



Frequently Asked Questions about Legal Authorities and Privacy Issues

What is the authority for BioSense?

CDC is generally authorized by the Public Health Service Act, Sections 301, 317 and 319D (42 U.S.C. 241, 247b and 247d-4) to maintain active surveillance of diseases through epidemiologic and laboratory investigations and data collection, analysis, and distribution.

Specifically, section 319D directs the Secretary of Health and Human Services to provide for the establishment of integrated public health surveillance between and among federal, state, and local public health officials, public and private health-related laboratories, hospitals, other health care facilities, and others. The purpose of these networks is for the timely sharing and discussion, in a secure manner, of essential information concerning bioterrorism or other public health emergencies, or recommended methods for responding to such an attack or emergency.

CDC has designed BioSense to establish these networks and mechanisms to ensure early event detection, health situational awareness, investigation and management of outbreaks related to bioterrorist events and other public health emergencies.

Are disclosures to BioSense required by law?

No. Disclosure of data to BioSense by the data sources described above is voluntary.

Does CDC need identifiable information for BioSense?

No. CDC does not need identifiable information. BioSense will not include individual names or other direct identifiers. It will however, include some specific dates (for example date of treatment) and geographic information, such as zip code that may make the information "identifiable" for purposes of the HIPAA Privacy Rule and other privacy protections.

Will identifiable information be disclosed to the public?

BioSense will not include names and other direct identifiers. In addition, identifiable data that may be collected will generally be protected from disclosure by Federal laws, such as the Privacy Act of 1974 and exemptions for disclosure of agency records under the Freedom of Information Act.

Are disclosures to BioSense permitted by the HIPAA Privacy Rule?

Yes. The Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information, Final Rule (Privacy Rule) [45 CFR pts. 160 and 164] protects the privacy of certain individually identifiable health data. The HIPAA Privacy Rule expressly permits entities to disclose, without individual authorization, protected health information to public health authorities "... authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions ..."

The CDC is a public health authority as defined by the HIPAA Privacy Rule, as it is an agency of the United States Department of Health and Human Services that is responsible for public health matters as part of its official mandate. BioSense is a public health activity authorized by law for which disclosure of protected health information by covered entities is permitted. CDC and its contractors will work with the individual data sources to define the minimum necessary protected health information necessary to accomplish the intended purposes of BioSense.

What will CDC do with the information provided to BioSense?

BioSense has been designed to provide a visualization of clinical case data during a possible health event. At the time of a possible health event, public health officials need to have a real-time community health "picture" to confirm or refute the existence of an event; to understand the number of suspect cases; and to monitor the size, location, and spread of suspect illness in the broad population.

Through BioSense, hospitals and health systems will stream real-time data to CDC to provide federal, state, and local officials, and participating hospitals with near real-time views of suspect illness trends and probable disease cases to allow for the visualization of clinical case data.

2/2/06

