

MAR 5 2007
HUMAN RESOURCES

HOUSE FILE 459
BY MASCHER

Passed House, Date _____ Passed Senate, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

1 An Act providing for the establishment of an expanded newborn
2 screening program, establishing a fee and a fund, and making
3 an appropriation.

4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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HF 459

1 Section 1. NEW SECTION. 135.26 EXPANDED SCREENING
2 PROGRAM -- GENETIC AND METABOLIC DISORDERS -- FEE -- FUND.

3 1. DEFINITIONS. As used in this section, unless the
4 context otherwise requires:

5 a. "Accredited laboratory" means any laboratory that holds
6 a valid certificate issued under the clinical laboratory
7 improvement amendments of 1988, 42 U.S.C. § 263a, as amended,
8 and that reports its screening results by using normal
9 pediatric reference ranges.

10 b. "Expanded screening" means screening for genetic and
11 metabolic disorders, including but not limited to amino acid
12 disorders, organic acid disorders, fatty acid disorders, and
13 other abnormal profiles, in newborn infants that can be
14 detected through the use of a tandem mass spectrometer.

15 c. "Tandem mass spectrometer" means an analytical
16 instrument used to detect numerous genetic and metabolic
17 disorders at one time.

18 2. Beginning July 1, 2004, all newborns shall be subjected
19 to expanded screening for the presence of genetic, endocrine,
20 or other metabolic disorders specified in paragraph "b", and
21 such other metabolic disorders as the department may deem
22 necessary. In establishing the expanded screening program
23 pursuant to this section, the department shall:

24 a. Implement an intensive educational program among
25 physicians, hospitals, public health nurses, and the public
26 concerning the diseases phenylketonuria, hypothyroidism,
27 galactosemia, and other metabolic disorders. The educational
28 program shall include information about the nature of the
29 disorders and examinations for their detection in early
30 infancy, in order that measures may be taken to prevent
31 resulting mental retardation.

32 b. Provide all newborns with expanded screening through
33 local health departments for phenylketonuria, galactosemia,
34 hypothyroidism, congenital adrenal hyperplasia, biotinidase
35 deficiency, and sickling disorders, as well as other amino

1 acid disorders, organic acid disorders, fatty acid oxidation
2 disorders, and other abnormalities detectable through the use
3 of a tandem mass spectrometer.

4 c. Supply the necessary treatment product where
5 practicable for diagnosed cases for as long as medically
6 indicated, when the product is not available through other
7 state agencies.

8 d. Arrange for or provide, if determined necessary, public
9 health nursing, nutrition, and social services, and clinical
10 consultation.

11 e. Require that all specimens collected via the expanded
12 screening be submitted for testing to an accredited laboratory
13 designated by the department to perform such tests, with the
14 results of the tests reported to the department. The
15 department shall establish a reasonable fee to cover the cost
16 of providing the expanded screening, and shall deposit the
17 fees collected into a special fund created within the state
18 treasury and designated as the metabolic screening and
19 treatment fund. Additional state and federal funds for
20 expenses related to metabolic screening, follow-up, and
21 treatment may also be deposited into the fund. Moneys
22 deposited into the fund are appropriated to the department
23 solely for the purpose of providing metabolic screening,
24 follow-up, and treatment. Notwithstanding section 8.33,
25 moneys deposited into the special fund that remain
26 unencumbered or unobligated at the close of the fiscal year
27 shall not revert to any other fund but shall remain available
28 for expenditure for the purpose designated in future fiscal
29 years. Notwithstanding section 12C.7, subsection 2, interest
30 or earnings on moneys deposited into the special fund shall be
31 credited to and remain a part of the special fund.

32 3. The expanded screening program established pursuant to
33 this section shall not be construed to prohibit any licensed
34 medical facility from collecting additional specimens for
35 testing for metabolic or neonatal diseases or any other

1 diseases or conditions which the facility deems necessary.

2 4. The provisions of this section shall not apply if a
3 newborn's parent or legal guardian submits a signed affidavit
4 to a physician or other person whose duty it is to administer
5 and report the results of the expanded screening stating that
6 the expanded screening conflicts with the tenets and practices
7 of a recognized religious denomination of which the newborn,
8 parent, or legal guardian is an adherent or member.

9 5. The department shall adopt rules relating to
10 administration of the educational program, expanded screening,
11 and reporting requirements required pursuant to this section.

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EXPLANATION

13 This bill provides for the establishment of an expanded
14 screening program for newborns for specified genetic and
15 metabolic disorders, including phenylketonuria, beginning July
16 1, 2004. The bill defines "expanded screening" to mean
17 screening for genetic and metabolic disorders, including but
18 not limited to amino acid disorders, organic acid disorders,
19 fatty acid disorders, and other abnormal profiles, in newborn
20 infants that can be detected through the use of a tandem mass
21 spectrometer.

22 The bill provides that in establishing the expanded
23 screening program, the Iowa department of public health shall
24 implement an intensive educational program among physicians,
25 hospitals, public health nurses, and the public concerning the
26 diseases phenylketonuria, hypothyroidism, galactosemia, and
27 other metabolic disorders, which shall include information
28 about the nature of the disorders and examinations for their
29 detection in early infancy. The bill provides that the
30 department shall provide all newborns with expanded screening
31 through local health departments for phenylketonuria,
32 galactosemia, hypothyroidism, congenital adrenal hyperplasia,
33 biotinidase deficiency, and sickling disorders, as well as
34 other amino acid disorders, organic acid disorders, fatty acid
35 oxidation disorders, and other abnormalities detectable

1 through the use of a tandem mass spectrometer.

2 The bill provides that the department shall supply the
3 necessary treatment product where practicable for diagnosed
4 cases for as long as medically indicated, when the product is
5 not available through other state agencies; arrange for or
6 provide necessary public health nursing, nutrition, and social
7 services, and clinical consultation; and require that all
8 specimens collected be submitted for testing to an accredited
9 laboratory designated by the department to perform such tests,
10 and require that the results of the tests be reported to the
11 department.

12 The bill provides that the department shall establish a
13 reasonable fee to cover the cost of providing the expanded
14 screening, and shall deposit the fees collected into a special
15 fund created within the state treasury and designated as the
16 metabolic screening and treatment fund. The bill provides
17 that additional state and federal funds for expenses related
18 to metabolic screening, follow-up, and treatment may also be
19 deposited into the fund, and that moneys deposited into the
20 fund are appropriated to the department solely for the purpose
21 of providing metabolic screening, follow-up, and treatment.

22 The bill provides that the expanded screening program shall
23 not be construed to prohibit any licensed medical facility
24 from collecting additional specimens for testing for metabolic
25 or neonatal diseases or any other diseases or conditions which
26 the facility deems necessary. The bill additionally provides
27 that the program requirements shall not apply if a newborn's
28 parent or legal guardian submits a signed affidavit objecting
29 to the screening on the basis of a religious conflict. The
30 bill provides that the department shall adopt rules relating
31 to administration of the educational program, expanded
32 screening, and reporting requirements.

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