physician authenticates each patient upon his or her arrival. In order for the patient to access their test results, this form can be sent to your practice along with the specimen. The form should gather sufficient information from the patient to permit your practice to comply with the requirements of the rule in the required timeframe (e.g., specify what PHI is being requested and desired delivery format, include patient contact information). Your practice can also print its fee or the method to calculate the fee (for example, $1.00 per copied page, if applicable) on this form, to the extent that fees will be charged by your practice for access to the test results.
- Amend its requisition form to include a check box for a patient can request a test report and ,if needed, space to provide contact information and/or how and where the information is requested to be sent. This check box can serve as an authorization to send a copy to the patient. Check your state laws to ensure this type of modification to an accession form is permissible.

When patients initiate contact with your practice, strive to make these experiences as pleasant as possible for them. Possible measures to consider include:

- Ensure that staff responsible for accepting patient requests understands the rule's requirements and your practice's policies. As noted above, consider using dedicated staff for this function
- Verify exactly what the patient wants -- a single test report, all test reports or all protected health information
- Inform the patient when they can expect to receive their reports (being cognizant of deadlines imposed by the rule)

- Verify how your practice will deliver the report to the patient
- Ask them if they would like to discuss their results with a pathologist Discussing test results or providing diagnostic opinions and guidance may create liability including malpractice liability. Pathologist should be attentive to this potential risk when developing their protocols.
- Notify the patient of any associated fees (if applicable)
- Once the report is delivered, follow-up with the patient to address any questions or concerns
- Ensure that all who have contact with your patients know how to handle these requests in a professional and consistent manner (e.g., billing department, phlebotomists, drivers, hospital information desk, etc.). This may require specialized training depending on the process you develop for access requests

The Delivery Process

Creating a streamlined process to deliver requested reports and protected health information should be a goal of your practice. The rule requires that the delivery method be in the "form and format" requested by the patient, or "in a mutually agreeable format" and requires that access to completed test reports generally be provided within 30 days of a request (subject to one 30-day extension under certain circumstances). While patients often request traditional paper/hard copies, many practices have learned that some patients prefer some type of electronic access via e-mail, or a "patient portal." Practices must comply with any applicable HIPAA security requirements and should consult with their legal counsel or refer to HIPAA regulations at 45 C.F.R. Part 64 Subpart C for guidance on these matters. .

Report Content

Many clinicians and health care professionals remain concerned about providing patients with test reports without the benefit of provider interpretation or without the knowledge to properly read and interpret the results. With a lack of this knowledge, patients may misinterpret and improperly act upon the results. Many test reports can be confusing to an untrained reader. As an increasing number of genetic and genomic tests become available, certain test reports may grow even more complicated.

While your practice is not required to interpret or create a new format for reports to be compliant with the rule, your practice may benefit from providing additional guidance to patients:

- Design a companion summary report explaining the results of the test
- Provide a summary explanation of the test and test results in a letter from the pathologist
- Encourage the patient to contact the pathologist to discuss the results. Some pathologists have provided patients with recommendations for additional testing or have recommended specialists
- Make a follow-up call to the patient to answer any questions
- In cases where a patient can come to the practice, meet with the patient and explain the results
- Design educational materials to accompany the test results that explain the patient's medical condition, and why the test was performed

Note: Providing additional information or summarizing a test report may create liability, including malpractice liability, if, e.g., the summary incorrectly describes the results or information in the materials is incorrect (e.g., if this task was delegated to a non-physician to do). Practices should be prudent in their development of collateral information to ensure that all information is correct, up to date and accurate.

Clinician Relationships

The rule does not impose on the physicians' obligation to review and discuss the test results with their patient. Often, a patient may have already met, or be scheduled to meet, with a physician regarding the results. Developing relationships with physicians can help your practice become better integrated into the care team:

- Notify the treating clinician (in accord with all applicable law) that their patient has requested a copy of the test results. While the rule does not require this kind of notification, many clinicians will appreciate the advance notice that the patient will be receiving the results.
- Provide the clinician with a copy of any written information sent to the patient explaining the results.
- Provide the clinician with a copy of any educational material given to the patient
- If the pathologist discussed the results with the patient in person or on the phone, provide a brief note to the clinician recapping these discussions and

identifying questions that the patient may have asked to avoid providing conflicting information

- Use this communication as an opportunity to discuss other testing options or patient care issues

Summary

The opportunities outlined in this guide may assist pathologists and their practices to become a more visible and integrated part of the health care team. Demonstrating "value" begins with becoming engaged in areas and in roles that not everyone associates with the practice of pathology. By applying innovative approaches pathology practices can galvanize their relationships with clinicians who need laboratory services. These "natural partnerships" will encourage pathologist involvement at various levels of the care continuum and enhance your practice's value.

Frequently Asked Questions

CAP's Economic and Regulatory Affairs office authored the following frequently asked questions:

Q1. What does the new final rule do?

A1. The new final rule amends the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) regulations to allow laboratories to give a patient, or a person designated by the patient, or the patient's "personal representative, access to the patient's completed test reports on the patient's or patient's personal representative's authenticated request . At the same time, the final rule eliminates the exception under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to an individual's right to access his or her protected health information when a CLIA-certified or CLIA-exempt laboratory holds it. While patients can continue to get access to their laboratory test reports from their doctors, these changes give patients a new option to obtain their test reports directly from the laboratory while maintaining strong protections for patients' privacy. The final rule results in the preemption of a number of state laws that prohibit laboratories from releasing test reports directly to patients

Q2. Why was the rule promulgated?

A2. The rule is part of the federal Department of Health and Human Services' ("HHS") efforts to make care more "patient-centered" and to empower patients to be informed partners with their health care providers.

Q3. To whom does the final rule apply?

A3. The rule applies to all CLIA-regulated laboratories and imposes additional obligations on those laboratories that engage in HIPAA "covered transactions" such as transmitting health care claims to a health plan, requesting prior authorization from a health plan, or sending an eligibility inquiry to a health plan.

Q4. What is the compliance date?

A.4. The final rule is effective April 7, 2014. Laboratories that are "covered entities" under HIPAA must comply with the final rule's HIPAA-related requirements by October 6, 2014. In effect, certain state restrictions on providing patients with their laboratory results are voided by the first deadline, and HIPAA Notices of Privacy Practices must be updated, and direct access to lab results must be available to patients in accord with HIPAA requirements by the second.

Thus, laboratories may voluntarily comply with the rule following April 7, 2014 and then are required to comply following October 6, 2014.

Q5. How long do laboratories have to give patients or their personal representatives their test results?

A5. After the compliance date of the rule on October 6, 2014, laboratories have 30 days following the request of the patient or their personal representative to provide test results. Laboratories may, upon notification of the patient that the completed test report the patient is seeking will take more than 30 days to produce, inform the patient in writing within the initial 30-day period of the need for the delay and rationale for it and receive a 30-day extension to produce the report. Only one 30-day extension is allowed. If state privacy laws provide for faster patient access, the results would need to be provided in the timeframe specified by state law, as is now required in those states.

Q6. What specifically must be provided?

A6. A HIPAA-covered laboratory is required to provide an individual with access only to information it actually maintains about the individual in a "designated record set" at the time the request for access is fulfilled. Only completed test reports—those containing all results associated with an ordered test—are considered to be part of a designated record set. *There is no general exception to the access rule for so-called sensitive test results (e.g., relating to sexually transmitted disease, genomic analysis, cancer, etc.). An extremely limited exception may apply in cases where a licensed health care professional determines life or physical safety is in jeopardy provided the denial is subject to review by an unaffiliated licensed health care professional.*

Q7. What format do the results need to be in?

A7. The HIPAA Privacy Rule requires a covered entity such as a clinical laboratory 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." If not, the copy must be either a readable hard copy or in another form or format as agreed upon by the covered entity and the individual. If an 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.

Q8. Can laboratories charge patients for providing the results? If so, how much can they charge?

A8. The rule states: 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. . ."[27]

Q9. Who is considered a personal representative?

A9. For adults, the only person besides the individual to which the test results apply who has a direct access right under this new rule to the individual's test result is their personal representative. "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).)"[28] For minors, the parent is usually the personal representative. HIPAA provides some exceptions to parents being the personal representatives for their minor children.

Q10. How do laboratories authenticate patients and their personal representatives' identity?

A10. The commentary to the final rule states: "… 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."[29]

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[27] 79 Fed. Reg. at 7301.
[28] 79 Fed. Reg. at 7297.
[29] 79 Fed. Reg. at 7297-98.

Q11. Can a laboratory provide results directly to patients if the patient has not requested the results?

A11. "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."[30] Whether or not a pathologist or laboratory can initiate such contact without a patient request will depend on applicable state law.

Q12. How will patients know which laboratories received their specimens so that they can exercise these new access rights?

A12. The new rule encourages but does not require a treating health care provider to inform an individual of the name of the laboratory to which a specimen is being sent.

Q13. Does the new law impose any other requirements beyond giving patients their results upon request?

A13. Yes, laboratories will need to update their Notices of HIPAA Privacy Practices. See §164.520(b)(3) of the HIPAA Privacy Rule. By the October 6, 2014 compliance date, HIPAA-covered laboratories must revise their Notices to inform individuals of their new access right and include a brief description of how to access the right. Laboratories must also remove any contrary statements and must make the revised Notices available.

[30] 79 Fed. Reg. at 7304.

CMS produced the following questions and answers to provide additional technical guidance for practices.

1. What are the changes to the CLIA regulations at 42 C.F.R. §493.1291?

The rule includes the following changes to the CLIA regulations at 42 C.F.R. §493.1291:

42 C.F.R. §493.1291(f) has been amended as follows:

> Except as provided in §493.1291(l), test results must be released only to authorized persons, and, if applicable, the persons responsible for using the test results and the laboratory that initially requested the test.

A new provision has been added as §493.1291(l) that reads:

> Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 C.F.R. § 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient.

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

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

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

An individual has generally been granted an absolute right to access his or her own completed laboratory test reports when those reports are held by a HIPAA-covered laboratory. The only persons other than the individual that have a right to access such test reports directly from a HIPAA-covered

laboratory are those persons who qualify as a person designated by the individual in accordance with the HIPAA Privacy Rule at §164.524(c)(3)(ii) or a "personal representative" of the individual. For the purposes of the Privacy Rule, a "personal representative" is defined at 45 C.F.R.§ 164.502(g) and, in certain contexts, includes a person who has authority under applicable law to make health care decisions for the individual. Such authority is generally determined under state law. HIPAA-covered laboratories are required under 45 C.F.R.§ 164.514(h) of the Privacy Rule to verify both the identity and authority of the person requesting an individual's protected health information.

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

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

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

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

Releasing Test Results Directly to Patients

Appendix 1: References and Resources

This appendix includes the following:

1. Summary: Notice of Privacy Practices for Protected Health Information
2. Sample Notice
3. Sample Notice – Other instructions for Notice
4. Sample Patient Request Form
5. Sample Letter to Patient – Not able to comply within 30 day period
6. Sample Method: Fee Calculation
7. Links to other resources
8. State Tables

Summary: Notice of Privacy Practices for Protected Health Information

This summary outlines the requirements for the Notice of Privacy Practices for Protected Health Information. For additional information about the notice, practices can consult the U.S. Department of Health and Human Services (HHS) at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/notice.html .

Practices considered to be "covered entities" must develop and distribute a notice that clearly explains patients' privacy rights for protected health information. HHS defines a covered entity as a health care provider that conducts certain transactions in electronic form, even if someone else conducts these transactions on the provider's behalf. These transactions are detailed at 45 C.F.R. Part 162 and include, but are not limited, to the following;

- Requesting to obtain payment, along with transmitting all required information from a health care provider to a health plan
- Transmitting an encounter form to a health plan
- Requesting eligibility to receive coverage of services and benefits from a health plan
- Requesting to obtain authorization for health care services or authorization to refer an individual to another health care provider, or responding to requests to either of the former
- Asking for information about the status of a health care claim or for a response about the status of a claim
- Requesting payment processing information, or information regarding the transfer of funds and acceptance of payment

Most practices are considered HIPAA covered entities and therefore must have a Notice of Privacy Practices. Notices must provide clear and user-friendly instructions and information regarding patients' rights related to their protected health information and the privacy policies of your practice.

A sample Notice adapted from a template produced by HHS follows. Practices may consider including language specifically referencing test results by inserting the phrase "including copies of completed test results" where references are made to "medical records." In addition, a practice may consider including instructions on how to make a request. (See Guide 2 for additional details)

SAMPLE NOTICE[31]

Your Information. Your Rights. Our Responsibilities.

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully.

LAYERED SUMMARY TEXT –

Your Rights

You have the right to:

- Get a copy of your paper or electronic medical record
- Correct your paper or electronic medical record
- Request confidential communication
- Ask us to limit the information we share
- Get a list of those with whom we have shared your information
- Get a copy of this privacy notice
- Choose someone to act for you
- File a complaint if you believe your privacy rights have been violated

Your Choices

You may choose how we use and share your personal health information

- Whether or not we tell family and friends about your condition
- Whether or not we share your information with other providers to help provide disaster relief
- Whether or not we share your mental health care notes with other providers
- Whether or not we include you in a hospital directory for providers
- Whether or not we use your information to market our services

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[31] Adapted from HHS.gov sample "Health Information Privacy" http://www.hhs.gov/ocr/privacy/hipaa/npp_hc_provider-text_version.doc accessed 07-01-2014.

- Whether or not we sell your information
- Whether or not we use your information to help raise funds
- Whether or not we use your information to respond to organ and tissue donation requests

Our Uses and Disclosures

We may use and share your information as we:

- Treat you
- Run our organization
- Bill for your services
- Help with public health and safety issues
- Do research
- Comply with the law
- Work with a medical examiner or funeral director
- Address workers' compensation, law enforcement, and other government requests
- Respond to lawsuits and legal actions

Your Rights

You have certain rights regarding your personal health information. This section explains your rights and some of our responsibilities to help you.

You have the right to get an electronic or paper copy of your medical record

- You can ask to see or get an electronic or paper copy of your medical record and other health information we have about you. Ask us how to do this.
- We will provide a copy or a summary of your health information, usually within 30 days of your request. We may charge a reasonable, cost-based fee.

You have the right to ask us to correct your medical record

- You can ask us to correct health information about you that you think is incorrect or incomplete. Ask us how to do this.
- We may say "no" to your request, but we'll tell you why in writing within 60 days.

You have the right to request confidential communications

- You can ask us to contact you in a specific way (for example, home or office phone) or to send mail to a particular address.
- We will say "yes" to all reasonable requests.

You have the right to ask us to limit what we use or share

- You can ask us not to use or share certain health information for treatment, payment, or our operations. We are not required to agree to your request, and we may say "no" if it would affect your care.
- If you pay for a service or health care item out-of-pocket in full, you can ask us not to share that information for the purpose of payment or for our operations with your health insurer. We will say "yes" unless a law requires us to share that information.

You have the right to get a list of those with whom we've shared information

- You can ask for a list (accounting) of the times we've shared your health information for six years prior to the date you ask, whom we shared it with, and why.
- We will include all the disclosures except for those about treatment, payment, and health care operations, and certain other disclosures (such as any you asked us to make). We'll provide one accounting a year for free but will charge a reasonable, cost-based fee if you ask for another one within 12 months.

You have the right to get a copy of this privacy notice

You can ask for a paper copy of this notice at any time, even if you have agreed to receive the notice electronically. We will provide you with a paper copy promptly.

You have the right to choose someone to act for you

- If you have given someone medical power of attorney or if someone is your legal guardian, that person can exercise your rights and make choices about your health information.
- We will make sure the person has this authority and can act for you before we take any action.

You have the right to file a complaint if you feel your rights are violated

- You can complain if you feel we have violated your rights by contacting us.
- You can file a complaint with the U.S. Department of Health and Human Services Office for Civil Rights by sending a letter to 200 Independence Avenue, S.W., Washington, D.C. 20201, calling 1-877-696-6775, or visiting **www.hhs.gov/ocr/privacy/hipaa/complaints/.**
- We will not retaliate against you for filing a complaint

Your Choices

For certain health information, you choose what we share. If you have a clear preference for how we share your information in the situations described below, talk to us. Tell us what you want us to do, and we will follow your instructions.

In these cases, you have both the right and choice to tell us to:

- Share information with your family, close friends, or others involved in your care
- Share information in a disaster relief situation
- Include your information in a hospital directory

If you cannot tell us your preferences, (for example if you are unconscious) we may go ahead and share your information if we believe it is in your best interest. We may also share your information when it is needed to lessen a serious and imminent threat to health or safety.

In these cases, we never share your information unless you give us written permission:

- Marketing purposes

- Sale of your information
- Most sharing of psychotherapy notes

In the case of fundraising:

- We may contact you for fundraising efforts, but you can tell us not to contact you again.

Our Uses and Disclosures

How do we typically use or share your health information?

We typically use or share your health information in the following ways:

To treat you

We can use your health information and share it with other professionals who are treating you.

Example: A doctor treating you for an injury asks another doctor about your overall health condition.

To run our organization

We can use and share your health information to run our practice, improve your care, and contact you when necessary.

Example: We use health information about you to manage your treatment.

To bill for your services

We can use and share your health information to bill and get payment from health plans or other entities.

Example: We give information about you to your health insurance plan so it will pay for services you received.

How else can we use or share your health information?

We are allowed or required to share your information in other ways – usually in ways that contribute to the public good, such as public health and research. We have to meet many conditions in the law before we can share your

information for these purposes. For more information see: www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/index.html.

To help with public health and safety issues

We can share health information about you for certain reasons such as:

- Preventing disease
- Helping with product recalls
- Reporting adverse reactions to medications
- Reporting suspected abuse, neglect, or domestic violence
- Preventing or reducing a serious threat to anyone's health or safety

To do research

We can use or share your information for health research.

To comply with the law

We will share information about you if state or federal laws require it, including with the Department of Health and Human Services if it wants to see that we're complying with federal privacy law.

To respond to organ and tissue donation requests

With your permission, we can share health information about you with organ procurement organizations.

To work with a medical examiner or funeral director

We can share health information with a coroner, medical examiner, or funeral director after death.

To address workers' compensation, law enforcement, and other government requests

We can use or share health information about you:

- For workers' compensation claims

- For law enforcement purposes or with a law enforcement official
- With health oversight agencies for activities authorized by law
- For special government functions, such as military, national security, and presidential protective services

To respond to lawsuits and legal actions

- We can share health information about you in response to a court or administrative order, or in response to a subpoena.

Our Responsibilities

- We are required by law to maintain the privacy and security of your protected health information
- We will let you know promptly if a breach occurs that may have compromised the privacy or security of your information
- We must follow the duties and privacy practices described in this notice and give you a copy of it
- We will not use or share your information other than as described here unless you tell us we can in writing. If you tell us we can, you may change your mind at any time. Let us know in writing if you change your mind

For more information see:
www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/noticepp.html.

Changes to the Terms of this Notice

We can change the terms of this notice, and the changes will apply to all information we have about you. The new notice will be available upon request, in our office, and on our website.

Other Instructions for Notice

- Insert notice's effective date
- Insert name or title of the privacy official (or other privacy contact) and his/her email address and phone number.
- Insert any special notes that apply to your entity's practices such as "we never market or sell personal information"
- The HIPAA Privacy Rule requires you to describe any state or other laws that require greater limits on disclosures. For example, "We will never share any substance abuse treatment records without your written permission." Insert this type of information here. If no laws with greater limits apply to your entity, no information needs to be added
- If your entity provides patients with access to their health information via the Blue Button protocol, you may want to insert a reference to it here
- If your entity is part of an OHCA (organized health care arrangement) that has agreed to a joint notice, use this space to inform your patients of how you share information within the OHCA (such as for treatment, payment, and operations related to the OHCA). Also, describe the other entities covered by this notice and their service locations. For example, "This notice applies to Grace Community Hospitals and Emergency Services Incorporated, which operate the emergency services within all Grace hospitals in the greater Dayton area"

Sample Patient Request Form

Practices may consider using this sample to create a request form for your patients. You can easily modify the form to meet your practice's compliance strategy. This form can also be modified to address requests for laboratory test results received from personal representatives of patients, which may require additional authentication methods. Consult with compliance professional or legal advisor to ensure the form meets all state and federal requirements.

Request for Laboratory Test Results

I, _____, request that ABC Pathology provide me with a copy of:

_____ My laboratory test report from (enter date of service)_____.

_____ All of my protected health information on file

Social Security Number _____ Date of Birth _____ Ordering Physician _____

Patient Address _____ Test(s) Performed _____

I understand that my test results will be delivered to me within 30 days of the "Date of Request" set forth next to my signature below to the extent completed results are available. ABC Pathology is not responsible for interpreting my results.

I understand that ABC pathology can deliver my results in one of the following ways (select one)

_____ I will personally pick the report up at ABC Pathology, at 123 Main Street, Anywhere, Oh.

_____ Have the report mailed to: _____

_____ Other method: _____

Consider providing examples such as "via encrypted email," "via CD," etc. In particular, if labs email PHI that is not encrypted potential risk exists and labs should seek patient permission to do so after advising patients of the risk involved.

_____ _____
Patient Signature Date of Request

Patient Authentication

For telephone requests, the patient must verify at minimum any 4 points of the following data:

____ Social Security Number ____ Date of Birth _____ Treating Physician _____ Test Type

____ Employer Name _____ Insurance Name/Number _____ Phone Number _____ Spouse/Next of Kin

For in-office pick-ups the patient must provide identification, including one of the following;

_____ Valid Drivers License _____ State ID Card _____ Passport _____ Other: _____

_____ _____
Practice Employee Signature Date

Delivery of Results

The above requested results were delivered by [specify method]_____to the patient on _____.

_____ _____
Practice Employee Signature Date

_____ In-Office pick-up: _____
Patient Signature

Sample Letter to Patient – Not able to comply within 30 day period

If your practice cannot comply with delivering the requested test results in the 30-day period (or other time frame based on state law) you must notify the patient. You may notify the patient in the form of a letter similar to the suggested approach below.

ABC Pathology

123 Main Street

Anywhere, Oh 43935

Date

Dear Patient Name;

ABC Pathology has received your request of (enter request date) for laboratory test results on a specimen sent to us by (enter referring physician name). We regret to inform you that the test results will not be finalized on or before the required delivery date of (enter the date results should have been ready).

Certain testing procedures require a long period of time to process and finalize, due to their complexity and the expertise required for analyzing them. Under the CLIA/HIPAA Patients' Access to Test Reports Final Rule issued by the U.S. Department of Health and Human Services on Feb. 6, 2014, we are requesting a 30-day extension to provide you with your completed test results.

We anticipate that your test results will be complete and final on (enter estimated date). If this date falls within our requested 30-day extension, we will send your requested report once these results are finalized. If your report will not be completed by the requested extension date, we will send you only that information that is available in the designated record set that we maintain for you as of that date. If you would like your test results when the laboratory report is completed, please contact (insert contact person or patient service center number below).

Should you have any questions, please contact our patient service center at (123) 456-7892.

Thank you,

ABC Pathology

Sample Method: Fee Calculation

The rule provides that a practice may charge a "reasonable, cost-based fee" to provide a patient with a copy of their results. The fee can only be based on the following items,

- Labor for copying the protected health information requested by the individual, whether in paper or electronic form
- Supplies for creating the paper copy or electronic media if the individual requests an electronic copy on portable media
- Postage, when the individual has requested the copy be mailed
- Preparation of an explanation or summary of the protected health information, if agreed to by the individual

No fees may be charged for searching for and retrieving the information, or for such things as verification, documentation, liability insurance or maintaining systems.

The worksheet below shows how a practice could calculate its fee. When calculating theses fees, retain all supporting documentation to validate the fee structure. Refer to your state laws to determine any other restrictions. Consulting your financial professional is recommended.

Labor Cost		**Supply Cost**		**Postage Cost**		**Prep of Summary**	
Actual Hourly Rate	$15.00	Paper Copy/Page	0.45	Actual Postage Expense	$0.75	Total Labor Cost	$19.05
Benefit Cost	27%	Total Pages	3			Actual Prep Time	15 Min
Total Hourly Rate	$19.05	Other: Media Cost					
Time to copy	15 min	Other: Media Cost					
Total Labor Cost:	**$4.76**	**Total Supply Cost**	**$1.35**	**Total Postage Cost**	**$0.75**	**Total Prep Cost**	**$4.76**
Total cost for request		**$11.62**					

Links to other resources

Department of Health and Human Service (HHS), Office of Civil Rights (OCR)

Health Information Privacy Overview - http://www.hhs.gov/ocr/privacy

How may the HIPAA Privacy Rule's requirements for verification of identity and authority be met in an electronic health information exchange environment? - http://www.hhs.gov/ocr/privacy/hipaa/faq/health_information_technology/569.html

How would a covered entity or health information organization (HIO), acting on its behalf, know if someone were a personal representative for the purpose of granting access under the HIPAA Privacy Rule? - http://www.hhs.gov/ocr/privacy/hipaa/faq/health_information_technology/551.html

How can a covered entity determine whether a person is a family member, or person involved in an individual's care prior to death, for purposes of sharing protected health information about the decedent after death? - http://www.hhs.gov/ocr/privacy/hipaa/faq/decedents/1505.html

How does a covered entity identify an individual's personal representative? - http://www.hhs.gov/ocr/privacy/hipaa/faq/personal_representatives_and_minors/226.html

If my family or friends call my health care provider to ask about my condition, will they have to give my provider proof of who they are? - http://www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_to_friends_and_family/526.html

HHS and EHR Regulations

https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html

Understanding Covered Entities

http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/personalreps.html

CLIA Guidance on electronic delivery of reports

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

Final Rule: Release of Test Results: Federal Register (PDF)

http://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf

State Tables

How the new rule impact by state

Tables 1-4 categorize all states according to their laws regarding the release of laboratory reports directly to the patient. The implementation of the new rule will impact all practices and laboratories to some degree, depending upon the existing laws in your state.

Table 1: In these states, no laws regarding the release of laboratory reports directly to the patient exist. Therefore, practices in these states may have internal policies permitting the release while others may not. All practices in these states will need to modify or create their policies to comply with the new rule

Table 1: No Existing State Laws			
Practices will need to modify or create policies to comply with new rule			
Alabama	Iowa	New Mexico	Texas
Alaska	Kentucky	North Carolina	Utah
Arizona	Louisiana	North Dakota	Vermont
Colorado	Minnesota	Ohio	Virgin Islands
Guam	Mississippi	Oklahoma	
Idaho	Montana	South Carolina	
Indiana	Nebraska	South Dakota	

Table 2: Practices/labs located in these states have been permitted to release test results only to health care providers and not to patients. These labs must create internal policies and modify other policies.

Table 2: States Having Allowed Release Only to Providers			
Practices will need to create and modify policies to comply with new rule			
Arkansas	Kansas	Rhode Island	Wyoming
Georgia	Maine	Tennessee	
Hawaii	Missouri	Washington	
Illinois	Pennsylvania	Wisconsin	

Table 3: These states have permitted practices/labs to release reports directly to patients. Labs in these states should have internal policies governing this activity

and may need to review these policies to ensure compliance with all provisions of the rule.

Table 3: States Having Allowed Release to Patients			
Practices will need to review policies to comply with new rule			
Delaware	New Hampshire	Nevada	Puerto Rico
D.C.	New Jersey	Oregon	West Virginia
Maryland			

Table 4: Practices located in these states have been allowed to release test results directly to the patient only with the approval of their health care provider. Creation of a direct access policy and modification of other internal policies may be required at these practices.

Table 4: States Having Allowed Release to Patient, with Provider Approval			
Practices will need to create and modify policies to comply with new rule			
California	Florida	Michigan	Virginia
Connecticut	Massachusetts	New York	

CAP has not independently verified the information contained in above tables.

Releasing Test Results Directly to Patients

Implementation Checklist with References

Use this checklist to ensure that your compliance plan includes your practice's processes. Have a compliance professional or legal advisor review your plan.

	Key Item	Reference
	Review the Toolkit	Guides 1-3, Appendix 1
	Check your state laws for provisions that may apply to your practice	Guide 2, Item #4
	Review/amend the CLIA policy manual • *Ensure the policy contains the appropriate access provisions*	Guide 1 "CLIA"
	Review/amend Notice of HIPAA Privacy Practices • *Ensure individuals are informed of their right of access* • *Describe how individuals can access their results* • *Remove contradictory language*	Guide1 "HIPAA" Appendix 1: "Sample Notice"
	Review/amend your practice's policies and procedures governing the release of test results (if applicable).	
	Review/revise CAP checklist at GEN.41304	Guide 1 "CAP Checklist"
	Develop or revise the following:	
	Method and policy to manage patient requests for results and associated request forms or other methods of request (i.e. accession form, clinician release form)	Guide 2, Item #1 Appendix 1 "Sample patient request"
	Process and policy for authentication of patient's identity	Guide 2, Item #2
	Record keeping policy covering requests and fulfillment	Guide 2, Item #3
	Policy and workflow addressing record retrieval and delivery	Guide 2, Item #4
	Methods used to deliver patient results (paper, portable devices, patient portals)	Guide 2, Item #5
	Policies governing denial of access to results	Guide 2, Items #7-#8
	Provide and document training of all employees	
	Practice level options:	
	Develop a cost-based fee schedule to charge patients	Guide 2, Item #6 Appendix 1 "Sample Method-Fee Calculation"
	Determine if the practice will offer an interpretation of results: if it will, create policy, procedure and format of interpretation	Guide 3

	(i.e. phone call, letter)	
	Determine if the practice will notify the referring clinician of the patient's request and develop appropriate policies and methods of notification	Guide 3
	Determine if the practice will offer patient education materials to be delivered with the results.	Guide 3
	Develop a template letter to use if results cannot be delivered in a timely fashion	Appendix 1 "Sample letter to patient"

Hospital-based practices *can consult with appropriate hospital administrative personnel (e.g., medical records) to determine what actions the practice must take.*

Releasing Test Results Directly to Patients

Implementation Checklist

Practices must comply with the new Patient Access Rule before October 6, 2014. This checklist is designed to assist practices in assessing areas that may be impacted. Seek the guidance of a compliance professional or legal advisor to ensure compliance to all state and federal laws.

Hospital-based practices can consult with the hospital compliance officer to ensure the practice remains compliant under the hospital's policies and procedures.

_____ Review the Toolkit and other recommended references

_____ Check for any applicable state laws that may impact your practice's policies

_____ Review and revise your Notice of Privacy Practices

_____ Review and, if necessary, revise your practice's policies and procedures. Remove conflicting language and incorporate language about the rule's provisions

_____ Review your CAP checklist/policy

_____ Develop or revise your patient authentication policy, procedure, and related forms

_____ Make necessary provisions for a delivery method (paper, patient portal, media device)

_____ Develop a workflow to manage requests, authentication, document retrieval and delivery to the patient

_____ Develop a cost-based fee schedule (Optional)

_____ Decide if/how your practice will offer interpretation of test results for the patient (Optional)

_____ Decide if/how your practice will notify the referring clinician of test requests and/or your discussions with the patient (Optional)

_____ Decide if your practice will offer educational materials to the patient (Optional)

_____ Provide training to your practice's staff. Document the training.