

By the Committee on Health Policy; and Senators Ring and Clemens

588-01568-13

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1 A bill to be entitled
2 An act relating to newborn screening for critical
3 congenital heart disease; amending s. 383.14, F.S.;
4 requiring the Department of Health to adopt and
5 enforce rules that require ambulatory surgical
6 centers, hospitals, and birth centers in this state to
7 conduct screening for critical congenital heart
8 defects in all newborns by using certain technologies;
9 providing an effective date.

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11 WHEREAS, congenital heart defects are structural
12 abnormalities of the heart which are present at birth.
13 Congenital heart defects range in severity from simple problems,
14 such as holes between chambers of the heart, to severe
15 malformations, such as the complete absence of one or more
16 chamber or valve. Some critical congenital heart defects can
17 cause severe and life-threatening symptoms that require
18 intervention within the first days of life, and

19 WHEREAS, congenital heart defects are the leading cause of
20 death of infants who have birth defects, and

21 WHEREAS, according to the United States Secretary of Health
22 and Human Services' Advisory Committee on Heritable Disorders in
23 Newborns and Children, congenital heart defects affect between
24 seven and nine of every 1,000 live births in the United States
25 and Europe, and

26 WHEREAS, annual hospital costs in this country for all
27 individuals who have congenital heart disease have reached \$2.6
28 billion, and

29 WHEREAS, current methods for detecting congenital heart

588-01568-13

2013124c1

30 defects generally include prenatal ultrasound screening and
31 repeated clinical examinations that can identify many affected
32 newborns. These screenings identify less than half of all cases
33 of critical congenital heart defects, and many of these heart
34 defects are frequently missed during routine clinical exams
35 performed before a newborn's discharge from an ambulatory
36 surgical center, hospital, or birth center, and

37 WHEREAS, pulse oximetry is a noninvasive test that
38 estimates the percentage of hemoglobin in blood which is
39 saturated with oxygen. When pulse oximetry is performed on a
40 newborn in a hospital or birth center, this test is effective in
41 detecting critical, life-threatening congenital heart defects
42 that otherwise go undetected by current screening methods, and

43 WHEREAS, newborns who have abnormal pulse oximetry results
44 require immediate confirmatory testing and intervention. Many
45 newborn lives could potentially be saved by earlier detection
46 and treatment of critical congenital heart defects if ambulatory
47 surgical centers, hospitals, and birth centers in this state
48 were required to perform the simple, noninvasive newborn
49 screening in conjunction with current methods of screening for
50 congenital heart defects, NOW THEREFORE,

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52 Be It Enacted by the Legislature of the State of Florida:

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54 Section 1. Subsection (2) of section 383.14, Florida
55 Statutes, is amended to read:

56 383.14 Screening for metabolic disorders, other hereditary
57 and congenital disorders, and environmental risk factors.—

58 (2) RULES.—After consultation with the Genetics and Newborn

588-01568-13

2013124c1

59 Screening Advisory Council, the department shall adopt and
60 enforce rules requiring that every newborn in this state shall,
61 before ~~prior to~~ becoming 1 week of age, be subjected to a test
62 for phenylketonuria and, at the appropriate age, be tested for
63 such other metabolic diseases and hereditary or congenital
64 disorders as the department may deem necessary from time to
65 time. The department shall also adopt and enforce rules that
66 require each ambulatory surgical center and hospital, as defined
67 in s. 395.002, and birth center, as defined in s. 383.302, which
68 provides maternity and newborn care services in this state, to
69 perform screening for critical congenital heart disease (CCHD)
70 by testing for low blood-oxygen saturation using pulse oximetry
71 or alternate peer-reviewed, evidence-based technologies on each
72 newborn after the first 24 hours of life or before a newborn is
73 discharged. After consultation with the Office of Early
74 Learning, the department shall also adopt and enforce rules
75 requiring every newborn in this state to be screened for
76 environmental risk factors that place children and their
77 families at risk for increased morbidity, mortality, and other
78 negative outcomes. The department shall adopt such additional
79 rules as are found necessary for the administration of this
80 section and s. 383.145, including rules providing definitions of
81 terms, rules relating to the methods used and time or times for
82 testing as accepted medical practice indicates, rules relating
83 to charging and collecting fees for the administration of the
84 newborn screening program authorized by this section, rules for
85 processing requests and releasing test and screening results,
86 and rules requiring mandatory reporting of the results of tests
87 and screenings for these conditions to the department.

588-01568-13

2013124c1

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Section 2. This act shall take effect July 1, 2013.