

☛ **07hr_JCR-AR_Misc_pt07**



☛ Details: DHFS Emergency Order, ch. HFS 115. Public hearing held May 20, 2008.

(FORM UPDATED: 08/11/2010)

WISCONSIN STATE LEGISLATURE ... PUBLIC HEARING - COMMITTEE RECORDS

2007-08

(session year)

Joint

(Assembly, Senate or Joint)

Committee for Review of Administrative Rules...

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
- Clearinghouse Rules ... **CRule** (w/Record of Comm. Proceedings)
- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
 - (**ab** = Assembly Bill) (**ar** = Assembly Resolution) (**ajr** = Assembly Joint Resolution)
 - (**sb** = Senate Bill) (**sr** = Senate Resolution) (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

Record of Committee Proceedings

Joint Committee for Review of Administrative Rules

DHFS Emergency Order, ch. HFS 115

Adds Severe Combined Immunodeficiency (SCID) and related conditions of immunodeficiency to the list of congenital and metabolic disorders and types of disorders, under ch. HFS 115, for which hospitals are required to screen newborns except if objected to for religious reasons. Set to expire May 30, 2008. 30 day extension.

May 20, 2008

PUBLIC HEARING HELD

Present: (10) Senators Jauch, Lehman, Kreitlow, Grothman and Leibham; Representatives LeMahieu, Zipperer, Friske, Black and Berceau.

Absent: (0) None.

Appearances For

- Alex Meyer, Madison — State Genetics Coordinator, DHFS

Appearances Against

- None.

Appearances for Information Only

- None.

Registrations For

- None.

Registrations Against

- None.

Registrations for Information Only

- None.

May 20, 2008

EXECUTIVE SESSION HELD

Present: (10) Senators Jauch, Lehman, Kreitlow, Grothman and Leibham; Representatives LeMahieu, Zipperer, Friske, Black and Berceau.

Absent: (0) None.

Moved by Senator Grothman, seconded by Senator Lehman that
DHFS Emergency Order, ch. HFS 115 be recommended for
adoption.

Ayes: (10) Senators Jauch, Lehman, Kreitlow, Grothman
and Leibham; Representatives LeMahieu,
Zipperer, Friske, Black and Berceau.

Noes: (0) None.

ADOPTION RECOMMENDED, Ayes 10, Noes 0

Sarah Barry
Committee Clerk

Vote Record

Joint Committee for Review of Administrative Rules

Date: 5/20/08

Moved by: Orath

Seconded by: Leh

HFS 115

AB _____ SB _____ Clearinghouse Rule _____
 AJR _____ SJR _____ Appointment _____
 AR _____ SR _____ Other _____

A/S Amdt _____
 A/S Amdt _____ to A/S Amdt _____
 A/S Sub Amdt _____
 A/S Amdt _____ to A/S Sub Amdt _____
 A/S Amdt _____ to A/S Amdt _____ to A/S Sub Amdt _____

Be recommended for:
 Passage Adoption Confirmation Concurrence Indefinite Postponement
 Introduction Rejection Tabling Nonconcurrence

<u>Committee Member</u>	<u>Aye</u>	<u>No</u>	<u>Absent</u>	<u>Not Voting</u>
Senator Robert Jauch, Co-Chair	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Representative Daniel LeMahieu, Co-Chair	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Senator John Lehman	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Senator Pat Kreitlow	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Senator Glenn Grothman	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Senator Joseph Leibham	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Representative Rich Zipperer	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Representative Donald Friske	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Representative Spencer Black	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Representative Terese Berceau	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Totals:	_____	_____	_____	_____

Motion Carried

Motion Failed



WISCONSIN STATE LEGISLATURE





State of Wisconsin
Department of Health and Family Services

Jim Doyle, Governor
Karen E. Timberlake, Secretary

April 29, 2008

The Honorable Robert Jauch
Co-Chairperson
Joint Committee for Review of Administrative Rules
Room 118 South, State Capitol
Madison, Wisconsin 53702

The Honorable Daniel LeMahieu
Co-Chairperson
Joint Committee for Review of Administrative Rules
Room 17 North, State Capitol
Madison, Wisconsin 53702

Dear Senator Jauch and Representative LeMahieu:

The Department issued an emergency order, effective January 1, 2008, to add Severe Combined Immunodeficiency (SCID) and related conditions of immunodeficiency to the list of congenital and metabolic disorders and types of disorders, under ch. HFS 115, for which hospitals are required to screen newborns except if objected to for religious reasons. The emergency order will expire on May 30, 2008.

30 days through June 1

This letter is to request the Joint Committee extend the effective period of the emergency order by 30 days, to June 30, 2008. The Department submitted permanent rules to the Senate and Assembly Presiding Officers on March 24, 2008. The Department projects that the review periods of the Senate and Assembly Committees will end on April 26, 2008 and April 28, 2008, respectively. The Department further projects that the permanent rules will be published in June, and become effective on July 1, 2008. Therefore, the Department has determined that it would be impossible to promulgate the permanent rules before the expiration of the emergency order on May 30, 2008.

Unless the Joint Committee extends the emergency order, hospitals will lose the authority to screen newborns for SCID, which is a potentially fatal condition.

Persons with SCID are extremely vulnerable to infections, to the degree that the condition is universally fatal without treatment within the first year of life. With an estimated prevalence of 1 in 66,000, and a Wisconsin annual birth rate around 71,000, the failure to screen for SCID

could result in the death of 1-2 infants in the state every year. In addition, babies who are undiagnosed or diagnosed late with SCID typically cost \$1-2 million each to treat (this figure is based on audited costs from Children's Hospital of Wisconsin, the facility which treats children with SCID, but without benefit of early diagnosis). Babies with SCID, diagnosed in the first week of life can be cured by bone marrow transplantation (estimate 75-95% cure rate) at a charge of \$170,000 per discharge (2005 J Peds, McGhee et.al.) In treating infants with SCID, the state would not assume responsibility for the bone marrow transplantation, since the Congenital Disorders Program historically pays only for initial follow-up visits and confirmatory testing. It is expected that the savings to Medicaid may be substantial for each eligible affected child receiving early diagnosis.

The Department held a public hearing on the emergency and permanent rules on March 6, 2008. All of the comments received by the Department about the rules were in support of the rules.

A copy of the emergency order and fiscal estimate, which includes additional analysis, is attached to this letter. If you have questions about the rules of fiscal estimate, please contact Alexandria Meyer at 608-267-7148.

Sincerely,



Karen E. Timberlake
Secretary

Attachments

cc: Senator Fred Risser
Speaker Michael Huebsch

**ORDER OF
DEPARTMENT OF HEALTH AND FAMILY SERVICES
TO ADOPT RULES**

The Wisconsin Department of Health and Family Services hereby adopts emergency rules to create s. HFS 115.04 to include the condition known as Severe Combined Immunodeficiency (SCID) and related conditions of immunodeficiency to the list of disorders and disorder types found under s. HFS 115.04.

FINDING OF EMERGENCY

The Department of Health and Family Services finds that an emergency exists and that the adoption of an emergency rule is necessary for the immediate preservation of the public health, safety and welfare. The facts constituting the emergency are as follows:

The early identification of particular congenital and metabolic disorders that are harmful or fatal to persons with the disorders is critical to mitigating the negative effects of such disorders. Therefore, Wisconsin Statute 253.13 requires that every infant born be subjected to blood tests for congenital and metabolic disorders, as specified in administrative rules promulgated by the Department; however, parents may refuse to have their infants screened for religious reasons. The Department has issued ch. HFS 115, Screening of Newborns for Congenital and Metabolic Disorders, to administer this statutory requirement. Currently, s. HFS 115.04 lists 13 congenital and metabolic disorders and types of disorders, for a total of 47 different disorders, for which the state hygiene laboratory must test newborn blood samples.

In determining whether to add or delete disorders from the list under s. HFS 115.04, s. HFS 115.06 directs the Department to seek the advice of persons with expertise and experience concerning congenital and metabolic disorders. For this purpose, the Department has established the Wisconsin Newborn Screening Umbrella Advisory Group. Section HFS 115.06 also lists 6 criteria on which the Department must base its decision to add or delete disorders from s. HFS 115.04. These criteria are as follows:

1. Characteristics of the specific disorder, including disease incidence, morbidity, and mortality.
2. The availability of effective therapy and potential for successful treatment.
3. Characteristics of the test, including sensitivity, specificity, feasibility for mass screening and cost.
4. The availability of mechanisms for determining the effectiveness of test procedures.
5. Characteristics of the screening program, including the ability to collect and analyze specimens reliably and promptly, the ability to report test results quickly and accurately and the existence of adequate follow-up and management programs.
6. The expected benefits to children and society in relation to the risks and costs associated with the testing for the specific condition.

In consideration of these criteria, the Wisconsin Newborn Screening Advisory Umbrella Advisory Group has recently recommended the Department add the condition known as Severe Combined Immunodeficiency (SCID) and related conditions of immunodeficiency to the 13 disorders and types of

disorders currently screened for and listed in s. HFS 115.04. Persons with SCID are extremely vulnerable to infections, to the degree that the condition is universally fatal without treatment within the first year of life. With an estimated prevalence of 1 in 66,000, and a Wisconsin annual birth rate around 71,000, the failure to screen for SCID could result in the death of 1-2 infants in the state every year.

The Advisory Group recommends the Department begin screening newborns for SCID and related conditions of immunodeficiency as soon as possible. Before screening can begin, however, the Department must add these conditions to the list in s. HFS 115.04, which is the subject of this emergency order.

The Department will immediately promulgate identical permanent rules to replace these emergency rules.

SUMMARY OF RULE

Statute interpreted: Section 253.13, Stats.

Statutory authority: Sections 253.13 (1) and s. 227.11 (2)

Explanation of agency authority:

Section 253.13 (1), Stats., stipulates that every infant born in Wisconsin to be subjected to blood tests for congenital and metabolic disorders, as specified in rules promulgated by the department. Section 227.11 (2), Stats., grants each agency rule-making authority, provided it conforms to expressly provided guidelines.

Related statute or rule: See the "Statute interpreted" section.

Plain language analysis:

The early identification of particular congenital and metabolic disorders that are harmful or fatal to persons with the disorders is critical to mitigating the negative effects of such disorders. Therefore, Wisconsin Statute 253.13 requires that every infant born be subjected to blood tests for congenital and metabolic disorders, as specified in administrative rules promulgated by the Department; however, parents may refuse to have their infants screened for religious reasons. The Department has issued ch. HFS 115, Screening of Newborns for Congenital and Metabolic Disorders, to administer this statutory requirement. Currently, s. 115.04 lists 13 congenital and metabolic disorders and types of disorders, for a total of 47 different disorders, for which the state hygiene laboratory must test newborn blood samples.

This emergency order will include SCID and related conditions of immunodeficiency. When SCID and related conditions of immunodeficiency are permanently added to those disorders and types of disorders listed in s. HFS 115.04, follow-up and management will be conducted by both specialists and primary care physicians. Families of infants will receive intensive counseling and be fully apprised of treatment options and availability. The Wisconsin Congenital Disorders Program will be responsible for coordinating the activities of the managing specialists, but will not provide direct patient care.

This rule change would add SCID to the 13 disorders and disorder types currently screened for under HFS 11.04. All newborn screening tests are currently paid for by user-generated fees. The State

Laboratory of Hygiene charges hospitals \$69.50 for each newborn screening sample collection card. Hospitals in turn charge parents for newborn screening, which is typically included in the labor and delivery bill and covered by the mother's insurance. The cost of adding SCID to the newborn screening panel will be supported by grant funds through 2008 at least. In years 2009, 2010, and 2011, the Wisconsin State Laboratory of Hygiene and Division of Public Health will actively seek additional grant funding in order to continue screening for SCID and related conditions of immunodeficiency at no cost to the state. However, such outside funding is not guaranteed. Thus, perhaps as early as January 1, 2009, the cost of the newborn screening sample card will need to be increased. The increase is currently estimated to be \$5.52, which would result in a new total cost of approximately \$75.00 per child screened. The annual cost of screening for SCID and related conditions of immunodeficiency in Wisconsin, based on the additional \$5.50 per child, would be approximately \$387,000 once grant funding expired and user-generated fees began covering costs (anticipated January 2012). In the absence of this screening, babies who are undiagnosed or diagnosed late with SCID typically cost \$1-2 million each to treat (This figure is based on audited costs from Children's Hospital of Wisconsin, the facility which treats children with SCID, but without benefit of early diagnosis.) Babies with SCID, diagnosed in the first week of life can be cured by bone marrow transplantation (estimate 75-95% cure rate) at a charge of \$170,000/discharge (2005 J Peds, McGhee et.al.). In treating infants with SCID, the state would not assume responsibility for the bone marrow transplantation, since the Congenital Disorders Program historically pays only for initial follow-up visits and confirmatory testing. It is expected that the savings to Medicaid may be substantial for each eligible affected child receiving early diagnosis.

Summary of, and comparison with, existing or proposed federal regulations:

There are no current federal regulations concerning newborn screening, nor are there any which specifically address screening newborn infants for the condition known as SCID.

Comparison with rules in adjacent states:

Illinois: Illinois currently has no rule or statute addressing newborn screening for SCID.

Iowa: Iowa currently has no rule or statute addressing newborn screening for SCID.

Michigan: Michigan currently has no rule or statute addressing newborn screening for SCID.

Minnesota: Minnesota currently has no rule or statute addressing newborn screening for SCID.

Summary of factual data and analytical methodologies:

The rule change will not affect small businesses as "small business" is defined in s. 227.114 (1) (a), Stats.

Analysis and supporting documents used to determine effect on small business:

The rule change will not affect small businesses as "small business" is defined in s. 227.114 (1) (a), Stats.

Effect on small business:

The rule change will not affect small business as "small business" is defined in s. 227.114 (1) (a), Stats., as small businesses are not involved in the process of screening newborns for congenital and metabolic disorders.

Agency contact person:

Alexandria M. Meyer, MS, CGC
Genetic & Newborn Screening Coordinator
Division of Public Health
1 West Wilson Street, Room 233
Madison, WI 53701
Phone: 608-267-7148
Email: meyeram@dhs.state.wi.us

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to the agency contact person that is listed above until the deadline given in the upcoming notice of public hearing. The deadline for submitting comments and the notice of public hearing will be posted on the Wisconsin Administrative Rules Website at <http://adminrules.wisconsin.gov> after the hearing is scheduled.

TEXT OF EMERGENCY RULE

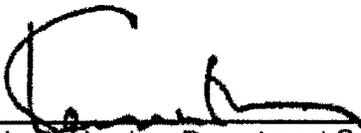
SECTION 1. HFS 115.04 (14) is created to read:

HFS 115.04 (14) Severe Combined Immunodeficiency and related conditions of immunodeficiency, ICD-9-CM 279.2

SECTION 2. EFFECTIVE DATE: The rules contained in this order shall take effect as emergency rules January 1, 2008, as provided in s. 227.24 (1) (c), Stats.

Wisconsin Department of Health and Family Services

Dated: December 14, 2007



Kevin R. Hayden, Department Secretary

SEAL:

ADMINISTRATIVE RULES – FISCAL ESTIMATE

1. Fiscal Estimate Version

Original Updated Corrected

2. Administrative Rule Chapter Title and Number

Chapter HFS 115 "Screening of Newborns for Congenital and Metabolic Disorders"

3. Subject

Screening of Newborns for Severe Combined Immunodeficiency (SCID)

4. State Fiscal Effect:

No Fiscal Effect

Indeterminate

Increase Existing Revenues

Decrease Existing Revenues

Increase Costs

Yes No

May be possible to absorb within agency's budget.

Decrease Costs

5. Fund Sources Affected:

GPR FED PRO PRS SEG SEG-S

6. Affected Ch. 20, Stats. Appropriations:

7. Local Government Fiscal Effect:

No Fiscal Effect

Indeterminate

Increase Revenues

Decrease Revenues

Increase Costs

Decrease Costs

8. Local Government Units Affected:

Towns Villages Cities Counties School Districts WTCS Districts Others:

9. Private Sector Fiscal Effect (small businesses only):

No Fiscal Effect

Indeterminate

Increase Revenues

Decrease Revenues

Yes No May have significant economic impact on a substantial number of small businesses

Increase Costs

Yes No

May have significant economic impact on a substantial number of small businesses

Decrease Costs

10. Types of Small Businesses Affected:

N/A

11. Fiscal Analysis Summary

Wisconsin Statute 253.13 requires that every infant born be subjected to blood tests for congenital and metabolic disorders; however, parents may refuse to have their infants screened for religious reasons. The Wisconsin Newborn Screening Umbrella Advisory Group has recommended to the Department the addition of Severe Combined Immunodeficiency (SCID) and related conditions of immunodeficiency to the screening panel. Infants with SCID are extremely vulnerable to infections, to the degree that the condition is universally fatal if not detected and treated within the first year of life.

The Department of Health and Family Services works closely with the Wisconsin State Laboratory of Hygiene to implement the program.

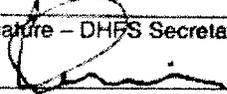
This rule change would add SCID and related conditions of immunodeficiency to the 13 disorders and disorder types currently screened for under HFS 115.04. All newborn screening tests are currently paid for by user-generated fees. The State Laboratory of Hygiene charges hospitals \$69.50 for each newborn screening sample collection card. Hospitals in turn charge parents for newborn screening, which is typically included in the labor and delivery bill and covered by the mother's insurance. A grant from the Jeffrey Modell Foundation, which is matched by the Children's Hospital of Wisconsin/Medical College of

Wisconsin, will fund the cost of testing for SCID through 2008 at least. In subsequent years, the Wisconsin State Laboratory of Hygiene and Division of Public Health will actively seek additional grant funding in order to continue screening for SCID and related conditions of immunodeficiency at no cost to the state.

If grant funding is not available, the fee for the newborn screening sample card will need to be increased by January 1, 2009. The annual cost of screening an estimated 71,000 births in Wisconsin for SCID will be approximately \$387,000. This increased cost will raise fees by \$5.50/child, for a total screening fee of \$75.00 per child screened. In the absence of this screening, babies who are undiagnosed or diagnosed late with SCID typically cost \$1-2 million each to treat. (This figure is based on audited costs from Children's Hospital of Wisconsin, the facility which treats children with SCID, but without benefit of early diagnosis.) Babies diagnosed in the first week of life can be cured by bone marrow transplantation (at least 75% cure rate) at a charge of \$170,000/discharge (2005 J Peds, McGhee et.al.). Typically, the cost of this treatment for infants with SCID is paid by the infant's health insurance or Medicaid and is not a cost to the Congenital Disorders Program, which pays only for initial follow-up visits and confirmatory testing. It is expected that the savings to Medicaid may be substantial for each eligible affected child receiving early diagnosis.

12. Long-Range Fiscal Implications

The surcharge for the newborn screening collection card, currently \$69.50, will need to be increased to approximately \$75.00 as early as January 1, 2009. This increase will be in user-generated fees. It is possible an increase in the surcharge will not be necessary until 2012, if additional grant funding is obtained.

13. Name - Prepared by Alexandria M. Meyer	Telephone Number 608-267-7148	Date 12/12/07
14. Name - OSF Analyst Reviewer Ellen Hadidian	608-266-8155	Date 12/28/07
Signature - DHFS Secretary or Designee 	Telephone Number 264-4410	Date 1-7-08



SENATOR BOB JAUCH
CO-CHAIR

P.O. Box 7882
MADISON, WI 53707-7882
(608) 266-3510



REPRESENTATIVE DANIEL LEMAHIEU
CO-CHAIR

P.O. Box 8952
MADISON, WI 53708-8952
(608) 266-9175

**JOINT COMMITTEE FOR
REVIEW OF ADMINISTRATIVE RULES**

May 20, 2008

The Honorable Fred Risser
Senate President
State Capitol Building
Room 220 South
Madison, WI 53702

The Honorable Michael Huebsch
Assembly Speaker
State Capitol Building
Room 211 West
Madison, WI 53702

Dear President Risser & Speaker Huebsch:

The Joint Committee for the Review of Administrative Rules met in Executive Session on May 20, 2008 and adopted the following motions:

- Moved by Senator Grothman, seconded by Senator Lehman that DHFS Emergency Order, ch. HFS 115, related to the addition of Severe Combined Immunodeficiency (SCID) and related conditions of immunodeficiency to the list of congenital and metabolic disorders and types of disorders, under ch. HFS 115, for which hospitals are required to screen newborns except if objected to for religious reasons be granted a 30-day extension. This rule is set to expire May 30, 2008.

Motion Passed 10-0.

- Moved by Senator Lehman, seconded by Senator Grothman that DOR Emergency Rule Extension, Tax 8.63, related to liquor wholesaler warehouse facilities be granted a 60-day extension. This rule is set to expire May 26, 2008.

Motion Passed 10-0.

- Moved by Senator Grothman, seconded by Senator Lehman that DWD Emergency Rule, affecting Section DWD 56.06 (1), related to reimbursement rates paid to child care providers by the Wisconsin Shares Child Subsidy program. Rates will not be adjusted for the year beginning January 1, 2008, and the rates effective on December 31, 2006 will remain in effect. This is a 60-day extension to the rule set to expire May 30, 2008. The extension will begin on May 31, 2008.

Motion Passed 8-2.

Sincerely,

Senator Bob Jauch
Senate Co-Chair

Representative Daniel LeMahieu
Assembly Co-Chair



WISCONSIN STATE LEGISLATURE



SENATOR BOB JAUCH
CO-CHAIR

P.O. Box 7882
MADISON, WI 53707-7882
(608) 266-3510



REPRESENTATIVE DANIEL LEMAHIEU
CO-CHAIR

P.O. Box 8952
MADISON, WI 53708-8952
(608) 266-9175

**JOINT COMMITTEE FOR
REVIEW OF ADMINISTRATIVE RULES**

May 20, 2008

Karen Timberlake, Secretary
Wisconsin Department of Health and Family Services
1 W. Wilson Street
Madison, WI 53703

Dear Secretary Timberlake:

The Joint Committee for the Review of Administrative Rules met in Executive Session on May 20, 2008 and adopted the following motion:

Moved by Senator Grothman, seconded by Senator Lehman that **DHFS Emergency Order, ch. HFS 115**, related to the addition of Severe Combined Immunodeficiency (SCID) and related conditions of immunodeficiency to the list of congenital and metabolic disorders and types of disorders, under ch. HFS 115, for which hospitals are required to screen newborns except if objected to for religious reasons be granted a 30-day extension. This rule is set to expire May 30, 2008.

Motion Passed 10-0.

Pursuant to s. 227.24(2)(c), stats., we are notifying the Legislative Reference Bureau of the Committee's action through copies of this letter.

Sincerely,

Senator Bob Jauch
Senate Co-Chair

Representative Daniel LeMahieu
Assembly Co-Chair

Cc: Bruce Hoesly, Legislative Reference Bureau
Ron Sklansky, Legislative Council





State of Wisconsin
Department of Health and Family Services

Jim Doyle, Governor
Karen E. Timberlake, Secretary

May 20, 2008

TO: The Join Committee for Review of Administrative Rules
FROM: Alex Meyer, Statewide Genetics Coordinator, DHFS
RE: Emergency rule extension for HFS 115.04

Good morning Senator Jauch, Representative LeMathieu and committee members. I'm Alex Meyer, Statewide Genetics Coordinator at the Department of Health and Family Services (DHFS).

Thank you for your prompt attention to the Department's request to extend the emergency rule that adds a fatal condition known as Severe Combined Immunodeficiency (SCID) to the newborn screening panel to HFS 115.04.

As we at the Department worked toward the adoption of a permanent rule for HFS 115, we put the emergency rule into place January 1, 2008.

Since the beginning of the year, the Wisconsin State Laboratory of Hygiene has screened every baby born in Wisconsin for this very serious disorder in addition to the previously established 46 other congenital and metabolic conditions using blood samples submitted by hospitals across the state. The Wisconsin Newborn Screening Program is the first of its kind to screen infants for SCID. Conservative estimates place the incidence of SCID at around 1 in 66,000. Babies born with this condition essentially have no functional immune system and are therefore extremely prone to infections and disease.

The permanent rule making process is almost done. Standing committees in both houses of the Legislature approved, allowing DHFS to file the permanent rule with the Legislative Referenced Bureau (LRB). We did this May 8, 2008. Per statute and LRB procedure, the rule will go into the Administrative Register in June and the effective date will be July 1, 2008.

The emergency rule is set to expire May 30, 2008. We are respectfully asking this committee to extend the emergency rule by 30 days to cover the month of June. Doing so will ensure authorize the State Lab of Hygiene to continue screening babies born during that interval for this fatal disease.

A public hearing to discuss both the emergency and permanent rule changes was held March 6, 2008. No opposition to the rule change was submitted either at the hearing or in writing during the public comment period. The Wisconsin Medical Society, the American Academy of Pediatrics Wisconsin chapter, the State Laboratory of Hygiene and the Medical College of Wisconsin all submitted letters in support of the rule revision.

Extending the emergency rule until the permanent rule goes into effect will allow Wisconsin to continue to be a leader in newborn screening and to eliminate the risk that a baby with SCID will go undetected and, therefore, untreated. Cases of untreated SCID are fatal, so early detection by screening is crucial.

Thank you again for the opportunity to testify before the committee. I would be happy to answer any questions you may have about this issue.