

1999 DRAFTING REQUEST

Bill

Received: **09/14/98**

Received By: **yacketa**

Wanted: **As time permits**

Identical to LRB:

For: **Administration-Budget**

By/Representing: **Jablonsky**

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

Drafter: **yacketa**

May Contact:

Alt. Drafters:

Subject: **Health - miscellaneous**

Extra Copies: **DAK**

Topic:

DOA:.....Jablonsky - Birth outcome program

Instructions:

See Attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?	yacketa 09/14/98	jgeller 09/16/98		_____			
/P1			lpaasch 09/16/98	_____	barmamj 09/16/98		S&L
/1	yacketa 12/6/98	jgeller 12/10/98	jfrantze 12/10/98	_____	lrb_docadmin 12/10/98		S&L
/2	yacketa 01/21/99	jgeller 01/21/99	hhagen 01/22/99	_____	lrb_docadmin 01/22/99		

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12/21 jlg *12/22* *12/22*

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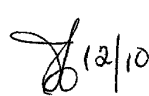

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For: **Administration-Budget**

By/Representing: **Geisler**

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

Drafter: **yacketa**

May Contact:

Alt. Drafters:

Subject: **Health - miscellaneous**

Extra Copies: **DHFS, DAK**

Topic:

DOA:.....Geisler - Birth outcome program

Instructions:

See Attached

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FE Sent For:

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Birth Outcome Program

Current Language

Section 253.12 of the statutes requires a physician who diagnoses or confirms that an infant or child has a physical condition that results from an adverse neonatal outcome, birth defect, or developmental disability to report this to the Department. The birth and developmental outcome monitoring program began operating in 1990.

Proposed Change

Repeal and recreate s. 253.12 of the statutes (see attached).

Effect of the Change

1. The Department will be allowed to use existing data, including data from the Office of Health Care Information, to prepare consistent reports that analyze the incidence of birth defects in Wisconsin.
2. The Department will establish a birth defect system advisory committee that will assist the Department in drafting rules concerning the definition of birth defects in Wisconsin and specifying the format for submitting the birth defect reports required by this chapter.
3. The Office of Health Care Information will be allowed to provide confidential data to this program concerning outpatient treatment of children with birth defects.

Rationale for the Change

When this program was created in 1990 it was staffed by four federally funded positions who collected data, produced reports, and educated physicians about the requirements of the birth outcome program. The purpose of the program was to collect and analyze data on adverse neonatal outcomes, birth defects, developmental disabilities and other disabilities in young children. When the federal funds ceased, the program was provided with 1.0 GPR FTE to staff the program. The level of physician reporting subsequently decreased, from 1,183 in FY 90 to 565 in FY 94, partly because there were not sufficient staff to offer provider training and also collect data and issue reports. Provider reporting was inconsistent which precluded effective use of the information for analyzing the prevalence of birth defects in Wisconsin.

Because the Department collects most of the targeted data through other programs and data systems, the Department proposed deleting this program and the 1.0 FTE in the 1997-99 biennial budget. The Governor's Office, however, agreed with advocates that the program should be maintained. The Department must now create a birth defect reporting system that will be as effective as possible, given limited resources.

DOH proposes to use existing data to create this system, supplemented by reports of cases not otherwise reported, to avoid duplication of effort on the part of providers and departmental staff. The Center for Health Statistics can now link birth, hospitalization and Medicaid eligibility and claims files. The only data that this reporting system does not capture is the number of children whose birth defects or disabilities do not appear at birth and who receive treatment on an outpatient basis, unless these children are on Medicaid. This proposed change will change current physician reporting requirements in that physicians will not be required to report diagnoses again that are reported through other systems.

Since the Office of Health Care Information (OHCI) will be collecting information on outpatient treatment of children with birth defects, DOH proposes to use this information for its required birth defect reports, rather than create a new requirement that would make providers report the same information twice. The confidentiality provision for OHCI information will be expanded to allow DOH to use this information for the purposes of these required reports. The revised statute will also explicitly allow for review of medical records for selected types of cases.

Desired Effective Date:	Upon Passage of Bill
Agency:	DHFS
Agency Contact:	Ellen Hadidian
Phone:	266-8155

Proposed statutory language: Birth Defect Prevention and Surveillance System

PURPOSE. The Birth Defect Prevention and Surveillance System is hereby established to develop and maintain a registry of infants and children diagnosed or treated for birth defects before age 6. This registry shall provide information which enables researchers and epidemiologists to:

1. Identify risk factors for birth defects;
2. Investigate the causes and prevalence of birth defects;
3. Develop preventive strategies to decrease the occurrence of birth defects;
4. Analyze incidence, prevalence and trends in birth defects through epidemiological studies;
5. Investigate the morbidity and mortality rates resulting from birth defects.

DEFINITIONS. In this section:

(a) "Birth defect" means one or more of the following conditions affecting an infant or child that occurs prior to or at birth, is diagnosed at any time before or after birth up to the age of 6 years, and which requires medical or surgical intervention or interferes with normal growth and development:

1. a structural deformation; and/or
2. a genetic, inherited or biochemical disease; and/or
3. a developmental disability as specified under s.51.01(5)(a) due to a birth defect

(b) "Surveillance" means the process of identifying and investigating birth defects in children under age 6.

REPORTING (a) The department, following consultation with the birth defect prevention and surveillance system advisory committee, shall promulgate rules:

1. To establish and maintain an up-to-date registry that shall document the diagnosis and/or treatment in Wisconsin of any birth defect in any child under age 6 years, regardless of the residence of the child.
2. Define conditions subject to the reporting requirements of this chapter.
3. Specify the content, format and procedures for submitting reports on birth defects as required by this chapter.

(b) As of (the effective date of this act), the following are required to report to the department the occurrence of birth defects:

1. The designated representative of any hospital and genetic specialty clinic that diagnoses or provides treatment, or both for children under age 6 with birth defects;
2. Any physician, surgeon, dentist or other health care practitioner who diagnoses or provides treatment, or both, for children under age 6 with birth defects;
3. The designated representative of any clinical laboratory that performs tests which identify children under age 6 with birth defects.
4. The director of any existing registry that includes information on individuals with birth defects, including the Wisconsin birth and death registries.

(c) All health care practitioners enumerated above shall, at the request of the department and with advance notification of at least 10 working days, make available to the

advance notice
from whom? Must make info
avail w/in 10 days after dept
requests?

Condition specified in

caused by 1 or 2?

primarily? or incidentally?

function of the lab?

department information contained in the medical records of patients who have a confirmed birth defect diagnosis.

[Option: The director of any legislatively-mandated electronic reporting system that collects patient-specific diagnosis and treatment information from hospitals, physicians, clinics, ambulatory surgery centers, and other health care practitioners that diagnose or treat children under age 6 with birth defects. Requires language to allow OHCI to provide confidential data to this program.]

CONFIDENTIALITY. (a) Access to individual-identifying birth defect surveillance system information is limited to authorized department employees and other persons with a valid scientific interest who are engaged in approved demographic, epidemiological or other studies related to birth defects and who agree in writing to maintain confidentiality. The process for obtaining approval shall be specified in rule by the department. (See Texas, 87.063) (b) Except as provided by (c, d and e) the surveillance system is prohibited from supplying any information by individual name or other personal identifier or in a form other than a statistical report which protects the confidentiality of individuals except for approved research or epidemiological purposes. (c) The system shall provide reported information to the parent or guardian of an infant or child for whom a report is made, upon receipt of a written request from the parent or guardian. (d) The system shall have the power to enter into agreements with neighboring states and the federal Centers for Disease Control and Prevention consistent with the requirements and restrictions of this chapter to obtain relevant information concerning Wisconsin residents who receive health-related services outside the state, and to provide similar information reported to the Wisconsin system regarding residents of other states. Data exchanges with other state and national birth defect surveillance registries are subject to inter-state data exchange protocols. These protocols shall preclude re-release of any information that might make it possible to identify an individual. (e) The system shall routinely inform state programs for children with birth defects regarding the existence of cases of interest to these programs and establish procedures for programs to contact families through their physicians of record.

✓ ADVISORY COMMITTEE. (a) The birth defect prevention and surveillance system shall be administered with the advice of an advisory committee appointed by the department secretary, and comprised of representatives nominated by the UW Medical School, the Medical College of Wisconsin, the lead agencies for public health and the Wisconsin Medicaid Program, the State Medical Society of Wisconsin, the Academy of Pediatrics-Wisconsin Affiliate, the Waisman Center or other genetic specialty clinic, the program director, and a minimum of two consumer representatives.

✓ INVESTIGATIONS. The department shall use surveillance system information to investigate the causes of birth defects, and design and evaluate measures to prevent the occurrence of birth defects. (a) The department may conduct investigations, including epidemiological or toxicological investigations, of cases of specified birth defects.

(b) The department may conduct these investigations to determine the nature and extent of the disease or the known or suspected cause of the birth defect and to formulate and evaluate control measures to protect the public health. The department's investigation may include geographic, temporal, occupational and past exposures. designs and protocols are subject to approval by an approved human subjects review board.



State of Wisconsin
1997 - 1998 LEGISLATURE

LRB-5289/P1

TAY:.....

D-NOTE

Jig

DOA:.....Jablonsky – Birth outcome program

FOR 1997-99 BUDGET — NOT READY FOR INTRODUCTION

① AN ACT ...; relating to: ~~Birth outcome program~~ the budget.

Analysis by the Legislative Reference Bureau

HEALTH AND SOCIAL SERVICES

HEALTH

This is a preliminary draft. An analysis will be provided in a later version.

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

② SECTION 1. 253.12^x of the statutes is repealed and recreated to read:

as affected by 1997 Wisconsin Acts 164 and 252,

3 253.12 Birth defect prevention and survey system. (1) DEFINITIONS. In

4 this section:

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

1 1. A structural deformation.

2 2. A genetic, inherited or biochemical disease.

3 3. A developmental disability, as defined in s. 51.01 (5) (a), that is caused by a
4 condition specified in subd. 1. or 2.

5 (b) "Genetic specialty clinic" means xxx???

6 (c) "Health care provider" has the meaning given in s. 146.81 (1).

7 (d) "Infant or child" means a human being from birth to the age of 6 years.

8 (2) REPORTING. (a) All of the following shall report in the manner prescribed
9 by the department under sub. (3) (c) a birth defect in an infant or child:

10 1. A hospital or genetic specialty clinic in which the birth defect is diagnosed
11 in an infant or child or treatment for the birth defect is provided to the infant or child.

12 2. A health care provider who diagnoses the birth defect or provides treatment
13 to the infant or child for the birth defect.

14 3. A clinical laboratory that performs tests that identify a birth defect in the
15 infant or child.

16 4. The custodian of any registry within this state that includes information on
17 an infant or child with birth defects.

18 (b) Upon request of the department, a health care provider shall provide to the
19 department information contained in the medical records of patients who have a
20 confirmed birth defect diagnosis. The health care provider shall provide that
21 information within 10 working days after the department requests it.

22 (3) DEPARTMENT DUTIES. The department shall do all of the following:

23 (a) Establish and maintain an up-to-date registry that documents the
24 diagnosis and treatment in this state of any infant or child who has a birth defect,

1 regardless of the residence of the infant or child. The department shall include in
2 the registry information that will facilitate all of the following:

- 3 1. Identification of risk factors for birth defects.
- 4 2. Investigation of the causes and prevalence[✓] of birth defects.
- 5 3. Development of preventive strategies to decrease the[✓] occurrence of birth
6 defects.
- 7 4. Analysis of the incidence, prevalence and trends in birth defects through
8 [✓]epidemiological studies.
- 9 5. Investigation of the morbidity and mortality rates resulting from birth
10 defects.

11 (b) Specify by rule the conditions the existence of which requires a report under
12 sub. (2)[✓] to be submitted to the department.

****NOTE: What kind of conditions? Health conditions?

13 (c) Specify by rule the content, format and procedures for submitting a report
14 under sub. (2).[✓]

15 (d) Investigate the causes of birth defects and design and evaluate measures
16 to prevent the occurrence of birth defects. The department may conduct
17 epidemiological or toxicological[✓] investigations of specific birth defect cases to
18 determine the nature and extent of the known or suspected cause of the birth defect
19 and to formulate and evaluate control measures to protect the public health. The
20 department's investigation may include geographic, temporal, occupational and past
21 exposures. Designs and protocols of the investigations are subject to approval by an
22 approved human subjects review board.

****NOTE: What is a human subjects review board and by whom must it be approved? Also, I'm not sure I understand the department's duty under this paragraph. Is there a reason that you think you need specific reference to the type of exposures the department is authorized to investigate?

1 (4) CONFIDENTIALITY. (a) Except as provided in pars. (b) to (e), the department
2 may not release information that is obtained from reports submitted under sub. (2)
3 that specifically identifies an infant or child.

4 (b) Upon written receipt of a request from the parent or guardian of an infant
5 or child who is the subject of a report submitted under sub. (2), the department shall
6 release the contents of that report to the parent or guardian.

7 (c) The department may release information obtained from reports submitted
8 under sub. (2) that specifically identifies an infant or child to health officials of
9 another state if the infant or child resides in that state and the department has
10 entered into a reciprocal agreement with that state for the provision of information
11 regarding birth defects in infants or children. An agreement entered into by the
12 department with that other state shall provide for the confidentiality of information
13 that specifically identifies an infant or child.

14 (d) The department may release information obtained from reports submitted
15 under sub. (2) that specifically identifies an infant or child to the federal Centers for
16 Disease Control and Prevention.

17 (e) The department may release information obtained from reports submitted
18 under sub. (2) that specifically identifies an infant or child to a person with a valid
19 scientific interest who is engaged in approved demographic, epidemiological or other
20 studies or a program related to birth defects if the person requests the information
21 in writing and agrees in writing to maintain the confidentiality of that information.

22 **SECTION 91XX. Nonstatutory provisions; health and family services**

23 (1) BIRTH DEFECT PREVENTION AND SURVEY SYSTEM ADVISORY COMMITTEE.

24 (a) *Composition.* The secretary of health and family services shall establish a
25 committee under section 15.04 (1)(c) of the statutes to advise the department of



1 health and family services in establishing a birth defects registry under section
2 253.12 (3) (a) of the statutes, as created by this act, and in drafting the rules required
3 to be promulgated under section 253.12 (3) (b) and (c) of the statutes, as created by
4 this act. The committee shall consist of all of the following appointed by the secretary
5 of health and family services:

6 1. Representatives nominated by the University of Wisconsin Medical School,
7 the Medical College of Wisconsin, the lead agencies for public health and the medical
8 assistance program, the State Medical Society of Wisconsin, the Academy of
9 Pediatrics–Wisconsin Affiliate, the Waisman Center or other genetic specialty clinic
10 and the program director.

11 2. Two consumer representatives.

12 (b) *Duties.* The birth defect prevention and survey system advisory committee
13 shall advise the department of health and family services regarding the
14 establishment of a registry that documents the diagnosis and treatment in the state
15 of an infant or child under the age of 6 who has a birth defect, as required under
16 section 253.12 (3) (a) of the statutes, as created by this act, and regarding the rules
17 that the department is required to promulgate under section 253.12 (3) (b) and (c) of
18 the statutes, as created by this act. The department of health and family services
19 shall consult with the birth defect prevention and survey system advisory committee
20 prior to establishing the registry under section 253.12 (3) (a) of the statutes, as
21 created by this act and prior to promulgating the rules under section 253.12 (3) (b)
22 and (c) of the statutes, as created by this act.

23 (END)

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-5289/P1dn

TAY, A:....

1/9

1. I did not include the legislative intent provisions that were included in the model legislation. Generally, we no longer draft statements of legislative intent or purpose except for recodification bills or in instances in which constitutionality is at issue. This policy has evolved to avoid redundancy to or conflict with statutory provisions, to avoid use of undefined terms, to forestall certain unforeseen effects in interpretation that such a statement may cause and to avoid the inclusion of promotional language in the statutes that may be subject to later misinterpretation. Instead, I have incorporated the provisions of the purpose statement into s. 253.12 (3) (a). Please review that provision to ensure that it comports with your intent.

2. In identifying the conditions that define a birth defect, the proposed statutory language lists "a developmental disability as specified under s. 51.01 (5) (a) due to a birth defect." Since "birth defect" is the very term being defined, it is confusing to use the term in the definition. I have attempted to clarify that part of the definition, but I am uncertain whether I've captured the department's intent. Therefore, please review s. 253.12 (1) (a) 3., as created in this draft, carefully.

Additionally, I assumed (from reading the purpose statement) that the reason that the age of diagnosis was included in the definition of "birth defect" was that the department only wants information on birth defects in children under the age of 6. However, that is clear from the provisions regarding reporting requirements. I therefore did not include the age of diagnosis in the definition as it seemed unnecessary. If I am wrong about the rationale for the inclusion of the age of diagnosis in the definition of "birth defect" please let me know and please let me know what you are trying to accomplish by including it so that I can effect your intent.

3. I did not use the word "surveillance" because it generally implies a close observation of a person or group under suspicion. The word "survey" seemed more appropriate. I did not feel it was necessary to define the word since its meaning in the statutes would not fall outside the dictionary definition and, at least in this draft, the word does not appear in the statutory provisions except in the title of the recreated section. I do feel that it is necessary for you to define "genetic specialty clinic," however, since that term does not appear elsewhere in the statutes and it is not obvious to me what kind of health facility would be included in that term.

4. For the most part, I have used the language provided in the instructions regarding those persons who are required to report birth defects to the department. The wording

is ambiguous, however. For example, the language requires a clinical laboratory "that performs tests which identify children under age 6 with birth defects" to report to the department. This could be interpreted to be a requirement of any clinical laboratory that performs tests if the test turns up evidence of a birth defect, or of just those laboratories that have as their function the performance of tests that identify birth defects. Which do you intend?

In addition, under the language provided, the department may receive multiple reports regarding the same child. For example, the language requires a health care provider who diagnoses a birth defect to report it to the department. The language also requires a clinic or hospital in which a birth defect is diagnosed to report it. The diagnostician likely would be employed either at a hospital or clinic. Is it your intent that multiple reports — one by the health care provider and one by the hospital or clinic in which the provider works — be made on the same child?

Finally, I'm not sure what is meant by "director of any existing registry". I have substituted the word "custodian" for "director" which seemed more appropriate since a registry is a list rather than an organization of which there is a director. Also, I have not made reference to the "Wisconsin birth and death registries" because it is unnecessary and confusing since there is no other statutory reference to a birth or death registry and I am therefore uncertain how to refer properly to such registries.

5. The instructions indicate that "at the request of the department and with advance notification of at least 10 working days" health care providers must make available to the department information contained in the medical records of those with birth defects. I was not sure what you meant by "advance notification". Please review s. 253.12 (2) (b), as created in this draft, to ensure that I captured your intent.

6. Regarding the Birth Defects Prevention and Survey System Advisory Committee I have placed the creation, duties and composition of that committee in a nonstatutory provision. This is required under s. 15.01 (3). That provision defines "committee" as a temporary body which, because of its temporary status, should not be created by statute but by session law. Did you intend the advisory body to be temporary (committee) or permanent (council)? If it is the latter, please let me know so that I can redraft that provision as a statutory provision. The drafting instructions state that "the birth defect and surveillance system shall be administered with the advice of an advisory committee." This suggests a more permanent advisory body, but I am uncertain what advice, besides advice regarding rules, the advisory committee is expected to give.

Also, it is unclear what you intend the composition of the committee to be. The instructions state that it is to be comprised of "representatives nominated by the UW Medical School, Medical College of Wisconsin" etc., but the instructions do not indicate what or whom those persons are representing. Do you mean that there are to be representatives from the UW Medical school, the Medical College of Wisconsin etc.? Or are the representatives to be nominated by all those groups? Also, you list the program director, but you do not specify of which program that person is the director and it is not clear whether you intend that person to be a committee member or someone who nominates a committee member. I am also unclear to what consumer

group you refer when you state that 2[✓] consumer representative^⑤ be included on the committee. Consumers of what service or product? Finally, how many people do you want on the committee?

7. Regarding the confidentiality provision, the instructions imply that information specifically identifying a child or infant may be released to "neighboring states and the federal Centers of Disease Control and Prevention". Is that correct?

Also, the instructions state that "the system is prohibited" from releasing individual-identifying information and that "the system shall have the power" to enter into certain agreements. A system is not an entity that can act. The department, which presumably will be the operator and primary user of the system, is the entity that can act. Therefore, I have given the department the authority and duties that you have enumerated for the system.

Finally, what are the state programs that the department must inform regarding the existence of birth defects? Do you mean all programs in the state for children with birth defects? And how is the department to determine whether a case is of interest to a program? It seems that the department's ability to release information to persons with a valid scientific interest who are engaged in approved demographic, epidemiological or other studies should be sufficient to get the information to those programs.

I would be happy to meet with you to discuss any questions that you may have about this draft or these drafter's notes.

Tina A. Yacker
Legislative Attorney
261-6927

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-5289/P1dn

TAY:jlg:km

Wednesday, August 19, 1998

1. I did not include the legislative intent provisions that were included in the model legislation. Generally, we no longer draft statements of legislative intent or purpose except for recodification bills or in instances in which constitutionality is at issue. This policy has evolved to avoid redundancy to or conflict with statutory provisions, to avoid use of undefined terms, to forestall certain unforeseen effects in interpretation that such a statement may cause and to avoid the inclusion of promotional language in the statutes that may be subject to later misinterpretation. Instead, I have incorporated the provisions of the purpose statement into s. 253.12 (3) (a). Please review that provision to ensure that it comports with your intent.

2. In identifying the conditions that define a birth defect, the proposed statutory language lists "a developmental disability as specified under s. 51.01 (5) (a) due to a birth defect." Since "birth defect" is the very term being defined, it is confusing to use the term in the definition. I have attempted to clarify that part of the definition, but I am uncertain whether I've captured the department's intent. Therefore, please review s. 253.12 (1) (a) 3., as created in this draft, carefully.

Additionally, I assumed (from reading the purpose statement) that the reason that the age of diagnosis was included in the definition of "birth defect" was that the department only wants information on birth defects in children under the age of 6. However, that is clear from the provisions regarding reporting requirements. I therefore did not include the age of diagnosis in the definition as it seemed unnecessary. If I am wrong about the rationale for the inclusion of the age of diagnosis in the definition of "birth defect" please let me know and please let me know what you are trying to accomplish by including it so that I can effect your intent.

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Legislative Attorney
261-6927

D-NOTE

1997-1998 LEGISLATURE

0178/01
LRB-5289/PT

TAY:jlq:km

RM not run ^{stays}
2

DOA:.....Jablonsky - Birth outcome program

1999-01
FOR 1997-99 BUDGET — NOT READY FOR INTRODUCTION

Do not gen

1 AN ACT ...; relating to: the budget.

Analysis by the Legislative Reference Bureau

HEALTH AND SOCIAL SERVICES

HEALTH

This is a preliminary draft. An analysis will be provided in a later version.

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

2 SECTION 1. 253.12^{lx} of the statutes, ~~as affected by 1997 Wisconsin Acts 164 and~~

3 ~~253.12~~ is repealed and recreated to read:

4 **253.12 Birth defect prevention and survey system.** (1) DEFINITIONS. In
5 this section:

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

- 1 1. A structural deformation.
- 2 2. A genetic, inherited or biochemical disease.
- 3 3. A developmental disability, as defined in s. 51.01 (5) (a),[✓] that is caused by a
- 4 condition specified in subd. 1. or 2.
- 5 (b) “Genetic specialty clinic” means xxx???
- 6 (c) “Health care provider” has the meaning given in s. 146.81 (1).[✓]
- 7 (d) “Infant or child” means a human being from birth to the age of 6[✓] years.
- 8 (2) REPORTING.[✓](a) All of the following shall report in the manner prescribed
- 9 by the department under sub. (3) (c) a birth defect in an infant or child:
- 10 1. A hospital or genetic specialty clinic in which the birth defect is diagnosed
- 11 in an infant or child or treatment for the birth defect is provided to the infant or child.
- 12 2. A health care provider who diagnoses the birth defect or provides treatment
- 13 to the infant or child for the birth defect.
- 14 3. A clinical laboratory that performs tests that identify a birth defect in the
- 15 infant or child.
- 16 4. The custodian of any registry within this state that includes information on
- 17 an infant or child with birth defects.
- 18 (b) Upon request of the department, a health care provider shall provide to the
- 19 department information contained in the medical records of patients who have a
- 20 confirmed birth defect diagnosis. The health care provider shall provide that
- 21 information within 10[✓] working days after the department requests it.
- 22 (3) DEPARTMENT DUTIES.[✓] The department shall do all of the following:
- 23 (a) Establish and maintain an up-to-date registry that documents the
- 24 diagnosis and treatment in this state of any infant or child who has a birth defect,

1 regardless of the residence of the infant or child. The department shall include in
2 the registry information that will facilitate all of the following:

3 1. Identification of risk factors for birth defects.

4 2. Investigation of the causes and prevalence of birth defects.

5 3. Development of preventive strategies to decrease the occurrence of birth
6 defects.

7 4. Analysis of the incidence, prevalence and trends in birth defects through
8 epidemiological studies.

9 5. Investigation of the morbidity and mortality rates resulting from birth
10 defects.

11 (b) Specify by rule the conditions the existence of which requires a report under
12 sub. (2) to be submitted to the department.

***NOTE: What kind of conditions? Health conditions?

13 (c) Specify by rule the content, format and procedures for submitting a report
14 under sub. (2).

15 (d) Investigate the causes of birth defects and design and evaluate measures
16 to prevent the occurrence of birth defects. The department may conduct
17 epidemiological or toxicological investigations of specific birth defect cases to
18 determine the nature and extent of the known or suspected cause of the birth defect
19 and to formulate and evaluate control measures to protect the public health. The
20 department's investigation may include geographic, temporal, occupational and past
21 exposures. Designs and protocols of the investigations are subject to approval by an
22 approved human subjects review board.

***NOTE: What is a human subjects review board and by whom must it be approved? Also, I'm not sure I understand the department's duty under this paragraph. Is there a reason that you think you need specific reference to the type of exposures the department is authorized to investigate?

1 (4) CONFIDENTIALITY. (a) Except as provided in pars. (b) to (e), the department
2 may not release information that is obtained from reports submitted under sub. (2)
3 that specifically identifies an infant or child.

4 (b) Upon written receipt of a request from the parent or guardian of an infant
5 or child who is the subject of a report submitted under sub. (2), the department shall
6 release the contents of that report to the parent or guardian.

7 (c) The department may release information obtained from reports submitted
8 under sub. (2) that specifically identifies an infant or child to health officials of
9 another state if the infant or child resides in that state and the department has
10 entered into a reciprocal agreement with that state for the provision of information
11 regarding birth defects in infants or children. An agreement entered into by the
12 department with that other state shall provide for the confidentiality of information
13 that specifically identifies an infant or child.

14 (d) The department may release information obtained from reports submitted
15 under sub. (2) that specifically identifies an infant or child to the federal centers for
16 disease control and prevention.

17 (e) The department may release information obtained from reports submitted
18 under sub. (2) that specifically identifies an infant or child to a person with a valid
19 scientific interest who is engaged in approved demographic, epidemiological or other
20 studies or a program related to birth defects if the person requests the information
21 in writing and agrees in writing to maintain the confidentiality of that information.

22 SECTION ⁹¹²³~~9123~~. Nonstatutory provisions; health and family services. ↓

23 (1) BIRTH DEFECT PREVENTION AND SURVEY SYSTEM ADVISORY COMMITTEE.

24 (a) *Composition.* The secretary of health and family services shall establish a
25 committee under section 15.04 (1) (c) of the statutes to advise the department of

1 health and family services in establishing a birth defects registry under section
2 253.12 (3) (a) of the statutes, as created by this act, and in drafting the rules required
3 to be promulgated under section 253.12 (3) (b) and (c) of the statutes, as created by
4 this act. The committee shall consist of all of the following appointed by the secretary
5 of health and family services:

6 1. Representatives nominated by the University of Wisconsin Medical School,
7 the Medical College of Wisconsin, the lead agencies for public health and the medical
8 assistance program, the State Medical Society of Wisconsin, the Academy of
9 Pediatrics–Wisconsin Affiliate, the Waisman Center or other genetic specialty clinic
10 and the program director.

11 2. Two consumer representatives.

12 (b) *Duties.* The birth defect prevention and survey system advisory committee
13 shall advise the department of health and family services regarding the
14 establishment of a registry that documents the diagnosis and treatment in the state
15 of an infant or child under the age of 6 who has a birth defect, as required under
16 section 253.12 (3) (a) of the statutes, as created by this act, and regarding the rules
17 that the department is required to promulgate under section 253.12 (3) (b) and (c) of
18 the statutes, as created by this act. The department of health and family services
19 shall consult with the birth defect prevention and survey system advisory committee
20 prior to establishing the registry under section 253.12 (3) (a) of the statutes, as
21 created by this act and prior to promulgating the rules under section 253.12 (3) (b)
22 and (c) of the statutes, as created by this act.

23 (END)

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

0177/P1dn
LRB-5289/P1dn

TAY:jlg:km

↑
stays

Wednesday, August 19, 1998 } new date

→ 1. This draft is identical to, and replaces, 1997 LRB-5289/P1. Please refer to this draft when requesting changes to it.

2. I did not include the legislative intent provisions that were included in the model legislation. Generally, we no longer draft statements of legislative intent or purpose except for recodification bills or in instances in which constitutionality is at issue. This policy has evolved to avoid redundancy to or conflict with statutory provisions, to avoid use of undefined terms, to forestall certain unforeseen effects in interpretation that such a statement may cause and to avoid the inclusion of promotional language in the statutes that may be subject to later misinterpretation. Instead, I have incorporated the provisions of the purpose statement into s. 253.12 (3) (a). Please review that provision to ensure that it comports with your intent.

3. In identifying the conditions that define a birth defect, the proposed statutory language lists "a developmental disability as specified under s. 51.01 (5) (a) due to a birth defect." Since "birth defect" is the very term being defined, it is confusing to use the term in the definition. I have attempted to clarify that part of the definition, but I am uncertain whether I've captured the department's intent. Therefore, please review s. 253.12 (1) (a) 3., as created in this draft, carefully.

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Legislative Attorney
261-6927

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0178/P1dn
TAY:jlg:lp

September 16, 1998

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261-6927

OSF

**Department of Health and Family Services
Office of Strategic Finance**

PO Box 7850
Madison WI 53707-7850
Phone (608) 266-3816
Fax (608) 267-0358

Date: October 17, 1998
To: Tina Yacker
Legislative Reference Bureau
From: Ellen Hadidian *EH*
Budget Section
Subject: LRB 0178

Attached you will find comments from Department of Public Health staff on this draft, which concerns the implementation of a statewide birth defects prevention and surveillance system. Please call me at 6-8155 if you have questions about our request or if you would like more information.

cc: Sue Jablonsky
Mike Bormett
Sharon Fleischfresser

COMMENTS RELATED TO LRB-0178/1
BIRTH DEFECTS PREVENTION AND SURVEILLANCE SYSTEM - 253.12

Overview of intent

The intent of this legislation is to implement a statewide birth defects prevention and surveillance system. In summary changes would:

- focus on reporting by hospitals, pediatric specialty clinics, genetic specialty clinics, laboratories that identify or confirm a birth defect as the result of a laboratory analysis instead of individual providers. The legislation should allow for individual physician reporting in the case where a report has not been made by the above. The legislation should allow for department access to information contained in medical record of patients with a confirmed or suspected birth defect diagnosis.
- focus reporting on infant or child to the age of two years.
- maintain confidentiality intent and add provisions related to research consistent with those proposed as part of the 255.04 (Cancer registry)
- provide a mechanism for the Wisconsin Program for Children with Special Health Care Needs to refer families to resources

-creation of advisory council composed of experts in public health, health care financing, pediatrics

Line by line review:

Page 1

Line 3: change survey to surveillance.
Centers for Disease Control and Prevention

Page 2

Line 1: A structural deformation, disrupt

Line 2: Okay

Lines 3-4: Strike.

Line 5: *ADD*: Genetic specialty clinic means a clinic whose primary focus is to provide diagnostic, counseling, and medical management services to those with birth defects and genetics disorders and their families by medical geneticists and genetic counselors.

ADD: Pediatric specialty clinic means a clinic whose primary focus is provide pediatric specialty diagnostic, counseling, and medical management services to those with birth

ped. spec. clinic
not nec to def.
b/c subsumed in
def. of genetic
Spec. clinic
+ "genetic disorders" is
part of def. of birth defect
NCSL
Your Legislative Support System

defects and genetics disorders by physician subspecialists. Examples include a craniofacial clinic, spina bifida clinic, neurodevelopmental or child development diagnostic clinic.

✓ Line 6: "Physician" means a person licensed to practice medicine or osteopathy under ch.448, Stats.

✓ Line 7: change age of 6 years to age of 2 years.

Line 10: A hospital or genetic specialty clinic or pediatric specialty clinic

Line 12: A physician who diagnoses the birth defect or provides treatment to the infant or child for the birth defect who is not receiving or has not received services from a genetic specialty clinic, pediatric specialty clinic. *(I am uncertain how to write this section to allow for reporting by the health care provider in those cases when the child would otherwise not be reported by the other sources but not to routinely require reporting.)*

ADD: If the hospital, pediatric specialty clinic, or genetic specialty clinic has submitted a report, the physician is not required to file a report.

Line 14: Intent was to require reporting from all labs that identify infants/children with birth defects, not limited to labs that specialize in this (if any). Suggest " A clinical

defects and genetics disorders by physician subspecialists. Examples include a craniofacial clinic, spina bifida clinic, neurodevelopmental or child development diagnostic clinic.

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✓ Line 14: Intent was to require reporting from all labs that identify infants/children with birth defects, not limited to labs that specialize in this (if any). Suggest "A clinical laboratory that identifies or confirms a birth defect in an infant or child as the result of laboratory analysis."

✓ Line 16 -17: Strike

✓ Line 18: *Upon request of the department a physician, hospital, pediatric specialty clinic, genetic specialty clinic shall...*

✓ Line 20: confirmed or suspected

✓ Lines 20-21. Intent was to require the department to give advance notification. Suggest "The department shall allow the physician, hospital, genetic specialty clinic, or pediatric specialty clinic, a minimum of 10 working days to assemble and make available the requested information."

Line 24: Strike "and treatment".

Page 3

Lines 3-10:

Line 3: Leave as is.

Lines 4: Change to: Investigation of the incidence, prevalence, and trends in birth defects using epidemiological surveys.

Line 5-6: Leave as is.

Lines 7-10. Strike 4. and 5.

Line 11: The "condition" referred to be birth defects. Suggest: Specify by rule the birth defects the existence of which require a report under sub (2) to be submitted to the department.

Line 15 - 22: Strike (Note Jean Gilpin's comment "the investigation authority proposed for (3)(d) on page 3 seems to overlap the DHFS authority under s. 250.04(3) to conduct investigations.)

Page 4 (The following is taken from existing BDOMP and proposed revisions to 255.04

(4) CONFIDENTIALITY: Any information reported to the department under sub. (2) which could identify any individual who is the subject of the report shall be confidential and may not be disclosed by the department except as provided in this section. No subpoena, court order, or administrative order shall be issued to compel the department to produce or disclose the confidential information. Any subpoena, court order, or administrative order issued contrary to this subsection shall be void. The department may disclose the confidential information to any of the following:

(a) ~~Upon written receipt of a request from the parent or guardian of an infant or child who is the subject of a report submitted under sub. (2), the department shall release the contents of that report to the parent or guardian~~ ^{to the}

(b) To a physician, hospital, pediatric specialty clinic or genetic specialty clinic reporting under sub. (2), for the purpose of verification of information reported by the physician, hospital, or clinic.

(c) To a representative of a federal or state agency, upon written request, information necessary to perform a legally authorized function of that agency, including investigation of causes, mortality, methods of prevention, treatment or care of birth defects, associated diseases or disabilities, except that 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 ^{paragraph} ~~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.

~~(d) To the Wisconsin Program for Children with Special Health Care Needs in the department, upon request, the name and address of an infant or child for whom a report is~~

~~made under sub. (2) and other information necessary to aid in providing services to the infant or child. 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 Wisconsin Program for Children with Special Health Care Needs may disclose information received under this paragraph only as necessary to provide services to the infant or child.~~

☛ To a local health officer:

1. If a local health officer submits to the department a written request for receipt of information submitted under sub. (2), the department shall forward to the local health officer an abstract of information received for an infant or child for whom the parent or guardian has provided informed, written consent to a release of the information and who resides in the area of jurisdiction of the local health officer.

2. The local health officer may disclose information in the abstract only as necessary to aid that local health officer in rendering or coordinating follow-up care for the infant or child or for conducting a health, demographic or epidemiological investigation. The local health officer shall destroy all information obtained no later than 365 days after he or she receives it, except that this requirement does not apply to information, including individual medical records, obtained by the local health officer subsequent to his or her receipt of information under this paragraph.

☛ An organization or institution proposing to conduct research, but only under the following circumstances:

1. The researchers shall apply to the department for approval to perform the requested research. No access to the confidential information shall occur unless the research project has received the department's approval;

2. The research shall be for the purpose of studies in connection with birth defects surveillance and prevention;

3. Any request for approval of a research project shall include a written protocol for the proposed research project, the researchers' professional qualifications to perform the proposed research, and any other information or documentation as requested by the department;

4. If the research involves direct contact with individuals who are the subjects or reports under sub (2) or with members of the individual's families, the department shall not approve the research unless the department has determined that the contact is necessary for meeting the research objectives and unless the project:

a. Is in response to a public health need; is for the purpose of birth defects surveillance or investigations sponsored and conducted by public health officials; or is otherwise designed in connection with birth defects surveillance and prevention. and

b. has been approved by a certified institutional review board or a committee for the protection of human subjects in accordance with the regulations for research involving human subjects required by the U.S. Department of Health and Human Services for projects supported by that agency;

5. the researchers shall not contact individuals who are the subjects of reports under sub. (2) or members of their families except in the manner and by the methods reviewed and approved by the department under this paragraph; and

6. The researchers shall enter into a written agreement with the department that includes the conditions imposed by the department for the research. The written agreement shall include the researchers' assurances that the information will be used only for the approved study for which it was provided to the researchers, the confidential information will not be released to any person except those researchers who are part of the approved study, and the final product of the research will not reveal information that may serve to identify any individual whose information is being released. The researchers shall comply with all terms of the written agreement.

Page 5:

The intent of the program is establishing a permanent advisory body; therefore, the "committee" would become a "council." The program director is the department person responsible for directing the birth defect prevention and surveillance system program. The Council members would represent the perspective of their home organizations.

Lines 6 -11: We suggest membership limited to no more than 15 persons. Representation should include: persons with technical expertise in the birth defects epidemiology from the University of Wisconsin Medical School and the Medical College of Wisconsin, the lead

agencies for public health and the Medical Assistance program, health care information (Bureau of Information Systems, Division of Health Care Financing), the Wisconsin State Medical Society, the American Academy of Pediatrics - Wisconsin Chapter

Lines 9 - 10 should read: Pediatrics-Wisconsin Chapter, certified geneticists and genetic counselors practicing in the state and the program director, and, two consumers: one from a non-profit organization whose primary purpose is the prevention of birth defects, the other a parent or guardian of a child with birth defects;

Line 9: strike "the Waisman Center"

Line 12: replace committee with council

Line 15: under the age of 2 years

Line 19: replace committee with council



(soon) (DRAFT)
State of Wisconsin
1999 - 2000 LEGISLATURE

LRB-0178/PR /

TAY:jlg:lp

(stays) ↑
RMR

(req. sheet has been changed)

DOA:..... Geisler - Birth outcome program

FOR 1999-01 BUDGET — NOT READY FOR INTRODUCTION

do not
refer

1 AN ACT ...; relating to: the budget.

Analysis by the Legislative Reference Bureau

HEALTH AND SOCIAL SERVICES HUMAN

HEALTH

This is a preliminary draft. An analysis will be provided in a later version.

USERT
NAL ✓

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

USERT
1-2 ✓

2 SECTION 1. 253.12 of the statutes is repealed and recreated to read:

3 253.12 Birth defect prevention and ~~survey~~ ^{surveillance} system. (1) DEFINITIONS. In

4 this section:

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

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

- 1 1. A structural deformation, ^{disruption or dysplasia}
- 2 2. A genetic, inherited or biochemical disease.
- 3 3. A developmental disability, as defined in s. 51.01(5)(a), that is caused by a
- 4 condition specified in subd. 1. or 2.

5 (b) "Genetic specialty clinic" means ~~xxx???~~ ^{a clinic the primary purpose of which is to provide diagnostic, counseling and medical management services to}

6 (c) "Health care provider" has the meaning given in s. 146.81(1) ^{persons with birth defects and to their families}

7 (d) "Infant or child" means a human being from birth to the age of 18 years, ^{except as provided in par. (b),}

8 (2) REPORTING. (a) ^{by medical geneticists and genetic counselors} All of the following shall report in the manner prescribed

9 by the department under sub. (3) (c) a birth defect in an infant or child:

- 10 1. A hospital or genetic specialty clinic in which the birth defect is diagnosed
- 11 in an infant or child or treatment for the birth defect is provided to the infant or child.
- 12 2. A ~~health care provider~~ ^{physician} who diagnoses the birth defect or provides treatment
- 13 to the infant or child for the birth defect.
- 14 3. A clinical laboratory that ~~performs tests that identify~~ ^{identifies} a birth defect in the
- 15 infant or child. ^{as the result of laboratory analysis}
- 16 4. The custodian of any registry within this state that includes information on
- 17 an infant or child with birth defects. ^{physician, hospital (or genetic specialty clinic)}

18 (b) Upon request of the department, a ~~health care provider~~ ^{physician} shall provide to the

19 department information contained in the medical records of patients who have a

20 confirmed ^{or suspected} birth defect diagnosis. The ~~health care provider~~ ^{physician} shall provide that

21 information within 10 working days after the department requests it.

22 (3) DEPARTMENT DUTIES. The department shall do all of the following:

- 23 (a) Establish and maintain an up-to-date registry that documents the
- 24 diagnosis ~~and treatment~~ ^{in this state} of any infant or child who has a birth defect,

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

1 regardless of the residence of the infant or child. The department shall include in
2 the registry information that will facilitate all of the following:

- 3 1. Identification of risk factors for birth defects.
- 4 2. Investigation of the ~~causes and~~ ^{incidentally} prevalence of birth defects. ^{and trends} ^{using epidemiological surveys}
- 5 3. Development of preventive strategies to decrease the occurrence of birth
6 defects.

7 4. Analysis of the incidence, prevalence and trends in birth defects through
8 epidemiological studies.

9 5. Investigation of the morbidity and mortality rates resulting from birth
10 defects.

11 (b) Specify by rule the ~~conditions~~ ^{birth defects} the existence of which requires a report under
12 sub. (2) to be submitted to the department.

***NOTE: What kind of conditions? Health conditions?

✓ 13 (c) Specify by rule the content, format and procedures for submitting a report
14 under sub. (2).

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15 (d) Investigate the causes of birth defects and design and evaluate measures
16 to prevent the occurrence of birth defects. The department may conduct
17 epidemiological or toxicological investigations of specific birth defect cases to
18 determine the nature and extent of the known or suspected cause of the birth defect
19 and to formulate and evaluate control measures to protect the public health. The
20 department's investigation may include geographic, temporal, occupational and past
21 exposures. Designs and protocols of the investigations are subject to approval by an
22 approved human subjects review board.

***NOTE: What is a human subjects review board and by whom must it be approved? Also, I'm not sure I understand the department's duty under this paragraph. Is there a reason that you think you need specific reference to the type of exposures the department is authorized to investigate?

⑤→5

INSERT

4-1

1 (4) CONFIDENTIALITY. (a) Except as provided in pars. (b) to (e), the department
2 may not release information that is obtained from reports submitted under sub. (2)
3 that specifically identifies an infant or child.

4 (b) Upon written receipt of a request from the parent or guardian of an infant
5 or child who is the subject of a report submitted under sub. (2), the department shall
6 release the contents of that report to the parent or guardian.

7 (c) The department may release information obtained from reports submitted
8 under sub. (2) that specifically identifies an infant or child to health officials of
9 another state if the infant or child resides in that state and the department has
10 entered into a reciprocal agreement with that state for the provision of information
11 regarding birth defects in infants or children. An agreement entered into by the
12 department with that other state shall provide for the confidentiality of information
13 that specifically identifies an infant or child.

14 (d) The department may release information obtained from reports submitted
15 under sub. (2) that specifically identifies an infant or child to the federal centers for
16 disease control and prevention.

17 (e) The department may release information obtained from reports submitted
18 under sub. (2) that specifically identifies an infant or child to a person with a valid
19 scientific interest who is engaged in approved demographic, epidemiological or other
20 studies or a program related to birth defects if the person requests the information
21 in writing and agrees in writing to maintain the confidentiality of that information.

22 ~~SECTION 9123. Nonstatutory provisions; health and family services.~~

23 (1) BIRTH DEFECT PREVENTION AND SURVEY SYSTEM ADVISORY COMMITTEE.

24 (a) *Composition.* The secretary of health and family services shall establish a
25 committee under section 15.04 (1) (c) of the statutes to advise the department of

1 health and family services in establishing a birth defects registry under section
 2 253.12 (3) (a) of the statutes, as created by this act, and in drafting the rules required
 3 to be promulgated under section 253.12 (3) (b) and (c) of the statutes, as created by
 4 this act. The committee shall consist of all of the following appointed by the secretary
 5 of health and family services:

6 1. Representatives nominated by the University of Wisconsin Medical School,
 7 the Medical College of Wisconsin, the lead agencies for public health and the medical
 8 assistance program, the State Medical Society of Wisconsin, the Academy of
 9 Pediatrics Wisconsin Affiliate, the ~~Waisman Center~~ ^{other} genetic specialty clinic
 10 and the program director.

11 ~~Two consumer representatives~~ ^{surveillance, created under s. 15.197(12)}
~~COUNCIL ON~~

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*

12 (b) ~~Duties~~. The birth defect prevention and ~~survey system advisory committee~~
 13 shall advise the department of ~~health and family services~~ regarding the
 14 establishment of a registry that documents the diagnosis and treatment in the state
 15 of an infant or child ~~under the age of 6~~ who has a birth defect, as required under
 16 section ~~253.12~~ ^{Sub.} (3) (a) of the statutes, as created by this act, and regarding the rules
 17 that the department is required to promulgate under section ~~253.12~~ ^{Sub.} (3) (b) and (c) of
 18 the statutes, as created by this act. The department of ~~health and family services~~
 19 shall consult with the ~~birth defect prevention and survey system advisory committee~~ ^{Council on surveillance}
 20 prior to establishing the registry under section ~~253.12~~ ^{Sub.} (3) (a) of the statutes, as
 21 created by this act and prior to promulgating the rules under section ~~253.12~~ ^{Sub.} (3) (b)
 22 and (c) of the statutes, as created by this act.

23 (END) ✓

(3)
 (4) COUNCIL ON BIRTH DEFECT PREVENTION AND SURVEILLANCE
 CS

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FROM THE
LEGISLATIVE REFERENCE BUREAU

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DHFS must also

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 ~~data and~~ information, publish an annual report, ~~submit the report annually to the chief clerk of each house of the legislature to counties in this state on the results of the information collected through the reports.~~ DHFS must ~~also~~ coordinate data dissemination activities of the department with those of the division for learning support, equity and advocacy in the department of public instruction (DPI) 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.

the

identified

This bill replaces BDOMP with a program that requires ~~reports of certain birth defects in children under the age of two to be made to DHFS by physicians, hospitals or clinics that primarily provide diagnostic, counseling and medical services to persons with birth defects, and clinical laboratories that identify birth defects.~~ 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.

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P physicians, hospitals, certain clinics
and laboratories
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FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0178/lins1-2
TAY.....

INSERT 1-2

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

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 health programs.

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

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

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

(g) A representative of the American Academy of Pediatrics[✓] — Wisconsin chapter.

(h) A representative of a non^gprofit organization that has as its primary purpose the prevention of birth defects.

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

(end ins)

INSERT 4-1

Section #. 253.12 (5) (a) of the statutes is amended to read:

(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.

253.12 (5) (a) The department may not release information specifically identifying an infant or child that is obtained from reports under sub. (2), except to the following, under the following conditions:

1. To the parent or guardian of an infant or child for whom a report is made under sub. (2), upon receipt of a written request from the parent or guardian.

2. To a local health officer, under sub. (6), upon receipt of a written request and informed written consent from the parent or guardian of the infant or child. The local health officer may

~~3. To the division for learning support, equity and advocacy in the department of public instruction, upon request, the name and address of an infant or child for whom a report is made under sub. (2) and other information necessary to aid the division in providing services to the infant or child. 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 division for learning support, equity and advocacy in the department of public instruction may disclose information received under this paragraph only as necessary to provide services to the infant or child.~~

3. To a physician or nurse reporting under sub. (2), for the purpose of verification of information reported by the physician or nurse. (hospital or genetic specialty clinic)

4. To a representative of a federal or state agency upon written request, information necessary 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, treatment or care of birth defects, associated diseases or disabilities, except that 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.

disclose information received under this subdivision only to the extent necessary to render and coordinate 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. yacketa (1/16/98) Wed Dec 2 1998 5:14 pm

1999-2000 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0178/lins4-1
TAY.....

§ (b) The department [✓] may also release confidential information to

insert 4-1 (cont.)

§ A person proposing to conduct research if all of the following conditions are met:

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

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

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

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

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

6. ~~A~~ The person agrees in writing that the final product of the research will not reveal information that may specifically identify the subject of a report made under sub. (2).[✓]

7. ~~A~~ The person agrees in writing to any other conditions imposed by the department.

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRB-0178/1dn

TAY.....
↑
JG

Sue Jablonsky:

I did not, as the department requested, define "pediatric specialty clinic" because it seemed like a subset of a genetic specialty clinic. The definition of "genetic specialty clinic" is broad enough to encompass a pediatric specialty clinic, at least as the department has defined the terms. Also, the department's definition of "genetic specialty clinic" included the phrase, "birth defects and genetic disorders." Since "genetic disorders" is included in the definition of birth defects, I did not include it.

It was still unclear how exactly the department wanted to structure the council on birth defects and genetic disorders. Please review s. 15.197 (12), as created in this draft, to determine if that effects the department's intent.

If you have any questions, please give me a call.

Tina A. Yacker
Legislative Attorney
261-6927

↓
Finally, please review the confidentiality provisions to ensure that I captured the department's intent. ~~There was~~

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRB-0178/1dn
TAY:jlg:jf

December 10, 1998

Sue Jablonsky:

I did not, as the department requested, define "pediatric specialty clinic" because it seemed like a subset of a genetic specialty clinic. The definition of "genetic specialty clinic" is broad enough to encompass a pediatric specialty clinic, at least as the department has defined the terms. Also, the department's definition of "genetic specialty clinic" included the phrase, "birth defects and genetic disorders." Since "genetic disorders" is included in the definition of birth defects, I did not include it.

It was still unclear how exactly the department wanted to structure the council on birth defects and genetic disorders. Please review s. 15.197 (12), as created in this draft, to determine if that effects the department's intent.

Finally, please review the confidentiality provisions to ensure that I captured the department's intent.

If you have any questions, please give me a call.

Tina A. Yacker
Legislative Attorney
261-6927

Yacker, Tina

From: Jablonsky, Sue [sue.jablonsky@doa.state.wi.us]
Sent: Thursday, January 21, 1999 8:46 AM
To: Yacker, Tina
Subject: FW: LRB 0178 - Birth Outcome Program



Birth Defects Surveillance.doc...

i could now open this-hope you can too

> -----Original Message-----

> From: Hadidan, Ellen
> Sent: Thursday, January 21, 1999 7:02 AM
> To: Jablonsky, Sue
> Subject: RE: LRB 0178 - Birth Outcome Program

>
> ok - I resaved the attachment, see whether you can open now.

>
> >>> Sue Jablonsky 01/20 5:10 PM >>>
> i can't open this

> -----Original Message-----

> From: Hadidan, Ellen
> Sent: Wednesday, January 20, 1999 10:15 AM
> To: Jablonsky, Sue
> Subject: LRB 0178 - Birth Outcome Program

>
> Attached are program and legal counsel comments on this draft requests for
> changes to the drafts. Could you please forward this to the drafter?
> Program
> staff also faxed me a copy of the language with their changes in it and
> I'll
> make a copy of that for you.
> << File: Birth Defects Surveillance.mlm >>
> <<Birth Defects Surveillance.doc>>

1. The language related to pediatric specialty clinic included in the previous draft should be maintained. A genetic specialty clinic may in fact be thought of as a type of pediatric specialty clinic.

2. Council - page 5

line 4 - change to read "created under s.15.197 (12), shall make recommendations to the department..."

line 8 - strike "The department shall consult with the council on birth defect prevention and surveillance prior to establishing the registry under sub. (3) (a) and prior to promulgating the rules under sub. (30 (b) and (c))."

3. The proposed legislation is a passive system. The Department should also have the ability to in some way assure the quality of the data that is reported. Does this draft allow us to monitor reporting for quality improvement purposes or do we need language authorizing us to do so? Program staff have submitted a paragraph description of the process in New Jersey which also has a passive reporting system but whose department does medical record abstraction as part of its monitoring of the quality of data reported as an example of what they would like to see in Wisconsin.

One suggestion was to include under (2) Reporting on page 4 line 14 a (d) language that describes this ability of the Department. It was also suggested that 146.82 be amended to cross reference the BDS statute within its exceptions.

(50071) (D-NOTE)

1999 - 2000 LEGISLATURE

LRB-0178/42

TAY:jl:gjf

DOA:.....Jablonsky – Birth outcome program

FOR 1999-01 BUDGET — NOT READY FOR INTRODUCTION

1 *do not gen*
AN ACT ...; relating to: the budget.

Analysis by the Legislative Reference Bureau

HEALTH AND HUMAN SERVICES

HEALTH

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 (DPI) 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 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.

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

2 (g) A representative of the American Academy of Pediatrics — Wisconsin
3 chapter.

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

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

INSERT
3-6

7 SECTION 2. 253.12 of the statutes is repealed and recreated to read:

8 **253.12 Birth defect prevention and surveillance system. (1)**

9 DEFINITIONS. In this section:

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

13 1. A structural deformation, disruption or dysplasia.

14 2. A genetic, inherited or biochemical disease.

15 (b) "~~Genetic~~^{pediatric} specialty clinic" means a clinic the primary purpose of which is to
16 provide ~~diagnostic, counseling and medical management services to persons with~~^{pediatric specialty}
17 birth defects ~~and to their families by medical geneticists and genetic counselors~~^{by physician subspecialist}

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

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

20 (2) REPORTING. (a) Except as provided in par. (b), all of the following shall report
21 in the manner prescribed by the department under sub. (3) ~~(a) 3.~~^{✓ (a) 3.} a birth defect in an
22 infant or child:

23 1. A hospital or ~~genetic~~^{pediatric} specialty clinic in which the birth defect is diagnosed
24 in an infant or child or treatment for the birth defect is provided to the infant or child.

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

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

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

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

14 (3) DEPARTMENT DUTIES. ^{(CS) AND POWERS (a) ✓} The department shall do all of the following:

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

19 ^{a.} 1. Identification of risk factors for birth defects.

20 ^{b.} 2. Investigation of the incidence, prevalence and trends of birth defects using
21 epidemiological surveys.

22 ^{c.} 3. Development of preventive strategies to decrease the occurrence of birth
23 defects.

24 ^{2.} 4. Specify by rule the birth defects the existence of which requires a report
25 under sub. (2) to be submitted to the department.

make recommendations to

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

3 (4) COUNCIL ON BIRTH DEFECT PREVENTION AND SURVEILLANCE. The council on
4 birth defect prevention and surveillance, created under s. 15.197 (12), shall ~~advise~~
5 the department regarding the establishment of a registry that documents the
6 diagnosis and treatment in the state of an infant or child who has a birth defect, as
7 required under sub. (3) (a) and regarding the rules that the department is required

8 to promulgate under sub. (3) ~~(a)~~ and ~~(b)~~ ^(a, 2, 3). The department shall consult with the
9 ~~council on birth defect prevention and surveillance prior to establishing the registry~~
10 ~~under sub. (3) (a) and prior to promulgating the rules under sub. (3) (b) and (d).~~

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

- 15 1. The parent or guardian of an infant or child for whom a report is made under
16 sub. (2).
- 17 2. A local health officer, upon receipt of a written request and informed written
18 consent from the parent or guardian of the infant or child. The local health officer
19 may disclose information received under this subdivision only to the extent
20 necessary to render and coordinate follow-up care for the infant or child or to conduct
21 a health, demographic or epidemiological investigation. The local health officer shall
22 destroy all information received under this subdivision within one year after
23 receiving it.

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

1 3. A physician, hospital or ~~genetic~~^{pediatric} specialty clinic reporting under sub. (2), for
2 the purpose of verification of information reported by the physician, hospital or
3 ~~genetic~~^{pediatric} specialty clinic.

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

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

16 1. The person proposing to conduct the research applies in writing to the
17 department for approval to perform the research and the department approves the
18 application. The application for approval shall include a written protocol for the
19 proposed research, the person's professional qualifications to perform the proposed
20 research and any other information requested by the department.

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

23 3. If the research will involve direct contact with a subject of a report made
24 under sub. (2) or with any member of the subject's family, the department determines
25 that the contact is necessary for meeting the research objectives and that the

1 research is in response to a public health need or is for the purpose of or in connection
2 with birth defects surveillance or investigations sponsored and conducted by public
3 health officials. The department must also determine that the research has been
4 approved by a certified institutional review board or a committee for the protection
5 of human subjects in accordance with the regulations for research involving human
6 subjects required by the federal department of health and human services for
7 projects supported by that agency. Contact may only be made in a manner and
8 method approved by the department.

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

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

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

16 7. The person agrees in writing to any other conditions imposed by the
17 department.

18 (END)

(INSERT 3-6)

Section #. 146.82 (1) [✓] of the statutes is amended to read:

1253.12 (2) ✓

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 or 979.01 or testimony authorized under s. 905.04 (4) (h).

History: 1979 c. 221; 1983 a. 398; 1985 a. 29, 241, 332, 340; 1987 a. 40, 70, 127, 215, 233, 380, 399; 1989 a. 31, 102, 334, 336; 1991 a. 39; 1993 a. 16, 27, 445, 479; 1995 a. 98, 169, 417; 1997 a. 35, 114, 231, 272, 292, 305; s. 13.93 (1) (b).

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRB-0178/2dn

TAY:

JLg

Sue Jablonsky:

This draft leaves the reporting process to the department to determine by rule. I see no reason that monitoring data couldn't be part of that process. However, although I don't believe it's necessary to specify that the department may monitor the data provided through the reports, I have nevertheless included the language requested. Let me know if it satisfies the department's intent.

Also, please note that I have changed the term "genetic specialty clinic" to "pediatric specialty clinic" and used the definition provided by the department for that term. If, as the department asserts, a genetic specialty clinic is a subset of a pediatric specialty clinic, there is no need to include both terms.

If you have any questions, feel free to call me.

Tina A. Yacker
Legislative Attorney
261-6927

Yacker, Tina

From: Jablonsky, Sue
Sent: Monday, February 08, 1999 3:20 PM
To: Yacker, Tina
Subject: RE: LRB-0178 (birth outcome program)

It's fine as it is--he hates having his power to choose restricted so my guess is he'd not like it that he'd have to accept the person nominated by the entity.

-----Original Message-----

From: Yacker, Tina
Sent: Monday, February 08, 1999 2:35 PM
To: Jablonsky, Sue
Subject: LRB-0178 (birth outcome program)

Sue:

Jeff Kuesel and Peter Dykman, upon review of the budget drafts, have both pointed out an ambiguity in LRB-0178. As drafted, the members of the Council on Birth Defect Prevention and Surveillance will be appointed by the Governor since under s. 15.09 1) (a) "unless otherwise provided by law, the governor shall appoint the members of councils for terms prescribed by law." Thus, as drafted, the governor will determine who the representatives from each specified entity will be. Is that ok? Should the Governor be directed to appoint the representatives selected by the specified entities? Let me know and I will surely change the draft and the budget bill to effect that change.

-- Tina

Tina Yacker, Legislative Attorney
Wisconsin Legislative Reference Bureau
P.O. Box 2037
Madison, WI 53701-2037
(608) 261-6927

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRB-0178/2dn
TAY:jlg:hmh

Thursday, January 21, 1999

Sue Jablonsky:

This draft leaves the reporting process to the department to determine by rule. I see no reason that monitoring data couldn't be part of that process. However, although I don't believe it's necessary to specify that the department may monitor the data provided through the reports, I have nevertheless included the language requested. Let me know if it satisfies the department's intent.

Also, please note that I have changed the term "genetic specialty clinic" to "pediatric specialty clinic" and used the definition provided by the department for that term. If, as the department asserts, a genetic specialty clinic is a subset of a pediatric specialty clinic, there is no need to include both terms.

If you have any questions, feel free to call me.

Tina A. Yacker
Legislative Attorney
261-6927



State of Wisconsin
1999 - 2000 LEGISLATURE

LRB-0178/2
TAY:jlg:jf

DOA:.....Jablonsky - Birth outcome program

FOR 1999-01 BUDGET -- NOT READY FOR INTRODUCTION

1 AN ACT ...; relating to: the budget.

Analysis by the Legislative Reference Bureau
HEALTH AND HUMAN SERVICES

HEALTH

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 (DPI) 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 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.

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

2 (g) A representative of the American Academy of Pediatrics — Wisconsin
3 chapter.

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

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

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

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

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

15 **253.12 Birth defect prevention and surveillance system. (1)**

16 **DEFINITIONS.** In this section:

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

20 1. A structural deformation, disruption or dysplasia.

21 2. A genetic, inherited or biochemical disease.

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

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

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

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

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

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

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

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

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

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

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

1 a. Identification of risk factors for birth defects.

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

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

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

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

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

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

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).

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

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

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

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

23 1. The person proposing to conduct the research applies in writing to the
24 department for approval to perform the research and the department approves the
25 application. The application for approval shall include a written protocol for the

1 proposed research, the person's professional qualifications to perform the proposed
2 research and any other information requested by the department.

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

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

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

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

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

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

25

(END)