

FACT SHEET ON BIRTH DEFECTS SURVEILLANCE AND HIPAA FOR HEALTH CARE PROFESSIONALS

Note: This fact sheet was created by the National Birth Defects Prevention Network Ethical, Legal, and Social Issues Committee for health care professionals. This fact sheet is a “template” and should be revised according to each state’s HIPAA laws and laws regarding tracking of birth defects. For your state’s laws, please consult the additional websites cited at the end of this fact sheet.

Birth Defects Surveillance

What is “birth defects surveillance”?

- Birth defects surveillance is the process of obtaining data about cases of birth defects to determine the type, frequency, and geographical location of cases.
- Data can be cross-referenced to identify anomalies, trends, clusters, and possible causes.
- Some states have laws that require reporting and/or surveillance of infants and children born with a birth defect.

Why is birth defects surveillance conducted?

- Information about infants and children with birth defects can assist with descriptive epidemiology, etiologic research, education, and advocacy.
- Such data also can be used to target and evaluate public health programs, and identify and refer infants and children to services and programs.

Who collects this information?

- Most surveillance is conducted through a collaboration of health care professionals with a state agency or a university, medical providers and/or other institutions and organizations for public health purposes.

Health Insurance Portability and Accountability Act (HIPAA)

What is “HIPAA”?

- The Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191), which was enacted in 1996, includes provisions for making health insurance more accessible and affordable.
- Title I of the HIPAA law deals with health care access, portability, and renewability. The intention is to protect health insurance coverage for workers and their families when they change or lose their jobs.
- Title II of the law, also known as "Administrative Simplification," deals with preventing health care fraud and abuse. The law provides authority for administrative regulations relating to medical records privacy, confidentiality, and electronic transactions involving medical records. These regulations, which became effective in part in April 2003, include the HIPAA Privacy Rule. When health care professionals and patients refer to medical records privacy and “HIPAA,” they are generally referring to the HIPAA Privacy Rule.
- The HIPAA Privacy Rule, which has the effect of law, provides a set of national standards and requirements that protect the confidentiality of medical records and other personal health information.
- These standards and requirements include the right to: receive notice of privacy practices; request to inspect and obtain a copy of health information; request amendment of health information; obtain an accounting of health information releases; request restrictions on the use of health information; request confidential communications; and file a complaint.

What is “protected health information” (PHI)?

- Medical information that includes any number of patient identifiers such as name, social security number, telephone number, medical record number, or zip code.
- The HIPAA Privacy Rule protects all individually identifiable health information in any form (i.e., oral, paper-based, electronic) that is transmitted or stored by a covered entity.

What is a “public health authority”?

- A “public health authority” is an agency or authority of the United States, a territory, a state, a political subdivision of a state or territory, or Indian tribe, or a person or an entity acting under a grant of authority from or contact with such public agency, including the agents and employees of such public agency or its contractors or entities or individuals to whom it has granted authority that is responsible for public health matters as part of its official mandates. (45 CFR § 164.501)

Who is a “public health authority”?

- Some examples include: state or local health departments where state law has granted a public health mandate; and the Centers for Disease Control and Prevention (CDC) and entities with whom they contract or to whom they have given authority to conduct public health activities such as birth defects surveillance.
- All CDC-funded surveillance programs are public health authorities for the purpose of the surveillance project or public health activity. This is because the program has a grant of authority from the CDC or because the program is required by CDC to be a “bona fide agent” of the state health department as a prerequisite to funding.
- In these cases, covered entities can disclose protected health information to that public health authority.
- Public health activities generally include health surveillance, interventions, and disease prevention in regards to certain at risk populations.

Who is affected by the HIPAA Privacy Rule?

- The law applies to three groups referred to as “covered entities.” These covered entities include: 1) health care providers; 2) health plans; and 3) health care clearinghouses. “Health plans” are defined as any individual or group plan that provides or pays health care costs. “Health care clearinghouses” are a public or private entity that transforms health care transactions from one format to another.

Can state laws require stricter privacy protections than HIPAA?

- Yes. The HIPAA Privacy Rule is considered basic federal standard for protection of protected health information (PHI). At minimum, states are required to abide by HIPAA rules, but states can have stricter rules for confidentiality of PHI.

Does HIPAA keep private health information from being shared by providers, health plans, and health care clearinghouses?

- No, but the HIPAA Privacy Rule has very specific rules that require a person to: give permission for his or her personal health information to be shared; allow the personal health information to be shared without permission; and require personal health information to be reported to the police without permission, like reporting child abuse or domestic violence. These rules are consistent with other important public activities.

HIPAA and Birth Defects Surveillance

Are there rules in HIPAA to protect health information (i.e., maintain data confidentiality) collected for public health purposes, including birth defects surveillance?

- Agencies that collect personal health information for public health purposes should have rules about how the information is kept and who can see it. Some examples include: employees must agree in writing to maintain confidentiality of the information; data must be stored in secure places; and computers must have passwords.
- Personal health information collected from birth defects surveillance activities cannot be shared with anyone else, contingent on applicable jurisdiction laws or administrative rules.
- These rules can be state and program-specific.

Will HIPAA interfere with reporting and surveillance of birth defects?

- No. HIPAA will not interfere with public health reporting. The HIPAA Privacy Rule permits providers to give information from medical records, including patient identifiers such as names, addresses, and patient-specific health information, to public health agencies without the individual's written authorization. The HIPAA privacy rule allows a covered entity to disclose personal health information to a public health authority for public health purposes (i.e., disease reporting) or public health surveillance (i.e., tracking of birth defects). In addition, HIPAA allows personal health information to be disclosed when required by law. (45 CFR § 164.512(a-b)) Thus, HIPAA permits disclosures where a public health authority is permitted by law to receive information for a public health purpose.

Does HIPAA require providers and public health authorities to enter into a confidentiality agreement to share data?

- No. The HIPAA Privacy Rule does not require providers to enter into limited data use agreements or business associate agreements with public health authorities.

Additional Information

- For more information on HIPAA: <http://www.hhs.gov/ocr/hipaa/>
- For more information on HIPAA and public health surveillance:
 - Centers for Disease Control and Prevention (CDC) Privacy Rule Guidelines: <http://www.cdc.gov/privacyrule>
 - CDC *Morbidity and Mortality Weekly Report (MMWR)* vol. 52 April 11, 2003 <http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf>
- For state-specific information on HIPAA:
 - <http://dirm.state.nc.us/hipaa/hipaa2002/links.html>
 - <http://63.135.106.87/NBDPN/links.html#%22hippa%22>
- Department of Health and Human Services Office of Civil Rights dedicated hotline for HIPAA questions: 1-866-627-7748.