Appendix 1A: Examples of Authorizing Language for Birth Defects Surveillance

In this appendix, we examine features and themes from the ***authorizing language*** in prior or existing state legislation to assist those interested in drafting or revising authorizing language concerning birth defects surveillance.

Legislation refers to a law enacted by an elected body. ***Regulations*** are created by agencies to guide how legislation is implemented. ***Public health authorities*** may make regulations that are mandatory, voluntary, directive, or prohibitive. Of note, in some states the authorizing language conveys general authority for public health surveillance, which encompasses birth defects surveillance activities without being specific to them. To establish a regulation mandating the reporting of birth defects, an agency (e.g., a state public health department) must have the power or authority to establish that type of regulation. This power can be based on state law, or on an act of the state governor's executive power. If the health department does not already have such regulatory power, two options exist:

(1) Propose a state law mandating birth defects reporting.
A state reporting law is straightforward and more democratic, because it is enacted by elected representatives and gives an agency clear authority to do what the law dictates. However, a state reporting law also places the power to modify or change the law in the hands of the legislative body, who may not have expertise in public health matters.

(2) Propose a state law granting authority to the health department to establish a regulation that would mandate birth defects reporting.
Since 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.

Authorizing language is legally binding and potentially difficult to change. However, program operations are also guided by agency and program policies. Policies can be adapted more readily in order to help birth defects surveillance programs align more closely with the NBDPN guidelines while still operating within the boundaries of their authorizing language.

Key Elements of Authorizing Language

Well-written authorizing language that facilitates birth defects surveillance should address these key elements, which are further illustrated with examples in the tables below:

- Designation of agency authority (**Table 1**)
- Purpose and priorities of the birth defects surveillance program activities (**Table 2**)
- Authority for access to data and records (**Table 3**)
- Data sharing and patient confidentiality (**Table 4**)

- Terminology and definitions (**Table 5**)
- Opt-out clauses and other limits (**Table 6**)
- Funding (**Table 7**)

Please note that the examples of authorizing language included below are real-world pieces of legislation. However, as each state's legislation may have been updated or changed over time, the language below may no longer be in effect.

Table 1. Designation of Agency Authority

Designation of Agency Authority	
Goals of the Authorizing Language	**Sample Authorizing Language**
• Specify the agency that has the overall grant of authority for the system. • Specify that the department has the authority to enact and enforce the regulations.	The State Department of Health shall establish and maintain a birth defects and severe neonatal jaundice registry which shall contain a confidential record of all birth defects that occur in [*state or region*], and any other information that the department deems necessary and appropriate in order to conduct thorough and complete epidemiologic surveys of birth defects that occur in this [*state or region*], and plan for and provide services to children with birth defects and their families.[1]
	The [*birth defects surveillance program name*] is established and is to be administered within the [*agency, organization, or location name*].[2]
	The [*birth defects surveillance program name*] is expressly authorized to contract for the production of any information, which the [*authority title and program name*] determines to be relevant to monitoring reproductive health.[2]
	The [*birth defects surveillance program name*] shall have the power to enter into agreements with other states and the Centers for Disease Control and Prevention consistent with the requirements and restrictions of this subchapter in order to obtain relevant information for the system concerning. [*state or region*] residents who receive health-related services outside the state.[2]
	It is the intent of the Legislature in enacting this section to affirm the authority of the [*state department, agency, or birth defects surveillance program name*] to contract with a qualified entity to operate the birth defects monitoring program statewide.[3]
	The Commissioner of Health may establish a system for the collection and verification of information concerning birth defects and other poor reproductive outcomes. The system shall be implemented statewide. The Commissioner may use the information collected and information available from other reporting systems and health providers to conduct studies to: 1. Investigate the causes of birth defects and poor reproductive outcomes; 2. Determine and evaluate measures designed to prevent their occurrences; 3. Where possible, ensure delivery of services for children identified with birth defects. The Department's investigation of poor reproductive outcomes shall include geographic, time-related or occupational associations, as well as investigations of past exposure to potentially harmful substances.[4]

Table 2. Purpose and Priorities of Birth Defects Surveillance Program Activities

Purpose and Priorities	
Goal of the Authorizing Language	**Sample Authorizing Language**
• Clearly articulate what the birth defects surveillance program should do, and what its priorities should be.	It is the intent of the Legislature in enacting this section to accomplish all of the following: (a) To maintain an ongoing program of birth defects monitoring statewide. (b) To provide information on the incidence, prevalence, and trends of birth defects, stillbirths, and miscarriages. (c) To provide information to determine whether environmental hazards are associated with birth defects, stillbirths, and miscarriages. (d) To provide information as to other possible causes of birth defects, stillbirths, and miscarriages. (e) To develop prevention strategies for reducing the incidence of birth defects, stillbirths, and miscarriages. (f) To conduct interview studies about the causes of birth defects. (g) To affirm the authority of the state department to contract with a qualified entity to operate the birth defects monitoring program statewide.[3]
	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. (4) Develop strategies to improve the access of children with birth defects to health and early intervention services.[5]
	The [*public health commissioner, agency, department, or birth defects surveillance program*] shall have the following powers and duties: (a) To conduct scientific investigations and surveys of the causes, mortality, methods of treatment, prevention and cure of birth defects and genetic and allied diseases. (b) To publish from time to time the results of such investigations and surveys for the benefit of the public health and from time to time collate such publications for distribution to scientific organizations and qualified scientists and physicians. (c) To carry on programs of professional education and training of medical students, physicians, nurses, scientists and technicians in the causes, methods of treatment, prevention and cure of birth defects and genetic and allied diseases. (d) To conduct and support counseling services.[6]

Table 3. Authority for Access to Data and Records

Access to Data and Records	
Goals of the Authorizing Language	**Sample Authorizing Language**
• Grant the birth defects surveillance program the authority to access medical records and hospital discharge data related to the program's scope of work. • Give the authority for the birth defects surveillance program to access additional data/records for follow-up as needed. • Require certain sources to report pertinent data to the birth defects surveillance program.	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.[3]
	The Commissioner of Health, in consultation with the Public Health Council, shall require confidential reporting to the Department of Health regarding all cases of suspected or confirmed birth defects.[7]
	Every health care facility and independent clinical laboratory shall allow access to or provide necessary information on children with birth defects.[7]
	Every physician, dentist, certified nurse midwife, or other health care professionals who treats, manages or who has any medical responsibility for, diagnoses or confirms birth defects shall report to the [*agency, department, or birth defects surveillance program*] each child diagnosed as having a birth defect not known to be previously reported.[7]
	The director of every clinical laboratory shall report to the [*agency, department, or birth defects surveillance program*] results of a postmortem examination from any child, indicating the existence of a birth defect, not known to be previously reported.[7]
	Every physician and hospital in attendance on an individual diagnosed within [*time frame for number of months or years since birth*] of birth as having one or more of the congenital anomalies listed in this section shall file a supplementary report with the State Commissioner of Health within 10 days of diagnosis thereof, using the forms prescribed by the Commissioner, to facilitate epidemiological investigation and surveillance.[6]
	The [*commissioner, agency, department, or birth defects surveillance program*], shall require the confidential reporting of all cases where a pregnancy results in a naturally aborted fetus or infant affected by a birth defect, and an electively aborted fetus that exhibits or is known to have a birth defect after [*number of weeks*] of gestation. The reporting requirements shall apply to all infants from birth through [*number of months or years*] of age.[7]

Table 4. Data Sharing and Patient Confidentiality

Data Sharing and Confidentiality	
Goals of the Authorizing Language	**Sample Authorizing Language**
• Specify who can have access to the data. • Identify how the confidentiality of the data will be protected.	All information collected and analyzed pursuant to this section shall be confidential insofar as the identity of the individual patient is concerned and shall be used solely for the purpose provided in this section. Access to such information shall be limited to the State Department of Health; provided, that the Commissioner may provide access to those scientists who are engaged in demographic, epidemiological or other similar studies related to health, and who agree, in writing as nonstate employees, to be identified and coded while maintaining confidentiality as described herein.[4]
	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. 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.[8]
	Such information, when received by the [*birth defects surveillance program*] or its authorized representatives shall be kept confidential and shall be used solely for the purposes of medical or scientific research, or the improvement of the quality of medical care through the conduction of medical audits. Such information shall not be admissible as evidence in any action of any kind in any court or before any other tribunal, board, agency, or person.[6]
	Such reports and information shall be kept confidential and shall not be admissible as evidence in an action or proceeding in any court or before any other tribunal, board, agency or person. The [*public health agency, department, or birth defects surveillance program*] may, however, publish analyses of such reports and information from time to time for scientific and public health purposes, in such a manner as to assure that the identities of the individuals concerned cannot be ascertained.[6]
	Nothing in this section shall prohibit the publishing of statistical compilations relating to birth defects or poor reproductive outcomes which do not in any way identify individual cases or individual sources of information.[4]

Table 5. Terminology and Definitions

Terminology and Definitions	
Goal of the Authorizing Language	**Sample Authorizing Language**
• Define terminology clearly, but not in an overly restrictive manner. ***Note:*** *Revising or amending narrowly written authorizing language can be a lengthy and difficult process. Legislating surveillance of specific defects may prove to be problematic in the long run as conditions change, medical coding designations evolve, 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.*	*Examples of a broad-but-clear definition:* "**Birth defect**" as used in this chapter means any medical problem of organ structure, function, or chemistry of possible genetic or prenatal origin.[3] In this chapter, "**birth defect**" means a physical or mental functional deficit or impairment in a human embryo, fetus, or newborn resulting from one or more genetic or environmental causes.[8] *Example of a narrower definition, which may result in birth defects surveillance program activities being limited to defects diagnosed at or shortly after birth, while potentially excluding prenatal diagnoses and miscarriages, and birth defects that were not manifest at the time of birth but which became apparent later in life:* As used in this act, "**birth defect**" means any physical or chemical abnormality present at birth.[4] *Example of a definition which addresses some but not all of the above concerns about narrow limitations:* When used in this document, "**birth defect**" means an abnormality of the body's structure or inherent function which is present at birth, whether such abnormality is manifest at the time of delivery or becomes apparent later in life.[7]
	The following term shall have the following meaning when used in this document: "**Infant**" means a child from birth to one year of age.[1]
	As used in this subchapter, unless the context otherwise requires: "**Board**" means the technical advisory board established in this legislation; "**System**" means the [*birth defects surveillance program*] system.[2]
	"**Health facilities**" as used in this section means general acute care hospitals, and physician-owned or operated clinics, that regularly provide services for the diagnosis or treatment of birth defects, genetic counseling, or prenatal diagnostic services.[3]
	In this chapter, "**health professional**" means an individual whose (A) vocation or profession is directly or indirectly related to the maintenance of health in another individuals; and (B) duties require a specified amount of formal education and may require a special examination, certificate, or license or membership in a regional or national association.[8]
	Example of a clear definition, which may become a limitation as the diagnostic coding system(s) used by the health care providers and/or birth defects surveillance program change over time: As used in this act, "**ICD-9-CM diagnostic code categories**" means the International Classification of Disease which assigns numbers to each of the congenital anomalies.[4]

Table 6. Opt-Out Clauses and Other Limits

Opt-Out Clauses and Other Limits	
Goals of the Authorizing Language	**Sample Authorizing Language**
• Some states require written consent from parents for a birth defects surveillance program to collect data from schools or health care providers on children with birth defects. Since obtaining written consent from parents can be problematic, some states handle this issue with an opt-out clause, which assumes consent unless otherwise stated, allowing the birth defects 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. • Specify limits on what individuals must submit to, and what data sources may/may not be held liable for when they release information.	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, certified nurse-midwives, clinical nurse specialists, and certified nurse practitioners. The method of distribution must include making the form available on the internet.[9]
	Nothing in this act shall be construed to compel any individual to submit to a medical examination or to Department of Health supervision.[1]
	A person shall provide medical, demographic, epidemiological, toxicological, and environmental information to the department under this chapter. A person is not liable in damages or other relief for providing medical or other confidential information to the department during an epidemiological or toxicological investigation.[8]

Table 7. Funding

Funding	
Goal of the Authorizing Language	**Sample Authorizing Language**
• Recognizing that cost can be an impediment to establishing a birth defects surveillance program, some states have authorizing language mandating special funds to cover the operating expenses of their birth defects surveillance program. Sources of special funds sometimes include fees for marriage licenses, birth certificates, and newborn screening.	It is the intent of the general assembly that the funds generated from the birth registration fees be appropriated and used as follows: (1) Beginning [*month, day, year*] and ending [*month, day, year*], five dollars of each fee for the birth defects institute central registry; then (2) Beginning [*month, day, year*] ten dollars of each fee for the birth defects institute central registry.[10]
	The [*birth defects surveillance program*] shall have the power to receive and expend grants, donations, and funds from public and private sources to carry out its responsibilities under this subchapter. The [*program site or affiliate organization*] is not required to implement this system unless sufficient funds are available as determined by the Medical Director of the [*program site or affiliate organization*]. The system may be implemented in stages or phases.[2]

References

1. NJ Rev Stat § 26:8-40.21 (2025)
2. Arkansas Code, § 20-16-201 through § 20-16-214. (2024).
3. California Health & Safety Code § 103825. (2025).
4. Oklahoma Public Health and Safety, 63 § 1-550.2. (2025).
5. Hawaii Revised Statutes, Chapter 321, § 321-422. (2025).
6. New York Public Health Law, § 2733 (2025).
7. New Jersey Rules, Chapter 20, Subchapter 1, 8:20-1.2. (2025).
8. Texas Health and Safety Code, Subchapter A-D § 87.001-87.065. (2024).
9. Ohio Revised Code, Title 37 Health-Safety-Morals, Chapter 3705 Vital Statistics, § 3705.35. (2025).
10. Iowa Code, Vital Statistics, § 144.13A. (2024).