



LEAH VUKMIR
STATE SENATOR

SENATE COMMITTEE ON HEALTH

PUBLIC HEARING ON SENATE BILL 523

January 29th, 2014

Mr. Chairman and committee members, thank you for giving Senate Bill 523 a Public Hearing today.

This bill seeks to address an important problem with the newborn screening process in Wisconsin. Under current state law, the Department of Health Services can add blood or urine tests to the Newborn Screening Process via administrative rule. As technology and testing methods evolve, there are now other testing methods that can help health care professionals detect diseases in newborns.

This bill would allow DHS to add any type of test to the newborn screening process through administrative rule. By allowing DHS to add test other than blood or urine tests we will empower them to take advantage of new tests and new testing methods.

In the current landscape, legislative action is required to add any test that is not a blood or urine test to the screening process. This inserts politics into a process that is otherwise dominated by health care professionals. By granting DHS the power to add any test through administrative rule, a simpler and better process can exist, that will allow tests to be added or updated without interjecting politics into the process.

This bill would create a smoother process for all future changes and additions to the newborn screening process. It would also address the current attempts to add a pulse oximetry test for congenital heart defects to the screening process. The pulse oximetry test is a point-of-service test, so under current state law, DHS cannot act on the recommendation of the Umbrella Newborn Screening Committee to add this test.

The beauty of this bill is that it would not only address this particular test and disorder, but will also create a simple process by which tests, regardless of type, could be considered by DHS and added to the screening process in the future.

Senate Bill 523 provides a simple and efficient solution to an ongoing problem in Wisconsin's newborn screening process.

Thank you for your time this morning and your consideration of this bill. I hope you can support its passage here in committee.



PAT STRACHOTA

STATE REPRESENTATIVE

Testimony on Newborn Screening Legislation 1/29/14

I introduced this bill to help provide a uniform and informed compromise approach for the state to decide which medical tests need to be performed on newborn babies. There are many hidden diseases and disorders that can be discovered early through newborn screening. Providing the best possible care for babies and the best information to parents on the health of their child is important. This information not only saves lives, but can help prevent disorders and diseases that will decrease the child's future quality of life if left undetected. In the United States, newborn screening saves or improves the lives of over 12,000 babies each year. Hearing loss is the most common disorder discovered by the screening process, with just over 5,000 babies diagnosed each year. Primary congenital hypothyroidism and sickle cell disease are next on the list, with 2,156 and 1,775 babies diagnosed each year respectively. They are followed by Cystic fibrosis which has roughly 1,248 diagnoses.

Currently, the Department of Health Services can issue rules dealing with infant blood and urine tests. This bill changes the statutes so that they may develop and include point of care tests, not simply blood and urine. An advisory board made up of health professionals and organizations will then be able to issue recommendations on which tests they feel would be beneficial to the health and survival of our newest Wisconsin citizens.

I support Rep. Kleefisch's bill requiring pulse oximetry screening for all newborns in Wisconsin. Unfortunately, this bill has not moved through the legislative process as easily as many had hoped. This test screens for critical congenital heart disease, which can cause sudden death in babies. The condition occurs in roughly eight out of every 1,000 live births nationwide. The bill before the committee today, SB 523, is a good compromise that will allow tests like the pulse oximetry to be put into place. Should there be a need to remove a test from the newborn screening list, the process outlined by this bill would allow it to be removed in the same manner it was added.

Concerns have been voiced that this bill will take away legislative power or oversight, but that is not the case. The process outlined in this bill to promulgate rules dealing with newborn testing requirements can still be overridden by a law passed by the Legislature. Additionally, this bill does not change laws in place dealing with newborn hearing tests. It also leaves in place the ability for a parent or legal guardian to object to a test on the grounds of their religious beliefs or practices.

WISCONSIN HOSPITAL ASSOCIATION, INC.



Date: January 29, 2014

To: Members of the Senate Committee on Health and Human Services

From: Judy Warmuth, Vice President Workforce Development
Kyle O'Brien, Vice President Government Relations

Re: WHA Support of SB 523 – Tests Administered to Newborns for Congenital Disorders

The Wisconsin Hospital Association is supportive of Assembly Bill 654 which removes limitations on the types of newborn tests that can be added or deleted to the Wisconsin Newborn Screening Program through a defined process led by medical experts.

For infants born in Wisconsin hospitals, testing of blood for forty-four possible congenital disorders and hearing screening is done as part of the newborn hospital admission. The number and type of tests are determined by Wisconsin statute and rule and there is a process defined in rule that outlines how additions (and deletions) to the screening program should be made.

When these regulations were created, blood and urine were the only identified sources of testing information for congenital disorders. As health science has evolved, it has become evident that other sources of clinical data, many of them collected at the bedside, may also be used to identify congenital disorders that could be treated early to prevent illness or disability.

WHA understands that the intent of Assembly Bill 654 is to maintain the current process whereby medical professionals recommend the addition or deletion of screens to the DHS Secretary. As health care evolves, policy makers may continue to be approached by interest groups to add additional state-mandated newborn tests. WHA has previously cautioned legislators about mandating medical practice in statute through the legislative process.

In fact, a June 2013 report^[1] from the Wisconsin Newborn Screening Task Force to the Secretary of DHS raised this same concern. The report said that “*disorders have a constituency*” who may “*turn to legislators to get a condition added to a state newborn screening panel.*” The report cautions against the legislature adding conditions without a “*well-designed framework*” that can take into account the “*complex medical, ethical, legal, economic and social impacts*” of each test. The report states that those considerations include the prevalence of false positives in children without the conditions, the cost of the test and the availability of treatment.

While Wisconsin has been a leader in newborn screening, research and new testing methods will clearly lead to other possible screening tests and assessments. WHA is supportive of a careful, analytic process for adding (and deleting) tests to this process.

^[1] June 2013, Report to the Secretary of the Wisconsin Department of Health Services, Newborn Screening Task Force

TO: Members of the Senate Health and Human Services Committee
FROM: Nicole Hudzinski, Government Relations Director, American Heart Association
DATE: January 29, 2014
RE: Senate Bill 523, tests administered to newborns for congenital disorders

Good morning Chairwoman Vukmir and members of the Committee. My name is Nicole Hudzinski and I am the Government Relations Director here in Wisconsin for the American Heart Association. I am grateful for the opportunity to come before you today and testify in support of Senate Bill 523.

Our interest in this legislation is specific to one newborn screening— screening for congenital heart defects. Congenital heart defects are malformations of the heart present at birth, and they are the most common type of birth defect. Some are minor and may never cause complications, but others are severe and may cause death or disability if not detected and treated soon after delivery. Some heart defects are detected on the 20-week ultrasound, and others are apparent when the baby is born (for example noticeable breathing problems, the baby's lips are blue, or baby is lethargic). However, some baby's look and sound completely healthy in the first days after delivery, even though they have a serious underlying heart problem. These are the babies we need to catch.

Thankfully, research shows performing a simple test called pulse oximetry on newborns can help detect serious heart problems that may otherwise be missed. Pulse oximetry is simple— on adults like you and me it's the grey clip the nurse puts on your finger in the emergency room. On babies, it's more commonly a probe with a light on the end that is attached to the baby's hand and foot with a band aide like adhesive. It doesn't puncture the baby's skin and only takes minutes to administer. The probe tests how well the baby's blood is saturated with oxygen, an indicator of how well the heart is functioning.

In September 2011, Health and Human Services Secretary Sebelius recommended, based on the guidance of a panel of experts, that all states consider adding critical congenital heart defect screening to their newborn screening programs. Since that time, over half the country has added it. Here in Wisconsin, our newborn screening program has not been able to add it because it's authority to add newborn screenings is limited to tests that can be done using the baby's blood or urine.

As research and technology advance, there is an increasing need for screenings like pulse ox to be considered. It doesn't involve the baby's blood or urine, but it is just as important and just as life-saving as blood and urine based screenings. I ask you to support Senate Bill 523 and I'm happy to answer any questions you have.



State of Wisconsin
Department of Health Services

Scott Walker, Governor
Kitty Rhoades, Secretary

January 29, 2014
Senate Committee on Health and Human Services
Public Hearing on Senate Bill 523
Renee O'Day – Asst. Deputy Secretary, DHS

Good morning committee members and thank you for allowing me to testify before the Committee. My name is Renee O'Day and I am the Assistant Deputy Secretary for the Department of Health Services. I will be testifying for information only.

Oversight of the Wisconsin newborn screening program is the responsibility of the Secretary of the Department of Health Services. Blood spot testing is performed by the State Lab of Hygiene. Interpretation and communication of all test results is under the direction of an advisory committee structure, which also recommends tests to be added to a list of blood tests that are required as part of the newborn screening process. Wisconsin has had this advisory committee structure since 1992.

As part of the advisory committee structure, seven subcommittees provide expertise in the areas of endocrinology, hearing, hemoglobinopathy, immunodeficiency, metabolics, education and molecular science. Individuals with expertise in medicine, statistics, epidemiology, ethics, law, public policy, laboratory medicine, the newborn screening program, as well as individuals with target conditions or their parents serve on the various committees charged with program oversight and analysis of prospective tests.

The advisory committee structure determines whether a prospective test fits the criteria listed in DHS 115.06. The criteria that must be considered in adding a disorder to the newborn screening process include:

- Characteristics of the specific disorder, including disease incidence, morbidity and mortality
- The availability of effective therapy and potential for successful treatment
- Characteristics of the test, including sensitivity, specificity, feasibility for mass screening and cost
- The availability of mechanisms for determining the effectiveness of test procedures
- Characteristics of the screening program
- The expected benefits to children and society in relation to the risks and costs associated with the test. (DHS 115.06)

Anyone can nominate a test to be reviewed for addition to the newborn screening panel. The prospective test is analyzed through an evaluation process and public comment is welcome. After a recommendation is made by the advisory committee structure, it is presented to the Secretary of Health Services. The Secretary has the ability to start the rules promulgation process to add the test to the list of congenital and metabolic disorders set forth in administrative rule.

Currently, statutes only allow blood and urine tests to the newborn screening test list. The proposed legislation would allow for "point-of-care" testing (such as pulse oximetry) to be considered and added. "Point-of-care" testing is completed at the hospital and does not require that a specimen be sent out to a lab.

The bill will allow for the advisory committee structure to use its scientific and medical expertise to analyze the potential addition of a greater variety of tests through a well-established, well-reasoned process. The deliberate pace of the administrative rules process will help to shelter these decisions from the political pressures, while still allowing for legislative oversight of the ultimate addition of tests to the current rule. The Newborn Screening Program gives the State

greater flexibility to change testing requirements than changes in statute. These changes are based on the latest information available in modern medical science and what is known through best practices.

Finally, it is also important to note current law allows a parent or guardian to opt out of the newborn screening process because of religious beliefs. This legislation would add personal conviction as a means for refusal of the tests. Again, thank you for your time and I would be happy to answer any questions that you may have.



**TO: Chairman Krug and Members of the Assembly Committee on Children and Families
Chairwoman Vukmir and Members of the Senate Committee on Health and Human Services**
FROM: Children's Hospital of Wisconsin
DATE: January 29, 2014
RE: AB654/SB 523

My name is Dr. Stuart Berger and I am the Medical Director of the Herma Heart Center at Children's Hospital of Wisconsin and Professor of Pediatric Cardiology at Medical College of Wisconsin. I am submitting this testimony on behalf of myself, my patients and Children's Hospital of Wisconsin in support of AB 654 and SB 523.

Thank you for holding a hearing on Assembly Bill 654/SB 523. This bill would grant the Department of Health Services the authority to add new types of tests to the newborn screening process. Once in place, this legislation would allow the Department to consider including additional life saving screens, such as the pulse oximetry screen for congenital heart disease. This bill is a smart and appropriate response to issues raised about adding newborn screens.

Children's Hospital of Wisconsin supports this bill and looks forward to an opportunity at the Department Health agency level to raise the issue of cost effectiveness and efficacy of adding pulse oximetry to the current screens.

The pulse oximetry screen for congenital heart defects prior to hospital discharge will save lives. Congenital heart defects are the most common birth defect, and early detection is critical for a baby's survival.

Without this legislation, the Department of Health may not be able to consider a test such as pulse oximetry for newborn screening. This bill simply allows the Department to consider this important decision. You should care about making this change because of the benefits of the pulse oximetry screen that could be under consideration at the Department:

- 8 out of 1,000 babies are born with a congenital heart defect making it the most common birth defect.
- A quarter of babies with CHD will be diagnosed with a Critical Congenital Heart Defect (CCHD) – a life-threatening condition that requires interventions such as surgery within the first days or months of life.
- Each year in the United States over 100 babies die of unrecognized CCHD.

Evidence indicates that performing a pulse oximetry screening on newborns would help prevent babies with unrecognized critical congenital heart defect from going home, only to have serious complications and require emergency care soon after. This screening is non-invasive, inexpensive and can potentially save a child's life; it's the right thing to do.

I thank you for your time. Please feel free to contact me with questions.





January 29, 2014

Testimony in Support of AB 654/SB 523
Relating to Tests Administered to Newborns for Congenital Disorders
Prepared and Presented by Maureen Kartheiser
Director of Program, Advocacy and Government Affairs

March of Dimes is very proud to work on behalf of infants born with birth defects and their families, through private sector research, community services, education, and advocacy. March of Dimes also counts on government to fulfill their role in protecting and improving family health and supporting the needs of newborns and their families. In the State of Wisconsin, we rely on the Department of Health Services (DHS) to provide critical services to ensure that each baby born is given the best chance at a healthy and abundant life.

Each year, approximately 68,000 newborns in Wisconsin are screened shortly after birth to detect rare heritable and congenital medical conditions and hearing impairment. The newborn screening system is designed to detect and treat these conditions as early as possible to prevent chronic illnesses, physical disability, mental retardation, developmental problems and even infant death. For the past 3 years, March of Dimes has worked with our colleagues and families to pass legislation to add Critical Congenital Heart Disease (CCHD) screening to the Newborn Screening Panel. We now have an alternative set of bills which may offer hope for the addition of CCHD screenings and other, yet to be determined, newborn screening tests.

AB 654 and companion bill SB 523 give DHS the authority, through administrative rules, to screen for additional disorders, diseases, and/or defects without pursuing legislative action to make this happen. Screening for CCHD through the use of pulse oximetry testing of every newborn, is one example of a disease that when missed at birth can have tragic consequences, including death of an apparently healthy newborn within hours of returning home. And there is a simple fix to this problem – the use of a non-invasive pulse oximetry test on every baby. We respectfully ask that DHS be given the authority to ensure that this current test and future, as yet unknown, tests be carefully yet swiftly added to the Newborn Screening Panel following clear guidance from DHS and recommendation of medical, ethical, and advocacy groups to do so.

AB 654/SB 523 ensure that DHS has the authority, which in this case is currently limited to newborn screenings that include blood, urine, or hearing tests, and the ability to improve newborn screening efforts through administrative rules as research and technologies advance.

Please contact Maureen Kartheiser at 414-203-3118 or mkartheiser@marchofdimes.com with questions.

Thank you.

Senate Committee on Health and Human Services

January 29, 2014

Senate Bill 523

Chairwoman Vukmir and members of the committee, I write today in support of Senate Bill 523. This bill puts the decision making process for required newborn screenings where it belongs; with the Department of Health Services (DHS).

Newborn screenings have always been important, but I am especially concerned that screenings for conditions that threaten the lives of children in their first few weeks of life be part of a required protocol. For example, screening newborns for congenital heart defects can be critical, but is not always performed prior to discharge from the hospital. My first child was born with four heart defects, which were diagnosed more than a week after I brought her home. Fortunately, she didn't have any emergency issues in the interim, but that isn't always the case. If a family lives in a rural area, getting medical help soon enough to save a 1- or 2-week old with an undiagnosed condition is unlikely.

As technology and best practices continue to change and develop, it will become increasingly important that DHS has the power to promulgate rules in this area of health care. I urge your support of this legislation.



Diane Handrick

Cottage Grove, WI

253.105 MATERNAL AND CHILD HEALTH

Updated 11–12 Wis. Stats. 10

given was the result of sexual assault in violation of s. 940.225, 944.06, 948.02, 948.025, 948.06, 948.085, or 948.09 and the violation was committed by the father.

(b) A claim for relief under par. (a) may include:

1. Damages arising out of the inducement of the abortion, including damages for personal injury and emotional and psychological distress.

2. Punitive damages for a violation that satisfies the standard under s. 895.043 (3).

(c) Notwithstanding s. 814.04 (1), a person who recovers damages under this subsection may also recover reasonable attorney fees incurred in connection with the action.

(d) A conviction under sub. (3) is not a condition precedent to bringing an action, obtaining a judgment, or collecting a judgment under this subsection.

(e) A contract is not a defense to an action under this subsection.

(f) Nothing in this section limits the common law rights of a person that are not in conflict with sub. (2).

(5) **CONFIDENTIALITY IN COURT PROCEEDINGS.** (a) In every proceeding brought under this section, the court, upon motion or sua sponte, shall rule whether the identity of any woman upon whom an abortion was induced or attempted to be induced shall be kept confidential unless the woman waives confidentiality. If the court determines that a woman's identity should be kept confidential, the court shall issue orders to the parties, witnesses, and counsel and shall direct the sealing of the record and exclusion of individuals from courtrooms or hearing rooms to the extent necessary to safeguard the woman's identity from public disclosure. If the court issues an order to keep a woman's identity confidential, the court shall provide written findings explaining why the woman's identity should be kept confidential, why the order is essential to that end, how the order is narrowly tailored to its purpose, and why no reasonable less restrictive alternative exists.

(b) Any person, except for a public official, who brings an action under this section shall do so under a pseudonym unless the person obtains the written consent of the woman upon whom an abortion was induced, or attempted to be induced, in violation of this section.

(c) The section may not be construed to allow the identity of a plaintiff or a witness to be concealed from the defendant.

(6) **CONSTRUCTION.** Nothing in this section may be construed as creating or recognizing a right to abortion or as making lawful an abortion that is otherwise unlawful.

History: 2011 a. 217.

253.11 Infant blindness. (1) For the prevention of ophthalmia neonatorum or infant blindness the attending physician or midwife shall use a prophylactic agent approved by the department.

(2) In a confinement not attended by a physician or nurse-midwife, if one or both eyes of an infant become inflamed, swollen and red or show an unnatural discharge at any time within 2 weeks after birth, the nurse, parents, or other person in charge shall report the facts in writing within 6 hours to the local health officer who shall immediately warn the person of the danger. The local health officer shall employ at the expense of the local health department a competent physician to examine and treat the case.

(3) Any person who violates this section may be required to forfeit not more than \$1,000.

History: 1979 c. 221; 1987 a. 332; 1993 a. 27 s. 314; Stats. 1993 s. 253.11.

253.115 Newborn hearing screening. (1) **DEFINITIONS.** In this section:

(a) "Hearing loss" means an inability in one or both ears to detect sounds at 30 decibels hearing level or greater in the frequency region of 500 to 4,000 hertz that affects speech recognition and auditory comprehension.

(b) "Hertz" means a unit of frequency equal to one cycle per second.

(c) "Hospital" has the meaning given in s. 50.33 (2).

(d) "Infant" means a child from birth to 3 months of age.

(e) "Newborn hearing screening program" means a system of a hospital under which an infant may be tested, using currently available medical techniques, to determine if the infant has a hearing loss.

(2) **SCREENING PROGRAM REPORT.** Beginning July 1, 2002, the department shall annually collect information from hospitals for the previous calendar year concerning the numbers of deliveries in each hospital and the availability in each hospital of a newborn hearing screening program. From this information, by July 31, 2003, and annually thereafter, the department shall determine the percentage of deliveries in this state that are performed in hospitals that have newborn hearing screening programs and shall report this information to the appropriate standing committees of the legislature under s. 13.172 (3).

(3) **HOSPITAL SCREENING PROGRAM.** If, by August 5, 2003, the department determines that fewer than 88% of all deliveries in this state are performed in hospitals that have a newborn hearing screening program and so notifies the hospitals, every hospital shall, by January 1, 2004, have a newborn hearing screening program that is available to all infants who are delivered in the hospital.

(4) **SCREENING REQUIRED.** Except as provided in sub. (6), the physician, nurse-midwife licensed under s. 441.15, or certified professional midwife licensed under s. 440.982 who attended the birth shall ensure that the infant is screened for hearing loss before being discharged from a hospital, or within 30 days of birth if the infant was not born in a hospital.

(5) **REFERRAL TO FOLLOW-UP SERVICES.** The department shall provide referrals to intervention programs for hearing loss.

(6) **EXCEPTIONS.** (a) Subsection (4) does not apply if the parents or legal guardian of the child object to a screen for hearing loss on the grounds that the test conflicts with their religious tenets and practices.

(b) No screening may be performed under sub. (4) unless the parents or legal guardian are fully informed of the purposes of a screen for hearing loss and have been given reasonable opportunity to object under par. (a) to the screen.

(7) **SCREENING RESULTS.** (a) The physician, nurse-midwife licensed under s. 441.15, or certified professional midwife licensed under s. 440.982 who is required to ensure that the infant is screened for hearing loss under sub. (4) shall do all of the following:

1. Ensure the parents or legal guardian are advised of the screening results.

2. If the infant has an abnormal hearing screening result, ensure the parents or legal guardian are provided information on available resources for diagnosis and treatment of hearing loss.

3. Send to the state laboratory of hygiene board screening results and the infant's risk factors to contract a hearing loss.

(b) The state laboratory of hygiene board shall send the information provided under par. (a) 3. to the department.

(8) **CONFIDENTIALITY.** Except as provided under sub. (7) (a) 3. and (b), no information obtained under this section from the parents or legal guardian may be disclosed except for use in statistical data compiled by the department without reference to the identity of any individual and except as provided in s. 146.82 (2).

History: 1999 a. 9, 185; 2009 a. 279; 2011 a. 260.

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 a 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 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.

(am) Any hospital in which a birth defect is diagnosed in an infant or child or treatment is provided to the infant or child may report the birth defect in the manner prescribed by the department under sub. (3) (a) 3.

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

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

(d) The department may not require a person specified under par. (a) 1. or 2. to report the name of an infant or child for whom a report is made under par. (a) if the parent or guardian of the infant or child refuses to consent in writing to the release of the name or address of the infant or child.

(e) If the address of an infant or child for whom a report is made under par. (a) is included in the report, the department shall encode the address to refer to the same geographical location.

(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 primary preventive strategies to decrease the occurrence of birth defects without increasing abortions.
- d. Referrals for early intervention or other appropriate services.

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).

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

(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.

(c) The department shall, not more than 10 years from the date of receipt of a report under sub. (2), delete from any file of the

department the name of an infant or child that is contained in the report.

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

(a) Make recommendations to the department regarding the establishment of a registry that documents the diagnosis 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. on the birth defects to be reported under sub. (2) and on the general content and format of the report under sub. (2) and procedures for submitting the report. The council shall also make recommendations regarding the content of a report that, because of the application of sub. (2) (d), does not contain the name of the subject of the report.

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

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

(d) Beginning April 1, 2002, and biennially thereafter, submit to the appropriate standing committees under s. 13.172 (3) a report that details the effectiveness, utilization and progress of the registry established under sub. (3) (a) 1.

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

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

2. A local health officer, a local birth-to-3 coordinator or an agency under contract with the department to administer the children with special health care needs program, 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 services and follow-up care for the infant or child or to conduct a health, demographic or epidemiological investigation. The local health officer shall destroy all information received under this subdivision within one year after receiving it.

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

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

(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.