

# AN ACT

To enact sections 3705.30, 3705.31, 3705.32, 3705.33, 3705.34, 3705.35, and 3705.36 of the Revised Code to require the Director of Health to establish a Birth Defects Information System and to repeal section 3705.34 four years after the effective date of this act in compliance with agency sunset provisions.

*Be it enacted by the General Assembly of the State of Ohio:*

SECTION 1. That sections 3705.30, 3705.31, 3705.32, 3705.33, 3705.34, 3705.35, and 3705.36 of the Revised Code be enacted to read as follows:

Sec. 3705.30. (A) As used in this section:

(1) "Freestanding birthing center" has the same meaning as in section 3702.51 of the Revised Code.

(2) "Hospital" means a hospital classified under section 3701.07 of the Revised Code as a general hospital or children's hospital.

(3) "Physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(B) The director of health shall establish and, if funds for this purpose are available, implement a statewide birth defects information system for the collection of information concerning congenital anomalies, stillbirths, and abnormal conditions of newborns.

(C) If the system is implemented under division (B) of this section, all of the following apply:

(1) The director may require each physician, hospital, and freestanding birthing center to report to the system information concerning all patients under five years of age with a primary diagnosis of a congenital anomaly or abnormal condition. The director shall not require a hospital, freestanding birthing center, or physician to report to the system any information that is reported to the director or department of health under another provision of the Revised Code or Administrative Code.

(2) On request, each physician, hospital, and freestanding birthing center shall give the director or authorized employees of the department of

health access to the medical records of any patient described in division (C)(1) of this section. The department shall pay the costs of copying any medical records pursuant to this division.

(3) The director may review vital statistics records and shall consider expanding the list of congenital anomalies and abnormal conditions of newborns reported on birth certificates pursuant to section 3705.08 of the Revised Code.

(D) A physician, hospital, or freestanding birthing center that provides information to the system under division (C) of this section shall not be subject to criminal or civil liability for providing the information.

Sec. 3705.31. If implemented under section 3705.30 of the Revised Code, the birth defects information system may be used for all of the following purposes:

(A) To identify and describe congenital anomalies, stillbirths, and abnormal conditions of newborns;

(B) To detect trends and epidemics in congenital anomalies, stillbirths, and abnormal conditions of newborns;

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

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

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

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

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

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

Sec. 3705.32. (A) Except as provided in this section, records received and information assembled by the birth defects information system pursuant to section 3705.30 of the Revised Code are confidential medical records.

(B)(1) The director of health may use information assembled by 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.

(2) The director may disclose information assembled by the system with the written consent of the parent or legal guardian of the child who is the subject of the information.

(C)(1) Access to information assembled by the system shall be limited

to the following persons and government entities:

- (a) The director of health;
- (b) Authorized employees of the department of health;
- (c) Qualified persons or government entities that are engaged in demographic, epidemiological, or similar studies related to health and health care provision.

(2) The director shall give a person or government entity described in division (C)(1)(c) of this section 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.

(3) The director shall maintain a record of all persons and government entities given access to the information in the system. The record shall include all of the following information:

- (a) The name of the person who authorized access to the system;
- (b) The name, title, and organizational affiliation of the person or government entity given access to the system;
- (c) The dates the person or government entity was given access to the system;
- (d) The specific purpose for which the person or government entity intends to use the information.

(4) The record maintained pursuant to division (C)(3) of this section is a public record, as defined in section 149.43 of the Revised Code.

(5) A person who violates an agreement described in division (C)(2) of this section may be denied further access to confidential information maintained by the director.

(D) The director may disclose information assembled by the system in summary, statistical, or other form that does not identify particular individuals or individual sources of information.

Sec. 3705.33. As used in this section, "local health department" means a health department operated by the board of health of a city or general health district or the authority having the duties of a board of health under section 3709.05 of the Revised Code.

A child's parent or legal guardian who wants information concerning the child removed from the birth defects information system shall request from the local health department or the child's physician a form prepared by the director of health. On request, a local health department or physician shall provide the form to the child's parent or legal guardian. The individual providing the form shall discuss with the child's parent or legal guardian the information contained in the system. If the child's parent or legal guardian signs the form, the department or physician shall forward it to the director.

On receipt of the signed form, the director shall remove from the system any information that identifies the child.

Sec. 3705.34. Not later than thirty days after the effective date of this section, the director of health shall appoint a council to advise on the establishment and implementation of the birth defects information system.

(A) The council shall 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 job and family services;
- (10) The commission on minority health;
- (11) Parents of children with congenital anomalies or abnormal conditions;
- (12) The march of dimes Ohio chapter;
- (13) The public.

(B)(1) Not later than thirty days after the initial appointments are made under division (A) of this section, the director shall convene the first meeting of the council. In consultation with and with the approval of the council, the director shall appoint, at the first meeting of the council, the chairperson and vice-chairperson of the council from among the members of the council. the chairperson may call additional meetings as the chairperson considers appropriate.

(2) The council may establish rules of procedure as necessary to facilitate the council's orderly conduct of business.

(3) Council members shall serve without compensation but, to the extent funds are available, shall be reimbursed for their actual and necessary expenses incurred in the performance of their duties.

(C) The council shall recommend to the director a list of congenital anomalies and abnormal conditions of newborns to be reported to the system.

Sec. 3705.35. Not later than one hundred eighty days after the effective date of this section, the director of health shall, in consultation with the council created under section 3705.34 of the Revised Code, adopt rules in accordance with Chapter 119. of the Revised Code to do all of the

following:

(A) Implement the birth defects information system;

(B) Specify the types of congenital anomalies and abnormal conditions of newborns to be reported to the system under section 3705.30 of the Revised Code;

(C) Establish reporting requirements for information concerning diagnosed congenital anomalies and abnormal conditions of newborns;

(D) Establish standards that must be met by persons or government entities that seek access to the system;

(E) 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, as defined in section 3705.33 of the Revised Code, and to physicians. The method of distribution must include making the form available on the internet.

Sec. 3705.36. Three years after the date a birth defects information system is implemented pursuant to section 3705.30 of the Revised Code, and annually thereafter, the department of health shall prepare a report regarding the birth defects information system. The council created under section 3705.34 of the Revised Code shall, not later than two years after the date a birth defects information system is implemented, specify the information the department is to include in each report. The department shall file the report with the governor, the president and minority leader of the senate, the speaker and minority leader of the house of representatives, the departments of mental retardation and developmental disabilities, education, and job and family services, the commission on minority health, and the news media.

SECTION 2. That section 3705.34 of the Revised Code is hereby repealed, effective four years after the effective date of this act.

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*Speaker* \_\_\_\_\_ *of the House of Representatives.*

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*President* \_\_\_\_\_ *of the Senate.*

Passed \_\_\_\_\_, 20\_\_\_\_

Approved \_\_\_\_\_, 20\_\_\_\_

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*Governor.*

Sub. H. B. No. 534

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The section numbering of law of a general and permanent nature is complete and in conformity with the Revised Code.

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*Director, Legislative Service Commission.*

Filed in the office of the Secretary of State at Columbus, Ohio, on the \_\_\_ day of \_\_\_\_\_, A. D. 20\_\_\_\_.

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*Secretary of State.*

File No. \_\_\_\_\_ Effective Date \_\_\_\_\_