

**ADMINISTRATIVE RULES  
REPORT TO LEGISLATURE  
CLEARINGHOUSE RULE 08-005**

**By the Department of Health and Family Services relating to Ch. HFS 115.04 (14), Screening of Newborns for Congenital and Metabolic Disorders**

**Basis and Purpose of Proposed Rule**

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.

The Department in an emergency order effective January 1, 2008, added Severe Combined Immunodeficiency (SCID) and related conditions of immunodeficiency to the list of congenital and metabolic disorders and types of disorders for which newborns are required to be screened, except when objected to for religious reasons, under s. HFS 115.04. 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. 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.

This proposed permanent rule is intended to replace the emergency rule currently in effect.

When SCID and related conditions of immunodeficiency are permanently added to the list of disorders under s. HFS 115.04, follow-up and management will be conducted by 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 is responsible for coordinating the activities of managing specialists, but will not provide direct patient care.

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 and the Medical College of Wisconsin, will fund the cost of testing for SCID through 2008. For the 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. 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 and related

conditions of immunodeficiency will be approximately \$387,000. This increased cost will raise fees by \$5.50 per 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 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.

### **Responses to Legislative Council Rules Clearinghouse Recommendations**

The Legislative Council Rules Clearinghouse made no recommendations or comments in their report to the agency.

### **Final Regulatory Flexibility Analysis**

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.

### **Changes to the Analysis or Fiscal Estimate**

#### **Analysis**

No changes were made to the rule's analysis.

#### **Fiscal Estimate**

No changes were made to the fiscal estimate.

## **Public Hearing Summary**

On January 29, 2008, the Department began accepting public comments on the emergency rule and the proposed permanent rule via the Wisconsin Administrative Rules website, mail, and email. One public hearing was held on March 6, 2008, which was attended by two persons other than the moderator. Comments were accepted by the Department until March 13, 2008.

### List of Public Hearing Attendees and Commenters

The following is a complete list of the persons who attended the public hearing or submitted comments on the proposed rule, the position taken by the commenter and whether or not the individual provided written or oral comments.

	Name and Address	Position Taken (Support or Opposed)	Action (Oral or Written)
1.	Ronald H. Laessig, PhD, representing the State Laboratory of Hygiene, 465 Henry Mall, Madison, WI 53706	Support	Oral
2.	Robert Kliegman, MD, representing the Medical College of Wisconsin, <i>address not provided</i>	Support	Written
3.	Mark Grapentine, JD, representing the Wisconsin Medical Society Council on Legislation, 330 East Lakeside Street, Madison, WI 53701-1109	Support	Written
4.	Halim Hennes, MD, FAAP, representing the American Academy of Pediatrics Wisconsin Chapter, Children's Corp. Center, Suite C550, PO Box 1997, Milwaukee, WI 53226	Support	Written
5.	Charles D. Brokopp, Dr. PH, Director of the Wisconsin State Laboratory of Hygiene, 465 Henry Mall, Madison, WI 53706	Support	Written

### Public Comments and Department Responses

The number(s) following each comment corresponds to the number assigned to the individual listed in the Public Hearing Attendees and Commenters section of this document.

Rule Provision	Public Comment	Department Response
General	<p>Strongly support proposed rule as it is beneficial to individuals, cost-effective to the state and feasible to implement (1).</p> <p>This rule change will result in the saving of lives of many infants (2).</p>	Comments accepted, no changes made to rule.

<b>Rule Provision</b>	<b>Public Comment</b>	<b>Department Response</b>
	<p>Screening and providing treatment for SCID is in the best interests of Wisconsin newborns (3).</p> <p>Wisconsin will be a national leader in implementing SCID screening and saving the lives of infants (4).</p> <p>The Wisconsin State Laboratory of Hygiene is prepared to handle the addition of SCID and believes it can be added with minimal effort and no difficulty (5).</p>	