CR 92-156

CERTIFICATE

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

I, Gerald Whitburn, Secretary of the Department of Health and Social Services and custodian of the official records of the Department, do hereby certify that the annexed rules relating to screening of newborns infants for congenital and metabolic disorders were duly approved and adopted by this Department on April 13, 1993.

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 13th day of April, 1993.

SEAL:

Gerald Whitburn, Secretary
Department of Health and Social Services

6-1-93

ORDER OF THE
DEPARTMENT OF HEALTH AND SOCIAL SERVICES
ADOPTING RULES

To create HSS 115, relating to screening of newborns congenital and metabolic disorders.

Analysis Prepared by the Department of Health and Social Services

Section 146.02(1), Stats., was recently amended by 1991 Wisconsin Act 177 to require the Department to specify in rules the congenital and metabolic disorders for which all newborn infants are to be screened by means of a blood test unless the parent or guardian of a newborn objects on religious grounds. The amendment will take effect on November 1, 1992. Until then the list of conditions for which newborns must be screened is contained in the statute. Beginning November 1, 1992 that list will be in the Department's rules. These are the proposed rules.

Each year there are about 72,000 births in the state. Nearly all of the newborns receive the screening. Testing of blood samples is carried out by the State Laboratory of Hygiene. In determining the conditions to be added or deleted from the required screening, the Department has sought guidance from medical experts, laboratory personnel and others with knowledge of congenital and metabolic disorders by convening a standing program advisory committee. The advisory committee has suggested criteria for adding or deleting screened conditions. These include benefits for the individual screened and technical and clinical efficacy of testing and of therapeutic intervention for identified conditions.

On the basis of recommendations from its advisory committee the Department's list of conditions for which newborn screening is to be carried out consists of phenylketonuria (PKU), galactosemia, congenital hypothyroidism, sickle cell anemia and related hemoglobin abnormalities, biotinidase deficiency and congenital adrenal hyperplasia. Two of these conditions, biotinidase deficiency and congenital adrenal hyperplasia, were not listed in s. 146.02(1), Stats. One of the conditions listed in s. 146.02(1), Stats., maple syrup urine disease, has been omitted from the Department's list because there has not been a positive test result in 10 years.

The Department's authority to create these rules is found in ss. 140.05(3) and 146.02(1), Stats. The rules interpret ss. 140.05(1) and 146.02, Stats.

SECTION 1. HSS 115 is created to read:

Chapter HSS 115

SCREENING OF NEWBORNS FOR CONGENITAL AND METABOLIC DISORDERS

HSS 115.01 AUTHORITY AND PURPOSE. This chapter is promulgated under the authority of ss. 146.02(1) and 227.11(2), Stats., to specify the congenital and metabolic disorders for which newborn infants are to be screened by means of a sample of blood taken from an infant shortly after birth and tests performed on that sample by the state laboratory of hygiene.

HSS 115.02 APPLICABILITY. This chapter applies to the attending physician licensed under ch. 448, Stats., nurse-midwife certified under s. 441.15, Stats., or other attendant at the birth of an infant born in Wisconsin, to the infant and the infant's parents or guardian, and to the state laboratory which carries out tests on the sample of blood taken from the infant.

HSS 115.03 DEFINITIONS. In this chapter:

(1) "Congenital disorder" means a disorder present at birth, either inherited or due to an influence occurring during gestation up to birth.

(2) "Department" means the Wisconsin department of health and social services.

(3) "ICD-9-CM" means the International Classification of Diseases, 9th Revision, Clinical Modification, October 1, 1991.

(4) "Medical consultant" means a physician licensed to practice medicine or osteopathy under ch. 448, Stats., who has expertise in treatment of one or more of the conditions listed under s. HSS 115.04.

(5) "Metabolic disorder" means a disorder of the chemical processes that take place in the body.

(6) "Screening" means checking each member of a population to identify presumptive medical conditions that indicate that diagnostic testing for congenital or metabolic disorders is needed.

(7) "State laboratory" means the state laboratory of hygiene under s. 36.25(11), Stats.

HSS 115.04 CONGENITAL AND METABOLIC DISORDERS. Blood samples taken from newborns as required under s. 146.02(1), Stats., shall be tested by the state laboratory for 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; and

(6) Congenital adrenal hyperplasia, ICD-9-CM 255.2.

HSS 115.05 LABORATORY TESTS. (1) PROCEDURES. The state laboratory shall establish procedures, with the approval of the department, for obtaining blood specimens for the testing required under s. 146.02, Stats., and this chapter, performing tests and reporting results of tests performed to the infant's physician and the department as required under s. 146.02(4), Stats.

(2) ADDITIONAL TESTS FOR RESEARCH AND EVALUATION PURPOSES. The department may direct the state laboratory to perform other tests on specimens for research and evaluation purposes related to congenital and metabolic disorders or laboratory procedures. In directing that additional testing be performed, the department shall ensure that all applicable laws relating to protection of human subjects of research are observed.

HSS 115.06 CRITERIA FOR ADDING OR DELETING CONDITIONS. In determining which disorders are to be added or deleted from s. HSS 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:

(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 Social Services

Dated: April 13, 1993

By: _____
Gerald Whitburn
Secretary

SEAL: