



H.B. 534

123rd General Assembly
(As Introduced)

**Reps. Salerno, Calvert, Goodman, Krebs, Logan, R. Miller, Mottley,
Terwilleger, Van Vyven, Verich**

BILL SUMMARY

- Requires the Director of Health to establish a birth defects information system.
- Requires the Director to appoint a council to advise on the implementation of the system and to recommend a list of congenital anomalies and abnormal conditions of newborns to be reported to the system.
- Permits the Director to require each hospital classified as a general hospital and each freestanding birthing center to report to the system information concerning all patients under age five with a primary diagnosis of a congenital anomaly or abnormal condition.

CONTENT AND OPERATION

Birth defects information system

(secs. 3705.30(A) and (C) and 3705.31)

The bill requires the Director of Health to establish a statewide birth defects information system for the collection of information concerning congenital anomalies, stillbirths, and abnormal conditions of newborns. The bill specifies that the system may be used for all of the following purposes:

- (1) To identify and describe congenital anomalies, stillbirths, and abnormal conditions of newborns;
- (2) To detect trends and epidemics in congenital anomalies, stillbirths, and abnormal conditions of newborns;

(3) To quantify morbidity and mortality of congenital anomalies and abnormal conditions of newborns;

(4) To stimulate epidemiological research regarding congenital anomalies, stillbirths, and abnormal conditions of newborns;

(5) To identify risk factors for congenital anomalies, stillbirths, and abnormal conditions of newborns;

(6) To facilitate intervention in and prevention of congenital anomalies, stillbirths, and abnormal conditions of newborns;

(7) To facilitate access to treatment for congenital anomalies and abnormal conditions of newborns;

(8) To inform and educate the public about congenital anomalies, stillbirths, and abnormal conditions of newborns.

In addition, the bill authorizes the Director to review vital statistics records and requires the Director to consider expanding the list of congenital anomalies and abnormal conditions of newborns reported on birth certificates.

Council to advise on system implementation

(sec. 3705.34; Section 2)

The Director is required to appoint a council to advise on the implementation of the birth defects information system and to recommend to the Director a list of congenital anomalies and abnormal conditions of newborns to be reported to the system. The council must include, at a minimum, persons representing each of the following interests:

(1) Obstetrics and gynecology;

(2) Pediatrics;

(3) Genetics;

(4) Epidemiology;

(5) Biostatistics;

(6) Hospital administration;

(7) The Department of Mental Retardation and Developmental Disabilities;

- (8) The Department of Education;
- (9) The Department of Human Services;
- (10) Parents of children with congenital anomalies or abnormal conditions;
- (11) The public.

The council must convene for its first meeting no later than 30 days after the bill's effective date. In consultation with and the approval of the council, the Director must appoint, at the first meeting, the chairperson and vice-chairperson from among the council members. The chairperson has the authority to call additional meetings as the chairperson considers appropriate. The council has the authority to establish rules of procedure as necessary to facilitate the council's orderly conduct of business. Council members are to serve without compensation but are reimbursed for their actual and necessary expenses incurred in the performance of their duties.

In accordance with the provisions of current law requiring the sunseting of certain governmental bodies, the Revised Code section authorizing the council is repealed four years after the bill's effective date.

Reports to the system

(sec. 3705.30(B) and (D))

The bill authorizes the Director to require each hospital classified as a general hospital and each freestanding birthing center to report to the system information concerning all patients under age five with a primary diagnosis of a congenital anomaly or abnormal condition.¹ On request, each general hospital and birthing center must give the Director or appropriate employees of the Department of Health access to the medical records of such patients. The Department must pay the costs of copying any medical records requested. A hospital or birthing center that provides information to the system is not subject to criminal or civil liability for providing the information.

¹ A "general hospital" is a hospital that primarily functions to furnish the array of diagnostic and therapeutic services needed to provide care for a variety of medical conditions, including diagnostic x-ray, clinical laboratory, and operating room services (Ohio Administrative Code 3701-59-01). "Freestanding birthing center" means any facility in which deliveries routinely occur, regardless of whether the facility is located on the campus of another health care facility, and which is not licensed as a level one, two, or three maternity unit or a limited maternity unit (Revised Code section 3702.51, not in bill).

Confidentiality and access to information assembled by the system

(sec. 3705.32)

With some exceptions, information assembled by the birth defects information system is confidential. Access to assembled information is limited to the Director of Health, appropriate employees of the Department of Health, and qualified persons or government entities that are engaged in demographic, epidemiological, or similar studies related to health and health care provision. A person or government entity may be given access to the system only if the person or a representative of the person or government entity signs an agreement to maintain the system's confidentiality. A person who violates the agreement may be denied further access to confidential information.

The Director is required to maintain a record of all persons and government entities given access to the information in the system. The record is a public record and must include all of the following information:

- (1) The name of the person who authorized access to the system;
- (2) The name, title, and organizational affiliation of the person or entity given access to the system;
- (3) The date the person or entity was given access to the system;
- (4) The specific purpose for which the person or entity intends to use the information.

Disclosure of information contained in the system

(sec. 3705.32(B) and (D))

The Director may use information assembled in the system to notify parents, guardians, and custodians of children with congenital anomalies or abnormal conditions of medical care and other services available for the child and family. The Director may disclose information assembled by the system only with the written consent of the parent or legal guardian of the child who is the subject of the information, but may disclose information in summary, statistical, or other form that does not identify particular individuals or individual sources of information.

Removal of information from the system

(sec. 3705.33)

A child's parent or legal guardian may have information concerning the child removed from the birth defects information system under certain conditions. The parent or guardian must request from the child's physician the form prepared by the Director (see "Rulemaking authority," below). The physician must provide the form to the child's parent or legal guardian on request and discuss with the parent or guardian the information contained in the system. If the parent or guardian signs the form, the physician must forward it to the Director who, on receipt, must remove all information concerning the child from the system.

Rulemaking authority

(sec. 3705.35)

Within 90 days after the bill's effective date, the Director is required to adopt rules to do all of the following:

- (1) Implement the birth defects information system;
- (2) Specify the types of congenital anomalies and abnormal conditions of newborns to be reported to the system;
- (3) Establish reporting requirements for information concerning diagnosed congenital anomalies and abnormal conditions of newborns;
- (4) Establish standards that must be met by persons or government entities that seek access to the system;
- (5) 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 physicians.

The rules must be adopted in accordance with the provisions of the Administrative Procedure Act that require a public hearing.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced H0534-I.123/rss	01-04-00	p. 1483