Legal Considerations in Cross-Jurisdictional Sharing of Public Health Laboratory Services

Molly R. Berkery, JD, MPH
Matthew S. Penn, JD, MLIS

ABSTRACT

The Centers for Disease Control and Prevention and the Association of Public Health Laboratories initiated the Laboratory Efficiencies Initiative in 2011 to help address issues related to public health laboratory (PHL) capacity to perform critically needed tests and services. One approach to improving capacity and efficiency is sharing PHL services with other states or jurisdictions. Cross-jurisdictional sharing implicates numerous federal and state laws, including federal and state privacy laws, laboratory certifications, packaging and shipping requirements for laboratory specimens, and state laws regarding fees and revenue. While federal laws generally do not present insurmountable barriers to sharing PHL services, state laws vary greatly, even within the same region of the country. This article summarizes some of the potentially relevant federal and state legal issues related to cross-jurisdictional sharing. It is important that states interested in cross-jurisdictional sharing consider all relevant laws, potential conflicts of law, as well as inconsistencies with agreements already in place among health departments and laboratories.
Public health laboratories (PHLs) play a critical role in advancing and protecting the public’s health. Both state and local PHLs monitor community health conditions, perform the vast majority of public health reference tests, help shape population-based interventions, advise health-care providers on appropriate patient care, and play a critical role in detecting the onset of disease threats and performing a high volume of testing during public health emergencies. They are an integral part of the nation’s laboratory system and serve as a first line of defense to protect the public’s health.\(^1\)

Due to recent economic constraints, many PHLs have suffered serious financial pressures, including budget and staffing cuts. As a result, some PHLs have had to stop performing certain tests, posing potential public health risks, including impairing the ability of public health authorities to respond effectively to conventional health risks and public health emergencies. The Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) initiated the Laboratory Efficiencies Initiative in 2011 to address issues related to PHL capacity to perform critically needed tests and services. The Laboratory Efficiencies Initiative aims to strengthen PHLs through the achievement of long-term sustainability by adopting practices that improve laboratory operating efficiency and strengthen their resilience in the face of financial and capacity challenges.\(^1\)

**CROSS-JURISDICTIONAL SHARING OF PHL TESTING SERVICES**

One approach to improving laboratories’ operating efficiency is to share testing services with PHLs in other states or jurisdictions. Cross-jurisdictional sharing of PHL services represents an innovative and effective practice that can strengthen the PHL system. The spectrum of sharing includes informal, customary arrangements (e.g., ad hoc arrangements), service-specific arrangements (e.g., memoranda of understanding or contractual arrangements), shared functions with joint oversight (e.g., shared capacity or joint projects), and regionalization (e.g., mergers or the creation of new entities).\(^2\) One example of an existing shared services arrangement is the Northern Plains Consortium, formed by the state PHLs of Montana, North Dakota, South Dakota, and Wyoming. Another example is the performance of newborn screening tests by the Oregon State Public Health Laboratory 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.

PHL directors have expressed interest in understanding the potential legal issues relevant to cross-jurisdictional sharing of testing services. In May 2012, CDC’s Public Health Law Program, in collaboration with CDC’s Laboratory Science, Policy, and Practice Program Office, published a report, “An Overview of Legal Considerations in Assessing Multijurisdictional Sharing of Public Health Laboratory Services,” to help PHL directors and their legal counsel explore these issues.\(^3\) The Overview of Legal Considerations is a companion report to “A Practical Guide to Assessing and Planning Implementation of Public Health Laboratory Service Changes,” which was published by APHL and CDC.\(^1\) The report provides a brief account of the range of federal and state laws that may be implicated in cross-jurisdictional test service sharing. This article is based on that report and focuses on legal considerations in interstate sharing of PHL services. This article does not include legal considerations in intrastate sharing or sharing services with other jurisdictions such as tribes or territories.

**FEDERAL AND STATE LEGAL CONSIDERATIONS**

**Federalism**

The U.S. Constitution establishes a government system based on “federalism,” or the sharing of power between the federal and state governments. During the drafting of the Constitution, a number of state-specific authorities were given to the federal government and are now referred to as the enumerated powers. However, states retained many inherent powers, particularly with regard to protecting the public’s health and welfare. The 10th 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.”\(^4\) 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. Local governments are creatures of state constitutions and statutes, and, generally, local government powers are enumerated much like the federal government.

Public health activities occur at all three levels of government. Widespread sharing of PHL testing services cross-jurisdictionally may implicate federal constitutional law. For example, Article 1, Section 10, Clause 3 of the U.S. Constitution, also known as the Compact Clause, 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 U.S. Supreme Court has
held that only a limited number of interstate agreements require Congressional consent. The Supreme 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.” Depending on the structure of sharing PHL services, states may need to address federal Constitutional issues. States may also need to consider state constitutional issues.

State public health legal authorities
Most states have enabling statutes that establish PHLs. Additionally, most states authorize the department of health or another state agency to promulgate rules or regulations regarding PHL activities. For example, North Carolina requires that the Commissioner of Health “adopt rules necessary for the operation of the State Laboratory of Public Health.” Two important legal considerations regarding the sharing of testing services are (1) whether a state is required to establish and operate a PHL and (2) where the PHL is located. For example, North Carolina establishes “[a] State Laboratory of Public Health . . . within the Department [of Health and Human Services],” whereas Iowa establishes “[t]he state hygienic laboratory . . . as a permanent part of the state university of Iowa.”

Other considerations include whether the state PHL must perform all PHL testing, whether a state can contract out for all or certain testing services, and whether a state PHL can perform services on out-of-state specimens. Public health-enabling statutes and related regulations may either facilitate or restrict shared services arrangements.

Another consideration is the relationship between arrangements for sharing day-to-day laboratory services and existing laws and arrangements triggered by public health emergencies or other surge events. Many states have laws that address cross-jurisdictional mutual aid agreements specifically for PHL services during declared emergencies. For example, Maryland has a specific law that addresses mutual aid agreements and PHLs in other states. In this context, Maryland defines a mutual aid agreement as “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.” 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.” Maryland law further includes specific requirements for mutual aid agreements, including employee travel, workers’ compensation, and expenses. Additionally, the Emergency Medical Assistance Compact (EMAC) is an interstate mutual aid agreement that enables states to share resources during emergencies and disasters. Congress ratified EMAC, and all 50 states, three territories (the U.S. Virgin Islands, Puerto Rico, and Guam), and the District of Columbia have enacted legislation to become members of EMAC.

PHL fees
State laws related to PHL fees are an important consideration to cross-jurisdictional test service sharing. Whether and how much a state PHL is authorized to charge for services varies from state to state. For example, some state laws limit fees to the actual cost of the test performed. South Dakota requires the fee for each PHL service or test to be “based on the actual cost of performing the service or test and the cost of operating the public health laboratory.” 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.” Other states require specific dollar amounts to perform certain tests. For example, Wyoming mandates a $5 fee for the testing of “[v]iral serology for vaccine status (IgG) [and for] each viral antigen (rubella, rubeola, mumps, or chickenpox).”

Some states also have laws governing where PHL revenue is directed. South Dakota, for example, 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.” It is important to note that states often have separate laws related to PHL fees for specialized laboratory testing (e.g., newborn screening tests).

In addition, contracting mechanisms vary from state to state. For example, procurement issues may depend on the structure of shared services arrangements (i.e., PHLs to PHLs vs. PHLs to private health laboratories), among other factors. It will be important to engage legal counsel when considering different shared services arrangements.

Health privacy
The applicability of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule is an important consideration to any agreement to share services. The HIPAA Privacy Rule outlines the requirements for covered entities’ use and disclosure
of protected health information, including the disclosure of protected health information for public health activities. A covered entity is defined as a health plan, a health-care clearinghouse, or a health-care provider that transmits any health information in electronic form in connection with a covered transaction. It is important to note that a PHL may be a hybrid entity that engages in covered and non-covered functions. For example, a PHL that provides health care, as defined under the HIPAA Privacy Rule, and bills for the services in electronic form will be subject to the rule. However, a PHL may also perform non-covered functions, such as testing services for a health department’s disease investigations or tuberculosis screening. While HIPAA may not impede cross-jurisdictional agreements for sharing PHL services between state health departments, PHLs vary from state to state, and such federal privacy laws should be considered and addressed.

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 from disease reporting to genetic testing, mutual aid, and forensic deoxyribonucleic acid. These laws may also cross-reference other state or federal privacy provisions. For example, Rhode Island’s disease reporting regulation states that “[t]he 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. . . .” It is important that states contemplating cross-jurisdictional sharing of PHL 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 developing security and confidentiality agreements (e.g., business associate agreements or data use agreements) to address data privacy and security.

**Newborn screening**

Most states have newborn screening laws, and PHLs are often primarily responsible for newborn screening tests. Ohio requires the state PHL to perform all newborn screening unless the state PHL is unable to perform screenings for a required disorder. If the director determines that the state PHL is unable to perform screenings, the director is required to select an alternative laboratory to perform screenings through a request for proposals, which may include both in-state and out-of-state laboratories. Rescreening may be performed by the Ohio State Public Health Laboratory or another designated laboratory. In contrast, Mississippi allows any laboratory in the U.S. to perform newborn screening testing, provided that the testing laboratory complies with all standards in Mississippi’s newborn screening laws.

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.” 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.” 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.”

**Laboratory certification**

States should consider federal and state laboratory certification requirements. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) “[set] 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. CLIA probably does not provide any barriers to shared service agreements; however, as states plan sharing arrangements, they may want to consider and address all necessary laboratory certifications.

**Shipping laboratory specimens**

States sharing PHL services with other states must comply with all applicable local, state, and federal laws governing shipping, packing, marking, and labeling. For example, laboratory specimens containing or suspected of containing infectious substances must be shipped according to applicable U.S. Department of Transportation and International Air Transport Association regulations.

**Risk management**

Lastly, states will want to address risk management issues. Liability, immunity from liability, indemnity, choice of law, and dispute resolution are important issues that states may want to address in formal agreements to share PHL services. States may also want to review constitutional provisions related to governmental
or sovereign immunity and state statutes, including tort claims acts. It is critical to consult with legal counsel on this issue. State tort claims and sovereign immunity laws can be drastically different from state to state. 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.

CONCLUSION

PHLs play a critical role in protecting the public’s health. Cross-jurisdictional sharing of PHL services is an innovative public health practice aimed at improving laboratory capacity and efficiency. This article offers states that are interested in cross-jurisdictional sharing of PHL services a starting point for considering potential federal and state legal issues. PHL directors should contact their attorneys and request assistance during any legal assessment. While federal laws may not present any inordinate barriers, state laws vary greatly, even within the same region of the country. States interested in cross-jurisdictional sharing should consider all relevant laws, potential conflicts of law, as well as inconsistencies with agreements already in place between health departments and laboratories.

The findings and conclusions in this article are those of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention. This article is a general overview of potential legal issues related to the interstate sharing of public health laboratory (PHL) services and should not be construed as legal guidance or advice on how state PHLs should navigate legal considerations discussed. The authors recommend seeking the advice of an attorney or other qualified professional with questions regarding the application of law to a specific circumstance.

REFERENCES

5. U.S. Constitution, Art. I, §10, Cl. 3.
16. 45 C.F.R. §160.