

## 1999 ASSEMBLY BILL 579

November 5, 1999 – Introduced by Representatives LADWIG, RHOADES, BOYLE, COGGS, FREESE, GUNDERSON, HASENOHRL, KELSO, KLUSMAN, J. LEHMAN, M. LEHMAN, LEIBHAM, MUSSER, POCAN, RILEY, RYBA, SERATTI, SPILLNER, STASKUNAS, STEINBRINK, STONE, SYKORA, TURNER, UNDERHEIM, VRAKAS, WASSERMAN and YOUNG, cosponsored by Senators PLACHE, DARLING, BAUMGART, BRESKE, DRZEWIECKI, GROBSCHMIDT, MOORE and ROESSLER. Referred to Committee on Children and Families.

1     **AN ACT to amend** 146.82 (1) and 253.13 (2); **to repeal and recreate** 253.12; and  
2             **to create** 15.197 (12) of the statutes; **relating to:** birth defects prevention  
3             surveillance.

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### ***Analysis by the Legislative Reference Bureau***

Under current law, the department of health and family services (DHFS) administers the birth and developmental outcome monitoring program, commonly referred to as BDOMP. Under that program, a report must be made to DHFS by a physician who is the first physician to make a diagnosis or confirm a suspected diagnosis that a child under the age of six has a condition resulting from a low birth weight, a chronic condition possibly requiring long-term care, a birth defect or a developmental disability or other severe disability. If no physician has treated the child, a nurse who has visited with the child and who knows or suspects with reasonable medical certainty that the child has such a condition must make the report. DHFS is required to develop and implement a system for the collection, updating and analysis of the information reported and to disseminate the information. DHFS must also publish an annual report and submit the report annually to the chief clerk of each house of the legislature and to counties on the results of the information collected through the reports. DHFS must coordinate data dissemination activities of the department with those of the division for learning support, equity and advocacy in the department of public instruction with respect to the information collected through the reports. Currently, information contained in a report that specifically identifies the subject of the report is confidential and, with certain exceptions, may not be released to any person.

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This bill replaces BDOMP with a program that requires physicians, hospitals, certain clinics and clinical laboratories to report birth defects identified in children under the age of two to DHFS. Under the bill, a birth defect is defined as a structural deformation, or a genetic, inherited or biochemical disease, that occurs prior to or at birth and that requires medical or surgical intervention or interferes with normal growth and development. The bill requires DHFS to establish and maintain a registry that documents the diagnosis of a birth defect in a child under the age of two. As under current law, personally identifying information that is contained in the reports made to DHFS is confidential and, with certain exceptions, may not be released to any person. Finally, the bill creates a council on birth defect prevention and surveillance to advise DHFS regarding the registry and rules related to reporting.

Also under current law, DHFS must contract with the state laboratory of hygiene to perform tests on newborns to identify congenital and metabolic disorders. DHFS must provide necessary diagnostic, special dietary treatment that is prescribed by a physician for a patient with a congenital disorder and follow-up counseling for the patient and his or her family. The state laboratory of hygiene is required to impose a fee on behalf of DHFS that is sufficient to cover the cost of the services provided.

This bill requires DHFS to provide medical services and counseling for individuals and families at risk for preventable congenital disorders.

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

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***The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:***

1           **SECTION 1.** 15.197 (12) of the statutes is created to read:

2           **15.197 (12)** COUNCIL ON BIRTH DEFECT PREVENTION AND SURVEILLANCE. There is  
3 created in the department of health and family services a council on birth defect  
4 prevention and surveillance. The council shall consist of the following members  
5 appointed for a 4-year term by the secretary of health and family services:

6           (a) A representative of the University of Wisconsin Medical School who has  
7 technical expertise in birth defects epidemiology.

8           (b) A representative from the Medical College of Wisconsin who has technical  
9 expertise in birth defects epidemiology.

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1 (c) A representative from the subunit of the department that is primarily  
2 responsible for the children with special health needs program.

3 (d) A representative from the subunit of the department that is primarily  
4 responsible for early intervention services.

5 (e) A representative from the subunit of the department that is primarily  
6 responsible for health statistics research and analysis.

7 (f) A representative of the State Medical Society of Wisconsin.

8 (g) A representative of the Wisconsin Health and Hospital Association.

9 (h) A representative of the American Academy of Pediatrics — Wisconsin  
10 Chapter.

11 (i) A representative of the council on developmental disabilities.

12 (j) A representative of a nonprofit organization that has as its primary purpose  
13 the prevention of birth defects and does not promote abortion as a method of  
14 prevention.

15 (k) A parent or guardian of a child with a birth defect.

16 (L) A representative of a local health department, as defined in s. 250.01 (4),  
17 who is not an employe of the department of health and family services.

18 **SECTION 2.** 146.82 (1) of the statutes is amended to read:

19 146.82 (1) CONFIDENTIALITY. All patient health care records shall remain  
20 confidential. Patient health care records may be released only to the persons  
21 designated in this section or to other persons with the informed consent of the patient  
22 or of a person authorized by the patient. This subsection does not prohibit reports  
23 made in compliance with s. 146.995, 253.12 (2) or 979.01 or testimony authorized  
24 under s. 905.04 (4) (h).

25 **SECTION 3.** 253.12 of the statutes is repealed and recreated to read:

1           **253.12 Birth defect prevention and surveillance system. (1)**

2           DEFINITIONS. In this section:

3           (a) “Birth defect” means any of the following conditions affecting an infant or  
4           child that occurs prior to or at birth and that requires medical or surgical  
5           intervention or interferes with normal growth and development:

6           1. A structural deformation, disruption or dysplasia.

7           2. A genetic, inherited or biochemical disease.

8           (b) “Pediatric specialty clinic” means a clinic the primary purpose of which is  
9           to provide pediatric specialty diagnostic, counseling and medical management  
10          services to persons with birth defects by physician subspecialist.

11          (c) “Infant or child” means a human being from birth to the age of 2 years.

12          (d) “Physician” has the meaning given in s. 448.01 (5).

13          **(2) REPORTING.** (a) Except as provided in par. (b), all of the following shall report  
14          in the manner prescribed by the department under sub. (3) (a) 3. a birth defect in an  
15          infant or child:

16          1. A hospital or pediatric specialty clinic in which the birth defect is diagnosed  
17          in an infant or child or treatment for the birth defect is provided to the infant or child.

18          2. A physician who diagnoses the birth defect or provides treatment to the  
19          infant or child for the birth defect.

20          3. A clinical laboratory that identifies a birth defect in the infant or child as the  
21          result of laboratory analysis.

22          (b) No person specified under par. (a) 1. to 3. need report under par. (a) if that  
23          person knows that another person specified under par. (a) 1. to 3. has already  
24          reported to the department the required information with respect to the same birth  
25          defect of the same infant or child.

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1 (c) If the department determines that there is a discrepancy in any data  
2 reported under this subsection, the department may request a physician, hospital or  
3 pediatric specialty clinic to provide to the department information contained in the  
4 medical records of patients who have a confirmed or suspected birth defect diagnosis.  
5 The physician, hospital or pediatric specialty clinic shall provide that information  
6 within 10 working days after the department requests it.

7 **(3) DEPARTMENT DUTIES AND POWERS.** (a) The department shall do all of the  
8 following:

9 1. Establish and maintain an up-to-date registry that documents the  
10 diagnosis in this state of any infant or child who has a birth defect, regardless of the  
11 residence of the infant or child. The department shall include in the registry  
12 information that will facilitate all of the following:

13 a. Identification of risk factors for birth defects.

14 b. Investigation of the incidence, prevalence and trends of birth defects using  
15 epidemiological surveys.

16 c. Development of primary preventive strategies to decrease the occurrence of  
17 birth defects without increasing abortions.

18 d. Referrals for early intervention or other appropriate services.

19 2. Specify by rule the birth defects the existence of which requires a report  
20 under sub. (2) to be submitted to the department.

21 3. Specify by rule the content, format and procedures for submitting a report  
22 under sub. (2).

23 4. Notify the persons specified under sub. (2) (a) of their obligation to report.

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1 (b) The department may monitor the data contained in the reports submitted  
2 under sub. (2) to ensure the quality of that data and to make improvements in  
3 reporting methods.

4 **(4) COUNCIL ON BIRTH DEFECT PREVENTION AND SURVEILLANCE.** The council on  
5 birth defect prevention and surveillance shall meet at least 4 times per year and shall  
6 do all of the following:

7 (a) Make recommendations to the department regarding the establishment of  
8 a registry that documents the diagnosis and treatment in the state of an infant or  
9 child who has a birth defect, as required under sub. (3) (a) 1. and regarding the rules  
10 that the department is required to promulgate under sub. (3) (a) 2. and 3.

11 (b) Coordinate with the early intervention interagency coordinating council to  
12 facilitate the delivery of early intervention services to children from birth to 3 years  
13 with developmental needs.

14 (c) Advise the secretary and make recommendations regarding the registry  
15 established under sub. (3) (a) 1.

16 (d) Beginning April 1, 2002, and biennially thereafter, submit to the governor,  
17 and to the legislature under s. 13.172 (2) a report that details the effectiveness of the  
18 registry established under sub. (3) (a) 1.

19 **(5) CONFIDENTIALITY.** (a) Any information contained in a report made to the  
20 department under sub. (2) that may specifically identify the subject of the report is  
21 confidential. The department may not release that confidential information except  
22 to the following, under the following conditions:

23 1. The parent or guardian of an infant or child for whom a report is made under  
24 sub. (2).

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1           2. A local health officer, a local birth-to-3 coordinator or an agency under  
2 contract with the department to administer the children with special health care  
3 needs program, upon receipt of a written request and informed written consent from  
4 the parent or guardian of the infant or child. The local health officer may disclose  
5 information received under this subdivision only to the extent necessary to render  
6 and coordinate follow-up care for the infant or child or to conduct a health,  
7 demographic or epidemiological investigation. The local health officer shall destroy  
8 all information received under this subdivision within one year after receiving it.

9           3. A physician, hospital or pediatric specialty clinic reporting under sub. (2),  
10 for the purpose of verification of information reported by the physician, hospital or  
11 pediatric specialty clinic.

12           4. A representative of a federal or state agency upon written request and to the  
13 extent that the information is necessary to perform a legally authorized function of  
14 that agency, including investigation of causes, mortality, methods of prevention and  
15 early intervention, treatment or care of birth defects, associated diseases or  
16 disabilities. The information may not include the name or address of an infant or  
17 child with a condition reported under sub. (2). The department shall notify the  
18 parent or guardian of an infant or child about whom information is released under  
19 this subdivision, of the release. The representative of the federal or state agency may  
20 disclose information received under this paragraph only as necessary to perform the  
21 legally authorized function of that agency for which the information was requested.

22           (b) The department may also release confidential information to a person  
23 proposing to conduct research if all of the following conditions are met:

24           1. The person proposing to conduct the research applies in writing to the  
25 department for approval to perform the research and the department approves the

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1 application. The application for approval shall include a written protocol for the  
2 proposed research, the person's professional qualifications to perform the proposed  
3 research and any other information requested by the department.

4 2. The research is for the purpose of studying birth defects surveillance and  
5 prevention.

6 3. If the research will involve direct contact with a subject of a report made  
7 under sub. (2) or with any member of the subject's family, the department determines  
8 that the contact is necessary for meeting the research objectives and that the  
9 research is in response to a public health need or is for the purpose of or in connection  
10 with birth defects surveillance or investigations sponsored and conducted by public  
11 health officials. The department must also determine that the research has been  
12 approved by a certified institutional review board or a committee for the protection  
13 of human subjects in accordance with the regulations for research involving human  
14 subjects required by the federal department of health and human services for  
15 projects supported by that agency. Contact may only be made in a manner and  
16 method approved by the department.

17 4. The person agrees in writing that the information provided will be used only  
18 for the research approved by the department.

19 5. The person agrees in writing that the information provided will not be  
20 released to any person except other persons involved in the research.

21 6. The person agrees in writing that the final product of the research will not  
22 reveal information that may specifically identify the subject of a report made under  
23 sub. (2).

24 7. The person agrees in writing to any other conditions imposed by the  
25 department.



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1           **(6)** INFORMATION NOT ADMISSIBLE. Information collected under this section is not  
2           admissible as evidence during the course of a civil or criminal action or proceeding  
3           or an administrative proceeding, except for the purpose of enforcing this section.

4           **SECTION 4.** 253.13 (2) of the statutes is amended to read:

5           253.13 **(2)** TESTS; DIAGNOSTIC, ~~DIETARY~~ THERAPY AND ~~FOLLOW-UP~~ COUNSELING  
6           PROGRAM; FEES. The department shall contract with the state laboratory of hygiene  
7           to perform the tests specified under this section and to furnish materials for use in  
8           the tests. The department shall provide necessary diagnostic and medical services,  
9           special dietary treatment as prescribed by a physician for a patient with a congenital  
10          disorder as identified by tests under sub. (1) or (1m) and ~~follow-up~~ counseling for the  
11          patient and his or her family and for individuals and families at risk for preventable  
12          congenital disorders. The state laboratory of hygiene board, on behalf of the  
13          department, shall impose a fee for tests performed under this section sufficient to pay  
14          for services provided under the contract and shall include as part of this fee and pay  
15          to the department an amount the department determines is sufficient to fund the  
16          provision of diagnostic and counseling services, special dietary treatment and  
17          periodic evaluation of infant screening programs under this section.

18          **SECTION 5. Nonstatutory provisions.**

19          (1) COUNCIL ON BIRTH DEFECT PREVENTION AND SURVEILLANCE. Notwithstanding  
20          section 15.197 (12) of the statutes, as created by this act, the initial terms of 4 of the  
21          members appointed under section 15.197 (12) of the statutes, as created by this act,  
22          expire on July 1, 2002; the initial terms of 4 of the members appointed under section  
23          15.197 (12) of the statutes, as created by this act, expire on July 1, 2004; and the

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1 initial terms of 4 of the members appointed under section 15.197 (12) of the statutes,  
2 as created by this act, expire on July 1, 2006.

3 (END)