



JESSIE RODRIGUEZ

STATE REPRESENTATIVE ★ 21ST ASSEMBLY DISTRICT

AB 371: Updating the Wisconsin Birth Defects Registry
Testimony of State Representative Jessie Rodriguez
Assembly Committee on Health
July 26, 2017

Good morning. Thank you committee Chairman Sanfelippo and committee members for the opportunity to testify on Assembly Bill 371, legislation that would provide necessary changes to Wisconsin's outdated birth defects registry.

Birth defects are the number one cause of infant mortality in the United States accounting for 23 percent of all infant deaths each year and costing families more than \$2.6 billion in hospital costs.

Last session I chaired the Children and Families committee. My committee was responsible for reviewing DHS 116, the administrative rule that governs the Wisconsin Birth Defects Registry. As the department will explain in greater detail in their testimony, we learned the current registry is ineffective and fails to capture comprehensive data documenting birth defects in Wisconsin.

Wisconsin is the only state in the country that has an opt-in registry, meaning when a child is born with a birth defect, the parents have the option to choose to include their child in the birth defects registry. However, this method is problematic as most providers are unable to find the additional time needed to notify parents leaving many of them unaware the registry even exists. As a result many children with birth defects are not included in the registry creating a registry that lacks comprehensive data. Lacking up-to-date and accurate data limits our



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understanding of the causes of birth defects and reduces the ability of medical providers to offer services and support to families in need.

Assembly Bill 371 will transform the birth defects registry to an opt-out system, meaning, when a child is born with a birth defect he or she will automatically be entered into the confidential birth defects registry. Parents will have the option to exclude their child from the registry if they choose.

Additionally, the bill will allow the Council on Birth Defects Prevention and Surveillance, within DHS, to recommend updates to the list of birth defects. The current list is stagnate and no longer reflects changes in birth defects research.

Updating the Wisconsin Birth Defects Registry will help increase our ability to reduce future birth defects and identify methods for improved treatment for children. This legislation will help foster strong families and lead to healthier birth outcomes for families across the state. I encourage your support for this legislation. Thank you for your time.

Alberta Darling

Wisconsin State Senator

Co-Chair, Joint Committee on Finance

TESTIMONY BEFORE THE ASSEMBLY COMMITTEE ON HEALTH
Assembly Bill 371
Senator Alberta Darling
July 26, 2017

Thank you Chair Sanfelippo and committee members for holding a public hearing on Assembly Bill 371. This important piece of legislation is part of the Red Tape Review and reforms the Wisconsin Birth Defects Registry (WBDR). The WBDR tracks birth defects in our state and provides crucial information on trends to the Department of Health Services (DHS).

Birth defects are a leading cause of infant mortality. Accordingly, the WBDR is vital to our state's ability to treat and prevent birth defects for our youth. However, the current statutory provisions regarding the WBDR are outdated and make the available data highly unreliable. This bill alters the WBDR in order to ensure that the data we collect about our kids is accurate and can be used in a meaningful way to prevent birth defects.

First, this bill automatically enters children with birth defects into the registry. Under current law, parents must opt into the registry. As many parents are unaware of the registry, this elective participation has created significant gaps in our data compared to other states. The bill will allow any parent to opt out of sharing information with the registry.

Additionally, this bill allows information to be shared with the state registrar and the DHS vital records system in order to determine if multiple reports have been made for the same child. The bill also safeguards information on the registry for more than 10 years. Keeping this information is crucial to obtaining longitudinal data on birth defects. All of these changes effectively balance privacy with the need for accurate reporting.

Finally, the bill reforms the method for classifying birth defects. Currently there is an unchanging list of birth defects set in DHS Chapter 116. This list is outdated, inefficient, and incapable of recognizing new birth defects. This bill allows the Council on Birth Defect Prevention and Surveillance to recommend that the Secretary of DHS add new birth defects to the registry.

The WBDR can be an effective tool to combat birth defects. If the data collected by this registry accurately reflected the trends in our state, it could be used to reduce the number of birth defects and increase healthy birth outcomes.

I'd like to thank Representative Rodriguez for her leadership on this important piece of legislation which is supported by DHS, the American Heart Association, Children's Hospital, March of Dimes, and the Wisconsin Medical Society. Thank you again committee members for your time and consideration. I hope I can count on your support for Assembly Bill 371.



State of Wisconsin
Department of Health Services

Scott Walker, Governor
Linda Seemeyer, Secretary

DHS Testimony in Support of AB 371

Dear Members of the Assembly Committee on Health,

Thank you for the opportunity to provide testimony in support of AB 371, relating to: various changes to birth defect prevention and surveillance system. My name is Jon Hoelter and I am the Legislative Advisor at the Department of Health Services.

While potential changes to Wisconsin's birth defect prevention registry have been discussed for a number of years, the ideas in this bill stem from information the Department of Health Services provided to The Assembly Committee on Children and Families during a red tape review session of DHS 116. DHS 116 is the Administrative Rule that covers the Wisconsin Birth Defect Prevention and Surveillance System. During the informational testimony we presented to committee members, we provided some options that might improve the usefulness of Wisconsin's Birth Defects Prevention Registry. This bill incorporates those options into statute, which will improve Wisconsin's registry. The main changes are outlined below.

1. Changes the collection of personal information from a parental opt-in to a parental opt-out.
2. Allows Wisconsin to link registry data to other data sets, such as vital records.
3. Removes the requirement that data is deleted after 10 years.
4. Incorporates these statutory changes into DHS 116 and creates a process to update the list of birth defects without having to change DHS 116.

As highlighted above, this bill changes the requirement that medical providers obtain active parental consent to collect personal information. Rather, there would be a requirement that parents may opt out of providing that information. Changing reporting of birth defect registry information from an opt-in to an opt-out is important for a number of reasons. Currently, healthcare providers have to take valuable time away from patient care in order to explain to patients why they should opt in. In some cases, providers simply do not have this time, which has led to a low number of records that contain this information. Changing this to an opt-in will allow Wisconsin to collect this information while allowing providers to focus their time on patient care.

One very important benefit of collecting this information is it will allow researchers to study for any correlation between data clusters of birth defects and local geography. This would give public health officers better tools to know if there may be local factors contributing to birth defects and could improve our ability to prevent more birth defects in the future.

Another way this will benefit Wisconsin is by improving the accuracy of our registry. Because Wisconsin's registry is currently full of records without any identifying information, there is a low level of accuracy in the data set. This is because some children with birth defects have their defects reported multiple times. For instance, it could be reported by the birthing doctor, by the child's primary care doctor, and again by a specialist that parents see to gain information and treatment options. While DHS staff attempt to de-duplicate these multiple records, there is no fail-safe way to do so absent identifying information.

By changing Wisconsin to an opt-out state, we expect most parents will be comfortable with sharing this information in a confidential manner, consistent with HIPAA guidelines. This, in turn, will make our registry data more accurate. Having accurate data is also important because the Centers for Disease Control and Prevention (CDC) allows states to apply for various grants to do research on birth defects. However, because there is a low level of confidence in the accuracy of Wisconsin's data, we are often unable to receive these grants. Having more accurate data would give Wisconsin a leg up when applying for these CDC funding opportunities that will help us more fully realize the value of this data.

In addition to changing the reporting of information to an opt-out, there are three other changes this bill makes. The first change would allow for the Department to link the registry data to other data we have. As described above, this will allow DHS to easily de-duplicate records by linking this data to vital records data. It will also allow for the investigation of other correlations. For instance, linking the birth defects registry to newborn screening data would allow the Department to investigate what correlations birth defects have to other birth data.

The bill also removes the prohibition in current law that allows DHS to only keep data for 10 years or less. Being allowed to keep data for more than 10 years would enable the possibility of longitudinal studies on how birth defects impact people over the course of their lives. It will put us in a better position to study trends in birth defects. By linking the registry data to the Department's services, it could even help determine the extent to which services like Birth to 3 are leading to better outcomes for children born with birth defects.

Lastly, this bill incorporates the statutory changes described above into DHS 116. This means DHS will not have to repromulgate DHS 116 in order for these changes to take effect. It also creates a process by which the list of birth defects can be changed outside of the rulemaking process if there is unanimous agreement on DHS's Birth Defects Prevention Board. As new diseases like Zika are studied for their links to birth defects, this important change will allow our list of birth defects to stay more up-to-date.

Before wrapping up, I would like to address a very important issue, keeping personal data safe and protected. In researching the potential changes discussed above, it seems clear the reason Wisconsin's birth defects law was initially required to obtain active parental consent was due to concerns about data privacy. It also seems clear that no one expected it to be this difficult to obtain active parental consent. The Department of Health Services takes privacy of health records extremely seriously. In fact, our Office of Health Informatics is currently undergoing a process to encrypt all our sensitive data, including our registry data, and are expected to complete this in the next 30 days. This data can only be accessed by a small number of select staff, and any outward access is limited to legitimate educational and research purposes, which can only be accessed after going through an extensive review by our Data Governance Board. All staff who would then access the data would be required to sign a data confidentiality agreement governing how the data can be accessed and used.

Thank you again for the opportunity to provide this testimony in support of AB 371 and thank you to Representative Rodriguez and Senator Darling for authoring this bill. I would be happy to respond to any questions.

CONFIDENTIAL BIRTH DEFECTS REGISTRY REPORT

Completion of this form by physicians and pediatric specialty clinics is mandated under the provisions of sections 253.12(1) and 253.12(2) of the Wisconsin Statutes. Completion of this form by hospitals is voluntary. Personally identifiable information collected on this form will be used for matching and deduplication purposes.

1. Print firmly and neatly 2. Use pen only with dark ink 3. Print inside boxes 4. Fax/mail original form 5. Darken circles completely 6. Mark errors like this:

A. GENERAL INFORMATION

- (1) Is this report a new report or a correction or addition to a previous report? New Correction
- (2) Has a Parental Consent Form been signed by a parent or guardian? Yes No
- (3) Has a Referral Already Been Made to:
 Regional Children with Special Health Care Needs Center Yes No
 Local Public Health Department Yes No
 Local Birth to 3 Program Yes No
 Other (specify): _____

B. REPORTER

Today's Date (mm/dd/yyyy) / /

Name, Title, Telephone and E-mail Address of Person Completing Form

C. REPORTING SOURCE

Facility Name/Number, Address, City, State and Zip Code (stamp acceptable)

D. CHILD'S INFORMATION

Last Name Date of Birth (mm/dd/yyyy) / /

First Name M.I. Medical Record Number

Street Address

City State Zip Code

Sex Race (check all that apply) Ethnicity List other names for child, if any

<input type="radio"/> Female <input type="radio"/> Male <input type="radio"/> Undesignated	<input type="radio"/> American Indian or Native Alaskan <input type="radio"/> Asian <input type="radio"/> Black/African American <input type="radio"/> Hawaiian/Pacific Islander	<input type="radio"/> White <input type="radio"/> Other <input type="radio"/> Unknown	<input type="radio"/> Hispanic or Latino <input type="radio"/> Not Hispanic or Latino
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Birth Birth weight Gestational Age Estimate Is Birth Birth Order (if multiple)

<input type="radio"/> Live <input type="radio"/> Stillbirth > 20 weeks gestation	<input type="radio"/> Grams <input type="radio"/> Pounds/Ounces _____	Weeks: 	<input type="radio"/> Single <input type="radio"/> Twin <input type="radio"/> Other Multiple _____ <input type="radio"/> Unknown	<input type="radio"/> First <input type="radio"/> Second <input type="radio"/> Other (specify): _____
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Place of Birth: Hospital Name/Code, Street Address, City, State, Zip Code

E. CHILD'S PRIMARY CARE PROVIDER

Name of Primary Care Provider, and Facility Name

Area Code Telephone Number -

INSTRUCTIONS
CONFIDENTIAL BIRTH DEFECTS REGISTRY REPORT

- (1) This report form is to be used by physicians, pediatric specialty clinics, and hospitals to report birth defects for children up to age two. The report is mandated under the provisions of sections 253.12(1) and 253.12(2) of the Wisconsin Statutes. The information is submitted to the Wisconsin Department of Health and Family Services, Bureau of Community Health Promotion, Maternal and Child Health Program.
- (2) Please fill out as much information as possible. Leave items **blank** if you don't have the information. Do not write "N/A" or similar in the spaces.
- (3) This report can be submitted via the secure website. Refer to the website at: <https://phin.wisconsin.gov/wbdr/index.html> for electronic forms and instructions.
- (4) If completing the report on paper, fax to Elizabeth Oftedahl, MPH, CYSHCN Epidemiologist, Bureau of Community Health Promotion at 608-267-3824. If sending by U.S. Postal Service mail, send to 1 W. Wilson Street, P.O. Box 2659, Madison, WI 53701-2659.
- (5) Be sure to provide a name, title, telephone number and e-mail address for the person filling out the report so that person can be contacted if there are any questions.
- (6) Use the list at the end of this page for section I of the report. If the reportable condition is longer than 25 letters and spaces, put in the proper code number and the first 25 letters and spaces of the reportable condition.
- (7) Be sure the parent/guardian has signed a parent consent form (provided and maintained by you or your facility) before submitting the report. If the parent/guardian refuses to sign a consent form, you are still required to report. However, do not provide a name or address for the child or for the child's parents. Do provide date of birth, medical record number (if available), birth hospital, sex, race, ethnicity, birth outcome, birth-weight, gestational age estimate, plurality and, if a multiple birth, birth order information.
- (8) Contact Elizabeth Oftedahl at 608-261-9304 if you have questions or comments or by e-mail at Elizabeth.Oftedahl@dhs.wisconsin.gov.

Wisconsin Birth Defects Registry Reportable Conditions

CARDIOVASCULAR

- 100 Atrial Septal Defect
- 101 Atrioventricular Canal/Endocardial Cushion Defect
- 102 Cardiac Arrhythmia (Congenital)
- 103 Coarctation of the Aorta
- 104 Hypoplastic Left Heart
- 105 Tetralogy of Fallot
- 106 Total Anomalous Pulmonary Venous Return
- 107 Transposition of the Great Vessels
- 108 Truncus Arteriosus
- 109 Valvular Heart Disease (Congenital)
- 110 Ventricular Septal Defect

CHROMOSOMAL

- 150 Down Syndrome (Trisomy 21)
- 151 Klinefelter Syndrome
- 152 Trisomy 13
- 153 Trisomy 18
- 154 Turner Syndrome
- 155 Velocardiofacial Syndrome (22q Deletion Syndrome)
- 156 Other Chromosomal Anomaly (*not Down Syndrome, Klinefelter Syndrome, Trisomy 13, Trisomy 18, Turner Syndrome or Velocardiofacial Syndrome*)

ENDOCRINE

- 200 Hypothyroidism (Congenital)

EYE

- 250 Cataract (Congenital or Early)
- 251 Coloboma
- 252 Glaucoma (Congenital)
- 253 Microphthalmia/Anophthalmia

GASTROINTESTINAL/ABDOMINAL

- 300 Biliary Atresia
- 301 Gastroschisis
- 302 Hirschsprung Disease
- 303 Omphalocele
- 304 Pyloric Stenosis
- 305 Rectal/Colonic Atresia/Stenosis
- 306 Small Bowel Atresia/Stenosis
- 307 Tracheo-Esophageal Fistula/Esophageal Atresia

GENITOURINARY

- 350 Ambiguous Genitalia
- 351 Epispadias
- 352 Extrophy of the Bladder/Cloaca
- 353 Hypospadias
- 354 Multicystic and/or Dysplastic Kidney
- 355 Obstructive Urinary Tract Defect (*not Posterior Valves; not Urethral Stenosis/Atresia*)
- 356 Polycystic Kidney Disease, Autosomal Dominant Form
- 357 Polycystic Kidney Disease, Autosomal Recessive Form
- 358 Polycystic Kidney Disease, Uncertain Form
- 359 Posterior Urethral Valves
- 360 Renal Agenesis/Hypoplasia
- 361 Urethral Stenosis/Atresia

HEMATOLOGIC

- 400 Hemophilia
- 401 Hereditary Spherocytosis
- 402 Von Willebrand Disease

MUSCULOSKELETAL

- 450 Achondroplasia
- 451 Amniotic Bands
- 452 Arthrogryposis Multiplex Congenita
- 453 Bone Dysplasia/Dwarfism, Other (*not Achondroplasia*)
- 454 Clubfoot (Congenital)
- 455 Hip Dislocation (Congenital)/Developmental Dysplasia of Hip (Congenital)
- 456 Hemivertebra
- 457 Osteogenesis Imperfecta
- 458 Scoliosis (Infantile) and/or Kyphosis
- 459 Reduction Deformity, Arm or Hand
- 460 Reduction Deformity, Leg or Foot

NEUROLOGIC

- 500 Anencephaly
- 501 Encephalocele
- 502 Holoprosencephaly
- 503 Hydranencephaly
- 504 Hydrocephalus (Congenital or Early)
- 505 Microcephaly (Congenital or Early)
- 506 Porencephaly
- 507 Spina Bifida
- 508 Spinal Muscular Atrophy (Infantile)

OROFACIAL

- 550 Choanal Atresia
- 551 Cleft Lip with or without Cleft Palate
- 552 Cleft Palate
- 553 Craniosynostosis
- 554 Microtia/Anotia

PULMONARY

- 600 Cystic Fibrosis
- 601 Diaphragmatic Hernia

SYNDROMES/ASSOCIATIONS

- 650 Angelman Syndrome
- 651 Beckwith-Wiedemann Syndrome
- 652 CHARGE Association
- 653 De Lange Syndrome (Cornelia De Lange Syndrome)
- 654 Marfan Syndrome
- 655 Noonan Syndrome
- 656 Oculoauriculovertebral Association (*including Goldenhar Association and Hemifacial Microsomia*)
- 657 Prader-Willi Syndrome
- 658 Robin Malformation Sequence (Pierre Robin Sequence)
- 659 Smith-Lemli-Opitz Syndrome
- 660 Sotos Syndrome
- 661 Stickler Syndrome
- 662 VATER Association
- 663 Williams Syndrome



TO: Members, Assembly Health Committee
FROM: Ann Dodge, Chair, American Heart Association Wisconsin Advocacy Committee and Nurse Practitioner,
Pediatric Cardiology, American Family Children's Hospital
DATE: July 26, 2017
RE: Support of Assembly Bill 371

Good morning Chairman Sanfelippo and members of the Committee. My name is Ann Dodge, and I am Chair of the American Heart Association's Wisconsin Advocacy Committee. I am also a Nurse Practitioner in Pediatric Cardiology at American Family Children's Hospital. I am happy to be here today to testify in support of Assembly Bill 371, relating to various changes to the birth defect prevention and surveillance system.

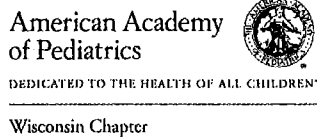
The American Heart Association (AHA) is a national voluntary health organization dedicated to building healthier lives, free of cardiovascular diseases and stroke. We are working toward improving the cardiovascular health of all Americans by 20 percent, and reducing deaths from cardiovascular diseases and stroke by 20 percent, by the year 2020.

Research is a cornerstone of the American Heart Association's lifesaving mission. It is a pillar upon which the AHA was founded nearly a century ago, and since then it has had tremendous impact. The new knowledge and advances that result from our research benefit millions of lives in every corner of the U.S. and around the world. The research findings made possible by the AHA are translated into guidelines which give healthcare providers the medical advancements and knowledge they need to most effectively treat cardiovascular disease (CVD).

One area of focus for our research is with congenital heart defects (CHDs). CHDs are structural abnormalities of the heart that are present at birth. These defects range in severity from simple holes or murmurs to severe malformations, such as the complete absence of one or more chambers or valves. Some heart defects are minor and an individual may never exhibit symptoms. Others are critical and require detection and intervention within the first days of life. Occurring in 8 out of every 1,000 live births, CHDs account for 27% of infant deaths that are caused by birth defects.

AB 371 will remedy underreporting of birth defects, including congenital heart defects, which we know is currently happening in Wisconsin. This will help us better understand prevalence, factors that may contribute to CHDs, and ways to prevent as well as treat CHDs. It will also bring Wisconsin's Birth Defects Registry in-line with how other states collect information, and it takes the burden off the parent to report the diagnosis.

In closing, I want to thank Representative Rodriguez and Senator Darling for authoring the bill, and Representative Sanfelippo for scheduling a hearing today. Please support AB 371.



The organizations listed above respectfully ask that the legislature act on the Birth Defects Prevention and Surveillance System Bills AB 371/SB 287 which will allow the state to better understand the incidence of birth defects in Wisconsin by adjusting the registry to an opt-out system. We thank Representative Jessie Rodriguez, Senator Alberta Darling, and the many legislative co-sponsors for their support of this legislation.

A birth defect is an abnormality of body structure, function or metabolism (inborn error of body chemistry) present at birth that results in physical or intellectual disabilities, or death. It is the leading cause of infant death, accounting for more than 20% of all deaths in the first year of life; birth defects are a major cause of morbidity and mortality throughout childhood. In the United States, about 1 in 33 babies, or an estimated 120,000 babies per year, are born with birth defects.

In Wisconsin, 1,515 babies were reported with birth defects in 2014, less than the expected 2100 (or 1 in 33) we should expect according to the CDC. This represents not only a significant gap in understanding the prevalence of birth defects, but also in providing the necessary familial support and services. The birth defect bill will remedy underreporting by ensuring that the incidence of birth defects is monitored and tracked more easily, while also addressing privacy concerns by protecting a parent's ability to opt out of the system should they choose.

With increasing rates of infants born with Neonatal Abstinence Syndrome, lead exposure, and the national threat of the Zika virus, it is incumbent upon Wisconsin to improve efforts to track birth defects, identify factors that might be associated with birth defects, find ways to prevent or reduce the impact of certain major birth defects, and help parents of infants with special health care needs get the services they need. The proposal is a thoughtful and practical approach that will help protect and care for the many kids and families served by the above organizations.

We ask that you support AB 371/SB 287 in the Assembly and Senate and approve this important legislation.

Testimony in Support of Assembly Bill 371
Public Hearing – Assembly Committee on Health
Provided by Angie Thies
July 26, 2017

Chairman Sanfelippo and members of the committee, my name is Angela Thies. I am the Director of Advocacy and Government Affairs for the March of Dimes in Wisconsin. I am here today to thank you for the hearing on AB 371 and to request support for this important legislation.

Founded in 1938, the mission of the March of Dimes is to improve the health of all women of childbearing age, infants and children by preventing birth defects, premature birth and infant mortality.

Birth defects are a health condition that is present at birth. Birth defects may change the shape or function of one or more parts of the body. They can cause problems in how the body develops, how the body works, or in the overall health of an individual. Some of the most common birth defects in the U.S. include congenital heart defects, Down Syndrome, cleft lip, cleft palate, and spina bifida without anencephaly.

Birth defects can be caused by genetic abnormalities or environmental factors, but the causes of about 60-70% of birth defects are unknown.

Nationally, birth defects are a major cause of morbidity and mortality throughout childhood. Approximately three percent of babies are born with a birth defect, with birth defects being the leading cause of infant death, accounting for approximately 200 deaths annually in the state of Wisconsin.

In 2014, 1,515 babies were born with reported birth defects in Wisconsin, significantly less than the estimated 2,100 (or 1 in 33) according to the Centers for Disease Control and Prevention (CDC).

This represents not only a significant gap in understanding the prevalence of birth defects, but an increased need to provide necessary services and familial support.

According to the Centers for Disease Control and Prevention, accurately tracking birth defects and analyzing the collected data is a first step in preventing birth defects. Birth defects tracking systems are critical to track birth defects and use the data for prevention and referral activities.

Birth defects tracking systems are important for finding and collecting information about birth defects. Information from birth defects tracking systems is used by public health officials, policymakers, and scientists for the following activities:

- To understand if the number of birth defects is increasing or decreasing over time.



A FIGHTING CHANCE FOR EVERY BABY™

Angela Thies
Director of Advocacy & Government Affairs

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athies@marchofdimes.org
marchofdimes.org

- To investigate possible causes of and risk factors for birth defects.
- To educate the public about birth defects and how to prevent them.
- To plan and evaluate activities aimed at preventing birth defects.
- To refer babies and families affected by birth defects to appropriate services.
- To help policymakers allocate resources and services for affected babies and their families.

The Wisconsin Birth Defects Registry is limited in that, unlike every other registry in the country, it places the burden on the parent to report the diagnosis of a birth defect. Currently, the registry is an opt-in system, meaning birth defect reporters (such as physicians) must get parental consent to report a birth defect. As a result, experts estimate about one in three birth defects are unreported. As indicated, the March of Dimes and the CDC estimate that Wisconsin should be reporting 2100 birth defects on an annual basis.

The following improvements to the Wisconsin Birth Defect Prevention and Surveillance System as included in AB 371 will allow for better monitoring of birth defects, and the ability to assist families in getting more timely support.

Specifically, the provisions in AB 371 will:

- Enable a more effective and efficient reporting system for providers, hospitals, and specialty clinics
- Require providers, specialty clinics, and hospitals to report birth defects within the first 2 years of life; and
- Ensure the collection of necessary data to monitor and analyze the occurrence of birth defects while preserving individual and familial privacy rights through an opt out option should the family choose not to be included in the program

In closing, I'd like to thank Representative Jessie Rodriguez and Senator Alberta Darling for their leadership on this issue and request your support for AB 371. Thank you Chairman Sanfelippo and committee members - I'm happy to take questions.

Sincerely,

Angela Thies
Director of Advocacy and Government Affairs



TO: Assembly Committee on Health
FROM: Jennifer Kilzer, Neonatal Nurse Practitioner, Children's Hospital of Wisconsin
DATE: Wednesday, July 26, 2017
RE: Support for AB 371—Various changes to birth defect prevention and surveillance system

Good afternoon, Chairman Sanfelippo and members of the committee. My name is Jennifer Kilzer and I am a neonatal nurse practitioner at Children's Hospital of Wisconsin. Thank you for allowing me this opportunity to testify today in support of AB 371 which relates to making changes to the birth defects registry. I want to thank the bill's authors Representative Jessie Rodriguez and Senator Alberta Darling for sponsoring this legislation.

Children's Hospital of Wisconsin (Children's) serves children and families in every county across the state. We have inpatient hospitals in Milwaukee and the Fox Valley. We care for every part of a child's health, from critical care at one of our hospitals, to routine checkups in our primary care clinics. Children's also provides specialty care, urgent care, emergency care, dental care, school health nurses, foster care and adoption services, family resource centers, child health advocacy, health education, child welfare services, family preservation and support, mental health services, pediatric medical research and the statewide poison hotline.

Children's Fetal Concerns Center is one of only a few perinatal centers in the country and the only one in Wisconsin specializing in complex complications with multiple births. We have a team of experts that work with women who have high-risk pregnancies and our specialists diagnose and treat a number of fetal health issues. We provide maternal and fetal testing, prenatal counseling and perform fetal surgery to repair defects while an infant is still in the womb. Our interdisciplinary team includes various specialties who are committed to delivering excellent quality care and improving treatment and outcomes through research and innovation.

The Wisconsin Department of Health Services is responsible for the Wisconsin Birth Defect Prevention and Surveillance Program which implements a confidential birth defects registry which comprises information on birth defects found in children from birth to two years of age. The Wisconsin Birth Defect Registry (WBDR) captures information on conditions that occur prior to or during birth which require medical or surgical intervention or interfere with normal growth and development. While birth defects are common, occurring approximately in about 1 of every 30 babies born in the United States, the cause of many birth defects remains unknown. Birth defects are the leading cause of infant deaths and stillbirths, and of the babies who die during their first year, 20% of deaths were caused by congenital anomalies. They are also the most common cause of medical and developmental disability in children.

Under current law and practice, when a child is diagnosed with a birth defect, physicians, pediatric specialty clinics and hospitals must obtain parent or guardian consent in order to be able to report data regarding the child's geographic location, environmental conditions and other information to the WBDR. Requiring parental consent diminishes the effectiveness of the WBDR as many health care providers are unable to obtain consent before submitting a report due to the administrative burden of contacting parents requesting consent and associated documentation.



Only 25% of the reports submitted to the WBDR contain parental consent, resulting in data that fails to adequately account for the number of children with birth defects and their geographical locations. AB 371 would change the WBDR's reporting process from a consent opt-in approach, to an opt-out approach. Instead of requiring health providers to obtain affirmative consent, this would allow parents or guardians to opt-out of the reporting by written refusal.

Changing the WBDR reporting protocol to an opt-out approach instead of an opt-in approach will result in more robust data collection to help the health community learn more about these prevalent, often life-changing conditions. The opt-out approach has been recognized as a best practice model favored by federal funding opportunities, and making this change would better position Wisconsin. In addition to capturing more data, this change would also amplify funding opportunities to continue researching and sharing important information on birth defects.

The Wisconsin Department of Health Services, Division of Public Health has taken measures to ensure patient and family privacy in the WBDR, including utilizing a secure web-based reporting system to protect important patient health information. Providers submitting patient information sign a user agreement and may only view the reports submitted by their organization. Access to the WBDR is limited to public health authorities who acknowledge and abide by the WBDR security and confidentiality policy, developed in accordance with HIPAA (Health Insurance Portability & Accountability Act of 1996) regulations.

AB 371 would also allow the WBDR to share identifying information with state and federal vital records data systems in order to reduce duplication of information entered in the WBDR. This sharing would be done under this specific scope and is critical to ensuring the most accurate information is being used in research and analysis. Sharing this information with the state would also further enable referrals for intervention and treatment to be made for the family to help provide the best care for their child.

Analyzing the information collected in the WBDR is critically important to studying birth defects in order to learn more about what causes them, understand trends and develop prevention strategies and health education. Increasing research and funding opportunities to help the most vulnerable infants in our communities will help Children's achieve our vision of Wisconsin's kids being the healthiest in the nation.

Chairman Sanfelippo and committee members, I thank you again for the opportunity to testify in support of AB 371. I am happy to answer any questions now. If you have any questions, comments or concerns after the hearing, please feel free to contact me via email at jkilzer@chw.org or via phone at 414-266-7506.

Testimony in Support of Assembly Bill 371
Public Hearing – Assembly Committee on Health
Provided by Joe Schmidt
July 26, 2017

Chairman Sanfelippo and members of the committee, my name is Joe Schmidt, I am the proud father of two daughters (Leah and Karalyn), spouse of Laura, senior project developer at Trane Co. Ambassador for the March of Dimes and President of Building2Learn Consortium. I am here today to thank you for the hearing on AB 371 and to request support for this important legislation.

In January 2014, we went in for a routine 20 week ultrasound. Like many parents, we were anxious to learn the gender of our second child. What we least expected was to learn that our daughter had a neural tube (spinal cord) defect. A diagnosis of spina bifida was confirmed a couple of days later. We knew little about what to expect and how severe our child's disability would be.

We were immediately referred to the Fetal Concerns Center at Children's Hospital of Wisconsin. They connected us with multiple specialists who helped prepare us for what we, and our daughter, may face in the months and years to come. Our daughter, Leah Grace, was welcomed into the world by a NICU team on June 4, 2014. She underwent a variety of tests and evaluations by specialists while in the NICU to evaluate common complications of spina bifida, such as bladder and kidney problems, hydrocephalus, and orthopedic issues.

Most babies born with spina bifida have an "open" sac covering their spinal cord defect and require surgery within 24-48 hours of birth. Leah was born with a more rare form called lipomyelomeningocele, which is a fatty mass surrounding the spinal cord, and is skin covered. This was good news in terms of prognosis, and it meant she could wait until an older age for surgery. At 6 months of age, she underwent spinal surgery for "detethering" of her spinal cord. Leah continues to amaze everyone with her abilities. Though she will face lifelong medical challenges, her future looks bright.

When Leah was born and diagnosed with a birth defect, our sources of information were the Fetal Concerns Center, Leah's doctors and any information we could glean from the World Wide Web, friends and family. Fortunately for our family my wife Laura is a nurse practitioner. This was instrumental in understanding and determining Leah's care plan. The majority of families don't have the medical knowledge to ask the right questions and seek out the right information and resources. We could very well have been told about the birth defect registry, but honestly I don't remember and to this date Leah is not included.

While we were able to get Leah the services and support she needed for a good outcome, I have no doubt that we would have had more choices and our family could have coped better with the diagnosis had we been connected with services and support from the state's program.

In closing, my wife and I are proud to lend our support to make the Wisconsin Birth Defect Prevention and Surveillance System more effective and am happy to work with Representative Rodriguez and Senator Darling to make the necessary changes. We wholeheartedly support AB 371 and encourage members of this committee to lend their support and pass this important legislation.