

Policy Guide for Public Health Laboratory Test Service Sharing



Laboratory Efficiencies Initiative

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ABBREVIATIONS USED IN THIS GUIDE

APHL	Association of Public Health Laboratories
CDC	Centers for Disease Control and Prevention
CLEP	Clinical Laboratory Evaluation Program
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare and Medicaid Services
DST	drug susceptibility testing
EMAC	Emergency Management Assistance Compact
FDA	Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act
HITECH Act	Health Information Technology for Economic and Clinical Health Act
HIV	human immunodeficiency virus
HRI	Health Research, Inc.
ICH	Institute for Community Health
LEI	Laboratory Efficiencies Initiative
LRN-B	Laboratory Response Network-Biological
LRN-C	Laboratory Response Network-Chemical
MOU	memorandum of understanding
NAT	nucleic acid testing
NBS	newborn screening
PHL	public health laboratory
PNEMA	Pacific Northwest Emergency Management Agreement
VPD	vaccine-preventable disease

SUMMARY

Public health laboratories face considerable challenges to ensuring performance of critically important testing services. These challenges stem from financial constraints and uncertainties, ever more sophisticated electronic systems, and new demands on laboratory professionals, among other factors. The Centers for Disease Control and Prevention and the Association of Public Health Laboratories cosponsor the Laboratory Efficiencies Initiative to help public health laboratories ensure long-term sustainability by exploring and adopting measures that can improve their efficiency and cost-efficiency. Interstate test service sharing is one of the most promising strategies toward that goal.

This *Policy Guide* is a resource that public health laboratory directors and their colleagues can use as they explore legal and other policy questions related to state public health laboratories' sharing test services with each other. The guide is primarily based on information that 17 state public health laboratory directors and their colleagues voluntarily provided about their experiences with addressing such questions.

Key Findings

- Of the sample of 17 public health laboratory directors interviewed, 13 reported participating in a total of 18 formal test service sharing agreements they had initiated. (Fifteen other state laboratories participated in those agreements with them.)
- Nine of the agreements were for emergency-related testing; seven were for newborn screening testing; and two were for disease-specific testing.
- All the emergency-related agreements were in the form of memoranda of understanding (MOUs); the other agreements were a mix of MOUs and contracts.
- All 17 laboratories also participated in test service sharing projects that CDC had initiated and sponsored.

Two legal concerns were identified as the most problematic for development of formal test service sharing agreements —

- liability: the potential that a state laboratory might be held legally liable for another state laboratory's actions or omissions to act; and
- exchange of funds: mechanisms for payment by one state laboratory to and receipt of payment from another laboratory for tests performed.

This *Policy Guide* presents practical information that laboratory directors might find helpful as they explore ways to address these and other questions. Among the resources included are a checklist and self-assessment template. The *Policy Guide* also includes a list of actual test service sharing MOUs and contracts that exemplify how individual public health laboratories have addressed such concerns. As appropriate, these can be used as templates for development of new test service sharing agreements in other states.

1. INTRODUCTION

1.1 The *Policy Guide*'s Purpose

This *Policy Guide* is a resource that public health laboratory directors and their colleagues can use to explore legal and other policy considerations related to state public health laboratories' sharing of test services with each other. The guide is primarily based on real-world experiences that state public health laboratory directors have had with such challenges, centering predominantly on testing that involves human specimens. As described in Section 1, a total of 17 directors participated in research for the guide. They generously volunteered information and lessons learned from their experiences as well as examples of relevant laws and other legal resources.

Many public health laboratories have experience in conducting tests for each other, often on an informal basis, in at least one of the following contexts:

- On an occasional basis when special expertise or testing resources might be needed that a public health laboratory temporarily lacks. Such testing typically involves low-volume testing.
- Routinely when one laboratory determines that another laboratory is better suited to perform a particular type of test on its behalf on a continuing basis.
- In emergency settings when the volume of tests exceeds a laboratory's capacity (e.g., as happened during the 2001 anthrax response and the 2009 influenza A [H1N1] pandemic) or when a temporary interruption in operations requires calling on another laboratory for surge capacity.
- In programs and projects sponsored by the Centers for Disease Control and Prevention (CDC) (e.g., the vaccine-preventable disease [VPD] reference laboratory project that CDC initiated in 2012). The participating laboratories have developed formal service sharing agreements for some, but not all, of these projects.

In addition to informal arrangements, certain state public health laboratories have developed formal agreements through which they perform specified tests for each other. Many laboratory directors are interested in exploring the potential benefits of expanding test service sharing. An important part of that exploration is identifying laws and other types of policies that support or, alternatively, constrain test service sharing.

This *Policy Guide* includes helpful resources for the reader interested in pursuing test service sharing agreements with another state.

- Resource 1 is a checklist for assessing and testing service sharing laws and legal considerations.
- Resource 2 is a self-assessment of laws and policies pertinent to interstate test service sharing agreements.
- Resource 3 lists selected test service sharing agreements contributed by participating laboratory directors; the full agreements are available on the APHL website for members.
- Resource 4 includes example provisions of service sharing agreements.
- Resource 5 is a bibliography of information sources.

1.2 The Public Health Laboratory Efficiencies Initiative

Additional impetus for test service sharing has come from financial and workforce constraints that have affected public health laboratories in recent years and from challenges posed by new testing platforms and the rapidly evolving health care sector. These and other factors place a premium on maximizing laboratories' operating efficiency.

CDC and the Association of Public Health Laboratories (APHL) inaugurated the Laboratory Efficiencies Initiative (LEI) in early 2011 to help address these concerns. LEI's mission is to help public health laboratories ensure their long-term sustainability through adoption of practices that can improve their operational and cost efficiencies. One of the LEI strategic goals is to ensure that individual public health laboratories and the public health system as a whole have the capacity needed to address health threats. Additional information about the LEI is available at <http://www.aphl.org/lei>.

1.3 Background

On August 17, 2012, the five state public health laboratory directors who composed APHL's standing Legislation and Policy Committee met in Atlanta, Georgia, to discuss policies related to interstate test service sharing. They were joined by representatives from APHL and several CDC programs.

Although the discussion considered federal policies, it focused primarily on state laws and policies ranging from statutes and regulations that expressly govern laboratory practices to privacy laws and agencies' policies related to financial, procurement, and other administrative matters. Examples were provided of laws and other policies that are supportive of test service sharing and examples of others that can constrain it. Committee members noted that, in certain cases, what laboratory directors believe are relevant laws might reflect perceptions rather than actual laws and policies.

The committee noted that information is limited regarding implications that laws and other policies have for test service sharing. The committee requested that APHL and CDC develop a practical resource that public health laboratory directors can use to better understand such concerns and to assess the pertinent laws and policies of their own states. This *Policy Guide* is that resource.

As used in this *Policy Guide*, key terms are defined as follows:

- *Public health laboratory* includes all state, local, environmental, agricultural, and food laboratories and laboratories that engage in testing for the health of the population.
- *Test service sharing* is the performance by one state public health laboratory of testing on behalf of another state public health laboratory.
- *Law* refers to statutes adopted by state legislatures and regulations adopted by state executive-branch agencies.
- *Other policies* refers to state policies that are subordinate to statutes and regulations (e.g., procurement policies adopted by centralized state administrative agencies or universities).

1.4 Methods Used to Develop the *Policy Guide*

Researchers with the nonprofit Institute for Community Health (ICH) located in Cambridge, Massachusetts, compiled information for the guide through interviews with the directors, senior staff, and legal counsel of 17 state public health laboratories who offered to participate in the research. Their work was funded by the Public Health Law Research Program at Temple University (Philadelphia, Pennsylvania) with support from the Robert Wood Johnson Foundation (Princeton, New Jersey). The research plan and protocols were reviewed and approved by ICH's institutional review board, and the interviews were conducted during April–July 2013. In parallel, the CDC Public Health Law Program reviewed and analyzed pertinent state and federal laws.

The following topics were suggested for the respondents' consideration, but they were invited to address other topics as well:

- authority to participate in test service sharing,
- payment for shared test services,
- risk management,
- privacy protection,
- certification and licensure,
- specimen management and use,
- disease reporting, and
- emergency management.

Information derived from interviews and legal research was supplemented with information that APHL and CDC staff received from state public health laboratory directors through routine channels (e.g., LEI teleconferences and meetings) and one-on-one interaction with public health laboratory directors and their senior staff. Because the available resources precluded gathering information from all states' laboratories, APHL polled its members to identify those interested in participating. Thirty-two (64%) of the state laboratory directors responded. The sample of 17 states was selected to represent state laboratories that had experience with test service sharing. (Local public health laboratories participated in the poll but were not included in the research because those responding to the poll reported limited experience with test service sharing.)

The public health laboratories that participated in this research serve Alabama, Arizona, California, Connecticut, Florida, Idaho, Illinois, Iowa, Kansas, Montana, New Hampshire, New Mexico, New York, Texas, Washington, Wisconsin, and Wyoming. The majority conduct a wide range of infectious disease testing as well as environmental testing. Fourteen perform genetic testing as part of their state's newborn screening (NBS) programs.

The 17 states include a mix of populous states with multiple metropolitan areas and sparsely populated, primarily rural states. With one exception (the Mid-Atlantic region), the states represent all U.S. regions and account for 50.8% of the total population (as of July 1, 2012). Fifteen of the laboratories are units of their states' public health departments, and two are integral parts of state public universities.

The laboratory directors were the researchers' points of contact and had the option of inviting staff to participate in interviews. Eleven state interviews were with the laboratory director alone. From two to seven state staff participated in the six other state interviews. Nine counsel in four states participated. In all, 41 persons were interviewed.

With permission of the laboratory directors, the ICH researchers recorded the interviews and returned verbatim transcripts to the directors for their review and emendation. The directors were assured that, aside from themselves and others they might authorize, only the research team would have access to the transcripts. All respondents were assured anonymity, if they wanted, and were given an opportunity to review and comment on a draft of the *Policy Guide* before its publication.

The CDC Public Health Law Program conducted online research regarding the laws of the 17 states pertinent to their public health laboratories' participation in interstate test service sharing. This research included analysis of specific laws the state respondents mentioned as relevant to test service sharing. Legal researchers also reviewed relevant federal laws.

1.5 Limitations and Disclaimer

The 17 laboratories are not necessarily representative of all state laboratories or of local public health laboratories. Enlarging the sample size undoubtedly would have allowed capture of additional, and perhaps different, information. Also, ICH researchers conducted interviews with a limited number of representatives from each participating laboratory. The research findings reported in this *Policy Guide* stem from their recall and extensive experience but might not reflect all the legal and related policy questions their laboratories have encountered in the context of test service sharing.

Although this *Policy Guide* reports on the views and information shared by public health laboratory directors and other state employees, the researchers, analysts, and writers who prepared it bear responsibility for any inaccuracies. Information in this guide does not constitute legal advice and does not represent the views of CDC or of the U.S. Department of Health and Human Services. Moreover, this guide is not intended as a substitute for professional legal or other advice.

2. KEY FINDINGS

The following summary of key findings is based on information that participating state public health laboratory directors and their colleagues shared with *Policy Guide* researchers, supplemented by information received from other public health laboratory professionals and from APHL and CDC programs.

2.1 Participation in Interstate Test Service Sharing

State public health laboratories frequently share test services with the laboratories of other states on an informal basis. Such testing typically responds to ad-hoc, short-term needs and involves a limited volume of tests.

Of the 17 state laboratories that participated in the *Policy Guide* research, 13 reported participating in 18 formal test service sharing agreements that they had initiated. Additionally, all 17 laboratories participated in one or more test service sharing programs or projects that CDC initiated. These projects range from the 50-state Laboratory Response Network (LRN) that began in 1999 to smaller-scale pilot projects initiated more recently and of limited duration.

2.2 Formal Agreement Vehicles

The directors reported using memoranda of understanding (MOUs) and contracts as the vehicles for the majority of the formal agreements initiated. Two laboratories reported using their states' Emergency Management Assistance Compact (EMAC) legislation as the initial vehicle for a NBS testing arrangement after Hurricane Katrina occurred in 2005. They later converted it to a contract. The MOUs and contracts shared with researchers indicated that states have addressed liability and payment questions in both types of vehicles.

Whether to use an MOU or contract or to rely on informal agreements is influenced by the perceptions held by the laboratory directors, state health officials, their legal counsel, and others regarding the laboratory's mission, the likelihood of exposure to liability claims, procurement laws, and other considerations. Selected contracts and MOUs provided by the participating laboratory directors are listed in Resource 3 of this guide; the full text of the agreements are available to APHL members in the APHL Members Resource Center.

2.3 Reported Legal Barriers to Test Service Sharing

The participating laboratory directors identified two legal considerations that have caused the most difficulty for their initiation of formal test service sharing agreements not related to CDC-funded testing arrangements —

- the potential that one state laboratory might be held legally liable for another state laboratory's actions or omissions to act; and
- payment by one state laboratory to another or receipt of payment for tests performed.

Directors also mentioned they had encountered legal questions related to privacy protection, laboratory accreditation, and employee certification and licensure when exploring development of test service sharing agreements. However, they indicated those had been less problematic than liability and payment questions. None of the states reported encountering serious legal concerns in the CDC-sponsored test service sharing projects.

2.4 Concerns Regarding Test Service Sharing

The majority of the 17 directors anticipated increasing their laboratories' participation in test service sharing in the future but expressed concern regarding such problems as

- The often lengthy and difficult process of negotiating formal agreements with officials in their own state and with those of other states;
- for a laboratory that requests testing services by another laboratory, the potential that it might lose capacity to perform high-priority tests and have difficulty in rebuilding that capacity if it were needed in the future;
- the possibility that the laboratory performing tests might give a requesting laboratory's tests lower priority, especially when the testing laboratory is in the midst of responding to a public health emergency in its own state; and
- the potential for reductions in a laboratory's funding and staff positions if participation in test service sharing is regarded as inappropriate outsourcing of testing to another state.

3. FORMAL TEST SERVICE SHARING ARRANGEMENTS

This section describes the interstate test service sharing arrangements that were instituted as of mid-2013 in the 17 participating states. It also summarizes test service sharing projects that CDC has initiated. Comparison of the two helps illuminate factors that can facilitate or impede formation of test service sharing across state lines. This section also describes selected principal reasons state laboratories and CDC programs have reported for forming such arrangements as well as factors considered as they were explored and shaped.

3.1 Overview of Formal Agreements Initiated by State Public Health Laboratories

Of the 17 laboratories that contributed to the *Policy Guide* research, 13 reported that as of mid-2013, they were participating in 18 total formal interstate test service sharing agreements they had initiated. However, additional agreements might have been in place that were not identified by the research.

- Two participated in two agreements (each with one other state laboratory) for disease-specific testing services.
- Seven participated in nine agreements for emergency-related testing.
- Nine participated in seven agreements for NBS testing.

Of the 18 formal agreements,

- six used contracts as the vehicle, and
- 12 used MOUs as the vehicle, including two termed *management agreement* or *partnership agreement*, both hereafter referred to as *MOUs*.

Table 1 summarizes these arrangements and indicates that the vehicles for test service sharing included MOUs and contracts.

Table 1. State-Initiated Test Service Sharing Agreements in Effect as of Mid-2013^{1,2}

Participating States	Services Provided	Vehicle	Payment for Services	Liability
A. Disease-specific testing				
South Carolina and Alabama	Alabama's PHL performs tuberculosis microbial-resistance testing for South Carolina's PHL for five primary drug susceptibilities	Contract	South Carolina reimburses Alabama for agreed-upon fees	Each state is responsible for its own actions and omissions

Participating States	Services Provided	Vehicle	Payment for Services	Liability
Florida and Louisiana	Florida’s PHL performs confirmatory tests for preliminary positive point-of-care HIV rapid test results	MOU	Louisiana reimburses Florida for agreed-upon fees	Each state is responsible for its own actions and omissions
B. Emergency-related testing				
New Mexico, Colorado, Utah, and Arizona (the Four Corners area)	Each PHL performs clinical and environmental tests for the other PHLs “to maintain their continuity of operations [if they are] temporarily unable to perform such testing”	MOU	Each PHL reimburses the other according to its own fee schedule	Each state is responsible for its own actions and omissions
Alaska, Idaho, Oregon, and Washington (the Cooperative of State Laboratories)	Any PHL may request surge support for routine disease outbreak and bioterrorism testing, and other relevant services	MOU	The requesting PHL replaces supplies the testing PHL uses	Each state is responsible for its own actions and omissions
Alaska, Idaho, Oregon, Washington, British Columbia, and the Yukon Territory (the Pacific Northwest Emergency Management Arrangement)	Any member may request emergency assistance from other members (not limited to laboratory services)	Management agreement with implementing state legislation ³	The requesting state must reimburse the assisting state if requested	The requesting state assumes liability for the testing state
Mississippi and Alabama	Each PHL may perform clinical and environmental tests for the other PHL during “a severe disruption of analytical services or an emergency”	MOU	“No compensation will be paid or requested”	Not addressed
Tennessee and Alabama	Each PHL may perform clinical and environmental testing for the other PHL during “a severe disruption of analytical services or an emergency”	MOU	“No compensation will be paid or requested”	Not addressed
Washington and California	Each PHL agrees to perform testing for the other PHL related to chemical terrorism or large-scale chemical incidents	MOU	Not addressed	Each state is responsible for its own actions and omissions

Participating States	Services Provided	Vehicle	Payment for Services	Liability
Idaho and Alaska	Idaho and Alaska “agree to cooperate and share laboratory services, procedures, responsibilities and reimbursement for . . . testing, training, and identification of drinking water contaminants”	Partnership agreement ³	The requesting PHL replaces supplies the testing PHL uses	Each state is responsible for its own actions and omissions
Montana and Idaho	Each PHL agrees to perform surge viral testing for the other PHL during emergencies	MOU	The testing PHL bills according to its own fee schedule	Not addressed
Montana and North Dakota	North Dakota’s PHL may perform molecular testing (for influenza A or B, norovirus, pertussis, herpes simplex virus, varicella zoster virus, and <i>Enterovirus</i>) during disasters	MOU	North Dakota bills for testing services according to its own fee schedule	Not addressed
C. NBS testing				
Alaska, Hawaii, Idaho, Nevada, and New Mexico	Oregon’s PHL performs tests on a routine basis for other states’ NBS programs as well as its own	Contracts between Oregon’s PHL and other states’ NBS programs	Oregon bills the other states’ NBS programs and health care providers	Not determined
Maine, New Hampshire, Rhode Island, and Vermont	The University of Massachusetts performs tests for Maine, New Hampshire, Rhode Island, and Vermont as well as for Massachusetts	Contracts	The University of Massachusetts bills the states’ health and human services agencies for actual costs ⁴	The contractor indemnifies the requesting state and holds it harmless for the contractor’s actions and omissions ⁴
Florida and Texas	Florida’s and Texas’ PHLs perform tests for each other during disasters and catastrophic technology failures	MOU between the NBS programs	The requesting NBS program reimburses the costs of testing	Each state is responsible for its own actions and omissions

Participating States	Services Provided	Vehicle	Payment for Services	Liability
North Dakota and Iowa	Iowa's PHL performs tests for the North Dakota health department	Contract	Iowa bills North Dakota for specified fees	Iowa indemnifies North Dakota for claims related to Iowa's actions
South Dakota and Iowa	Iowa's PHL performs tests for South Dakota	Contract	Iowa bills South Dakota health care providers and birthing centers	Iowa assumes negligence-related liability
Montana and Wisconsin	Wisconsin's PHL performs tests for Montana's PHL	MOU	Wisconsin bills Montana's PHL according to Wisconsin's fee schedule	Not addressed
Colorado and Wyoming	Colorado's PHL performs tests for Wyoming's NBS program	Contract	Not determined by research for this <i>Policy Guide</i>	Not determined by research for this <i>Policy Guide</i>

Abbreviations: HIV, human immunodeficiency virus; MOU, memorandum of understanding; NBS, newborn screening; and PHL, public health laboratory.

- ¹ A list of selected MOUs and contracts referenced in this table is included in Resource 3, and the contracts and MOUs are online at the Association of Public Health Laboratories members resource center.
- ² Reported by the 17 state public health laboratories that participated in the *Policy Guide* research.
- ³ Considered MOUs for the purposes of this *Policy Guide*.
- ⁴ Provisions of the New Hampshire contract.

3.2 Test Service Sharing Vehicles

This section describes the contracts and MOUs that laboratory directors who participated in the *Policy Guide* research reported using for formal test service sharing agreements. This section also reviews legal and other policy questions the directors encountered as they explored and developed those arrangements. Supplemental information is included based on related communications that APHL and CDC had with other public health laboratories.

States have inherent authority to enter into contracts and typically delegate that authority to executive-branch agencies. Of the 17 states represented, at least seven appear to delegate contracting authority to their state health departments.

Certain conventional distinctions between contracts and MOUs are that contracts define the parties' responsibilities in more detail, contain greater specificity (about such factors as payment, liability, and conformity with standards), and can be enforced through court proceedings,

arbitration, or other means. A standard legal reference, for example, states “A contract is a promise or set of promises for the breach of which the law gives a remedy, or the performance of which the law in some way recognizes as a duty.”¹

Three elements typically are required to make a contract a binding agreement: an *offer* — one party proposes to provide a service to the other party; *acceptance* — the receiving party accepts the offer; and *consideration* — the receiving party agrees to pay for the service.

In contrast, MOUs often are thought to articulate and document parties’ general roles in a collaborative venture and not to involve payment between the parties or to be legally enforceable. These conceptual distinctions, however, can be less clear in practice than in legal theory. Some test service sharing MOUs referenced in Table 1 underscore this point because they contain specific provisions regarding liability, indemnification, payment, and compliance with federal and state privacy laws. One even specifies the state whose laws will govern any dispute between the parties.

Public health laboratories’ legal counsel best understand how the laws of their states apply to contracts and MOUs for test service sharing.

3.2.1 Contracts

Five of the 17 participating state laboratories reported successfully entering into a total of six test service sharing contracts.

- Alabama and South Carolina developed a contract through which the Alabama laboratory performs tuberculosis antimicrobial susceptibility testing for South Carolina. This arrangement started as an MOU and was converted to a contract a year later. The contract negotiations reportedly were uncomplicated, in part because of the successful track record under the MOU. Liability provisions, among other details, had been resolved in the MOU. In addition, the states’ counsels were credited with understanding the importance of continuing the testing program.
- Five contracts were for NBS test services. In these cases, a state public health laboratory that agrees to perform NBS tests might contract with its counterpart laboratory in the other state or with that state’s NBS program. Three states with small populations chose to have another state’s public health laboratory perform their NBS testing. Costs might be further elevated when new types of tests are mandated that involve expensive new technologies. Small-population states also might opt to have NBS tests performed in another state if they lack the expertise needed to perform clinical follow-up steps based on NBS test results.
- Three of the NBS agreements involve broad test panels: the Oregon state public laboratory conducts NBS testing for Alaska, Idaho, Nevada, and New Mexico; Colorado tests for Wyoming; and Iowa tests for North Dakota and South Dakota. During emergencies, Florida and Texas are authorized to conduct tests for each other. The focus is narrower in one of the five agreements: Wisconsin performs tandem mass-spectrometry tests for Montana.

¹ Restatement (Second) of Contracts, Section 30. The American Law Institute, 1981.

3.2.2 MOUs

The state laboratory directors who contributed to the *Policy Guide* research reported entering into 12 test service sharing MOUs. A total of 22 states participated in those MOUs.

Disease-Specific Testing

During 2012, the Miami regional public health laboratory, part of the state public health laboratory, entered into an MOU with the Louisiana public health laboratory to perform Food and Drug Administration (FDA)-approved human immunodeficiency virus (HIV)-1 Western blot confirmatory tests for presumptive positive point-of-care HIV test results. Florida statutes authorize interstate test service sharing only in the event of an emergency. In this context, Florida counsel deemed the fact that the Louisiana laboratory cannot perform this test as constituting an emergency. The agreement specifies payment by Louisiana and, for purposes of liability, specifies that each state is responsible only for its own actions and omissions to act.

Emergency-Related Test Service Sharing

Seven of the directors interviewed reported using a total of nine MOUs as vehicles for emergency-related test service sharing. In this context *emergency* is variously defined as including large-scale disasters and public health emergencies, unforeseen disruption of a laboratory's operations by flooding or other external event, and interruption of testing services (e.g., when a laboratory temporarily closes for planned maintenance or cleaning). The majority of the nine MOUs do not provide for reimbursement to the testing laboratory. Moreover, in the majority of the MOUs, the parties agree to be legally responsible only for their own acts or failures to act; some MOUs do not address liability.

- Arizona, Colorado, New Mexico, and Utah executed the Four Corners MOU in 2009 and renewed it in 2013. Under this agreement, each laboratory may request testing assistance from the others in a broad set of emergency-related circumstances. Members agree to reimburse each other for testing services they provide. The agreement specifies that the states are not liable for each other's actions.
- Dating from 1996, the Pacific Northwest Emergency Management Agreement (PNEMA) among five U.S. states and two Canadian provinces is in the general form of an MOU. It authorizes broad provision of mutual assistance by all relevant state/provincial agencies, including state public health laboratories. Oregon and possibly other states enacted legislation to further specify activities under PNEMA. Members agree to reimburse for services rendered if requested. The jurisdiction that requests assistance assumes liability.
- Four Pacific Northwest state laboratories executed the Cooperative of State Labs agreement in 2004 specifically to provide "surge capacity for routine disease outbreaks and bioterrorism events." Each laboratory agrees to replenish supplies the assisting laboratory uses on its behalf; each laboratory assumes liability only for its own actions and omissions to act.
- Alabama's public health laboratory has MOUs with Mississippi and Tennessee authorizing all three to perform clinical and environmental testing services when one of the other laboratories' operations are disrupted or during emergencies. These MOUs do not address reimbursement and liability.

- California and Washington executed an MOU in 2005 for mutual aid in the event of biochemical terrorism. It provides for replenishment of supplies and specifies that each state is responsible for its own actions.
- The Montana state public health laboratory has two emergency-related MOUs in place. The MOU with Idaho refers to emergencies in broad terms. The MOU with North Dakota provides for the North Dakota laboratory to perform molecular testing for Montana for different infectious diseases during disasters when results are needed urgently for patient decisions or outbreak investigations. Neither MOU addresses liability, but both provide for reimbursement.
- The *Policy Guide* researchers learned of other test service sharing agreements that did not involve the 17 states. In one MOU, for example, a state public health laboratory agrees to perform variola virus confirmatory testing for the public health laboratory of a neighboring state in response to a “real or perceived terrorist attack.” That MOU does not address payment or liability questions. (Both laboratories requested anonymity.)

NBS Testing

Four states reported using MOUs as the vehicle for agreements to perform NBS testing.

- An MOU between the Florida and Texas state NBS programs commits their respective state laboratories to performing NBS testing for each other when needed in the context of disasters and “catastrophic technology failures.” The requesting NBS program is expected to reimburse the costs of testing. Each state agrees to be responsible for any liability associated with its actions or failures to act.
- The Wisconsin state public health laboratory entered into an MOU to perform NBS tests for the Montana state NBS program. The Wisconsin laboratory bills Montana’s health department for specified costs.

3.2.3 Negotiating Provisions of Contracts and MOUs

The participating laboratory directors mentioned two unsuccessful attempts to develop MOUs that would have supported testing surge capacity during emergency situations. One, the former Mid America Alliance initiated in 2004, failed to reach agreement over specific legal provisions, reportedly centering on liability concerns. At least one of the states that participated in those negotiations ultimately engaged a private laboratory to assist in surge testing. The other attempt was to develop surge capacity for environmental testing but was not finalized, at least in part because of disagreements over indemnification and accreditation of the member laboratories by the National Environmental Accreditation Conference.

The laboratory directors indicated considerable variation in their state partners’ understanding of parameters on the use of MOUs. One director said that her state’s MOUs are legally binding. Another indicated that MOUs are a traditional vehicle that is sanctioned by the office that handles contracts. Other states indicated they use MOUs specifically as a legally accepted alternative to the cumbersome processes their states are required to use when developing and executing contracts.

The majority of the identified MOUs provide for payment by one state to another. Some include elements more typical of contracts (e.g., provisions related to liability and privacy protection). Directors noted that certain elements have proven difficult to resolve while proposing and negotiating MOUs.

3.2.4 Comparing Vehicles

Contracts and MOUs

Table 1 reveals apparent distinctions among the states' use of contracts and MOUs as vehicles for formal test service sharing.

- Two of the seven NBS test service sharing agreements were in the form of contracts.
- All but one of the other agreements were MOUs; the exception is the five-year contract between the Alabama and South Carolina public health laboratories for tuberculosis microbial resistance testing.

Overall, contracts appear to have been used for test service sharing arrangements that have the following characteristics:

- an expected volume of tests that are performed on a frequent and routine basis, as is the case with NBS testing;
- a well-defined set of markers or conditions for which testing is performed;
- an established array of tests and test methods that adhere to widely accepted quality standards (e.g., standards of the Newborn Screening Quality Assurance Program) and thus help allay concerns regarding liability; and
- an institutionalized source of funding (e.g., health insurance plans) and established billing systems.

In contrast, MOUs appear to have been used in test service sharing arrangements with the following general characteristics:

- unpredictable volumes of tests that are performed infrequently, for which advance warning is limited or nonexistent, or that might have potential to overwhelm the testing capacity of a laboratory;
- tests that might be for novel (e.g., influenza A [H1N1]) or especially dangerous biologic, chemical, or radiologic pathogens and toxins; and
- no established, uniform source or mechanism for payment.

Aside from their use in NBS testing agreements, the laboratory directors reported that contracts were their least-favored vehicle for test service sharing because of

- the complex procedural aspects of complying with states' procurement regulations, especially if a proposed contract is subject to competitive bidding and award; (Several of the laboratory directors reported that fulfilling mandatory procedural requirements could take months, and one director reported that it had taken 3 years to execute an interstate test service sharing contract.)

- states' often disparate contract requirements that might require extended negotiations between their respective legal counsels; and
- concerns regarding the participating states' liability if they fail to fulfill the procedural requirements of a contract or if a patient or community alleges that the laboratory did not exercise responsible judgment in conducting tests and reporting test results.

Laboratory directors cited multiple attempts to develop test service sharing contracts that ultimately were not concluded. Differences in states' requirements related to protection against liability claims were reported to have been a frequent point of disagreement.

Despite such challenges, some laboratory directors reported that their states prefer, or require, contracts as the vehicles for test service sharing, especially when one state pays another state. Other directors reported a preference for MOUs because they might be easier to negotiate and more readily modified, if necessary, as laboratories gain experience implementing test service sharing.

Informal Agreements

Some laboratory directors reported preferring ad-hoc or director-to-director agreements to formal agreements but understood that they might not be entirely risk-free. These agreements exemplify the practical, mission-driven ethos typical of public health practitioners; tend to be grounded in preexisting, professional relationships among laboratory directors; and to a certain extent, reflect states' geographic proximity.

Two directors determined that making informal arrangements for test service sharing for chemical terrorism was easier than establishing an MOU for that purpose. The problem in that case was less one of legal impediments than the perception that elected officials might object to one laboratory's taking on additional workload when the decision had been made earlier to reduce state funding for that laboratory.

Informal test service sharing appears to be practiced by laboratories whose leaders meet regularly to explore opportunities for collaboration in multiple areas. Some regional consortia of state laboratories have completed inventories of their testing capabilities so that each state laboratory can know which of the others might be able to perform a rare or low-volume test for which it lacks the needed capacity.

The Northern Plains Consortium arrangement is the longest existing of these consortia. The state laboratories that serve Montana, North Dakota, South Dakota, and Wyoming began collaborating in 1999; the Idaho laboratory joined the consortium in 2013. A modest CDC grant in 2005 assisted the consortium in strengthening the region's clinical laboratories' antimicrobial sensitivity testing abilities. Thereafter, the state laboratories, using their own resources, have performed designated testing services for each other that are low in volume but entail high cost for laboratories that have to maintain capacity to perform those tests. Some of the shared testing services are for the HIV multispot test, 16s ribosomal bacterial identification, hantavirus serology, certain IgM serologies, and pulsed-field gel electrophoresis for nonenteric pathogens. Payment between the laboratories, which is infrequent, is by invoice and is based on the testing

laboratory's fee schedule. The consortium state laboratories also collaborate in workforce development, communication planning, specimen exchange, electronic laboratory data exchange, and reducing procurement costs.

3.3 Test Service Sharing Sponsored by CDC

As of mid-2013, CDC programs sponsored and funded eight systems or projects in which state public health laboratories performed tests for each other for designated purposes. Some participating public health laboratories also exchanged other services with each other (e.g., training and technical consultation).

Four of these projects supported national networks whose members included all or the majority of state public health laboratories, multiple county or city public health laboratories, and CDC laboratories. Other federal laboratories also participate in the Laboratory Response Network-Biological (LRN-B) and the Laboratory Response Network-Chemical (LRN-C). The following networks have been in continuous operation since they were established:

- PulseNet was established in 1996 to detect and facilitate investigation of foodborne bacterial outbreaks by using pulsed-field gel electrophoresis to accurately subtype pathogens.
- CaliciNet was initiated in 2009 to improve detection of norovirus outbreaks.
- The LRN-B was created in 1999 to improve detection of biologic threats associated with terrorism. CDC requires each LRN-B laboratory, as part of a biennial requalification process, to affirm that, "As a member of the network and as state and local resources and priorities permit, our laboratory agrees to support surge capacity testing associated with testing exigencies, especially during a declared national emergency."
- Also in 1999, the LRN-C was established to improve detection of biologic and chemical threats associated with acts of terrorism. CDC requires all Level 3 LRN-C laboratories to establish MOUs with LRN-C laboratories in other jurisdictions.

Each of these networks has tiers of laboratories with progressively greater analytic capacity. In the LRN-B, for example, suspect biologic samples that cannot be accurately typed by a sentinel laboratory can be referred to approximately 160 reference laboratories (the majority of them public health laboratories) that have greater analytic capacity and, if necessary, can be referred further to CDC and other federal laboratories for definitive analysis.

The following four CDC-sponsored projects were smaller-scale reference-center pilots with lifespans of only 2–5 years, extending into 2013. These projects made highly specialized testing and related laboratory methods available to public health laboratories that lack that capability, to assess the feasibility of concentrating certain testing services in selected state public health laboratories, and for other reasons.

- The Influenza Resistance Testing project was established to ensure that three sophisticated types of antimicrobial resistance testing are available to all states, including states that lack that capacity. As of mid-2013, New York's state public health laboratory performed pyrosequencing resistance testing for 15-20 public health laboratories lacking that capacity

(and for certain public health laboratories with it). Three state public health laboratories (California, Utah, and Washington) performed virus isolation testing and neuraminidase inhibition testing for all other states.

- In the HIV NAT Referral Project, the Florida and New York state public health laboratories performed nucleic acid testing (NAT) for 29 submitting public health laboratories.
- During a tuberculosis project, the Colorado state public health laboratory performed first-line drug susceptibility testing (DST) for the Montana, North Dakota, South Dakota, Utah, and Wyoming state laboratories and for Denver’s public health laboratory. The California state public health laboratory performed pyrosequencing to detect resistance-associated mutations and DST for Wisconsin.
- Through the Vaccine-Preventable Disease Reference Laboratories project, the California, Minnesota, New York, and Wisconsin state public health laboratories provided testing for measles, mumps, rubella, varicella-zoster virus, rotavirus, pertussis, *Haemophilus influenzae*, *Neisseria meningitidis*, and *Streptococcus pneumoniae* for 30 state and nine county public health laboratories.

During these projects, the laboratories performing testing services also provided other laboratories with assay protocols, education, and other services. Table 2 indicates the purpose of each of the CDC-sponsored projects, the services provided, and the public health laboratories that participated in them as of mid-2013.

Table 2. CDC-Sponsored Test Service Sharing Projects in Effect as of Mid-2013

Project	Purpose and Participation ¹	Services Provided
PulseNet	<ul style="list-style-type: none"> • Improve detection of foodborne disease outbreaks; 87 state and local PHLs, state agricultural, and federal food regulatory agency laboratories participate 	<ul style="list-style-type: none"> • 8 regional or area PHLs provide surge capacity for subtyping (e.g., pulsed-field gel electrophoresis) for member PHLs (e.g., during widespread outbreaks and laboratory staffing shortages) • 8 regional PHLs also provide training and troubleshooting for PHLs in their areas
CaliciNet	<ul style="list-style-type: none"> • Improve detection of norovirus outbreaks; 28 state PHLs and 4 local PHLs participate 	<ul style="list-style-type: none"> • 32 PHLs perform real-time polymerase chain reaction testing to detect norovirus in outbreak samples and conduct sequencing-based subtyping • Five outbreak support centers provide norovirus sequencing for PHLs lacking that capacity
LRN-B	<ul style="list-style-type: none"> • Improve preparedness and response to biologic public health threats; all state PHLs participate 	<ul style="list-style-type: none"> • Private, commercial, and public clinical laboratories refer suspicious samples to ~160 reference laboratories (state and local PHLs and others) • National laboratories (CDC, the US Army Medical Research Institute for Infectious Diseases, and the Naval Medical Research Center) perform the highest-level tests

Project	Purpose and Participation ¹	Services Provided
LRN-C	<ul style="list-style-type: none"> • Improve response to chemical public health threats; all state PHLs and the PHLs of the District of Columbia, Los Angeles County, New York City, and Puerto Rico participate 	<ul style="list-style-type: none"> • 54 Level 3 laboratories assist hospitals, and first responders identify and coordinate response to chemical exposure incidents • 36 Level 2 laboratories identify and coordinate response to chemical exposures and test to detect exposure to multiple toxic chemicals • 46 Level 1 laboratories identify and coordinate response to chemical exposure incidents and test to detect exposure and act as surge capacity for CDC
Influenza Resistance Testing	<ul style="list-style-type: none"> • Assist identification of resistant influenza strains • Perform tests for PHLs lacking testing capacity • Provide surge capacity for CDC 	<ul style="list-style-type: none"> • The New York PHL performs pyrosequencing resistance testing for PHLs lacking that ability (and for some of the 20 PHLs that have it) and for CDC for surge purposes • The California, Utah, and Washington PHLs (“contract laboratories”) perform virus isolation and neuraminidase inhibition testing for all other state PHLs • The California, Utah, and Washington PHLs send viral isolates to CDC for further characterization and for use in vaccine strain selection
Vaccine Preventable Disease Reference Laboratories	<ul style="list-style-type: none"> • Determine if turnaround time is acceptable for broader implementation • Provide viral molecular and bacterial assays to reference laboratories not available commercially • Harmonize assays for interpretation consistency and simplify proficiency 	<ul style="list-style-type: none"> • The California, Minnesota, New York, and Wisconsin state PHLs test measles, mumps, rubella, varicella-zoster virus, rotavirus, pertussis, and <i>Haemophilus influenzae</i>, <i>Neisseria meningitidis</i>, and <i>Streptococcus pneumoniae</i> for 30 state and nine county PHLs • Sequencing and genotyping is provided for viral vaccine-preventable diseases, except rotavirus • Wisconsin develops and provides proficiency testing panels for Bordetella species, <i>N. meningitidis</i>, and <i>H. influenzae</i> for all state PHLs not performing such tests
Tuberculosis Testing	<ul style="list-style-type: none"> • Explore alternative service delivery models and evaluate potential cost savings and impact on quality of service delivery 	<ul style="list-style-type: none"> • Rapid direct detection by NAA testing • Iowa performs NAA tests for Missouri • DST <ul style="list-style-type: none"> — California performs pyrosequencing to detect resistance-associated mutations and conventional DST for Wisconsin — Colorado performs first-line DST for Denver, Montana, North Dakota, South Dakota, Utah, and Wyoming — New York performs DST for Rhode Island • NAA testing <ul style="list-style-type: none"> — Montana performs NAA testing for Wyoming — Montana, North Dakota, and Wyoming conducted combined educational campaign with tuberculosis program managers and infectious disease physicians
HIV NAT Referral Project	<ul style="list-style-type: none"> • Perform NAT testing for PHLs with cost-inefficient testing volume 	<ul style="list-style-type: none"> • Florida and New York provide NAT for 29 submitting sites

Abbreviations: DST, drug susceptibility testing; HIV, human immunodeficiency virus; LRN-B, Laboratory Response Network-Biological; LRN-C, Laboratory Response Network-Chemical; NAA, nucleic acid amplification; NAT, nucleic acid testing; and PHL, public health laboratory.

¹ See also the services provided column for additional participation information.

No legal or other policy concerns that might have impeded public health laboratories' participation in the projects were reported in five of the eight projects. Potentially problematic legal questions reported for the three other projects were related to laboratories' receipt of payment from other states for testing services they provide to those states, state procurement law and payment for testing services, and licensure for laboratory professional staff. As noted in more detail in Section 4, these questions were resolved successfully, and the concerned state laboratories were able to participate in the projects with minimal hindrance.

3.4 Why Public Health Laboratories Participate in Test Service Sharing

The public health laboratory directors who participated cited four principal reasons for initiating test service sharing, separate from sharing initiated by CDC. The reasons, which varied from state to state, included the following:

- The high cost of performing and maintaining capacity to perform certain low-volume tests. Laboratory directors serving large but sparsely populated states cited the challenge of maintaining testing capacity for rare or unusual diseases (e.g., botulism, hantavirus, and certain VPDs). The related costs include establishing the testing apparatus, training and maintaining the skills of the staff who perform the tests, and meeting quality-control and proficiency testing requirements.
- The high cost of developing capacity to perform new assays or tests for novel diseases and conditions.

Approximately one-half of the interviewed directors cited the challenges associated with developing capacity to perform newer tests (e.g., influenza A [H1N1] during the pandemic of 2009, genetic tests added to newborn screening panels, and whole genome sequencing). Although all directors expressed interest in developing such capacity, they recognized that not all laboratories can afford the new equipment and expertise such tests require. Relatedly, two states also cited the challenges that state procurement laws and procedures can pose when new testing platforms must be acquired.

- Emergency response and continuity of operations planning. Many of the directors said that strengthening their laboratories' ability to respond to public health and other emergencies was a major impetus to developing test service sharing arrangements with other states' laboratories. The majority of the directors had experience managing laboratories during epidemics, natural disasters, and major disruptions of their laboratories' work. All of the directors considered that their laboratories' highest priorities include protecting the public from major threats and that providing for surge testing capacity through test service sharing is crucial for fulfilling that role.
- Fulfillment of mission to serve the public. Underlying all the other reasons for initiating test service sharing is the state public health laboratory directors' commitment to fulfilling their laboratories' overriding mission of protecting the public's health. The APHL publication *The Core Functions of State Public Health Laboratories* defines functional elements needed to support that mission.²

² Association of Public Health Laboratories. *The Core Functions of State Public Health Laboratories*. Silver Spring, MD: APHL; 2010. Available at: http://www.aphl.org/aboutaphl/publications/documents/com_2010_corefunctionsphls.pdf.

The interviewed laboratory directors explicitly discussed the potential that test service sharing can help fulfill that mission, especially given the deep budget and staff cuts their laboratories have experienced during the economic recession and the directors' expectation that substantial new resources are unlikely to materialize.

Laboratory directors cited these and additional benefits to participating in test service sharing activities that CDC sponsors, such as the following:

- the ability for requesting laboratories to have tests performed that might exceed their technical capacity, especially testing that involves new or expensive methods and platforms;
- the ability all the participating laboratories have to obtain test results on high-priority disease concerns for the populations they serve; and
- the opportunity such arrangements offer for the laboratories that perform tests to build and strengthen their technical and scientific capacity.

CDC's purposes in the projects in which all state public health laboratories participate — PulseNet, CaliciNet, LRN-B, and LRN-C — are to improve nationwide detection of foodborne disease outbreaks and preparedness and response to biologic and chemical threats and to terrorism. They signify the federal government's recognition that states lack the capacity and mandate to ensure that the nation's public health laboratory system can address those health priorities adequately. CDC provides funding to the participating laboratories and, in certain instances, also provides reagents, training, and technical consultation.

A common goal for the other projects CDC sponsors is to determine whether a limited number of adequately resourced public health laboratories can perform tests — against defined criteria — for states that lack the necessary testing capacity. Criteria for evaluating success include turnaround time (24 hours in the case of the VPD project) and other service-quality indicators. An additional purpose of the LRN-C and Influenza Resistance Testing projects is to perform tests for CDC when the volume of testing needed exceeds CDC's capacity.

3.5 Selected Concerns Regarding Test Service Sharing

Laboratory directors' appreciation of the potential benefits of test service sharing was tempered by perceived risks. Key concerns expressed included the following:

- Potential loss of in-house testing capacity.
Directors noted that relying on another state's laboratory can result in loss of professional staff, expertise, and equipment and render their laboratories unable to perform critically important tests if needed in the future. A laboratory that divests itself of vital institutional knowledge and capacity might not have a credible backup plan if the laboratory that performs tests on its behalf finds it cannot continue that service.
- Potential loss of control over high-priority testing.
Public health laboratory directors who are considering having another laboratory perform tests on their behalf are concerned that that laboratory might feel compelled — especially in the context of an anthrax attack such as that of 2001 or a multistate epidemic — to place first priority on completing its own state tests.

- Potential impediments to supporting the mission of the state’s public health agency. Interviewed directors reported they would be happy to perform tests for another state laboratory if the needed agreements could be arranged. In contrast, they also acknowledged that they are reluctant to give up testing capabilities, particularly for routine and high-visibility tests. They consider that service to their states’ own population, programs, and other stakeholders to be their laboratories’ defining mission, and that relinquishing testing to another state’s laboratory has potential for reducing their laboratory’s ability to fulfill that mission.
- Potential loss of support among elected officials. States’ public health leaders ultimately are accountable to executive and legislative officials. Laboratory directors appreciate the importance of maintaining those officials’ support for the laboratory and do not want participation in test service sharing to result in misperceptions about the laboratory. Agreeing to perform tests for another state laboratory or to have another laboratory do tests might result in questions, for example, about the laboratory’s level of funding, its use of state resources, and its responsiveness to state needs, or conversely, the possibility of transferring additional testing services to other public or private entities. The interviewed laboratory directors underscored the importance of engaging state health officials, state epidemiologists, and state public health program leaders who rely on laboratory test results during any exploration of potential test service sharing. All these partners have standing expectations for laboratory services that support their decision making and program operations. They might have concerns that the laboratory’s potential participation in test service sharing will affect their access to essential test results and related information.

Despite these reservations, the directors acknowledged the benefits of working collaboratively across states to maintain testing services, especially during emergencies. They also acknowledged that the likely persistence of budget constraints will require more creative thinking regarding ways to ensure continuity of existing testing services.

4. REVIEW OF LAWS AND LEGAL CONSIDERATIONS

The state public health laboratory directors and colleagues who participated in the *Policy Guide* research were asked in interviews to identify and comment on laws, legal questions, and other policy challenges they have found to be supportive of or impediments to test service sharing. The following eight topics were suggested for their consideration (the directors were invited to discuss additional topics as well):

- authority to participate in test service sharing,
- payment for shared test services,
- risk management,
- privacy protection,
- certification and licensure,
- specimen management and use,
- disease reporting, and
- emergency management.

Section 4 reports on the information that directors and their colleagues provided during those interviews and includes supplemental information, as appropriate.

Briefly, the principal findings were as follows:

- None of the 17 states appears to have laws that expressly authorize or prohibit test service sharing.
- With only one exception, the absence of such authority does not appear to have precluded development of formal test service sharing agreements.
- Concerns that stem from state laws associated with liability and payment for test services have complicated states' initiation of formal test service sharing agreements.
- Other laws and legal mandates are relevant to test service sharing and might warrant attention by public health laboratory directors who want to explore developing formal test service sharing agreements.

4.1 Authority to Participate in Test Service Sharing

A threshold question is whether public health laboratories have legal authority to engage in test service sharing. Legal authority that supports public agency actions can take different forms, including legislatively enacted statutory provisions that expressly permit, or even require, specified actions and administrative regulations or rules. In certain cases, the absence of an express legal prohibition might be construed as condoning given activities. The majority of states have enacted laws that establish public health laboratories, or their parent public health departments, and that authorize promulgation of rules and regulations regarding the laboratories' activities.

The 17 participating directors (and their legal counsel) indicated that none of their states' laws expressly authorize the laboratories' entering into formal agreements for test service sharing. In contrast, the majority believed that the statutes that authorize and enable the laboratories or

their parent agencies confer sufficient authority to do so. For example, enabling statutes might require the public health laboratory or its parent agency to perform tests important to the public's health or to ensure that such tests are performed. Some directors interpreted such provisions as authority to share test services with other state laboratories if, in their professional judgment, doing so would help fulfill that responsibility (e.g., because a laboratory lacks crucial staff or equipment, to ensure surge capacity, or for other reasons).

One director had been advised by counsel that the absence of express legal authority prohibits the laboratory from entering into test service sharing agreements with other states. The director indicated that the public health department was exploring the potential for new legislation that would expressly authorize test service sharing. The two directors whose laboratories are part of state universities indicated that the universities have authority to approve interstate test service sharing agreements and have granted that approval to the laboratories.

One laboratory is authorized to enter into such agreements only for emergency preparedness and response purposes. Over time, its successive legal counsel have voiced different interpretations of what constitutes an *emergency*. An earlier opinion held that *emergency* specifically denotes a statewide state of emergency declared by the governor. As of mid-2013, however, the incumbent counsel interpreted the term more broadly to include any situation that prevents the public health laboratory from performing tests that are required to protect the public's health (e.g., equipment failure, temporary loss of testing capability because of staff turnover, or a mandate to perform a new test that the laboratory is not equipped to perform). On that basis, this state has developed an MOU with another state laboratory for NBS testing.

All states have enacted essentially uniform legislation authorizing provision and receipt of interstate mutual aid related to emergencies that are declared by governors. These statutes followed Congressional approval of EMAC in 1996.³ States' EMAC agreements encompass all emergency-related state agencies and programs.⁴ *Policy Guide* research identified one use of EMAC authority for public health test service sharing: the Iowa state public health laboratory's performance of NBS tests for Louisiana for a year after Hurricane Katrina occurred in 2005.

More generally, the model federal EMAC statute includes a provision for "temporary suspension of any statutes or ordinances that restrict the implementation of EMAC-authorized mutual aid." Declaring an EMAC emergency might enable a state to engage in test service sharing by suspending its standing prohibition. Even if that happened, the authority for test service sharing would be in effect only for the duration of the governor's declaration of emergency.

4.2 Payment for Shared Test Services

The interviewed laboratory directors reported that making and receiving payment for test services that one state public health laboratory performs for a counterpart in another state can result in some of the most serious legal questions related to test service sharing. The state laws that govern public health laboratories' charges for test services are highly diverse. Some laws are interpreted as prohibiting such charges. Among the states that do allow charges, some specify

³ P.L. 104-321, 110 Stat. 3877 (1996).

⁴ See, for example, the California EMAC statute: Cal. Code Sec. 3.7-179.

a fixed amount, whereas others permit full cost recovery. Laws often exempt certain types of testing from charges (e.g., tests conducted for reportable diseases or for the state's public health department).

States vary also in the disposition of revenues received from testing charges. Arizona law, for example, requires them to be deposited in the state treasury to support general state needs. In contrast, Texas law directs testing receipts to a fund that is designated to support the state's public health services. Kansas, Minnesota, Ohio, and possibly other states direct testing payments to funds designated specifically to support their public health laboratories. These heterogeneous approaches have diverse implications as laboratory leaders explore the merits of test service sharing.

In more detail, directors reported the following legal parameters related to interstate exchange of funds for test services:

- The majority of laboratories have legal authority to make payment to and receive payment from other states' public health laboratories, but the directors reported legal limits on their laboratories' ability to retain and use payment revenues.
- Two laboratories lack authority to pay or receive payment from other states' public health laboratories.
- Seven of the laboratories have authority to deposit test-related (and other) revenues in dedicated funds they control. The Florida state laboratory, for example, deposits the payments it receives from Louisiana for HIV-related testing in a fund established specifically for use by the Bureau of Public Health Laboratories.
- Multiple states require that such payments go to the state's general fund or other funds that the laboratories do not control, preventing them from recouping their costs. In certain cases, only revenues that exceed a specified level must go to those funds.
- The state laboratories that perform NBS tests for other states use contracts that include agreed-upon fees they charge for the service. The testing laboratories have legal authority to charge such fees and to use the income to cover the testing costs. The contracts are executed with the NBS programs of the client states rather than with their state laboratories.

States' EMAC statutes expressly authorize them to pay each other for mutual assistance, greatly facilitating test service sharing during governor-declared emergencies. (See Resource 4 for an example of that standard provision). In contrast, state laboratories have had to rely on informal arrangements with other states when their operations are interrupted by flooding, equipment failure, and other developments that do not warrant a governor's declaration of emergency.

Related concerns that laboratory directors voiced include

- the difficulty some laboratories have in obtaining legislative or executive branch approval to charge fees that cover tests' actual costs, which tend to increase over time; and
- the possibility that a laboratory that performs tests might be required to charge testing fees that the requesting laboratory cannot afford.

APHL and CDC staff reported that the two following, potentially problematic, legal questions had surfaced, but were resolved, during planning for two CDC-sponsored test service sharing projects:

- Some of the laboratories that planned to submit specimens to VPD reference laboratories indicated that their state procurement laws would require them to solicit competitive bids from other public and private laboratories if the reference laboratories charged a fee for the testing. Inclusion of those laboratories might have detracted from the pilot-test design. In the final event, the fact that CDC provided funds to support the reference laboratories' activities avoided that potential problem.
- In the HIV NAT Referral Project, the Florida state public health laboratory — one of the laboratories selected to perform NAT testing for the other participating laboratories — reportedly was prohibited by law from receiving payment from other states. This potential problem was averted by CDC's financial support for the Florida laboratory's activities, also extended through an APHL cooperative agreement.

One laboratory director stated that his laboratory would need to have third-party billing capability before it could participate in test service sharing and that new legislative authority would be required to bill insurance plans. The director was not optimistic that approval would be forthcoming and also noted that the likely volume of tests would be too low to justify costly investment in new billing capability.

4.3 Risk Management

State governments want to minimize their liability for acts of commission or omission by other parties, including acts by either of the state laboratories engaged in test service sharing. The directors reported that concerns about liability have ranked high among the challenges to developing test service sharing contracts between states. In this context, actions that might prompt claims include delayed or inaccurate reporting of test results, loss or misuse of specimens, and breaches of privacy.

Laboratories can address liability concerns as they negotiate formal test service sharing agreements, whether they use contracts or MOUs as vehicles. Negotiation can identify and allocate the responsibility for liability risks between the involved states. One option, for example, is to include an indemnification provision in which one or all parties agree to compensate the others for loss or damages they suffer. Such a provision can specify the indemnifying state's liability and provide for recovery of fees and other costs incurred in exercising indemnification. The participating states also can choose, if they desire, to define the types of events that might trigger indemnification and the scope of actions to which indemnification applies.

Several state laboratory directors reported they had worked for extended periods to develop new test service sharing agreements only to be rebuffed when counsel for the involved states were unable to resolve liability concerns, including "choice of law" and jurisdiction (i.e., specification of the state whose laws will govern in the case of a dispute).

Directors often reported success in resolving liability questions through negotiation with their counsel and the partnering state laboratory. Instances include, for example, the 2013 Four

Corners MOU for surge testing during emergency situations and the Florida-Texas MOU for backup NBS testing. Both include mutual indemnification clauses that limit liability to the party deemed responsible for a specified act.

Laboratory directors also reported success in increasing their counsels' understanding of the laboratories' work. This included appreciation for the extensive quality-assurance measures that help protect the privacy and confidentiality of the persons associated with test specimens, accreditation requirements that help ensure compliance with federal guidelines, and other safeguards that reduce the likelihood of claims against the state.

4.4 Privacy Protection

Public health laboratories are subject to federal and state laws that protect individuals' privacy and the confidentiality of information related to their health. However, laboratories that are part of public universities might be subject to additional protections adopted by those institutions. Research for this *Policy Guide* did not identify any substantial impediments to interstate test service sharing related to federal or state privacy and confidentiality laws and policies.

4.4.1 The Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act

The pertinent federal law is the Health Insurance Portability and Accountability Act (HIPAA) of 1996.⁵ HIPAA created national privacy and security safeguards for individually identifiable health information — protected health information — including standards for health information that is transmitted electronically. Protected health information comprises any health information that “identifies an individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.” Congress revised and strengthened those protections in the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act.⁶ The U.S. Department of Health and Human Services issued a final rule to implement the 2009 provisions on January 25, 2013.⁷

HIPAA establishes nationally uniform, minimal safeguards for individually identifiable information that typically applies to “covered entities” (e.g., health care providers, health plans, and health clearing houses). They also apply to those entities' affiliated “business associates” (e.g., claims processors and data services). HIPAA permits disclosure of such information to “public health authorities” and allows them to use and disclose it “consistent with the laws, regulations, and policies applicable to [that] public health authority.”⁸

⁵ P.L. 104-191. 110 Stat. 1936 (codified as amended in sections of Titles 18, 26, 29, and 42 of the U.S. Code).

⁶ Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), P.L. 111-5, 123 Stat. 226 (codified at 42 U.S.C. sections 300jj et. seq.; sections 17901 et. seq).

⁷ See: Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act: Other Modification to the HIPAA Rules, 78 Fed. Reg. 17.5566-5702 (Jan. 25, 2013). To be codified at 45

⁸ Hodge, J. The HIPAA Privacy Rule and Public Health Laboratories: Guidance prepared for the Association of Public Health Laboratories. Not dated. Available at: http://www.schs.state.nc.us/hipaa/references/APHL_HIPAA_Guide1-for-Public-Health-Labs.pdf.

A public health laboratory that performs tests or other services related to the provision of health services to an individual — in addition to tests for public health purposes — might be considered a covered entity or a hybrid entity and thus be required to comply with HIPAA. The New Mexico public health laboratory, for example, is located within the state department of health, which is a covered entity. At least two more of the 17 state public health laboratories appear to be hybrid entities (i.e., performing both covered and noncovered functions). Covered entities must have agreements in place with business associates to ensure that they too comply with the HIPAA protections. One of the effects of the HITECH Act was to strengthen the requirements of business associates, including making them directly liable for compliance.⁹

HIPAA privacy and security requirements have had implications for at least one of the existing test service sharing arrangements initiated by the 17 states: the Four Corners MOU among Arizona, Colorado, New Mexico, and Utah. The New Mexico laboratory is a covered entity and thus must comply with the HITECH Act requirements. The three other state laboratories are considered business associates of the New Mexico laboratory, and New Mexico requested they sign those new agreements. Ultimately, the confidentiality agreements those states require their employees to sign were determined to be sufficient for the purpose, and the new MOU was finalized in 2013.

As reported by the 17 laboratory directors and their colleagues, the HIPAA requirements appear to have had no other implications for interstate test service sharing.

4.4.2 State Privacy Laws

All states have adopted legal protections for health information that supplement and, in certain cases, go well beyond the HIPAA protections. States may not adopt protections that are weaker than or conflict with the HIPAA protections.

Public health laboratory directors, staff, and counsel interviewed by the *Policy Guide* researchers reported instances in which state privacy-related laws and policies have surfaced related to test service sharing.

- One laboratory reported that its state public records law prohibits disclosure of an individual's health information except when the person consents, during a medical emergency, pursuant to a court order, or for specified health research purposes. This provision affected implementation of an emergency-related agreement with another state because it prohibited use of identifiable patient information during a joint emergency exercise.
- The Florida-Texas MOU supports NBS testing in the event of an emergency. As part of developing that agreement, Texas was required to confirm it would comply with the provisions of Florida's open records law regarding protection of patient-identifiable information from public disclosure.
- Public health agencies and other entities often enter into data-use agreements to define parties' rights to use data that others have developed and to specify parties' responsibility for privacy and confidentiality. During *Policy Guide* research, at least one state public

⁹ 42 U.S.C. section 17931.

health laboratory director indicated he planned to require other state laboratories to sign data-use agreements before sharing tests and test results.

- One point that surfaced as the Four Corners MOU was updated in 2013 was whether unlawful use or disclosure of a patient's protected health information should be reported by the testing laboratory to all three of the other members. The conclusion reached was that such events would be reported to all three but that individually identifiable information should be reported only to the requesting state laboratory.

4.5 Certification and Licensure

Public health laboratories operate under externally imposed systems designed to ensure they meet specified quality standards. Some of these systems are based in federal or state law and are administered by government agencies. Others have been designed by independent, scientific bodies. The systems also vary according to the types of tests that a given laboratory performs. The concerns discussed in this section relate mainly to the predominant focus the *Policy Guide* has on testing that involves human specimens. Laboratory directors interested in exploring test service sharing might want to review certification and licensure information relevant to environmental and other types of testing that do not involve human specimens.

4.5.1 Clinical Laboratory Improvements Amendments

The federal Clinical Laboratory Improvement Amendments (CLIA) of 1988 require all private and public laboratories in the United States that test human specimens for health assessment or to diagnose, prevent, or treat disease be inspected and certified by the Centers for Medicare and Medicaid Services (CMS). Exceptions are laboratories in New York State and Washington State whose state-mandated inspection and certification requirements CMS deems equivalent to those of CLIA. Certain private and public laboratories also are accredited by such organizations as the nonprofit College of American Pathologists.

All state public health laboratories are CLIA-certified or are accredited by other programs authorized by CMS for that purpose. The majority of the laboratory directors interviewed during *Policy Guide* research agreed that another laboratory's CLIA certification is sufficient evidence of its quality practices to qualify it legally to perform tests on behalf of their own laboratories.

CLIA requires that the name of the laboratory that performs a test be documented in the test results. The interviewed laboratory directors noted that tests one state's public health laboratory conducts for another state's laboratory must include that information. This reportedly is done routinely. One laboratory includes such a requirement in its test service sharing agreements.

CLIA, in sum, does not appear to pose any substantial impediments to test service sharing. In fact, CLIA's requirements for maintaining testing proficiency might be an impetus to sharing. Interviewed laboratory directors often indicated that maintaining testing proficiency for low-volume tests can be expensive and time-consuming, which encourages state laboratories to consider having other states perform those tests for them.

4.5.2 State Laboratory Accreditation

New York state law requires that all laboratories that conduct diagnostic tests on human specimens collected in New York be certified by the state's Clinical Laboratory Evaluation Program (CLEP). Although some out-of-state commercial and hospital laboratories are CLEP-certified, no other states' public health laboratories are. CLEP certification entails considerable work and time. Further, even after certification, New York State must approve each test method as well. These burdens are among the reasons that no other state's public health laboratory has been CLEP-certified, and thus, this statutory mandate is a barrier to the New York public health laboratory's participating as a requesting state in test service sharing. To perform tests for New York State, an out-of-state public health laboratory must be CLEP-certified, even if New York needs its assistance in responding to emergencies.

Even though Washington State, like New York State, operates its own CLIA-like certification program, its public health laboratory is legally allowed to have other states' public health laboratories perform tests on its behalf as long as they are certified by CLIA. The Washington laboratory participates actively in test service sharing.

4.5.3 State Personnel Requirements

In addition to the CLIA personnel requirements, 12 states and Puerto Rico have established their own laboratory personnel licensure requirements (the states are California, Florida, Georgia, Hawaii, Louisiana, Montana, Nevada, New York, North Dakota, Rhode Island, Tennessee, and West Virginia).

Some states that have such standards require out-of-state laboratories to comply with them when sharing specimens with in-state laboratories, whereas others provide an exemption to the additional requirements for CLIA-certified laboratories. The responsibility rests with the submitting laboratory to ensure testing personnel have the necessary licenses for those states.

4.6 Specimen Management and Use

Participating laboratory directors were asked whether, in their experience, legal factors related to use and management of test specimens had posed substantial impediments to test service sharing. No concerns were identified, whether related to shipping, use in tests, or disposition of samples after testing.

Public health laboratories' use of specimens they receive from other states is governed mainly by the laboratories' standard operating practices. The Four Corners MOU, as one example, does not include mention of specimen-related concerns. Interviewed laboratory directors noted that controversies in recent years have centered on practices related to NBS testing samples — for example, their use in biomedical research — but reported that they have not experienced negative consequences regarding test service sharing.

One laboratory director, whose state was involved in a specimen-related controversy, described the data-use agreement it developed with another state as they shaped an NBS test service sharing MOU to provide surge capacity during emergency situations. This director observed that the laboratory's legal counsel favors adopting formal policies for key elements of the NBS testing process; however, that step had not been taken as of mid-2013, and whether any implications would result for that state's participation in NBS test service sharing is unclear.

A different question this state laboratory and its partner laboratory addressed as they developed the MOU was how to align their different, legislatively mandated test panels. This prerequisite to execution of the MOU was resolved through technical discussions during months-long negotiations.

4.7 Disease Reporting

The participating public health laboratory directors did not report encountering problems stemming from states' disease reporting requirements. Nonetheless, the potential for such problems was recognized. Such requirements often apply to public health laboratories and can entail responsibilities with which a given laboratory is unfamiliar or, conceivably, unprepared or unauthorized to fulfill.

All 17 participating states require laboratories to report selected communicable diseases. The states' laws vary in terms of who is required to report, the diseases that are reportable, to whom reports must be made, reporting time frames, report content, reporting methods, and other points. State laboratories that are considering entering into a test service sharing agreement might want to review such requirements and assess their implications.

Some states have disease-reporting laws that specifically address out-of-state laboratory testing and that might have implications for test service sharing by public health laboratories. For example,

- Florida requires out-of-state laboratories that collect or receive Florida specimens to report results by using the same procedures as do in-state laboratories.¹⁰
- Connecticut requires out-of-state laboratories that conduct examinations on specimens that have been referred from Connecticut to submit reports in the same manner as in-state laboratories, along with “a clear statement that such findings were obtained in [the out-of-state] laboratory” and including the name and location.¹¹
- Both California and Wisconsin stated that, when an out-of-state laboratory obtains a positive result for (a reportable disease or condition, as defined in their laws) and reports its finding to an in-state laboratory, the California or Wisconsin laboratory is responsible for notifying the appropriate California and Wisconsin health authorities as if their own laboratories had performed the tests.¹²
- Iowa requires out-of-state laboratories to report any confirmed or suspected case of a reportable disease or condition in an Iowa resident to its department of health.¹³

¹⁰ Fla. Admin. Code R. 64D-3.031.

¹¹ Regs. Conn. State Agencies section 19a-36-D32.

¹² See: 17 Cal. Code Regs. Section 2505, and Wis. Admin, Code DHS section 145.09.

¹³ Iowa Admin. Code 641-1.4.

4.8 Emergency Management

Laboratory directors did not cite emergency management laws as having posed problems for test service sharing. As noted previously, two state public health laboratories used their EMAC statutes as authority for sharing test services.

At the same time, the possibility exists that state or federal emergency management laws might complicate test service sharing agreements, and laboratory directors might want to consider that possibility as they explore developing such agreements. This section gives an overview of selected pertinent laws and reviews their potential implications for developing and implementing formal test service sharing agreements.

4.8.1 General State Emergency Management Laws

All states have enacted laws that authorize preparation for and execution of actions related to public health and other types of emergencies. Although these laws vary in key ways from state to state, the majority have important common elements.

- **Definition of *Emergency*** — In this context, state laws typically define an emergency as a catastrophic event that affects a wide area and causes severe injury, loss of life, or property damage. Natural disasters are examples. Some states further define *public health emergencies* as including the occurrence of a disease or appearance of an infectious agent that poses substantial risk for death or disability to a considerable number of persons. States also sometimes specify intentionally caused biologic, chemical, and radiologic threats as public health emergencies.¹⁴
- **Interstate Emergency Assistance** — Certain states have entered into mutual aid agreements that authorize them to provide assistance to each other to mitigate the effects of public health and other types of emergencies.
- **Planning for and Responding to Actual Emergencies** — Different aspects of states' emergency management laws might have implications for state public health laboratories' participation in test service sharing during planning for and response to actual emergencies. For example, some states empower their governors to execute emergency-related mutual aid agreements; some states condition that authority on approval by their legislature. Other states allow the adjutant general or even the directors of local emergency management agencies to enter into mutual aid agreements, subject to approval by the governor.
- **Services Provided** — The scope of mutual aid services that can be provided varies across states' laws. Some authorize broad services; others are narrow. Some but not all states also have passed laws and developed interstate agreements that specifically authorize provision of services related to public health laboratories' operations.

¹⁴ See, for example, section 104 of the Model State Emergency Health Powers Act. The Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities. Available at: <http://www.publichealthlaw.net/ModelLaws/MSEHPA.php>.

4.8.2 EMAC Legislation

All states, the District of Columbia, Puerto Rico, Guam, and the U.S. Virgin Islands have enacted uniform EMAC legislation to authorize provision of a broad spectrum of services to each other. An important precondition is that assistance can be provided under EMAC authority only if the governor of the affected state officially declares that an emergency exists.

EMAC provisions facilitate test service sharing during declared emergencies, but the same provisions conceivably might address legal questions that complicate test service sharing outside of emergencies.

- **Liability** — States’ EMAC statutes address liability directly. They specify that “officers or employees of a party state rendering aid in another state” are covered by the tort liability and immunity provisions of the requesting state. This clause provides uniform protection to the assisting states. Its inclusion in all the states’ EMAC statutes reflected recognition that liability questions, if left unresolved, would pose serious complications for effective response and that a common solution was needed. Although the EMAC liability clause appears to address the question adequately for state public health laboratories’ purposes in the context of declared emergencies, no similar solution appears to be available during nonemergent settings.
- **Reimbursement** — The EMAC statutes provide for reimbursement of the costs an assisting state incurs. That state “shall be reimbursed by the [requesting] state for any loss or damage to or expense incurred in the operation of any equipment and the provision of any services in answering a request for aid and for the costs incurred in collection with such requests” This, however, is not a blanket mandate. Assisting states can opt to bear some of the costs. Further, the participating states can agree to “establish a different allocation of costs” These qualifications provide useful flexibility to the states.
- **Licenses and Permits** — The EMAC statutes are also helpful regarding legal questions outside of declared emergency situations through licensing and related requirements pertinent to public health laboratories. In essence, the Licenses and Permits clause of the EMAC statutes deems that “any person, who holds a license, certificate, or other permit issued by any state party” meets the counterpart requirements of a state requesting assistance. One exception to this reciprocity provision is that the governor of the requesting state can apply limits on such recognition “by executive order or otherwise.” The EMAC laws, however, appear not to address two points important to state public health laboratories’ participation in mutual aid. One is that a laboratory professional in the assisting state might not hold a license that a requesting state requires of its own laboratory professional. In such a case, the requesting state might not be able to deem that professional qualified to assist. Also, the EMAC statutes do not address facility licensing (i.e., laboratory licensing requirements). At least hypothetically, a state laboratory that proposes to provide assistance but is not licensed by the requesting state might not be able to do so legally, unless the governor of the requesting state invokes the exception noted previously.

5. EXPLORING POLICY CONSIDERATIONS

This section presents selected considerations — based on the experiences of the 17 laboratories that participated in the *Policy Guide* research — that public health laboratory leaders and their counsel might find helpful as they explore the potential benefits and feasibility of sharing testing services with other state public health laboratories.

5.1 Assessing the Potential Value of Shared Testing Services

Assessing the potential value of sharing services is the starting point for exploring policies that are supportive of test service sharing. Questions that laboratory directors and their staff ask as part of these assessments often focus on potential cost savings in laboratory operations, quality and timeliness of test results, and the ability to maintain laboratory capacity in light of rapid changes in technology and the larger health care–public health system.

Specific examples of the types of factors that two state laboratories have considered appear in LEI’s *Practical Guide to Assessing and Planning Implementation of Public Health Laboratory Service Changes*.¹⁵ The following questions address some of these concerns:

- Is it cost-effective to perform low-volume, labor-intensive tests in-house?
- Can the investment be justified for acquiring and maintaining the new equipment?
- Is the expertise needed to perform new types of tests available in-house?
- If a laboratory is considering performing tests for another state’s laboratory, does it have the necessary staff proficiencies or can it acquire them at an affordable cost? (Both laboratories might need to ensure they retain the workforce needed for high-volume surge testing related to an extended public health emergency.)
- Can a laboratory that is considering having another laboratory perform tests on its behalf be confident that critically important tests will be conducted and reported correctly during emergencies and other high-visibility events?

5.2 Assessing Laws and Legal Considerations

This *Policy Guide* is a resource that public health laboratory directors and their staff and counsel can use in exploring legal and other policy considerations that can be important factors in their decision whether and how to enter into test service sharing with other state laboratories.

5.2.1 Checklist

The checklist in Resource 1 outlines steps that public health laboratory directors might want to consider taking as they organize and conduct assessments of the laws and policies of their states that are relevant to formal agreements for test service sharing.

¹⁵ Available at: http://www.aphl.org/MRC/Documents/LEI_2012Nov_Public-Health-Laboratory-Service-Changes-Practical-Guide.pdf.

5.2.2 Self-Assessment Tool

The self-assessment tool in Resource 2 can be helpful when exploring policy concerns by posing questions related to the legal topics included in Section 4 of this *Policy Guide*. This tool is intended to be a beginning point. Laboratory directors and their colleagues will have additional questions and topics that reflect their particular goals and circumstances; they should modify the tool to suit their own purposes, as necessary.

Directors might use self-assessment results for different purposes, including, for example,

- pinpointing specific obstacles to test service sharing;
- bringing those problem areas to the attention of legal counsel, administrators, and others who might be able to help resolve them; and
- as a basis for exploring the benefits and feasibility of potential legislative or policy changes, if that is deemed necessary.

Directors might find that taking a team approach to using the self-assessment tool is most productive. Laboratory scientists and technicians, laboratory and program managers, health department policy staff and counsel, and managers in the health department and the state procurement agency all can bring valuable knowledge to bear.

5.2.3 Exploring Existing Laws and Policies

The existing laws and policies that public health laboratories have identified as supportive of test service sharing are a valuable resource. Resource 3, available in full to APHL members in the APHL Members Resource Center, lists the contracts and MOUs that laboratory directors offered for inclusion in this *Policy Guide*, along with others identified by the *Policy Guide* researchers. These might be used as templates for development of new test service sharing agreements in other states.

Examples of the supportive provisions that are available in these resources include the following:

Payment for Shared Test Services

- Minnesota legislation, enacted in 2013 and effective in 2014, authorizes the infectious diseases laboratory to charge submitters for the full cost of performing tests, with exemptions for tests for mandated disease reporting. Earlier law had allowed only a handling fee of \$25/test. The income will be deposited into a fund for use by the laboratory.

Liability

- A provision of the Four Corners MOU states that each participating laboratory assumes liability for its actions but does not waive the state's sovereign immunity.
- The contract between the South Carolina and Alabama state public health laboratories includes a section that limits their liability to their own acts and omissions.
- A similar EMAC provision states, "No party state or its officers or employees rendering aid . . . shall be liable on account of any act or omission in good faith"

Privacy

- The privacy provisions of the Four Corners MOU that were crafted specifically to comply with HIPAA and HITECH Act requirements include a data-use agreement as an integral part.
- The open records provision of the MOU that the Florida and Texas laboratories developed for NBS test service sharing specifically addresses privacy concerns.

Resource 4 contains additional examples of such provisions.

Alternative Legal Vehicles

Assessing the potential that other existing or new state laws can have for facilitating test service sharing can be useful. One example is the laws that the vast majority, if not all, of states have enacted that give broad authority to their agencies to exchange services with the agencies of other states. These statutes have varying titles (e.g., “intergovernmental cooperation agreements,” “joint powers agreements,” and “interlocal cooperation acts”), many of which authorize interstate as well as intrastate service sharing. Legal analysis can determine if such broad authorities preclude the need to attain express permission to share testing services.

The following are two such examples:

- The New Mexico Joint Powers Agreements Act authorizes “two or more public agencies [to] jointly exercise any power common to the contracting parties, even though one or more of the contracting parties may be located outside this state, . . .” subject to approval by the state secretary of finance and administration.
- The Minnesota Joint Exercise of Powers statute authorizes “any agency of the state” to enter into agreements with “another state,” among other types of entities, for cooperative activities and to make related payments. The law also speaks to liability concerns.

Laboratory directors also might want to explore potential adoption of new state legislation. Maryland passed legislation in 2011 that authorizes its state and local public health laboratories to enter into mutual aid agreements with counterparts in other states, provide assistance to them, and receive assistance from them. The legislation follows EMAC provisions. Among other points, it provides for mutual indemnification and for expenditures to be charged to Maryland funding sources. (Other Mid-Atlantic states pursued parallel legislation but were unsuccessful. Consequently, the Maryland statute was inactive at the time this *Policy Guide* was prepared.)

5.2.4 Bibliography

Resource 5 lists selected reports, analyses and other publications relevant to test service sharing that can be helpful as laboratory directors and their colleagues explore legal and other policy considerations.

5.3 Working with Current and New Partners

The laboratory directors who contributed to this *Policy Guide* underscored the importance of communicating effectively with key partners in exploring policy options for interstate test service sharing.

5.3.1 Current Partners

Public health laboratories' established partners and stakeholders typically include, at a minimum, state health officials, state epidemiologists, leaders of the health agencies' programs that rely on test results and other laboratory services, legal counsel, state procurement officials, and senior decision makers in the laboratory's parent organization. Elected policymakers also might be key stakeholders.

The participating laboratory directors pointed to barriers that diverse professional cultures can pose. Legal counsel and procurement officials, for example, are expected to ensure adherence to rules that are broadly applicable to state government agencies. They might not be aware that those rules have unintended and problematic consequences for laboratories' effectiveness. Communicating with these partners before an emergency occurs can help them better understand the crucial role the laboratory plays in protecting health, the need to maximize the laboratory's effectiveness, and the potential benefits of participating in test service sharing arrangements with other jurisdictions.

At a more granular level, laboratory directors made concrete recommendations for improving the development process for new MOUs and contracts with other states by —

- using clauses and provisions that the involved states have accepted in earlier negotiations. One source of frustration when developing a new test service sharing agreement is for one of the states to propose provisions that had been rejected during negotiations over an earlier agreement. A more productive and time-saving approach, the directors recommended, is for both parties to agree to use already approved language as the basis for a new agreement.
- using provisions that other states have identified as supportive of their test service sharing goals and that their counsel, procurement officials, and other administrative officers have endorsed. Examples of such provisions appear in Resource 4.

5.3.2 Potential New Partners

Laboratory directors reported that exploring collaboration with new types of partners can be fruitful. Three examples of such potential partners follow:

Public Institutions of Higher Education

- The directors of public health laboratories that are part of their states' public universities reported that they typically have greater flexibility in establishing formal agreements with counterparts in other states and in making and receiving payment for shared test services. Directors of laboratories that are part of state agencies might find exploring opportunities to partner with institutions of higher education productive.

Nonprofit Public Health Institutes

- Established in 1953, the nonprofit Health Research, Inc. (HRI) is chartered to assist the New York State health department “to effectively evaluate, solicit, and administer external financial support for DOH . . . projects, and to disseminate the benefits of scientific expertise through programs such as technology transfer.” Among other activities, HRI may apply for federal and other grants on behalf of the New York public health laboratory, make purchases on the laboratory’s behalf, and hire staff for specified projects.
- Approximately 30 states are served by nonprofit public health institutes. Some are free-standing nonprofit organizations themselves, whereas others are affiliated with public universities. (A directory to public health institutes is available from the National Network of Public Health Institutes at <http://www.nnphi.org/>.)

Philanthropic Foundations

- Many states and metropolitan areas are served by philanthropic foundations dedicated to improving health and the health system, of which public health laboratories are a vital part. Examples include the Kansas Health Foundation and The Health Foundation of Greater Cincinnati.
- During the 1980s and 1990s, a considerable number of health care insurers (e.g., Blue Cross Blue Shield plans) . . . converted from nonprofit to for-profit status.” These “conversion foundations” often have mandatory public service responsibilities and thus experience collaborating with state and local public health agencies. In its 2009 report, *A Profile of Foundations Created from Health Care Foundations*, Grant Makers in Health identified 1,997 US conversion foundations.¹⁶

Laboratory directors’ dialogue with leaders of these nonprofit organizations revealed ways in which they can support test service sharing (e.g., by acting as partners of the laboratory’s parent health agency, similar to New York’s HRI) or in other capacities.

¹⁶ Available at: http://www.gih.org/usr_doc/2009_Conversion_Report.pdf.

RESOURCES

Resource 1: Checklist for Assessment of Test Service Sharing Laws and Legal Considerations

This checklist is offered as a broad outline of steps state public health laboratory directors might consider taking as they explore legal and policy concerns relevant to shaping formal agreements for interstate test service sharing. The checklist is intended to be flexible and adaptable to the specific goals and interests of any given public health laboratory. Directors should modify it and take other approaches as needed.

The checklist reflects elements of the assessment framework in the *Practical Guide to Assessing and Planning Implementation of Public Health Laboratory Service Changes* that the Association of Public Health Laboratories and the Centers for Disease Control and Prevention published in May 2012 as part of the Laboratory Efficiencies Initiative. The user should refer to the *Practical Guide* for additional information (available at: http://www.cdc.gov/MRC/Documents/LEI_2012May_PHL-Service-Changes-Guide.pdf). The checklist is organized into three parts, in a general chronological manner —

- Planning for a legal assessment
- Implementing a legal assessment
- Synthesizing and applying findings

Step	Notes
A. Planning for a legal assessment	
<ol style="list-style-type: none"> 1. Deciding whether to conduct a multistate assessment <ul style="list-style-type: none"> • Weighing the advantages of conducting a legal assessment in collaboration with another state's public health laboratory versus completing one's own state assessment first 2. Deciding whom to involve in the assessment process, for example, <ul style="list-style-type: none"> • The laboratory director, senior managers, and policy advisers • Legal counsel to the laboratory • Health department leadership • The state epidemiologist • Leaders of health department programs 3. Establishing goals for the assessment <ul style="list-style-type: none"> • Reviewing the goals for engaging in test service sharing • Reviewing the scope of test service sharing — that is, which testing services to be shared 4. Developing the assessment plan <ul style="list-style-type: none"> • Identifying the assessment deliverables • Developing a work plan and timeline • Setting out participants' roles and responsibilities 	

Step	Notes
B. Implementing a legal assessment	
<ol style="list-style-type: none"> 1. Deciding on a framework for the assessment <ul style="list-style-type: none"> • The Self-Assessment Tool that appears in Resource 2 of this <i>Policy Guide</i>, with any modifications, or • Another tool or template the assessment team identifies that better reflects the priorities and goals of its state 2. Determining priority considerations <ul style="list-style-type: none"> • Identifying laws and legal considerations that experience has proven to be problematic for test service sharing • Communicating with other states' public health laboratory leaders to identify laws they have identified as supportive of test service sharing 3. Conducting the assessment <ul style="list-style-type: none"> • Assigning subject-matter–expert participants to priority concerns • Assisting their assessments <ul style="list-style-type: none"> — Existing laws — Alternative legal vehicles — Working with current and new partners • Monitoring preliminary findings and shaping assessment efforts as needed 	
C. Synthesizing and applying findings	
<ol style="list-style-type: none"> 1. Reviewing assessment findings <ul style="list-style-type: none"> • Assessing the quality and completeness of the assessments • Identifying the laws and related practices that appear to have the most promise for supporting test service sharing • Identifying those that appear to pose problems for test service sharing 2. Integrating the findings of parallel assessments performed by a partnering state laboratory or laboratories <ul style="list-style-type: none"> • Identifying findings from parallel assessments that indicate the greatest opportunity for development of supportive laws and legal practices 3. Developing plans to apply assessment findings <ul style="list-style-type: none"> • Communicating with health department stakeholders about plans • Communicating with external stakeholders (e.g., other state agencies and health care partners) • Communicating with policymakers • Developing consensus among stakeholders on optimal action plans • Implementing those plans 	

Resource 2: Self-Assessment of Laws and Policies Pertinent to Interstate Test Service Sharing

Test Service Sharing Function	Assessment Comment
1. Performance of tests for another state's public health laboratory (PHL)	
a. Does our PHL have authority to perform tests for another state PHL?	
b. Does our PHL have authority for another state's PHL to perform tests for us?	
c. Are formal agreements (e.g., memoranda of understanding or contracts) in place to implement test service sharing?	
2. Payment and revenues	
a. Do our state's laws and policies authorize our PHL to charge another state's PHL or its programs for tests we perform for them?	
b. Do our state laws and policies authorize our PHL to charge health insurance plans and other third parties for tests?	
c. Do our state laws and policies authorize our PHL to set fees and charges?	
d. Do the laws and policies of our state authorize our PHL to retain revenues it receives from another state's PHL?	
3. Risk management	
a. Do the liability, indemnification, and other laws and policies of our state support our PHL's performance of tests for another state's PHL?	
b. Do the liability, indemnification, and other laws and policies of our state support having another state's PHL perform tests for our PHL?	

Test Service Sharing Function	Assessment Comment
4. Privacy and exchange of information	
a. Are policies in place to ensure protection of privacy and confidentiality related to shared tests?	
b. Does our PHL have authority to exchange information related to tests and test results with another state's PHL?	
c. Does our PHL have authority to exchange information with health care providers, health information exchanges, and other entities?	
5. Certification and licensure	
a. Do the certification and licensure laws and policies of our state support our PHL's performance of tests for other state?	
b. Do the certification and licensure laws and policies of our state support another state's performance of tests for our PHL?	
6. Management of specimens	
a. Do our state laws and policies enable our PHL to send specimens to and receive specimens from another state's PHL?	
b. Do the laws and policies of our state and of other states provide for safe management and final disposition of specimens used in shared testing?	
c. Do the laws and policies of our state and other states provide for the research use (or other secondary uses) of specimens that are used in shared testing?	
7. Test result reporting	
a. Do the laws and policies of our state and of potential test service sharing states enable timely reporting of test results to support the surveillance and other program needs of the state that requests testing?	

Resource 3: Selected Test Service Sharing Agreements

Copies of the following memoranda of understanding (MOUs) and contracts — adopted by public health laboratories that participated in the *Policy Guide* research — are available to Association of Public Health Laboratories members in the Members Resource Center at <http://www.aphl.org/Pages/default.aspx>.

1. “Contract Between South Carolina Department of Health and Environmental Control, Bureau of Laboratories, and Alabama Department of Public Health,” 2011 — For tests for primary drug susceptibilities for *Mycobacterium tuberculosis* complex.
2. “Memorandum of Understanding: Florida Bureau of Public Health Laboratories and [insert National HIV Behavioral Surveillance participant name],” undated — For confirmatory tests for preliminary positive point-of-care human immunodeficiency virus rapid test results.
3. “Memorandum of Agreement by and Between State of New Mexico Department of Health Scientific Laboratory Division, State of Colorado Public Health Laboratory, State of Utah Public Health Laboratory, State of Arizona Public Health Laboratory” (the “Four Corners MOU”), 2013 — For laboratory continuity of operations.
4. “Memorandum of Understanding Between Alaska Department of Health and Social Services, Public Health Laboratory, Idaho Department of Health and Welfare, Public Health Laboratory, Oregon Department of Human Services, Public Health Laboratory, Washington State Department of Health Public Health Laboratory” (the “Cooperative of State Labs”), 2004 — For testing, training, and identification of infectious diseases or suspected bioterrorism select agents.
5. “Pacific Northwest Emergency Management Arrangement Between The Government of the State of Alaska, The Government of The State of Idaho, The Government of The State of Oregon, The Government of the State of Washington, The Government of The Province of British Columbia, and The Government of The Yukon Territory” (“PNEMA”), circa 1996 — For coordination of emergency preparedness, response, and recovery. Annex B, 2005.

Also: “Memorandum to Provide Mutual Aid through Sharing Public Health Laboratory Services, Washington State Department of Health and the Ministry of Health Services, British Columbia,” 2010 — To “further the goals of [PNEMA] during an outbreak of disease, foodborne contamination, or suspected bio or chemical terrorism . . . that requires the expertise or capacity of the other Party’s laboratories.”
6. “Memorandum of Understanding — Laboratory Support Between the Mississippi Public Health Laboratory and the Bureau of Clinical Laboratories, Alabama Department of Public Health,” 2004–2005 — For assistance in a severe disruption of analytical services or an emergency situation.
7. “Memorandum of Understanding — Laboratory Support Between the Tennessee Public Health Laboratory, Tennessee Department of Health, and the Bureau of Clinical Laboratories, Alabama Department of Public Health,” 2009 — For assistance during a severe disruption of analytical services or an emergency situation.
8. “Memorandum of Understanding Between State of Washington, Washington State Department of Health, Division of Public Health Laboratories, and State of California, California Department of Health Services,” 2005 — For Level 1 chemical agent analysis.

9. “Partnership Agreement Between the Idaho Bureau of Laboratories and the Alaska State Environmental Health Laboratory,” 2011 — To cooperate and share laboratory services, procedures, responsibilities, and reimbursement for laboratory testing, training and identification of drinking water contaminants as listed in the Safe Drinking Water Act.
10. “Memorandum of Understanding Among Montana DPHHS Public Health Laboratory (MTPHL) and Idaho Public Health Laboratory (IDPHL),” 2010 — To perform viral testing as a result of a naturally occurring or intentionally caused disaster.
11. “Memorandum of Understanding Among Montana DPHHS Public Health Laboratory (MTPHL) North Dakota Public Health Laboratory (NDPHL),” 2011 — To perform routine molecular testing (influenza A and B, norovirus, pertussis, herpes simplex virus, varicella zoster virus, or *Enterovirus*) caused by a naturally occurring or intentionally caused disaster.
12. Contract between the New Hampshire Department of Health and Human Services and the University of Massachusetts, 2009 — For newborn screening testing.
13. “Memorandum of Agreement Between The Florida Department of Health, Newborn Screening Program, and The Texas Department of State Health Services, Newborn Screening Program,” 2013 — For newborn screening during disasters or catastrophic technology failures.
14. Purchase of service agreement/contract between the North Dakota Department of Health and The University of Iowa, 2013 — For newborn screening testing.
15. State of South Dakota consultant contract/letter of agreement for consultant services between The University of Iowa and the South Dakota Department of Health, 2012 — For newborn screening testing.

Also available in the APHL Member Resource Center:

16. “Memorandum of Agreement Cooperative Services Agreement During Emergency Situations Between [State A Public Health Laboratory] and [State B Public Health Laboratory],” undated — For variola virus testing.
17. Legislation that Maryland enacted in 2007 to authorize Maryland public health laboratories to share testing services with public health laboratories in other states “to alleviate an emergency at one of the Maryland laboratories.” Maryland Health-General Code Ann. Sec. 17-104.

Resource 4: Selected Provisions of Service Sharing Agreements

This resource presents selected provisions of state laws that have been adopted in formal public health laboratory test service sharing agreements (e.g., memoranda of understanding [MOUs] or contracts). They include provisions identified during *Policy Guide* research and others identified by the Association of Public Health Laboratories and the Centers for Disease Control and Prevention staff. The majority of these provisions were designed by state public health laboratory leaders to facilitate test service sharing in the context of their own laboratories' roles and plans. They are offered here as examples that other public health laboratory directors might find helpful as they explore test service sharing arrangements to address their own unique goals and concerns. These provisions are not necessarily recommended for adoption by other states.

A. Authority to Participate in Test Service Sharing

Express Authority for Test Service Sharing

- Maryland (Md. Code Ann., Health-Gen. section 17-104 (West 2008))
 “A public health laboratory in the state may enter into or renew a mutual aid agreement with a public health laboratory operated by another state.”
 “Mutual aid agreement means a written agreement . . . to assist each other in providing temporary testing services to alleviate an emergency at one of the laboratories.”

Authority for General Emergency Mutual Aid

- California Emergency Management Assistance Compact (Cal. Code Sec. 3.7-179)
 “The purpose of this compact is to provide for mutual assistance between the states entering into this compact in managing any emergency or disaster that is duly declared by the governor of the affected state, whether arising from natural disaster, technological hazard, man-made disaster, civil emergency aspects of resource shortages, community disorders, insurgency, or enemy attack.”

Joint Powers Agreements

- Minnesota (Minn. Stat. Sec. 471.59)
 “Two or more governmental units . . . may jointly or cooperatively exercise any power common to the contracting parties The term ‘governmental unit’ as used in this section includes every city, county . . . other political subdivision of this or another state, another state, . . . and any agency of the state of Minnesota”
- New Mexico (N.M. Stat. Ann. section 11-1-3 (West 1978))
 “[T]wo or more public agencies [may] jointly exercise any power common to the contracting parties, even though one or more of the contracting parties may be located outside this state”

B. Payment for Shared Test Services

- Model Emergency Management Assistance Compact (EMAC) state legislation enacted by Congress (P.L. 104-321, 110 Stat. 3877)
“Any party state rendering aid in another state pursuant to this compact shall be reimbursed by the party state receiving such aid for any loss or damage or expense incurred . . . in connection with such requests; provided, that any aiding party state may assume in whole or in part such loss . . . and provided further, that any two or more party states may enter into supplementary agreements establishing a different allocation of costs”
- “Cooperative of State Labs” MOU, Attachment A, 2004 (See Resource 3)
“This MOU is a non-financial agreement . . . and no billing for services will occur . . . The Requestor will replace Testing Lab’s supplies with like supplies as soon as possible The Testing Lab may waive replacement of expenditures for supplies.”
- Minnesota 2013 legislation (Article 12 Health Dept. Sec. 13)
“[T]he commissioner of health may enter into a contractual agreement to recover costs incurred for analysis of diagnostic purposes for each specimen submitted to the Department of Health by any hospital, laboratory, clinic, or physician Funds . . . shall be deposited in a special account and are appropriated to the commissioner for purposes of providing the services specified in the contracts.”
- State of South Dakota Consultant Contract, 2012 (See Resource 3)
“Consultant agrees to . . . direct bill each submitting health care provider or birthing facility monthly, according to the fee schedule . . . attached hereto and incorporated herein.”

C. Risk Management

- Contract between South Carolina Department of Health and Environmental Control, Bureau of Laboratories, and Alabama Department of Public Health, 2011 (See Resource 3)
“Neither party shall be liable for any claims, demands, expenses, liabilities, and losses (including reasonable attorney’s fees) which may arise out of any acts or failures to act by the other party, its employees or agents, in connection with the performance of services pursuant to this contract.”
- “Four Corners” MOU, 2005, renewed 2013 (See Resource 3)
“Each party shall be solely responsible for fiscal or other sanctions occasioned as a result of its own violations or alleged violation of requirements applicable to the performance of the agreement. Each party shall be liable for its actions in accordance with this agreement, and federal and state law as applicable, including law of sovereign and governmental immunity. No term or terms of this MOA [memorandum of agreement] may be construed as an express or implied waiver of sovereign and governmental immunity.”

- Florida and Louisiana MOU for newborn screening, 2013 (See Resource 3)
 “Each party to this agreement shall be responsible for its own acts and omissions and those of its officers, employees, and agents. No party to this agreement shall be responsible for the acts or omissions of entities not a party to this agreement. No party to this MOU agrees to release, hold harmless, or indemnify the other party from liability that may arise or relate to this MOU. Nothing herein is intended to serve as a waiver of sovereign immunity. Nothing herein shall be construed by any person or court as consent by a state agency or political subdivision of the State of [X] to be sued by third parties in any matter arising out of contract.”
- Model Emergency Management Assistance Compact state legislation enacted by Congress. (P.L. 104-321, 110 Stat. 3877)
 “Officers or employees of a party state rendering aid in another state pursuant to this compact shall be considered agents of the Requesting State for tort liability and immunity purposes; and no party state or its officers or employees rendering aid in another state pursuant to this compact shall be liable on account of any act or omission in good faith on the part of such forces while so engaged or on account of the maintenance or use of any equipment or supplies in connection therewith. Good faith in this article shall not include willful misconduct, gross negligence, or recklessness.”
- Purchase of Service Agreement/Contract, North Dakota Department of Health and The University of Iowa State Hygienic Lab, 2013 (See Resource 3)
 “Contractor agrees to defend, indemnify, and hold harmless the state of North Dakota, its agencies, officers and employees (State) from and against claims based on the vicarious liability of the State or its agents, but not against claims based on the State’s contributory negligence, comparative and/or contributory negligence or fault, sole negligence, or intentional misconduct.”
- Template MOU: Florida Bureau of Public Health Laboratories (See Resource 3)
 “Florida law, without giving effect to its choice of law principles, governs all matters arising under or related to the MOU. Venue for any legal actions arising herefrom is a state court of competent jurisdiction in Leon County, Florida.”

D. Privacy Protection

- “Four Corners” Memorandum of Understanding, 2005, renewed 2013 (See Resource 3)
 “The parties agree to comply with the applicable provisions of the Administrative Simplification section of the Health Insurance Portability and Accountability Act of 1996 . . . as amended by Health Information Technology for Economic and Clinical Health Act of 2009 . . . and the requirements of any regulations promulgated hereunder including . . . [the ‘Federal Privacy Regulations’ and the ‘Federal Security Regulations’.] The parties agree not to use or further disclose any protected health information . . . or individually identifiable health information . . . concerning a patient other than as permitted by this Agreement and the requirements of HIPAA

. . . . The parties shall implement appropriate safeguards to prevent the use or disclosure of a patient’s Protected Health Information other than as provided for by this Agreement. If a party that receives data pursuant to this Agreement becomes aware that a use or disclosure of such data was a use or disclosure of a patient’s Protected Health Information not provided for by this Agreement or in violation of HIPAA [Health Insurance Portability and Accountability Act], the Federal Privacy Regulations, or the Federal Security Regulations, the party will promptly notify each of the other parties of the use or disclosure In the event a party, with the approval of another party in writing, contracts with any contractors and/or agents to whom the party provides a patient’s Protected Health Information received from the party, that party shall include provisions in such agreements whereby the contractor and/or agent agree to the same restrictions and conditions that apply to that party”

- State of South Dakota Consultant Contract, 2012 (See Resource 3)
“Consultant is a ‘hybrid entity’ as defined in the Health Insurance Portability and Accountability Act . . . and will abide by the rules and regulations set forth in [HIPAA] as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act”
- New Hampshire Department of Health and Human Services Contract with the University of Massachusetts for Newborn Screening Testing, 2009 (See Resource 3)
“Business Associate [the University of Massachusetts] shall not use, disclose, maintain, or transmit Protected Health Information (PHI) except as reasonably necessary to provide the services outlined under Exhibit A of the Agreement.”

“Business Associate shall require all of its business associates that receive, use, or have access to PHI under the Agreement, to agree in writing to adhere to the same restrictions and conditions on the use and disclosure of PHI contained herein”

E. Certification and Licensure

- Contract between South Carolina Department of Health and Environmental Control, Bureau of Laboratories, and Alabama Department of Public Health, 2011 (See Resource 3)
“[E]ach party shall maintain its respective federal and state licenses, certifications, and accreditations required for the provision of services therein.”
- California Emergency Management Assistance Compact, 2005 (See Resource 3)
“Whenever any person holds a license, certificate, or other permit issued by any state party to the compact . . . and when such assistance is requested by the receiving party state, such person shall be deemed licensed, certified, or permitted by the state requesting assistance to render aid involving such skill to meet a declared emergency of disaster, subject to such limitations and conditions as the governor of the requesting state may prescribe by executive order or otherwise.”

F. Specimen Management and Use

- “Cooperative of State Labs” MOU, Attachment A, 2004 (See Resource 3)
“The Requestor is responsible for the . . . integrity of specimens [in shipping]. If the Testing Lab has safety standards for . . . transport of specimens within its borders, the Requestor shall incorporate [them] into its packaging and shipping processes.” “The Testing Lab will return positive samples to Requestor . . . as Requestor is responsible for integrity of specimens and chain of custody” “The Testing Lab will destroy negative samples according to its established procedures.”

G. Disease Reporting

- Florida (Fla. Admin. Code Ann. R. 64D-3.031)
“(4) Laboratories located out of state, licensed under Part I, Chapter 483, F.S., who collect specimens in Florida or who receive the initial order for testing from a practitioner, blood bank, plasmapheresis center, or other health care provider located in Florida, shall report in the same way as if the findings had been made by a laboratory located in Florida.”

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