

Chapter 2

Legislation

Table of Contents

2.1 Introduction.....	2-1
2.2 Legislation, Regulation, and Authority.....	2-2
2.3 Key Elements of Model Legislation.....	2-3
2.3.1 Designation of Agency Authority.....	2-3
2.3.2 Purpose and Priorities.....	2-3
2.3.3 Access to Data and Records	2-4
2.3.4 Ability to Share Data While Maintaining Confidentiality.....	2-4
2.3.5 Terminology and Definitions	2-5
2.3.6 Opt-out Clauses	2-5
2.3.7 Advisory Committee	2-6
2.3.8 Funding.....	2-6
2.4 Federal Laws	2-8
2.4.1 Health Insurance Portability and Accountability Act (HIPAA)	2-8
2.4.2 Family Educational Rights and Privacy Act (FERPA).....	2-13
2.4.3 Privacy Act.....	2-14
2.4.4 Public Health Service Act	2-14
2.4.5 Freedom of Information Act 5 USC §522 (FOIA)	2-15
2.4.6 Advocacy.....	2-16
2.5 References.....	2-17

Appendices

Appendix 2.1 Sample State Legislation	A2.1-1
Appendix 2.2 Table of Birth Defects Legislation.....	A2.2-1
Appendix 2.3 Definitions Used to Determine Covered Entity Status Under the Privacy Rule.....	A2.3-1
Appendix 2.4 Office of Civil Rights (OCR) HIPAA Privacy Regulation Text.....	A2.4-1

Acronyms

CDC	Centers for Disease Control and Prevention
CE	Covered Entity
FERPA	Family Educational Rights and Privacy Act
DHHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
OCR	Office of Civil Rights
PHA	Public Health Authority
PHI	Protected Health Information
PR	Privacy Rule

2.1 Introduction

Legislation supporting birth defects surveillance activities is important for several reasons. For example, legislation serves to define the purposes of surveillance activities, specifies the kinds of data or information to be collected, and designates who is responsible for this activity. The first birth defects legislation was passed in New Jersey in 1926. During the past 20 years, the majority of states have enacted legislation mandating reporting of birth defects to the health department. As of April 2004, 41 states had existing legislation or rule related to birth defects surveillance.

Although there are a number of advantages to having legislation that supports birth defects surveillance, some limitations may also accrue. Early in their planning process, new or relatively new state programs should consider both the benefits and the possible limitations of birth defects surveillance legislation. At this early stage in a program's development, the opportunity exists to advocate for and perhaps assist in crafting clearly written, effective legislation that will serve the needs of the program in years to come.

In this chapter we discuss the distinction between the terms 'legislation', 'regulation', and 'authority' (Section 2.2); key elements of model legislation (Section 2.3); and federal laws that can affect birth defects surveillance programs (Section 2.4). References cited in this chapter may be found in Section 2.5.

To assist those interested in drafting or revising state legislation concerning birth defects surveillance, we append sample legislation from Arkansas, California, New Jersey, New York, Oklahoma, and Texas (see Appendix 2.1). Additional appendices include a table of birth defects legislation (Appendix 2.2), definitions used to determine 'covered entity' status under the Privacy Rule (Appendix 2.3), and an excerpt from the text of the Health Insurance Portability and Accountability Act (Appendix 2.4).

2.2 Legislation, Regulation, and Authority

‘Authority’ to mandate the reporting of birth defects to a surveillance program can be granted through ‘legislation’ or ‘regulation’. In this section we explore distinctions among these and other related terms.

Legislation is the process of enacting laws by a legislative body. The type of law depends on the legislative authority granted. State legislatures and Congress have complex processes to enact legislation. These processes vary from state to state. In the simplest terms, state and federal legislative bodies create **statutory law**, also called a **legislative act**. These terms denote a bill that has been passed by one house in a bicameral legislature. After enactment by both houses, the terms ‘law’ and ‘act’ may be used interchangeably. A **statute** is the formal written enactment of a legislative body, whether federal, state, city, or county.

State and federal agencies are arms of the executive branch of the government. Such agencies have broad power granted under state and federal law to make **regulations** that govern activities for which they are responsible. Leaders of public health and other state agencies are not elected, but rather appointed by the executive, usually the governor of a state. Under current public health legislation, public health authorities may make regulations that can be mandatory, voluntary, directive, or prohibitive.

In sum, the term ‘legislation’ refers to a law enacted by an elected body, whereas ‘regulations’ are created by agencies.

For an agency, such as a state public health department, to establish a regulation mandating the reporting of birth defects, the health department must have the power or the **authority** to establish that type of regulation. This power can be based on state law or on an act of the executive power of the state, such as the governor. If the health department does not already have such regulatory power, then two options exist, namely, proposing a state law mandating birth defects reporting or proposing a state law granting authority to the health department to establish a regulation.

A state reporting law is straightforward and more democratic because it is enacted by elected representatives and gives an agency clear power or authority to do whatever the law states. However, a state reporting law also places the power to modify or change the law in the hands of the legislative body, despite the fact that the legislature may not be well informed about public health matters. Because most legislative bodies recognize the expertise of the people who run public health agencies, they generally grant them the necessary authority to conduct their work properly. Thus, the legislative bodies of many states have given the health department power to enact the regulations they deem necessary to protect the public health and welfare.

2.3 Key Elements of Model Legislation

Birth defects legislation should be considered early in the developmental phase of a surveillance program, if possible. This allows for legislation to be written clearly to support facilitation of surveillance activities. Language should be broad and flexible enough to cover all of the areas necessary to meet programmatic objectives, yet not to be so vague as to be confusing or meaningless. Well-written legislation that facilitates birth defects surveillance should address the key elements outlined in the Sections 2.3.1 through 2.3.8 below. These include:

- Designation of agency authority
- Purpose and priorities
- Access to data and records
- Ability to share data while maintaining confidentiality
- Terminology and definitions
- Opt-out clauses
- Advisory committee
- Funding

2.3.1 Designation of Agency Authority

Model state legislation for birth defects surveillance should specify the agency that has the overall grant of authority for the system. This authority usually resides within the department of health, which has the power to enact rules and regulations, establish criteria for reportable conditions, and implement and oversee procedures for reporting. In most cases, there is no need to detail the specific regulations in the legislation. However, legislation should specify that the department has the authority to enact and enforce the regulations.

2.3.2 Purpose and Priorities

The purpose of the program will drive decision-making about its scope and activities. The purpose will also help states define outcomes, ages to be covered, and the most important sources of data to be included. Language should clearly articulate what the system should do and what its priorities should be. For example, Hawaii's legislation contains the following language:

“The department of health shall establish the statewide birth defects program to:

- 1) Collect surveillance information on birth defects and other adverse reproductive outcomes;*
- 2) Report the incidence, trends and causes of birth defects and other adverse reproductive outcomes;*
- 3) Report information for the development of prevention strategies to reduce the incidence of birth defects and other adverse reproductive outcomes; and*
- 4) Develop strategies to improve the access of children with birth defects to health and early intervention services.” (Hawaii Revised Statutes, Chapter 321, §321)*

2.3.3 Access to Data and Records

Legislation should grant the birth defects surveillance program the authority to access hospital discharge data and medical records or to require reporting with access for follow-up as needed. Legislation that provides for access to medical records grants surveillance programs the opportunity to obtain more complete and reliable reporting of birth defects, while also ensuring that surveillance data sets are large enough to be useful to researchers and service providers.

California's birth defects surveillance law states that:

“... The director shall require health facilities, with 15 days' notice, to make available to authorized program staff the medical records of children suspected or diagnosed as having birth defects, including the medical records of their mothers. In addition, health facilities shall make available the medical records of mothers suspected or diagnosed with stillbirths or miscarriages and other records of persons who may serve as controls for interview studies about the causes of birth defects ...” (California Health and Safety Code, Part 2, Chapter 1, §103830)

Legislation with mandated reporting should include language that allows a program to access medical records for follow-up to ensure data quality. For example, New Jersey's legislation stipulates that:

“The Commissioner of Health, in consultation with the Public Health Council, shall require the confidential reporting to the Department of Health of all cases ...” (New Jersey, Chapter 26:8-40.2)

Then, in its regulations, the department of health addresses the follow-up component:

“Every health facility and independent clinical laboratory shall allow access to, or provide necessary information on infants with birth defects ...” (New Jersey Rules, Chapter 20, Subchapter 1, 8:20-1.2j)

2.3.4 Ability to Share Data While Maintaining Confidentiality

Legislation should specify who can have access to the data and how the confidentiality of the data will be protected. Many states have specific guidelines regarding the use of data for research purposes, and legislation may stipulate that persons who violate rules about data use or confidentiality are subject to civil penalties. For example, Texas' legislation states that:

“(a) Access to the central registry information is limited to authorized department employees and other persons with a valid scientific interest who are engaged in demographic, epidemiological, or other studies related to health and who agree in writing to maintain confidentiality.

(b) The department shall maintain a listing of each person who is given access to the information in the central registry. The listing shall include:

- (1) the name of the person authorizing access;*
- (2) the name, title, and organizational affiliation of each person given access;*
- (3) the dates of access; and*
- (4) the specific purpose for which the information was used.*

(c) The listing is public information, is open to the public under the open records law, Chapter 424, Acts of the 63rd legislature ... and may be inspected during the department's normal hours of operation.” (Texas Health and Safety Code, Subchapter D, § 87.062)

2.3.5 Terminology and Definitions

Terminology should be defined clearly, but not in an overly narrow or restrictive manner. For instance, it is more effective to specify surveillance for the general category of ‘birth defects’ rather than for a narrow or finite list of specific defects such as spina bifida, anencephaly, Down syndrome, and so on.

The state of California defines **birth defect** as:

“... any medical problem of organ structure, function, or chemistry of possible genetic or prenatal origin.” (California Health and Safety Code, Chapter 1, §103825 [a])

The legislation also specifies that **health facilities** are:

“... general acute care hospitals, and physician-owned or operated in clinics ... that regularly provide services for the diagnosis or treatment of birth defects, genetic counseling, or prenatal diagnostic services.” (California Health and Safety Code, Chapter 1 §103830)

Broader language is more flexible, inclusive, and comprehensive than narrow language and allows for future modifications in program priorities or activities, whereas revising or amending narrowly written legislation can be a lengthy and difficult process. Legislating surveillance of specific defects may prove to be problematic in the long run as conditions change or as it becomes necessary or desirable to collect data on additional defects or combinations of defects. Definitions should be in the agency’s regulations, not in the enabling legislation.

2.3.6 Opt-out Clauses

In most cases, parental consent is not required in order for a surveillance program to be able to collect data on children with birth defects from schools or health care providers. Some states, however, do require written consent from parents. Because obtaining written consent from parents can be problematic, some states handle this issue with an opt-out clause.

For example, Ohio’s opt-out clause states that the health department shall adopt rules that will:

“Establish a form for use by parents or legal guardians who seek to have information regarding their children removed from the system and a method of distributing the form to local health departments ... and to physicians. The method of distribution must include making the form available on the internet.” (Ohio, House Bill No.534, § 3705.35[e])

Opt-out clauses assume consent unless otherwise stated, allowing the surveillance program to collect data unless a child’s parent or legal guardian submits a written request that their child’s information be removed from the surveillance system. Opt-out clauses eliminate the need for providers and surveillance program staff to obtain written consent from parents and contribute to more complete data collection.

2.3.7 Advisory Committee

States that consider the potential impact of legislation in the planning stages of their programs have the advantage of influencing the development of legislation that can support the overall growth and development of the program. In some states, for example, legislation calls for establishing an advisory committee to provide guidance and oversight for the design and implementation of birth defects surveillance. Advisory committees made up of experts from fields such as epidemiology, hospital administration, biostatistics, maternal and child health, and public health can develop recommendations and provide the expertise necessary to ensure that the program meets well-defined standards and goals. Some advisory committees also include parents of children with birth defects. For example, Vermont's legislation calls for the establishment of a 'birth information council'.

“(a) The commissioner of health, in collaboration with the March of Dimes, shall appoint a birth information council to advise on the need for and implementation of a comprehensive, integrated, and confidential birth information system.

(b) The council shall be composed of nine members, who represent each of the following interests:

- (1) obstetrics and gynecology;*
- (2) pediatrics and genetics;*
- (3) the Vermont Children's Health Improvement Program;*
- (4) a parent of a child with special medical needs;*
- (5) an adult with special medical needs;*
- (6) the commissioner of health, or his or her designee;*
- (7) the Family, Infant, and Toddler Program;*
- (8) the Vermont chapter of the March of Dimes; and*
- (9) the Vermont Program for Quality Health Care.” (Vermont, H.636, § 5084)*

2.3.8 Funding

Cost can be an impediment to establishing a birth defects surveillance system.

Some states have legislation mandating special funds to cover the operating expenses of their birth defects surveillance program. Sources of special funds include marriage license, birth certificate, and newborn screening fees. For example, Iowa's special fund is supported through birth registration fees:

“It is the intent of the general assembly that the funds generated from the registration fees be appropriated and used as follows:

- (1) Beginning July 1, 2003, and ending June 30, 2005 ... five dollars of each fee for the birth defects institute central registry established pursuant to section 136A.6.*
- (2) Beginning July 1, 2005, ... ten dollars of each fee for the birth defects institute central registry established pursuant to section 136A.6.” (Iowa Code, §144.13A)*

In summary, paying due consideration to how legislative language can affect the design, implementation, and operation of the surveillance program and further ensuring that the birth defects surveillance program itself has input into legislative language from the time the program is established can have a significant impact on the long-term success of the program.

2.4 Federal Laws

A broad range of federal laws must be considered when planning state legislation, local regulations, or new birth defects surveillance programs. While state laws will govern most of the activities of the program, the impact of federal privacy regulations must also be considered. Depending upon how the birth defects program is structured, it may need to follow the Health Insurance Portability and Accountability Act (HIPAA) discussed in Section 2.4.1, the Family Educational Rights and Privacy Act (FERPA) discussed in Section 2.4.2, and other federal regulations such as the Privacy Act (Section 2.4.3), the Public Health Service Act (Section 2.4.4), and the Freedom of Information Act (Section 2.4.5). The following sections provide basic information about major federal laws that must be considered when setting up a birth defects surveillance program. In Section 2.4.6 we discuss the supportive role that can be played by state health officials or staff of the Centers for Disease Control and Prevention (CDC) in conjunction with planning state legislation or local regulations for birth defects surveillance programs.

2.4.1 Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act was passed in 1996 to protect consumers of the insurance industry. The Privacy Rule (or PR, also referred to as the Rule), which implements the Act, became effective on April 14, 2001, and creates national standards to protect an individual's medical records and other personal health information, known as *protected health information* (or PHI). The Rule gives patients more control over their health information and establishes appropriate safeguards that health care providers and other *covered entities* (or CEs) must establish to protect the privacy of PHI. Violators are subject to civil and criminal penalties if they violate patients' privacy rights as stated in the Privacy Rule. The Rule allows for disclosure of some forms of data for activities carried out by *public health authorities* (or PHAs) but limits release of information to the minimum necessary for the purpose of the disclosure. In addition, the covered entity may rely on the public health authority for what constitutes the 'minimum necessary'.

The Privacy Rule requires health care providers who are covered entities to provide information to patients about their privacy rights and how their information can be used, to adopt clear privacy procedures and adequately train employees in these procedures, and to designate an individual to be responsible for seeing that the privacy procedures are adopted and followed. Privacy protections should not, however, interfere with a patient's access to health care or the quality of health care delivered.

Basic Provisions of the Privacy Rule That Affect Birth Defects Reporting

A state, county, or local health department that performs functions that make it a covered entity, or otherwise meets the definition of a covered entity, may elect to call itself a *hybrid entity*. For example, a state Medicaid program is a covered entity (i.e., a health plan) as defined in the Privacy Rule. Some health departments operate health care clinics and thus are health care providers. If these health care providers transmit health information electronically, in connection with a transaction covered in the HIPAA Transactions Rule, they are covered entities.

Most of the requirements of the Privacy Rule apply only to the hybrid entity's health care provider component(s). If a health department elects to be a hybrid entity, there are restrictions on how its health care component(s) may disclose protected health information to other components of the health department. Birth defects surveillance components that provide genetic counseling and other types of

health care services will most likely be required to comply with the Rule's 'covered entities' provisions, if they bill electronically for their services. (See 45 C.F.R. § 164.504 (a) – (c) for more information about hybrid entities.)

For further information, see the definitions of 'covered entity', 'health care provider', 'health plan', and 'health care clearinghouse' in 45 C.F.R. §160.103. See also, the "Covered Entity Decision Tools" posted at:

<http://www.cms.gov/hipaa/hipaa2/support/tools/decisionsupport>

Uses and Disclosures for Which an Authorization or Opportunity to Agree or Object Is Not Required

Section 164.512 of the Privacy Rule sets forth the conditions under which a covered entity, as defined previously, may disclose protected health information without the individual's consent or authorization. Below is a discussion of the application of the Rule to the birth defects surveillance system. The actual text of the regulation can be found in Appendix 2.4.

Consent and notice. The US Department of Health and Human Services (DHHS) made changes to the Privacy Rule effective August 14, 2002, to protect privacy while eliminating barriers to treatment. The notice requirement was strengthened, making consent for routine health care delivery purposes optional. The Rule requires covered entities to provide patients with notice of a patient's privacy rights and the privacy practices of the covered entity. The strengthened notice requires direct treatment providers to make a good faith effort to obtain patients' written acknowledgement of the notice of privacy rights and practices. The modified Rule removes mandatory consent requirements while providing covered entities with the option of developing a consent process that works for that entity. The Rule also allows consent requirements already in place to continue, but does not mandate any particular standard.

In states where data collection for birth defects surveillance is ongoing and there is no mandatory reporting law, it would be helpful to approach the data source with a request to have the public health authority listed in the privacy notice that is provided to patients. Note, however, that this does not circumvent the accounting provisions of the Rule for the covered entity.

Mandatory reporting – 'Required by law' versus 'permitted'. Extensive discussion has ensued within the public and private health care sectors regarding the need for mandatory reporting laws in states in order for birth defect surveillance programs to collect data. Note that this section of the Rule, §164.512, has two subsections.

- (a) Standard: uses and disclosures required by law.
- (b) Standard: uses and disclosures for public health activities.

Subsection (a) is the provision for disclosures that are required by law. If a state has a mandatory birth defects reporting law, then this is the provision in the Privacy Rule that allows that law to remain intact. The definitions in the section below explain what 'required by law' means under the Privacy Rule. However, if a state health department meets the definition below of a public health authority, then the

health department may have authority to collect birth defects data based on the department's broad grant of authority from the state to protect and promote health, prevent and control disease, or other activity.

As noted earlier, each state health department has specific authority granted it under the laws of that state. Most health departments do have some regulatory authority and can, therefore, make birth defects reporting mandatory under that authority. If the health department does not have the present authority to make such a regulation, or conduct such activity, then the health department may request that this authority be granted by the legislature, after which the department may promulgate its regulation. This method is acceptable under the Privacy Rule.

The most significant distinction to make is that subsection (a) is for reporting **required by law**, whereas subsection (b) is for reporting **authorized by law**. Although there is no definition of 'authorized by law' in the Rule, DHHS has sought to make this point more clearly in the Preamble to the Rule (64 FR, page 59929):

“When we describe an activity as ‘authorized by law,’ we mean that a legal basis exists for the activity. The phrase ‘authorized by law’ is a term of art that includes both actions that are permitted and actions that are required by law.”

In addition to this comment, new Office of Civil Rights (OCR) guidelines state:

“The HIPAA Privacy Rule permits disclosures that are required by law. Furthermore, disclosures to public health authorities that are authorized by law to collect or receive information for public health purposes are also permissible under the Privacy Rule.”(OCR HIPAA Privacy Dec 3, 2002, <http://www.hhs.gov/ocr/hipaa>)

In short, public health authorities have two different paths by which to access data for surveillance, a mandatory reporting law, or the regulatory or program authority to collect the data. (See Appendix 2.4 for OCR HIPAA privacy regulation text.)

Data Sharing and Public Health Authorities

A public health authority that has either a mandatory reporting law, or a regulation, or some other grant of authority to collect data under the previously discussed §164.512, may use those data in any way that is permitted under state and federal law. Data that are collected by a third party, such as a university, under a grant or a contract on behalf of a public health authority, such as the Centers for Disease Control and Prevention (CDC), whether a bona fide agent or not of that health department, falls under the Privacy Rule definition of a 'public health authority':

“‘Public health authority’ means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.”(45 CFR §164.512(b)(1)(i))

The Rule does not comment on what the public health authority may or may not do with the data it has legally collected. HIPAA seeks to regulate the release and use of protected health information by covered entities, and a public health authority is not a covered entity under the Rule (unless they have designated themselves as such). The grantee, holder of a cooperative agreement, or contractor conducting a public health activity, as a public health authority, as defined above, may share the data in ways that comport with all previously promulgated laws and regulations. Once data are in the possession of a public health

authority, the Rule should not be an issue for the PHA because the Rule does not regulate the use or disclosure of protected health information by a PHA.

A number of health departments have designated some of their components as covered components because they provide health care as defined in the Rule. In this case, the entire health department may be called a ‘hybrid entity’. The consequences for data sharing are the same as if the designated component, or covered entity, were any other health care provider. The covered entity component of the health department can share the data it collects from individuals with the non-covered PHA component of the health department. The covered entity would have to provide the individual with the ‘notice of privacy practices’, which would include information to the effect that the covered entity was sharing data with other components of the health department. The covered component would also have to comply with all other provisions of the Rule, including accounting for disclosures to public health authorities. Some health departments may even provide consents to the individual based on the requirements of a state or local requirement, or to increase public confidence in the health department.

Nor is the data-sharing that flows from a public health authority to a covered entity after data collection regulated by the Privacy Rule. In cases where the public health authority wishes to refer a case to another covered entity, such as a health care provider, for a public health intervention, and the covered entity may report back its findings, remember that the definition of ‘public health activities’ includes the following:

“A public health authority that is 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.”(45 CFR §164512(b)(1)(i))

When requesting data from a covered entity, it is also important to note that even though public health authorities are exempted from the need for the authorization of the person for disclosure, the covered entity is only required to provide for the minimum necessary information to accomplish the public health mission of the PHA. In addition, the covered entity may, under the Rule, reasonably rely on the representation of the PHA for what constitutes the ‘minimum necessary’ information.

Some state grantees conducting birth defects and other kinds of surveillance funded by CDC have asked what kind of proof of identification (ID) they need to show to the covered entity to assure them that they are in fact a PHA and have the authority to obtain the data they seek from the CE. Business cards, government identification badges, letterhead, or other types of official representation are sufficient. Because there are so many different types of ID, DHHS chose to be very broad in this area by not specifying one type.

Data Clearinghouses and Business Associates

Some state health departments do not carry out actual surveillance and data collection; instead, hospitals voluntarily report birth defects data to a data collection entity or clearinghouse that compiles the data and then reports the information in some form to the health department. In these cases, the hospital and clearinghouse are required to execute a data use agreement, and the covered entity must disclose this information in the privacy notice provided to patients. The clearinghouse may provide the data to the public health authority under that Rule just as the covered entity could do, without the authorization or consent of the person for purposes of public health activities, surveillance, and, under some circumstances, research.

Surveillance versus research under the Privacy Rule. Research is covered under a separate section of the Privacy Rule. Unlike the public health authority provisions discussed above, the research provisions do not exempt public health authorities from compliance with the Rule as research is not a public health activity as defined in the Privacy Rule. The Rule defines *research* as:

“A systematic investigation, including research development, testing, evaluation, designed to develop or contribute to generalizable knowledge.” (45CFR 164.501)

The recent revision in the Privacy Rule sought to bring the definition of ‘research’ in the Rule in line with the definition for the same term in the Common Rule. The Common Rule definition of ‘research’ is the one used by CDC (45 CFR 46.102[e]).

De-identified data use. For research purposes, a covered entity may always use or disclose health information that has been de-identified (45 CFR 164.502(d) and 164.514[a]-[c]). The Rule has a very strict definition of ‘de-identified’ that truly eliminates all possibility of re-identification of the individual. However, a covered entity may enter into a data use agreement with a researcher that would allow the CE to disclose to the researcher a limited data set for the purposes of research, public health, or health care operations (45 CFR 164.514[e]). A *limited data set* is specifically defined in the Privacy Rule to exclude certain direct identifiers; however, the limited data set contains sufficient geographical and vital information – such as birth, death, admit and discharge data – that it can be very useful for birth defects research. In addition, there are other specific requirements that must be included in the data use agreement. These include:

- Stating the permitted uses and disclosures of the limited data set
- Limiting who can receive the data
- Requiring the researcher to agree to:
 - Abide by and not violate a data use agreement
 - Protect the data from re-disclosure
 - Report any unauthorized use or disclosure
- Binding all contractors or agents to the data use agreement
- Refraining from identifying or contacting the individual

Another way to obtain access to protected health information for research without authorization from the individual is to obtain documented Institutional Review Board (IRB) or Privacy Board approval for an exemption (45 CFR 164.512[i][1][i]). This provision is most practical for conducting records searches when use of de-identified data is not useful. There are extensive requirements under this section of the Rule that must be adhered to. Another way to obtain access to data for research without authorization of the individual is when preparing a research protocol preparatory to research (45 CFR 164.512 [i][1][ii]). Except for these limited exceptions, the disclosure or use of protected health information for research purposes requires the written authorization of the individual.

2.4.2 Family Educational Rights and Privacy Act (FERPA)

The Family Educational Rights and Privacy Act (20 U.S.C. § 1232g; 34 CFR Part 99) is a federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the US Department of Education. There are some privately funded schools to which FERPA does not apply.

FERPA gives parents specific rights with respect to their children's educational records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level. Students to whom the rights have transferred are defined as *eligible students* in FERPA.

- Parents or eligible students have the right to inspect and review the student's education records maintained by the school.
- Parents or eligible students have the right to request that a school correct records that they believe to be inaccurate or misleading.
- Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record.

However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31):

- School officials with legitimate educational interest
- Other schools to which a student is transferring
- Specified officials for audit or evaluation purposes
- Appropriate parties in connection with financial aid to a student
- Organizations conducting certain studies for or on behalf of the school
- Accrediting organizations
- Appropriate officials in cases of health and safety emergencies
- State and local authorities, within a juvenile justice system, pursuant to specific state law
- To comply with a judicial order or lawfully issued subpoena

Access to educational records can be necessary to a birth defects surveillance program for follow-up and early intervention services. FERPA generally prohibits access to educational records without the prior written consent of the parent or guardian.

Surveillance versus research under FERPA. For compliance with FERPA, there is no distinction made between surveillance and research. The issue in FERPA is who holds the data and who wants access to the data and why. The fact that the information in the educational record is medical, behavioral, sociological, or psychological in nature in no way alters the inability to access the information without parental consent. All information, other than student directory information, in an educational record maintained by a school, regardless of the nature of the information, is considered to be an educational record. It is important to note that HIPAA specifically states that nothing in HIPAA in any way alters FERPA. As a result, FERPA, unlike HIPAA, defines its 'protected records' simply by who possesses them, whereas in HIPAA the analysis of what is protected and the exceptions are more complex.

2.4.3 Privacy Act

The Privacy Act of 1974, 5 U.S.C. § 552a (2000), which has been in effect since September 27, 1975, can generally be characterized as an omnibus ‘code of fair information practices’ that attempts to regulate the collection, maintenance, use, and dissemination of personal information by federal executive branch agencies. However, the Act’s imprecise language, limited legislative history, and somewhat outdated regulatory guidelines have rendered it a difficult statute to decipher and apply. Moreover, even after more than 25 years of administrative and judicial analysis, numerous Privacy Act issues remain unresolved or unexplored. Adding to difficulties in interpretation is the fact that many Privacy Act cases are unpublished district court decisions. The general rule contained in the Privacy Act is:

“No agency shall disclose any record which is contained in a system of records by any means of communication to any person, or to another agency, except pursuant to a written request by, or with the prior written consent of, the individual to whom the record pertains [subject to 12 exceptions].” (5 U.S.C. § 552a[b])

States have adopted similar laws that should be considered when drafting legislation for a birth defects surveillance program. For further information, see the Department of Justice website at <http://www.doj.gov>.

2.4.4 Public Health Service Act

The Public Health Service Act of July 1, 1944 (42 U.S.C. §201), consolidated and substantially revised all existing legislation relating to the US Public Health Service, of which the CDC is a part. The Public Health Service Act is a broad compilation of authorities under which CDC administers national and international programs for the prevention and control of communicable and vector-borne diseases and other preventable conditions. The Public Health Service Act is only applicable to federal agencies within the Public Health Service.

Title III of the Public Health Service Act sets forth the general powers and duties of the Public Health Service. Within this title, Sections 301, 307, 311, and 317 provide CDC and other agencies within the Service with general operating authorities, including but not limited to:

- Encourage, cooperate with and render assistance to other appropriate public health authorities, scientific institutions, and scientists in the conduct and promotion of activities relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases.
- Make grants-in-aid to universities, hospitals, laboratories, and other public and private research institutions.
- Participate with other countries in cooperative endeavors in biomedical research, health care technology, and health services research for the purpose of advancing the status of health sciences in the United States.
- Cooperate with and assist states and their political subdivisions in the prevention and suppression of communicable diseases and other public health matters.

In regard to provisions of the Public Health Service Act which promote, encourage, and influence activities in the area of birth defects study and prevention, Section 317C was added to the Public Health Service Act by the Children’s Health Act of 2000. Section 317C provides the general operating authority for the National Center on Birth Defects and Developmental Disabilities (NCBDDD), a center within the

CDC. This authority was recently renewed in accordance with the Birth Defects and Developmental Disabilities Prevention Act of 2003. In part, Section 317C allows NCBDDD to:

- Collect, analyze, and make available data on birth defects and developmental disabilities.
- Operate regional centers for the conduct of applied epidemiological research on the prevention of such defects and disabilities.
- Provide information and education to the public on the prevention of such defects and disabilities.

The Public Health Service Act is codified in Title 42 of the United States Code.

2.4.5 Freedom of Information Act 5 USC §522 (FOIA)

All federal agencies are generally required under the Freedom of Information Act (FOIA) to disclose records they maintain when requested in writing by any person. Most states have adopted state laws that mirror the federal law. Therefore, it is important for a state birth defects surveillance program to be aware of the state law and know which records they may have to provide to the public when requested. However, federal agencies may withhold information pursuant to nine exemptions and three exclusions contained in the statute, and states have generally adopted similar exemptions. The exemptions that are most pertinent here are the FOIA exemptions 3 and 6.

Exemption Number 3:

Specifically exempted from mandatory disclosure by statute (other than the Privacy Act), provided that such statute:

(i) Requires that the matters be withheld from the public in such a manner as not to leave any discretion on the issue, or

(ii) Establishes particular criteria for withholding or refers to particular criteria for withholding or refers to particular types of matters to be withheld.

This exemption is useful for protecting birth records in surveillance programs when the authorizing legislation specifically exempts the information in the statute.

Exemption Number 6:

Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The FOIA applies only to federal agencies and does not create a right of access to records held by Congress, the courts, or by state or local government agencies. Each state has its own public access laws that should be consulted for access to state and local records. Each federal agency is responsible for meeting its FOIA responsibilities for its own records. Likewise, each federal agency component is responsible for processing FOIA requests for the records that it maintains. For more information and a list of FOIA federal contacts, see the Department of Justice website at <http://www.doj.gov>.

2.4.6 Advocacy

In this section we discuss advocacy for the development and implementation of surveillance systems in terms of both the state's role and CDC's role in such advocacy.

The role of the state in advocacy. State health officials and surveillance staff can be important partners for advocates in the development and implementation of surveillance systems. While state employees may be limited in terms of what activities they can participate in within advocacy, they can work together with advocates throughout the process in order to create or improve birth defects systems. State officials and health department surveillance staff bring planning, technical assistance, and an understanding of the political environment to the planning and implementation process.

The role of the CDC in advocacy. The CDC can also work with states and with advocates to provide technical assistance in the design, planning, and implementation stages of a birth defects surveillance system and can make recommendations for improving ongoing programs. CDC can also play a substantial role in educating policymakers and the public about the benefits of a birth defects surveillance program.

2.5 References

Lynberg MC, Edmonds LD. Surveillance of birth defects. In: Halperin W, Baker EL Jr, eds. *Public Health Surveillance*. New York, NY: Van Nostrand Reinhold; 1992:157-177.

US Government Printing Office. *Code of Federal Regulations, 2003-2004*. <http://www.gpoaccess.gov/cfr/index.html>. Accessed December 10, 2003.

US Government Printing Office, National Archives and Records Administration. *Federal Register, January 5, 2004*. <http://www.gpoaccess.gov/fr/index.html>.