

2. Clarifying Legal and Policy Issues

Clarifying Legal Authority Guide

Citizens of the United States hold a centuries-old social contract with their government that permits the government to collect health information, without individual consent, to help control infectious diseases. Such a broad social contract does not yet exist in areas beyond infectious diseases. For this reason, even though your agency may be accustomed to collecting and using data from health care organizations for a multitude of purposes, it is never prudent to assume that it has the legal authority to do so with any new program. Such assumptions can lead to significant legal issues.

The questions below highlight key points your planning team should thoroughly investigate and answer before meeting with agency attorneys. Your responses will help them determine if your agency has the required legal authority to collect and use data from health care organizations for the purposes of your surveillance program. This process of verifying legal authority represents one of the most important steps for you to take. These questions will also help you address security and privacy concerns in your planning process.

1. Are we collecting personally identifiable data, or are we collecting de-identified or summary data?

Address this critical question first, because it bears on all subsequent questions. The more identifiable and real-time the data, the more privacy concerns; the more privacy concerns, the more privacy protections and security procedures required. The answer to this question also helps determine whether or not the program has the legal authority to collect and use the data. Collecting summary data for surveillance purposes may come under one statute, but personally identifiable data may come under another or even require specific enabling legislation.

2. Under what law do we believe our surveillance program to be authorized?

The surveillance program might be authorized under specific enabling legislation, a more general public health authority or something in between those two. The more specifically and strongly the statute relates to your surveillance purposes, the more solid your case for having the legal authority to develop the program and collect and use the data for its intended purposes.

3. What is the likelihood that we have sufficient legislative support for our surveillance program?

Although a current law may appear to sufficiently authorize creation of the surveillance program, gauging the degree of likely legislative support for it may prove helpful if you seek a future legislative appropriation for the program and lessen potential difficulties with privacy advocates who may publicly challenge the need for the program. Work with your legislative liaisons to discuss legislative reactions to similar programs in the past, identify potential program champions and opponents, and to determine the range of possible issues that might arise. When gauging the likely legislative support, answer the following questions:

- What opposition to our program may exist?

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Privacy concerns are the Achilles heel of most public health surveillance and registry programs. It is unwise to underestimate the level of privacy advocacy or anti-big-government sentiment that could undermine your program. Work with your agency attorney and legislative liaisons early on to get a feel for the privacy landscape in your jurisdiction.

- What is our agency's status under HIPAA?
You should determine how your agency is classified under the Health Insurance Portability and Privacy Act (HIPAA), because this classification will dictate, among other issues, if you need to enter into Business Associate Agreements (BAA) with any health care organizations providing the data for your program.
- Will the proposed surveillance activity require new data use agreements or can existing BAA or other agreements be used or adapted?
While this question is most relevant at the pilot and implementation phases of your program, having this discussion with your agency attorneys early can help you discover in advance if you need to develop any new data use agreements.