

By the Committee on Health Regulation; and Senator Ring

588-02355-12

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1 A bill to be entitled

2 An act relating to newborn screening for critical
3 congenital heart disease; creating s. 383.146, F.S.;
4 providing definitions; providing requirements for
5 screening newborns for critical congenital heart
6 disease; providing an exception; requiring that the
7 physician, midwife, or other person attending the
8 newborn maintain a record if the screening has not
9 been performed and attach a written objection signed
10 by the parent or guardian; requiring appropriate
11 documentation of the screening completion in the
12 medical record; requiring that each hospital and each
13 licensed birth center designate a lead physician and a
14 licensed health care provider, respectively, to
15 provide programmatic oversight for the screening;
16 requiring that the screening for critical congenital
17 heart disease be conducted on all newborns in
18 hospitals and birth centers in this state; authorizing
19 the Department of Health to adopt rules to administer
20 the screening program; providing powers and duties of
21 the department; providing an effective date.

22
23 WHEREAS, congenital heart disease is the most common birth
24 defect in infants, affecting 8 out of every 1,000 newborn
25 babies, and

26 WHEREAS, early detection of congenital heart disease is
27 crucial to the health of a newborn baby because, if the
28 condition goes undiagnosed, it can cause major problems later in
29 the child's life, and

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30 WHEREAS, pulse oximetry is a noninvasive method of
31 monitoring the oxygen level in the blood and is recommended as a
32 method of screening a patient for critical congenital heart
33 disease, and

34 WHEREAS, physical exertion and participation in sports can
35 cause excess stress on the heart and, if the disease is not
36 detected and is severe enough, participation in strenuous
37 activity can result in death, NOW, THEREFORE,

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

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41 Section 1. Section 383.146, Florida Statutes, is created to
42 read:

43 383.146 Newborn screening for critical congenital heart
44 disease.-

45 (1) DEFINITIONS.-As used in this section, the term:

46 (a) "Department" means the Department of Health.

47 (b) "Newborn" means an age range from birth through 29
48 days.

49 (c) "Screening" means measuring blood oxygen saturation
50 using pulse oximetry to determine whether a newborn needs
51 additional diagnostic evaluation for critical congenital heart
52 disease.

53 (2) REQUIREMENTS FOR SCREENING OF NEWBORNS; REFERRAL FOR
54 ONGOING SERVICES.-

55 (a) Each licensed hospital that provides maternity and
56 newborn care services shall ensure that, prior to discharge, all
57 newborns are screened for the detection of critical congenital
58 heart disease.

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59 (b) Each licensed birth center that provides maternity and
60 newborn care services shall ensure that, prior to discharge, all
61 newborns are screened for the detection of critical congenital
62 heart disease.

63 (c) If the parent or legal guardian of the newborn objects
64 to the screening, the screening must not be completed,
65 notwithstanding any other provision of this section. In such
66 case, the physician, midwife, or other person who is attending
67 the newborn shall maintain a record that the screening has not
68 been performed and attach a written objection that must be
69 signed by the parent or guardian.

70 (d) For home births, the health care provider in attendance
71 is responsible for the screening.

72 (e) Appropriate documentation of the screening completion,
73 results, interpretation, and recommendations must be placed in
74 the medical record within 24 hours after completion of the
75 screening procedure.

76 (f) Each hospital shall formally designate a lead physician
77 who is responsible for programmatic oversight of newborn
78 congenital heart disease screening. Each licensed birth center
79 shall designate a licensed health care provider to provide such
80 programmatic oversight. Such physician or health care provider
81 shall ensure that the appropriate referrals are completed
82 following a positive screening test result.

83 (g) By October 1, 2012, screening for critical congenital
84 heart disease must be conducted on all newborns in hospitals and
85 birth centers in this state following birth admission.

86 (3) RULES.—After consultation with the Genetics and Newborn
87 Screening Advisory Council, the department shall adopt and

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88 enforce rules requiring that every newborn in this state be
89 screened for critical congenital heart disease. The department
90 shall adopt such additional rules as are necessary for the
91 administration of this section, including rules providing
92 definitions of terms, rules relating to the methods used and
93 time or times for testing as accepted medical practice
94 indicates, rules relating to charging and collecting fees for
95 the administration of the newborn screening program required by
96 this section, rules for processing requests and releasing test
97 and screening results, and rules requiring mandatory reporting
98 of the results of tests and screenings for this condition to the
99 department.

100 (4) POWERS AND DUTIES OF THE DEPARTMENT.—The department
101 shall administer and provide services required pursuant to this
102 section and shall:

103 (a) Furnish to all physicians, county health departments,
104 perinatal centers, birth centers, and hospitals forms on which
105 the results of tests for critical congenital heart disease shall
106 be reported to the department.

107 (b) Have the authority to charge and collect fees
108 sufficient to administer the newborn screening program required
109 under this section.

110 Section 2. This act shall take effect July 1, 2012.