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# Privacy and Security Solutions for Interoperable Health Information Exchange

## Releasing Clinical Laboratory Test Results: Report on Survey of State Laws

Prepared for

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This survey was conducted in 2008. The authors have attempted to assure that the information presented is accurate as of December 2008. The information in this report is intended to provide an overview of a specific subset of the state statutes and regulations governing the reporting of clinical laboratory results. It should not be used as a substitute for legal or other expert advice.

# CONTENTS

# EXECUTIVE SUMMARY

## Background and Purpose

This report is one of a series produced under RTI International's contract with the Agency for Healthcare Research and Quality (AHRQ). The contract, entitled Privacy and Security Solutions for Interoperable Health Information Exchange, is managed by AHRQ and the Office of the National Coordinator for Health Information Technology (ONC). In the first phase of this project, 33 states and 1 territory (collectively referred to as state teams) conducted an assessment of variation in business practices, policies, and laws that might be perceived as barriers to electronic health information exchange, suggested possible solutions to these barriers, and prepared plans to implement these solutions. In doing so, states identified the federal Clinical Laboratories Improvement Amendments (CLIA) and related state laws as potential barriers to laboratories' exchange of health care information directly with the patient,[1] with health information organizations (HIOs), or with other similar organizations who may participate in electronic health information exchange.[2]

In very general terms, CLIA permits clinical laboratories to release test results only to an individual authorized under state law to order or receive test results and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule does not interfere with this regulatory framework.

In addition to specifying who may receive clinical laboratory test results, CLIA requires laboratories to have in place adequate manual or electronic systems to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry to final report destination, in a timely manner (42 C.F.R. § 493.1291). Some have expressed concern that states may independently impose similar or more stringent standards.

Under a subcontract with RTI International, Georgetown University undertook a survey of state statutes and regulations that govern to whom a clinical laboratory may release test results (i.e., who is authorized to receive test results). In this particular project, we focused on clinical laboratory and hospital licensing laws (that contain standards for hospital

[1] This report uses the term *patient* to refer to the subject of the laboratory test to avoid confusion with terms used in other federal laws. Although HIPAA uses the term *individual* to refer to the subject of health information, CLIA uses the term *individual* in a much broader sense to refer to any person or entity.

[2] A health information organization is "[a]n organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards." Electronic health information exchange is "[t]he electronic movement of health-related information among organizations according to nationally recognized standards." The National Alliance for Health Information Technology (2008, April). Report to the Office of the National Coordinator for Health Information Technology on Defining Key Health Information Technology Terms.

laboratories). We also examined general state medical record access laws to determine whether they provided an avenue for patients to access their clinical laboratory results directly. State law often imposes additional restrictions on the disclosure of health information related to sensitive health conditions. We reviewed state laws governing the release of HIV/AIDS tests to provide an example of how this type of law may further impact the ability of clinical laboratories to release related test results both to other providers and to the patients. Finally, we reviewed state clinical laboratory and hospital licensing laws to determine whether they set standards for the manner of transmitting test data to the final destination. The results of the study, conducted from the summer of 2008 through spring of 2009, are summarized in this report.

## Findings

Although the issue of state restrictions on the release of laboratory test results has at times been characterized as a privacy issue, it is also appropriate to view it as a licensing issue. State restrictions on who is legally authorized to order or use the results of a clinical test are tied to state standards specifying to whom such results may be released. This framework partially explains some of the restrictions that states have imposed on the release of laboratory test results.

The licensing laws of 26 states are silent concerning who may receive laboratory test results. In these states, CLIA generally sets the standards for who qualifies as a person authorized to receive test results.

The majority of states (29) have licensing laws that expressly address to whom a clinical laboratory may or must release test results. Many of these states expressly permit or require a clinical laboratory to release test results only to the authorized person who requested the test (or their agent). Some expressly permit disclosure to persons authorized to use or responsible for using the test, often in conjunction with permitting release to the health care provider who ordered the test.

Only a handful of states' clinical laboratory licensing laws expressly permit or require laboratories to release test results directly to patients. Another potential avenue for patients to obtain access to their laboratory results directly from laboratories is through state medical record access laws—general laws that may apply to a broad range of health care entities. The scope of these laws is often ambiguous. However, under the best of circumstances, states that grant patients the right to obtain test results directly from clinical laboratories are in the minority.

Many states have laws that specifically address the confidentiality of HIV/AIDS test information. These laws impose an additional layer of complexity on the manner in which clinical laboratories may release test results. First, it is not always clear whether clinical laboratories are subject to these laws, which are written to encompass a broad range of

entities. In addition, the framework of these laws can be complicated, with a general prohibition against disclosing information followed by a detailed list of instances in which disclosure is permitted without the patient's permission. Provisions that permit release of information for treatment can be nuanced, and appear to require subjective judgments, which may make it difficult to translate these requirements to an electronic environment. In some states, however, HIV/AIDS confidentiality laws appear to give patients a right to receive HIV/AIDS test results directly from a clinical lab even when patients do not have a similar right to receive other test results.

Most states do not expressly or specifically set standards for transmitting test data to their final destination. To the extent states address this issue, most incorporate the requirements of CLIA.

A broad overview of our findings is provided in Table A-1, Overview of State Clinical Laboratory Test Release Laws. More detailed summaries of the relevant text of state statutory or regulatory provisions reviewed are contained in Table A-2, State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results; Table A-3, State Laws Governing Patient Access to Clinical Laboratory Test Results; Table A-4, State Clinical Laboratory Licensing Laws and HIV Information Confidentiality Laws That Permit Release of Test Results for Treatment; Table A-5, State Clinical Laboratory Licensing Laws and HIV Information Confidentiality Laws That Permit Release of Test Results to Patients; and Table A-6, State Clinical and Hospital Licensing Laws Addressing Accurate Delivery of Test Results.

## Conclusion

Under many states' laws, clinical laboratories may directly release test results only to the person who ordered the test. Laws in a number of states do not expressly provide for the release of test results from the laboratory to anyone other than the person who ordered the test. In addition, in most states, patients do not have a right to obtain their test results directly from a clinical laboratory. HIV/AIDS confidentiality laws often allow the release of test results to health care providers other than the person who requested the test, but often impose additional conditions on the release, which may make electronic exchange of these test results more difficult. We found no states that set standards for transmitting test results to report destination that were more specific or stringent than those set in CLIA.

# 1. BACKGROUND AND PURPOSE

In the first phase of the Privacy and Security Solutions for Interoperable Health Information Exchange contract, 33 states and 1 territory (collectively referred to as state teams) conducted an assessment of variation in business practices, policies, and laws that might be perceived as barriers to electronic health information exchange, suggested possible solutions to these barriers, and prepared plans to implement these solutions. The resulting Assessment of Variation and Analysis of Solutions (AVAS) report, an earlier product of this project, presented an overview of the major areas states identified as presenting challenges to the privacy and security of electronic health information exchange. In doing so, states identified the federal Clinical Laboratories Improvement Amendments (CLIA), as one of the potential barriers to laboratories' exchange of health care information directly with the patient, with health information organizations (HIOs), or with other similar organizations who may participate in electronic health information exchange.[3]

## 1.1 Federal Law Overview: CLIA and HIPAA

Generally speaking, CLIA comprehensively regulates laboratory testing performed on humans in the United States.[4] In total, CLIA covers approximately 200,000 laboratory entities.[5] With respect to disclosing the results of clinical laboratory tests CLIA provides that:

> Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test [42 C.F.R. § 493.1291(f)].

The term *authorized person* is defined in CLIA as, "[A]n individual authorized under state law to order tests or receive test results, or both" [42 C.F.R. § 493.2]. The term *individual responsible for using the test results* is not defined in the CLIA regulations, but the clause is generally understood to include the person who ordered the test. The Division of Laboratory Services, the portion of the Centers for Medicare and Medicaid Services (CMS) that is tasked with implementing the CLIA program has further interpreted this phrase to include other providers in a treatment relationship with the patient. However, it appears that many private stakeholders are unaware of this interpretation. For example, on October 20, 2009, at a hearing held by the HIT Policy Committee's Information Exchange workgroup on the

[3] Dimitropoulos, L. et al. (2007, July). *Privacy and Security Solutions for Interoperable Health Information Exchange, Assessment of Variation and Analysis of Solutions*. Report prepared for the Agency for Healthcare Research and Quality and the Office of the National Coordinator.

[4] There are exceptions to CLIA's regulatory framework including laboratories that solely conduct research and those that conduct forensic testing.

[5] Centers for Medicare and Medicaid Services, U.S. Dept. of Health and Human Services, *Clinical Laboratory Improvement Amendments: Overview*. Available at: http://www.cms.hhs.gov/CLIA/. Accessed May 7, 2009.

electronic exchange of laboratory information testifiers reiterated this difference in interpretation.[6]

Under this regulatory scheme, the scope of persons who are authorized to receive laboratory results directly from a clinical laboratory largely depends on state law. If state law specifies who is authorized to receive test results, the state definition of authorized person controls. If state law is silent, clinical laboratories may send results only to the person who ordered the test or who is responsible for using the test.[7]

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule also applies to clinical laboratories that conduct covered electronic transactions. The HIPAA Privacy Rule permits covered entities, including health care providers such as clinical laboratories, to disclose protected health information for treatment, payment, and health care operations without a patient's permission to other persons and entities when certain additional circumstances are met [see 45 C.F.R. § 164.506(c)].[8] However, while such disclosures may be permitted by the HIPAA Privacy Rule, they nevertheless may be impermissible under CLIA.

As a general rule, the HIPAA Privacy Rule also affords patients the right of access to (the right to inspect and obtain a copy of) their protected health information held by covered entities. However, the HIPAA Privacy Rule specifically exempts from the right of access protected health information that is subject to CLIA to the extent the provision of access to the patient would be prohibited by law or that is maintained by a laboratory that is exempt from CLIA [see 45 C.F.R. § 164.524(a)(1)(iii)(A) and (B)].[9] As a result, under the HIPAA Privacy Rule patients' rights to access their test results directly from a clinical laboratory generally depend on whether state law permits such access.

## 1.2 Project Purpose

As noted in the AVAS, the intersection of Federal and state regulations related to clinical laboratory information may impact the ability of a clinical laboratory to exchange test results directly with a patient, health information organizations (HIOs), or with other similar

[6] http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_907369_0_0_18/Horton-IEAnswers.pdf

[7] *See* U.S. Dept. of Health and Human Services, *Standards for Privacy of Individually Identifiable Health Information: Final Rule*, ("Preamble Final Rule") 65 Fed. Reg. 82462, 82485 (Dec. 28, 2000).

[8] It should be noted that there are specific conditions which must be met for a covered entity to disclose protected health information to another entity for the health care operations of the receiving entity.

[9] CLIA-exempt laboratories are those that meet specific accreditation requirements or are licensed in a state that has a licensure program that is approved by CMS as being exempt from the CLIA program [42 C.F.R. § 493.2 (defining *CLIA-exempt laboratory*) and § 493.3(a)(2)].

organizations who may participate in electronic health information exchange.[10] In May 2006, the American Health Information Community recommended addressing variations in *authorized persons* under the various state statutes, regulations, policies, and practices.[11] The purpose of this project is to assist in addressing these concerns by exploring in more detail the laws of the 50 states, the District of Columbia, and the territories that govern the ability of clinical laboratories to disclose test results to others.[12]

[10] Dimitropoulos, L. et al. (2007, July). *Privacy and Security Solutions for Interoperable Health Information Exchange, Assessment of Variation and Analysis of Solutions*. Report prepared for the Agency for Healthcare Research and Quality and the Office of the National Coordinator for Health Information Technology.

[11] American Health Information Community, *Meeting Report*, May 16, 2006.

[12] The states, territories, and the District of Columbia are referred to collectively in this report as "states."

# 2. METHODOLOGY

State laws governing the disclosure of laboratory results are found in a variety of state law provisions. Although these laws are often contained in state laboratory licensure laws, they may also be found in health care practitioner licensing laws, more general medical information confidentiality laws, medical information access laws, public health laws that govern the disclosure of specific types of health information (e.g., HIV test results), laws of evidence, insurance laws, or elsewhere. An exhaustive and comprehensive survey of all these state laws was beyond the resources of this project.

To provide a consistent view across the states within our resources, we limited this survey primarily to a review of specific categories of state laws: clinical laboratory licensing and operating laws; hospital licensure and operating laws, which contain standards for hospital laboratories; and state medical record access laws. We also reviewed state laws governing HIV test results to provide an example of how condition-specific protections may further impact the ability of clinical laboratories to release test results. In addition, we searched state statutes and regulations using the terms *Clinical Laboratory Amendments, CLIA* with and without the term *authoriz!*[13] to identify state statutes and regulations that may incorporate the federal provisions by reference. We used electronic legal research search engines (Lexis or Westlaw) to identify relevant state statutes, administrative regulations, and, where relevant, case law that interprets these provisions. We also reviewed state attorney general opinions interpreting these state statutes and regulations to the extent such opinions were available either through the legal search engine or through the website of the state attorney general. Although these opinions are not binding, they afford useful interpretations of the state law.

We did not review or address public health laboratories because they are often subject to a different set of statutory or regulatory provisions governing government data in general. We limited our research to reports of laboratory tests ordered by health care providers. We did not review reporting requirements for tests ordered or requested directly by patients.

Within this framework, we set about to answer the following questions:

1. Does the state have a statutory or regulatory provision within its clinical laboratory licensing or hospital licensing laws that specifies who is an authorized person to receive test results from an independent or hospital clinical laboratory (or conversely to whom a clinical laboratory may or must release test results)?
2. If yes, does the law expressly provide that a clinical lab may or must release the results of tests ordered by a health care provider:

   A. To the provider who ordered the test?

[13] The symbol *!* is used in a search as a wildcard" to find variations on a root term. Here, using the term *authoriz!* located statutes and regulations that contain the word *authorize* as well as variations such as *authorization* and *authorized*.

B. To the provider's agent, designee, or representative?

C. Directly to the patient?

   i. Does the provision require the written request or permission of the person who ordered the test?

   ii. Are there other restrictions? If so, describe.

D. To other licensed health care providers?

   i. Are there restrictions?

   ii. If so, what type(s) of restrictions? (e.g., those caring for the patient; only those authorized to order such tests)?

E. To payers?

F. To others?

We recognize that laws may implicitly give authority to release information to others. The extent to which they may do so is subject to various interpretations. To ensure uniformity for comparison's sake, we focused on the express language of the statute or regulation as well as formal court or attorney general interpretations.

3. Does the state have a general medical records access law that gives patients the right of access to records maintained by independent clinical laboratories?

We focused on independent laboratories because the HIPAA Privacy Rule clearly gives individuals the right of access to protected health information held by hospitals, which would include hospital laboratory results that have been incorporated into patients' hospital records. In contrast, for independent clinical laboratories, a patient's right of access to laboratory results under the HIPAA Privacy Rule and state law is based entirely on whether state law authorizes such access.

4. Does the state have a statute or regulation that specifically governs the confidentiality of HIV/AIDS test results maintained by clinical laboratories? If so, how does the HIV/AIDS confidentiality law impact the ability of a clinical laboratory to release HIV/AIDS test results to health care providers for treatment and to the patient directly?

5. Does the state statute or regulation require the clinical laboratory to ensure test results are accurately and reliably sent from the point of data entry to the final report destination (or an equivalent requirement)?

We recorded our findings in Excel charts, summarized the relevant portions of the statute or regulation, and then answered the questions described above. Where a state clinical laboratory licensing law expressly addressed who was authorized to order a test, we included this information in our summary. (We did not delve into the practitioner licensing statutes and regulations to determine whether they more specifically delineated which categories of health care providers may order what specific types of tests.)

# 3. FINDINGS

## 3.1 General Findings

Although the issue of state restrictions on the release of laboratory test results has at times been characterized as a privacy issue, one may also view it as a licensing issue. State laws that govern the release of test results are closely intertwined with those that govern the licensing and practice of health care providers. Often, state clinical laboratory licensing laws expressly provide that a laboratory may examine specimens only at the request of a physician or other person authorized by law to order the test or use the findings of the examination.[14] The clinical laboratory licensing law may delineate specific health care providers for whom a lab may examine specimens (e.g., doctors of medicine and surgeons), or it may use a more general *as authorized by law* standard. The limits on who is legally authorized to order or use the results of a clinical test are tied to state standards specifying to whom such results may be released. Viewing clinical laboratory disclosure laws as a means of enforcing state limits on the practice of medicine and other health care professions partially explains some of the restrictions that states have imposed on the release of laboratory test results.

Many state licensing laws are silent with respect to who may receive laboratory test results.[15] In these states, CLIA generally sets the standards for who qualifies as a person authorized to receive test results.

The majority of states have licensing laws that expressly address to whom a clinical laboratory may or must release test results, permitting or requiring a clinical laboratory to release test results to the authorized person who requested the test (or their agent) or, more broadly, to persons authorized to use or responsible for using the test. In a handful of states, the state's licensing laws permit or require laboratories to release test results directly to patients. Some state medical record access laws may also be broad enough to give patients the right to obtain copies of their test results directly from clinical laboratories. However, the scope of many of these laws is unclear. In sum, under most states' laws, clinical laboratories may release test results only to the person who ordered the test. Most states' laws do not expressly allow release of test results directly to other health care providers (such as physicians to whom a patient has been referred by the ordering health care provider) or to health plans. In addition, in most states, patients do not have a right to obtain their test results directly from a clinical laboratory.

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[14] State practitioner licensing laws often specifically delineate the scope of practice in which a practitioner may engage. Reviewing these statutes and regulations was beyond the scope of this project.

[15] States may have statutory or regulatory provisions governing the release of specific types of health care information that may also impact who is authorized to receive test results. This survey did not address all potential types of laws, but focused on clinical laboratory licensing statutes where most of these restrictions are likely to be located.

State laws governing the disclosure of HIV/AIDS test results add an additional layer of complexity to these issues. They are often nuanced and subjective, making it difficult to determine how they apply in an electronic environment.

Few states have established standards for transmitting test results to their final destination. None of these standards are more specific or stringent than those included in CLIA.

Table A-1, Overview of State Clinical Laboratory Test Release Laws, provides a broad overview of our findings. This table is limited to laws that *expressly* permit the release of clinical laboratory test results to various parties.

Table A-2, State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results, contains more detailed summaries of the relevant text of state licensing statutory or regulatory provisions. This table includes not only the summary of the provisions addressing release of clinical laboratory results, but also the provisions that address who may request a laboratory to examine a human specimen where such a provision is included in the clinical laboratory licensing law.

Table A-3, State Laws Governing Patient Access to Clinical Laboratory Test Results, presents the pertinent text of state medical record access laws that may apply to clinical laboratories. For comparison's sake, this table also includes provisions of clinical laboratory licensing laws that address releasing test results to patients.

Similarly, Table A-4, State Clinical Laboratory Licensing Laws and HIV/AIDS Confidentiality Laws that Expressly Permit the Release of Test Results for Treatment, contains a brief summary of the relevant text of state laws that permit the release of HIV/AIDS test results without the permission of the patient.

Table A-5, State Clinical Laboratory Licensing Laws and HIV/AIDS Confidentiality Laws that Expressly Permit the Release of Test Results to Patients, gives an overview comparison of a clinical laboratory's ability to release test results directly to patients under the respective state provisions.

Table A-6, State Clinical and Hospital Licensing Laws Addressing Accurate Delivery of Test Results, contains summaries of the pertinent state laws addressing standards for the means of delivering test results.

## 3.2 Specific Findings

### *3.2.1 Release to Persons Who Ordered or Requested Test*

Of the states with licensing laws that address the authorized recipient issue, 24 states expressly permit or require clinical laboratories to release laboratory test results to the authorized health care provider or person who requested the test (see Table A-1). These

provisions vary somewhat in their scope. Although the language is not identical, a few general categories emerge.

Some state laws stipulate that the test results may be released only to the person who ordered the test; [see, e.g., Kan. Stat. Ann. 65-1,108(a); Mo. Code Regs. Ann. tit. 19, § 30-20.098970 (2008)]. Some state laws enumerate the health care providers authorized to order a test and then permit test results to be released to such authorized persons. These laws often contain a catchall provision that allows release to *other persons authorized by law* to order such tests; [see, e.g., Ky. Rev. Stat. Ann. § 333.150 (2008) ("The results of a test shall be reported directly to the licensed physician, dentist or other authorized person who requested it.") and Ga. Code Ann. § 31-22-4(c) (2008) ("The results of a test shall be reported only to or as directed by the licensed physician, dentist, or other authorized person requesting such test.")] (see Table A-2).

Laws in some states also expressly permit the release of results to the agent or designee of the health care provider who ordered the test [see, e.g., Wash. Admin. Code § 246-338-070(3) (2008)] ("Test reports must . . . be released only to authorized persons or designees"). However, many interpret the right to release to an agent of a physician as being implicit in the right to release to the physician.[16]

### *3.2.2 Release to Persons Authorized to Use the Test*

Ten states have laws that expressly permit or require clinical laboratories to release test results to persons who are authorized to *use* the test results (see Table A-1) [also see, e.g., Or. Rev. Stat. § 438.430 (2007)] ("A person may not report the result of any test, examination, or analysis of a specimen submitted for evidence of human disease expect to. . . a physician, dentist, their agents, or other person authorized by law to employ the results thereof in the conduct of a practice or in the fulfillment of official duties."). These provisions permit the release of test results not only to the requesting health care provider (who presumably is authorized to order and use the test) but also to others who are authorized to use such test results. In fact, these provisions are often found in conjunction with those that permit release of test results to the authorized person who ordered the test [see, e.g., N.J. Admin. Code § 8:44-2.7(i) (2008)] ("The original…of the laboratory report shall be sent promptly to the licensed physician or other authorized person who requested the test. . . . The results of laboratory tests. . . shall be sent to the licensed physician, dentist or other person authorized by law to use the findings of laboratory examinations.").

### *3.2.3 Release with Patient Permission*

Two states take a patient-centric approach and allow patients to exercise a large degree of control over their laboratory test results. In the District of Columbia and New Hampshire,

[16] See National Governors Association, State Alliance for e-Health, Health Care Practice Taskforce Meeting, Transcript, April 26-27, 2007.

clinical laboratories may release test results to the physician or practitioner who ordered the test as well to as the patient. However, laboratories may not release test results to others without the written permission of the patient [see D.C. Code Ann. 44-211 (2008) and N.H. Code Admin. R. Ann. He-P 808.14(j) (2008)]. This approach fundamentally differs from CLIA and most state clinical laboratory licensing laws that are health care provider-centric, giving the laboratory and the ordering health care provider the control of the laboratory test result.

### *3.2.4 Restrictions on Release to Out-of-State Health Care Providers*

Reporting laboratory results across state lines appears to present distinct challenges. Some state laws expressly limit the release of test results to health care providers licensed within their state. For example, Connecticut law appears to allow laboratory findings to be reported only to certain health care providers licensed under Connecticut law.

The Connecticut provision provides in pertinent part:

> Laboratory findings on a specimen shall be reported directly to the licensed provider who ordered the testing pursuant to authority granted to such provider by chapter 370 [medical doctors & surgeons], 372 [chiropractic], 373 [naturopathy], 375 [podiatry], 377 [midwifery], 378 [nursing], 379 [dentistry], 380 [optometry] or 400j [pharmacy]. . . [Conn. Agencies Regs. § 19a-36-D32(a) (2008); and Conn. Gen. Stats. Chaps. 370, 372, 373, 375, 377, 378, 379, 380, or 400j].

Hawaii has similar requirements, allowing the release of test results to the *authorized person* who ordered the test, while defining the *authorized person* in terms of health care providers who are licensed under state law. Specifically, the law provides:

> "Authorized person" means a physician licensed pursuant to HRS [Hawaii Revised Statutes] Chapter 453, osteopath licensed pursuant to HRS Chapter 460, dentist licensed pursuant to HRS Chapter 448. . .naturopathic physician licensed pursuant to HRS 455, podiatrist licensed pursuant to HRS Chapter 463E. . . [Haw. Code R. §§ 11-110.1-2 (2007) (defining *authorized person*) and 11-110.1-16 (providing that test results may only be reported to the authorized person who ordered the test and their designee)].

This approach is consistent with the state's medicine and surgery licensing laws that allow a fully licensed out-of-state physician to practice medicine in Hawaii only in consultation with a physician licensed in Hawaii [see Haw. Code R. § 453-2 (2008)].

These state laws are yet another example of the interconnected nature of clinical laboratory licensing laws and health care provider licensing laws. They appear intended to restrict or prohibit the practice of health care across state lines.[17]

In contrast, Arizona has addressed the interstate issue by specifically providing that a laboratory must examine specimens from and report test results to certain persons licensed under state law as well as "a person licensed to practice medicine or surgery in another state" [see Ariz. Rev. Stat. § 36-470 (2008)].

In sum, clinical laboratory licensing laws generally restrict the release of test results to the person who ordered the test or the person who is authorized to use the test. Some go further and restrict release to those within the state authorized to engage in such activities. These laws are closely linked to health care practitioner licensing laws that specify the limits of a practitioner's practice.

### *3.2.5 Patient Access*

The emergence of personal health records as a potential vehicle for exchanging personal health information raises the issue of how patients will be able to populate these records. Although the right of access in the HIPAA Privacy Rule should facilitate patients' ability to directly access some of their personal health information and to direct where copies of that information may be sent,[18] clinical laboratory results present distinct challenges. Under the HIPAA Privacy Rule, patients do not have the right of access to protected health information that is held by a clinical laboratory that is subject to CLIA to the extent the provision of access to the individual would be prohibited by law or that is exempt from CLIA [45 C.F.R. §164.524(a)(1)]. CLIA generally permits disclosure of test results only to the person who ordered the test or those authorized under state law to order or receive test results. As a consequence, state law largely determines whether patients are able to directly access laboratory test results from a clinical laboratory (or direct where those results may be sent).[19] CLIA only governs clinical laboratories, however, so patients remain free to obtain their results from the provider who ordered the test.

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[17] We have heard that, in other contexts, some states interpret this type of reference to state licensing provision as distinguishing among different *types* of health care providers as opposed to distinguishing between in-state and out-of-state health care providers (e.g., a reference the state's medical licensing provisions refers to doctors of medicine in general, as opposed to doctors licensed within the state). However, such an interpretation is not obvious from the face of these provisions.

[18] Under HIPAA, an individual has the right to request, and a covered entity must accommodate a reasonable request for, the covered entity to communicate through alternative means or to an alternative location [45 C.F.R. § 164.522]. Additionally, the HIPAA rules on access require the covered entity to provide protected health information in the form or format requested by the individual, if readily available in that form [45 C.F.R. § 164.524]. Presumably, these requirements would allow an individual who requests access to protected health information to specify that the information be delivered to a particular address or even, where the technical capabilities readily exist, to a personal health record.

[19] This discussion centers on independent laboratories since hospital laboratory results are incorporated into patients' hospital records, which are clearly accessible under HIPAA.

Most state clinical laboratory licensing laws do not expressly permit or require clinical laboratories to release test results directly to patients. What is more interesting is that licensing laws in seven states expressly provide that test results may be released by a laboratory directly to a patient *only* with the permission of the person who ordered the test (see Table A-1).

Licensing laws in six other states, however, expressly permit or require clinical laboratories to release test results directly to patients and do not require the ordering health care provider's permission. Some of these state laws are designed to give the health care provider a chance to discuss test results with the patient prior to the clinical laboratory's delivery of the information to the patient. For example, Maryland requires notification of the person who requested the test that the results will be released to the individual tested [see Md. Code Regs. 10.10.06.04 (2008)]. Oregon takes a slightly different approach and imposes a 7-day waiting period from the time of the request until the time when a laboratory may respond directly to the patient [Or. Rev. Stat. § 438.430 (2007)]. These states have attempted to find a balance between a patient's right of access and the health care provider's need to interpret the test results.

Clinical laboratory licensing laws are not the sole source of patient access rights. Many states have medical record access laws—more general laws that apply to a wide range of health care providers and facilities and require these entities to provide patients access to health information in their possession. These laws may be found in the health code, evidence code, or other sections of a state's compiled laws. Twenty-three states have medical record access laws that appear broad enough to encompass records maintained by clinical laboratories.

In some states, the medical record access law clearly applies to clinical laboratories. New Hampshire's clinical laboratory licensing laws expressly cross-reference the state's medical record access law and require clinical laboratories to comply with its requirements [N.H. Code Admin. R. Ann. He-P 808.14(i) (2008) and N.H. Rev. Stat. Ann. § 151:21(X) (2008)]. Similarly, Michigan's Medical Record Access Act applies to a *health facility*, a term which expressly includes *a clinical laboratory* [Mich. Comp. Laws § 333.20106 (2008)].

California's Patient Access to Health Records Act has general access rules for most health information but includes distinct, detailed provisions specifically governing the *[r]eport to patient of results of clinical laboratory test*. Under these provisions, a clinical laboratory may release test results directly to the patient only if the health care professional who requested the test makes such an arrangement. The professional must review the results before they are supplied to the patient. In addition, the results may be conveyed in electronic form only if requested by the patient and if that method is deemed most appropriate by the health care professional who requested the test [Cal. Health & Safety Code § 123148 (2008)].

In most states, however, it is less clear whether medical record access laws even apply to clinical laboratories.

Some states' medical record access laws are found in their evidentiary codes.[20] In general, these provisions are broadly written and appear to include records held by clinical laboratories. For example, Pennsylvania law provides as follows:

> A patient or his designee, including his attorney, shall have the right of access to his medical charts and records and to obtain copies of the same without the use of a subpoena *duces tecum* [42 Pa. Cons. Stat. Ann § 6155(b) (2008)].

Given the broad purpose of the statute, it appears to encompass test results maintained by clinical laboratories.

In many states, the medical record access laws found in the health code or in other codifications apply to a wide range of health care entities. The definitions of these entities are often facially broad enough to encompass clinical laboratories. In Arizona, for example, a health care institution must provide access to or copies of its medical records to the patient [Ariz. Rev. Stat. § 12-2293 (2008)]. *Health care institution* is defined as follows:

> every place, institution, building or agency, whether organized for profit or not, which provides facilities with medical services, nursing services, health screening services, other health related services, supervisory care services, personal care services or directed care services and includes home health agencies as defined in section 36-151 and hospice service agencies . . . [Ariz. Rev. Stat. §§ 12-2291(4)(b) (2008) (defining *health care provider*, as including "a health care institution as defined in section 36-401"); 36-401 (2008) (defining *health care institution*)].

There is little, if any, case law or guidance interpreting these or similar provisions in other states' laws.

Two states, Montana and Utah, have medical record access laws that facially appear to give patients access to clinical laboratory records but, in practice, may afford limited rights. Under Utah's medical record access law, for example, clinical laboratories (and other health care providers) not covered by HIPAA are required to provide patients access to their medical records [see Utah Code Ann. §§ 78B-3-403 (2008) (defining *health care provider* as including clinical laboratory technologists and others rending similar care and services); 78B-5-618 (requiring health care providers not covered by HIPAA to provide patients access to their records unless restricted by law) (2008)]. Most clinical laboratories, however, would appear to be covered entities under HIPAA and, thus, not subject to this provision of law.

[20] See, e.g., Del. Code Ann. tit. 10, § 3926 (2008); Okla. Stat. tit. 76, § 19(A)(2) (2008). These laws are considered to be generally applicable since the health care provider is not charged with determining whether the person seeking a record is contemplating a law suit.

For covered entities, the state medical record access law directs them to comply with HIPAA [Utah Code Ann. § 78B-5-618]. This approach is problematic since the various statutes cross-reference each other. State law defers to HIPAA, HIPAA defers to CLIA, and CLIA defers to state law that, with respect to covered entities, defers to HIPAA. The extent to which patients actually have the right of access to clinical laboratory results in these states is unclear.

Taken together, state clinical laboratory licensing laws and medical record licensing laws may give patients the right of access to clinical laboratory test results in as many as 25 states. Conversely, patients in 30 states or territories do not have the right to access their test results directly from clinical laboratories.

### *3.2.6 HIV/AIDS Test Results*

Most states have statutory or regulatory provisions that specifically govern the confidentiality and disclosure of information related to human immunodeficiency virus (HIV) and/or acquired immunodeficiency syndrome (AIDS), including test results (hereinafter HIV/AIDS confidentiality laws). At least 32 states have HIV/AIDS confidentiality laws that appear broad enough to apply to independent clinical laboratories. The scope of some of these laws is ambiguous and may be limited only to information that has been reported to public health authorities [see Ind. Code Ann. § 16-41-8-1(f) (2008); Wyo. Stat. Ann. § 35-4-132(d) (2008)].

Typically, these state laws deem HIV/AIDS test results to be confidential, prohibit the release of test results without the permission of the patient, and provide a detailed list of specific exceptions to this general rule. HIV/AIDS confidentiality laws in six states specifically provide that test results must or may be released to the person who ordered the test. Twenty-five states appear to permit the disclosure of HIV/AIDS test results to health care providers and health care facilities for treatment of the patient without the express permission of the patient (see Table A-4).

In a number of states, the circumstances under which HIV/AIDS test results may be shared with other providers is unclear. For example, two states permit the disclosure of HIV/AIDS test results in accordance with *customary* means for exchanging health information among health care providers [see Wash. Rev. Code § 70.24.105 (2008); Idaho Code Ann. § 39-609 (2008)]. It is unclear how this *customary* standard applies in an electronic interchange of laboratory test results. Other states expressly allow the release of HIV/AIDS test results without the patient's express permission for continuing care of the patient [see Okla. Stat. tit. 63, § 1-502.2(A) (2008) (permitting release *within the continuum of care*); Haw. Rev. Stat. Ann. § 325-101(a)(10) (2008) (permitting release for the continued care of the patient)]. These laws might be interpreted as limiting the timeframe during which a clinical laboratory is permitted to release test results without the patient's permission. Many state HIV/AIDS confidentiality laws impose a *need to know* standard on the release of test results

[see Conn. Gen. Stat. 19a-583(a)(4) (2008) (release permitted when knowledge of the HIV-related information is necessary to provide appropriate care or treatment to the protected individual); and Ohio Rev. Code. Ann. § 3701.243(B) (2008) (disclosure permitted to a health care provider who "has a medical need to know the information and is participating in the diagnosis, care, or treatment of the individual on whom the test was performed")]. These standards for releasing HIV/AIDS test results are nuanced and subject to various interpretations.

Many HIV/AIDS confidentially laws permit the release of test results directly to the patient who was tested. These HIV/AIDS-specific provisions must be read along with clinical laboratory laws to assess their impact on clinical laboratories' ability to disclose test results directly to patients. In six states, HIV/AIDS confidentiality laws (that apply to a broad range of entities, including clinical laboratories) expressly permit the release of HIV/AIDS test results to the patient, while the state's clinical laboratory permits release to the test subject only with the permission of the person who ordered the test; see Table A-5**.** Read together, these provisions appear to permit a clinical laboratory to release HIV/AIDS test results directly to the patient only with the permission of the person who ordered the test. California takes this approach one step further and affirmatively prohibits the provision of an HIV/AIDS test result to a patient via the Internet or via other electronic means. As noted above, state laws that expressly require the providers' permission to release test results to patients may make it more difficult for patients to receive such information through electronic exchange, such as through their PHRs.

In a number of states, the provisions of the clinical laboratory licensing laws do not expressly provide that test results may be released directly to the patient. As a result, the patient generally does not have the right to access their test results directly from the laboratory. However, some of these same states have HIV/AIDS confidentiality laws, applicable to clinical laboratories, which expressly permit release of HIV/AIDS test results to the patient [see Mo. Rev. Stat. § 191-656(1)(1)(h) (2008) (permitting disclosure of test results to any individual who tests positive); Ohio Rev. Code Ann. § 3701.243(B)(1) (2008) (which permits disclosure to an individual who was tested for HIV)]. In these states, patients can receive their HIV/AIDS test results directly from clinical laboratories, even though they do not have the same right with respect to other test results.

As our review of HIV/AIDS confidentiality laws demonstrates, state laws that afford heightened confidentiality for specific medical conditions impose an additional layer of complexity on the manner in which clinical laboratories may release test results. First, it is not always clear whether clinical laboratories are subject to these condition-specific statutes and regulations, which are written to encompass a broad range of entities. In addition, the framework of these laws can be complicated, with a general prohibition against disclosing information followed by a detailed list of instances in which disclosure is permitted without the patient's permission. Provisions that permit release of information for treatment can be

nuanced, and appear to require subjective judgments, difficult to enforce in an electronic environment. In some states, however, HIV/AIDS confidentiality laws appear to give patients a right to receive HIV/AIDS test results directly from a clinical laboratory even when patients do not have a similar right to receive other test results.

### *3.2.7 Delivery of Test Results*

CLIA requires laboratories to have in place adequate manual or electronic systems to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry to final report destination, in a timely manner [42 C.F.R. § 493.1291]. Some have expressed concern that states may independently impose similar or more stringent standards. This does not appear to be the case.

Approximately 20 states have expressly incorporated by reference general CLIA standards, which would encompass this accurate delivery rule [see, e.g., 10 144 256 Me. Code R. § 5 (2008) (requiring laboratories to meet the CLIA '88 requirements and interpretive guidelines of 42 CFR, Chapter IV Part 493 Subpart K); N.H. Code Admin. R. Ann. He-P 808 15(a) (2008) (All laboratories shall comply with all regulations contained in 42 CFR § 493)]. Many of these provisions are in hospital licensing laws [see, e.g., Ariz. Admin. Code R 9-10-218 (2008) (hospital laboratory services must be provided by laboratories certified under CLIA)]. A handful of states have clinical laboratory licensing laws that set general standards requiring the accurate, reliable and prompt reporting of test results [see, e.g., Ga. Comp. R. & Regs. 290-9-8-.09 (2008)]. We did not find more detailed standards for transmitting test results to the final report destination in any state [see Table 6, Appendix].

# 4. CONCLUSION

Under most states' laws, clinical laboratories may release test results only to the health care provider who ordered the test. Most states' laws do not expressly allow release of test results directly to other health care providers (such as physicians to whom a patient has been referred by the ordering provider). In addition, patients in most states do not have the right to obtain their test results directly from a clinical laboratory. State laws that govern the confidentiality of specific medical conditions, such as HIV/AIDS, often permit the disclosure of test results to health care providers for treatment, but often impose other conditions that may be difficult to address in an electronic environment (e.g., determining when the information is necessary for treatment).

To the extent state laws may address the delivery of test results to point of destination, they usually incorporate general CLIA standards. We found no states that set standards for transmitting test results to point of destination that were more specific or restrictive than those set in CLIA.

Our analysis was limited to a direct reading of the statutory and regulatory provisions. Additional research should be undertaken to determine how the states actually interpret these provisions, particularly those that are facially nuanced. In addition, it would be useful to determine whether, as a matter of practice, the limits in the clinical laboratory licensing laws are enforced.

# APPENDIX A:
# OVERVIEW AND DETAILED TABLES

# APPENDIX A:
# STATE RELEASE LAW OVERVIEW TABLES

## Table A-1. Overview of State Clinical Laboratory Test Release Laws

October 2008

| State | State Licensing Law Expressly* Permits Clinical Laboratories to Release Test Results to Authorized Person Who Requested Test | State Licensing Law Expressly* Permits Clinical Laboratories to Release Test Results to Persons Authorized to Use or Receive or Responsible for Using or Receiving Test Results | State Licensing Law Expressly* Permits Clinical Laboratories to Release Test Results to Agent or Designee of Person Who Requested or Is Authorized to Receive Test | State Licensing Law Expressly* Permits Clinical Laboratories to Release Test Results as Directed by Person Who Requested Test | State Licensing Law Expressly* Permits Clinical Laboratories to Release Test Results to patient (No Other Permission Required) | State Licensing Law Expressly* Permits Clinical Laboratories to Release Test Results to patient Only With Permission of Person Who Ordered Test |
|---|---|---|---|---|---|---|
| Alabama | — | — | — | — | — | — |
| Alaska | — | — | — | — | — | — |
| Arizona | yes[1] | — | — | — | — | — |
| Arkansas | yes | — | — | — | — | — |
| California | — | yes[2] | yes[3] | — | — | yes[4] |
| Colorado | — | — | — | — | — | — |
| Connecticut | yes | yes[5] | — | — | — | yes[6] |
| Delaware | — | — | — | — | — | — |
| District of Columbia | yes[7] | — | — | — | yes | — |
| Florida | yes | yes[8] | — | — | — | yes |
| Georgia | yes | — | — | yes | — | — |
| Guam | — | — | — | — | — | — |
| Hawaii | yes | — | yes[9] | — | — | — |
| Idaho | — | — | — | — | — | — |
| Illinois | yes | — | — | — | — | — |
| Indiana | — | — | — | — | — | — |
| Iowa | — | — | — | — | — | — |
| Kansas | yes | — | — | — | — | — |
| Kentucky | • | — | — | — | — | — |
| Louisiana | — | — | — | — | — | — |
| Maine | yes | — | — | — | — | — |
| Maryland | yes | — | — | — | yes | — |
| Massachusetts | yes | — | — | yes | — | yes |
| Michigan | — | — | — | — | — | yes |
| Minnesota | — | — | — | — | — | — |
| Mississippi | — | — | — | — | — | — |
| Missouri | yes | — | — | — | — | — |
| Montana | — | — | — | — | — | — |
| Nebraska | — | — | — | — | — | — |
| Nevada | yes | yes[5] | — | — | yes | — |
| New Hampshire | yes[7] | — | — | — | yes | — |
| New Jersey | yes | yes[2] | — | — | yes | — |
| New Mexico | — | — | — | — | — | — |
| New York | yes | yes[2] | yes[10] | — | — | yes |
| North Carolina | — | — | — | — | — | — |
| North Dakota | — | — | — | — | — | — |
| N. Mariana Islands | — | — | — | — | — | — |
| Ohio | — | — | — | — | — | — |

(continued)

## Table A-1. Overview of State Clinical Laboratory Test Release Laws

| State | State Licensing Law Expressly* Permits Clinical Laboratories to Release Test Results to Authorized Person Who Requested Test | State Licensing Law Expressly* Permits Clinical Laboratories to Release Test Results to Persons Authorized to Use or Receive or Responsible for Using or Receiving Test Results | State Licensing Law Expressly* Permits Clinical Laboratories to Release Test Results to Agent or Designee of Person Who Requested or Is Authorized to Receive Test | State Licensing Law Expressly* Permits Clinical Laboratories to Release Test Results as Directed by Person Who Requested Test | State Licensing Law Expressly* Permits Clinical Laboratories to Release Test Results to patient (No Other Permission Required) | State Licensing Law Expressly* Permits Clinical Laboratories to Release Test Results to patient Only With Permission of Person Who Ordered Test |
|---|---|---|---|---|---|---|
| Oklahoma | — | — | — | — | — | — |
| Oregon | — | yes[2] | yes[10] | — | yes[11] | yes |
| Pennsylvania | yes | — | yes[10] | — | — | — |
| Puerto Rico | yes | — | — | — | yes | — |
| Rhode Island | yes | — | — | — | — | — |
| South Carolina | — | — | — | — | — | — |
| South Dakota | — | — | — | — | — | — |
| Tennessee | yes | yes[8] | — | — | — | — |
| Texas | — | — | — | — | — | — |
| Utah | — | — | — | — | — | — |
| Vermont | — | — | — | — | — | — |
| Virgin Islands | — | — | — | — | — | — |
| Virginia | — | — | — | — | — | yes |
| Washington | yes | yes | yes[9] | — | — | — |
| West Virginia | — | — | — | — | — | — |
| Wisconsin | — | yes | — | — | — | — |
| Wyoming | yes | — | — | yes | — | — |

Key: * = Table includes state statutes and regulations that expressly contain the noted provisions. It does not address whether some provisions implicitly allow release of test results to others.

Notes:

[1] Statutory provisions only apply to laboratories not subject to CLIA.
[2] To physicians or other licensees authorized by law to use or employ the results.
[3] To "representatives" of healing arts licensees, limited to nurse or other member of licensee's staff acting on behalf of licensee.
[4] Requires provider to review tests before they may be released to patient. Prohibits the Internet posting or other electronic means of releasing results of: HIV antibody test, presence of antigens indicating a hepatitis infection, abusing the use of drugs, and test results related to routinely processed tissues, including skin biopsies, Pap smear tests, products of conception, and bone marrow aspirations for morphological evaluation, if they reveal a malignancy.
[5] To providers treating the patient.
[6] To lay person upon written request of person who ordered the test.
[7] Release only to ordering licensed practitioner unless written consent from the client to release to others.
[8] To individual responsible for utilizing or using test results (except patients).
[9] To designee of person who ordered test.
[10] To agent of physician or other person authorized by law to employ results of test.
[11] After 7 days from receiving request. Release of reports prior to 7-day waiting period requires written authorization of person who ordered test.

**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results***

October 2008

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| Alabama | N/A | N/A |
| Alaska | N/A | N/A |
| Arizona | Ariz. Rev. Stat. § 36-470 (2008) | The provisions of this article [Ariz. Rev. Stat. § 36-461 through §36-479] apply to all clinical laboratories and directors of clinical laboratories but do not apply to the following:<br>• Clinical laboratories operated, licensed, or certified by the United States government.<br>Ariz. Rev. Stat. § 36-461 (2008).<br>[Note: Exception includes laboratories certified under CLIA]<br><br>Except as otherwise provided, a clinical laboratory shall examine specimens at the authorization of any person licensed pursuant to title 32, chapter 7 [podiatry], 8 [chiropractic], 13 [medicine & surgery], 14 [naturopathic physicians], 17 [osteopathic physicians & surgeons] or 29 [homeopathic] or title 32, chapter 11, article 2 [dentists], a person licensed to practice medicine or surgery in another state, or a person authorized by law or department rules.<br><br>The result of a test shall be reported to the person who authorized it.<br>Ariz. Rev. Stat. § 36-470(A)-(B) (2008).<br><br>A person authorized to request clinical laboratory examinations pursuant to this section may direct that a clinical laboratory examine a person's specimens at that person's request if the authorization is given pursuant to department rules and specifies:<br>• The name of the person authorized to request an examination and to receive the results of that examination.<br>• The type of examinations to be performed by the laboratory.<br>• The total number of examinations the authorized person may request.<br>• The beginning and expiration dates of the authorization.<br>• The identification of the person giving the authorization.<br>The laboratory shall report test results ordered pursuant to subsection F [above] to the person who authorized the test and to the person who requested it.<br>Ariz. Rev. Stat. § 36-470(F)-(G) (2008). |

(continued)

**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| Arkansas | 016-24-007 Ark. Code R. § 19(D)(7) (2008) | The [hospital] laboratory report shall be sent promptly to the authorized person who requested the test. 016-24-007 Ark. Code R. § 19(D)(7) (2008). |
| California | Cal. Bus. & Prof. Code § 1288 (2008) | Any person conducting or operating a clinical laboratory may accept assignments for tests only from and make reports only to persons licensed under the provisions of law relating to the healing arts or their representatives. Cal. Bus. & Prof. Code § 1288. |
| Colorado | N/A | N/A |
| Connecticut | Conn. Agencies Regs. § 19a-36-D32(a) (2008). | Laboratory findings on a specimen shall be reported directly to the licensed provider who ordered the testing pursuant to authority granted to such provider by chapter 370 [medical doctors & surgeons], 372 [chiropractic], 373 [natureopathy], 375 [podiatry], 377 [midwifery], 378 [nursing], 379 [dentistry], 380 [optometry] or 400j [pharmacy] and may be provided by laboratories other than the department...[of public health's] laboratory to lay persons upon the written request of the provider who ordered the testing. Laboratories other than the department...[of public health's] laboratory may also provide findings upon the written request of providers who did not order the testing, so long as the requesting provider is also statutorily authorized to order such testing pursuant to chapter 370, 372, 373, 375, 377, 378, 379, 380 or 400j of the Connecticut General Statutes, and is providing care to the patient who is the subject of the testing. Conn. Agencies Regs. § 19a-36-D32(a) (2008); and Conn. Gen. Stats. Chaps. 370, 372, 373, 375, 377, 378, 379, 380 or 400j. |
| Delaware | N/A | N/A |
| District of Columbia | D.C. Code Ann. § 44-211 (2008). | A patient may request, in writing, access to or copies of the results of the patient's own laboratory tests.<br><br>All requests for clinical laboratory services, the results of all clinical laboratory tests, and the contents of patient specimens shall be confidential.<br>. . . .<br>Persons other than the patient or the patient's physician may have access to the results of the patient's laboratory tests if:<br>• The patient has given written consent to the person seeking access for the release of the records for a specific use...<br>. . . . |

(continued)

**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| District of Columbia (cont.) | D.C. Code Ann. § 44-211 (2008). (cont.) | All clinical laboratory results shall be reported to the requesting physician. When there is no requesting physician, the clinical laboratory shall report the test results to the patient and shall recommend that the patient forward the laboratory results to the patient's personal physician as soon as possible.<br>D.C. Code Ann. § 44-211 (2008). |
| Florida | Fla. Stat. § 483.181 (2008).<br><br>Fla. Admin. Code Ann. r. 59A-7.028(5) (2008). | A clinical laboratory may examine human specimens at the request only of a licensed practitioner or other person authorized by law to use the findings of clinical laboratory examinations. . . .<br>Fla. Stat. § 483.181 (2008).<br><br>The results of a test must be reported directly to the licensed practitioner or other authorized person who requested it. . . .<br>Fla. Stat. § 483.181 (2008).<br><br>The laboratory report must be sent promptly to the authorized person or laboratory that initially requested the test.<br>Fla. Admin. Code Ann. r. 59A-7.028(5)<br><br>The results or transcripts of laboratory tests or examinations must be released only to the authorized person requesting the test or the individual responsible for utilizing the test results except as provided in paragraph 59A-7.028(7)(b), F.A.C.<br>Fla. Admin. Code Ann. r. 59A-7.028(5)(e) (2008).<br><br>No report of any test or transcript thereof shall be sent to the patient concerned except with the written consent of the authorized person who requested the test.<br>Fla. Admin. Code Ann. r. 59A-7.028(7)(b) (2008). |
| Georgia | Ga. Code Ann. § 31-22-4 (2008)<br><br>Ga. Comp. R. & Regs. 290-9-8-.25 (2008) | A clinical laboratory shall examine human specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations.<br>Ga. Code Ann. §31-22-4(a) (2008).<br><br>The results of a test shall be reported only to or as directed by the licensed physician, dentist, or other authorized person requesting such test.<br>Ga. Code Ann. §31-22-4(c) (2008); Ga. Comp. R. & Regs. 290-9-8-.25 (2008). |
| Guam | N/A | N/A |

(continued)

**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| Hawaii | Haw. Code R. § 11-110.1-2 (2007)<br><br>Haw. Code R. § 11-110.1-16 (2007) | "Authorized person" means a physician licensed pursuant to HRS Chapter 453, osteopath licensed pursuant to HRS Chapter 460, dentist licensed pursuant to HRS Chapter 448...naturopathic physician licensed pursuant to HRS 455, podiatrist licensed pursuant to HRS Chapter, 463E, advanced practice nurse practitioner licensed pursuant to Chapter 457, therapeutically certified optometrist licensed pursuant to HRS Chapter 459, physician assistant licensed pursuant to HRS Chapter 453 under the supervision of a licensed physician, pharmacist licensed pursuant to HRS Chapter 461in collaboration with a licensed physician, chiropractor licensed pursuant to HRS Chapter 442 to determine referral to internal medical physician or other health care practitioner for supportive patient care management, or designee of an authorized person, and others deemed qualified by the department to order, receive and interpret laboratory test results within the scope of their practice. Qualifications shall include successfully completing an accredited training program and passing a certified examination that demonstrates competency and interpreting laboratory test results.<br>Haw. Code R. § 11-110.1-2 (2007).<br><br>[A] clinical laboratory shall examine specimens only at the request of an authorized person.<br>Haw. Code R. § 11-110.1-16(b) (2007).<br><br>The result of a test shall be reported only to the authorized person who ordered the test and the designee(s) of the person who ordered the test.<br>Haw. Code R. § 11-110.1-16(c) (2007). |
| Idaho | N/A | N/A |
| Illinois | 210 Ill. Comp. Stat. Ann. 25/7-102 (2008). | A clinical laboratory shall examine specimens only at the request of (i) a licensed physician, (ii) a licensed dentist, (iii) a licensed podiatrist, (iv) a therapeutic optometrist for diagnostic or therapeutic purposes related to the use of diagnostic topical or therapeutic ocular pharmaceutical agents, as defined in subsections (c) and (d) of Section 15.1 of the Illinois Optometric Practice Act of 1987 [225 ILCS 80/15.1], (v) a licensed physician assistant in accordance with the written guidelines required under subdivision (3) of Section 4 and under Section 7.5 of the Physician Assistant Practice Act of 1987 [225 ILCS 95/4 and 225 ILCS 95/7.5], (v-A) an advanced practice nurse in accordance with the written collaborative agreement required under Section 65-35 of the Nurse Practice Act [225 ILCS 65/65-35].<br>210 Ill. Comp. Stat. Ann. 25/7-101 (2008). |

(continued)

**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| Illinois (cont.) | 210 Ill. Comp. Stat. Ann. 25/7-102 (2008). (cont.) | The result of a test shall be reported directly to the licensed physician or other authorized person who requested it.<br>210 Ill. Comp. Stat. Ann. 25/7-102 (2008).<br><br>"Physician" means, unless otherwise indicated in this Act, a person licensed by the Department of Professional Regulation, pursuant to the requirements of the Medical Practice Act of 1987 [225 ILCS 60/1 et seq.]; or a person licensed as a physician under the laws of another state or territory of the United States.<br>210 Ill. Comp. Stat. Ann. 25/2-116 (2008). |
| Indiana | N/A | N/A |
| Iowa | N/A | N/A |
| Kansas | Kan. Stat. Ann. § 65-1,108a(a) (2006). | Information obtained through tests performed under 42 CFR Part 493 and amendments thereto (CLIA '88) . . . conducted by a laboratory approved under K.S.A. 65-1,107 and 65-1,108 and amendments thereto by the secretary of health and environment to perform such tests shall be confidential and shall not be disclosed or made public by officers or employees, or former officers and employees, of such laboratory, except that such laboratory test results shall be released only to: (1) The person who ordered such tests be made; [and the secretary of health and environment for specified purposes under certain conditions].<br>Kan. Stat. Ann. § 65-1,108a(a) (2006). |
| Kentucky | Ky. Rev. Stat. Ann. § 333.150 (2008) | A medical laboratory shall examine human specimens only at the request of a licensed physician, podiatrist, dentist, or other person authorized by law to use the findings of medical laboratory examinations. The results of a test shall be reported directly to the licensed physician, dentist, or other authorized person who requested it.<br>Ky. Rev. Stat. Ann. § 333.150 (2008). |
| Louisiana | N/A | N/A |
| Maine | Me. Rev. Stat. Ann. tit. 22, § 2031 (2008) | The result of a test shall be reported directly to the licensed physician or other person authorized by law who requested it.<br>Me. Rev. Stat. Ann. tit. 22, § 2031 (2008). |

(continued)

**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| Maryland | Md. Code Regs. 10.10.01.03 (2008)<br><br>Md. Code Regs. 10.10.06.02 (2008) | "Authorized person" means an individual allowed to request a laboratory test. "Authorized person" is limited to those individuals identified under COMAR [Code of Maryland Regulations] 10.10.06.02.<br>Md. Code Regs. 10.10.01.03 (2008). |
| | Md. Code Regs. 10.10.06.04 (2008) | A laboratory may not perform a laboratory test, except a cholesterol or HDL-C, without obtaining written or electronic authorization from:<br>• A court of law;<br>• A doctor of medicine, osteopathy, podiatric medicine, or dentistry; or<br>• Another person authorized to order laboratory tests under the Annotated Code of Maryland.<br>Md. Code Regs. 10.10.06.02(A) (2008).<br><br>Other persons authorized to order laboratory tests include:<br>• A nurse midwife certified by the Maryland State Board of Nursing under COMAR 10.27.05;<br>• A nurse practitioner certified by the Maryland State Board of Nursing under COMAR 10.27.07 and authorized to order tests under a written agreement with a physician;<br>• A physician's assistant, as authorized by the physician's assistant's supervising physician;<br>• A chiropractor requesting a test on blood or urine; and<br>• An employer requesting a job-related test for alcohol or controlled dangerous substances.<br>Md. Code Regs. 10.10.06.02(B) (2008).<br><br>A laboratory shall report or release test results, except results of a health awareness test, only to an authorized person.<br>. . . .<br>For all test results except those from a health awareness test performed at a temporary laboratory or from a job-related alcohol or controlled dangerous substance test, a licensee shall ensure that the laboratory:<br>• Reports medical test results only to the physician, dentist, or other authorized person who requested the test, or to another laboratory that requested the test; |

(continued)

**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| Maryland (cont.) | Md. Code Regs. 10.10.01.03 (2008)<br><br>Md. Code Regs. 10.10.06.02 (2008)<br><br>Md. Code Regs. 10.10.06.04 (2008) (cont.) | • Sends a copy of a test result . . .directly to the individual tested only after the laboratory:<br>– Receives a written request from the individual, and<br>– Notifies the authorized person who requested the test that the results will be released to the individual tested…<br>Md. Code Regs. 10.10.06.04 (2008). |
| Massachusetts | Mass. Gen. Laws ch. 111D, § 8 (2008)<br><br>105 Mass. Code Regs. 180.280 (2008)<br><br>105 Mass. Code Regs. 180.290 (2008) | A clinical laboratory shall not:<br>[E]xamine any specimen derived from a human body except upon the written request of a licensed physician, licensed dentist, licensed chiropractor, licensed surgeon, licensed podiatrist, licensed osteopath or . . . other person authorized to use the report of such examination by provision of chapter one hundred twelve [registration of certain professions and occupations]. . .<br>Mass. Gen. Laws ch 111D, § 8(7) (2008).<br><br>[R]eport an examination of any specimen derived from a human body except to or as directed by the licensed physician, licensed chiropractor, licensed surgeon, licensed podiatrist, licensed osteopath or . . . other authorized person who requested such examination in writing . . . .<br>Mass. Gen. Laws ch 111D, § 8(8) (2008).<br><br>The laboratory shall examine specimens only at the written request of a licensed physician, dentist, osteopath, chiropractor, nurse practitioner, physician's assistant, or other person authorized by [Mass.Gen.Laws chapter] 112 to use the report of laboratory examinations. Reports shall be delivered only to those authorized by law to receive such results.<br>105 Mass. Code Regs. 180.280 (2008).<br><br>The laboratory report shall be sent promptly to the licensed physician or other authorized person who requested the test . . . . The result of laboratory tests, including procedures or transcripts of results, shall not be sent directly to the patient concerned except with the written consent of the physician or other authorized person who requested the test.<br>105 Mass. Code Regs. 180.290 (2008). |

(continued)

**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| Michigan | Mich. Admin. Code r. 325.2351 (2008)<br><br>Mich. Admin. Code r. 325.2353 (2008) | The laboratory may examine specimens at the request of a physician, dentist, or other person authorized by law to receive such results.<br>Mich. Admin. Code r. 325.2351(2008).<br><br>A laboratory receiving specimens for examination from another laboratory shall report to the submitting laboratory.<br>Mich. Admin. Code r. 325.2353 (2008).<br><br>The results of laboratory tests or procedures or copies thereof shall not be given or sent to the patient concerned, except with the written consent of the physician or other authorized person who requested the test.<br>Mich. Admin. Code r. 325.2353 (2008). |
| Minnesota | N/A | N/A |
| Mississippi | N/A | N/A |
| Missouri | Mo. Code Regs. Ann. tit.19, § 30-20.098(7) (2008). | [R]eports of all laboratory examinations shall become a part of the [hospital] patient's medical record. Reports of tests on outpatients and from referring laboratories shall be sent promptly to the individual or facility ordering the test.<br>Mo. Code Regs. Ann. tit.19, § 30-20.098(7) (2008). |
| Montana | N/A | N/A |
| Nebraska | N/A | N/A |
| Nevada | Nev. Rev. Stat. Ann. § 652.190 (2007)<br><br>Nev. Rev. Stat. Ann. § 652.193 (2007) (cont.) | A laboratory may examine specimens only at the request of:<br>• A licensed physician;<br>• Any other person authorized by law to use the findings of laboratory tests and examinations...<br>Nev. Rev. Stat. Ann. § 652.190(1) (2008).<br><br>Except as otherwise provided in NRS 441A.150 [reporting communicable disease]; 442.325 [reporting birth defects and adverse birth results]; and 652.193 [rural hospitals], the laboratory may report the results of the examination only to:<br>• The person requesting the test;<br>• A provider of health care who is treating the patient or providing assistance in treatment;<br>• A provider of health care to whom the patient has been referred; and<br>• To the patient for whom the testing was performed.<br>Nev. Rev. Stat. Ann. § 652.190(2) (2008). |

(continued)

**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| Nevada (cont.) | Nev. Rev. Stat. Ann. § 652.190 (2007)<br><br>Nev. Rev. Stat. Ann. § 652.193 (2007) (cont.) | [A] licensed laboratory may release the results of tests performed at the laboratory regarding a patient of a rural hospital only to:<br>• The patient;<br>• The physician who ordered the tests;<br>• A provider of health care who is currently treating or providing assistance in the treatment of the patient.<br>Nev. Rev. Stat. Ann. § 652.193(1) (2008).<br><br>As used in Section 652.193, "provider of health care" means a "physician licensed pursuant to chapter 630, 630A or 633 of NRS, physician assistant, dentist, licensed nurse, dispensing optician, optometrist, practitioner of respiratory care, registered physical therapist, podiatric physician, licensed psychologist, licensed marriage and family therapist, licensed clinical professional counselor, chiropractor, athletic trainer, doctor of Oriental medicine in any form, medical laboratory director or technician, pharmacist or a licensed hospital as the employer of any such person." Nev. Rev. Stat. Ann. §§ 652.193(2) (2008) (incorporating definition in NRS 629.031); 629.031 (2008) (defining "provider of health care"). |
| New Hampshire | N.H. Code Admin. R. Ann. He-P 808.14(i), (j) (2008). | The licensee shall provide a client or their legal representative with a copy of his or her client record, pursuant to the provisions of RSA 151:21, X, [Patient Bill of Rights] upon request.<br>N.H. Code Admin. R. Ann. He-P 808.14(i) (2008).<br><br>The laboratory shall develop a facility system that will ensure that only the client and the ordering licensed practitioner are allowed to receive a copy of the results unless the laboratory has written consent from the client to release the test results to others.<br>N.H. Code Admin. R. Ann. He-P 808.14(j) (2008). |
| New Jersey | N.J. Admin. Code § 8:44-2.7 (2008). | The laboratory shall examine specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations and shall report only to those authorized by law to receive such results.<br>N.J. Admin. Code § 8:44-2.7(g) (2008).<br><br>The original or true duplicate of the laboratory report shall be sent promptly to the licensed physician or other authorized person who requested the test.<br>N.J. Admin. Code § 8:44-2.7(i) (2008). |

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**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| New Jersey (cont.) | N.J. Admin. Code § 8:44-2.7 (2008). (cont.) | The results of laboratory tests or procedures or transcripts thereof shall be sent to the licensed physician, dentist or other person authorized by law to use the findings of laboratory examinations. The patient may request a copy of such reports. The laboratory may charge a reasonable fee for copying.<br>N.J. Admin. Code § 8:44-2.7(i)(3) (2008). |
| New Mexico | N/A | N/A |
| New York | N.Y. Comp. Codes R. & Regs. tit. 10, § 58-1.11(b)(2) (2008).<br><br>N.Y. Comp. Codes R. & Regs. tit. 10, § 58-1.8 (2008).<br><br>N.Y. Comp. Codes R. & Regs. tit. 10, § 34-2.11(b) (2008). | Each clinical laboratory or blood bank shall produce a laboratory report and shall supply the original of said report to the physician or other authorized person submitting each specimen for analysis.<br>N.Y. Comp. Codes R. & Regs. tit. 10, § 58-1.11(b)(2) (2008).<br><br>No person shall report the result of any test except to a physician, his agent, or other person authorized by law to employ the results.<br>N.Y. Comp. Codes R. & Regs. tit. 10, § 58-1.8 (2008).<br><br>No person shall report the result of any test, examination or analysis of a specimen submitted for evidence of human disease or medical condition except to a physician, his agent, or other person authorized by law to employ the results thereof in the conduct of his practice or in the fulfillment of his official duties. Reports shall not be issued to the patients concerned except with the written consent of the physician or other authorized person, except that information concerning blood type and Rh factor may be provided in writing to the individual whose blood was tested without the consent of the individual's physician.<br>N.Y. Comp. Codes R. & Regs. tit. 10, § 58-1.8 (2008).<br><br>A clinical laboratory shall not communicate to a patient of a referring health services purveyor the results of a clinical laboratory test, including, but not limited to, a Pap smear. A clinical laboratory shall not prepare such communication for the health services purveyor to send, or otherwise facilitate the preparation or sending of such communication by the health services purveyor. Such communication or its facilitation shall be deemed consideration given for referral of specimens for performance of clinical laboratory services and is prohibited, except that: |

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**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| New York (cont.) | N.Y. Comp. Codes R. & Regs. tit. 10, § 58-1.11(b)(2) (2008).<br><br>N.Y. Comp. Codes R. & Regs. tit. 10, § 58-1.8 (2008).<br><br>N.Y. Comp. Codes R. & Regs. tit. 10, § 34-2.11(b) (2008).<br>(cont.) | A clinical laboratory may communicate in writing to the patient (by mail or electronically) an accurate and complete account of the result of the laboratory test along with information required to be included in a report of test results pursuant to Subpart 58-1 of Title 10 under the following circumstances:<br>• the referring health services purveyor authorized by law to order and use the results of laboratory tests has provided affirmative written authorization (on paper or electronically), which specifically names the patient;<br>• the laboratory test results have already been, or are simultaneously being communicated to the referring health services purveyor authorized by law to order and use the results of laboratory tests;<br>• the clinical laboratory advises the patient that the referring health services purveyor authorized by law to order and use the results of laboratory tests has received or is receiving the test results;<br>• the clinical laboratory shall include, in the communication to the patient, a clear statement, presented in a prominent manner, to the effect that the communication should not be viewed as medical advice and is not meant to replace direct communication with a physician or other health service purveyor;<br>• the clinical laboratory directs the patient's inquiries regarding the meaning or interpretation of the test results to the referring health services purveyor; and<br>• the communication to the patient does not include any information which would be consideration given for referral of specimens, including, but not limited to, medical advice specifically directed at the patient concerning the patient's condition, including diagnosis or treatment of the patient's condition.<br>N.Y. Comp. Codes R. & Regs. tit. 10, § 34-2.11(b) 2008. |
| North Carolina | N/A | N/A |
| North Dakota | N/A | N/A |
| Northern Mariana Islands | N/A | N/A |
| Ohio | N/A | N/A |
| Oklahoma | N/A | N/A |

(continued)

**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| Oregon | Or. Rev. Stat. § 438.430 (2007).<br><br>Or. Admin. R. 333-024-0050 (2008). | A clinical laboratory shall examine specimens only at the request of a physician, dentist, or other person authorized by law to use the findings of laboratory examinations.<br>Or. Rev. Stat. § 438.430(1) (2007).<br><br>The clinical laboratory shall examine specimens only at the oral, written or electronic request of a physician, dentist or other person authorized by law to use the findings of laboratory examinations.<br>Or. Admin. R. 333-024-0050(5)(a) (2008).<br><br>A person may not report the result of any test, examination, or analysis of a specimen submitted for evidence of human disease except to:<br>• The patient; and<br>• A physician, dentist, their agents, or other person authorized by law to employ the results thereof in the conduct of a practice or in the fulfillment of official duties.<br>Or. Rev. Stat. § 438.430(2) (2007).<br><br>Not sooner than seven days after receiving a request from a patient for the results of any test, examination or analysis of a specimen submitted by the patient, a clinical laboratory shall provide the results in writing to the patient.<br>Or. Rev. Stat. § 438.430(3) (2007).<br><br>No person shall report the result of any test, examination, or analysis of a specimen submitted or evidence of human disease except to a physician, dentist, their agents, or other person authorized by law to employ the results thereof in the conduct of their practice or in the fulfillment of their official duties. Reports shall not be issued to the patient concerned except with the written consent of the physician or other authorized person.<br>Or. Admin. R. 333-024-0050(5)(c) (2008).<br>[Note: This regulation was last amended in 2001, prior to the 2003 amendment to Or. Rev. Stat. § 438.430 which added the requirement that clinical laboratories furnish patients their test results upon request.] |
| Pennsylvania | 28 Pa. Code § 5.47 (2008). | Reports of clinical laboratory findings shall be made only to the person submitting the specimen or requesting the analysis, or his authorized agent.<br>28 Pa. Code § 5.47 (2008). |

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**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| Puerto Rico | 9 P.R. Regs. § 7189, art. 5 (2006) | The laboratory will promptly give or send all reports of test results to the patient or the authorized doctor who ordered the test.<br>9 P.R. Regs. § 7189, art. 5 (2006). |
| Rhode Island | 14-090-008 R.I. Code R. § 10.2 (2008)<br><br>14-090-008 R.I. Code R. § 13.2 (2008) | Specimens shall be examined only at the documented request of a licensed physician or other authorized medical personnel, pursuant to statutory provisions of this state.<br>14-090-008 R.I. Code R. § 13.2 (2008).<br><br>Test results shall be submitted promptly to the licensed physician or other authorized medical personnel who requested the test(s).<br>14-090-008 R.I. Code R. § 10.2 (2008). |
| South Carolina | N//A | N//A |
| South Dakota | N/A | N/A |
| Tennessee | Tenn. Code Ann. § 68-29-121 (2008)<br><br>Tenn. Comp. R. & Regs. 1200-6-3-.01 (2008)<br><br>Tenn. Comp. R. & Regs. 1200-6-3-.08 (2008) | No person, except patients who are performing tests on themselves by order of their physician, shall examine human specimens without the written request of a physician, an intern or resident in an American Medical Association approved training program, a duly licensed optometrist, a duly licensed dentist, a duly licensed chiropractic physician, or other health care professional legally permitted to submit to a medical laboratory a written request for tests appropriate to that professional's practice, or the written request of a law enforcement officer acting in accordance with § 55-10-406.<br>Tenn. Code Ann. § 68-29-121(a) (2008).<br><br>The results of a test shall be reported directly to the physician, optometrist, dentist, chiropractic physician, designated entity or other health care professional who requested it.<br>Tenn. Code Ann. § 68-29-121(b) (2008).<br><br>The laboratory must perform tests only at the written or electronic request of an authorized person.<br>Tenn. Comp. R. & Regs. R. 1200-6-3-.08(b) (2008).<br><br>Outpatient laboratory testing in Tennessee hospitals may be ordered by the following:<br>• Any licensed Tennessee practitioner who is authorized to do so by T.C.A. § 68-29-121;<br>• Any out of state practitioner who has a Tennessee telemedicine license issued pursuant to rule 0880-2-.16; or |

(continued)

**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| Tennessee (cont.) | Tenn. Code Ann. § 68-29-121 (2008)<br><br>Tenn. Comp. R. & Regs. 1200-6-3-.01 (2008)<br><br>Tenn. Comp. R. & Regs. 1200-6-3-.08 (2008) (cont.) | • Any duly licensed out of state health care professional as listed in T.C.A. § 68-29-121 who is authorized by his or her state board to order outpatient laboratory testing in hospitals for individuals with whom that practitioner has an existing face-to-face patient relationship as outlined in rule 0880-2-.14(7)(a)1., 2., and 3.<br>Tenn. Comp. R. & Regs. R. 1200-6-3-.08(b) (2008).<br><br>"Authorized person" is defined as "A physician or intern or resident in an American Medical Association approved training program or a duly licensed optometrist or a duly licensed dentist or a duly licensed chiropractic physician or other health care professional legally permitted to submit to a medical laboratory a written request for tests appropriate to that professional's practice or a law enforcement officer acting in accordance with T.C.A. [Tenn. Code Annotated] § 55-10-406."<br>Tenn. Comp. R. & Regs. 1200-6-3-.01(3) (2008).<br><br>The results of a laboratory test shall be reported promptly to the authorized person, the individual responsible for using the test results, the laboratory initially requesting the test, or other person required by statute or rule to receive test results.<br>Tenn. Comp. R. & Regs. R. 1200-6-3-.08(d) (2008). |
| Texas | N/A | N/A |
| Utah | N/A | N/A |
| Vermont | N/A | N/A |
| Virginia | Va. Code Ann. § 54.1-2409.4(B) (2008) | The health care practitioner, at his sole discretion, may authorize the laboratory to provide a copy of the report of the result directly to the patient or his legal guardian. The patient or his legal guardian shall then be considered authorized to receive the report or result for the purposes of the Clinical Laboratory Improvement Amendments.<br>Va. Code Ann. § 54.1-2409.4(B) (2008). |
| Virgin Islands | N/A | N/A |
| Washington | Wash. Admin. Code §§ 246-338-010(2) (2008) & 246-338-070(3)(b) (2008) | Test reports must . . . be released only to authorized persons or designees. Wash. Admin. Code § 246-338-070(3) (2008).<br><br>"Authorized person" means any individual allowed by Washington state law or rule to order tests or receive test results.<br>Wash. Admin. Code § 246-338-010(2) (2008). |

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**Table A-2. State Licensing Statutes and Regulations Addressing Persons Authorized to Receive Clinical Laboratory Test Results* (continued)**

| State Name | Statute or Regulation Permitting Release of Test Results | Statute or Regulation Summary |
|---|---|---|
| West Virginia | N/A | N/A |
| Wisconsin | Wis. Admin. Code HSS § 165.16(2) (2008) | Laboratories shall report specimen findings to persons authorized or allowed by law to receive such reports. Wis. Adm. Code HSS § 165.16(2) (2008). |
| Wyoming | Wyo. Stat. Ann. § 33-34-107(b) (2007)<br><br>048-0136-002 Wyo. Code R. § 7(c) (2008) | A clinical laboratory may examine human specimens only at the request of a licensed physician, dentist or other person authorized by law to use the findings of laboratory examinations. Wyo. Stat. Ann. § 33-34-107(a) (2007); 048-0136-002 Wyo. Code R. § 7(b) (2008).<br><br>The results of a test may only be reported to or as directed by the person who requested it. Wyo. Stat. Ann. § 33-34-107(b) (2007); 048-0136-002 Wyo. Code R. § 7(c) (2008). |

* Includes provisions governing who may authorize or order test only where provision appears in conjunction with those governing ability to release test results.

## Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results

October 2008

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| Alabama | N/A | N/A |
| Alaska | N/A | N/A |
| Arizona | [O]n the written request of a patient or the patient's health care decision maker for access to or copies of the patient's medical records, the health care provider in possession of the record shall provide access to or copies of the medical records to the patient or the patient's health care decision maker.<br>Ariz. Rev. Stat. § 12-2293 (2008).<br><br>"Health care provider," is defined as including "a health care institution as defined in section 36-401."<br>Ariz. Rev. Stat. § 12-2291(4)(b) (2008).<br><br>"Health care institution" means every place, institution, building or agency, whether organized for profit or not, which provides facilities with medical services, nursing services, health screening services, other health related services, supervisory care services, personal care services or directed care services and includes home health agencies as defined in section 36-151 and hospice service agencies.<br>Ariz. Rev. Stat. § 36-401 (2008). | N/A |
| Arkansas | In contemplation of, preparation for, or use in any legal proceeding, any person who is or has been a patient of a doctor, hospital, ambulance provider, medical health care provider, or other medical institution shall be entitled to obtain access, personally or by and through his or her attorney, to the information in his or her medical records upon request and with written patient authorization, and shall be furnished copies of all medical records pertaining to his or her case upon the tender of the expense of such copy or copies. Ark. Code Ann. §16-46-106(a)(1) (2008).<br><br>"Medical institution" and "medical health care provider" are not defined. | N/A |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| California | (a) Notwithstanding any other provision of law, a health care professional at whose request a test is performed shall provide or arrange for the provision of the results of a clinical laboratory test to the patient who is the subject of the test if so requested by the patient, in oral or written form. The results shall be conveyed in plain language and in oral or written form, except the results may be conveyed in electronic form if requested by the patient and if deemed most appropriate by the health care professional who requested the test.<br><br>(b)(1)Consent of the patient to receive his or her laboratory results by Internet posting or other electronic means shall be obtained in a manner consistent with the requirements of Section 56.10 or 56.11 of the Civil Code. In the event that a health care professional arranges for the provision of test results by Internet posting or other electronic manner, the results shall be delivered to a patient in a reasonable time period, but only after the results have been reviewed by the health care professional. Access to clinical laboratory test results shall be restricted by the use of a secure personal identification number when the results are delivered to a patient by Internet posting or other electronic manner.<br><br>. . . .<br>(f) Notwithstanding subdivisions (a) and (b), none of the following clinical laboratory test results and any other related results shall be conveyed to a patient by Internet posting or other electronic means:<br>• HIV antibody test.<br>• Presence of antigens indicating a hepatitis infection.<br>• Abusing the use of drugs.<br>• Test results related to routinely processed tissues, including skin biopsies, Pap smear tests, products of conception, and bone marrow aspirations for morphological evaluation, if they reveal a malignancy.<br><br>Cal. Health & Safety Code § 123148 (2008). | N/A |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| Colorado | N/A | N/A |
| Connecticut | N/A | Laboratory findings on a specimen . . . may be provided by laboratories [other than that of the Department of Health] to lay persons upon the written request of the person who ordered the testing.<br>Conn. Agencies. Regs. § 19a-36-D32(a) (2008). |
| Delaware | A health care provider who receives an appropriate authorization duly signed by an existing or former patient, guardian or personal representative, shall produce a true and correct complete copy of the requested medical records.<br>Del. Code Ann. tit. 10, § 3926(a) (2008).<br><br>"Health care provider" is not defined. | N/A |
| District of Columbia | N/A | A patient may request, in writing, access to or copies of the results of the patient's own laboratory tests.<br>D.C. Code Ann. § 44-211(a) (2008). |
| Florida | N/A | N/A |
| Georgia | N/A | N/A |
| Guam | N/A | N/A |
| Hawaii | N/A | N/A |
| Idaho | N/A | N/A |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| Illinois | Every health care facility and health care practitioner must upon the request of any patient who has been treated by the health care practitioner or facility, or any person, entity, or organization presenting a valid authorization for the release of records signed by the patient or the patient's legally authorized representative, permit the patient and the patient's health care practitioner or authorized attorney, or any person, entity, or organization presenting a valid authorization for the release of records, including but not limited to those relating to the diagnosis, treatment, prognosis, history, charts, pictures and plates, kept in connection with the treatment of such patient.<br>735 Ill. Comp. Stat. 5/8-2001(b) and (c) (2008).<br><br>"Health care facility" or "facility" means a public or private hospital, ambulatory surgical treatment center, nursing home, independent practice association, or physician hospital organization, or any other entity where health care services are provided to any person. The term does not include a health care practitioner.<br>735 Ill. Comp. Stat. 5/8-2001 (2008).<br><br>"Health care practitioner" means any health care practitioner, including a physician, dentist, podiatrist, advanced practice nurse, physician assistant, clinical psychologist, or clinical social worker. The term includes a medical office, health care clinic, health department, group practice or any other organizational structure for a licensed professional to provide health care services. The term does not include a health care facility.<br>735 Ill. Comp. Stat. 5/8-2001 (2008). | N/A |
| Indiana | N/A | N/A |
| Iowa | N/A | N/A |
| Kansas | N/A | N/A |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| Kentucky | Upon a patient's written request, a hospital licensed under Ky. Rev. Stat. Ann. 216B or a health care provider shall provide, without charge to the patient, a copy of the patient's medical record.<br>Ky. Rev. Stat. Ann. § 422.317(1) (2008).<br><br>"Health care provider" is not defined. | N/A |
| Louisiana | N/A | N/A |
| Maine | Upon the written signed authorization of the patient, a health care practitioner must release copies of all treatment records of a patient or a narrative containing all relevant information in the treatment records to the patient.<br>Me. Rev. Stat. Ann. tit. 22, §§ 1711-B (2008).<br><br>"Health care practitioner" means a person licensed by the state to provide or otherwise lawfully providing health care, including partnerships or corporations made up of those persons and their employees.<br>Me. Rev. Stat. Ann. tit. 22, §§ 1711-B, 1711-C (2008).<br><br>"Health care" means "preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, services, treatment, procedures or counseling . . . that affects an individual's physical, mental or behavioral condition, including individual cells or their components or genetic information, or the structure or function of the human body or any part of the human body…"<br>Me. Rev. Stat. Ann. tit. 22, § 1711-C (2008).<br><br>Directors of clinical laboratories must be licensed in the state of Maine.<br>Me. Rev. Stat. Ann. tit. 22, § 2029 (2008). | N/A |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| Maryland | N/A | For all test results except those from a health awareness test performed at a temporary laboratory or from a job-related alcohol or controlled dangerous substance test, a licensee shall ensure that the laboratory:<br>. . .<br>Sends a copy of a test result … directly to the individual tested only after the laboratory:<br>• Receives a written request from the individual, and<br>• Notifies the authorized person who requested the test that the results will be released to the individual tested…<br>Md. Code Regs. 10.10.06.04 (2008). |
| Massachusetts | A health care provider who maintains records for a patient treated or examined by such provider shall permit inspection of such records by such patient or an authorized representative of the patient, and upon request a copy of such patient's record shall be furnished upon payment of a reasonable fee. . . . "Health care provider" means any person or entity providing medical care or services, including but not limited to, physicians, and surgeons, therapists, dentists, nurses, optometrists, chiropractors, psychologists, and podiatrists. Mass. Gen. Laws ch. 112, § 12CC. | The result of laboratory tests . . . may *not* be sent directly to the patient concerned except with the written consent of the physician or other authorized person who requested the test. 105 Mass. Code Regs.180.290 (2008). |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| Michigan | A health facility or agency shall comply with the medical records access act.<br>Mich. Comp. Laws § 333.20170 (2008).<br><br>"Health facility or agency" means. . . "a clinical laboratory."<br>Mich. Comp. Laws § 333.20106 (2008).<br><br>An individual…who wishes to examine or obtain a copy of the patient's medical record shall submit a written request that is signed and dated by that individual not more than 60 days before being submitted to the health care provider or health facility that maintains the medical record that is the subject of that request. Upon receipt of a request under this subsection, a health care provider or health facility shall . . .make the medical record available for inspection or copying, or both, at the health care provider's or health facility's business location during regular business hours or provide a copy of all or part of the medical record….Mich. Comp. Laws §§ 333.26265 (2008); 333.26261 (2008) (designating the short title of the act as the "medical records access act"). | The results of laboratory tests or procedures or copies thereof shall *not* be given or sent to the patient concerned, except with the written consent of the physician or other authorized person who requested the test.<br>Mich. Admin. Code r. 325.2353 (2008). |
| Minnesota | Upon a patient's written request, a provider, at a reasonable cost to the patient, shall promptly furnish to the patient copies of the patient's health record, including but not limited to laboratory reports. . .<br>Minn. Stat. § 144.292, subd. 5.<br><br>"Provider" means. . . "a health care facility licensed under this chapter [144] or chapter 144A."<br>Minn. Stat. § 144.291.<br><br>Clinical laboratories are certified under chapter 144. See Minn. Stat. § 144.12(16); Minn. R. 4740.2050. | N/A |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| Missouri | All physicians, chiropractors, hospitals, dentists, and other duly licensed practitioners in this state, herein called "providers," shall, upon written request of a patient, or guardian or legally authorized representative of a patient, furnish a copy of his or her record of that patient's health history and treatment rendered to the person submitting a written request.<br>Mo. Rev. Stat. § 191.227 (2008).<br><br>"Practitioner" is not defined for purposes of this provision | N/A |
| Mississippi | N/A | N/A |
| Montana | The following access provisions only apply to health care providers that are not subject to the HIPAA Privacy Rule.<br>Mont. Code Ann. §§ 50-16-505 (2007).<br><br>Upon receipt of a written request from a patient to examine or copy all or part of the patient's recorded health care information, a health care provider…shall . . .make the information available to the patient for examination…or, provide a copy, if requested, to the patient.<br>Mont. Code Ann. §§ 50-16-541 (2007); 50-16-504(7) (2007) (defining "health care provider" as a person who is licensed, certified or otherwise authorized by the laws of Montana to provide health care in the ordinary course of business); 50-16-504(12) (2007) (defining "person" as an individual, corporation, business trust, estate, partnership, association, joint venture, government, governmental subdivision or agency, or other legal or commercial entity); 50-16-504(4) (2007)(defining "health care" as "any care, service or procedure provided by a health care provider, including medical or psychological diagnosis, treatment, evaluation, advise, or other services that affect the structure or any function of the human body.") | N/A |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| Nebraska | Upon receiving a written request from the patient, a provider must furnish a copy of the records within 30 days or allow examination of the record as promptly as required under the circumstances, but no later than 10 days after receipt of the request. Neb. Rev. Stat. § 71-8403 (2008).<br><br>"Provider," is defined as a physician, psychologist, chiropractor, dentist, hospital, clinic, and any other licensed or certified health care practitioner or entity. Neb. Rev. Stat. §§ 71-8402(5) (2008). | — |
| Nevada | Each provider of health care shall make the health care records of a patient available for physical inspection by: the patient or a representative with written authorization from the patient Nev. Rev. Stat. § 629.061 (2008).<br><br>"Provider of health care" means a physician licensed pursuant to chapter 630, 630A or 633 of NRS, physician assistant, dentist, licensed nurse, dispensing optician, optometrist, practitioner of respiratory care, registered physical therapist, podiatric physician, licensed psychologist, licensed marriage and family therapist, licensed clinical professional counselor, chiropractor, athletic trainer, doctor of Oriental medicine in any form, *medical laboratory director or technician*, pharmacist or a licensed hospital as the employer of any such person. Nev. Rev. Stat. § 629.031 (2008). | The laboratory may report results to . . . the patient for whom the testing was performed. Nev. Rev. Stat. Ann. § 652.190 (2008). |
| New Hampshire | Medical information contained in the medical records at any facility licensed under this chapter shall be deemed to be the property of the patient. The patient shall be entitled to a copy of such records upon request. N.H. Rev. Stat. Ann. § 151:21(X) (2008). | The licensee shall provide a client or their legal representative with a copy of his or her client record, pursuant to the provisions of RSA 151:21, X, [Patient Bill of Rights] upon request. N.H. Code Admin. R. Ann. He-P 808.14(i) (2008). |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| New Jersey | N/A | The patient may request a copy of such reports [of laboratory examinations].<br>N.J. Admin. Code § 8:44-2.7(i)(3) (2008). |
| New Mexico | N/A | N/A |
| New York | N/A | Reports shall not be issued to the patients concerned except with the written consent of the physician or other authorized person, except that information concerning blood type and Rh factor may be provided to the individual whose blood was tested without the consent of the individual's physician.<br>N.Y. Comp. Codes R. & Regs. tit. 10, § 58-1.8 (2008). |
| North Carolina | N/A | N/A |
| North Dakota | Upon the request for medical records with the signed authorization of the patient, the health care provider shall provide medical records [at a copying charge].<br>N.D. Cent. Code § 23-12-14 (2008).<br><br>"'[H]ealth care provider' means a licensed individual or licensed facility providing health care services."<br>N.D. Cent. Code § 23-12-14(1) (2008). | N/A |
| Northern Mariana Islands | N/A | N/A |
| Ohio | N/A | N/A |
| Oklahoma | Any person who is or has been a patient of a doctor, hospital, or other medical institution is entitled, upon request, to obtain access to and a copy of the information contained in the patient's medical records, including any x-ray or other photograph or image.<br>Okla. Stat. tit. 76, § 19 (A) (2) (2008). | — |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| Oregon | N/A | Not sooner than 7 days after receiving a request from a patient for the results of any test, examination or analysis of a specimen submitted by the patient, a clinical laboratory must provide the results in writing to the patient.<br>Or. Rev. Stat. § 483.430(3) (2008).<br><br>Release of lab reports to patients prior to 7-day waiting period requires written authorization from the ordering physician or other authorized person who ordered the test.<br>Oregon Depart. Of Human Services, Ordering and Reporting Medical and Non-Medical Laboratory Tests. Available at: http://oregon.gov/DHS/ph/lcqa/docs/order.pdf.<br><br>No person shall report the result of any test, examination, or analysis of a specimen submitted or evidence of human disease except to a physician, dentist, their agents, or other person authorized by law to employ the results thereof in the conduct of their practice or in the fulfillment of their official duties. Reports shall not be issued to the patient concerned except with the written consent of the physician or other authorized person.<br>Or. Admin. R. 333-024-0050(5) (2008).<br>[Note: This regulation precedes the 2003 amendment to Or. Rev. Stat. § 438.430 which added the requirement that clinical laboratories furnish patients their test results upon request.] |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| Pennsylvania | A patient or his designee, including his attorney, shall have the right of access to his medical charts and records and to obtain copies of the same without the use of a subpoena duces tecum.<br>42 Pa. Cons. Stat. Ann § 6155(b) (2008). | — |
| Puerto Rico | Providers and medical-hospital institutions must provide patients with speedy access to and with a copy of their files and records upon request.<br>P.R. Laws Ann. tit. 24, § 3049(e) (2005).<br><br>"Provider" means "any person or entity authorized by laws of Puerto Rico to render or provide medical-hospital health care services in commonwealth of Puerto Rico."<br>P.R. Laws Ann. tit. 24, § 3041 (2005). | The laboratory will promptly give or send all reports of test results to the patient or the authorized doctor who ordered the test.<br>9 P.R. Regs. § 7189, art. 5 (2006). |
| Rhode Island | N/A | N//A |
| South Carolina | N//A | N/A |
| South Dakota | A licensee of the healing arts shall provide copies of all medical records, reports and x-rays pertinent to the health of the patient, if available, to a patient or the patient's designee upon receipt by the licensee of a written request or a legible copy of a written request signed by the patient.<br>S.D. Codified Laws § 36-2-16 (2008).<br><br>"Healing art" means "any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, unhealthy or abnormal physical or mental condition."<br>S.D. Codified Laws § 36-2-1(3) (2008). | N/A |
| Tennessee | N/A | N/A |
| Texas | N/A | N/A |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| Utah | Pursuant to 45 C.F.R., Parts 160 and 164, Standards for Privacy of Individually Identifiable Health Information, a patient or a patient's personal representative may inspect or receive a copy of the patient's records from a health care provider when that health care provider is governed by the provisions of 45 C.F.R., Parts 160 and 164. When a health care provider as defined in § 78B-3-403 is not governed by [the HIPAA Privacy Rule], a patient or a patient's personal representative may inspect or receive a copy of the patient's records unless access to the records is restricted by law or judicial order. Utah Code Ann. § 78B-5-618 (2008).<br><br>"Health care provider" includes any person, partnership, association, corporation, or other facility or institution who causes to be rendered or who renders health care or professional services as a hospital, health care facility, physician, dentist, *clinical laboratory technologist*, and others rendering similar care and services relating to or arising out of the health needs of persons or groups of persons and officers, employees, or agents of any of the above acting in the course and scope of their employment. Utah Code Ann. § 78B-3-403 (2008) (emphasis added). | — |
| Virginia | Health care entities must disclose health records to the individual who is the subject of the health record. Va. Code Ann. § 32.1-127.1:03(A)(1) (2008).<br><br>"Health care entities," meaning any health care provider, health plan or health care clearinghouse. Va. Code Ann. § 32.1-127.1:03(B). (2008).<br><br>"Health care provider" means those entities listed in the definition of "health care provider" in § 8.01-581.1, Va. Code Ann. § 32.1-127.1:03(B) (2008). | The health care practitioner, at his sole discretion, may authorize the laboratory to provide a copy of the report of the result directly to the patient or his legal guardian. The patient or his legal guardian shall then be considered authorized to receive the report or result for the purposes of the Clinical Laboratory Improvement Amendments. Va. Code Ann. § 54.1-2409.4(B) (2008). |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| Virginia (cont.) | "Health care provider" means (i) a person, corporation, facility or institution licensed by this Commonwealth to provide health care or professional services as a physician or hospital, dentist, pharmacist, registered nurse or licensed practical nurse . . . , optometrist, podiatrist, chiropractor, physical therapist… (ii) a professional corporation, all of whose shareholders or members are so licensed; (iii) a partnership, all of whose partners are so licensed…. (vi) a corporation, partnership, limited liability company or any other entity…which employs or engages a licensed health care provider and which primarily renders health care services; or (vii) a director, officer, employee, independent contractor, or agent of the persons or entities referenced herein, acting within the course and scope of his employment or engagement as related to health care or professional services.<br>Va. Code Ann. § 8.01-581.1 (2008). | — |
| Virgin Islands | N/A | — |
| Vermont | N/A | — |
| Washington | Upon receipt of a written request from a patient to examine or copy all or part of the patient's recorded health care information, a health care provider generally must make the requested information available to the patient.<br>Wash. Rev. Code § 70.02.080 (2008).<br><br>"Health care provider" means a person who is licensed, certified, registered, or otherwise authorized by Washington law to provide health care in the ordinary course of business or practice of a profession.<br>Wash. Rev. Code § 70.02.010(9) (2008).<br><br>"Health care" means any care, service, or procedure provided by a health care provider:<br>To diagnose, treat, or maintain a patient's physical or mental condition; or<br>That affects the structure or any function of the human body.<br>Wash. Rev. Code § 70.02.010(5) (2008). | — |

(continued)

**Table A-3. State Laws Governing Patient Access to Clinical Laboratory Test Results (continued)**

| State Name | General Medical Record Access Laws* | Clinical Laboratory Licensing Laws‡ |
|---|---|---|
| West Virginia | Any licensed, certified or registered health care provider so licensed, certified or registered under the laws of this state shall, upon the written request of a patient, his authorized agent or authorized representative, within a reasonable time, furnish a copy, as requested, of all or a portion of the patient's record to the patient, authorized agent or authorized representative. . .<br>W. V. Code Ann. § 16-29-1 (2008).<br><br>Clinical laboratories are licensed under Chapter 16. See W.V. Code Ann. Chap. 16, art. 5J. | — |
| Wisconsin | N/A | — |
| Wyoming | N/A | — |

* Laws that grant patients the right of access (to inspect and obtain a copy of) records held by "health care practitioners," "health care providers," and similar broad categories of health care entities. This table includes statutes that are ambiguous but that may, due to their breadth, apply to clinical laboratories.

‡ Includes state clinical laboratory laws that expressly restrict patient access for comparison purposes.

**Table A-4. HIV/AIDS Confidentiality Laws Expressly Permitting Clinical Laboratories to Disclose Test Information for Treatment Without Patient Permission***

| State | Relevant Statutory or Regulatory Provision Permitting Disclosure |
|---|---|
| Alabama | — |
| Alaska | — |
| Arizona | [To a]n agent or employee of a health facility or health care provider to provide health services to the protected person or the protected person's child…<br>Ariz. Rev. Stat. Ann. § 36-664(A)(3)(2008) |
| Arkansas | — |
| California | [HIV test results] may be recorded by the physician who ordered the test in the test subject's medical record or otherwise disclosed without written authorization of the subject of the test. . . to the test subject's providers of health care. . . for purposes of diagnosis, care or treatment of the patient.<br>Cal Health & Safety Code § 120985(a) (2008) |
| Colorado | State law requiring patient authorization to release of information (specifically including AIDS/HIV) does not apply to HIPAA covered entities.<br>Colo. Rev. Stat. § 18-4-412(5) (2008) |
| Connecticut | To a health care provider or health facility when knowledge of the HIV-related information is necessary to provide appropriate care or treatment to the protected individual . . .or when confidential HIV-related information is already recorded in a medical chart or record and a health care provider has access to such record for the purpose of providing medical care to the protected individual.<br>Conn. Gen. Stat. 19a-583(a)(4) (2008) |
| Delaware | [To h]ealth care providers providing medical care to the subject of the test, when knowledge of the test results is necessary to provide appropriate emergency care or treatment.<br>Del. Code Ann. tit. 16 § 1203(a)(4) (2008) |
| District of Columbia | — |
| Florida | Health care providers consulting between themselves or with health care facilities to determine diagnosis and treatment.<br>Fla. Stat. § 381.004(4)(2008). |
| Georgia | To the person who ordered such tests of the body fluids or tissue of another person.<br>Ga. Code Ann. § 24-9-47 (2008) |
| Guam | — |
| Hawaii | [When] release is made by the patient's health care provider to another health care provider for the purpose of continued care or treatment of the patient.<br>Haw. Rev. Stat. Ann. § 325-101 (a)(10) (2008) |
| Idaho | Preventing AIDS requires that confidentiality of patient information be maintained. Not intended to limit the usual and customary exchange of information between health care providers.<br>Idaho Code Ann. 39-609 (2008). |
| Illinois[1] | — |

(continued)

**Table A-4. HIV/AIDS Confidentiality Laws Expressly Permitting Clinical Laboratories to Disclose Test Information for Treatment Without Patient Permission* (continued)**

| State | Relevant Statutory or Regulatory Provision Permitting Disclosure |
|---|---|
| Indiana | Release may be made of medical. . . information [involving communicable disease] to the extent necessary to . . . protect the health or life of a named party.<br>The provisions of this section regarding confidentiality apply to information obtained under IC 16-41-1 through 16-41-16 [public health reporting].<br>Ind. Code Ann. 16-41-8-1 (a)(3),(f) (2008) [Note: The provisions restricting disclosure of communicable disease information may apply only to HIV information in health department records. ]<br><br>General health privacy rule "does not prohibit a provider from obtaining a patient's health records from another provider without the patient's consent if the health records are needed to provide health services to the patient.<br>Ind. Code Ann. 16-39-5-1 (2008). |
| Iowa | To an authorized agent or employee of a health facility or health care provider, if the health facility or health care provider ordered or participated in the testing or is otherwise authorized to obtain the test results, the agent or employee provides patient care or handles or processes samples, and the agent or employee has a medical need to know such information.<br><br>To a health care provider providing care to the subject of the test when knowledge of the test results is necessary to provide care or treatment.<br>Iowa Code Ann. § 141A.9(2)(c)-(d) (2008) |
| Kansas | If a medical emergency exists and the disclosure is to medical personnel qualified to treat AIDS or HIV infection, except that any information disclosed pursuant to this paragraph shall be disclosed only to the extent necessary to protect the heath or life of a named party.<br>Kan. Stat. Ann. § 65-6002 (2008). |
| Kentucky | To a physician, nurse, or other health-care personnel who has a legitimate need to know the test result in order to provide for his protection and to provide for the patient's health and welfare;<br><br>Health-care providers consulting between themselves or with health-care facilities to determine diagnosis and treatment<br>Ky Rev. Stat. Ann. § 214.181(5)(d)(2),(3)-(4) (2008); Ky Rev. Stat. Ann. § 214.625(5)(c)(3)-(4) (2008) |
| Louisiana | To a health care provider or health facility when knowledge of the HIV test results is necessary to provide appropriate care or treatment to the patient.<br>La. Rev. Stat. Ann. § 40:1300.14(B)(2)-(3) (2008) |
| Maine | — |
| Maryland | No HIV specific confidentiality law.<br><br>General privacy rule, however, would permit disclosure without patient permission:<br>If a health care provider makes a professional determination that an immediate disclosure is necessary, to provide for the emergency health care needs of a patient or recipient.<br><br>As otherwise provided by law.<br>Md. Code Ann. Health-Gen. § 4-305(b) (2008). |

(continued)

**Table A-4. HIV/AIDS Confidentiality Laws Expressly Permitting Clinical Laboratories to Disclose Test Information for Treatment Without Patient Permission* (continued)**

| State | Relevant Statutory or Regulatory Provision Permitting Disclosure |
|---|---|
| Massachusetts | No HIV specific law.<br><br>General privacy rule however may permit release in certain circumstances without patient permission.<br><br>Disclosure of medical facts without the consent of the patient, may in certain circumstances, be an invasion of privacy under Mass. Ann. Laws ch. 214 § IB. However, the exchange of information between physicians consulting for treatment and diagnosis of patients within their care is generally seen as "desirable, as it generally improves the medical care rendered." The determination of whether a disclosure is reasonable is made on a case by case basis. See *Tower v. Hirschhorn*, 492 N.E. 2d 728, 732 (MA. 1986). |
| Michigan | To other health care providers to diagnose and care for a patient.<br>Mich. Comp. Laws § 333.5131 (2008).[2] |
| Minnesota | No HIV specific rule.<br>General rule permits disclosure of patient information:<br><br>For a medical emergency when the provider is unable to obtain the patient's consent due to the patient's condition or the nature of the medical emergency.<br>Minn. Stat. Ann. § 144.293 (2007). |
| Mississippi | — |
| Missouri | To health care personnel working directly with the infected individual who have a reasonable need to know the results for the purpose of providing direct patient health care.<br>Mo. Rev. Stat. § 191.656 (2008). |
| Montana | To the extent a recipient needs to know the information, if the disclosure is to a person who is providing health care to the patient.<br>Mont. Code Ann. § 50-16-1009; § 50-16-529 (2007). |
| Nebraska | — |
| Nevada | No HIV specific law.<br><br>Covered entity that transmits electronically identifiable health information in compliance with HIPAA is exempt from any state law that contains more stringent requirements or provisions concerning the privacy or confidentiality of individually identifiable health information.<br><br>Other than Medicaid patients, individuals have ability to opt out of having information shared electronically.<br>Nev. Rev. Stat. § 439.538 (2007). |
| New Hampshire | No HIV specific law.<br><br>General health privacy law prohibits disclosure of health information without the consent of the patient "unless provided for by law" or by the need to protect the welfare of the individual or the public interest.<br>N.H. Rev. Stat. Ann. § 332-I:2(I)(e) (2008). |

(continued)

**Table A-4. HIV/AIDS Confidentiality Laws Expressly Permitting Clinical Laboratories to Disclose Test Information for Treatment Without Patient Permission* (continued)**

| State | Relevant Statutory or Regulatory Provision Permitting Disclosure |
|---|---|
| New Jersey | To qualified personnel directly involved in the diagnosis and treatment of the person.<br><br>In all other instances authorized by State or federal law.<br>N.J. Stat. Ann. § 26:5C-8 (b) (2008). |
| New Mexico[1] | — |
| New York | To an agent or employee of a health facility or health care provider if (1) the agent or employee is permitted to access medical records, (2) the health facility or health care provider itself is authorized to obtain the HIV related information, and (3) the agent or employee provides health care to the protected individual, or maintains or processes medical records for billing or reimbursement.<br><br>To a health care provider or health facility when knowledge of the HIV related information is necessary to provide appropriate care or treatment to the protected individual.<br>N.Y. Pub. Health Law § 2782 (2008) |
| North Carolina | To health care personnel providing medical care to the patient.<br>N.C. Gen. Stat. § 130A-143 (2008). |
| North Dakota | As permitted under title 45, Code of Federal Regulations, part 164. section 512<br>N.D. Cent. Code 23-07.5-06 (2008) |
| N. Mariana Islands | — |
| Ohio | To the individual's physician<br>Ohio Rev. Code. Ann. § 3701.243(B) (2008)<br><br>To a health care provider, or an authorized agent or employee of a health care facility or a health care provider, if the provider, agent, or employee has a medical need to know the information and is participating in the diagnosis, care, or treatment of the individual on whom the test was performed.<br>Ohio Rev. Code. Ann. § 3701.243(B)(2008) |
| Oklahoma | Among health care providers, their agents or employees, within the continuum of care for the purpose of diagnosis and treatment of the person whose information is released.<br>Okla. Stat. tit. 63, § 1-502.2 (A) (2008). |
| Oregon | As permitted by federal law<br>Or. Rev. Stat. § 433.045 (2008).<br><br>To the person ordering the test<br><br>When information has been made part of a medical record to persons who must review record for treatment.<br>Or. Admin. R. 333-012-0270(3) (2008) |

(continued)

**Table A-4. HIV/AIDS Confidentiality Laws Expressly Permitting Clinical Laboratories to Disclose Test Information for Treatment Without Patient Permission* (continued)**

| State | Relevant Statutory or Regulatory Provision Permitting Disclosure |
|---|---|
| Pennsylvania | To the person who ordered the test<br><br>To individual health care providers involved in the care of the subject when knowledge of the condition or test result is necessary to provide emergency care or treatment appropriate to the individual<br><br>To health care providers consulted to determine diagnosis and treatment of the individual<br>. . . .<br>35 Pa. Stat. Ann. § 7607 (2008). |
| Puerto Rico | — |
| Rhode Island | To a patient's licensed physician or other medical personnel who requested the test<br>R.I. Gen. Laws § 23-6-17(a) (2008) |
| South Carolina | — |
| South Dakota | — |
| Tennessee | No-HIV specific statute.<br><br>General health privacy statute permits access without patient permission:<br>To health care providers from whom the patient receives or seeks care.<br>Tenn. Code. Ann. § 63-11-1503(a)(3) (2008) |
| Texas | To the physician or other person authorized by law who ordered the test:<br>To a physician, nurse, or other health care personnel who have a legitimate need to know the test result in order to provide. . . for the patient's health and welfare. . .<br>Tex. Health & Safety Code Ann. § 81.103 (2007) |
| Utah | — |
| Vermont | — |
| Virgin Islands | — |
| Virginia | To health care providers for purposes of consultation or providing care and treatment to the person who was the subject of the test…To health care providers for purposes of consultation or providing care and treatment to the person who was the subject of the test…<br>Va. Code Ann. § 32.1-36.1(A) (2008) |
| Washington | May disclose pursuant to customary methods utilized for the exchange of medical information among health care providers to provide health care services to the patient<br>Wash. Rev. Code § 70.24.105 (2008). |
| West Virginia | — |
| Wisconsin | To a health care provider who provides care to the test subject, including those instances in which a health care provider provides emergency care to the subject.<br>Wis. Stat. Ann. § 252.15 (2007) |
| Wyoming | — |

(continued)

* = Clinical laboratories are generally only one of many categories of health care entities covered by these HIV/AIDS confidentiality laws.

This table includes text of general health privacy statute which would apply to HIV test information where there is no statute or regulation that specifically applies to the release of HIV/AIDS related information.

Notes: [1] A number of states have provisions that prohibit disclosure of HIV test information without the patient's permission; provide that disclosure may be made to "an authorized agent or employee of a health care provider or health care facility if the facility or provider itself is authorized to obtain the test results" and the agent or employee is involved in patient care, but have no distinct provision permitting release of test results to a health care facility or provider without the patient's permission. See, e.g., "Ill. Admin. Code tit. 77 § 697.140(a)(3)(A)-(C)(i) (2008); Del. Code Ann. tit. 16 1203(a) (2008); N.M. Stat. § 24-2B-6 (C), (2008). We have interpreted these laws as requiring patient permission to disclose information to a health care provider or health care facility in the first instance, but permitting the receiving provider or facility to share information with their employees and agents directly involved in the patient's care. Because this type of exchange would be considered a "use" of health information under HIPAA we have not included these provisions in this table.

[2] Given context of provision, which generally prohibits release of name of subject of test, this provision may allow disclosure to diagnose and care for contacts and others who may have been infected, as opposed to subject of the test.

**Table A-5. State Clinical Laboratory Licensing Laws and HIV /AIDS Confidentiality Laws That Permit Release of Test Results to Patients**

| State | State Clinical Laboratory Law Permits Release to patient only with permission of person who ordered test | State Clinical Laboratory Law Permits Release to patient (no other permission required) | HIV/AIDS Confidentiality Law Permits Release to test subject |
|---|---|---|---|
| Alabama | — | — | — |
| Alaska | — | — | — |
| Arizona | — | — | yes |
| Arkansas | — | — | — |
| California | yes[1] | — | yes[2] |
| Colorado | — | — | — |
| Connecticut | yes[3] | — | yes |
| Delaware | — | — | yes |
| District of Columbia | — | yes | — |
| Florida | yes | — | yes |
| Georgia | — | — | yes |
| Guam | — | — | — |
| Hawaii | — | — | — |
| Idaho | — | — | — |
| Illinois | — | — | yes |
| Indiana | — | — | yes |
| Iowa | — | — | — |
| Kansas | — | — | — |
| Kentucky | — | — | yes |
| Louisiana | — | — | — |
| Maine | — | — | yes |
| Maryland | — | yes | — |
| Massachusetts | yes | — | — |
| Michigan | yes | — | — |
| Minnesota | — | — | — |
| Mississippi | — | — | — |
| Missouri | — | — | yes |
| Montana | — | — | — |
| Nebraska | — | — | — |
| Nevada | — | yes | — |
| New Hampshire | — | yes | — |
| New Jersey | — | yes | — |
| New Mexico | — | — | — |
| New York | yes | — | yes |
| North Carolina | — | — | — |
| North Dakota | — | — | yes |

(continued)

**Table A-5. State Clinical Laboratory Licensing Laws and HIV /AIDS Confidentiality Laws That Permit Release of Test Results to Patients (continued)**

| State | State Clinical Laboratory Law Permits Release to patient only with permission of person who ordered test | State Clinical Laboratory Law Permits Release to patient (no other permission required) | HIV/AIDS Confidentiality Law Permits Release to test subject |
|---|---|---|---|
| N. Mariana Islands | — | — | — |
| Ohio | — | — | yes |
| Oklahoma | — | — | — |
| Oregon | yes | yes[4] | yes |
| Pennsylvania | — | — | yes |
| Puerto Rico | — | yes | — |
| Rhode Island | — | — | — |
| South Carolina | — | — | — |
| South Dakota | — | — | — |
| Tennessee | — | — | — |
| Texas | — | — | yes |
| Utah | — | — | — |
| Vermont | — | — | — |
| Virgin Islands | — | — | — |
| Virginia | yes | — | yes |
| Washington | — | — | — |
| West Virginia | — | — | yes |
| Wisconsin | — | — | yes |
| Wyoming | — | — | — |

***** Table includes state statutes and regulations that expressly contain the noted provisions. It does not address whether some provisions implicitly allow release of test results to others.

Notes: (1) Provider must review and arrange for test results to be released to the patient. Patient must consent to Internet posting or other electronic notification of results.
(2) Only after provider has reviewed test results and arranged for them to be released to the patient. HIV test results, as well as certain other test results may not be provided to patient over Internet or other electronic means.
(3) To "lay person" upon written request of person who ordered the test.
(4) After 7 days from receiving request. Release of reports prior to 7 day waiting period require written authorization of person who ordered test.

## Table A-6. State Clinical and Hospital Licensing Laws Addressing Accurate Delivery of Test Results

October 2008

| State Name | Statutory or Regulatory Provision |
|---|---|
| Alabama | 42 C.F.R. part 482.27 as revised as of Oct. 1, 1992, "is hereby incorporated by reference and made a part of this rule as if set out in full…"<br>Ala. Admin. Code r. 420-5-7-.13 (2008).<br><br>"The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter."<br>42 C.F.R. § 482.27 (2008). |
| Alaska | A facility (including a hospital) that provides laboratory services must comply with [title 7 of the Alaska Admin. Code §§ 12.790—12.850] and must meet the requirements of 42 C.F.R. Part 493, laboratory Requirements, as revised as of Oct. 1. 2005, and adopted by reference.<br>Alaska Admin. Code tit. 7, § 12.790 (2008).<br><br>"Facility" is defined as a general acute care, specialized, rural primary care, critical access or long-term acute care hospital; nursing home; ambulatory surgical center; home health agency; nursing home; mental health center; intermediate care facility for the mentally retarded; birth center; and frontier extended stay clinic.<br>Alaska Admin. Code tit. 7, § 12.990 (2008). |
| Arizona | Clinical laboratory services and pathology services [must be] provided by a hospital through a laboratory that holds a certificate of accreditation or certificate of compliance issued by the United States Department of Health and Human Services under the 1988 amendments to the Clinical Laboratories Improvement Act of 1967.<br>Ariz. Admin. Code § R9-10-218(1) (2007). |
| Arkansas | Clinical laboratories in hospitals and related institutions shall meet the requirements of the most current rule of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).<br>016-24-007 Ark. Code R. § 19(A)(2) (2008). |
| California | Each clinical laboratory must establish and maintain a quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1201) of Title 42 of the Code of Federal Regulations.<br>Cal. Bus. & Prof. Code § 1220(d)(2)(B). |
| Colorado | Clinical pathology services in general hospitals shall comply with the requirements set forth in the Clinical Laboratory Improvement Amendments (CLIA).<br>6 Colo. Code Regs. § 1011-1(10.102)(2) (2008).<br><br>All clinical laboratories must provide proof of certification status through the provision of the CLIA number in order to participate in the Medical Assistance Program.<br>10 Colo. Code Regs. § 2505-10(8.660.2.B.) (2008). |
| Connecticut | The clinical laboratory shall be operated in compliance with all applicable state and federal laws and regulations, including but not necessarily limited to CLIA Title 42 Part 493 of the code of federal regulations.<br>Conn. Agencies Regs. § 19a-36-D38(a) (2008). |

(continued)

**Table A-6. State Clinical and Hospital Licensing Laws Addressing Accurate Delivery of Test Results (continued)**

| State Name | Statutory or Regulatory Provision |
|---|---|
| Delaware | To be certified to perform testing on human specimens, an independent laboratory must meet the conditions under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).<br>40-850-018 Del. Code Regs. § 3.1.1 (2008) (regulations governing Medicaid reimbursements for clinical tests). |
| District of Columbia | N/A |
| Florida | The lab shall establish and follow quality control procedures to assure the accuracy and reliability of patient test results and reports in accordance with CLIA requirements.<br>Fla. Admin. Code Ann. r. 59A-7.029(1) (2008). |
| Florida | N/A |
| Georgia | The lab shall establish a quality assurance program to monitor and evaluate the total testing process from specimen collection to reporting of test results. The program shall identify and correct problems, assure the accurate, reliable, and prompt reporting of test results and assure adequacy and competency of staff.<br>Ga. Comp. R. & Regs. 290-9-8.-09 (2008). |
| Guam | N/A |
| Hawaii | N/A |
| Idaho | N/A |
| Illinois | The hospital shall have a clinical laboratory certified under the Clinical Laboratory Improvement Amendments of 1988.<br>Ill. Admin. Code tit. 77, § 250.510 (2008). |
| Indiana | For purposes of Medicare reimbursement, clinical laboratory procedures are subject to the Clinical Laboratories Improvement Act (CLIA) rules and regulations.<br>40 Ind. Admin. Code 5-18-1 (2008).<br><br>The hospital shall have laboratory services performed in a facility possessing a valid certificate, in accordance with 42 CFR 493.<br>410 Ind. Admin. Code 15-1.5-3(b) (2008). |
| Iowa | Medicaid reenrolled entities providing laboratory services are subject to the provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).<br>Iowa Admin. Code r. 441-79.13(249A) (2008).<br><br>The hospital must ensure that all laboratory services provided to its patients are performed in a laboratory certified in accordance with the Code of Federal Regulations in 42 CFR Part 493, October 1, 2004.<br>Iowa Admin. Code r. 481-51.18(135B) (2008). |

(continued)

**Table A-6. State Clinical and Hospital Licensing Laws Addressing Accurate Delivery of Test Results (continued)**

| State Name | Statutory or Regulatory Provision |
|---|---|
| Kansas | The laboratories performing analytical tests within the hospital shall hold a valid CLIA certificate for the type and complexity of all tests performed.<br>Kan. Admin. Regs. § 28-34-11(b) (2008).<br><br>Each laboratory seeking approval of the department to perform tests on biological specimens for controlled substances shall require a determination by the division director or the director's designee that the lab meets the requirements for certification under CLIA for the type and complexity of the tests being performed.<br>Kan. Admin. Regs. § 28-33-12(b) (2008). |
| Kentucky | Any provider of laboratory testing participating in the Medicaid Program shall comply with certification requirements specified in 42 CFR Part 493 unless the state's licensure program has been approved by the HHS and the provider is appropriately licensed or certified under the state-exempt licensing program.<br>907 Ky. Admin. Regs. 1:575(2) (2007). |
| Louisiana | The hospital shall provide laboratory services or make contractual arrangements with a laboratory certified in accordance with the Clinical Laboratory Improvement Amendments (CLIA) of 1988.<br>La. Dept. of Health, Final Rule, 29 La. Reg. 2399 amending La. Admin. Code tit. 48, § 9371(A) ( 2003). |
| Maine | Laboratories must meet the CLIA '88 requirements and interpretive guidelines of 42 CFR, Chapter IV Part 493 Subpart K Quality Control and Subpart P Quality Assurance.<br>10 144 256 Me. Code R. § 5 (Weil 2008). |
| Maryland | N/A |
| Massachusetts | N/A |
| Massachusetts | N/A |
| Michigan | N/A |
| Minnesota | N/A |
| Missouri | N/A |
| Mississippi | N/A |
| Montana | N/A |
| Nebraska | All laboratory testing, whether provided directly by the hospital or through agreement, must comply with the Clinical Laboratory Improvement Amendments of 1988 as amended (CLIA). Laboratory services must be under the direction of a physician, preferably a pathologist.<br>175 Neb. Admin. Code § 9-006.09E (2008). |
| New Hampshire | All laboratories shall comply with all regulations contained in 42 CFR § 493.<br>N.H. Code Admin. R. Ann. He-P 808.15(a) (2008).<br><br>Regarding Medicaid, all participating laboratory service providers shall be CLIA certified in accordance with 42 U.S.C. 263a.<br>N.H. Code Admin. R. Ann. He-W 577.03(c) (2008). |
| New Jersey | N/A |

(continued)

**Table A-6. State Clinical and Hospital Licensing Laws Addressing Accurate Delivery of Test Results (continued)**

| State Name | Statutory or Regulatory Provision |
|---|---|
| New Mexico | N/A |
| New York | N/A |
| Nevada | N/A |
| North Carolina | N/A |
| North Dakota | N/A |
| Northern Mariana Islands | N/A |
| Ohio | N/A |
| Oklahoma | N/A |
| Oregon | Each laboratory's quality assurance program must assure the accurate, reliable and prompt reporting of test results.<br>Or. Admin. R. 333-024-0043 (2008). |
| Oregon | N/A |
| Pennsylvania | N/A |
| Puerto Rico | N/A |
| Rhode Island | N/A |
| South Carolina | N/A |
| South Dakota | N/A |
| Tennessee | Laboratories must employ and maintain a system that provides for accurate result reporting.<br>Tenn. Comp. R & Regs. 1200-6-3.08 (2008).<br><br>The laboratory must establish and follow written quality control procedures…general quality control shall assure the accuracy and reliability of patient test results and reporting.<br>Tenn. Comp. R. & Regs. 1200-6-3.09 (2008). |
| Tennessee | N/A |
| Texas | Hospital laboratory services must comply with the requirements of CLIA, 42 C.F.R. §§ 493.1 – 493.1780, and labs that hospitals contract with must also be in compliance<br>25 Tex. Admin. Code § 133.41(h)(1) (2008). |
| Utah | N/A |
| Virginia | N/A |
| Virgin Islands | N/A |
| Vermont | N/A |

(continued)

**Table A-6. State Clinical and Hospital Licensing Laws Addressing Accurate Delivery of Test Results (continued)**

| State Name | Statutory or Regulatory Provision |
|---|---|
| Washington | Each medical test site performing moderately complexity or high complexity testing must have a quality assurance program to "assure the accurate, reliable, and prompt reporting of test results."<br>Wash. Admin. Code § 246-338-080 (2008).<br><br>"The medical test site must use quality control procedures, providing and assuring accurate and reliable test results and reports."<br>Wash. Admin. Code § 246-338-090 (2008). |
| West Virginia | N/A |
| Wisconsin | N/A |
| Wyoming | State Dept of Health shall adopt rules and regulations, where feasible the rules and regulations shall equal or exceed minimum standards in CLIA of 1967 and subsequent federal clinical laboratory acts.<br>Wyo. Stat. Ann. § 33-34-105(d) (2007). |