

Clearinghouse Rule 99-081

CERTIFICATE

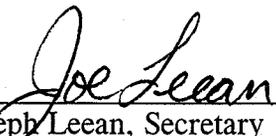
STATE OF WISCONSIN)
) SS
DEPARTMENT OF HEALTH AND FAMILY SERVICES)

I, Joseph Leean, Secretary of the Department of Health and Family Services and custodian of the official records of the Department, do hereby certify that the annexed rules relating to screening of newborn children for congenital and metabolic disorders were duly approved and adopted by this Department on November 4, 1999.

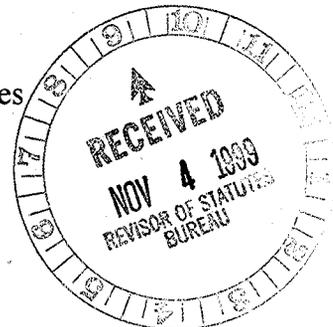
I further certify that this copy has been compared by me with the original on file in the Department and that this copy is a true copy of the original, and of the whole of the original.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the Department at the State Office Building, 1 W. Wilson Street, in the city of Madison, this 4th day of November, 1999.

SEAL:



Joseph Leean, Secretary
Department of Health and Family Services



99-081
1-1-00

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



To amend HFS 115.04 (intro.) and (1) to (7) and 115.06 and to create HFS 115.04 (8), relating to screening of newborns for congenital and metabolic disorders.

Analysis Prepared by the Department of Health and Family Services

The Department of Health and Family Services administers the Newborn Screening Program under s. 253.13, Stats. Under that program a sample of blood is drawn from nearly every newborn infant in the state before a child is discharged from the hospital, if the child was born in a hospital, or within one week of birth, if the child was born elsewhere, and tests are conducted by the State Laboratory of Hygiene on each blood sample to detect any of the congenital or metabolic disorders specified in ch. HFS 115, the Department's rules for the program. The conditions for which testing is done were specified by statute before November 1, 1992. Since then, s. 253.13 (1), Stats., has directed the Department to specify those conditions by rule.

The Department adds to or deletes from the rules conditions for testing of blood samples on the advice of the Newborn Screening Advisory Group made up of medical consultants, State Laboratory of Hygiene staff and other persons with expertise and experience in dealing with congenital and metabolic disorders, and in accordance with 6 criteria listed in s. HFS 115.06. The criteria include the availability of effective therapy for the condition and potential for successful treatment, the availability of mechanisms for determining the effectiveness of test procedures, and the expected benefits to children and society in relation to the risks and costs of the testing.

The Newborn Screening Advisory Group has unanimously supported the recommendation of Department staff to add at this time Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCAD) and 13 other fatty oxidation and branched chain amino acid disorders as a new condition for which testing of blood samples drawn from newborns is conducted. It is estimated that through this testing 15 to 20 babies a year in Wisconsin will be identified as having one of the disorders. Morbidity and mortality are high for persons with the condition if treatment is not begun before the onset of clinical symptoms. Prompt initiation of treatment results in nearly 100% survival and normal development. Treatment is simple (diet supplementation and regulation) and inexpensive. The screening technology has only recently been developed.

This rulemaking order adds MCAD and the other 13 fatty acid oxidation and branched chain amino acid disorders as a new condition to the list of conditions in s. HFS 115.04 for which blood samples taken from newborns will be tested. The order also converts the lists found in ss. HFS 115.04 and 115.06 to a new form required by revised drafting standards.

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

SECTION 1. HFS 115.04 (intro.) and (1) to (7) are amended to read:

HFS 115.04 Congenital and metabolic disorders. Blood samples taken from newborns as required under s. 253.13 (1), Stats., shall be tested by the state laboratory for all of the following conditions:

- (1) Phenylketonuria (PKU), ICD-9-CM 270.1~~;~~
- (2) Galactosemia, ICD-9-CM 271.1~~;~~
- (3) Congenital hypothyroidism, ICD-9-CM 243~~;~~
- (4) Sickle cell disease and related hemoglobin abnormalities, ICD-9-CM 282.6~~;~~
- (5) Biotinidase deficiency, ICD-9-CM 266.9~~;~~
- (6) Congenital adrenal hyperplasia, ICD-9-CM 255.2~~;~~ ~~and~~
- (7) Cystic fibrosis, ICD-9-CM 277.0.

SECTION 2. HFS 115.04 (8) is created to read:

HFS 115.04 (8) Medium chain acyl-coenzyme A dehydrogenase deficiency (MCAD) and related disorders of lipid metabolism, ICD-9-CM 272.9.

SECTION 3. HFS 115.06 is amended to read:

HFS 115.06 Criteria for adding or deleting conditions. In determining which disorders are to be added or deleted from s. HFS 115.04, the department shall seek the advice and guidance of medical consultants, staff of the state laboratory and other persons who have expertise and experience in dealing with congenital and metabolic disorders. Criteria to be considered in adding or deleting disorders shall include all of the following:

- (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; ~~and~~.

(6) The expected benefits to children and society in relation to the risks and costs associated with testing for the specific condition.

The rules contained in this order 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: November 4, 1999

By: _____


Joseph Leean
Secretary

SEAL: