1999 DRAFTING REQUEST

Assembly Amendment (AA-ASA1-AB133)

Received: **06/23/99**	Received By: **yacketa**
Wanted: **As time permits**	Identical to LRB:
For: **Senate Democratic Caucus 6-2257**	By/Representing: **Walter**
This file may be shown to any legislator: **NO**	Drafter: **yacketa**
May Contact:	Alt. Drafters:
Subject: **Health - miscellaneous**	Extra Copies: **DAK**

Pre Topic:

SDC:......Walter - #3205,

Topic:

Birth defects and outcome monitoring

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?	yacketa 06/27/99	jgeller 06/27/99		_______ _______			
/1			mclark 06/28/99	_______ _______	lrb_docadmin 06/28/99		

FE Sent For:

<END>

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/?	yacketa	/1 6/27 jlg	6/28 mrc	cmh/RJM 6/28			

FE Sent For:

<END>

yes

caucus number 2635

duplicate flag:

duplicate with:

Other reference numbers: Paper 510

LFB Sum #: pages 398-402

bill number/amendment number:

LRB draft #

LRB P-draft:

description: Repeal requirement that premiums collected from HIRSP policyholders must equal 60% of the plan costs and that providers must each provide 50% of the remaining 40% of the plan costs. Instead, establish max premium cost at 150% of cost for standard plan.

other notes

drafting instructions: see above. And add that insurers and providers each provide 50% of the remaining plan costs.

more instructions:

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caucus number 3205

duplicate flag:

duplicate with:

Other reference numbers:

FM 1165

LFB Sum #: page 295

bill number/amendment number:

LRB draft #

LRB P-draft:

description: Provides additional GPR for birth defects and outcome monitoring program. Includes provisions to create a birth defect prevention surveillance system

other notes 33,000 99-01 67,000 00-01 ($100,000) TOTAL

drafting instructions: Provide ~~$200,000 GPR in 1999-00 and $400,000 GPR in 2000-01~~

more instructions:

---

caucus number 3207

duplicate flag:

duplicate with:

Other reference numbers:

LFB Sum #:

bill number/amendment number:

LRB draft #

LRB P-draft:

description: Allows multiple municipalities in a county to establish a local board of health

other notes

drafting instructions: See above and attached

more instructions:

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caucus number 3304

duplicate flag:

duplicate with:

Other reference numbers:

LFB Sum #:

bill number/amendment number:

LRB draft #

LRB P-draft:

description: Provide $400,00 GPR to the State Lab of Hygiene and $250,000 to the City of Milwaukee Public Health Department to each purchase DNA probe machines.

other notes

drafting instructions: See above and attached.

more instructions:

+

CN 3205

HEALTH AND FAMILY SERVICES -- PUBLIC HEALTH

Birth Defect Prevention Surveillance, pg. 295 of the LFB Summary of the Governor's Budget.

Governor: Create a birth defect prevention surveillance system and repeal all current statutory provisions relating to the current birth and developmental outcome monitoring program.

Joint Finance: Remove this provision to be introduced as separate legislation. Adopted Motion #1165 by Plache, which provides $100,000 GPR in 1999-00 and $200,000 GPR in 2000-01 to support medical record abstractor expenses and database programming and management costs for birth defects and outcome monitoring program. LFB Comparative Summary, page 417, #20.

Plache: Provide $200,000 GPR in 1999-00 and $400,000 GPR in 2000-01 rather than the amounts above. In addition, include the Governor's provisions to create a birth defect prevention surveillance system and repeal current statutory provisions.

Chg to Joint Finance: ~~$300~~,000 GPR

$33,000 99-01

$67,000 00-01

$100,000 Total

* LFB Summary of Gov's Budget.

no GPR funds were expended from this appropriation. The administration assumes that no GPR funding will be expended from this appropriation in the 1999-01 biennium.

[Bill Section: 425]

17. BIRTH DEFECT PREVENTION SURVEILLANCE

Governor: Create a birth defect prevention surveillance system and repeal all current statutory provisions relating to the birth and developmental and outcome monitoring program.

Definitions. Define a "birth defect" as any of the following conditions affecting an infant or child that occurs prior to or at birth and that requires medical or surgical intervention or interferes with normal growth and development: (a) a structural deformation, disruption or dysplasia; and (b) a genetic, inherited or biochemical disease. Define a "pediatric specialty clinic" as a clinic with the primary purpose of providing pediatric specialty diagnostic, counseling and medical management services to persons with birth defects by physician subspecialists. Define "infant or child" as a human being from birth to two years of age. Define "physician" as an individual possessing the degree of doctor of medicine or doctor of osteopathy or an equivalent degree as determined by the medical examining board, and holding a license granted by the Medical Examining Board.

Reporting. Require the following individuals to report a birth defect in an infant or child to DHFS, unless that person knows that another person has already reported this information to DHFS: (a) a hospital or pediatric specialty clinic in which the birth defect is diagnosed in an infant or child or treatment for the birth defect is provided to the infant or child; (b) a physician who diagnoses the birth defect or provides treatment to the infant or child for the birth defect; and (c) a clinical laboratory that identifies a birth defect in the infant or child as the result of a laboratory analysis.

Require physicians, hospitals and pediatric specialty clinics to provide DHFS, within 10 working days of receiving a request, information contained in the medical records of patients who have a confirmed or suspected birth defect diagnosis.

Department Duties and Powers. Require DHFS to establish and maintain an up-to-date registry that documents the diagnosis of any infant or child who has a birth defect that was diagnosed or treated in the state, regardless of the residence of the infant or child. Require DHFS to include information in the registry that would facilitate: (a) identification of risk factors for birth defects; (b) investigation of the incidence, prevalence and trends of birth defects using epidemiological surveys; and (c) development of preventive strategies that would decrease the occurrence of birth defects.

Require DHFS to promulgate rules that would: (a) specify the birth defects which would require a report to DHFS; and (b) specify the content, format and procedures for reporting birth defect information to DHFS. Authorize DHFS to monitor the data contained in birth defect reports in order to ensure the quality of the data and to make improvements in reporting methods.

Confidentiality. Specify that any information contained in a birth defect report made to DHFS that could specifically identify the subject of the report would be confidential. Prohibit DHFS from releasing this confidential information except to: (a) the parent or guardian of an infant or child for whom a birth defect report is made; (b) a local health officer (LHO), upon receipt of a written request and informed written consent from the parent or guardian of the infant or child; (c) a physician, hospital or pediatric specialty clinic for the purpose of information verification; and (d) a representative of a federal or state agency, upon written request if 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.

Specify that a LHO could only disclose this information to the extent necessary to provide and coordinate follow-up care for the infant or child or to conduct a health, demographic or epidemiological investigation. Require a LHO to destroy all information within one year after receiving it.

Specify that information released to a representative of a federal or state agency could not contain the name or address of the infant or child. Require DHFS to notify the parent or guardian of the release of information to a state or federal agency. Authorize the representative of the state or federal agency to disclose this information only as necessary to perform the legally authorized function of the agency for which the information was requested.

Release of Information to Researchers. Authorize DHFS to release confidential information to a person proposing to conduct research if: (a) the person proposing to do the research submits a written application that includes a written protocol for the proposed research, the requestor's professional qualifications and any other information requested by DHFS; (b) the purpose of the research is to study birth defect surveillance and prevention; (c) DHFS determines that, if the research involves direct contact with a subject or with a member of the subject's family, the contact is necessary for meeting the research objectives, the research is in response to a public health need or is in connection with birth defect surveillance or investigation sponsored and conducted by public health officials, the research had been approved by a certified institutional review board or committee for the protection of human subjects in accordance with federal regulations and the contact between researchers and infants, children or their families is be conducted in a manner approved by DHFS.; (d) the person agrees in writing that the information would only be used for research approved by DHFS; (e) the person agrees in writing that the information provided would not be released to anyone except other persons involved in the research; (f) the person agrees in writing that the final product of the research would not reveal information that could specifically identify the subject of a birth defect report; and (g) the person agrees in writing to any other conditions imposed by DHFS.

Council on Birth Defect Prevention and Surveillance. Create a Council on Birth Defect Prevention and Surveillance to make recommendations regarding the establishment of a birth defect registry and rules for the reporting of birth defect information.

Attach the Council to DHFS and specify that the Council would include (a) a representative of the University of Wisconsin Medical School who has technical expertise in birth defects epidemiology; (b) a representative of the Medical College of Wisconsin who has technical expertise in birth defects epidemiology; (c) a representative from the DHFS Division of Public Health; (d) a representative of the DHFS Division of Health Care Financing: (e) a representative of the DHCF Bureau of Health Information; (f) a representative of the State Medical Society; (g) a representative of the Wisconsin Chapter of the American Academy of Pediatrics; (h) a representative of a nonprofit organization whose primary purpose is the prevention of birth defects; and (i) a parent or guardian of a child with a birth defect.

[Bill Sections: 33, 2253 and 2440]

18. TUBERCULOSIS

Governor: Make numerous changes to provisions relating to state and local responsibilities relating to the detection and treatment of tuberculosis (TB).

Repeal Obsolete References. Delete all current references to private, county and joint county home and county TB sanatoriums and hospitals. In addition, delete all references to TB acute treatment centers and community based residential facilities that provide care to TB patients.

Definitions. Delete the current definition of TB. Instead, define "infectious tuberculosis" as a disease of the respiratory tract, capable of producing infection or disease in others as demonstrated by the presence of acid-fast bacilli in the sputum or bronchial secretion or by chest radiograph and clinical findings. Define "suspect tuberculosis' as an illness marked by symptoms and laboratory tests that may be indicative of tuberculosis, such as a prolonged cough. prolonged fever. hemoptysis. compatible roentgenographic findings or other appropriate medical imaging findings. Define "isolate" as a population of mycobacterium tuberculosis bacteria that has been obtained in pure culture medium. Define "isolation" as the separation from other persons of a person with infectious TB in a place and under conditions that prevent the transmission of the infection.

Laboratory Requirements. Require any laboratory that receives a specimen for TB testing to report all positive results obtained by any appropriate procedure, including a procedure performed by an out-of-state laboratory, to a local health officer (LHO) and DHFS. Require any laboratory that performs primary culture for mycobacterium to also perform organism identification for mycobacterium TB complex using an approved rapid testing procedure as specified by DHFS by rule. Require any laboratory that identifies mycobacterium TB to ensure that antimicrobial drug susceptibility tests are performed on the initial isolate. The laboratory would be required to report the results of these tests to the LHO and DHFS.

Senator Plache

⑩ - 6

MISCELLANEOUS

Birth Defects and Outcome Monitoring Program

Motion:

Move to provide $100,000 GPR in 1999-00 and $200,000 GPR in 2000-01 to support medical record abstractor expenses and database programming and management costs for the birth defects and outcome monitoring program (BDOMP).

Note:

Under the current BDOMP program, physicians and nurses must report to DHFS if they confirm or diagnose that an infant or child has a physical condition that results from an adverse neonatal outcome, birth defect or developmental disability. DHFS must develop and implement a system for collecting, updating, analyzing and disseminating this information. DHFS is authorized 1.0 GPR position to support this program.

[Change to Bill: $300,000 GPR]

Motion #1165

Soon

b7047/1

1999 – 2000 LEGISLATURE

LRB-~~2749/1~~

TAY:jlg:hmh

Stays

R Not Run

1999 BILL

SDC

At the locations indicated, amend the substitute amendment as follows:

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

~~*Analysis by the Legislative Reference Bureau*~~

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

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

~~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.~~

~~Insert 2-1~~

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

→ # Page 24, line 16: after that line insert:

33b letter ✓

c1 **SECTION** ~~1~~. 15.197 (12) 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.

INS 2-1

(g) A representative of the American Academy of Pediatrics — Wisconsin Chapter.

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

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

#. page 1158, line 11: after that line insert:

"SECTION ~~2.~~ 2251gm 146.82 (1) of the statutes is amended to read: ← (B)

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

#. Page 1218, line 17: after that line insert:

"SECTION ~~3.~~ 2440b 253.12 of the statutes is repealed and recreated to read: ✓

253.12 Birth defect prevention and surveillance system. (1) DEFINITIONS. In this section:

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

1. A structural deformation, disruption or dysplasia.

2. A genetic, inherited or biochemical disease.

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

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

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

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

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

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

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

(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.

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

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

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

a. Identification of risk factors for birth defects.

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

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

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

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

(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.

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

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

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

2. A local health officer, 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 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.

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

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

(b) The department may also release confidential information to 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. The person agrees in writing that the information provided will not be released to any person except other persons involved in the research.

6. 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. The person agrees in writing to any other conditions imposed by the department.”. ✓

(END)

insert 2–1

1. Page ~~130~~ 193, line 1: ✓ increase the dollar amount for fiscal year 1999–00 by $33,000 and increase the dollar amount for fiscal year 2000–01 by $67,000 for birth defect prevention and surveillance.

State of Wisconsin
1999 - 2000 LEGISLATURE

LRBb1047/1
TAY:jlg:mrc

SDC:......Walter – #3205, Birth defects and outcome monitoring

FOR 1999–01 BUDGET — NOT READY FOR INTRODUCTION

CAUCUS AMENDMENT
TO ASSEMBLY SUBSTITUTE AMENDMENT 1,
TO 1999 ASSEMBLY BILL 133

At the locations indicated, amend the substitute amendment as follows:

1. Page 24, line 16: after that line insert:

"**SECTION 33b.** 15.197 (12) 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 nonprofit organization that has as its primary purpose the prevention of birth defects.

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

2. Page 193, line 1: increase the dollar amount for fiscal year 1999–00 by $33,000 and increase the dollar amount for fiscal year 2000–01 by $67,000 for birth defect prevention and surveillance.

3. Page 1158, line 11: after that line insert:

"**SECTION 2251gm.** 146.82 (1) of the statutes is amended to read:

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

4. Page 1218, line 17: after that line insert:

"SECTION **2440b.** 253.12 of the statutes is repealed and recreated to read:

253.12 Birth defect prevention and surveillance system. (1) DEFINITIONS. In this section:

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

1. A structural deformation, disruption or dysplasia.

2. A genetic, inherited or biochemical disease.

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

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

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

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

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

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

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

(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.

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

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

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

a. Identification of risk factors for birth defects.

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

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

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

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

(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.

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

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

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

2. A local health officer, 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 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.

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

4. A representative of a federal or state agency upon written request and to the extent that the information is necessary to perform a legally authorized function of that agency, including investigation of causes, mortality, methods of prevention,

treatment or care of birth defects, associated diseases or disabilities. The information may not include the name or address of an infant or child with a condition reported under sub. (2). The department shall notify the parent or guardian of an infant or child about whom information is released under this subdivision, of the release. The representative of the federal or state agency may disclose information received under this paragraph only as necessary to perform the legally authorized function of that agency for which the information was requested.

(b) The department may also release confidential information to 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. The person agrees in writing that the information provided will not be released to any person except other persons involved in the research.

6. 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. The person agrees in writing to any other conditions imposed by the department.".

(END)