An Overview of

Legal Considerations

in Assessing Multijurisdictional Sharing of Public Health Laboratory Testing Services

May 2012

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

LEI
LABORATORY EFFICIENCIES INITIATIVE
Creating a Sustainable Public Health Laboratory System

This report was prepared by Molly R. Berkery, J.D., M.P.H. and Matthew M. Penn, J.D., M.I.L.S. in the Public Health Law Program, Office for State, Tribal, Local and Territorial Support, in collaboration with Anthony D. Moulton, Ph.D. in the Laboratory Science, Policy and Practice Program Office, Office of Surveillance, Epidemiology and Laboratory Services at the Centers for Disease Control and Prevention (CDC). For additional information or technical assistance on legal issues related to multijurisdictional sharing of public health laboratory testing services, please contact the CDC Public Health Law Program at 404-498-0470 or visit http://www.cdc.gov/phlp/. Additionally, the authors may be directly contacted at mberkery@cdc.gov or mpenn@cdc.gov. For additional information on other, non-legal issues related to shared testing services, please contact the CDC Laboratory Science, Policy and Practice Program Office at 404-498-6400 or visit http://www.cdc.gov/osels/lspppo/.

Public Health Laboratories' Vital Role

Public health laboratories play an invaluable and indispensable role in protecting America's health. They perform the vast majority of public health reference tests, monitor community health conditions, help shape population-based interventions, and advise healthcare providers on appropriate patient care. Of special note is the critical role public health laboratories play in the detection of the onset of disease threats and in the high volume of testing during public health emergencies.

Public health laboratories are integral members of the nation's public health laboratory system, along with environmental, food safety, agricultural, forensic, occupational health, and other laboratories that perform tests to protect the health of the public. The Centers for Disease Control and Prevention (CDC) is the principal federal member of the nation's public health laboratory system.

The Public Health Laboratory Efficiencies Initiative

Public health laboratory directors work in a highly dynamic environment. In recent years, most have experienced serious financial pressures, driven largely by state and local governments' responses to the economic recession. Many public health laboratories' budget and staffing numbers have been cut substantially, and, as a result, some have stopped performing certain tests.

CDC and the Association of Public Health Laboratories (APHL) are concerned that many public health laboratories are in danger of losing the capacity to perform critically needed tests and services. This has the potential to impair the ability of public health authorities to respond effectively to conventional health risks as well as to public health emergencies, such as influenza pandemics.

CDC and APHL inaugurated the Laboratory Efficiencies Initiative (LEI) in 2011 to help address these concerns. Additional LEI partners include public health department directors and epidemiologists, public health and laboratory associations, leaders in clinical laboratory practice, and representatives of private industry.

The purpose of LEI is to help public health laboratories achieve long-term sustainability by adopting management practices that improve laboratory operating efficiency and strengthen their resilience in the face of financial and capacity challenges. Its strategic goal is to help maintain a sustainable public health laboratory system for the nation.

Multistate Sharing of Testing Services

The LEI supports public health laboratory directors' exploration of a number of models for testing services that have potential for greater efficiency. One model is for public health laboratories in two or more states or other jurisdictions (e.g., tribes, localities, and territories) to share testing services. Examples of existing shared services arrangements include:

- Formation of the Northern Plains Consortium by the state public health laboratories of Montana, North Dakota, South Dakota and Wyoming to facilitate sharing of testing services.
- Performance of newborn screening tests for five New England states by the University of Massachusetts Medical School.
- Newborn screening tests conducted for six states, birthing centers of the Navajo Nation, Guam, the Marshall Islands, Saipan (in the Northern Mariana Islands), and a military base in California by the Oregon State Public Health Laboratory.

Purpose and Limitations

Public health laboratory directors and managers have expressed interest in understanding legal considerations relevant to sharing testing services. This report is a resource for public health laboratory directors and their legal counsel as they explore potential legal issues related to sharing testing services with other jurisdictions. As used in this report, the term "law" refers primarily to statutes, regulations, and ordinances. Legal considerations include both legal provisions that support shared testing services and those that may prohibit shared testing services.

This report offers a brief overview of some of the generally relevant federal and state legal considerations. It does not attempt to create a comprehensive review and should be considered a starting point for more detailed analysis by interested laboratory directors and their legal counsel.

This report was prepared by the Public Health Law Program, part of the Office for State, Tribal, Local and Territorial Support, in collaboration with the Laboratory Science, Policy and Practice Program Office, part of the Office of Surveillance, Epidemiology and Laboratory Services at CDC. It is important to note that this report does not represent the official views of CDC. It does not constitute legal advice nor is it intended to support or oppose any proposed or pending federal, state, or other law. In all cases, public health laboratory directors should consult with their legal counsel for official legal advice.

This report is a companion to "A Practical Guide to Assessing and Planning Implementation of Public Health Laboratory Service Changes" developed by CDC and APHL and published in May 2012. The guide is accessible at http://www.aphl.org/lei.

Assessing Multijurisdictional Sharing of Public Health Laboratory Testing Services

Public health laboratory directors interested in multijurisdictional sharing of public health laboratory services may want to consider several preliminary steps. First, it is important for public health laboratory directors to contact their attorneys and request assistance during the planning stages. The more the attorneys know about the project, the more they will be able to help. Second, it is important to determine what laboratory services will be shared. For example, shared screening and diagnostic tests (e.g., communicable disease, newborn screening) vs. tests related to public health investigations (e.g., DNA fingerprinting related to foodborne illness outbreaks or communicable disease outbreaks). Applicable legal issues may vary depending on what services are being shared. Last, public health laboratory directors may want to consider under what circumstances services will be shared. Answers to these questions will greatly impact legal considerations.

Once the above are determined, each partner state or jurisdiction may want to address compatibility with relevant laws, and address any potential conflicts of law, including potential inconsistencies with agreements already in place between health departments and laboratories. For example, many states have entered into mutual aid agreements and memorandums of understanding or agreement with other states and territories that address surge capacity, emergency laboratory management, and the sharing of public health data, supplies, resources, equipment, and personnel.[1] Further, some states have laws specifically addressing mutual aid during public health emergencies. An important consideration is the relationship between agreements for sharing day-to-day public health laboratory services and existing laws and agreements for public health emergencies. Public health laboratory directors contemplating entering into any shared services arrangement may want to consider doing so in the form of a written agreement so that all parties understand the intended scope and responsibilities.

[1] For more information on mutual aid agreements, *see* DANIEL D. STIER & MELISA L. THOMBLEY, *Public Health Mutual Aid Agreements – A Menu of Suggested Provisions*, *available at* http://www.cdc.gov/phlp/docs/Mutual_Aid_Provisions.pdf.

Legal Considerations

Shared public health laboratory services arrangements are affected by numerous federal and state legal issues from constitutional law to federal and state health information privacy to technical procurement issues. Federal laws generally do not present insurmountable barriers to sharing public health laboratory services across state lines; however, states laws vary greatly, even within the same region. It is important for states interested in exploring multijurisdictional sharing of public health laboratory services to consider all potential legal barriers to shared services arrangements.

Overview of the Interaction between Federal and State Law

The United States Constitution established a government system based on "federalism," or the sharing of power between the national, and state (and local) governments.[2] Public health activities occur at all three levels of government. When the states came together to draft the Constitution, they agreed to give up some of the authority they had under the colonial system and the Articles of Confederation, such as minting their own currency or raising their own armies. A number of these specific authorities were given to the federal government and are now referred to as the enumerated powers. However, states retained many of their inherit powers, especially when it came to protecting the health and welfare of their citizens. Indeed, the Tenth Amendment to the Constitution recognizes the states' reservation of authorities, and provides that "powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."[3] The public health powers reserved by the states are part of what are called the "police powers." Further, although the police powers are considered a state authority, some states share the powers with local governments.[4]

All states will need to assess their own laws to determine what laws will affect a shared services arrangement with other states or jurisdictions (e.g., tribes, localities, and territories), whether any of those laws present barriers to entering a shared services arrangement, and, if so, how those barriers can be overcome.

[2] Federalism and its division of authority amongst three levels of government should not be confused with the separation of powers doctrine. Under that concept, the authority at each level of government is divided amongst three branches of government: legislative, executive, and judicial.
[3] U.S. CONST. amend. X.
[4] Local governments are creatures of state constitutions and statues, and generally, their powers are enumerated much like the federal government.

Federal Law Considerations

Although federal laws may not provide any insurmountable barriers to multijurisdictional shared public health laboratory services agreements, states interested in sharing services may want to consider the following federal laws. Application of the following will depend on what activity or service is undertaken or provided, as well as the structure of sharing.

Constitutional Law

States interested in interstate sharing of public health laboratory testing services may want to address the following constitutional law issues. The Constitution of the United States, Article I, Section 10, Clause 3, states that "No State shall, without the Consent of the Congress … enter into any Agreement or Compact with another state…"[5] Despite a literal reading of the Compact Clause, the United States Supreme Court has held that only a limited number of interstate agreements require Congressional consent.[6] The Court has consistently held that application of the Compact Clause is limited to agreements that lead to an increase or decrease of political power of any one state, or "which may encroach upon or interfere with the just supremacy of the United States."[7] Additionally, U.S. Constitution, Article I, Section 8, Clause 3, states that Congress has the power "to regulate Commerce…among the several States."[8] An agreement to share public health laboratory services across state lines may implicate the exchange of commerce among several states.

States may choose to address constitutional law implications in an agreement to share public health laboratory services, with a provision similar to the following:

> *Nothing in this Agreement is to be construed as an encroachment of the full and free exercise of U.S. federal authority, as an interference with the just supremacy of the U.S. or its several states, as affecting the federal structure of the U.S. or as enhancing the political power of the party states at the expense of each other or other states.*[9]

Although the Compact Clause and Commerce Clause may not provide barriers to entering into interstate shared public health laboratory services agreements, a provision similar to the above may alleviate any concerns partner jurisdictions may have.

Health Privacy

An important consideration to any agreement to share public health laboratory services is the applicability of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. The HIPAA Privacy Rule establishes regulations for covered entities' use and disclosure of protected health information (PHI), including the disclosure of PHI for public health activities. The Privacy Rule permits covered entities to disclose PHI, without

---

[5] U.S. CONST. art. I, § 10, cl. 3.
[6] *See* Virginia v. Tennessee, 148 U.S. 503, 519 (1893) (limiting the scope of the Compact Clause).
[7] Virginia v. Tennessee, 148 U.S. at 519; *see also* U.S. Steel Corp. v. Multistate Tax Comm'n, 434 U.S. 452 (1976).
[8] U.S. CONST. art. I, § 8, cl. 3.
[9] STIER ET AL., *supra* note 1, at 12.

authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability.[10] This includes disclosures, for example, for disease reporting, vital records, and conducting public health surveillance, investigations, or interventions.[11]

It is important to note that a health department may be a hybrid entity. For example, a health department that operates a health clinic is probably subject to Privacy Rule requirements for the health care services delivered in that clinic. States may want to address these nuances depending on what laboratory services are being shared.

While HIPAA may not impede interstate agreements for sharing public health laboratory services, it is important that both federal and state privacy laws (discussed below) be considered and addressed. This is especially important because HIPAA is often a perceived barrier to data sharing of any kind, and many unfamiliar with all of its provisions are unaware of the Privacy Rule's provision for the disclosure of PHI for public health purposes.

Laboratory Certification

Additionally, it is important states consider federal laboratory certification requirements. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) "sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens" for health assessment or the diagnosis, prevention, or treatment of disease.[12] CLIA probably does not provide any barriers to shared service agreements; however, states may want to consider an agreement provision that addresses all necessary laboratory certifications, similar to the following:

> *The Parties will comply with all Federal and State laws relating to provision of services under this Agreement and will maintain in effect all permits, licenses, governmental approvals and accreditations that may be necessary for that purpose. The Parties will notify each other immediately of any material change in such permits, licenses, governmental approvals or accreditation that would adversely affect the ability of the Parties to perform under this Agreement*.[13]

Packing and Shipping Infectious Substances

Lastly, it is important states consider all federal and state laws (discussed below) related to packing and shipping of laboratory specimens. In the United States, the Department of Transportation regulates the transportation of dangerous goods by both air and ground carriers.[14]

---

[10] *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104–191, 110 Stat. 1936 (1996).
[11] *Id.*
[12] Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903; 42 U.S.C. § 263a (1988).
[13] STIER ET AL., *supra* note 1, at 9.
[14] For more information on packing and shipping infectious substances, *see* the U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration, *available at* http://phmsa.dot.gov/hazmat/regs.

State Law Considerations

State laws governing public health laboratories and public health laboratory services vary greatly from state to state. The following is an overview of some of the generally relevant state legal considerations. Application of the following will depend on what activity or service is undertaken or provided, as well as the structure of sharing.

General Public Health Legal Authorities

Most states have enabling statutes that create public health laboratories and authorize the state health department to promulgate rules or regulations. For example, North Carolina establishes "[a] State Laboratory of Public Health…within the Department [of Health and Human Services]" and authorizes the Department "to make examinations, and provide consultation and technical assistance as the public health may require." [15] Additionally, North Carolina law requires that the Commissioner of Health "adopt rules necessary for the operation of the State Laboratory of Public Health."[16]

States may want to review general public health enabling statutes and related health department regulations to identify any facilitators or barriers to shared services arrangements. Considerations may include whether a state is required to establish and operate a public health laboratory; whether all public health laboratory testing must be performed by the state public health laboratory or whether a state can contract out for all or certain testing services; and, whether a state public health laboratory can perform services on out-of-state specimens. States may also consider whether shared services arrangements will include only human specimens or if they will include veterinary laboratory services for zoonotic diseases such as rabies.

Mutual Aid

Some states have laws that address interstate mutual aid agreements for public health laboratory services during declared emergencies. For example, in Maryland, a "[m]utual aid agreement means a written agreement between a public health laboratory in the State and a public health laboratory operated by another state to establish and carry out a plan to assist each other in providing temporary testing services to alleviate an emergency at one of the laboratories."[17] Maryland law requires that "[a] public health laboratory operated by another state that enters into a mutual aid agreement shall provide written documentation of the statutory authority required for that state to meet the responsibilities set forth in the agreement."[18] Maryland law further includes specific requirements for mutual aid agreements including employee travel, workers' compensation, and expenditures.[19]

States may consider the relationship between arrangements for sharing day-to-day laboratory services and existing laws and arrangements that would be triggered during public health

[15] N.C. GEN. STAT. ANN. § 130A-88 (West 1983).
[16] *Id.*
[17] MD. CODE ANN., HEALTH-GEN. § 17-104 (West 2007).
[18] *Id.*
[19] *See id.*

emergencies or other surge events. An important consideration is whether day-to-day services and emergency services arrangements could conflict in any way, or whether the parties could be better served by one consolidated agreement.

Newborn Screening

Most states have newborn screening laws, and public health laboratories are often primarily responsible for newborn screening tests. For example, the state of Ohio requires all newborn screening be performed by the state public health laboratory unless the state public health laboratory is unable to perform screenings for a required disorder.[20] If the director determines the state public health laboratory is unable to perform screenings, the director is required to select an alternative laboratory to perform the screenings through a request for proposals, which may include both in-state and out-of-state laboratories.[21] Rescreening may be performed by the Ohio State Public Health Laboratory or other designated laboratory.[22]

In contrast, Mississippi allows newborn testing to be performed at any laboratory in the United States.[23] However, Mississippi requires that any laboratory providing newborn testing must be compliant with all standards in Mississippi's newborn screening laws.[24]

Texas requires that all newborn screening "be performed by the laboratory established by the department or by a laboratory approved by the department…."[25] The Texas Department of State Health Services "may develop a program to approve any laboratory that wishes to perform the tests required to be administered."[26]

Additionally, some states have laws that specifically address newborn screening and mutual aid agreements. Texas law allows the Department of State Health Services to "enter into a mutual aid agreement to provide newborn screening laboratory services to another state and to receive newborn screening laboratory services from another state in the event of an unexpected interruption of service, including an interruption caused by a disaster."[27] Maryland law states that "[e]xcept as set forth in a Departmental mutual aid agreement, the Department's public health laboratory is the sole laboratory that may hold a State permit to perform and that may perform a *first-tier* newborn screening test on a newborn infant" (emphasis added).[28] However, "[a] medical laboratory other than the State's public health laboratory may obtain a permit to perform: [a] supplemental test; [a] second-tier test; or [s]upplemental and second-tier tests."[29]

States may want to review laws related to newborn screening programs to evaluate any potential facilitators or barriers to sharing laboratory services.

---

[20] *See* OHIO REV. CODE ANN. § 3701.501 (West 2003).
[21] *See id.*
[22] *See id.*
[23] *See* MISS. CODE ANN. §41-21-201 (2012).
[24] *See id.*
[25] TEX. HEALTH & SAFETY CODE ANN. § 33.011 (West 2009).
[26] *Id.* at § 33.016 (West 2009).
[27] *Id.* at § 12.01221 (West 2009).
[28] MD. CODE REGS. 10.10.13.04 (2009).
[29] *Id.*

Public Health Laboratory Fees

All states have laws that establish public health laboratory fees. State laws vary as to the amount a state is statutorily authorized to charge for services, and what agency has the authority to set the fee schedule. For example, in Connecticut:

> The Commissioner of Public Health may establish a schedule of fees, provided the commissioner waives the fees for local directors of health and local law enforcement agencies. If the commissioner establishes a schedule of fees, the commissioner may waive (1) the fees, in full or in part, for others if the commissioner determines that the public health requires a waiver, and (2) fees for chlamydia and gonorrhea testing for nonprofit organizations and institutions of higher education if the organization or institution provides combination chlamydia and gonorrhea test kits. The commissioner shall also establish a fair handling fee which a client of a state laboratory may charge a person or third party payer for arranging for the services of the laboratory. Such client shall not charge an amount in excess of such handling fee.[30]

Some state laws limit fees to the actual cost of the test being performed. For example, South Dakota law requires the fee for each public health laboratory service or test be "based on the actual cost of performing the service or test and the cost of operating the public health laboratory."[31] In Illinois, "the Laboratory's service fees…shall not exceed the Department's actual costs to provide the Laboratory's services, and shall consider the current fees charged by private laboratories for comparable services."[32] Other states require specific dollar amounts for performing certain tests. For example, Wyoming mandates a five-dollar fee for the testing of "[v]iral serology for vaccine status (IgG) [and for] each viral antigen (Rubella, Rubeola, Mumps or Chickenpox)."[33]

States also have laws governing where public health laboratory revenue is directed. For example, South Dakota requires "any money that may be received…shall be deposited in a special revenue fund in the state treasury which is established and designated as the state laboratory fund."[34]

States often have separate laws related to public health laboratory fees for specialized laboratory testing (e.g., newborn screening tests).

States may want to consider laws related to public health laboratory fees and revenue to determine the best approach for any multijurisdictional sharing of public health laboratory services.

---

[30] CONN. GEN. STAT. ANN. § 19a-26 (West 2010).
[31] S.D. CODIFIED LAWS § 1-49-3 (1995).
[32] ILL. ADMIN. CODE TIT. 77, § 475.25 (1996).
[33] WY ADC HLTH PHL CH. 1 S 5 (2010).
[34] S.D. CODIFIED LAWS § 1-49-4 (1985).

Procurement

In addition to laboratory fee schedules, all states have government procurement laws. Issues involving procurement may depend on the structure of sharing (i.e., public-to-public health laboratories vs. public-to-private health laboratories). For example, Wisconsin law allows intergovernmental procurements (procurements from any municipality and from any unit of the federal government) without bidding, if approved by the health department.[35] Under Wisconsin law, interstate public-to-public sharing arrangements may not be subject to a competitive bidding process, but public-to-private may be.

State procurement laws vary greatly, and states may want to review laws to determine the applicability to proposed shared laboratory services agreements.

Disease Reporting Requirements

All states have laws that require general disease reporting, but variability exists regarding diseases and conditions to be reported, reporting mechanisms, timeframes for reporting, persons and facilities required to report, and agencies that receive reports. For example, in South Carolina, "a laboratory, within or outside the State, responsible for performing a test for any of the infectious or other diseases required by the Department of Health and Environmental Control to be reported…shall report positive or reactive tests to the department."[36] States may want to address disease reporting laws, including who is responsible for reporting laboratory test results and isolates, in any interstate agreement for shared laboratory services.

Health Privacy

In addition to federal health privacy laws, all states have laws related to health data privacy and security. State privacy laws are expansive and cover a range of topics including disease reporting, genetic testing, mutual aid, and forensic DNA. These laws may also cross-reference other state or federal privacy provisions. For example, Rhode Island's disease reporting regulation states "The HIPAA Privacy Rule expressly permits disclosures without individual authorization to public health authorities authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, public health surveillance, investigation, and intervention…."[37] Minnesota's statute related to newborn screening requires:

> Persons with a duty to perform [newborn screening] testing…shall advise parents of infants (1) that the blood or tissue samples used to perform testing thereunder as well as the results of such testing may be retained by the Department of Health, (2) the benefit of retaining the blood or tissue sample, and (3) that the following options are available to them with respect to the testing: (i) to decline to have the tests, or (ii) to elect to have the tests but to require that all blood samples and records of test results be destroyed within 24 months of the testing. If the parents of an infant object in writing to testing for

[35] *See* WIS. ADMIN. CODE ADM § 8.08 (1986).
[36] S.C. CODE ANN. § 44-29-15 (2010).
[37] R.I. CODE R. § 31 5 34 (West 2011).

> heritable and congenital disorders or elect to require that blood samples and test results be destroyed, the objection or election shall be recorded on a form that is signed by a parent or legal guardian and made part of the infant's medical record.[38]

It is important that states contemplating multijurisdictional sharing of public health laboratory services review all applicable privacy laws. All state parties may wish to ensure that their own privacy laws are properly addressed as laboratory services are shared. States may also consider the development of security and confidentiality agreements (e.g., Business Associate Agreements or data use agreements) to address data privacy and security.

Shipping and Handling Laboratory Specimens

All states have laws related to the shipping and handling of laboratory samples or specimens (e.g., virology specimens). For example, in Illinois, "[e]ach sample or specimen submitted to the Laboratory for any analysis must be delivered or shipped in a container and manner to preserve the sample/specimen from contamination or destruction and allow it to reach the Laboratory in a condition that permits a reliable laboratory analysis."[39] It is important for states to review all applicable federal and state laws related to the packing, shipping, and handling of laboratory specimens, including state postal regulations related to virology specimens.

State Liability and Immunity

Lastly, states may want to address liability, immunity from liability, and indemnity in any agreement to share public health laboratory services. This may include a review of state constitutional provisions related to governmental or sovereign immunity, and state statutes, including tort claims acts. It is critical to consult with state legal counsel on this issue. State tort claims and sovereign immunity laws can be drastically different across states. Failure to adequately address liability in an agreement could expose a state to significant financial losses that could have been avoided and addressed at the outset in a properly worded provision.

[38] MINN. STAT. ANN. § 144.125 (West 2009).
[39] ILL. ADMIN. CODE TIT. 77, § 475.20 (1996).

Conclusion

Public health laboratories play a critical role in protecting the public's health. The Laboratory Efficiency Initiative supports public health laboratory directors' exploration of a number of models for testing services that have potential for greater efficiency. This report offers states interested in multijurisdictional sharing of public health laboratory services a starting point for considering potential federal and state law issues. This report offers only an overview of some of the generally relevant federal and state legal considerations. It does not attempt a comprehensive or in-depth review, and public health laboratory directors should contact their attorneys and request assistance during any legal assessment. While federal laws may not present inordinate barriers, state laws vary greatly, even within the same region. It is important for states to consider all relevant laws, potential conflicts of law, as well as inconsistencies with agreements already in place between health departments and laboratories.