

## Clearinghouse Rule 08-005

### PROPOSED ORDER OF DEPARTMENT OF HEALTH AND FAMILY SERVICES TO ADOPT RULES

The Wisconsin Department of Health and Family Services proposes to create HFS 115.04 (14) relating to screening newborns for Severe Combined Immunodeficiency and related conditions of immunodeficiency (SCID).

#### SUMMARY OF PROPOSED RULE

**Statute interpreted:** Section 253.13, Stats.

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

**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 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.

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

There are no current federal regulations concerning newborn screening, nor are there any that 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:**

In determining whether to add or delete SCID and related conditions of immunodeficiency to the list of disorders under s. HFS 115.04, the Department sought advice from the Wisconsin Newborn Screening Umbrella Advisory Group (Advisory Group). The Department and the Advisory Group considered the following criteria under s. HFS 115.06:

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 Advisory Group recommended the Department add the condition known as and related conditions of immunodeficiency to the 13 disorders and types of disorders currently screened for under s. HFS 115.04.

**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:**

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**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 PROPOSED 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: 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), Stats.

Wisconsin Department of Health and Family Services

Dated:

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Kevin R. Hayden, Department Secretary

SEAL: