2015 DRAFTING REQUEST

Bill

Received:	**11/11/2014**	Received By:	**swalkenh**
Wanted:	**As time permits**	Same as LRB:	**-1493**
For:	**Julie Lassa (608) 266-3123**	By/Representing:	**Danielle Williams**
May Contact:		Drafter:	**swalkenh**
Subject:	**Health - abortion/maternal/child**	Addl. Drafters:	
		Extra Copies:	

Submit via email: **YES**
Requester's email: **Sen.Lassa@legis.wisconsin.gov**
Carbon copy (CC) to: **sarah.walkenhorstbarber@legis.wisconsin.gov**
tamara.dodge@legis.wisconsin.gov

Pre Topic:

No specific pre topic given

Topic:

Newborn child screening for certain Lysosomal storage disorders

Instructions:

See attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?	swalkenh 12/19/2014	kfollett 12/19/2014		_____ _____			
/P1	swalkenh 1/14/2015		jfrantze 12/19/2014	_____ _____	sbasford 12/19/2014		State
/1		kfollett 1/14/2015	jfrantze 1/14/2015	_____ _____	mbarman 1/14/2015	srose 2/9/2015	State

FE Sent For:

at
intro

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1/14/15

- Call from Sen Lassa's office (Danielle) requesting that 0595 be drafted as /1

- only change to take out **** note

- would like yet today

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/?	swalkenh	12/19	12/19		12/19		

FE Sent For:

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Dodge, Tamara

From: Williams, Danielle
Sent: Tuesday, November 11, 2014 9:55 AM
To: Dodge, Tamara
Subject: Sen. Lassa Legislation Request
Attachments: LSD Newborn Screening Facts_Generic09242013.pdf; Lysosomal Storage Diseases.docx; NBS Cost Analysis for NJ.docx; What are Leukodystrophies.docx; What conditions are screened for in Wisconsin.docx; What is Krabbe Newborn Screening.docx; What is Krabbe.docx; What is newborn screening.docx

Hi Tamara,

Senator Lassa would like to draft legislation for the 2015-16 session that mandates newborn child screening for certain Lysosomal storage disorders (LSDs), including: Globoid Cell Leukodystrophy (Krabbe), Fabry, Pompe, Niemann-Pick, Gaucher, and Hurler Syndrome (MPS I). I have included information provided by the constituent that gives background on the disease in case you need that, but otherwise you can find similar legislation passed in Pennsylvania here: http://www.legis.state.pa.us/CFDOCS/Legis/PN/Public/btCheck.cfm?txtType=PDF&sessYr=2013&sessInd=0&billBody=H&billTyp=B&billNbr=1654&pn=2274.

If you have any questions, please feel free to contact me.

Sincerely,

Danielle Williams
Policy Analyst, Office of State Senator Julie Lassa
State Capitol
P.O. Box 7882
Madison, WI 53707-7882
(608) 266-3123
danielle.williams@legis.wi.gov

From: Sen.Lassa
Sent: Friday, October 24, 2014 4:53 PM
To: Julie Lassa; Williams, Danielle; Knickelbine, Mark
Subject: FW: Mark: Re: Kevin Cushman phone conversation from 10/24

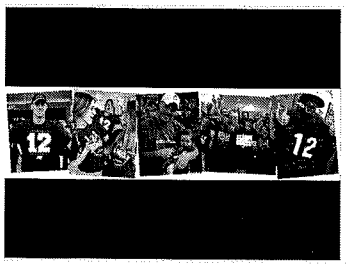
From: The Youth Guy [mailto:theeyouthguy@yahoo.com]
Sent: Friday, October 24, 2014 3:45 PM
To: Sen.Lassa
Subject: Mark: Re: Kevin Cushman phone conversation from 10/24

Hello Mark,

This is Kevin Cushman - Father to Collin.
We spoke on the phone earlier today in regards to Newborn Screening for Krabbe Leukodystrophy.

I've attached quite a bit of information that I hope will be helpful. There should be a total of 8 files.

Welcome to Hunters Hope! - Hunter's Hope Foundation is a great place for more information



Welcome to Hunters Hope! - Hunter's Hope Foundation

Thank you for your continued prayers and support for the Kel...

View on www.huntershope.org Preview by Yahoo

Anna Grantham (anna@huntershope.org or 251-3000-4321) would be the contact person at Hunters hope

Please feel free to contact me anytime.

Thanks.

Team Cushman
Kevin, Judy, Collin & Kendra

Hunter's Hope Foundation

Krabbe ~ Leukodystrophies ~ Newborn Screening

Newborn Screening for Krabbe and other Lysosomal Storage Disorders (LSDs)

NFL Hall of Fame Quarterback Jim Kelly and his wife Jill created the Hunter's Hope Foundation in 1997 after their son, Hunter (2/14/97 – 8/5/05), was diagnosed with Krabbe Leukodystrophy. Krabbe is a rare inherited disorder that affects the central and peripheral nervous systems. If untreated, children affected by the disorder suffer greatly and are not expected to live beyond their 2nd birthday.

In order for the only available treatment for Krabbe to be effective, it *must* be detected at birth through Newborn Screening.

In 2006, New York became the first state to begin screening for Krabbe disease. In August of 2012, Missouri began screening for Krabbe disease and one other LSD. New Jersey and Illinois plan to implement LSD newborn screening by the end of 2014 and New Mexico has passed legislation for LSD screening though an implementation date has yet to be determined. Important progress is being made, as these diseases are thought to have a collective incidence of 1:5,000.

Screening is available for Krabbe and five similar LSDs (Fabry, Gaucher, Pompe, MPS I and Niemann-Pick A/B) in a single assay. Although the assays would need to be validated in the particular state as the cutoffs may vary, there is experience in the states previously mentioned for a state lab to build upon.

Effective treatment for many of the LSDs is now available and supported by data gathered during clinical trials and published in the medical literature. Umbilical cord blood transplantation has been shown to significantly extend life and to improve the quality of life for children with LSDs. If the procedure is performed early in the course of disease, 80-90% of patients survive with good quality of life. This treatment has been shown to be effective in ameliorating the course of Krabbe disease and MPS I, and it is clear that treatment must be initiated at a very early age to be effective. In Krabbe disease, it must be initiated before any clinical manifestations appear. Enzyme replacement therapy is effective in the treatment of Gaucher disease, Fabry disease, Pompe disease, MPS I and MPS II and has been approved in each case by the Food and Drug Administration.

Should a state begin screening for these diseases, a quality assurance program for LSD newborn screening is in place at the CDC and would be available to the laboratory. Additionally, significant reduction in costs can be anticipated – certainly the care of children with Krabbe disease and other LSDs, would be much less costly when children are functional and do not require continuous nursing care. There would also be a reduction in costs related to the birth of second affected children before the first child was diagnosed. Additionally, it is estimated that the medical cost of an untreated child affected by Krabbe and similar diseases costs a state at least $700,000 annually.

For more information, please contact: Anna Grantham anna@huntershope.org or 251.300.4321.

Economics of Newborn Screening in New Jersey
NJ – 2010 live births – 110,434
# of Births financed by Medicaid = ~ 35% (www.statehealthfacts.org)
1:5000 diagnosed with LSD = 21 potential cases (7 potential Medicaid cases)
$700,000 annually for medical expenses to care for a child with LSD
$700,000 x 21 = $14,700,000 (annual care for children born in NJ w/ LSD)
$14,700,000 X 2 = $29,400,000 – (care for LSD children with expected lifespan of 2 years)

Potential of 7 children born annually with LSD under NJ Medicaid
$4,900,000 for 1 year of medical care for children on Medicaid (7 children x $700,000 annual cost for med expense)
$9,800,000 for 2 years of medical care for children on Medicaid
Transplant expense ranges from $300,000 - $700,000 (a one time expense)
$500,000 x 7 = $3,500,000

65 % Economic benefit for the state to screen at birth and administer treatment than to care for undiagnosed Medicaid cases
$9,800,000 care for 2 years vs $3,500,000 for treatment
Because of the rareness of these diseases, diagnosis is made too late for treatment to be an option. Newborn Screening is the only way for medical professionals to detect these diseases in time for treatment to be a viable option.

What conditions are screened for in Wisconsin?

Amino Acid Disorders

- **Argininosuccinic aciduria (ASA)**
  State preferred name: argininosuccinic acidemia
- **Benign hyperphenylalaninemia (H-PHE)**
- **Biopterin defect in cofactor biosynthesis (BIOPT-BS)**
- **Biopterin defect in cofactor regeneration (BIOPT-REG)**
- **Citrullinemia, type I (CIT)**
- **Citrullinemia, type II (CIT II)**
- **Classic phenylketonuria (PKU)**
- **Homocystinuria (HCY)**
- **Hypermethioninemia (MET)**
- **Maple syrup urine disease (MSUD)**
- **Tyrosinemia, type I (TYR I)**
- **Tyrosinemia, type II (TYR II)**
- **Tyrosinemia, type III (TYR III)**

Endocrine Disorders

- **Congenital adrenal hyperplasia (CAH)**
- **Primary congenital hypothyroidism (CH)**

Fatty Acid Oxidation Disorders

- **2,4 Dienoyl-CoA reductase deficiency (DE RED)**
- **Carnitine acylcarnitine translocase deficiency (CACT)**
- **Carnitine palmitoyltransferase type II deficiency (CPT-II)**
- **Carnitine uptake defect (CUD)**
- **Glutaric acidemia, type II (GA-2)**
- **Long-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency (LCHAD)**
- **Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)**
- **Medium-chain ketoacyl-CoA thiolase deficiency (MCAT)**
- **Medium/short-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency (M/SCHAD)**
- **Trifunctional protein deficiency (TFP)**
- **Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD)**

What conditions are screened for in Wisconsin?

Hemoglobin Disorders

- Hemoglobinopathies (Var Hb)
- S, Beta-thalassemia (Hb S/ßTh)
- S, C disease (Hb S/C)
- Sickle cell anemia (Hb SS)

Organic Acid Conditions

- 2-Methyl-3-hydroxybutyric acidemia (2M3HBA)
- 3-Hydroxy-3-methylglutaric aciduria (HMG)
- 3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC)
- 3-Methylglutaconic aciduria (3MGA)
- Beta-ketothiolase deficiency (BKT)
- Glutaric acidemia type I (GA1)
- Holocarboxylase synthetase deficiency (MCD)
- Isovaleric acidemia (IVA)
- Methylmalonic acidemia (cobalamin disorders) (Cbl A,B)
- Methylmalonic acidemia (methymalonyl-CoA mutase deficiency) (MUT)
- Methylmalonic acidemia with homocystinuria (Cbl C, D, F)
- Propionic acidemia (PROP)

Other Disorders

- Biotinidase deficiency (BIOT)
- Classic galactosemia (GALT)
- Critical congenital heart disease (CCHD)
- Cystic fibrosis (CF)
- Hearing loss (HEAR)
- Severe combined immunodeficiency (SCID)

What is Krabbe?

The full name for Krabbe disease is Globoid Cell Leukodystrophy. Krabbe (Crab-a) disease is a rare, inherited disorder that affects the central and peripheral nervous systems.

Those who inherit the disease lack an important enzyme (GALC) the body needs to produce healthy myelin. Myelin, or *white matter,* is the protective covering of the nerve cells. It acts like insulation surrounding an electric wire. The absence of GALC enzyme leads to the rapid destruction of both the cells that make myelin and the myelin itself.

Krabbe disease has four types: early onset infantile, later onset infantile, adolescent, and adult. The type is determined by the age of onset of symptoms. A baby with a positive newborn screening result for Krabbe disease can fall into any one of these types. Or, the baby with a positive newborn screen result for Krabbe may not have any of these types of the disease, but may just be a carrier, which means they will not experience any symptoms. For more information click here.

What if my child has Krabbe?

There are varying forms of Krabbe disease and it is important that a diagnosis is made as soon as possible to ensure that appropriate treatment is administered. The vast majority of infants with a positive screen for Krabbe either do not have the most severe form of the disease, or they are carriers.

For infants that are affected by the most severe form of the disease, ***Early Onset Infantile Krabbe Disease***, there is HOPE – through early diagnosis, children who receive treatment (Cord Blood Transplant) before the disease is too far progressed have the potential for a healthy life.

Your child's doctor may recommend that your child be medically followed. This is to ensure that your child does not have a more rare form of the disease that could potentially require treatment in the future.

Krabbe Disease

What is Krabbe Disease?
Globoid Cell Leukodystrophy, commonly known as Krabbe (crab-ay) Disease, is a genetic disorder that affects the central and peripheral nervous systems.

Those affected by Krabbe typically appear healthy until onset, or when an individual experiences symptoms, of the disease. Onset can vary from the first few weeks or months of life (Early Infantile Onset) into adulthood (Adult Onset).

Those who suffer from Krabbe Disease have a deficiency of an important enzyme called Galactosylceramidase (GALC).

Krabbe Disease is both a Leukodystrophy and Lysosomal Storage Disorder (LSD). Leukodystrophies are characterized as degenerative diseases of the white matter of the brain. LSDs occur when a part of the cell, called the lysosome, does not function properly. In a healthy individual, enzymes break down material in the lysosomes, however, if the body does not produce enough of a specific enzyme (ex: GALC), material builds up and becomes toxic.

What parts of the body are affected?
Krabbe Disease affects both the central and peripheral nervous systems, which are responsible for all of the body's voluntary and involuntary movements.

The central nervous system is made up of the nerves within the brain and spinal cord and is the primary control center of the body.

The peripheral nervous system's primary function is to carry information from the brain and spinal cord throughout the body to the limbs and organs.

What are the different forms of Krabbe Disease?

Early Infantile Krabbe Disease (EIKD)
Early Infantile Krabbe Disease is the most severe form and is often initially misdiagnosed as colic, reflux, food/milk allergy, or even cerebral palsy.

Affected babies begin to show symptoms, including severe irritability, feeding issues, stiffness and unmet developmental milestones, within the first months of life.

Symptoms: General irritability (excessive crying), stiffness, decline in motor skills, loss of previously attained milestones, difficulty in feeding, seizures, arching of the back, jerking of the arms and/or legs

Later Onset Infantile Krabbe Disease
Those with Later Onset Krabbe Disease begin to show symptoms between 6 months and 3 years of age. Symptoms are similar to those described in Early Infantile Krabbe Disease.

Symptoms: General irritability (excessive crying), stiffness, decline in motor skills, loss of previously attained milestones, difficulty in feeding, seizures, arching of the back, jerking of the arms and/or legs.

Juvenile Onset Krabbe Disease and Adult Onset Krabbe Disease
Those with Juvenile Onset Krabbe Disease typically show an initial regression of motor skills at 3 years of age or later. After the initial decline, the disease progresses slowly, often lasting years.

Adult Onset Krabbe Disease often results in initial vision problems, generally followed by muscle stiffness and difficulty walking. It is possible that Adult Onset Krabbe Disease can be misdiagnosed as multiple sclerosis.

Symptoms: Progressive loss of vision, difficulty walking (ataxia), loss of manual dexterity, muscle weakness

Is there a treatment for Krabbe Disease?
Yes, when diagnosed early.

Individuals diagnosed before the disease is too far progressed may be eligible for a *Cord Blood Transplant*. Through this procedure, stem cells from umbilical cord blood are given to the affected patient in order to slow the progression of the disease. These stem cells come from umbilical cords that are stored after live, healthy births of unaffected donors. To learn more, please visit the Carolinas Cord Blood Bank.

Unfortunately, myelin that has already been damaged by the disease cannot be repaired by this treatment. This is why it is important for Krabbe Leukodystrophy to be detected as early as possible, ideally through each state including Krabbe in their newborn screening program.

What if my child was diagnosed too late for a transplant?
Tragically, unless a child is born in a state that screens for Krabbe at birth, or has a known family history of the disease, the vast majority of children are diagnosed after they are symptomatic and too far progressed to benefit from a transplant.

However, numerous families have found that their child's symptoms and pain can be managed through various medications, adaptive equipment and therapies – including physical, respiratory, occupational, and speech.

To learn more about experiencing the joy of living with a child affected by Krabbe Disease, visit the Hope for Life section of our website.

Why is the GALC enzyme needed in the body?
GALC is needed for the body to make normal myelin in the central and peripheral nervous systems and to break down material in the lysosomes. When too little GALC is produced, it causes toxicity in the brain, leading to myelin loss. This changes brain cells and causes neurological damage.

Why is myelin so important in the nervous systems?
Myelin is the protective covering of the nerve cells and acts like insulation surrounding an electric wire. Myelin is needed for the transmission of information from neurons. When myelin is damaged, some communication is lost during transmission. This results in the loss of voluntary and involuntary function in the body. Currently, there is no known method to reverse damage to myelin.

How do you get Krabbe Disease?
Krabbe Disease is genetic, which means that it is an inherited disorder. Krabbe is an autosomal recessive disorder, meaning that if both parents are carriers of the disease, each child has a 1 in 4 chance of developing Krabbe.

When both parents pass on a specific mutated gene, their child has a 25% chance of being affected by the disease, a 25% chance of neither being a carrier or affected and a 50% chance of being a carrier, like the parent.

Could other children in the family also have Krabbe Disease?
If both parents are carriers, each child has a 1 in 4 chance of being affected. If not affected, other children in the family could also be a carrier of the gene causing the disease.

To determine if other children in the family are affected by Krabbe Disease, it is best to consult with your genetic counselor or your child's physician.

How is Krabbe Disease diagnosed?
Krabbe Disease is diagnosed through a series of tests. Oftentimes a blood test is used to determine the level of GALC enzyme activity. Other tests may include a MRI, CT, nerve conduction study and genetic testing for mutation analysis.

Although newborn screening for Krabbe is available, it is NOT a diagnostic test, however, newbornn screening can lead to a proper and early diagnosis upon confirmatory testing.

What research is being done to find better treatments& a cure for Krabbe Disease?
Hunter's Hope is committed to funding research for better treatments and a cure for Krabbe and other Leukodystrophies. To learn more about the groundbreaking research currently underway, visit the Research section of our website.

Families affected by Krabbe are in integral part of advancing research for this disease. To learn more about how your family can participate in our World Wide Registry for Krabbe Disease, visit the Clinical Research page and contact Kathleen Scott.

Krabbe and Leukodystrophies

Krabbe Disease is 1 of over 40 known Leukodystrophies, which are genetic, progressive disorders that affect the brain, spinal cord and nervous systems.

Alone, each Leukodystrophy may be considered rare, but as a group, Leukodystrophies affect approximately 1 in 7,000 individuals.

As more unclassified variants of Leukodystrophies are identified, this number may increase to as high as 1 in 2,000 individuals.*

Although Leukodystrophies may have a greater prevalence than commonly known disorders such as Cystic Fibrosis, they remain virtually unknown in the general population and within the medical community.

As a Foundation, Hunter's Hope strives to bring **HOPE** and encouragement to families affected by all Leukodystrophies. We are privileged to serve over 700 families affected by these dreadful diseases through various Family Care Programs, research initiatives and advocacy efforts for newborn screening, both federally and in states nationwide.

We invite you visit the Hunter's Hope Wall of Fame to see the beautiful faces of hundreds affected by Leukodystrophies.

Lysosomal Storage Diseases

Lysosomal Storage Diseases are a group of rare inherited metabolic disorders that result from defects in lysosomal function. This means they are missing a particular enzyme that normally breaks down unwanted material in the cell resulting in destruction. It is the accumulation of this "toxic" substance that causes demyelination in children with Krabbe.

Each disorder is the result of a particular enzyme that then causes destruction to certain parts of the central and peripheral nervous system and organs.

Leukodystrophies

What is a Leukodystrophy?
Leukodystrophies are a group of disorders that affect the white matter in the brain. The word comes from *Leuko*, which means white, and *dystrophy*, which means imperfect growth. Therefore, Leukodystrophies are characterized by imperfect growth of the white matter in the brain.

How many Leukodystrophies are there?
Currently, there are over 40 known Leukodystrophies, although many still remain unclassified. This list has grown significantly in the last ten years and as research advances, scientists will continue to discover and classify new variations in this family of diseases.

As a group, Leukodystrophies are estimated to affect approximately 1 in 7,000 people, however as more unclassified variants are identified this number may increase to as high as 1 in 2,000.

For a listing of classified Leukodystrophies to date, please download the PDF.

Why do you get a Leukodystrophy?
Most Leukodystrophies are genetic, which means that they are passed from parents to children. Depending on the Leukodystrophy, the manner in which a mutated gene is passed down will differ.

Although rare, recent research has also indicated that some Leukodystrophies develop sporadically, meaning that neither parent is a carrier of a mutated gene.

How are Leukodystrophies diagnosed?
Often times, MRIs used to produce detailed images of the brain help in the initial diagnosis of a Leukodystrophy. Depending on the Leukodystrophy, additional diagnostic measures may include, blood tests, urine tests, hearing tests, nerve biopsies, CT scans or lumbar punctures.

Newborn screening can also be used to help detect a limited number of Leukodystrophies. Currently, newborn screening exists only for Krabbe Disease and Adrenoleukodystrophy (ALD). However, this group is anticipated to grow as research continues to advance. Unfortunately, not all states include Krabbe and ALD in their newborn screening panels.

Is there treatment for Leukodystrophies?
Depending on the type and stage of the Leukodystrophy, some treatments may be available such as cord blood or bone marrow transplantation. However, in many cases, treatment must be administered before the disease is too far progressed.

Research studies exploring the effectiveness of enzyme replacement and gene therapy are also underway for some Leukodystrophies.

Often, treatment is limited to symptom management. This includes, but is not limited to, various medications, adaptive equipment, physical, speech and occupational therapy, nutritionists, nursing, etc. Although this does not stop the progression of the disease, this proactive approach greatly improves the child's comfort level as well as quality of life. For more information, visit our Hope for Life webpage.

What are the symptoms of Leukodystrophies?
Most commonly, Leukodystrophies are defined by a gradual decline in development. An infant or child, who was previously exhibiting normal development, may experience progressive loss in gait, body tone, vision, hearing, swallowing and ability to eat.

What makes Leukodystrophies similar? What makes them different?
All Leukodystrophies are the result of an improper growth of myelin. Myelin is the protective covering of nerve cells and acts like insulation surrounding an electric wire. Myelin is made up of thousands of chemicals, each of which affects the myelin sheath in some way. The myelin sheath, which is the main component of the white matter, is extremely complex. Leukodystrophies are caused by a deficiency in one of these chemical substances, which results in problems within the myelin sheath.

Many genes are involved in the process of making healthy myelin. A mutation, or defect, in any of the genes associated with this process may result in a Leukodystrophy. Symptoms vary, depending on the type and stage of each specific disease.

What research is being done to help those with Leukodystrophies?
Through Hunter's Hope Foundation, scientists at the Hunter James Kelly Research Institute are investigating various aspects of Leukodystrophies in hopes of improving available therapies and ultimately finding a cure for these diseases.

Several research projects are currently underway to help improve the lives of Leukodystrophy patients. For a list of research projects that Hunter's Hope has, or is currently funding, please visit the Research Projects section of the Hunter's Hope website.

Krabbe Newborn Screening

Early detection for the most agressive form of Krabbe, Early Infantile Krabbe Disease (EIKD), is crucial. The symptoms of EIKD normally are not noticeable for the first weeks of life. For infants affected by the EIKD form of the disease, treatment must be administered as soon after birth as possible to avoid irreversible consequences. Therefore, if your child has been screened positive for Krabbe disease, it is critical that you follow up with your pediatrician immediately upon receiving the positive result.

What is newborn screening?

A few drops of blood were taken from your baby's heel and placed on a card that was sent to your state's newborn screening lab. The results were then sent to your baby's pediatrician and the hospital where they were born. Newborn screening looks for serious developmental, genetic, and metabolic disorders that would not otherwise be detected. For these diseases, early detection is essential so that they may be treated before irreversible consequences occur. Newborn screening does **not** diagnose diseases, but identifies which babies need *additional* testing to confirm or rule out these diseases. Although these diseases are very rare, they are treatable if caught early.

PRINTER'S NO. 2274

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1654 Session of 2013

INTRODUCED BY CRUZ, DAVIS, YOUNGBLOOD, GALLOWAY, CLAY, CALTAGIRONE, BROWNLEE, McGEEHAN, WATSON, B. BOYLE, COHEN, KIRKLAND, SABATINA, MURT, BOBACK AND DiGIROLAMO, AUGUST 26, 2013

REFERRED TO COMMITTEE ON HUMAN SERVICES, AUGUST 26, 2013

AN ACT

Amending the act of September 9, 1965 (P.L.497, No.251), entitled, as amended, "An act requiring physicians, hospitals and other institutions to administer or cause to be administered tests for genetic diseases upon infants in certain cases," further providing for newborn child screening and follow-up program.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 3(a)(1) of the act of September 9, 1965 (P.L.497, No.251), known as the Newborn Child Testing Act, amended July 4, 2008 (P.L.288, No.36), is amended to read:

Section 3. Newborn Child Screening and Follow-up Program.--

(a) In order to assist health care providers to determine whether treatment or other services are necessary to avert mental retardation, permanent disabilities or death, the department, with the approval of the Newborn Screening and Follow-up Technical Advisory Committee, shall establish a program providing for:

(1) The screening tests of newborn children for the

following diseases:

(i) Phenylketonuria (PKU).

(ii) Maple syrup urine disease (MSUD).

(iii) Sickle-cell disease (hemoglobinopathies).

(iv) Galactosemia.

(v) Congenital adrenal hyperplasia (CAH).

(vi) Primary congenital hypothyroidism.

(vii) Certain Lysosomal storage disorders (LSDs), including:

(A) Globoid Cell Leukodystrophy (Krabbe).

(B) Fabry.

(C) Pompe.

(D) Niemann-Pick.

(E) Gaucher.

(F) Hurler Syndrome (MPS I).

* * *

Section 2. This act shall take effect in 60 days.

FILE

SWB

Telephone Conference
w/ Sen. Lassa's office 12/9/14

- Sen. Lassa's office will follow up with Legal as needed

- Agrees timing of "prior to discharge, or w/in a week, whichever is earlier" or something similar

- Put in delayed effective date to allow agency action as needed; Let's start with 60 days for now

- Let's put in a provision for DHS to regularly review list of tests, determine if more appropriate

- Noted this is a preliminary draft and that they should let me know if want changes or to make introducible

State of Wisconsin
2015 – 2016 LEGISLATURE

LRB-0595/2
SWB:...

IN 12/19/14

NEEDED TODAY 12/19/14

PRELIMINARY DRAFT – NOT READY FOR INTRODUCTION

Gen

AN ACT ...; **relating to:** newborn screening for certain lysosomal storage disorders.

Analysis by the Legislative Reference Bureau

Under current law, the attending physician or nurse–midwife must ensure that every infant born undergoes testing for certain congenital and metabolic disorders prior to the infant's discharge from the hospital or maternity home. For infants born elsewhere, the attending physician, nurse–midwife, or other birth attendant must ensure that the infant is tested within a week of birth. As authorized by current law, the department of health services (DHS) specifies by rule the congenital and metabolic disorders for which newborn infants are to be screened. Current law allows an exception to the testing requirement if the parents or legal guardian object on the basis of a conflict with religious tenets and practices or with their personal convictions.

This bill requires that, in addition to the other congenital and metabolic disorders for which testing is currently required under the DHS rules, the attending physician, nurse–midwife, or in certain circumstances, other birth attendant, must ensure that every infant born undergoes testing for certain lysosomal storage disorders, specifically, globoid cell leukodystrophy, also known as Krabbe disease; Fabry disease, Pompe disease; Niemann–Pick disease; Gaucher disease, and Hurler syndrome, also known as mucopolysaccharidosis type I (MPS I). For infants born in a hospital or maternity home, the attending physician or nurse–midwife must ensure this testing is completed before the infant is discharged from the hospital or within one week of birth, if the infant has not yet been discharged. For births

occuring outside a hospital or maternity home setting, the attending physician, nurse–midwife, or other birth attendant must ensure testing is done within one week of birth. The parental objection exemption under current law also applies to the testing required under this bill.

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

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

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

253.13 **(1)** TESTS; REQUIREMENTS. The attending physician or nurse licensed under s. 441.15 shall cause every infant born in each hospital or maternity home, prior to ~~its~~ the infant's discharge ~~therefrom~~, to be subjected to tests for congenital and metabolic disorders, as specified in rules promulgated by the department. If the infant is born elsewhere than in a hospital or maternity home, the attending physician, nurse licensed under s. 441.15, or birth attendant who attended the birth shall cause the infant, within one week of birth, to be subjected to these tests.

History: 1977 c. 160; 1983 a. 157; 1985 a. 255; 1987 a. 27; 1989 a. 31; 1991 a. 39, 177; 1993 a. 27 s. 316; Stats. 1993 s. 253.13; 1995 a. 27 s. 9126 (19); 2001 a. 16, 52; 2007 a. 20 s. 9121 (6) (a); 2009 a. 28, 279; 2011 a. 32; 2013 a. 135.

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

253.13 **(1g)** SCREENING FOR CERTAIN LYSOSOMAL STORAGE DISORDERS. (a) In addition to the testing required under sub. (1), the attending physician or nurse licensed under s. 441.15 shall cause every infant born in each hospital or maternity home, prior to the infant's discharge or within one week of the birth if the infant has not yet been discharged, to be subjected to tests for the following lysosomal storage disorders:

1. Globoid cell leukodystrophy, also known as Krabbe disease.
2. Fabry disease.
3. Pompe disease.

4. Niemann–Pick disease.

5. Gaucher disease.

6. Hurler syndrome, also known as mucopolysaccharidosis type I.

(b) If the infant is born elsewhere than in a hospital or maternity home, the attending physician, nurse licensed under s. 441.15, or birth attendant who attended the birth shall cause the infant, within one week of birth, to be subjected to the tests under par. (a).

(c) No later than June 1, 2018, and every two years thereafter, the department shall evaluate the appropriateness of mandatory newborn testing for lysosomal storage disorders in addition to those listed under par. (a). If the department determines that testing for one or more lysosomal storage disorders in addition to those listed under par. (a) is appropriate, the department, under the authority granted under sub. (1), may promulgate rules adding to the list of disorders for which newborn testing is required.

****NOTE: Are there any specific factors you would like DHS to take into account in evaluating? If the bill does not indicate otherwise, the criteria that apply to all other congenital and metabolic disorders under DHS 115 (specifically DHS 115.06) will apply.

SECTION 3. Effective date.

(1) This act takes effect on the first day of the 3rd month beginning after publication.

(END)

State of Wisconsin
2015 – 2016 LEGISLATURE

LRB–0595/P1
SWB:kjf:jf

PRELIMINARY DRAFT – NOT READY FOR INTRODUCTION

IN 1/14/15
DUE: TODAY please

Reser

AN ACT ***to amend*** 253.13 (1); and ***to create*** 253.13 (1g) of the statutes; **relating to:** newborn screening for certain lysosomal storage disorders.

Analysis by the Legislative Reference Bureau

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(c) No later than June 1, 2018, and every 2 years thereafter, the department shall evaluate the appropriateness of mandatory newborn testing for lysosomal storage disorders in addition to those listed under par. (a). If the department determines that testing for one or more lysosomal storage disorders in addition to those listed under par. (a) is appropriate, the department, under the authority granted under sub. (1), may promulgate rules adding to the list of disorders for which newborn testing is required.

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(END)

Basford, Sarah

From: Williams, Danielle
Sent: Monday, February 09, 2015 10:47 AM
To: LRB.Legal
Subject: Draft Review: LRB -0595/1 Topic: Newborn child screening for certain Lysosomal storage disorders

Please Jacket LRB -0595/1 for the SENATE.