



GEORGETOWN UNIVERSITY

HIT Policy Committee
Information Exchange Workgroup

Electronic Exchange of Laboratory Information

Statement of

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Introduction

Thank you for the opportunity to speak with you today on issues surrounding the electronic exchange of laboratory information. I am a lawyer and a Research Associate Professor at Georgetown University's Health Policy Institute. In my position at Georgetown, I conduct research and analysis on a range of issues related to the exchange of health information. Much of my work has focused on the Privacy Rule issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), its scope and its interaction with state health law. I have written extensively on this topic including: *The State of Health Privacy* (2002); *Implementing the Federal Health Privacy Rule in California* (2002); "Altered States: State Health Privacy Laws and the Impact of the Federal Health Privacy Rule," *Yale Journal of Health Policy, Law, and Ethics* (Spring 2002); and "Preemption Analysis Under HIPAA—Proceed with Caution," *In Confidence* (April 2003); and state-specific consumer guides on how to obtain and amend medical records under a combination of the HIPAA Privacy Rule and state law (2007), available at <http://hpi.georgetown.edu/privacy/records.html>.

Most recently, I have worked with the Office of National Coordinator (ONC), U.S. Department of Health and Human Services and RTI International on a series of legal surveys of state laws addressing the following topics:

- "Consent" requirements for disclosing health information for treatment;
- Permitted means and requirements for transmitting prescriptions;
- Individuals' rights to access health information; and
- Clinical laboratory licensing laws restricting the disclosure of test results.

The purpose of my statement today is to provide you with a summary of the research and analysis we conducted with respect to the ability of clinical laboratories to release test results directly to:

- Other health care providers; and
- To the patient who was the subject of the lab test.

This study has been completed and is in the clearance process at HHS. I hope to be able to provide the full report to the Committee in the near future.

This statement is made solely in my individual capacity and does not represent the views of ONC, RTI or any other party.

Interaction of Federal and State Law

The release of clinical laboratory test results is governed by a combination of federal and state law.¹ At the federal level, regulations issued under the Clinical Laboratory Improvement Amendments (CLIA) govern the majority of clinical laboratory testing performed on humans in the United States.² In total, CLIA covers approximately 200,000 laboratory entities.³ With respect to disclosing the results of clinical laboratory tests CLIA provides as follows:

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 regulation lists three distinct categories of entities to which laboratories may release clinical laboratory test results:

- “Authorized persons;”
- The individual responsible for using the test results;
- And the laboratory that initially requested the test.

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. Thus, who is authorized to receive test results as an “authorized person” is determined under state law.⁴ HHS has indicated in the past that, under this provision, if a state does not define the term “authorized person”, the person permitted to receive the test result is the person who orders the test.⁵

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule also applies to clinical laboratories. The HIPAA Privacy Rule permits covered entities, including health care providers such as clinical laboratories, to disclose to others protected health information for treatment, payment and health care

¹ As used in this statement, the term state includes the territories Guam, Puerto Rico and the Virgin Islands.

² Law citations

³ 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/01_Overview.asp#TopOfPage

⁴ The term “individual responsible for using the test results” is not defined in the CLIA regulations, and its meaning is uncertain. It is generally understood, however, to include the person who ordered the test. The last category refers to laboratories that request another laboratory to perform a test on their behalf. These categories would be interpreted under federal law and were therefore not included under our study.

⁵ U.S. Dept. of Health and Human Services, *Standards for Privacy of Individually Identifiable Health Information: Final Rule*, (“Preamble Final Privacy Rule”) 65 Fed. Reg. 82462, 82485 (Dec. 28, 2000).

operations without the consent of the patient. See 45 C.F.R. § 164.506(c).⁶ With respect to disclosures of protected health information, the HIPAA Privacy Rule does not preempt “more stringent” laws, *i.e.*, those that prohibit or restrict a disclosure that would otherwise be permitted by the HIPAA Privacy Rule.⁷ As a consequence, the more restrictive provisions of CLIA and state laws regarding the disclosure of laboratory test results remain in effect.

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. 45 C.F.R. §164.524(a)(1). As noted above, CLIA restricts the release of test results to only “authorized persons” (*i.e.*, “an individual authorized under State law to order tests or receive test results”) and the person who orders the test.⁸ Thus, patients’ rights to access their test results directly from a clinical laboratory generally are dependent on whether state law permits these laboratories to furnish such results directly to patients.⁹

Methodology

Due to limited resources, we limited the 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 used electronic legal research search engines (Lexis or Westlaw) to identify relevant state statutes, administrative regulations, and, where relevant, case law which 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. While these opinions are not binding they afford useful interpretation of the state law. 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. In order 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.

⁶ It should be noted that there are specific conditions which must be met in order for a covered entity to disclose protected health information to another entity for the health care operations of the receiving entity.

⁷ See 45 C.F.R. §§ 160.202 (defining “more stringent” in the context of comparing state standards with HIPAA); 160.203 (establishing rule that HIPAA does not preempt more stringent state health privacy laws) and *Preamble Final Rule*, 65 Fed. Reg. 82485 (discussing interaction of Privacy Rule with other federal laws).

⁸ U.S. Dept. of Health and Human Services, *Standards for Privacy of Individually Identifiable Health Information: Final Rule*, (“Preamble Final Privacy Rule”) 65 Fed. Reg. 82462, 82485 (Dec. 28, 2000).

⁹ With respect to individual access, a state law is considered “more stringent” than the HIPAA Privacy Rule if it provides a greater right of access than the federal rule. See 45 C.F.R. § 160.202.

Findings

While 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. States license various types of health care providers, and often limit the categories of providers who may order clinical laboratory tests or use such test results.

Authorized to order tests

At the outset, we note that the categories of providers who are authorized to order laboratory tests vary from state to state. For example, some states permit naturopaths to order lab tests, while other states do not. A complete analysis of which providers are authorized to order laboratory tests across the states was beyond the scope of our study. To obtain a clearer view on this issue, further research delving into licensing laws that govern specific categories of health care providers would be required.

Laboratory licensing laws: Release to health care providers

The majority of states (29) have clinical laboratory licensing laws that expressly address to whom a laboratory may or must release test results.

Of the states with licensing laws that address the “authorized recipient” issue, 16 states expressly permit or require clinical laboratories to release laboratory test results only to the health care provider or person who requested the test, or to their agent, or designee. Laboratories licensed in these states would appear to be limited to electronically transmitting lab test results either to the provider who ordered the test or to those who have been designated by the person who ordered the test.

Clinical laboratory laws in 8 other states expressly permit release of test results to either the person who ordered the test or persons *authorized to use* or receive or responsible for using or receiving test results. Two more states generally permit laboratories to release test results to persons authorized to use test results. In general, these provisions permit the release of test results not only to the health care provider who requested the test initially (who presumably is authorized to order and use the test) but also to other providers who are authorized to use such test results (e.g., specialists).

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. In contrast, at least one state 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.”¹⁰

¹⁰ See Ariz. Rev. Stat. § 36-470 (2008).

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, clinical laboratories may release test results to the physician or practitioner who ordered the test and to the patient. Laboratories may not, however, release test results to others without the written consent of the patient. This approach fundamentally differs from CLIA and most state clinical laboratory licensing laws which are health care provider-centric, giving the laboratory and the ordering health care provider the control of the laboratory test result.

The clinical laboratory licensing laws of 26 states are silent with respect to who is authorized to receive laboratory test results. Under HHS's interpretation of CLIA, issued in conjunction with the release of the Privacy Rule in 2000, in these states the person authorized to receive test results is the person who ordered the test.¹¹

In sum, clinical laboratory laws are closely linked to health care practitioner laws and must be considered within that context. Sixteen of the states have statutes or regulations that by their express terms generally restrict the release of test results to the person who ordered the test (or their agent or designee). An additional 26 states are silent with respect to "authorized person". Under current conservative interpretations of federal and state law, it appears that clinical laboratories may release test report directly only to the provider or person who ordered the test or their designee in as many as 42 states.

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 the ability of patients to directly access some of their personal health information and to direct where copies of that information may be sent,¹² 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 subject to CLIA to the extent the provision of access to the individual would be prohibited by law. 45 C.F.R. §164.524(a)(1). As interpreted, 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.¹³ As a consequence, whether patients are able to directly access laboratory test results (or direct where those results may be sent) is largely determined under state law.¹⁴

¹¹ Preamble Final Privacy Rule, 65 Fed. Reg. at 82485.

¹² Under HIPAA, an individual has the right to specify an alternative address or other method of contact for communicating with a covered entity. 45 C.F.R. § 164.522. Presumably, this would allow an individual who requests access to protected health information to specify that the information be delivered to the individual's personal health record.

¹³ Preamble Final Privacy Rule, 65 Fed. Reg. at 82485.

¹⁴ This discussion assumes that the test was ordered by the health care provider. In many states, patients may directly request certain types of laboratory tests. In this case, the patient would be entitled to a copy of the test result as "the person authorized to order the test."

Laboratory licensing laws: permitted to release to patient

Most state clinical laboratory licensing laws do not expressly permit or require clinical laboratories to release test results directly to patients. In fact, licensing laws in seven states expressly provide that test results may be released to a patient *only* with the authorization of the person who ordered the test.

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 authorization. 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. One state, for example, requires notification of the person who requested the test that the results will be released to the individual tested.¹⁵ Another state 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.¹⁶ These states have attempted to find a balance between the patients' right of access and the health care providers' need to interpret the test results.

Medical record access laws: right of access

Clinical laboratory licensing laws are not the sole source of patient access rights. Many states have "medical record access laws." These are 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 on their face appear broad enough to encompass records maintained by clinical laboratories.

In some states, it is clear that the medical record access law applies to clinical laboratories. The clinical laboratory law may, for example, expressly cross-reference the state's medical record access law.¹⁷ In other states, clinical laboratories are expressly included in the definition of the entities covered by the medical records access law.¹⁸

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

As a whole, 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. Viewed from the converse perspective, patients in 30 states or territories do not have the clear right to access their test results directly from clinical laboratories.

¹⁵ See Md. Code Regs. 10.10.06.04 (2008).

¹⁶ Or. Rev. Stat. § 438.430 (2007).

¹⁷ See N.H. Code Admin. R. Ann. He-P 808.14(i) (2008) and N.H. Rev. Stat. Ann. § 151:21(X) (2008).

¹⁸ 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).

Further Study

I am currently working on a follow up study with the National Academy for State Health Policy, funded by the California HealthCare Foundation and ONC that is undertaking a more detailed look at clinical laboratory laws in five states representing some of the varied approaches to releasing test results discussed above. We are interviewing various state stakeholders to determine the policy factors underlying these various categories of state laws and to examine whether, and to what extent, these laws are enforced. This report is scheduled to be released in January 2010.

Conclusion

In most states, clinical laboratories may release test results only to the health care provider who ordered the test. Laws in most states 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. Rather, they must obtain the results of lab tests from the provider who ordered the test.

The statutes and regulations may impede the ready exchange of laboratory test results both to health care providers and to patients. It is clearly time to re-examine these restrictions in light of developing health information exchange.

I look forward to making the reports discussed above available to this Committee and assisting you in your ongoing work on this issue.