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Electronic Release of Clinical Laboratory Results: A Review of State and Federal Policy

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by

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About the Foundation

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I. Introduction

HEALTH INFORMATION TECHNOLOGIES (HIT) and electronic health information exchange (HIE) are increasingly recognized as necessary tools for a high-performing, effective health care system. State and national initiatives that use these strategies have gained momentum with the passage of the American Recovery and Reinvestment Act of 2009 (ARRA), which provides over \$40 billion in associated resources to promote the adoption of HIT, including electronic health records (EHRs) and HIE. This paper, based on a review of state laws and interviews with key stakeholders, provides background information for state and federal policymakers on the policy issues and challenges related to electronically sharing a critical HIE data element: laboratory results.

Research suggests that some 70 to 80 percent of data contained in a medical record consists of laboratory records and results, and that approximately 70 percent of clinical decisionmaking is based on or assisted by laboratory test results.^{1,2} Nonetheless, one study of more than 5,000 medical charts determined that patients were not informed of seven of every 100 abnormal test results.³ A related study found that 17 to 32 percent of physicians lack a reliable system to ensure that all ordered test results are reviewed.⁴ HIT systems have the potential to help providers by automatically flagging abnormal results, documenting result review, and—through HIE—assuring that members of a patient’s care team have all results available at the point of care.

Many HIE initiatives currently underway identify the sharing of laboratory test results as a priority; however the legal and policy framework that permits the exchange of laboratory results is not clear. The release of results is guided by regulations issued under the Clinical Laboratory Improvement Amendments (CLIA) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as well as numerous state-specific medical release and laboratory licensing laws. These laws are subject to disparate interpretation by various stakeholders.

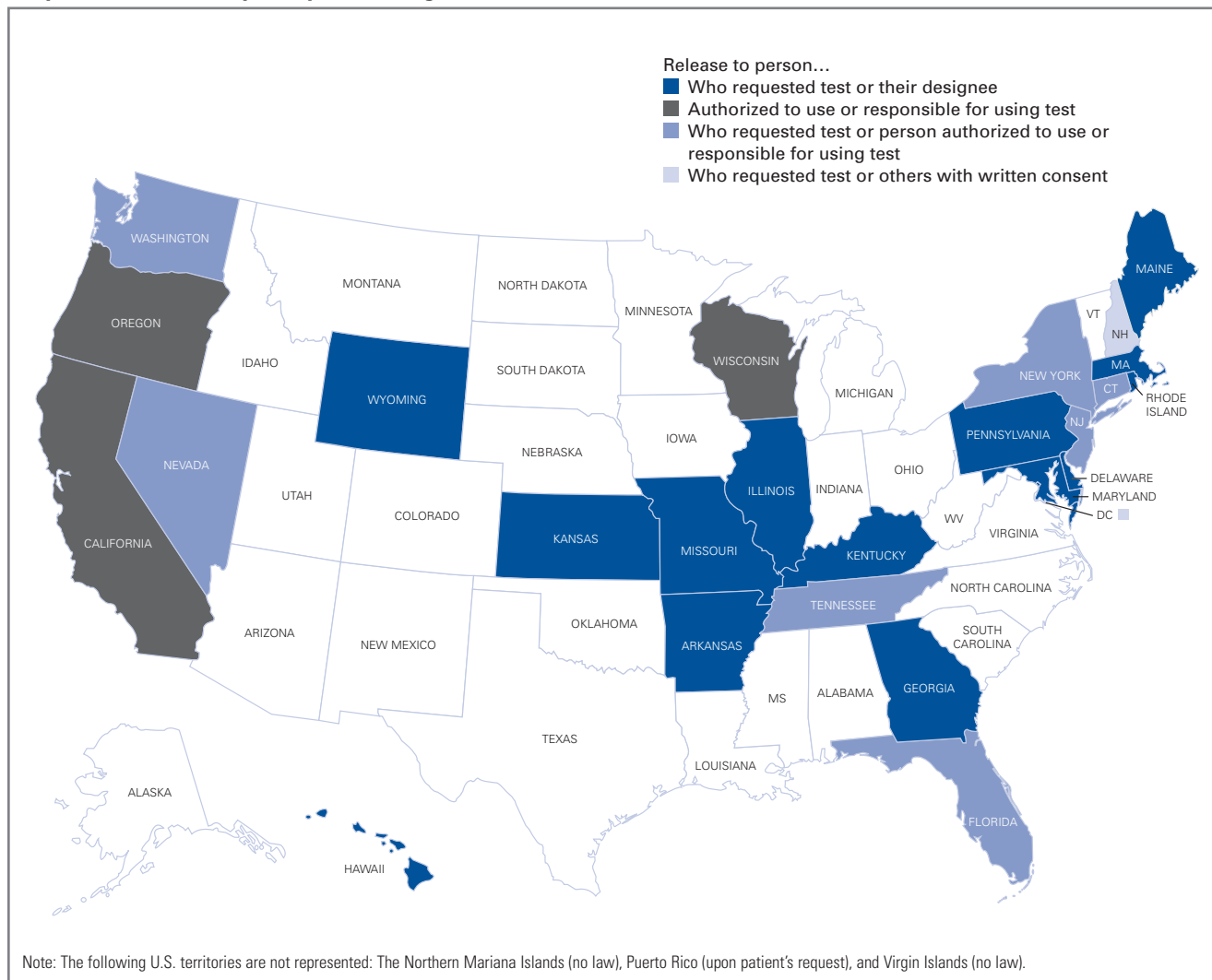
As states pursue widespread adoption of HIT and electronic HIE in partnership with the federal government, they may need to revisit statutes that regulate this exchange. These laws may need to be reviewed, reinterpreted, and in some cases updated to reflect new electronic infrastructure and capabilities. In addition, given the important role the federal government plays in the development of HIT and HIE infrastructures and in regulating clinical laboratories, guidance from that level regarding CLIA and its interactions with state law and HIT/HIE may be particularly helpful.

II. Methods

AS A FOUNDATIONAL RESOURCE, THIS STUDY relied on a report from Georgetown University’s Health Policy Institute titled “Privacy and Security Solutions for Interoperable Health Information Exchange: Releasing Clinical Laboratory Test Results: Report on Survey of State Laws.”⁵ This report, commissioned by the Agency for Healthcare Research and Quality, summarizes the results of a

2008 nationwide survey and analysis of state clinical laboratory release laws.⁶ The licensing statutes and regulations of 26 states and territories are silent with respect to who is authorized to receive laboratory test results. Licensing laws in the remaining 29 states and territories expressly address who is authorized to receive laboratory test results. Based on the plain text of these statutes and regulations,⁷ the

Map 1. State Laws Expressly Permitting Clinical Laboratories to Release Test Results to Health Care Providers



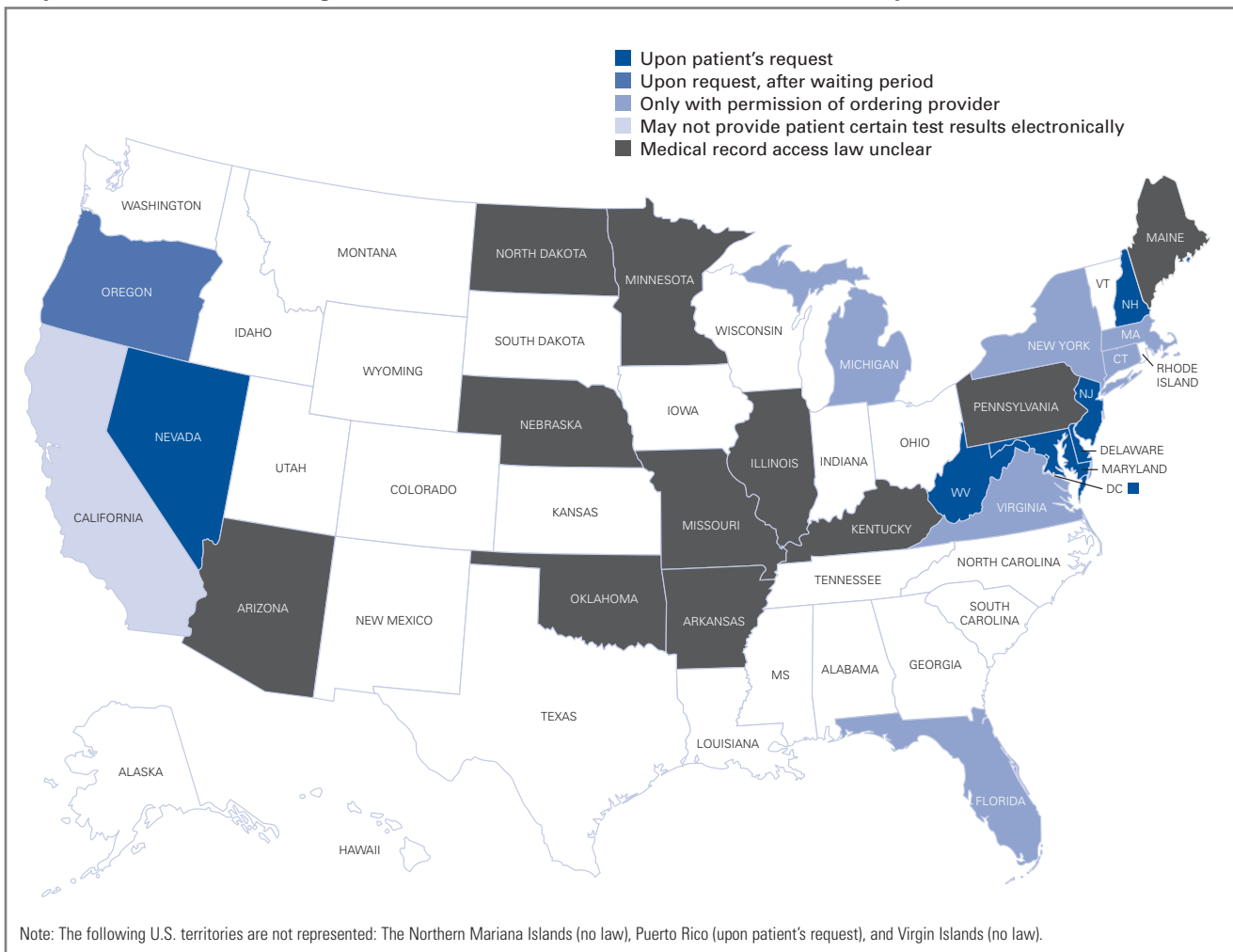
report identified six general categories of entities to which clinical laboratories may release test results, including:

1. The authorized person who requested the test;
2. Persons authorized to use, receive, or responsible for using or receiving test results;
3. An agent or designee of the person who requested the test or who is authorized to receive the test;
4. As directed by the person who requested the test;
5. The patient (no other permission required); and

6. The patient only with the permission of the person who ordered the test.

Map 1 illustrates categories 1 to 4. Any single state may permit release to one or a combination of the six categories of recipients. Of the states that specify authorized persons, eight have statutes or regulations that expressly permit clinical laboratories to release test results only to the person who requested or ordered the test. Licensing laws in seven states expressly permit clinical laboratories to release test results directly to the patient who is the subject of the test without the need to obtain the permission of the ordering provider (see Map 2).⁸

Map 2. State Laws Permitting Clinical Laboratories to Release Test Results Directly to Patient



Based on this analysis and categorization of state laws, a range of states was selected to represent the various approaches to permitting release of test results: California, Georgia, Maryland, New Hampshire, New York, and Oregon. To gain insight into each state’s experience, key informant interviews were conducted with state officials who had responsibility for, or deep familiarity with, clinical laboratory result-sharing laws in their respective states. State interviewees were identified through a variety of methods, including a Centers for Medicare

& Medicaid Services (CMS) list of CLIA state survey agency contacts, peer referrals, and other related contacts.⁹ Prior to each interview, the interviewee was provided with an interview protocol that included an informed consent form.

Following the interview, interviewees had the opportunity to ensure that the information they shared had been accurately recorded in the interview notes. A literature review and interviews with non-state stakeholders were also conducted.

Table 1. Entities to Which Interviewed States’ Licensing Laws Expressly Permit Test Result Release, 2009

	CA	GA	MD	NH	NY	OR
Authorized person who requested test		✓	✓	✓	✓	
Persons authorized to use/employ results	✓				✓	✓
Representatives/agents/designees of person who requested test or who is authorized to receive test	✓				✓	✓
As directed by the person who requested the test		✓				
Patient (no other permission required)			✓	✓		7-day waiting period
Patient only with permission of person who ordered test	✓				✓	✓

Note: This information is based solely on plain text of statute or regulation.

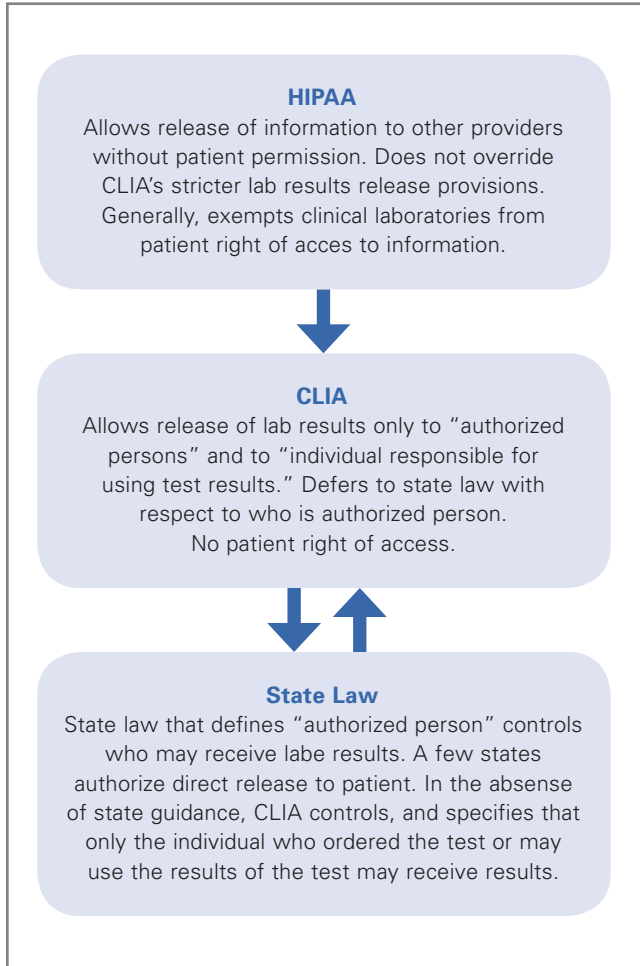
III. Federal Policy Regarding Laboratory Result Release

CLINICAL LABORATORIES NATIONWIDE ARE regulated by CMS through CLIA, its regulations, and federal interpretive guidance. The parameters of sharing and exchanging laboratory test results (either electronically or through traditional means, such as mail or fax) are determined through the interplay of CLIA, the Privacy Rule issued under HIPAA, and a multitude of state-specific laws.¹⁰ See Figure 1.

In general, CLIA permits clinical laboratories only to release test results to specified recipients including “individuals authorized under state law to order or receive tests.”¹¹ Absent state guidance, CLIA allows for the release of laboratory results to “the individual responsible for using the test results and the laboratory that initially requested the test.”¹² Those individuals responsible for using the test results, however, are not defined under CLIA. It appears that many stakeholders believe that the phrase permits disclosure of test results only to the person who ordered the test. Notably, CLIA does not expressly permit clinical laboratories to release test results directly to patients. Rather, CLIA defers to state law with respect to this issue.

While the HIPAA Privacy Rule permits disclosure of protected health information without patient permission for treatment, payment, and health care operations, HIPAA does not interfere with the CLIA framework under which laboratories may release test results.¹³ HIPAA also requires health care providers to furnish patients access to their protected health information upon request.¹⁴ But again, HIPAA does not overrule CLIA’s more specific limitations on clinical laboratories’ ability to disclose test results.^{15,16} As a result, state law (as deferred to by CLIA) generally determines whether a clinical laboratory

Figure 1. Relationships Between HIPAA, CLIA, and State Laws



may directly furnish test results to others, including other health care providers and patients.

CLIA also contains many technical standards that laboratories must follow. Of note for this discussion is the requirement that the laboratory must have an adequate system in place to “ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry . . .to final report destination.”¹⁷

IV. Issues and Findings Across States

AS DISCUSSED, STATES VARY WIDELY ON THEIR laboratory statutes and regulations, both expressly (as evidenced by state statute, regulation, or written interpretation) but also in practice and philosophy. The goals of this project were therefore to go beyond the express differences in state laws previously identified and to: (1) engage states in their current thinking on laboratory release law; (2) facilitate a discussion on various perspectives; and (3) identify the policy issues that might promote or impede full exchange of laboratory test results. Through these discussions, several issues emerged that may be helpful to state and federal policymakers as they pursue statewide HIE.

Care Coordination Among Providers

While HIPAA generally supports the coordination of care by permitting most providers to share health information for treatment without the patient's consent, CLIA as well as laws in many states treat clinical laboratories differently. These laws often require that laboratory test results be delivered to the authorized person before these results can be shared.

Of the states that define an “authorized person,” 16 expressly permit release of laboratory results either to the person who ordered the test or to those authorized by the ordering provider.¹⁸ Georgia's laboratory statute reads, in part: “The results of a test shall be reported only to or as directed by the licensed physician, dentist, or other authorized person requesting such a test.”¹⁹ Interviews with Georgia officials indicated that this language has been strictly interpreted to mean that laboratory test results flow only through the ordering provider or their designee. Others, including treating physicians or specialists

and the patient, must contact the ordering physician's office to obtain test results.

Interviewees saw this approach as potentially troublesome. For instance, statutory limitations such as Georgia's may limit the availability of test results to providers in emergency care settings. Some patient frustration was also noted in Georgia, particularly among elderly people, many of whom have multiple chronic conditions and an interest in seeing information shared more efficiently among multiple care providers.

California's laboratory release law has been interpreted on the more restrictive end of this spectrum. The statute holds that “(a)ny 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.”²⁰ Although on its face, the law appears to allow disclosure to any licensed provider, California authorities interpret this law narrowly as permitting laboratories to release test results only to the licensed provider who ordered the test. Discussion with California CLIA authorities emphasized that, for laboratory information, protecting the privacy and security of an individual's information was paramount. These officials viewed the ordering health care provider as the “gatekeeper” of health information, ensuring that only those actively involved in patient care have access to laboratory test results. California policy reflects these concerns. See sidebar, page 8.

In contrast, other states have interpreted laboratory test result laws in a manner that may facilitate care coordination. Oregon's statute permits

Laboratory Result Release in California

California law allows laboratories to accept test orders and release test results only to individuals licensed under applicable California law, and to the representatives of such individuals. Once laboratory results have been released to the licensed ordering provider or representative, the provider must either directly supply the patient with the test results or arrange for the delivery of test results to the patient, if results are requested. A clinical laboratory may convey test results in electronic form directly to a patient only if:

- The patient has consented to receive test results by Internet posting or other electronic form in a manner consistent with the Confidentiality of Medical Information Act (CMIA);
- The health care provider who ordered the test has arranged with the laboratory to provide the test results directly to the patient;
- The health care provider who ordered the test has deemed electronic release to be appropriate; and
- The provider has reviewed the test results.*

California law contains additional restrictions against the release of information by providers using electronic means. California law contains an explicit prohibition against sharing the following test results electronically with the patient:

- 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.†

*California Health and Safety Code, Section 123148.

†California Health and Safety Code, Section 123148(f).

laboratories to report test results 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.”²¹

From 1969 through 2003, this statute had been interpreted similarly to laws in California and Georgia as allowing access to laboratory results only through the ordering provider. In 2003, the Oregon Attorney General’s office revised its opinion to better align the statute with HIPAA. As currently construed, Oregon law allows (but does not require) clinical laboratories to release results to any and all providers involved in the treatment of the patient.²² Laboratories therefore must develop their own protocols and procedures for determining and confirming that a requesting provider is, in fact, involved in the treatment of the individual with whom the test result is being shared.

In the 26 states that are silent as to whom a laboratory may release test results, CLIA alone controls.²³ CLIA language permits release to the authorized person (defined by state law) and “if applicable, the individual responsible for using the test results....” For the states that are silent on laboratory data release and therefore defer to CLIA, the definition of “individual responsible for using test results” is unclear. Interpretation of this phrase to mean that non-ordering providers involved in the treatment of the individual (as licensed by state law and within their scope of practice) can access test results directly from the laboratory would allow better care coordination.

Policy Considerations

- With respect to states that permit release only to the ordering provider (and their agents), allowing all treating providers to access laboratory results directly from the laboratory may be a vehicle for improving coordination of care.
- Guidance on accepted mechanisms that laboratories may use to ensure the identity of the provider requesting test results and the provider’s relationship to the patient may alleviate some of

the concerns about laboratories' ability to preserve confidentiality.

- Federal guidance on interpreting CLIA to allow access to other treating providers may significantly improve care coordination and other health system improvement benefits associated with HIE in the states that do not define “authorized person.”

Patient-Centered Care

Health care providers, state policymakers, payers, and insurers are increasingly looking to involve patients in self-care, decisionmaking, prevention, and the management of chronic illness.^{24,25} An industry has grown in recent years to offer tools and electronic platforms to assist providers and patients in partnering through office-based patient education and the use of self-management tools to assist people at home in tracking and managing their own care.²⁶ Issues regarding the direct-to-consumer laboratory testing industry, while outside the scope of this paper,

were raised repeatedly as emerging issues by state legislators. See box below.

Aligning with this patient-centered care perspective, recent studies demonstrate that patients want to receive laboratory test results, and are more satisfied with their care when they do.^{27–31} However, only seven states have licensing laws that allow direct access to laboratory test results by the patient.³² Once a doctor or other health care provider has received laboratory results from a clinical laboratory, patients have the right under HIPAA to access their laboratory results through that provider. Highly divergent attitudes on the practice of direct release of laboratory results to patients were noted in interviews with key informants.

New York State law, for instance, requires a health provider's written consent to issue reports to patients except for a few standard test results such as blood type and direct-to-consumer test results. New York's Clinical Laboratory Evaluation Program director reinforced the importance of this framework: The ordering physician is the laboratory's client, and test

Direct-to-Consumer and Internet Laboratory Service

Over-the-counter testing kits that entail mailing specimens to a laboratory for analysis have long been available to detect certain conditions, including drug use and some sexually transmitted diseases. In recent years, through the use of online services, the range of conditions that consumers can test for without a physician's direct involvement has greatly increased. From region-specific allergen profiles to genetic analysis, consumers are able to purchase over 900 different tests and profiles without ever meeting a physician.

Internet laboratory services present new challenges for state regulators. As a result of ambiguities in legal interpretation, some laboratories may be in violation of state laboratory testing and information exchange laws and regulations, including ordering tests without a provider's prescription, cross-border information exchange, direct release to consumers, and failure to follow state licensing/certification procedures. Concern has also been expressed about the increasing availability of testing without physician involvement.

Several states have a growing list of specific tests that can be performed, and test results released, directly to consumers. Some states have also been proactive in regulating laboratories operating in this marketplace. In California, laboratories that offer testing for residents are contacted by the Department of Public Health's Division of Laboratory Science and instructed on the requirements for doing business in the state. California requires that the laboratory must be licensed in California if it is testing California patients. In addition, California requires that there be a physician order, and that results be reviewed by the authorized person before they are released to the patient.

results belong to the provider, not the patient. In fact, laboratory practices that provide patient-specific interpretation of test results directly to the patient are considered a “value-added service,” and specifically prohibited under New York’s anti-kick-back laws.

Concerns were expressed in interviews with state CLIA representatives about direct patient access to laboratory results. Several of the representatives were concerned about patients’ ability to understand complex laboratory reports because results are often expressed in ranges; they must be interpreted in relationship with other medical conditions, treatments, or medications; they may indicate different issues for people with co-morbid conditions; and they may have different significance for various age groups. Also frequently cited was the concern that patients receiving difficult diagnoses would be harmed by unfiltered test results, and that liability (to physicians or to the laboratories) could be associated with this harm. Interviewees raised additional concerns about the potential for laboratories with uninformed or unscrutinized consent from patients to sell aggregate information for other purposes outside health care delivery.

At the other end of the spectrum is New Hampshire’s laboratory release law and associated attitudes on who controls and “owns” test results. New Hampshire law requires testing laboratories to provide a copy of results to the patient or patient’s personal representative upon request. Under this law, the information belongs to the patient; a laboratory may not release test results to anyone else, other than the provider who ordered the test, without the patient’s consent. In addition, further release of the record by the patient’s physician can only occur with patient consent.

Oregon charts a middle course between patient and provider control of laboratory results. The state permits release of results directly to the patient seven

days after receiving the request from the patient. Release of the test results prior to the end of the seven-day period requires a written authorization from the ordering physician. Thus, patients may obtain information without the provider intermediary if necessary or desired (after a waiting period), and the provider is also given time to make contact and relay information if that course of action is desirable.

Policy Consideration

Patients are increasingly involved in and responsible for managing their own care. States should consider reviewing their laboratory release laws and regulations in the context of the patients’ interests, assuring that appropriate mechanisms and timeframes allow them access to health care information including laboratory results.

Emerging Trends in HIE

Most state laws addressing laboratory release were written prior to the use of EHRs, patient registries, e-prescribing, and many other tools that electronically exchange health information to improve the quality of care and reduce cost. The influx of ARRA funding and increased focus by state leadership will hasten the spread of these new technologies and support the capacity of providers to appropriately share important health information for these purposes.

Laboratory release laws that largely pre-date the widespread use of HIE can be, but need not be, barriers. Some states that have revisited these laws within the last decade address electronic communication in their revised statutes in varying ways. Interpretation of laboratory release law hinges on how electronic HIE is being implemented and how it is viewed by state regulators. Point-to-point exchange may be seen as analogous to a mailbox

or telephonic communication and supported by existing language that allows the laboratory to “send” or “report” to the provider. Health Information Organizations (HIOs) and Regional Health Information Organizations (RHIOs) that hold health information in a clinical data repository or, through a federated system, aggregate data from multiple sources and make it available simultaneously to multiple providers, may be viewed more as a third party or business associate. For this kind of exchange, states may want to look at the interpretation of language found in many state statutes that allows for delivery of test results to a provider’s agent, representative, or designee.

New York’s statute allows communication of results to the patient either by mail or electronically in certain situations. When discussing regional HIE activities, New York representatives opined that laboratories may be reluctant to routinely transfer reports to patients due to the added cost, but that an electronic exchange would facilitate this information-sharing by minimizing these costs to laboratories. However, specific authorization would still be required from the patient for this type of exchange.

In California, the authorized practitioner is a conduit for the electronic exchange of laboratory results. The state’s laboratory release law includes several provisions that may present barriers to HIT and HIE:

- It requires additional authorization for laboratory test results to be released to patients via electronic transmittal; and
- It restricts the types of laboratory tests that may be transmitted, deeming certain test results too sensitive for this type of conveyance, even if the ordering provider has reviewed the results.

In effect, the California law creates a special class of information that exceeds the HIPAA privacy standards regulating all other types of personal health information.

Tennessee, in contrast, supports the HIE model with a 2007 statute that addresses the electronic transmission of test results.³³ In addition to permitting the release of results to ordering providers, the law adds “designated entities” to the list of authorized results recipients. A “designated entity” is defined as one that “performs actions or functions on behalf of the provider, payer, or patient for the purposes of creating an electronic health record.”³⁴ Stakeholders believe that this will facilitate HIE by removing ambiguity as to whether the sharing of laboratory test results with a central repository that exists for HIE purposes is permissible. Donald Horton, vice president for public policy and advocacy at LabCorp, a major clinical laboratory firm, described the Tennessee legislation as coming “close... to a comprehensive solution.”³⁵

It appears that many states have not fully engaged state laboratory oversight offices charged with oversight and implementation of CLIA and related state law in the development or deployment of HIT and HIE systems. Due to their frequent communication with their federal and state government, as well as state, regional, and national laboratory communities, these offices may be an untapped resource in identifying and resolving laboratory result exchange barriers at the state level.

Policy Considerations

- States have an opportunity to review and clarify laboratory release laws and regulations that predated advances in HIE.
- States may consider revisiting and amending statutes so they align more expressly with state HIE initiatives.

- Explicitly including the clinical laboratory regulating offices and their constituencies in HIE planning and discussions may benefit all HIE stakeholders.

Interstate Exchange of Clinical Information

Health care treatment and services routinely cross state boundaries as both patients and information become increasingly mobile. Clinical laboratories, especially in border areas, are often uncertain as to which state's laws govern their actions with regard to a cross-border patient. State stakeholders are often unclear how to approach conflicting practices in bordering states.

For example, while New Hampshire allows laboratories to release results to the patient directly, neighboring Massachusetts requires the written consent of the ordering provider in order to release results to the patient. New Hampshire's regulatory body frequently fields calls from patients in the southern part of the state who, accustomed to seamlessly conducting business on either side of the border, are frustrated by the differing treatment of laboratory results. Oregon also cited the interstate issue as one that is raised by consumers.

States' differing definitions of who is authorized to order and receive tests can be highly inconsistent from one state to another. States that define "authorized person" as a health care provider who is licensed in that particular state may not honor orders from providers across the border. National laboratories also cite the lack of consistent interpretation of state border issues as a barrier to appropriate exchange of health data across state lines.

Policy Consideration

States may want to work with neighboring states on a regional approach to laboratory release to minimize

inconsistency and promote coordination of care across state lines.

Federal Law and Interpretation

The complexities related to the legal and regulatory interpretation of laboratory result release, exchange, and use can benefit from both federal and state review and guidance. The many issues revealed by informants and state stakeholders during this study highlighted this juxtaposition.

It was clear that in order to facilitate appropriate electronic exchange of laboratory results, attention must be paid not only to the impact of these laws and regulation on policymakers, physicians, and patients, but also on laboratories. For example, several key stakeholders noted the CLIA requirement that laboratories have in place systems that verify accurate receipt of laboratory reports at the point of final destination.³⁶ In an age of constant electronic innovation, health information may be delivered to a computer screen in a primary care practice, to a laptop in a remote location, to a physician's PDA, or to an HIO that then applies the data to any number of situations. These stakeholders are concerned that requiring laboratories to verify that the actual view of laboratory results reporting at the terminal includes all CLIA-required data elements in all scenarios has become increasingly onerous.

Moreover, as the federal government invests in EHRs through the ARRA initiatives, the "meaningful use" requirements for providers eligible to receive CMS EHR incentives have many EHR vendors rapidly adapting their systems to comply. Laboratory results retrieval is necessarily a large component due to the importance in medical decisionmaking. However, the management of CLIA requirements, laboratory results presentation, and result-sharing capabilities of the EHR will be needed to assure the goals of HIT are achieved.

Policy Considerations

- Federal guidance that interprets CLIA in the context of the HIE and HIT requirements tied to ARRA funding for states could assist states in implementing these programs in a manner that ultimately achieves the goals of a high-quality, cost-effective health care system.
- Interpretive guidance by CMS, that provides for standards and certification for laboratory information exchange, as opposed to the form of retrieval, could improve access to laboratory data across systems.
- Additional guidance on the management of laboratory information such as designation as to which other providers may receive results through the EHR certification process may be an effective and cost-efficient mechanism to promote widespread adherence.

V. Conclusion

LABORATORY TEST RESULTS ARE A CRITICALLY important source of information for medical decisionmaking and an integral data component of EHRs and electronic HIE. Both state and nationally convened groups have recognized that laws governing electronic laboratory results use and exchange must be reviewed and made compatible in order to facilitate the benefits of HIT and HIE. Many states are currently revisiting, re-interpreting, and in some instances amending statutes to move statewide HIT and HIE efforts forward. The federal government also has an opportunity to provide states with guidance on the appropriate interpretation of federal law to assure that laboratory data is included in nationwide HIE and HIT efforts. State and federal laboratory result release laws need not impede HIE. States, in partnership with the federal government, can leverage CLIA and state laws and regulations to promote appropriate HIE and use these tools to support care coordination, patient-centered care, and broad health care delivery system improvements.

Endnotes

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6. The survey reviewed the clinical laboratory licensing laws of the 50 states, Washington, D.C., as well as the United States territories, Guam, Puerto Rico, Northern Marian Islands and the Virgin Islands. These jurisdictions are referred to collectively as “the states.”
7. All figures in the Georgetown study refer to the express plain language of state statutes and regulations. The study did not address and the figures do not include an analysis of whether such provisions might implicitly permit the release of test results to others.
8. Licensing laws in an additional seven states permit laboratories to release test results to patients only upon the request of or with the permission of the person who ordered the test.
9. Centers for Medicare & Medicaid Services. *Clinical Laboratory Improvement Amendments (CLIA) State Survey Agency Contacts* (www.cms.hhs.gov/CLIA/downloads/CLIA.SA.pdf).
10. The pertinent parts of HIPAA, commonly referred to as the “administrative simplification” provisions, are codified at United States Code, title 42, §1320d–1320d-9.
11. Code of Federal Regulations, title 42, §493.2 (defining “authorized person”) and §493.1291(f) (providing that “[t]est 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.”)
12. Code of Federal Regulations, title 42, §493.1291(f).
13. Code of Federal Regulations, title 45, §164.506.
14. Code of Federal Regulations, title 45, §164.524.
15. U.S. Department of Health and Human Services, *Standards for Privacy of Individually Identifiable Health Information: Final Rule*, Federal Register, 65; 82462 at 82482, December 28, 2000.
16. HIPAA specifically exempts from this right to access, protected health information that is subject to CLIA to the extent that access to the patient would be prohibited by law. HIPAA also exempts from the right to access protected health information that is maintained by a laboratory that is exempt from CLIA. See Code of Federal Regulations, title 45, §164.524(a)(1)(iii)(A) and (B). 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. Code of Federal Regulations, title 42, §493.2 (defining *CLIA-exempt laboratory*) and §493.3(a)(2)).
17. Code of Federal Regulations, title 42, §493.1291.
18. Figure includes states that permit release in the following categories as identified by Georgetown: “to authorized person who requested test,” “to agent or designee of person who requested test,” and “as directed by the person who requested the test.” Release directly to patients is not taken into account in this figure.
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