

Legal Considerations in Electronic Laboratory Reporting

A Report of the
CSTE-CDC Electronic Laboratory Reporting Task Force
Legal Considerations Workgroup

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by

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DISCLAIMERS

This report and the information contained therein do not constitute legal advice. States or other entities considering adoption of ELR-related laws should seek the assistance of their legal counsel.

This report represents the consensus of the CSTE-CDC Electronic Laboratory Reporting Task Force Legal Considerations Workgroup. It should not be interpreted to represent the views of any individual member of the Workgroup.

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EXECUTIVE SUMMARY

In late 2010, the Council of State and Territorial Epidemiologists (CSTE), in collaboration with the Centers for Disease Control and Prevention (CDC), launched the CSTE-CDC Electronic Laboratory Reporting Task Force. To do this work, the Task Force established the Legal Considerations Workgroup. The Workgroup consisted of 22 members, including members from CSTE, the Association of Public Health Laboratories (APHL), and CDC. Members brought a variety of expertise, including surveillance, informatics, epidemiology, public health, and law. The initial goal of the Task Force was to develop a model state law for electronic laboratory reporting. Later the Task Force determined that drafting a model law was premature and it replaced that goal with a broader one--to investigate the role of legal considerations in the adoption of electronic laboratory reporting in the states.

In June 2011, CSTE launched a 50-state assessment survey of state laws and legal issues related to electronic laboratory reporting. CSTE sent the assessment to all 50 state epidemiologists with a request that it be completed with input from the state health department's attorney. At the conclusion of this survey, CSTE shared the results with the Workgroup. Subsequently, the Workgroup selected eight states for in-depth legal research, including a comprehensive review of each selected state's notifiable disease case reporting laws, and informal interviews with state epidemiologists and public health attorneys.

Results of the interviews and the CSTE survey indicated that during 2011, 27 of 49 responding states (55%) had laws interpreted by the respondent as regulating or governing electronic laboratory reporting for any reportable disease or condition, and 17 states (35%) had laws interpreted by the respondent as requiring electronic laboratory reporting. All states had laws that require general disease reporting, but substantial variability existed in the diseases and conditions to be reported, reporting mechanisms, time-frames for reporting, persons required to report and agencies to receive reports. Also, substantial variation existed in the interrelationship among statutes, regulations, and public health policies regulating disease reporting, including electronic laboratory reporting. The Workgroup concluded that, as a general matter, laws do not constitute a major obstacle for the adoption of ELR in the states, although a minority of states had found it necessary to change their laws to accommodate ELR. The Workgroup made seven recommendations related to ELR law in the states, including additional research and analysis to determine the robustness of different regulatory structures on disease reporting.

“From a legal standpoint, the experience in [our state] has been that the challenge lies in the reporting of communicable disease, not the mechanism of the reporting.”

-- A state epidemiologist, responding to a question in the CSTE State Assessment Survey of ELR Law, August 2011

I. INTRODUCTION

Electronic laboratory reporting (ELR) is the “direct, automated messaging of reportable disease laboratory information from clinical laboratory information management systems ... to the appropriate public health jurisdiction’s ... system (1).” ELR is already beginning to improve the timeliness and completeness of notifiable disease case reporting in state and local health departments. Ultimately, ELR can reduce the human effort required to notify public health authorities about reportable diseases uncovered in laboratories, and improve the speed and completeness of reporting (1).

The inclusion of ELR as a “meaningful use” objective under the Health Information Technology for Economic and Clinical Health (HITECH) Act served as a catalyst to accelerate its adoption (2). The Meaningful Use incentive program was launched by the Centers for Medicare & Medicaid Services (CMS) as the “Medicare and Medicaid Programs: Electronic Health Records Incentive Program.” The purpose of this program is to provide incentive payments to eligible professionals, eligible hospitals, and Critical Access Hospitals (CAHs) participating in the Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified electronic health records (EHR) technology, including ELR (3).

On May 10, 2010, the Council of State and Territorial Epidemiologists (CSTE) and CDC inaugurated the CSTE-CDC Electronic Laboratory Reporting Task Force.ⁱ The vision of the Task force was that

All labs (public and private) conducting clinical testing identify laboratory results that indicate a potential reportable condition for one of the jurisdictions they serve, format the information in a standard manner, and transmit appropriate messages to the responsible [public health] jurisdiction. [All] jurisdictions can and do receive and utilize the data (4).

The initial priorities of the new task force were to: 1) develop a strategic plan for ELR coordination among states, CDC, and the Office of the National Coordinator for Health Information Technology (ONC), 2) develop, evaluate and endorse standards to reduce variation in what is required for ELR across the nation, 3) collaborate with the Association of Public Health Laboratories (APHL) to assure that laboratory messages (formats, vocabulary, and transmission) and National Electronic Disease Surveillance System

ⁱ See

<http://www.cste.org/dnn/ProgramsandActivities/ELRTaskforceWorkgroupActivitiesandProducts/tabid/564/Default.aspx>.

(NEDSS) messages are consistent and compatible, in order to leverage the laboratory message infrastructure to communicate with clinicians, CDC, or state/local surveillance systems; 4) develop a model state law for electronic laboratory reporting and make available for other states to adopt;ⁱⁱ and 5) articulate what resources are needed to implement state/local ELR through a needs/capacity assessment CDC program.

The Task Force established five workgroups to address these priorities and charged each workgroup with addressing a specific aspect of ELR, ranging from establishing the value of ELR and the application of the “meaningful use” regulation, to ELR standards and management. The third of the workgroups was termed the Model Law and Policy for ELR Workgroup, later renamed as the Legal Considerations Workgroup. The Task Force named two public health experts to co-chair this workgroup. Representing CSTE was David Blythe, MD, MPH, the Maryland State Epidemiologist; representing CDC was Frederic E. Shaw, MD, JD, the Associate Director for Science of CDC’s Public Health Surveillance and Informatics Program Office (PHSIPO).

The Legal Considerations Workgroup acquired several additional members from CSTE, APHL, CDC, and other organizations, held a series of organizational meetings, conducted preliminary literature research, and informally discussed ELR-related laws with CSTE members and others who had experience with such laws in their own states. One of the immediate actions of the Workgroup was to recommend to the Task Force a change in the objectives of the Workgroup. The members of the Workgroup felt that creation of a model law was premature, and that the objective of drafting a model law on ELR should be replaced by a broader goal of considering the legal implications of ELR. The Task Force accepted this recommendation. In June 2011, the Workgroup received data from an assessment survey on the status of ELR law conducted by CSTE. The Workgroup subsequently conducted in-depth legal research and interviews with state epidemiologists and public health attorneys in eight selected states.

This document serves as the Workgroup’s final report to the Task Force. The report first provides background information on the legal basis for electronic laboratory reporting, then outlines the formation and charge of the Workgroup, reviews the methods used by the Workgroup to acquire the information needed, presents the findings of its work, discusses certain results, and makes some recommendations for the future.

II. BACKGROUND ON THE LEGAL BASIS FOR ELECTRONIC LABORATORY REPORTING

In the United States, disease reporting is almost entirely a matter of state law. All states have laws that require certain entities to report diseases and conditions that appear on an official list, and these laws set out the manner and timing of information to be reported. For decades, CSTE has taken the lead in establishing the list of nationally notifiable diseases. CDC’s role is limited and mainly remains one of coordination and consultation with CSTE, compilation of national statistics, and providing funds to the states to assist with disease reporting activities (5).

ⁱⁱ This was later revised. See text.

Although ELR is relatively new in public health history, public health disease reporting extends back in time to the 17th century and the British Colonies. Some legal elements of disease reporting were established in Rhode Island as early as 1741, and broader disease reporting laws became more common in the United States in the late 19th century (6). The source of the states' authority to require disease reporting is the "police power," the inherent power of sovereign governments to protect their inhabitants' public safety, health, and morals (7). The states' police power may be manifested in several ways: statutes adopted by the state legislatures, executive orders from the governor or other executives, administrative regulations (rules) issued by state executive agencies, and other directives from state health officials that carry the force of law.

Enactments of the Legislature

Statutes are expressions of the will of democratically-elected legislatures and they form the basic governmental commands by which the people and their organizations must live. All states have at least one statute that authorizes the collection of information needed to maintain the health of the public. However, the specificity of the authorization varies greatly from state to state. Some statutes are nonspecific and give a broad authorization to the state health department to do what is necessary to prevent and control diseases in the population. For example, a public health statute in Kentucky states,

The secretary shall formulate, promote, establish, and execute policies, plans, and programs and shall adopt, administer, and enforce throughout the Commonwealth all applicable state laws and all administrative regulations necessary under applicable state laws to protect, develop, and maintain the health, personal dignity, integrity, and sufficiency of the individual citizens of the Commonwealth and necessary to operate the programs and fulfill the responsibilities vested in the cabinet (8).

This statute contains a delegation of authority to the executive branch of government in Kentucky to "adopt, administer, and enforce" administrative regulations necessary to carry out the mission set forth in the statute. Many states have similarly broad statutes that authorize the executive branch of government to create necessary administrative regulations. Through these delegations of authority, the legislature empowers the executive branch to fill in the details of the legislature's general authorization.

In addition to broad statements of mission and delegation of authority to the executive branch, states generally have statutes that set out requirements for disease reporting. The form of these statutes varies greatly from state to state, but they all set out in general terms the entities that must report, the types of diseases that must be reported, and the method of reporting. For example, Florida's statute states,

Any practitioner licensed in this state to practice medicine, osteopathic medicine, chiropractic medicine, naturopathy, or veterinary medicine; any hospital licensed under part I of chapter 395; or any laboratory licensed under chapter 483 that diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the Department of Health (9).

These reporting statutes also vary greatly from state to state as to their specificity and the types of entities that must report. Generally these statutes govern all disease reporting in the state, regardless of the method of reporting.

In addition to general reporting statutes, some states have statutes that are specific to laboratory reporting, and some states have statutes that are specific to ELR. For example, a statute from New York sets out with some specificity how electronic reports shall be sent:

Whenever a clinical laboratory or blood bank is otherwise required by this chapter to report evidence of a disease or health condition to the commissioner or a local health officer, the laboratory director shall report the test results and such data elements as are determined by the commissioner to be necessary as authorized by law. All reports shall be sent electronically to the department in a standards based electronic format, using a network, communications protocol, clinical syntax and vocabulary all as determined by the commissioner to be compatible with national health information standards promulgated by the federal centers for disease control and prevention and the department of health and human services (10).

Two facets of this statute are especially notable. First, the statute authorizes the commissioner of health to determine what data elements shall be part of the electronic laboratory report and the standards that shall be used. Second, the statute specifies that reports shall be compatible with national health information standards promulgated by CDC and the U.S. Department of Health and Human Services.

Some statutes approach a greater level of specificity, such as this one passed in 2011 in Connecticut, which specifies the time period within which a laboratory must report to the health department, the number of findings that qualifies a laboratory to be subject to the ELR requirement, and also gives authority to the commissioner of health to approve the format of electronic laboratory reports: ⁱⁱⁱ

A clinical laboratory shall report each finding identified by such laboratory of any disease identified on the commissioner's list of reportable laboratory findings to the Department of Health not later than forty-eight hours after such laboratory's findings. A clinical laboratory that reports an average of more than thirty findings per month shall make such reports electronically in a format approved by the commissioner. Any clinical laboratory that reports an average of less than thirty findings per month shall submit such reports in writing, by telephone or in an electronic format approved by the commissioner (11).

ⁱⁱⁱ The CSTE State Reportable Conditions Assessment collects data annually on reporting requirements for infectious and non-infectious conditions that must be reported to public health. A perusal of the Assessment results shows huge variation from state to state. See <http://www.cste.org/dnn/programsandactivities/publichealthinformatics/statereportableconditionsqueryresults/tabid/261/default.aspx>.

States have made different decisions about how disease reporting requirements should be embodied in law. Some have elected to place general requirements in statute and to delegate the details to the commissioner of health. Others have elected to place a higher level of detail in the statute. When the legislature, through statute, delegates the details of a requirement to the commissioner (or sometimes to another official or to the department as an entity), it becomes the job of the commissioner to “put flesh on the bone,” to promulgate the requirement in a level of detail that regulated entities can understand and obey. The commissioner has two options. First, she can promulgate an administrative regulation under the authority given to her in the statute. Second, she can promulgate the requirement through some form of official policy making, such as a letter or some other issuance. The commissioner’s authority to make official policy, like her authority to promulgate administrative regulations, must come from a delegation in statute.

Promulgation of Administrative Regulations

Administrative regulations (also often called “rules”) are created by an action of an executive agency under a statutory delegation from the legislature. To create a regulation, executive agencies must follow a specific procedure that is set out in statute (e.g., the state’s administrative procedures act), which usually includes a public notice of the proposed regulation, public comments, deliberation of the comments by the agency, and publication of a final regulation. Regulations have the force of law and generally carry penalties for disobedience.

Disease reporting regulations vary greatly from state to state in their organization, structure, and level of specificity. In contrast to statutes, regulations usually are much more detailed and technical. A disease reporting regulation often describes exhaustively the specific reporting procedure to be used (e.g., method of communication), the required time frame, and all the many details that are needed by providers in order to properly comply. For example, a New Hampshire regulation, N.H. Code Admin. R. He-P 301.02 (2012), provides great detail about which diseases are reportable in the state and how and when they shall be reported (e.g., “any laboratory test indicative of or highly correlated with infection of ... *Clostridium botulinum*” [botulism] within 24 hours”) (12).

Many states have adopted specific regulations on the electronic laboratory reporting of reportable diseases. For example, a regulation from Nebraska reads:

Beginning no later than three months after the effective date of these regulations, all laboratories performing clinical testing on Nebraska residents must electronically report laboratory test results for the diseases specified in 173 NAC 1-004 and the tests specified in 1-005.02. This may be accomplished either through manual online data entry into Nebraska's electronic disease reporting system, or through automated electronic laboratory reporting. Paper reports will be accepted only when established electronic transmission methods are inoperable (13).

A regulation from Oregon states,

(1) A licensed laboratory that...sends an average of greater than 30 records per month to the local public health administrator shall electronically send all reportable disease data to the Authority in accordance with the standards set forth in the Authority's Manual for Mandatory Electronic Laboratory Reporting, dated February 2009, and incorporated by reference. (2) Prior to reporting data electronically, a licensed laboratory shall seek and obtain approval from the Authority for its electronic reporting.... (3) A licensed laboratory that fails to seek approval from the Authority for electronic reporting or fails to obtain approval within one year from seeking approval from the Authority may be subject to civil penalties.... (14)

And a similar regulation from Massachusetts reads:

All laboratories, including those outside of Massachusetts, performing examinations on any specimens derived from Massachusetts residents that yield evidence of infection due to the organisms listed below shall report such evidence of infection directly to the Department through secure electronic laboratory reporting mechanisms, or other method, as defined by the Department, within 24 hours (15).

Executive agencies administer and execute the law; they do not create the law. Thus, as a principle of law, all regulations must be authorized in statute by the state legislature. The separation of powers doctrine, which exists in varying degrees in the states as well as the federal government, means that a state health department is not free to simply write regulations on its own authority; it must have a grant to do so from the legislature. In addition, an agency's role is not to create policy from whole cloth but to fill in details not specified by the legislature. Regulations that are not authorized by the legislature or that assume the policymaking role of the legislature may be challenged and declared invalid by a court. A case that illustrates this principle was *Boreali v. Axelrod* (71 N.Y.2d 1, 517 N.E.2d, New York Court of Appeals, 1987) in which New York's highest court invalidated anti-smoking regulations promulgated by the New York Public Health Council. In 1986, the Public Health Council adopted a far-reaching set of regulations that would prohibit smoking in a wide variety of places. The court invalidated the regulations because the Council acted on its own ideas of sound public policy instead of the ideas of the legislature. As the court said, the Council was not empowered to "write on a clean slate."

In addition to a legally valid delegation from the legislature, executive departments must adopt state regulations in accordance with specific procedures set out by the legislature in statutes generally called "administrative procedure acts." All 50 states have such acts and state health departments may only adopt regulations using the procedure set out by the state's act. For example, the Kentucky administrative procedure act states,

An administrative body may promulgate administrative regulations to implement a statute only when the act of the General Assembly

creating or amending the statute specifically authorizes the promulgation of administrative regulations...(16).

Likewise, the New Hampshire administrative procedure act states, “No agency rule is valid or effective against any person or party, nor may it be enforced by the state for any purpose, until it has been filed as required in this chapter (17).” Disease reporting regulations adopted by state health departments may be declared invalid by a court if they are adopted using a procedure that is contrary to the requirements of the state administrative procedure act. A regulation can also be declared invalid if it conflicts with a statute, is beyond the statutory authorization delegated by the legislature, or tries to modify or vitiate a statute.

Official Actions of the Commissioner or Department

Some states have placed requirements relating to disease reporting not in statute or regulation, but instead in official actions of the state health department or commissioner. Perhaps the most common example of this is the list of diseases and conditions that must be reported to the state health department. These lists are intended to have the force of law, meaning that a physician or other entity could be punished for failing to report.^{iv} In some states, the commissioner, by her own action, without a change in statute or regulation, can change this list. In certain states, the commissioner's authority to change the list comes from statute. For example, Connecticut’s disease reporting statute specifically authorizes the commissioner of health to create both a list of reportable diseases and a list of reportable laboratory findings:

The commissioner shall have the power and duty to: ... annually issue a list of reportable diseases, emergency illnesses and health conditions and a list of reportable laboratory findings and amend such lists as the commissioner deems necessary and distribute such lists as well as any necessary forms to each licensed physician and clinical laboratory in this state (18)

In some other states, the specific authority to issue such a list comes not from statute but from regulation. For example, in Tennessee, the following appears in the state administrative code:

List – Means the List of Reportable Disease and Reporting Mechanisms as set forth by the Commissioner.... All healthcare providers and other persons knowing of or suspecting a case, culture, or specimen of a reportable disease or event shall report that occurrence to the Department of Health in the time and manner set forth by the Commissioner in the List.... The Commissioner shall re-evaluate, update, and post the List at least annually and from time to time as appropriate. The Commissioner shall post the annual update on or before November 15th of each year and this new List shall become effective starting January 1st of the following year. If the Commissioner posts an updated List more

^{iv} Only rarely do states attempt to punish physicians or other health care providers who fail to report (5). In some states, the penalty for failure to report is spelled out. In other states it is not.

frequently than on an annual basis, then the updated List will become effective on the date stated in the List. The List shall be available online at the Department of Health's web page and in print (19).

The Tennessee commissioner's authority to issue a reportable disease list is not specifically mentioned in statute as in Connecticut, but instead derives from the commissioner's general authority to "promulgate and publish such rules and regulations as may be necessary to prevent the spread of contagious or communicable diseases in order to protect the public health and welfare (20)." When the Tennessee commissioner updates and posts the list as specified in statute, he or she does not go through the rulemaking requirements of the Tennessee Administrative Procedures Act.

Judicial Review

A principle of administrative law is that all regulations, state or federal, are subject to judicial review, i.e., examination by courts. An aggrieved party may go to court and challenge the validity or application of an administrative rule, and the court has the power to review it, and if needed, invalidate it. The state administrative procedure act often specifies exactly how and when judicial review shall take place. For example, New Hampshire's Act allows the validity or applicability of a rule to be determined in an action for declaratory judgment in superior court, even if the rule has not been officially promulgated (21).

Legal Challenges to State Disease Reporting Requirements

Challenges to state regulations may be based on a variety of alleged errors by the defendant health department. A plaintiff might allege that the department did not have an adequate delegation of authority from the legislature to adopt the regulation, or that the health department failed follow the requirements of the state administrative procedure act or its own departmental procedures, or that the factual basis on which the department adopted the rule was flawed, or that the rule was unjustified in some other way as a matter of law.

However, such challenges are rare. The Workgroup searched the law for cases in which a party sued a state government or health official to slow or stop a disease reporting requirement. The Workgroup found no such cases.^v As the Workgroup members asserted and confirmed during in-depth interviews, most state health departments have a longstanding and cooperative relationship with the laboratories, hospitals, or doctors to be regulated and have worked out any differences with them long before beginning the regulatory process. Nearly all of this is done informally, but formal rulemaking provides additional opportunities for laboratories and other affected parties to comment on proposed regulations. Furthermore, even if an aggrieved party did go so far as to bring a challenge in court, they swim against the stream of "judicial deference." When courts review administrative regulations on questions of law, they show deference to the expertise and judgment of state administrative agencies, and are reluctant to overturn administrative regulations that the state health agency feels are needed for the health of the public (22). On the other hand, this deference is not unlimited (23).

^v In one case, an AIDS advocacy group unsuccessfully sued the health commission to prevent it from eliminating anonymous HIV testing (*ACT-UP Triangle v. Commission for Health Services of the State of N.C.*, 345 N.C. 699, 483 S.E.2d 388, 1997).

Use of Regulation vs. Statute vs. Official Action

When states establish disease reporting requirements, they can choose to place them in statute, in regulation, or in an official action of the department or commissioner of health.^{vi} Each has its own advantages and disadvantages. Placing a disease reporting requirement in statute lends it the weight of the democratic legislative process. Statutes have value as a symbol of the preferences of the people and thus may be seen by regulated entities as less challengeable (24). Another advantage of the statutory route is that it is inherently more stable than a regulation. For example, some legislatures meet less than annually and getting a matter before it is difficult.

The legislative route also has disadvantages. The same ponderousness that lends stability to a statute makes a statute relatively difficult to create. Public health bills must compete with other bills from all other parts of government—roads, taxes, criminal laws, etc. Health departments sometimes fear taking policy changes to the legislature because the very process of introducing a bill may open settled statutes to unwanted amendments or repeal. The desired policy change might get lost in a flurry of politics and the result might be worse than if the bill had never been introduced.

Regulations, too, carry advantages and disadvantages. One of the advantages is that they often can be adopted more quickly than statutes. In some states, a regulation can be adopted entirely by an action of the health department in a relatively simple, quick, “notice and comment” rulemaking process, although in some states some form of approval is needed by the legislature, the governor, or another lawmaking body. Also, the rulemaking route often is seen as less political than the adoption of statutes, in part because the process takes place at a distance from the inherently political legislative process.

Another advantage of rulemaking is that it is better suited to the adoption of technical requirements than legislation. The health department almost always has more expertise in the technical details of the regulatory issue than the legislature. For example, while experts at the health department are well able to determine technical standards for the transmission of electronic laboratory report messages, the legislature would have little knowledge or expertise on this subject.

But rulemaking also has disadvantages. It is not always easy and quick. In some states, the legislature retains oversight over the rulemaking procedure and all proposed regulations must cycle through a legislative committee. For example, in some states all new regulations must be approved by a legislative committee. Governors, too, can impact the rulemaking process. For example, in Florida, newly-elected Governor, Rick Scott, on his first day in office in January 2011 issued an executive order suspending agency rulemaking and created an additional level of executive review before a rule could proceed through the rulemaking process. In states where rulemaking is very difficult, the health department might have an easier time achieving a new statute than a new rule.

A third option for regulating disease reporting is for the health department, state board of health, or other official entity to simply issue an official order. In some states (e.g. Connecticut) such orders are issued under a specific grant of authority from an enabling statute. An advantage to this route is that, in such states the issuance of an order need not go through the legislative process, or the rulemaking process set out in the state's administrative procedure act.

^{vi} When a new disease needs tracking, most departments have the authority to promulgate an emergency regulation very quickly, postponing temporarily some of the rulemaking procedural requirements.

In some other states, the issuance of an official order is authorized through a regulation that itself was authorized generally by a statute. In Tennessee, for example, the official list of reportable diseases is issued by the commissioner pursuant to a regulation that was adopted in accordance with the state's administrative procedure act, although the list itself is not promulgated through a rulemaking procedure.

III. THE LEGAL CONSIDERATIONS WORKGROUP

The original charge to the Workgroup, transmitted from the Task Force in October 2010, focused on the creation of a model state law for ELR. However, after early discussion in late 2010, the Workgroup determined that creation of a model law would be premature. In addition, creating a model law for ELR could entail hundreds of hours of attorney time for a benefit that was uncertain.

After the Workgroup's second meeting on November 10, 2010, the Workgroup requested that the Task Force change the name of the Workgroup to the "Legal Considerations Workgroup," and revise its charge to "identifying the most important legal issues surrounding the implementation of ELR in the states, and ... researching how selected states with illustrative or generalizable experiences have coped with such legal issues." The ultimate purpose of the group's work would be to collect information that could be used by the states to improve laws and regulations applicable to ELR, and thereby to promote states' ability to adopt ELR. In January, after receiving additional information about the resources that would be available to the group, the Workgroup made additional modifications and the final charge of the Workgroup became,

Charged with a) identifying key legal issues surrounding the implementation of ELR in the states, b) researching how selected states with illustrative or generalizable experiences have coped with such legal issues, and c) based on information acquired and if appropriate, developing recommendations for law-related products or tools useful to states that may wish to implement or modify ELR.

The initial membership of the Workgroup was expanded early in the process to add several state public health lawyers on the rationale that they would have a detailed understanding of the operation of laws in their states.

The Workgroup had a series of meetings during the latter part of 2010 and the first half of 2011. The Workgroup participated in several scheduled meetings of the Task Force, and kept the Task Force apprised of progress. Dr. Blythe and Dr. Shaw made multiple presentations to the Task Force on the ongoing work of the Workgroup. In September 2011, Dr. Shaw made a presentation on the work to the 2011 Public Health Informatics Conference at a session called, "CSTE and CDC Electronic Laboratory Reporting Task Force."

IV. METHODS OF THE WORKGROUP

In late 2010 and early 2011, the Workgroup held a series of meetings to discuss the state of ELR-related laws in the states represented by the Workgroup members. Epidemiologists and attorneys from those

states held a series of meetings with the Workgroup to discuss the situation in their own states. Beginning in August 2010, the Workgroup conducted pilot research on laws related to ELR in the nine jurisdictions represented by Workgroup membership: Florida, Idaho, Iowa, Maryland, Massachusetts, New Hampshire, New York, Tennessee and Utah. Pilot research included feedback from Workgroup members on the status of ELR implementation in their jurisdiction, existing or pending laws related to ELR, and any known legal issues or barriers associated with the adoption of ELR.

CSTE State Assessment Survey

In November 2010, CSTE determined that a comprehensive overview of all 50 U.S. state laws related to ELR was needed to adequately assess legal issues associated with the implementation of ELR. In June 2011, CSTE launched an assessment of state laws and legal issues related to ELR. The assessment was sent by email to all 50 state epidemiologists and copied to deputy state epidemiologists, with the request that it be completed by the state epidemiologist or designee with input from the attorney who provides the state health department with legal advice on issues related to electronic laboratory reporting. The questionnaire was delivered through Survey Monkey, an online survey tool. Assessment questions were developed with input from all Workgroup members. To assess which states had laws interpreted as either regulating or requiring ELR, the survey asked two questions: “Does your jurisdiction have any laws that you interpret as regulating or governing ELR for any reportable disease or condition?” and “Does your jurisdiction have any laws that you interpret as requiring ELR for any reportable disease or condition?” The Workgroup chose to use the term “law” instead of “legislation” to encompass all ELR-related statutes, regulations, and policies that had the force of law. Various other questions were asked to address barriers to implementation, health information exchanges, meaningful use, and access to the state public health attorney.

In-depth Legal Research and Interviews: Eight States

On the basis of findings and conclusions from the pilot legal research and the CSTE assessment survey, the Workgroup selected eight states for in-depth inquiry. The goal was to understand more deeply the underlying forces determining the legal status of ELR; i.e., not just the law, but also the causes, rationales, and interpretations behind the law. The Workgroup selected a range of states to represent states that had laws requiring ELR; states that had laws permitting ELR but where ELR had not yet been implemented; and states that had no laws related to ELR. In selecting the eight states, the Workgroup paid particular attention to states that reported experiences with ELR that could be illustrative or generalizable to other U.S. states, states that reported or anticipated facing legal issues or controversies surrounding the implementation ELR, and states that showed a high level of interest, ingenuity, or novelty. The selected states were Connecticut, Florida, Massachusetts, Nebraska, New York, Oregon, South Carolina, and Tennessee.

From June through October 2011, the Workgroup conducted a detailed qualitative review of statutes, regulations, and other law related documents pertaining to ELR for each of the eight states. This research was done using the online research databases, LexisNexis and Westlaw, and state statutory and regulatory indices. The Workgroup restricted its research to state-level law, and did not inquire into federal or local law.

From June to December 2011, the Workgroup (Drs. Blythe and Shaw, Ms. Berkery, and Ms. Huang) conducted interviews with the selected states' epidemiologists and public health attorneys. The Workgroup set up these interviews as nonsystematic informal conversations to learn more about what each selected state had done regarding ELR law, and how their experiences might be generalizable or educational to other states. In accordance with CSTE policy, findings from specific states will not be made public in this report.

V. FINDINGS AND CONCLUSIONS

This section presents the statistical results of the CSTE assessment survey and the in-depth interviews, the overall thematic findings, and key legal issues identified.

CSTE State Assessment Survey

The 50-state CSTE assessment survey allowed the Workgroup to quantitate the national prevalence of legal considerations regarding the adoption of ELR. The in-depth interviews in eight states provided complementary anecdotal information: e.g., narratives on the role of the law in ELR adoption under the circumstances of individual states; anecdotes on the degree of importance of the various legal issues; relationships among those issues in individual states; attitudes of the state epidemiologist and attorney toward the meaning of their laws; and the role of the state epidemiologist and the state legal counsel in forming and enforcing the law.

Of the 50 states to which CSTE sent the questionnaire, 49 responded. Of the 49 responses, 48 were completed by the state epidemiologist or designee, and 24 of these consulted a public health attorney to complete the assessment (Table). Of the respondents who consulted their public health law attorney, nearly all said that it was easy to identify the appropriate attorney and easy to obtain their input.

Among the 49 respondent states, 27 (55%) answered "yes" to having laws they interpreted as regulating or governing ELR for any reportable disease or condition; only 17 (35%) responded "yes" to having laws requiring ELR. Notably, only 10 states reported having to analyze, manage, cope with, or otherwise address any legal issues or controversies related to the adoption of ELR; an identical number reported that they anticipated having to do this within the next 12 months. Thus, the total number of states that said they had to do deal with legal issues either now or in the next 12 months was only 20 of 49 (41%). Notably, only three states said any law in their jurisdiction constituted a barrier or obstacle to the adoption of ELR, and only six states said they felt their reporting laws would need to be modified in response to Medicare/Medicaid "meaningful use" electronic health records incentive payments.

A total of 16 states (32%) answered affirmatively a question about whether additional laws or changes to current laws would be desirable to better manage or address legal issues or controversies related to ELR. About a third of these 16 were states that already had laws regulating ELR. A total of 6 states said that their laws needed to be modified in response to "meaningful use" regulations.

The CSTE assessment also allowed respondents to write open-ended comments at the end of each question. Of the 10 states each that said they had had to cope with legal controversies in the past or

anticipated doing so in the next 12 months, seven comments referred to a need to rewrite statutes or administrative codes. For example, one respondent wrote,

[T]he present law only allows electronic health information exchange between providers for the purposes of treatment – not for public health purposes. May wish to extend law to allow public health disease reporting.

Another respondent referred to a recent change in statute specifically aimed at ELR. Yet another respondent said their state's reportable disease regulations,

did not reflect the changing technical environment of healthcare and public health. Our laws assume paper-based methods of reporting and do not encourage the use of system-to-system exchange in a standard, meaningful way...

On the other hand, a few comments said there might be no need to change statutes or regulations because the current ones may cover ELR:

[The state's] law does not prohibit the use of ELR for reporting purposes, nor does it explicitly address this method of reporting, unlike paper-based methods such as postal mail and fax. In the next 12 months we anticipate a review of our reportable disease law to determine if the language in effect today requires change to fully support statewide adoption of ELR for reportable disease and conditions.

A total of four respondents mentioned that privacy, confidentiality, and security of reportable disease records were important issues. In general, these issues related not to ELR specifically, but to all methods of disease reporting, although the advent of ELR might have made the issues more salient. One respondent said providers were concerned about the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. A few others mentioned broad issues related to patient privacy and data security with electronic transmission.

A total of four respondents mentioned that, as the state began setting up ELR, hospitals or laboratories requested additional specific business agreements with the health department before proceeding. Other commenters mentioned additional issues (e.g., general antiquity of the reporting statute, and meaningful use).

A total of three states that said a law in their jurisdiction constituted a barrier or obstacle to the adoption of ELR. In the first state, the respondent said that, at first glance, one statute appeared to provide state agencies with broad rulemaking to require ELR, but another statute seemed to limit that authority. The second statute covers electronic business transactions of all types, not just medical or laboratory records. This conflict of statutes, the respondent said, might need to be resolved by the legislature. No other state cited conflict with any law on electronic business transactions as a possible obstacle to ELR. In the second state, the respondent said a recently-adopted statute involving the confidentiality of HIV/AIDS reports containing identifying information might not be storable on certain types of computers. In that state, for HIV/AIDS cases only, a legislative fix might be required. This would not affect other types of laboratory

reports. In the third state, the respondent said only that its ability to use health information exchanges for ELR might be limited by statute. Presumably this would not affect ELR generally, but only ELR information contained in health information exchanges.

Regarding their ability to consult with the state's public health attorney, one respondent wrote, "Helpful to include attorney in this process – from a survey standpoint and also from the standpoint of generating internal discussions about ELR." Another wrote, "It took a little more time to obtain the attorney's input, and she was not well versed in ELR, but this raised her level of awareness as we continue to push ELR forward." Yet another wrote, "The only 'hard part' was discovering the path by which the PH attorney's help could be requested: we are not permitted to access her directly; must go through a 'gate keeper.'" And another wrote, "[Health information exchanges] and ELR are rather new frontiers for most of us working in public health, so our public health legal counsel are on a learning curve, too. It is possible that unforeseen legal obstacles or barriers will emerge."

Thematic Findings

After reviewing the initial research, the CSTE assessment survey, and the in-depth interviews, the Workgroup was able to place its findings into seven main themes.

1. The law of ELR is primarily the law of disease reporting, but the adoption of ELR does invoke some special legal considerations in certain states.

One of the primary lessons learned by the Workgroup is that the law of ELR exists primarily as the law of disease reporting. For the most part, ELR is not treated in law as a topic separate from disease reporting. While many states have statutes and regulations that apply specifically to ELR, they are mainly narrow and technical (e.g., they establish that ELR is a legally-approved method of reporting, or set out technical requirements for making electronic laboratory reports). The largest legal issues raised by the adoption of ELR are those of disease reporting generally. As one state epidemiologist wrote in his comments on the CSTE assessment survey, "From a legal standpoint, the experience in [our state] has been that the challenge lies in the reporting of communicable disease, not the mechanism of the reporting."

When respondents to the CSTE assessment survey or in-depth interviewees were asked to provide citations to statutes or regulations governing ELR, the majority cited to statutes and regulations that govern disease reporting generally, not to ELR in particular. As one illustration of this, the Workgroup found that the greatest law-related issues cited by states were related to the privacy, confidentiality, and security of reportable disease data. But these issues are triggered by the receipt and storage of electronic disease reports from all providers, not just from laboratories.

As another illustration, one state reported that the rulemaking process could make it difficult to establish a new reporting requirement for a disease. The same state reported that, although the state health department might be interested to know certain negative laboratory test results, no current legal mechanism was available to require laboratories to report negative test results electronically. Both of these issues were part of the general characteristics of rulemaking in the state and were not specifically related to ELR.

The Workgroup also found that, although most legal issues related to ELR are really those related to disease reporting generally, the adoption of ELR does create certain issues specific to ELR. These are

related to the electronic nature of the laboratory reports and to new infrastructure and business relationships that must be established with providers to make ELR operational. On the first point, it is important to remember that reporting by laboratories to state health departments has been required for decades. Only electronic transmission is new. The electronic method and the automation of report generation and receipt have many technical aspects, but for most states these do not require fundamental changes in statutes. For many, even needed changes in regulations may be minimal. The second point, regarding new business relationships needed for ELR, also is not primarily a legal issue and in the vast majority of states does not require fundamental changes in the law.

2. Like most public health laws, the law of disease reporting and ELR varies greatly from state to state.

Scholars and practitioners of public health law have long observed that the laws of public health vary dramatically from state to state (25). For example, laws related to quarantine, infectious disease control, and immunization have long been found to vary tremendously from state to state (26). The Workgroup affirmed that a patchwork of legal structures and provisions exists for disease reporting, and also for ELR.

Reporting laws in most states have developed over more than a century, and have been amended repeatedly to adapt to emerging diseases and the evolving needs of disease control (26). The Workgroup was impressed with the variety of laws relating to ELR and disease reporting, all with different provisions and hierarchies, levels of specificity, and timing. From state to state, great variation exists regarding diseases and conditions to be reported, reporting mechanisms, time-frames for reporting, persons required to report, and agencies to receive reports. The variation in laws extends not only to “black letter” law (i.e., the law written down in statutes and regulations) but also to the interpretation of the law by state epidemiologists and their attorneys.

The variation in ELR-related laws exists both in statute and in regulation. As an example, the states vary greatly in the way they designate which laboratories must report electronically. In the CSTE assessment survey, one state cited a statute saying that only laboratories with more than an average of 30 “findings” per month must report electronically. In another state, the requirement applies only to laboratories that average more than 50 reports in the previous calendar year, and in yet another state the number is 400 reports per year. Similarly, states varied in whether and when they made ELR mandatory, and if mandatory, in exactly how they established the requirement in law. Some states set dates certain in statute for ELR mandates, while others left it to regulation or delegated it to the health commissioner.

3. Of the many issues facing state health departments regarding the adoption of ELR, legal considerations are not among the most pressing.

Legal considerations are not among the most pressing issues regarding the adoption of ELR in the states. In the in-depth interviews, a majority of the states said that legal considerations were not more than a relatively minor consideration among the many issues related to ELR. Some had to think very hard to even identify a single legal issue associated with ELR. In the assessment survey, only 10 of 49 respondent states each said that they had had to cope with legal issues in the past or expect to do so in the next 12 months.

During the in-depth interviews, the Workgroup asked a question about whether the state had experienced any lawsuits, legal complaints, or threat of legal action related to ELR. The Workgroup asked the same question of CSTE officials and other people familiar with the field. The Workgroup did not learn of a single

lawsuit, legal complaint, or threat of legal action nationwide. No such lawsuit or complaint was mentioned by any state on the CSTE assessment survey. All the interviewed states said even the threat of such a lawsuit was extremely unlikely, because the states routinely work collaboratively with hospitals and laboratories to create reasonable expectations and accommodations for ELR requirements. Before establishing regulatory requirements, most states go through a process of consulting affected laboratories before beginning the rulemaking process. The collaborative atmosphere between health department and laboratories usually means that no parties are sufficiently aggrieved to take or threaten legal action. Indeed, some states have achieved high levels of ELR reporting even without any state mandate on laboratories (27). In certain states, during the rulemaking process that made ELR mandatory, the state health department received no comments from providers.

This is not to say that laboratories have embraced everything the health departments have sought to do in regard to ELR. One state said that they saw “pushback” from some large hospitals regarding mandatory reporting of healthcare-associated infections, but the hospitals withdrew the objection quickly after discussions with the state health department.

All interviewed states said that they would not impose a legal requirement on providers without extensive discussion and negotiation. In some states, the providers themselves sought legal requirements from the state health departments, for a variety of reasons. For example, a hospital laboratory might seek a legal requirement in order to force its own hospital administration to commit financial resources to ELR.

4. In all but a few states, legal considerations do not constitute a barrier or obstacle to the adoption or implementation of ELR and are unlikely to do so in the near future.

The results of the CSTE assessment survey and the in-depth interviews establish definitively that existing state laws do not stand as a substantial obstacle to the adoption of ELR in the states. A total of 46 of 49 responding states said that no laws were such an obstacle. Of the three remaining states, only one said that state laws constitute a barrier to ELR adoption. The other two states said that the possible obstacles were very narrow and would not affect the adoption of ELR project generally.

5. Certain states might need to alter their ELR regulatory language as the environment continues to change.

In both the CSTE assessment survey and the in-depth interviews the Workgroup identified a handful of states in which under- or over-specific wording in statutes or regulations might need to be changed as the ELR environment changes. The Workgroup identified a handful of other gaps that might require revision of regulations or amendments to statutes. For example, in several states, reporting to the health department is required “in a time and manner determined by the health department,” or similar language. One state said they were considering a change in such language toward more specificity to make the requirement more legally defensible. A few states said they might need to change their laws in response to “meaningful use” requirements.

Additionally, a few states have regulations that address specifically the platform in which electronic laboratory reports can be accepted by the health department (e.g. earlier Health Level Seven versions). These states may need to revise the legal language to allow reports to be received in accordance with “meaningful use standards,” which require a later standard.

6. Many states have not fully formed their legal stance to the advent of ELR, and many said they wished to learn from the experience of other states.

Some respondents to the CSTE assessment survey noted that the state had not yet fully assessed the legal implications of ELR adoption. Some states said they needed to further assess whether statutes or regulation needed to be updated to allow ELR or to smooth the implementation of ELR. For example, in certain states, ELR is not specifically allowed or prohibited. Is there an advantage in such states to establishing laws that specifically allow ELR, or is the lack of a prohibition sufficient? Another state suggested that ELR might be expedited by making it a requirement of laboratory licensure.

The Workgroup learned that several states were interested in learning more about other jurisdictions' proven practices. For example, one question is whether it is optimal to revise health department regulations first, when the ELR capability is uncertain, or to develop/deploy ELR capability first and then follow with ELR legislation or regulation? Other questions are: What is the appropriate level of specificity related to ELR requirements? Is there a best practice for drafting wording to reflect a gradual implementation process (e.g. if a state only has the capacity to accept ELR from large laboratories at first)?

7. The Workgroup was not able to determine definitively the ease with which state epidemiologists were able to consult their attorneys, but some clues indicate that collaboration is relatively easy.

Through the CSTE assessment survey, the Workgroup found that among those state epidemiologists that sought help from their attorneys, it was easy for them to identify the proper attorney to work with and to get the attorney's input. The in-depth interviews revealed that, with a few exceptions, state epidemiologists in the interviewed states knew their attorneys well and worked with them easily. However, because the assessment survey asked questions about ease of collaboration only from the 24 state epidemiologists that accessed their attorneys to answer the questions, the Workgroup could not determine the degree to which all 49 state epidemiologists were able to access their attorneys.

Key Legal Issues

In accordance with its charge to identify key legal issues surrounding the implementation of ELR in the states, the Workgroup reviewed the results of its initial legal research, the CSTE assessment survey, and the in-depth interviews. Key issues identified were:

General adequacy of legal authority. The adequacy of legal authority for adoption of ELR did not appear to be a large issue in the states. With some exceptions, state epidemiologists and legal counsel indicated that current law provided adequate authority to regulate and require ELR. A few states indicated that they had revamped their disease reporting regulations to cover ELR; in some cases, these regulations had become outmoded or referred only to paper-based reports from laboratories, or were otherwise inadequate to address the advent of ELR. A few states found it necessary to go to the legislature for new statutes. A few other states said they expected to review their laws to, as one state explained, "determine if the language in effect today requires change to fully support statewide adoption of ELR for reportable diseases and conditions." The Workgroup concluded that the states appeared to be universally aware of their legal authority for ELR and had done a good job of assessing the need for additional legal authority. In the unusual cases where additional laws were needed, the states were taking steps to establish new laws.

Specificity of laws. A related issue came to the attention of the Workgroup-- the specificity of state laws on disease reporting. Must enabling statutes specifically authorize ELR, or is a general statute that requires, for example, reporting "in a manner specified by the Commissioner" adequate to cover ELR? The answer will be different for each state. Several states indicated that they were researching this question. Although this question is of legal interest, it did not appear to be a stumbling block for ELR adoption. Still, it may be an issue to follow as ELR adoption increases.

Hierarchical placement of ELR requirements in law. Another legal issue that came to the Workgroup's attention is where in the legal hierarchy ELR requirements should be placed. This is an interesting issue that might have some importance in how readily ELR laws could be defended in the highly unlikely event of a challenge. Are ELR requirements best placed in statute, in regulation, or may they be placed in official actions of the department or commissioner?^{vii} One state epidemiologist who had recently participated in a rewrite of his state's laws said he chose the statutory route for the ELR requirement because it seemed to have a greater policy weight, and because another state had done well taking that approach. Most states with requirements for ELR have placed them in regulation.

To explore this further, assume that a state placed some of its ELR requirements (or other disease reporting requirements) in an official action of the health commissioner. In the highly unlikely event that such a placement were challenged, the challenger might argue that the commissioner's action did not have the force of law. The case likely would turn on two issues: 1) whether the commissioner's action was enabled ultimately by a delegation of authority from the legislature, 2) whether the commissioner's action was in accordance with the state's administrative procedure act. For the latter, the challenger might argue that the official action violated the administrative procedure act because the commissioner's action imposed a legal obligation and in effect constituted the establishment of an administrative rule, but had not been subjected to the rulemaking procedures required under the act.

Although this is an interesting issue from a legal perspective, the Workgroup viewed it as more theoretical than practical, because 1) judging by past experience, such a challenge is extremely unlikely, 2) state disease reporting offices have a long tradition of harmonious relationships with reporting providers, and a dispute about legal force almost certainly would be resolved informally, 3) courts traditionally give wide latitude to the actions of state health departments and would be unlikely to invalidate such an action. However, the Workgroup is aware that, in other areas of the law, courts have not hesitated to invalidate actions of state agencies that did not comport with administrative procedure acts. One state attorney told the Workgroup that, in his state, any official action by the commissioner that purported to have the force of law must go through rulemaking.^{viii} In that state, an action of the commissioner that is intended to have

^{vii} The authors of a 2010 CDC report, "Menu of Suggested Provisions for State Tuberculosis Prevention and Control Laws," wrote in their introduction, "... [W]hen deciding whether to adopt any of the provisions in the Menu, careful consideration should be given to whether a provision should appear in statute or regulation. States may wish to adopt broad or general statutes that confer discretion to the regulatory process, which can be more expeditiously exercised to make changes or updates. Regulations must be authorized by statute (i.e., there can be a statute without a regulation, but not a regulation without an authorizing statute). Some of the factors that go into this decision are: the timeframe in which the regulation may be promulgated by the authorized agency or the statute enacted by the legislature, how often changes might need to be made to the law, whether the subject matter of the legal provision is technical and regular updates are likely according to advances in technology or practice, and whether statutory authority exists to promulgate a regulation (28)."

^{viii} This state has provisions in regulation to add diseases to the reportable list in emergencies.

legal effect is, by definition, a rule and is subject to the requirements of the state's administrative procedure act.

It is not impossible to envision a situation, perhaps in a state with an especially polarized political environment, where a laboratory might see a health commissioner's decision to require certain reports as unreasonable and onerous, and it might resort to a legal action. In theory, in an urgent situation in which laboratory data were providing critical public health information, a lawsuit, even an unsuccessful one, could temporarily interrupt the flow of data. In states where the authority of the commissioner to establish a reporting requirement is unclear, or where the application of the state administrative procedure act to a commissioner's action is unclear, an assumption of authority by the commissioner outside of regulation could, in theory, represent some level of legal risk. As noted, judging by history, the probability of a legal challenge is exceedingly low.

This scenario likely would play out differently in different states. Some states have a tradition of strict constructionism regarding rulemaking and have a history of putting all acts of the state that impose a legal obligation through the requirements of the state administrative procedure act. A declaration by the commissioner not formally enabled in statute would not be permitted. Other states allow more liberal construction of the requirements of the administrative procedure act or of legislative delegations. The Workgroup concluded that this issue is a potentially important topic for further consideration by legal scholars and practitioners.

Use of ELR with health information exchanges. Only a few states have proceeded far into the establishment of health information exchanges and have considered the legal aspects of ELR in these exchanges. Some of the respondents indicated that additional legal analysis was needed to better understand this issue. One attorney said his state's laws "did not prohibit it," but did not say whether he considered the absence of a prohibition enough authority to proceed. A few states indicated that new laws would be needed to use HIE's for electronic laboratory reports.

VI. DISCUSSION

This report, created as the final work product of the CSTE-CDC Electronic Laboratory Reporting Task Force, Legal Considerations Workgroup, appears to be the first detailed analysis of the legal aspects of electronic laboratory reporting. The largest finding of the Workgroup was that legal considerations are not currently a major factor in the adoption of ELR in the states, and they are not likely to be a major factor in the near future. Even so, some states have not fully formed their legal stance on the advent of ELR and uncertainty remains about the future.

Although this is the first detailed analysis of the legal aspects of ELR, it is not the first to examine a survey of the states on this topic. The Electronic Laboratory Reporting National Snapshot Survey captures an annual picture of the current and future status of ELR in the United States (29). The survey has been conducted since 2004. Early in the Snapshot's history, it added a question about ELR legislation. By 2008, the Snapshot was asking, "Does your state/jurisdiction have legislation specifically requiring/regulating electronic laboratory reporting?" In 2011, the Snapshot changed the question to "Does your state/jurisdiction have formal requirements (reporting rules, mandates, legislation, etc.) specifically requiring/regulating electronic lab reporting?"

The Workgroup reviewed the results of the Snapshot Survey as it sought to understand the prevalence of various ELR laws in the United States. However, the Workgroup found the results of the Snapshot question difficult to interpret. For example, until the 2010 survey, the Snapshot based its law-related questions on “legislation,” a term that is ambiguous in this context. Did an established statute qualify as “legislation?” It probably did, but an administrative regulation almost surely did not. Therefore, a state could have had a legal requirement for ELR embodied in a regulation that might not have been captured by the Snapshot prior to 2011. By 2011, the Snapshot question was somewhat clearer, but, still, in the follow-up question in 2011, the survey still asked about “legislation details.” In part because of these ambiguities, CSTE elected to use different language in its assessment survey questions about the existence of ELR-related laws:

Does your jurisdiction have any laws that you interpret as regulating or governing ELR for any reportable disease or condition?

and

Does your jurisdiction have any laws that you interpret as requiring ELR for any reportable disease or condition?

While ideally, CSTE might have used the same wording as the Snapshot Survey to allow longitudinal comparisons, after consulting with the Workgroup, CSTE concluded that this wording was more precise.

CSTE used the words, “you interpret,” intentionally to recognize that all questions about legal requirements are a matter of interpretation. In addition, as part of the assessment survey, CSTE provided a definition of the word, “laws.” A “law” was defined as a statute, regulation, or administrative rule, and CSTE intended that these would be the only types of laws that would be captured. This differs substantially from the wording of the Snapshot Survey, which in 2011 used the terms, “formal requirements (reporting rules, mandates, legislation, etc.)” in one question and “legislation” in a follow-up question (29).

CSTE also decided to ask separate questions for laws that “regulate or govern” ELR and laws that “require” it. These two questions are collapsed in the Snapshot survey. Many state laws (perhaps the majority of them) regulate or govern ELR but do not require ELR. CSTE wished to separate these two types of laws, and the results indicated that 27 respondents cited laws that regulate or govern ELR, but only 17 cited laws that require ELR.

Other characteristics of the two surveys also prevent them from being comparable. For example, in the results for 2011, the Snapshot reported that 17 states or jurisdictions reported that they have “formal requirements (reporting rules, mandates, legislation, etc.) specifically requiring/regulating electronic lab reporting” for at least some notifiable conditions. This compares with the 27 states that answered “yes” to the CSTE assessment survey question, “Does your jurisdiction have any laws that you interpret as regulating or governing ELR for any reportable disease or condition?” The proportion of states that answered affirmatively in the two surveys is very different.

The CSTE assessment survey provided an interesting window into the relationship between the state epidemiologists and the public health attorneys. The Workgroup’s found that in a few states

epidemiologists reported difficulty accessing legal advice, or difficulty accessing the state public health attorney. State health department access to legal advice has recently been highlighted by the Institute of Medicine in a 2011 report on of public health law (30). Certain states reported that the CSTE assessment survey was helpful to open a discussion with the state public health attorney regarding disease reporting laws. Some participants, however, reported difficulty in accessing their state public health attorney.

Limitations

The Workgroup is aware that several key limitations apply to its work. First, the Workgroup did not inquire into federal laws that might affect ELR adoption in the states. The federal role in the legal aspects of the adoption of ELR appears to be quite limited, although with the advent of the HITECH Act and the Affordable Care Act, federal law could take on a greater role. At least one respondent to the CSTE assessment survey mentioned the possible effects of HIPAA, a federal law. While the Workgroup recognized that this and other federal laws might affect ELR adoption, the Workgroup interpreted its charge to inquire into state law only. Likewise, the Workgroup did not consider local or municipal laws.

A second limitation is that the Workgroup was not at liberty to disclose the results of the CSTE assessment survey or the in-depth interviews for particular states. The Workgroup also was not in a position to provide an analysis of any particular state's laws. The Workgroup did not view this limitation as severe, because most of the lessons learned from the work need not be tied to the experience or laws of an identified state. Future analyses of state ELR or disease reporting laws may provide lessons from identified states.

A few limitations apply to the CSTE assessment survey. One is that the assessment was completed mainly by state epidemiologists and not state public health attorneys. Only about half of the respondent state epidemiologists or designees consulted their public health attorneys. But, as the Workgroup determined, state epidemiologists often have substantial expertise in the public health laws of their state. On the other hand, attorneys are able to spot certain legal issues that would not be obvious to a non-lawyer. The Workgroup cannot predict whether the results of the assessment would be different if all state epidemiologist respondents had consulted attorneys.

Through the CSTE assessment survey, the Workgroup found that among those state epidemiologists that sought help from their attorneys, it was relatively easy for them to identify the proper attorney to work with and to get the attorney's input. The in-depth interviews revealed that, with a few exceptions, state epidemiologists in the interviewed states knew their attorneys well and worked with them easily. However, because the assessment survey asked questions about ease of collaboration only from the 24 state epidemiologists that accessed their attorneys to answer the questions, the Workgroup could not determine the degree to which all 49 state epidemiologists were able to access their attorneys.

A limitation of the in-depth interviews is that they are not generalizable to the rest of the states. The in-depth interviews were meant as an opportunity to inquire more deeply into the experience of a limited number of states and gather useful insights into the reasoning of state epidemiologists and attorneys regarding ELR-related laws. The information is anecdotal.

VII. RECOMMENDATIONS

The final charge of the Workgroup from the CSTE-CDC Electronic Laboratory Reporting Task Force stated, “based on information acquired and if appropriate, considering whether law-related products or tools useful to states regarding legal issues should be developed in the future.” The Workgroup has interpreted this charge liberally to make seven broad recommendations:

1. Creation of an ELR-related model law or other guidance document is not warranted currently, but could be warranted in the future if key legal considerations arise.

While model laws have great utility in certain parts of public health, the Workgroup felt that creation of a model law for ELR would be premature. Legal considerations are not a key issue for the adoption of ELR in most states. Even in the few states in which legal considerations might be important, the utility of a model law is uncertain. The provisions that make up the law of ELR in the states are born of a variety of needs, and these are different in each state. One state’s ELR-related law might be driven by privacy, confidentiality, and data security concerns. Another state’s might be driven by business and contractual issues. In addition, each state differs by the healthcare and regulatory environments, and by the array of laboratories that must be regulated. The Workgroup concluded that, at this point in the history of ELR, creation of a model law is not indicated. In the next few years, greater uniformity might become more important. At that time, the idea of a model law could be revisited.

Another kind of guidance document might be a "menu" of suggested legal provisions for ELR, but the Workgroup felt that this, too, would be premature. At the inception of the Workgroup in 2010, the CDC Division of Tuberculosis Elimination rejected creating a model law for tuberculosis issues, but instead designed a “menu” of suggested legal provisions. The division published the “Menu of Suggested Provisions for State Tuberculosis Prevention and Control Laws” as a compendium of legal provisions from many states that can be used by other states seeking new laws on tuberculosis control (28). The Menu was well-received. In the next few years, as the legal issues around ELR crystallize, creation of such a menu could be considered for ELR. However, the Workgroup recognized that the legal considerations surrounding tuberculosis control are very different from the legal considerations for ELR, and this should be taken into account if a menu is considered.

2. National groups concerned with ELR adoption should keep in touch with legal issues, especially those that might harm ELR adoption in multiple states.

Although legal considerations have not yet become key in the adoption of ELR, several states indicated in their comments on the CSTE assessment survey that the law in their state was not yet known, was unsettled, or remained unclear. Some combination of CSTE, APHL, and CDC should keep in touch with possible legal issues as they arise in the next few years, paying special attention to legal issues that could harm the adoption of ELR in more than one state. The Electronic Laboratory Reporting National Snapshot Survey could be a key component of this (see separate recommendation related to this survey). In addition, CSTE might consider keeping an up-to-date citation index of statutes and regulations concerning ELR that are provided by states. The initial index could be based on the CSTE assessment survey.

3. The authors of the Electronic Laboratory Reporting National Snapshot Survey should consider revisions or additions of law-related questions to make the survey more legally precise, and should consider consulting with an attorney to ensure the precision of the questions.

The Electronic Laboratory Reporting National Snapshot Survey remains the only ongoing national survey of the states on ELR, and it is therefore of primary importance in monitoring the adoption of ELR. However, in the discussion section of this report, the Workgroup outlines some potential problems with the interpretation of law-related questions on the Snapshot Survey. The Workgroup recommends that the authors of the Snapshot Survey consider revisions or additions in the law-related questions to make them more precise. For example, they should consider discontinuing entirely the use of the word, “legislation” to indicate statutes or regulations. In addition, the authors of the Snapshot Survey should consider consulting with an attorney to ensure the precision of the terminology in the law-related questions.

4. If key legal issues arise, national groups should consider reconvening the Workgroup.

Legal issues can arise idiosyncratically and unpredictably. As CSTE and CDC keep in touch with ELR-related legal issues, they may identify new legal issues regarding ELR. For example, a legal issue could arise in legislation or in a lawsuit. If key legal issues arise, the three organizations should consider reconvening the Workgroup.

5. Although not related only to ELR, a potentially important topic for further consideration by legal scholars and practitioners is the hierarchical placement of public health commands in law.

The Workgroup spent considerable energy examining the implications of placing legal commands at various levels in the hierarchy of law (i.e., in statute vs. regulation vs. official action). This is not a legal issue specific to ELR; it arises any time a government issues a command. The Workgroup feels that this topic has not been sufficiently researched or discussed in legal circles. State legal counsel and state epidemiologists could benefit by more research on how the states have made decisions about placement, the theory and advantages and disadvantages of various approaches, and relevant experiences in the states. The Workgroup recommends that legal scholars and practitioners consider this as a topic for research and training, especially as it applies to public health. Research should cover the legal standing of commands at various levels in various states, and possible vulnerabilities related to state administrative procedure acts.

6. Where needed, state legal counsel should educate themselves on ELR and consult with their state’s expert on ELR adoption and the state epidemiologist.

Some open-ended comments from the CSTE assessment survey indicated that, in a handful of states, public health legal counsel were not familiar with ELR or “were on a learning curve,” as one state epidemiologist wrote. As ELR accelerates under federal “meaningful use” regulations, legal issues might become a bigger consideration. In some states public health legal counsel may need to educate themselves about possible legal issues in their state. This education can begin by consulting with the one or two persons at the state health department who are managing the adoption of ELR. Legal counsel should have no difficulty in finding these people and consulting with them about possible legal issues. Simultaneously, legal counsel should consult with the state epidemiologist, and with other states that have more experience with ELR.

7. Recommendations for exploration of other topics.

Through the CSTE assessment survey, in-depth legal research and informal interviews, the Workgroup identified several other possible topics for further exploration. They are grouped here by general subject area.

Application of ELR-related laws

- Relative silence in state law on health information exchanges, and specifically, development of policies and legal agreements related to implementation of a statewide health information exchanges
- Level of clarity on who is responsible for reporting, which tests and results are reportable, and which fields are mandatory

Privacy, confidentiality, and data security

- General privacy concerns for ELR reports
- State confidentiality issues caused by the use of CDC systems to collect data
- Privacy concerns related to specific laboratory tests – e.g. HIV
- Confidentiality of communicable disease records in order to support the development of a statewide HIE
- State laws inconsistent with HIPAA guidelines
- Handling of sensitive protected health information

Business-related legal concerns

- Business risk and adverse legal action if information is exchanged
- Laboratories requesting additional agreements prior to establishing ELR (e.g., business associate agreements)
- Inconsistency with agreements already in place between the health department and laboratories
- Alignment of reportable disease requirements with meaningful use implementation guidance
- Technology limitations related to electronic information exchange

Other

- Reportable disease regulations that do not reflect the changing technical environment of healthcare and public health
- Lengthy rulemaking process given current political climate in some states

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Table: Legal issues related to electronic laboratory reporting, CSTE Assessment of State Legal Issues Related to Electronic Laboratory Reporting, 49 states, 2011

Question	Yes (%)	No (%)	No answer (%)
Does your jurisdiction have any laws that you interpret as <u>regulating or governing</u> ELR for any reportable disease or condition?	27 (55)	21 (43)	1 (2)
Does your jurisdiction have any laws that you interpret as <u>requiring</u> ELR for any reportable disease or condition?	17 (35)	32 (65)	0 (0)
Has your jurisdiction had to analyze, manage, cope with, or otherwise address any legal issues or controversies related to the adoption of ELR for reportable diseases or conditions?	10 (20)	38 (78)	1 (2)
In the next 12 months, do you anticipate having to address any legal issues or controversies related to the adoption of ELR for reportable diseases or conditions?	10 (20)	38 (78)	1 (2)
In your opinion, does any law in your jurisdiction constitute a barrier or obstacle to the adoption or implementation of ELR for reportable diseases or conditions?	3 (6)	46 (94)	0 (0)
In your opinion, would any additional laws or changes to existing laws be desirable in order to better manage or address legal issues or controversies related to ELR?	16 (33)	32 (65)	1 (2)
Do you anticipate that your jurisdiction’s reporting laws, including any authorizing/requiring ELR, will need to be modified in response to Medicare/Medicaid “meaningful use” electronic health records incentive payments?	6 (12)	42 (86)	1 (2)
Do your jurisdiction’s laws currently permit ELR via some non- health department mechanism, such as through a Health Information Exchange?	27 (55)	18 (37)	4 (8)
Did you obtain input from a public health attorney in order to complete this assessment?	24 (49)	25 (51)	0 (0)
Was it easy to identify the appropriate attorney to consult? (of 24 jurisdictions that obtained input from a public health attorney)	24 (100)	0 (0)	0 (0)
Was it easy to obtain the attorney’s input? (of 24 jurisdictions that obtained input from a public health attorney)	23 (96)	1 (4)	0 (0)