

**Carol Roessler**
STATE SENATOR

To: Members of the Senate Committee on Health, Children, Families, Aging and Long Term Care
From: Senator Roessler, Chair
Date: January 13, 2003
Re: Clearinghouse Rules Referred to the Committee

Four administrative rules have been referred to the Health, Children, Families, Aging and Long Term Care Committee. I have enclosed the rules for your review.

If you would like the committee to hold a hearing on any of the four rules, please contact Sara Jermstad in my office at 266-5300. The committee has jurisdiction over these rules until February 10, 2003.

CR 02-112, relating to the custody and control of sexually violent persons placed at facilities under s.980.065. Stats

The Department of Health and Family Services proposes to amend the title and several provisions in ch. HFS 95, "Use of Force: Ch. 980, Stats., Patients," and create a new section of in the chapter, entitled "Escorted Temporary Patient Leave."

CR 02-117, relating to a birth defect prevention and surveillance system

The Department of Health and Family Services is proposing rules for the Birth Defect Prevention and Surveillance System (enacted in 1999 Wisconsin Act 114 on May 8, 2000), which is replacing the Birth and Developmental Outcome Monitoring Program.

CR 02-118, relating to Medicare Supplement insurance policies

The Office of the Commissioner of Insurance is offering amendments to maintain compliance of the Wisconsin Medicare supplement insurance regulation. These amendments are necessary due to the federal Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act (BIPA).

CR 02-136, relating to screening of newborns' blood for congenital and metabolic disorders

The Department of Health and Family Services is adding five aminoacidopathies (i.e., amino acid related disorders) to the eight congenital and metabolic disorders currently screened for in every infant and listed in s. HFS 115.04

**PROPOSED ADMINISTRATIVE RULES – HFS 115
ANALYSIS FOR LEGISLATIVE STANDING COMMITTEES
PURSUANT TO S. 227.19 (3), STATS.**

Need for Rules

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. Parents, however, 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 eight congenital and metabolic 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 who have expertise and experience with congenital and metabolic disorders. For this purpose, the Department established the Wisconsin Newborn Screening Umbrella Advisory Group. Section HFS 115.06 also lists six criteria on which the Department must base its decision to add to or delete disorders from s. HFS 115.04. These criteria are:

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 testing for the specific condition.

In consideration of these criteria, the Wisconsin Newborn Screening Umbrella Advisory Group recently recommended that the Department add five aminoacidopathies, i.e., amino acid-related disorders, to the eight disorders currently screened for and listed in s. HFS 115.04. These disorders are:

- Maple Syrup Urine Disease;
- Homocystinuria;
- Tyrosinemia;
- Citrullinemia; and
- Argininosuccinic Acidemia.

Persons with these disorders can experience serious medical consequences such as failure-to-thrive, developmental delays, seizures, mental retardation and death.

The additional costs associated with these five additional screening tests is less than a dollar per baby screened because the amino acids in the blood sample are measured simultaneously with the acylcarnitines for Fatty Acid Oxidation and Organic Acidemias. In the absence of this screening, the Department estimates the annual Wisconsin costs for these

disorders to be \$144,909. The Department also estimates the annual Wisconsin costs of this screening to be \$29,134. Therefore, the cost benefit from these five screening tests is \$115,775.

The Advisory Group also recommended that the Department immediately begin screening newborns for these additional disorders. Before this testing can begin, the Department must change its rules to add the five new disorders to the existing list under s. HFS 115.04. Therefore, the Department issued identical emergency rules that became effective on October 12, 2002. These proposed permanent rules are intended to replace the emergency rules currently in effect.

Response to Clearinghouse Recommendations

The Clearinghouse did not have comments on the proposed rule.

Public Hearings Summary

The department held one public hearing on the proposed rule in Madison on December 17, 2002. The Department accepted comments until December 20, 2002.

One person, Elizabeth A. Schumacher of the Wisconsin Medical Society attended the hearing and submitted a letter of support. Another person, Carl S. L. Eisenberg, M.D., Fellow of the American Academy of Pediatrics, submitted a letter of support on behalf of the Wisconsin Chapter of the American Academy of Pediatrics.

Final Regulatory Analysis

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

PROPOSED ORDER OF THE
DEPARTMENT OF HEALTH AND FAMILY SERVICES
AMENDING RULES

To create HFS 115.04 (9) to (13), relating to screening of newborns' blood for congenital and metabolic disorders.

Analysis Prepared by the Department of Health and Family Services

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. Parents, however, 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 eight congenital and metabolic 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 who have expertise and experience with congenital and metabolic disorders. For this purpose, the Department established the Wisconsin Newborn Screening Umbrella Advisory Group. Section HFS 115.06 also lists six criteria on which the Department must base its decision to add to or delete disorders from s. HFS 115.04. These criteria are:

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 testing for the specific condition.

In consideration of these criteria, the Wisconsin Newborn Screening Umbrella Advisory Group recently recommended that the Department add five aminoacidopathies, i.e., amino acid-related disorders, to the eight disorders currently screened for and listed in s. HFS 115.04. These disorders are:

- Maple Syrup Urine Disease;
- Homocystinuria;
- Tyrosinemia;
- Citrullinemia; and
- Argininosuccinic Acidemia.

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The additional costs associated with these five additional screening tests is less than a dollar per baby screened because the amino acids in the blood sample are measured

simultaneously with the acylcarnitines for Fatty Acid Oxidation and Organic Acidemias. In the absence of this screening, the Department estimates the annual Wisconsin costs for these disorders to be \$144,909. The Department also estimates the annual Wisconsin costs of this screening to be \$29,134. Therefore, the cost benefit from these five screening tests is \$115,775.

The Advisory Group also recommended that the Department immediately begin screening newborns for these additional disorders. Before this testing can begin, the Department must change its rules to add the five new disorders to the existing list under s. HFS 115.04. Therefore, the Department issued identical emergency rules that became effective on October 12, 2002. These proposed permanent rules are intended to replace the emergency rules currently in effect.

The Department's authority to create these rules is found in ss. 253.13 (1) and 227.11 (2) (a), Stats. The rules interpret s. 253.13 (1), Stats.

SECTION 1. HFS 115.04 (9) to (13) are created to read:

HFS 115.04 (9) Maple Syrup Urine Disease, ICD-9-CM 270.3.

(10) Homocystinuria, ICD-9-CM 270.4.

(11) Tyrosinemia, ICD-9-CM 270.2.

(12) Citrullinemia, ICD-9-CM 270.6.

(13) Argininosuccinic Acidemia, ICD-9-CM 270.6.

This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided in s. 227.22 (2) (intro.), Stats.

Wisconsin Department of Health
and Family Services

Dated:

By: _____
Phyllis Dubé
Secretary

SEAL:

Fiscal Estimate – 2001 Session

<input checked="" type="checkbox"/> Original	<input type="checkbox"/> Updated	LRB Number	Amendment Number if Applicable
<input type="checkbox"/> Corrected	<input type="checkbox"/> Supplemental	Bill Number	Administrative Rule Number HFS 115

Subject
 Screening of Newborns for Congenital Disorders

Fiscal Effect

State: No State Fiscal Effect

Check columns below only if bill makes a direct appropriation or effects a sum sufficient appropriation.

- | | |
|--|---|
| <input type="checkbox"/> Increase Existing Appropriation | <input type="checkbox"/> Increase Existing Revenues |
| <input type="checkbox"/> Decrease Existing Appropriation | <input type="checkbox"/> Decrease Existing Revenues |
| <input type="checkbox"/> Create New Appropriation | |

Increase Costs – May be possible to absorb within agency's budget.

Yes No

Decrease Costs

Local: No Local Government Costs

- | | |
|--|--|
| 1. <input type="checkbox"/> Increase Costs
<input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory | 3. <input type="checkbox"/> Increase Costs
<input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory |
| 2. <input type="checkbox"/> Decrease Costs
<input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory | 4. <input type="checkbox"/> Decrease Costs
<input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory |

5. Types of Local Government Units Affected:

- | | | |
|---|---|---------------------------------|
| <input type="checkbox"/> Towns | <input type="checkbox"/> Villages | <input type="checkbox"/> Cities |
| <input type="checkbox"/> Counties | <input type="checkbox"/> Others: | |
| <input type="checkbox"/> School Districts | <input type="checkbox"/> WCTS Districts | |

Fund Sources Affected

- GPR FED PRO PRS SEG SEG-S

Affected Chapter 20 Appropriations

Assumptions Used in Arriving at Fiscal Estimate

Wisconsin Statute 253.13 requires that every infant born be subjected to blood tests for congenital and metabolic disorders. Parents, however, 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 5 aminoacidopathies to the screening panel. Persons with these disorders can experience serious medical consequences such as failure-to-thrive, developmental delays, seizures, mental retardation and death.

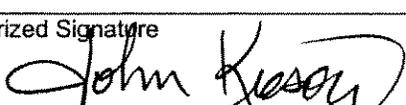
The Department of Health and Family Services works closely with the Wisconsin State Lab of Hygiene to implement the program.

This rule change adds 5 amino acid-related disorders to the 8 disorders currently screened for under HSS.115.04. Minimal additional laboratory resources are needed because the amino acids are measured simultaneously with the acylcarnitines for Fatty Acid Oxidation and Organic Acidemias. The additional costs to screen for aminoacidopathies is less than \$1.00 per specimen. Therefore, there is no anticipated increase in the surcharge during the proposed five-year pilot phase of adding these tests. The annual Wisconsin costs due to implementation of screening will total approximately \$29,000 and will be absorbed by the current lab and surcharge funds.

An estimated \$115,000 savings is anticipated with early diagnosed and treated patients because they will require less hospitalization and other medical care.

Long Range Fiscal Implications

The need to increase the surcharge will not be determined until after the completion of the five-year pilot project.

Prepared By: Susan Uttech	Telephone Number 267-3561	Agency DHFS/DPH/BFCH/FHS
Authorized Signature 	Telephone Number 266-9622	Date (mm/dd/ccyy) 10/07/02