

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1625 Session of 1999

INTRODUCED BY SCHULER, PISTELLA, JAMES, GEORGE, TIGUE, STERN,
ORIE, COY, GODSHALL, NAILOR, SEYFERT, WOJNAROSKI,
E. Z. TAYLOR, HESS, S. MILLER, KENNEY, FRANKEL, ARMSTRONG,
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SATHER, SAYLOR, SHANER, WILT, ZIMMERMAN, DALEY, CALTAGIRONE,
YOUNGBLOOD, SANTONI, THOMAS, STEELMAN, BAKER, MUNDY,
YUDICHAK, GRUCELA AND RUBLEY, JUNE 9, 1999

AS AMENDED ON THIRD CONSIDERATION, HOUSE OF REPRESENTATIVES,
FEBRUARY 9, 2000

AN ACT

1 Providing for surveillance, research and services relating to
2 the prevention of birth defects, for powers and duties of the
3 Department of Health, for a Statewide registry, for reporting
4 requirements and for confidentiality of information; and
5 imposing penalties.

6 The General Assembly finds and declares as follows:

7 (1) Birth defects represent a significant public health
8 concern and too little is known about the causes and
9 occurrences of these problems.

10 (2) These conditions lead to severe mental anguish on
11 the part of parents and relatives and frequently lead to high
12 medical care costs.

13 (3) A system to obtain more information about these
14 conditions could result in the identification of causal
15 problems and lead to development of preventive measures to
16 decrease incidence in the future.

1 (4) Birth defects can be caused by adverse health
2 conditions during pregnancy or genetic mutations. Prevention
3 efforts are slowed by lack of information about the number
4 and causes of birth defects.

5 (5) Each year in this Commonwealth, 3 to 4% of the
6 140,000 live births have at least one birth defect. Many
7 birth defects are preventable.

8 (6) One in five infant deaths is due to birth defects,
9 making them the leading cause of infant mortality.

10 (7) Birth defects of the heart and circulatory system
11 are the most common, affecting roughly one in 115 newborns.

12 (8) Severe birth defects may require special lifelong
13 medical treatment. Because many conditions cannot be fully
14 corrected, birth defects are major cause of childhood and
15 adult disability.

16 (9) The average lifetime medical care costs for a child
17 with a major birth defect is \$60,000 to \$300,000.

18 (10) Therefore, it is the intent of the General Assembly
19 to establish and maintain a Birth Defects Surveillance and
20 Registry Program in the Commonwealth to accomplish the
21 following:

22 (i) To maintain an ongoing systematic collection,
23 analysis and interpretation of health data essential to
24 the planning, implementation and evaluation of public
25 health practice.

26 (ii) To provide information on the incidence,
27 prevalence and trends of birth defects, stillbirths and
28 miscarriages.

29 (iii) To provide information to determine whether
30 environmental hazards are associated with birth defects,

1 stillbirths and miscarriages.

2 (iv) To develop prevention education and advocacy
3 strategies for reducing the incidence of birth defects
4 and to guide and assess the progress of these prevention
5 strategies.

6 (v) To provide a case registry for analytic research
7 to identify risk factors.

8 The General Assembly of the Commonwealth of Pennsylvania
9 hereby enacts as follows:

10 Section 1. Short title.

11 This act shall be known and may be cited as the Birth Defects
12 Surveillance Act.

13 Section 2. Definitions.

14 The following words and phrases when used in this act shall
15 have the meanings given to them in this section unless the
16 context clearly indicates otherwise:

17 "Birth defect." An anomaly, functional or structural, that
18 presents in infancy or later in life and that is caused by
19 events preceding birth, whether inherited or acquired.

20 "Department." The Department of Health of the Commonwealth.

21 "Secretary." The Secretary of Health of the Commonwealth.

22 Section 3. Birth defects surveillance system and registry.

23 (a) General rule.--The secretary shall establish and
24 maintain a permanent system for the collection of information
25 necessary to accomplish the purposes of this act.

26 (b) Components of system.--The system shall operate
27 Statewide and shall include the following:

28 (1) Forms.

29 (2) Registry.

30 (3) Systematic review of medical records.

1 (4) Analysis.

2 (5) Monitoring and investigation of clusters.

3 (6) Reports.

4 (7) Evaluation of additional services.

5 (c) Reporting required.--The secretary shall require all
6 licensed health care facilities and health care providers to
7 report within 30 days of initial diagnosis all occurrences of
8 children suspected or diagnosed as having birth defects.

9 (d) Sources of reporting.--The information to be reported
10 shall be obtained from the following sources: vital records,
11 hospital records, existing data sources, special data sources
12 and clinical examinations.

13 ~~(e) Maternal and Child Health Advisory Council.~~ The (E) <—

14 MATERNAL AND CHILD HEALTH ADVISORY COUNCIL.--

15 (1) THE department shall utilize the services of the
16 Maternal and Child Health Advisory Council, which is hereby
17 established within the department, to advise on the
18 implementation of the birth defects surveillance system and
19 registry. ~~The Governor shall make~~ <—

20 (2) THE GOVERNOR SHALL MAKE appointments to the council <—

21 ~~and~~ FROM A LIST OF 20 CANDIDATES, FIVE OF WHOM SHALL BE <—

22 RECOMMENDED BY THE PRESIDENT PRO TEMPORE OF THE SENATE, FIVE

23 OF WHOM SHALL BE RECOMMENDED BY THE MINORITY LEADER OF THE

24 SENATE, FIVE OF WHOM SHALL BE RECOMMENDED BY THE SPEAKER OF

25 THE HOUSE OF REPRESENTATIVES, AND FIVE OF WHOM SHALL BE

26 RECOMMENDED BY THE MINORITY LEADER OF THE HOUSE OF

27 REPRESENTATIVES. THE PERSONS SUBMITTING THE RECOMMENDATIONS

28 shall assure the inclusion of professionals from the

29 disciplines of maternal and child health, INCLUDING AT LEAST <—

30 ONE PEDIATRIC PHYSICIAN, public health, epidemiology,

1 hospital administration and biostatistics.

2 Section 4. Reporting requirements.

3 (a) Births.--Any infant who is born to a resident of this
4 Commonwealth or who is born within the bounds of this
5 Commonwealth and who shows evidence of a birth defect either at
6 birth or at any time during the first year of life shall be
7 reported to the department.

8 (b) Stillbirths.--Any stillbirth occurring within the bounds
9 of this Commonwealth shall be reported to the department.

10 (c) Post mortem examinations.--The director of each clinical
11 laboratory shall report to the department the results of any
12 post mortem examination from an infant indicating the existence
13 of a birth defect not known to have been previously reported.

14 (D) EXCEPTION.--THIS SECTION SHALL NOT APPLY IF THE PARENTS <—
15 OR GUARDIAN OF THE INFANT OBJECT TO THE REPORTING ON RELIGIOUS
16 GROUNDS.

17 Section 5. Confidentiality of information.

18 All information collected and analyzed under this act shall
19 be confidential insofar as the identity of the patient is
20 concerned and shall be used solely for the purpose provided for
21 in this act. All Federal and State laws relating to the privacy
22 of information shall apply to the data and information that is
23 collected under this system.

24 Section 6. Access to information.

25 Access to the information collected and analyzed under this
26 act shall be limited to authorized program staff and to persons
27 with a valid scientific interest upon approval of the secretary.
28 Such persons must be engaged in demographic, epidemiological or
29 other similar studies related to health and must agree in
30 writing to maintain confidentiality.

1 Section 7. Record of access.

2 The department shall maintain an accurate record of all
3 persons who are given access to the information in the system.
4 The record shall include: the name of the person authorizing
5 access; name, title, and organizational affiliation of persons
6 given access; dates of access; and the specific purpose for
7 which information is to be used.

8 Section 8. Research.

9 All research proposed to be conducted by persons other than
10 department staff using the information in the system shall be
11 reviewed and approved by the secretary in accordance with the
12 established national guidelines for the protection of human
13 subjects.

14 Section 9. Violation of confidentiality.

15 Any person who violates the confidentiality of information
16 under this act, discloses any information provided pursuant to
17 this act or who uses information provided under this act in a
18 manner other than as approved by the secretary shall:

19 (1) Be denied further access to any confidential
20 information maintained by the department.

21 (2) Be subject to a civil penalty of \$5,000.

22 The penalty provided in this section shall not be construed as
23 restricting any remedy provided by law for the benefit of the
24 department or any individual.

25 Section 10. Grants and contracts.

26 In the administration of section 3, the secretary may make
27 grants to and enter into contracts with public and nonprofit
28 private entities.

29 SECTION 11. ANNUAL REPORT.

30 THE DEPARTMENT SHALL SUBMIT TO THE GOVERNOR AND THE GENERAL

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1 ASSEMBLY AN ANNUAL REPORT RELATING TO THE REGISTRY UNDER SECTION

2 3. THE REPORT SHALL INCLUDE THE FOLLOWING:

3 (1) THE DEPARTMENT'S FINDINGS AND RECOMMENDATIONS ON THE
4 ADMINISTRATION AND OPERATION OF THE REGISTRY.

5 (2) DATA RELEVANT TO THE INCIDENCE OF BIRTH DEFECTS IN
6 THIS COMMONWEALTH IN SUMMARY FORM, REPORTED IN ACCORDANCE
7 WITH THE CONFIDENTIALITY REQUIREMENTS UNDER SECTION 5.

8 Section ~~11~~ 12. Effective date.

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9 This act shall take effect July 1, 2000, or immediately,
10 whichever is later.