

# Laboratory Efficiencies Initiative

## Legal and Policy Work Group Meeting

August 17, 2012



## Summary of Proceedings

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The Legal and Policy Workgroup of the Laboratory Efficiencies Initiative (LEI) met on Friday, August 17, 2012, to explore selected legal and policy issues that are relevant to state and local public health laboratories' adoption of higher-efficiency laboratory management practices.

Section A below summarizes key points related to the LEI that were discussed during the meeting. Section B summarizes key points made about policy issues related to three other topics. Section C presents action steps. Section D is a roster of meeting participants.

### **A. Discussion Points Related to the LEI**

#### **LEI Background**

The LEI is cosponsored by the Association of Public Health Laboratories (APHL) and the Centers for Disease Control and Prevention (CDC). The Laboratory Science, Policy and Practice Program Office (LSPPPPO) coordinates CDC's participation in the LEI.

The LEI's strategic goal is to maintain a sustainable national public health laboratory system able to provide high-confidence scientific evidence for public health decision making. Toward that goal, the LEI focuses on assisting public health laboratories to adopt higher-efficiency practices such as:

- Within-state and multi-state sharing of testing services
- Procurement cost-savings
- Standardization or harmonization of testing platforms
- Enhanced informatics capabilities
- Revenue generation
- Workforce preparedness, and
- Improved management of laboratory workflow.

LEI workgroups that are exploring and acting on these priorities have identified a variety of policy issues that are supportive of laboratories' adoption of these practices and other policies that impede, or are thought to impede, adoption.

The Legal and Policy Workgroup met on Aug. 17 to clarify understanding of these issues, to determine which are of greatest current importance to LEI progress, and to identify practical steps that could be taken to assist public health laboratory directors in addressing them.

Participants in the meeting included the directors of five state public health laboratories, directors and senior staff of a number of CDC national centers and offices, and senior APHL and LSPPO staff.

## Key Points

This section outlines key points made during the August 17 meeting related to LEI higher-efficiency practices. As appropriate, it also outlines recommendations for follow-up action.

### 1. Within-state and multi-state sharing of testing services

#### Recent Public Health Laboratory Experience

- a. The California and Washington labs have an MOU that covers testing for radiological purposes. The MOU does not provide for payment for services. The process of developing the MOU was complex and took two years to complete.
- b. Three California county labs share services through a joint powers agreement (JPA) that covers a broad array of services. The labs contract for specific services under the JPA umbrella. JPAs allow detailed specification of the terms of the relationship.
- c. A state lab director noted that following the Fukushima event Oregon and Washington wanted to share testing for radioactive contamination of salmon but that the interstate agreement the two states already had in place did not accommodate environmental (i.e., non-human) sample testing.
- d. New England state labs informally share bioterrorism testing, for example, when one state has an instrument that is out of commission, as happened to the New Hampshire state lab in early 2012 due to flooding. They also share reagents.
- e. The Wisconsin, Illinois, and Iowa labs have attempted to execute a multi-state test sharing agreement but the issues are complex and the agreement has not been executed to date.
- f. While the Connecticut state lab was under construction, the state attempted to work out an agreement with a Veterans Administration healthcare system in Connecticut to do TB testing. It took two years to complete the agreement.
- g. New York and New Jersey plan to explore sharing NBS testing.
- h. The Iowa lab has explored executing a test sharing agreement with tribal agencies in South Dakota but it has not been put in place to date. (The Iowa lab is a unit of the university.)
- i. Following Hurricane Katrina, the Iowa state lab performed NBS tests for Louisiana and billed through the Univ. of Iowa.
- j. In some cases, privacy and confidentiality laws can impede sharing testing services. For example, Texas referred some H1N1 specimens to the Virginia public health lab. But Texas legal counsel advised that Texas law prohibited Virginia from reporting test results electronically. The results had to be faxed to Texas instead.

- k. Multi-state sharing is more likely to succeed with higher-level, more sophisticated types of tests than with routine and fast-turnaround tests where the epidemiology program needs immediate test results.
- l. State labs that operate within a university or that can partner with a nonprofit public health institute or similar organization generally have more flexibility in establishing sharing agreements and in retaining payments received for services (rather than be required to deposit them to the state’s general fund). Two labs have been allowed to retain small payments they received but believe they might be required to deposit larger amounts to the general funds.
- m. Several state labs have found that contracts can be an effective way to enter into test service sharing arrangements because they allow specificity about the conditions under which testing services are provided.

Additional Notes

- a. A CDC representative noted that some states have laws that require their state lab to perform TB tests; this type of requirement could impede multi-state sharing. A state lab director noted it is not necessarily difficult to revise such laws if required. (Following the Aug. 17 meeting, it was determined that most such laws are in the form of state regulations which might be more amenable to revision than are statutes.)
- b. A state lab director noted that it may be difficult to regionalize “front-line” testing that generates results that local or state public health officials need to have rapidly to address urgent needs.
- c. A state lab director noted that the anticipated growth in public health labs’ use of next-generation sequencing will give impetus to “regionalization” since not all state labs will be able to acquire the necessary bioinformatics capacity and the professional staff needed to interpret test data.
- d. A question to be addressed is how CDC, in supporting multi-state sharing, can do so in a way that is fair to all public health labs in terms of the allocation of CDC funds and other resources.

2. Procurement Cost-Savings

Discussion focused on:

- a. The potential for expanding public health labs’ use of the National Association of State Procurement Officers (NASPO)-Western States Contracting Alliance (WSCA) laboratory purchasing mechanism and for expanding the number of vendors available through it. (This mechanism currently allows purchases for select items only from Fischer Scientific and VWR.)
- b. Expanding use of rental and lease contracts for testing platforms.

- c. Expanding purchasing through GSA schedules or negotiating for GSA rates with GSA vendors from whom public health labs purchase directly. For example, CDC contracts for biosafety hood inspections at low cost; state labs potentially could negotiate for the same prices.
- d. Using CDC “direct assistance” to acquire equipment and service contracts.

### 3. Standardization or harmonization of testing platforms

#### Public Health Laboratory Director Notes

- a. Some lab directors noted that some states used standardized platforms for H1N1 testing very successfully.
- b. Labs should retain flexibility in using platforms and not be locked into platforms by manufacturers; for example, many LRN protocols call for specific reagents or platforms.
- c. Lab directors have considerable ability to influence manufacturers’ decisions on platforms. One lab director’s office met with a manufacturer in 2011; the manufacturer sought direction from the lab on its future platform preferences. APHL will meet with its corporate partners in Sept. 2012.
- d. A lab director indicated willingness to post all of that lab’s testing methods on its website to indicate its platform preferences to manufacturers.
- e. Lab directors requested that CDC develop an agency-wide policy on standardization for public health labs.
- f. Lab directors noted that their labs’ administrative burden would be reduced if all CDC cooperative agreements would use common terms and conditions. They requested CDC implement this change.

### 4. Enhanced Informatics Capacity

#### Public Health Laboratory Director Notes

- a. Some public health labs are hindered in developing informatics capacity because they do not have in-house IT and informatics staff.
- b. Another problem is that much of the data labs receive is low in quality—incomplete and disorganized—and results in potentially valuable public health information being lost.
- c. As public health labs continue to explore ways to achieve higher efficiency, CDC should specify the types of test data it wants to continue receiving from the labs.

### 5. Revenue Generation

#### Public Health Laboratory Director Notes

- a. One state lab has contracted with a private firm that handles all of its billings electronically. The firm charges 10% of the receipts.

- b. Among the problems labs face in billing is that CPT codes are not uniform across tests and are not uniform across providers.

6. Workforce preparedness

Public Health Laboratory Director Notes

- a. To deal with a statewide government hiring freeze, one lab got permission to transfer funds originally appropriated for employee compensation to engage contracted staff.
- b. One lab director recommended CDC encourage retiring senior staff and Commissioned Corps officers to apply for positions in universities that also have public health laboratory responsibilities because this is a good way to acquire immediate, deep expertise while providing retirees ways to ease into retirement.
- c. Public health laboratories should look at veterans who have trained in military labs to fill vacancies. APHL is entering into conversations with DOD about this.

CDC Staff Comments

- a. ELC grant funds can be used to pay for lab employees and contractors.
- b. CDC grant funds can be used as “direct assistance”; CDC would station CDC employees in public health labs.
- c. Approximately 120 CDC Public Health Associates (PHAs, in the Public Health Associates Program) are on assignment to public health departments. PHAs also can serve in public health labs.

**B. Discussion Points Related to Topics Other than the LEI**

**Testing for Newborn Screening**

Meeting participants identified state policy as an issue of critical importance to ensuring that newborn screening continues and to permit retention of dried blood spots for research purposes. The states currently have taken a variety of different approaches to retention policies but there does not appear to be consensus on best practices. One laboratory director noted that a requirement that DNA specimens be destroyed could preclude their use to help diagnose or treat people later in life.

Lab directors recommended that CDC work with APHL, ASTHO, and other pertinent groups to identify best practices, based, at least in part, on such examples as the Michigan BioTrust for Health (where research uses are allowed if parents sign a consent form.)

The CDC Public Health Law Program is tracking state newborn screening legislation and plans to post information on the internet.

## **Specimen Management Policies**

Many state public health laboratories maintain collections of specimens for research purposes. One laboratory director requested that CDC post the new agency-wide policy it is developing for all CDC specimen collections as a resource public health labs can use.

## **Health Care Reform**

The workgroup observed that public health laboratory services (unlike clinical laboratory services) are not being considered for inclusion in the “essential health benefits” that currently are being defined under the Affordable Care Act and that policy makers should be encouraged to include them.

One lab director noted that Iowa is actively exploring public health agencies’ role in the new ACA/Accountable Care Organization framework, including potential roles for the state’s public health lab.

## **C. Action Steps**

The following action steps were identified during the August 17 meeting.

### **1. LEI-Related Policies**

The laboratory directors recommended that new resources be created that public health lab directors and senior staff can use to identify: a) policies that are supportive of higher lab efficiency (especially of test service sharing); b) policies that impede higher efficiency; and c) approaches labs have taken to address or “work around” policies that are barriers.

These resources could take several forms.

- a. One recommendation was that a “menu” of supportive policies be developed, based on the actual experiences of public health labs. Such a menu could present the language of specific supportive policies and workarounds collected from labs that have them in place. The directors preferred a menu over a “model” law or policy because the menu could present options if, for example, two states take different approaches to supporting a given type of management efficiency.
- b. A related recommendation was for development of a template of policies that lab directors could use in assessing their own existing and policies and determining, on that basis, if they want to propose any changes to them.

LSPPPPO committed to drafting a proposal for such resources for review.

### **2. Newborn Screening**

APHL and LSPPPO committed to exploring how to identify best practices in state newborn screening policy. The CDC Public Health Law Program is tracking state newborn screening legislation and plans to post information about that legislation on its website.

3. Healthcare Reform

LSPPPO committed to bringing the issues discussed to the attention of CDC's Office of Health Reform Strategy, Policy, and Coordination toward the goal of developing policies that support public health laboratories' role in protecting the public's health in the context of the Affordable Care Act, wide adoption of the accountable care organization model, and other structural changes in the healthcare sector.

4. Health Economics

Documentation is needed of public health labs' value, for example, money saved by surveillance and early detection.

5. Public Health Lab Research

Establish a forum of public health labs that conduct research and share knowledge. (This could be a project for the NCPHLL cohort.)

6. Plan a follow-up meeting of this group.