
THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1625 Session of
1999

INTRODUCED BY SCHULER, PISTELLA, JAMES, GEORGE, TIGUE, STERN,
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CURRY, DeWEESE, COSTA, STURLA, SNYDER, TRELLO, HARHAI,
SATHER, SAYLOR, SHANER, WILT AND ZIMMERMAN, JUNE 9, 1999

REFERRED TO COMMITTEE ON AGING AND YOUTH, JUNE 9, 1999

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; imposing
5 penalties; and making an appropriation.

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.

17 (4) Birth defects can be caused by adverse health
18 conditions during pregnancy or genetic mutations. Prevention

1 efforts are slowed by lack of information about the number
2 and causes of birth defects.

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

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

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

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

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

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

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

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

27 (iii) To provide information to determine whether
28 environmental hazards are associated with birth defects,
29 stillbirths and miscarriages.

30 (iv) To develop prevention education and advocacy

1 strategies for reducing the incidence of birth defects
2 and to guide and assess the progress of these prevention
3 strategies.

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

6 The General Assembly of the Commonwealth of Pennsylvania
7 hereby enacts as follows:

8 Section 1. Short title.

9 This act shall be known and may be cited as the Birth Defects
10 Surveillance Act.

11 Section 2. Definitions.

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

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

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

17 Section 3. Birth defects surveillance system and registry.

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

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

23 (1) Forms.

24 (2) Registry.

25 (3) Systematic review of medical records.

26 (4) Analysis.

27 (5) Monitoring and investigation of clusters.

28 (6) Reports.

29 (7) Evaluation of additional services.

30 (c) Reporting required.--The secretary shall require all

1 licensed health care facilities and health care providers to
2 report within 30 days of initial diagnosis all occurrences of
3 children suspected or diagnosed as having birth defects.

4 (d) Sources of reporting.--The information to be reported
5 shall be obtained from the following sources: vital records,
6 hospital records, existing data sources, special data sources
7 and clinical examinations.

8 (e) Maternal and Child Health Advisory Council.--The
9 department shall utilize the services of the Maternal and Child
10 Health Advisory Council, which is hereby established within the
11 department, to advise on the implementation of the birth defects
12 surveillance system and registry. The Governor shall make
13 appointments to the council and shall assure the inclusion of
14 professionals from the disciplines of maternal and child health,
15 public health, epidemiology, hospital administration and
16 biostatistics.

17 Section 4. Reporting requirements.

18 (a) Births.--Any infant who is born to a resident of this
19 Commonwealth or who is born within the bounds of this
20 Commonwealth and who shows evidence of a birth defect either at
21 birth or at any time during the first year of life shall be
22 reported to the department.

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

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

29 Section 5. Confidentiality of information.

30 All information collected and analyzed under this act shall

1 be confidential insofar as the identity of the patient is
2 concerned and shall be used solely for the purpose provided for
3 in this act. All Federal and State laws relating to the privacy
4 of information shall apply to the data and information that is
5 collected under this system.

6 Section 6. Access to information.

7 Access to the information collected and analyzed under this
8 act shall be limited to authorized program staff and to persons
9 with a valid scientific interest upon approval of the secretary.
10 Such persons must be engaged in demographic, epidemiological or
11 other similar studies related to health and must agree in
12 writing to maintain confidentiality.

13 Section 7. Record of access.

14 The department shall maintain an accurate record of all
15 persons who are given access to the information in the system.
16 The record shall include: the name of the person authorizing
17 access; name, title, and organizational affiliation of persons
18 given access; dates of access; and the specific purpose for
19 which information is to be used.

20 Section 8. Research.

21 All research proposed to be conducted by persons other than
22 department staff using the information in the system shall be
23 reviewed and approved by the secretary in accordance with the
24 established national guidelines for the protection of human
25 subjects.

26 Section 9. Violation of confidentiality.

27 Any person who violates the confidentiality of information
28 under this act, discloses any information provided pursuant to
29 this act or who uses information provided under this act in a
30 manner other than as approved by the secretary shall:

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

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

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

7 Section 10. Grants and contracts.

8 In the administration of section 3, the secretary may make
9 grants to and enter into contracts with public and nonprofit
10 private entities.

11 Section 11. Appropriation.

12 The sum of \$2,000,000, is hereby appropriated from the
13 Tobacco Litigation Settlement entered into between the
14 Commonwealth and tobacco industry to the Department of Health to
15 carry out the provisions of this act.

16 Section 12. Effective date.

17 This act shall take effect in 60 days.