CR 95-30

CERTIFICATE

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

I, Richard W. Lorang, Acting 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 newborn infants for cystic fibrosis were duly approved and adopted by this Department on June 8, 1995.

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 8th day of June, 1995.

SEAL:

Richard W. Lorang, Acting ~~Secretary~~
Department of Health and Social Services

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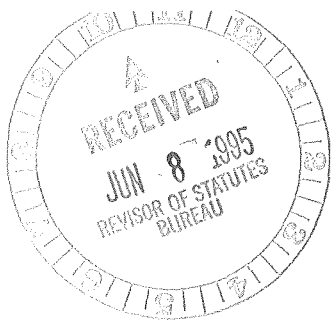
JUN 8 1995
REVISOR OF STATUTES BUREAU

8-1-95



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

To amend HSS 115.04(5) and (6) and to create HSS 115.04(7), relating to screening of newborn infants for cystic fibrosis.

Analysis Prepared by the Department of Health and Social Services

The Department operates a program under s.253.13, Stats., for screening nearly all newborn infants in the state for the presence of certain congenital disorders, and referral of infants who are tested positive for special dietary treatment and other therapeutic intervention which, if begun early can prevent the full development of the condition or mitigate its effects. Screening is by means of a blood test unless the parent or guardian of a newborn objects on religious grounds. The same blood sample is tested to determine the presence of all congenital or metabolic disorders specified in ch. HSS 115.

This rulemaking order adds cystic fibrosis (CF) to the list of congenital and metabolic disorders in ch. HSS 115 for which the blood sample taken from a newborn infant is tested.

Cystic fibrosis is a serious and life threatening congenital disorder which, while present at birth, typically does not manifest itself symptomatically until later in childhood. Approximately 20 infants are born each year in Wisconsin with this condition. CF has traditionally been diagnosed and medical treatment begun at a point where the disease is well advanced, with pulmonary and other symptoms beginning to appear. Four years ago a research project operated by the University of Wisconsin Medical School and funded by a National Institute of Health, in conjunction with the state newborn screening program, began to test infants at birth for CF, with the dual purpose of improving the accuracy of neonatal testing and evaluating the benefits of medical interventions for CF prior to the onset of symptoms.

A committee of medical experts advising the Department on newborn screening studied the results of the research study and the current medical literature on CF generally and recommended adding this condition to the Newborn Screening Program under s. 253.13, Stats., and ch. HSS 115. The advisory committee concluded that medical knowledge and technology have advanced to the point where neonatal testing and treatment for CF meet the criteria for screening that are established in ch. HSS 115. The medical advisers found that early medical treatment of children with preclinical CF is effective in delaying the onset and progression of the disease and in reducing its severity in those affected.

The advisers also concluded that neonatal screening for CF would have economic benefits. Currently, approximately 1500 children a year in Wisconsin require sophisticated medical examinations at CF centers to rule out the presence of the disease, but as infants are tested and identified at birth this number is expected to decline dramatically. Also, children

with CF for whom treatment is begun early in life will later require less costly medical care and, in particular, less inpatient hospital care. The newborn screening procedure which will be used for CF will combine the standard enzyme test for the condition with a newer DNA procedure. This will increase the accuracy of the screening and substantially reduce the number of infants who would otherwise have to be referred for further diagnostic testing.

The federal agency financing the University of Wisconsin research on newborn screening for cystic fibrosis agreed with the findings of the Department's advisory committee and recently terminated its financial support for the research because the testing was no longer research. While the screening for cystic fibrosis was being done for research purposes; it was permitted under s. HSS 115.05(2). But since it is no longer research, for screening to be continued the condition must be listed in ch. HSS 115.

These rules will replace identical emergency rules published on January 31, 1995.

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

SECTION 1. HSS 115.04(5) and (6) are amended to read:

HSS 115.04(5) Biotinidase deficiency, ICD-9-CM 266.9; ~~and~~

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

SECTION 2. HSS 115.04(7) is created to read:

HSS 115.04(7) Cystic fibrosis, ICD-9-CM 277.0.

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: June 8, 1995

By: _____
Richard W. Lorang
Acting Secretary

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