STATEMENT OF SCOPE
WISCONSIN DEPARTMENT OF HEALTH SERVICES

CHAPTER: DHS 115
RELATING TO: Screening Newborns for Congenital and Metabolic Disorders
RULE TYPE: Emergency and Permanent
SCOPE TYPE: Original

FINDING OF EMERGENCY

The department contracts with the Wisconsin State Laboratory of Hygiene to test most newborns for certain congenital and metabolic disorders that are listed by the Department in s. DHS 115.04. The department proposes to add Carnitine Palmitoyltransferase IA ("CPT IA") and Spinal Muscular Atrophy ("SMA") to the rule.

Preservation of the public health and welfare requires screening newborns for CPT IA and SMA. These disorders present serious health risks in childhood and are unlikely to be detected and prevented in the absence of newborn screening. Interventions are reasonably available at this time, and have been shown, in well-designed studies, to be safe and effective in preventing or ameliorating serious health consequences stemming from a delayed or missed diagnosis of these disorders.

Since legislative review of the proposed permanent rule is not available until the first day of the next regular session of the Legislature, the department proposes to promulgate an emergency rule (followed by a permanent rule) to begin immediate screening for CPT IA and SMA.

SUMMARY

Description of rule objective/s

The objective of the rule is to add CPT IA and SMA to s. DHS 115.04

Existing policies relevant to the rule

Subject to certain exceptions, s. 253.13 (1), Stats., requires every infant born in each hospital or maternity home, prior to its discharge therefrom, to be subjected to tests for congenital and metabolic disorders, as specified in rules promulgated by the department. The criteria for adding or deleting disorders are set forth in s. DHS 115.06.

Policies proposed to be included in the rule

The department proposes to add CPT IA and SMA to s. DHS 115.04.

Analysis of policy alternative

There are no reasonable alternatives to the proposed rulemaking. CPT IA and SMA were selected based upon the criteria set forth in s. DHS 115.06 and based on careful review, deliberation and recommendation from the Secretary's Advisory Committee on Newborn Screening (SACNBS). Membership of the SACNBS includes representatives with collective knowledge and expertise in the following areas: medicine and science; statistics and epidemiology; ethical, legal, social, and policy

analysis; and laboratory medicine. The SACNBS includes representation from practicing physicians, the newborn screening program, and individuals with target conditions or their parents.

Failure to promulgate the proposed rule, and to therefore screen for CPT IA and SMA, could result in serious health consequences to newborns because of delayed or missed diagnosis of these disorders.

Statutory authority for the rule

a. Explanation of authority to promulgate the proposed rule

The department was given express statutory authority by the Legislature to specify congenital and metabolic disorders for newborn screening.

b. Statute/s that authorize/s the promulgation of the proposed rule

Section 253.13 (1), Stats., reads:

(1) TESTS; REQUIREMENTS. The attending physician or nurse licensed under s. 441.15 shall cause every infant born in each hospital or maternity home, prior to its discharge therefrom, to be subjected to tests for congenital and metabolic disorders, as specified in rules promulgated by the department. If the infant is born elsewhere than in a hospital or maternity home, the attending physician, nurse licensed under s. 441.15, or birth attendant who attended the birth shall cause the infant, within one week of birth, to be subjected to these tests.

c. Statute/s or rule/s that will affect the proposed rule or be affected by it

Sections 253.13 (2) to (5), Stats., read:

(2) Tests; diagnostic, dietary and follow-up counseling program; fees. The department shall contract with the state laboratory of hygiene to perform any tests under this section that are laboratory tests and to furnish materials for use in the tests. The department shall provide necessary diagnostic services, special dietary treatment as prescribed by a physician for a patient with a congenital disorder as identified by tests under this section, and follow-up counseling for the patient and his or her family. The department shall impose a fee, by rule, for tests performed under this section sufficient to pay for services provided under the contract. The department shall include as part of the fee established by rule amounts to fund the provision of diagnostic and counseling services, special dietary treatment, and periodic evaluation of infant screening programs, the costs of consulting with experts under sub. (5), the costs of administering the hearing screening program under s. 253.115, and the costs of administering the congenital disorder program under this section and shall credit these amounts to the appropriation accounts under s. 20.435 (1) (ja) and (jb).

(3) EXCEPTIONS. This section shall not apply if the parents or legal guardian of the child object thereto on the grounds that the test conflicts with their religious tenets and practices or with their personal convictions. No tests may be performed under this section unless the parents or legal guardian are fully informed of the purposes of testing under this section and have been given reasonable opportunity to object as authorized in this subsection to such tests.

(4) CONFIDENTIALITY AND REPORTING.

(a) The state laboratory of hygiene shall provide its laboratory test results to the physician, who shall advise the parents or legal guardian of the results. No information obtained under this section from the parents or guardian or from tests performed under this section may be disclosed except for use in statistical data compiled by the department without reference to the identity of any individual and except as provided in s. 146.82 (2). The state laboratory of hygiene board shall provide to the department the names and addresses of parents of infants who have positive test results.

(b) The department may require reporting in connection with the tests performed under this section for use in statistical data compilation and for evaluation of infant screening programs.

(5) RELATED SERVICES. The department shall disseminate information to families whose children suffer from congenital disorders and to women of child-bearing age with a history of congenital disorders concerning the need for and availability of follow-up counseling and special dietary treatment and the necessity for testing infants. The department shall also refer families of children who suffer from congenital disorders to available health services programs and shall coordinate the provision of these programs. The department shall periodically consult appropriate experts in reviewing and evaluating the state's infant screening programs.

Estimates of the amount of time that state employees will spend to develop the rule and other necessary resources

The department estimates that it will take approximately 160 hours to develop the proposed rules. This includes time required for research and analysis, coordinating the advisory committee meeting, rule drafting, preparing any related documents, holding a public hearing, and communicating with affected persons and groups.

Description of all of the entities that may be affected by the rule, including any local governmental units, businesses, economic sectors, or public utility ratepayers who may reasonably be anticipated to be affected by the rule

Newborns and parents of newborns will benefit from early diagnosis through newborn screening and follow-up treatment. The Wisconsin State Laboratory of Hygiene will provide ongoing testing for additional conditions and the WI Newborn Screening Program will have additional newborn screening conditions to follow-up and report on. Expert consultants in the newborn screening field and health care providers will have a slight increase in patient care for those diagnosed through newborn screening.

Summary and preliminary comparison of any existing or proposed federal regulation that is intended to address the activities to be regulated by the rule

The department knows of no existing or federal regulation that addresses the activities of this rule.

Anticipated economic impact, locally or statewide

The proposed rule is anticipated to have little or no economic impact. CPT IA testing can be accomplished with existing technology. The addition of SMA may necessitate a minor increase to the newborn screening blood card fee, assessed under s. DHS 115.055. However, this increase will be addressed in future rulemaking through a more comprehensive review of program costs.

Agency contacts

Gary M. Kirk, MD, MPH
Chief Medical Officer
Bureau of Community Health Promotion
608-266-5818
Gary.Kirk@dhs.wisconsin.gov

Tami Horzewski, MS, CHES
Newborn Screening Program Coordinator
Bureau of Community Health Promotion
608-266-8904
Tami.Horzewski@dhs.wisconsin.gov