

1999 DRAFTING REQUEST

Bill

Received: **08/06/1999**

Received By: **yacketa**

Wanted: **As time permits**

Identical to LRB:

For: **Bonnie Ladwig (608) 266-9171**

By/Representing: **Janine Stippich**

This file may be shown to any legislator: **NO**

Drafter: **yacketa**

May Contact:

Alt. Drafters:

Subject: **Health - miscellaneous**

Extra Copies: **DAK**

Pre Topic:

No specific pre topic given

Topic:


Birth defect surveillance

Instructions:

See Attached; companion to LRB-3347

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	Jacketed	<u>Reouired</u>
/?	yacketa 08/06/1999	gilfokm 08/06/1999		_____			S&L
/1			mclark 08/11/1999	_____	lrb-docadmin 08/11/1999		S&L
/2	yacketa 10/26/1999	j geller 11/01/1999	jfrantze 11/02/1999	_____	lrb-docadmin 11/02/1999	lrb-docadmin 11/04/1999 lrb_docadmin 11/04/1999	

EE Sent For: 11/03/1999


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/2	yacketa 10/26/1999	jgeller 11/01/1999	jfrantze 11/02/1999	_____	lrb-docadmin 11/02/1999		

FE Sent For:

11-03 A⁹
↑

<END>

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/?	yacketa 08/06/1999	gilfokm 08/06/1999		_____			S & L
/1		<i>1/2</i> <i>1/1</i> <i>jlq</i>	mclark 08/11/1999	_____	lrb_docadmin 08/11/1999		

FE Sent For:

1/2 *1/1* *jlq*
11/2 *1/1* *km*
11/2
<END>

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1?	yacketa	1-8-6-99 Kmg	MRC 8/11	MRC/KM 8/11			

FE Sent For:

<END>

Yacker, Tina

From: Stippich, Janine
Sent: Friday, August 06, 1999 9:44 AM
To: Yacker, Tina
Subject: Request draft of a companion bill

Tina,

Rep. **Ladwig** would like to request a draft of a companion bill to Sen. Plache's draft of LRB 3347 relating to Birth Defects Surveillance. If you have any questions about this request, please feel free to contact me. Also, could you please e-mail me back with a confirmation of this request.

Thank you,

Janine Stippich

*Janine Stippich, Chief of Staff
Office of Representative Bonnie Ladwig
113 West, State Capitol
P. O. Box 8952
Madison, WI 53708
(608)266-9171
janine.stippich@legis.state.wi.us*

3384 /
LRB-33471
TAY:jlg/km
↑ stays
Redraft not run

1999 BILL

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

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.

This bill replaces BDOMP with a program that requires physicians, hospitals, certain clinics and clinical laboratories to report birth defects identified in children

BILL

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.

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

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

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

9 (c) A representative from the subunit of the department that is primarily
10 responsible for the administration of public health health programs.

11 (d) A representative from the subunit of the department that is primarily
12 responsible for the administration of the medical assistance program.

13 (e) A representative from the subunit of the department that is primarily
14 responsible for health care information.

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

BILL

1 (g) A representative of the American Academy of Pediatrics - Wisconsin
2 Chapter.

3 (h) A representative of a nonprofit organization that has as its primary purpose
4 the prevention of birth defects.

5 (j) A parent or guardian of a child with a birth defect.

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

7 146.82 **(1) CONFIDENTIALITY.** All patient health care records shall remain
8 confidential. Patient health care records may be released only to the persons
9 designated in this section or to other persons with the informed consent of the patient
10 or of a person authorized by the patient. This subsection does not prohibit reports
11 made in compliance with s. 146.995, 253.12 (2) or 979.01 or testimony authorized
12 under s. 905.04 (4) (h).

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

14 **253.12 Birth defect prevention and surveillance system. (1)**

15 **DEFINITIONS.** In this section:

16 (a) "Birth defect" means any of the following conditions affecting an infant or
17 child that occurs prior to or at birth and that requires medical or surgical
18 intervention or interferes with normal growth and development:

19 1. A structural deformation, disruption or dysplasia.

20 2. A genetic, inherited or biochemical disease.

21 ~~(b)~~ ^{STAFF} (b) "Pediatric specialty clinic" means a clinic the primary purpose of which is
22 to provide pediatric specialty diagnostic, counseling and medical management
23 services to persons with birth defects by physician subspecialist.

24 ^{STAFF} (c) "Infant or child" means a human being from birth to the age of 2 years.

25 (d) "Physician" has the meaning given in s. 448.01 (5).

BILL

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

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

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

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

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

14 (c) Upon request of the department, a physician, hospital or pediatric specialty
15 clinic shall provide to the department information contained in the medical records
16 of patients who have a confirmed or suspected birth defect diagnosis. The physician,
17 hospital or pediatric specialty clinic shall provide that information within 10
18 working days after the department requests it.

19 (3) **DEPARTMENT DUTIES AND POWERS** (a) The department shall do all of the
20 following:

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

25 a. Identification of risk factors for birth defects.

BILL

1 b. Investigation of the incidence, prevalence and trends of birth defects using
2 epidemiological surveys.

3 c. Development of preventive strategies to decrease the occurrence of birth
4 defects.

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

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

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

12 (4) **COUNCIL ON BIRTH DEFECT PREVENTION AND SURVEILLANCE.** The council on
13 birth defect prevention and surveillance, created under s. 15.197 (12), shall make
14 recommendations to the department regarding the establishment of a registry that
15 documents the diagnosis and treatment in the state of an infant or child who has a
16 birth defect, as required under sub. (3) (a) 1. and regarding the rules that the
17 department is required to promulgate under sub. (3) (a) 2. and 3.

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

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

24 2. A local health officer, upon receipt of a written request and informed written
25 consent from the parent or guardian of the infant or child. The local health officer

BILL

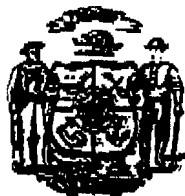
1 may disclose information received under this subdivision only to the extent
2 necessary to render and coordinate follow-up care for the infant or child or to conduct
3 a health, demographic or epidemiological investigation. The local health officer shall
4 destroy all information received under this subdivision within one year after
5 receiving it.

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

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

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

21 1. The person proposing to conduct the research applies in writing to the
22 department for approval to perform the research and the department approves the
23 application. The application for approval shall include a written protocol for the
24 proposed research, the person's professional qualifications to perform the proposed
25 research and any other information requested by the department.



STATE OF WISCONSIN

DEPARTMENT OF HEALTH AND FAMILY SERVICES

FACSIMILE COVER MESSAGE
(608) 266-7882 (FAX #)

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To: Janine Rep. Ladwig Location: _____

FAX Number: 4-8384 Telephone Number: _____

From: Office of the Secretary: Kevin Lewis
Name

Office of Legal Counsel: _____
Name

Division: _____
Name

Telephone: _____

Number of pages including cover sheet: 5

IF THERE IS A PROBLEM WITH THIS TRANSMISSION, PLEASE CONTACT:

_____ at _____
Name Telephone Number

MESSAGE:

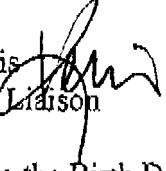


State of Wisconsin
Department of Health and Family Services

Tommy G. Thompson, Governor
Joc Lccan, Secretary

October 6, 1999

TO: Representative Bonnie Ladwig
Senator Kim Plache

FROM: Kevin Lewis 
Legislative Liaison

RE: Revisions to the Birth Defects Prevention Bill Draft

The attached document represents the final package of suggested **changes** agreed to by the Wisconsin Council on Developmental Disabilities, the March of Dimes Birth Defects Foundation, Wisconsin Right to Life, and the Department of Health and Family Services.

Please let me know if you have any questions. Thank you.

LRB 3384 & 3347

Section 1.

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

- (j) ✓ (1) A parent or guardian of a child with a birth defect.
- (g) ✓ (2) A pediatrician recommended by the American academy of pediatrics - Wisconsin chapter.
- (e) ✓ (3) A representative of the university of Wisconsin-Madison medical school who has technical expertise in birth defects epidemiology..
- (b) ✓ (4) A representative of the medical college of Wisconsin who has technical expertise in birth defects epidemiology.
- (c) ✓ (5) A representative of the Wisconsin health and hospital association
- (c) ✓ (6) A representative of the state medical. society of Wisconsin.
- (c) ✓ (7) A representative of local health departments who is not an employe of the department of health and family services.
- (h) ✓ (8) A representative of the council on developmental disabilities.
- (h) ✓ (9) A representative of the March of Dimes Birth Defects Foundation. - see rep Ludwig email
- (h) ✓ (10) A representative of the unit in the department of health and family services that deals with children with special health care needs.
- (h) ✓ (11) A representative of the unit in the department of health and family services that deals with health statistics research and analysis. is that not h.c. info?
- (h) ✓ (12) A representative of the unit in the department of health and family services that deals with early intervention services.

(b) The council has the functions specified in s. 253.12 (4).

unrec. don't specify functions in ch. 15. (that's what s. 253.12(4) is for.

[Section 2 is unchanged.]

Section 3

253.12(2) REPORTING

(c) To ensure data integrity, upon request of the department may in the event of any discrepancies in data reporting request a physician, hospital or pediatric specialty clinic shall to provide to the department information contained in the medical records of patients who have a confirmed or suspected birth defect diagnosis. The physician, hospital or pediatric specialty clinic shall provide that information within 10 working days after the department requests it.

only in the event of discrepancies
yes per Kern Lewis

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

- ✓ 1. c. Development of primary prevention preventive strategies to decrease the occurrence of birth defects without increasing abortions.
- ✓ d. Referral for early intervention services or other appropriate services subject to sub. (5). why subj. to that?
- ✓ 4. Notify mandated reporters specified under (2)(a) of the obligation to report.

7. Stads. serve as notice

(4) COUNCIL ON BIRTH DEFECT PREVENTION AND SURVEILLANCE. The council on birthdefect prevention and surveillance, created under s. 15.197(12), shall do all of the following:

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

- ~~(b) Coordinate with the ~~early intervention inter-agency coordinating~~ council to facilitate the delivery of early intervention services to children from birth to age 3 with developmental needs.~~
- (c) Advise the secretary of the department and make recommendations based on the findings established under subd. (3)(a)1.a. to d.
- (d) By April 1, 2002; and biennially thereafter, submit a report to the governor and the chief clerk of ~~each house of the legislature for distribution to the legislature and the appropriate standing committees under s. 13.172 (3) concerning its findings in the areas under subd. (3)(a)1.a. to d.~~
- (e) Meet at least 4 times annually.

(5) CONFIDENTIALITY

- (a) Any information contained in a report made to the department under sub. 2 that may specifically identify the subject of the report is confidential. The department may not release that confidential information except to the following, under the following conditions:
 1. The parent or guardian of an infant or child for whom a report is made under sub. (2).
 2. A local health officer, a local birth-to-3 coordinator, or the children with special health care needs program, upon receipt and informed written consent from the parent or guardian of the infant or child. The local health officer, local birth-to-3 coordinator, or the children with special health care needs program may disclose information received under this subdivision only to the extent necessary to render and coordinate services and follow-up care for the infant or child or to conduct a health, demographic or epidemiological investigation. The local health officer shall destroy all information received under this subdivision within one year after receiving it.
 3. A physician, hospital or pediatric specialty clinic reporting under sub. (2), for the purpose of verification of information reported by the physician, hospital or pediatric specialty clinic.
 4. A representative of a federal or state agency upon written request and to the extent that the information is necessary to perform a legally authorized function of that agency, including investigation of causes, mortality, methods of prevention and early intervention, treatment or care of birth defects, associated diseases or disabilities. The information may not include the name or address of an infant or child with a condition reported under sub. (2). The department shall notify the parent or guardian of an infant or child about whom information is released under this subdivision, of the release. The representative of the federal or state agency may disclose information received under this paragraph only as necessary to perform the legally authorized function of that agency for which the information was requested.

(6) IMMUNITY

~~(c) A physician, hospital or pediatric specialty clinic reporting under sub. (2) shall have immunity from any liability, civil or criminal, that results from his or her actions. In any proceeding, civil or criminal, the good faith or any person participating in the requirements of this section shall be presumed.~~

Per Kevin Lewis

(d) Notwithstanding s. 904.02, information collected under this section is not admissible as evidence during the course of a civil or criminal action or proceeding or an administrative proceeding, except for the purpose of enforcing this section.

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

253.13(2) Tests; diagnostic, ~~dietary~~ therapy and ~~follow-up~~ counseling program; fees, The department shall contract with the state laboratory of hygiene to perform the tests specified under this section and to furnish materials for use in the tests, The department shall provide necessary diagnostic and medical services, special dietary treatment as prescribed by a physician for a patient with a congenital disorder as identified by tests under sub. (1) or (1 m) and ~~follow-up~~ counseling for the patient and his or her family and for individuals and families at risk for preventable congenital disorders. The state laboratory of hygiene board, on behalf of the department, shall impose a fee for tests performed under this section sufficient to pay for services provided under the contract and shall include as part of this fee and pay to the department an amount the department determines is sufficient to fund the provision of diagnostic and counseling services, special dietary treatment and periodic evaluation of infant screening programs under this section.

Note: When s. 253.13(2) was first passed into the law, PKU and *metabolic* congenital disorders were the birth defects of concern at that time and so current language references "special dietary treatments." However the legislative intent at the time of passage was that the surcharge to the newborn screening fee would be used by the Department to pay for necessary medical and related services for infants and their families with the conditions that were screened for. Subs, (1j and (1m) both mention congenital, disorders in *general*. Non-metabolic congenital disorders - such as sickle cell disease and cystic fibrosis - are important parts of the newborn screening panel. This statutory language change would clarify that medical services for congenital disorders are to be included as allowable services.

In addition, the statutes currently are specific to counseling services for patients and the families of patients who have already tested positive for a congenital disorder. Counseling services for individuals and families at risk for preventable congenital disorders should fall under the rubric of allowable expenditures of funds from the congenital disorders surcharge because preventive counseling can result in better perinatal results and lessen the demand for the more costly counseling for families of children born with congenital disorders.

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Yacker, Tina

From: Hale, Janine
Sent: Wednesday, October 06, 1999 3:19 PM
To: Yacker, Tina
Subject: Additional changes to the Birth Defects Bill

Tina,

This morning Rep. **Ladwig** and I visited you with changes to LRB **3384/1** relating to birth defects prevention surveillance. We have one additional change that we would like **to** the bill.

In the memo we gave you from DHFS, under **Section 1**, 15.197 (12) Council on Birth Defect Prevention and Surveillance, (9) stated "a representative of the March of Dimes Birth Defects Foundation". Rep. **Ladwig** would like to keep the original language of the bill which states, "a representative on a nonprofit organization that has as its primary purpose the prevention of birth defects" (Page 3, line 3). Rep. **Ladwig** would also like to add after this language, "...and does not promote abortion as a method of prevention."

In summary, the /2 would then contain the following language on page 3, line 3:

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

I do not know if Senator Plache would also like the above change to the companion bill (LRB **3347/1**). You will need to confirm with their office or wait to hear from them.

I would greatly appreciate a confirmation of this change from you.

Thank you,

Janine Hale

*Janine Hale, Chief of Staff
Office of Representative Bonnie Ladwig
113 West, State Capitol
P. O. Box 8952
Madison, WI 53708
(608)266-9171
janine.hale@legis.state.wi.us*

|
She does

-3384

§ 1 unit of dept that deals w/ health stats research
≠ health care information?

§ 3 ① May DHFS request info only in event of discrepancy?
Yes - per Kevin Lewis

② Why req. DHFS to notify reporters? Stats serve as
notice - it's ok leave in

What does it mean to give info to a program?
Is that program administered by DHFS? If
so, info is already going to DHFS. If not, to
whom is it going?

What is the liability envisioned in the
immunity provisions?

10/25

Called Kevin Lewis (will call back)



State of Wisconsin
1999 - 2000 LEGISLATURE

LRB-3384/2

TAY;jlg:mrc

D-NOTE

RMR

1999 BILL

get cut

1 **AN ACT** to ~~amend 149.22 (1); to repeal and recreate 253.12; and to create~~
2 15.197 (12) of the statutes; relating to: birth defects prevention surveillance.

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.

This bill replaces BDOMP with a program that requires physicians, hospitals, certain clinics and clinical laboratories to report birth defects identified in children

BILL

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.

INSERT
ANAL ✓

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

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

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

appointed for a 4-year term by the secretary of health and family services ✓

15.197 (12) COUNCIL ON BIRTH DEFECT PREVENTION AND SURVEILLANCE. There is created in the department of health and family services a council on birth defect prevention and surveillance. The council shall consist of the following members:

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

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

(c) A representative from the subunit of the department that is primarily responsible for the ~~administration of public health~~ ^{children with special health needs} programs.

(d) A representative from the subunit of the department that is primarily responsible for the ~~administration of the medical assistance program~~ ^{early intervention services}.

(e) A representative from the subunit of the department that is primarily responsible for health ~~care information~~ ^{statistics research and analysis}.

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

(G) I
early intervention services

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- § (g) A representative of the Wisconsin Health and Hospital Association.
- 1 ~~§ (h)~~ A representative of the American Academy of Pediatrics - Wisconsin Chapter.
- 2 ~~§ (i)~~ A representative of the c d developmental disabilities.
- 3 ~~§ (j)~~ A representative of a nonprofit organization that has as its primary purpose
- 4 the prevention of birth defects and does not promote abortion as a method of prevention
- 5 ~~§ (k)~~ A parent or guardian of a child with a birth defect:

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

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

SECTION 3. 253.12[✓] of the statutes is repealed and recreated to read:

253.12 Birth defect prevention and surveillance system. (1)

DEFINITIONS. In this section:

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

- 1. A structural deformation, disruption or dysplasia.
- 2. A genetic, inherited or biochemical disease.

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

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

(d) "Physician" has the meaning given in s. 448.01 (5).

~~(e)~~ A representative of a local health department, as defined in s. [✓]250.01(4), who is not an employe of the department of health and family services.

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

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

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

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

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

14 (c) ~~Upon request of~~ the department ^{may request} a physician, hospital or pediatric specialty
15 clinic ~~shall~~ ^{to} provide to the department information contained in the medical records
16 of patients who have a confirmed or suspected birth defect diagnosis. The physician,
17 hospital or pediatric specialty clinic shall provide that information within 10
18 working days after the department requests it.

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

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

25 a. Identification of risk factors for birth defects.

[If the department determines that there is a discrepancy in ^{any} data reported under this subsection,

BILL

do referrals for early intervention - other appropriate services.

1 b. Investigation of the incidence, prevalence and trends of birth defects using
2 epidemiological surveys.

3 c. Development of *primary* preventive strategies to decrease the occurrence of birth
4 defects. *without increasing abortions*

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

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

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

shall meet at least 4 times per year and

do all of the following:

12 (4) COUNCIL ON BIRTH DEFECT PREVENTION AND SURVEILLANCE. The council on
13 birth defect prevention and surveillance, ~~created under s. 15.197 (2)(a)~~ shall *(a)*
14 make recommendations to the department regarding the establishment of a registry that
15 documents the diagnosis and treatment in the state of an infant or child who has a
16 birth defect, as required under sub. (3) (a) 1. and regarding the rules that the
17 department is required to promulgate under sub. (3) (a) 2. and 3.

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18

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

Special health care needs program

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

24 2. A local health officer, *a local birth-to-3 coordinator or an agency under*
25 *contract with the department to administer the children with* upon receipt of a written request and informed written
consent from the parent or guardian of the infant or child. The local health officer

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

BILL

1 may disclose information received under this subdivision only to the extent
2 necessary to render and coordinate follow-up care for the infant or child or to conduct
3 a health, demographic or epidemiological investigation. The local health officer shall
4 destroy all information received under this subdivision within one year after
5 receiving it.

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

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

and early
intervention

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

21 1. The person proposing to conduct the research applies in writing to the
22 department for approval to perform the research and the department approves the
23 application. The application for approval shall include a written protocol for the
24 proposed research, the person's professional qualifications to perform the proposed
25 research and any other information requested by the department.

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

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

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

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

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

21 7. The person agrees in writing to any other conditions imposed by the
22 department.

(END)

INSERTS
7-22
7-22A23
7-22B

INSECT 7-22A

the law revision committee under s. 13.83 (1) (c) 4., stats. After careful consideration of the various provisions of the bill, the law revision committee has determined that this bill makes minor substantive changes in the statutes, and that these changes are desirable as a matter of public policy.

1 SECTION 1. 253.13 (2) of the statutes is amended to read:

2 253.13 (2) TESTS; DIAGNOSTIC, ~~DIETARY~~ THERAPY AND FOLLOW-UP COUNSELING

3 PROGRAM; FEES. The department shall contract with the state laboratory of hygiene

4 to perform the tests specified under this section and to furnish materials for use in

5 the tests. The department shall provide necessary diagnostic and medical services,

6 special dietary treatment as prescribed by a physician for a patient with a congenital

7 disorder as identified by tests under sub. (1) or (1m) and ~~follow-up~~ counseling for the

8 patient and his or her family and for individuals and families at risk for preventable

9 congenital disorders. The state laboratory of hygiene board, on behalf of the

10 department, shall impose a fee for tests performed under this section sufficient to pay

11 for services provided under the contract and shall include as part of this fee and pay

12 to the department an amount the department determines is sufficient to fund the

13 provision of diagnostic and counseling services, special dietary treatment and

14 periodic evaluation of infant screening programs under this section.

15

~~(END)~~

(end ins 7-22A)

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

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TAY.....
JLg

confidentiality
'to the extent that
the provisions are
relevant;

After consulting with Kevin Lewis of the Department of Health and Family Services, I made the following modifications to the department's requested changes:

1. I did not include in proposed s. 253.12 (3) (a) 1. d. (directing the department to include in its registry any information that would facilitate referrals) any reference to sub. (5) (which relates to confidentiality of patient-identifying information). All of the information included in the registry is subject to the confidentiality provisions, so the reference was^{is} superfluous and would have call~~ed~~ into question whether other information would also be subject to the confidentiality requirements.

2. In proposed s. 253.12 (5) I refer to an "agency with which the department contracts to administer the children with special health care needs program."

3. I did not include the civil and criminal immunity provision because it was difficult for either Kevin or me to conceive of how liability would attach for the mere reporting of information required to be reported.

In addition, upon a closer reading of the department's request, the intent of proposed s. 253.12 (4) (c) and (d) was unclear. Those paragraphs refer to "findings" under the provision requiring the establishment of a registry, but a registry is not generally established to yield "findings." This particular registry, in fact, is to be established to provide what appears to be general information that could facilitate research. Please review s. 253.12 (4) (c) and (d) to determine if I have captured the department's intent.

Finally, since the terms of the board members are now specified, it is customary to stagger the terms, which is what I have done in this draft. That is done to prevent a periodic complete turnover of a council (or other body), which would hamper a council's ability to accomplish its goals. On the other hand, if the department intends this council to exist only for 4 years, staggered terms are inappropriate and an in-text sunset may be desirable.

D-N
INSERT

of the council

Tina A. Yacker
Legislative Attorney
Phone: (608) 261-6927
E-mail: Tina.Yacker@legis.state.wi.us

D-Note INS

#. The Proposed s. 253.12 (6), like s. 253.12 (8), stats., refers to "information" collected under s. 253.12. One reading of this language is that once the information is reported, it can never be used in court, even if a litigant has a source for the information that is independent of (or even entirely unrelated to) the report required under s. 253.12. Is that your intent? Or do you mean to make the report itself inadmissible for purposes of proving the information contained in them?

JEO

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-3384/2dn
TAY&JEO:jlg:jf

November 2, 1999

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Tina A. Yacker
Legislative Attorney
Phone: (608) 261-6927
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**SUBMITTAL
FORM**

**LEGISLATIVE REFERENCE BUREAU
Legal Section Telephone: 266-3561
5th Floor, 100 N. Hamilton Street**

The attached draft is submitted for your inspection. Please check each part carefully, proofread each word, and sign on the appropriate line(s) below.

Date: 11/02/1999

To: Representative Ladwig

Relating to LRB drafting number: LRB-3384

Topic

Birth defect surveillance

Subject(s)

Health - miscellaneous

1. **JACKET** the draft for introduction Bonnie Ladwig
in the **Senate** or the **Assembly** (check only one). Only the requester under whose name a drafting request is entered in the LRB's drafting records may authorize the draft to be submitted. Please allow one day for the preparation of the required copies.

2. **REDRAFT.** See the changes indicated or attached _____
A revised draft will be submitted for your approval with changes incorporated.

3. Obtain **FISCAL ESTIMATE NOW**, prior to introduction Bonnie Ladwig.

Done 11-03-99
MB



If the analysis indicates that a fiscal estimate is required because the proposal makes an appropriation or increases or decreases existing appropriations or state or general local government fiscal liability or revenues, you have the option to request the fiscal estimate prior to introduction. If you choose to introduce the proposal without the fiscal estimate, the fiscal estimate will be requested automatically upon introduction. It takes about 10 days to obtain a fiscal estimate. Requesting the fiscal estimate prior to introduction retains your flexibility for possible redrafting of the proposal.

If you have any questions regarding the above procedures, please call 266-3561. If you have any questions relating to the attached draft, please feel free to call me.

Tina A. Yacker, Legislative Attorney
Telephone: (608) 261-6927