

House File 2539 - Introduced

HOUSE FILE 2539
BY COMMITTEE ON HUMAN
RESOURCES

(SUCCESSOR TO HSB 690)

(COMPANION TO SF 2345 BY
COMMITTEE ON HUMAN RESOURCES)

A BILL FOR

1 An Act relating to the newborn screening.

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

1 Section 1. Section 136A.2, Code 2022, is amended by adding
2 the following new subsection:

3 NEW SUBSECTION. 1A. *“Congenital and inherited disorders*
4 *advisory committee”* or *“advisory committee”* means the congenital
5 and inherited disorders advisory committee created in this
6 chapter.

7 Sec. 2. NEW SECTION. 136A.3A **Congenital and inherited**
8 **disorders advisory committee established — process for addition**
9 **of conditions to newborn screening.**

10 1. A congenital and inherited disorders advisory committee
11 is established to assist the center for congenital and
12 inherited disorders and the department in the development of
13 programs that ensure the availability and access to quality
14 genetic and genomic health care services for all Iowans.

15 2. The members of the advisory committee shall be appointed
16 by the director and shall include persons with relevant
17 expertise and interest including parent representatives.

18 3. The advisory committee shall assist the center for
19 congenital and inherited disorders and the department in
20 designating the conditions to be included in the newborn
21 screening and in regularly evaluating the effectiveness and
22 appropriateness of the newborn screening.

23 4. *a.* Beginning July 1, 2022, the advisory committee shall
24 ensure that all conditions included in the federal recommended
25 uniform screening panel as of January 1, 2022, are included in
26 the newborn screening.

27 *b.* Within twelve months of the addition of a new condition
28 to the federal recommended uniform screening panel, the
29 advisory committee shall consider and make a recommendation
30 to the department regarding inclusion of the new condition in
31 the newborn screening, including the current newborn screening
32 capacity to screen for the new condition and the resources
33 necessary to screen for the new condition going forward.

34 If the advisory committee recommends inclusion of a new
35 condition, the department shall include the new condition in

1 the newborn screening within eighteen months of receipt of the
2 recommendation.

3 5. The department shall submit a status report to the
4 general assembly, annually, by December 31, regarding all of
5 the following:

6 a. The current conditions included in the newborn screening.

7 b. Any new conditions currently under consideration or
8 recommended by the advisory committee for inclusion in the
9 newborn screening.

10 c. Any new conditions considered but not recommended by the
11 advisory committee in the prior twelve-month period and the
12 reason for not recommending any such conditions.

13 d. Any departmental request for additional program capacity
14 or resources necessitated by the inclusion of a recommended new
15 condition in the newborn screening.

16 e. Any delay and the reason for the delay by the advisory
17 committee in complying with the specified twelve-month time
18 frame in considering or recommending the inclusion of a new
19 condition in the newborn screening to the department.

20 f. Any delay and the reason for the delay by the department
21 in complying with the specified eighteen-month time frame in
22 including a new condition in the newborn screening following
23 receipt of a recommendation from the advisory committee
24 recommending the inclusion of such condition.

25 6. The state hygienic laboratory shall establish the
26 newborn screening fee schedule in a manner sufficient to
27 support the newborn screening system of care including
28 laboratory screening costs, short-term and long-term follow-up
29 program costs, the newborn screening developmental fund, and
30 the cost of the department's newborn screening data system.

31 Sec. 3. Section 136A.5, Code 2022, is amended to read as
32 follows:

33 **136A.5 Newborn metabolic screening.**

34 1. All newborns born in this state shall be screened for
35 congenital and inherited disorders in accordance with rules

1 adopted by the department.

2 2. An attending health care provider shall ensure that every
3 newborn under the provider's care is screened for congenital
4 and inherited disorders in accordance with rules adopted by the
5 department.

6 3. [This section](#) does not apply if a parent objects to
7 the screening. If a parent objects to the screening of a
8 newborn, the attending health care provider shall document the
9 refusal in the newborn's medical record and shall obtain a
10 written refusal from the parent and report the refusal to the
11 department as provided by rule of the department.

12 Sec. 4. Section 136A.5A, subsections 1 and 4, Code 2022, are
13 amended to read as follows:

14 1. Each newborn born in this state shall receive a critical
15 congenital heart disease screening by pulse oximetry or other
16 means as determined by rule, in conjunction with the ~~metabolic~~
17 newborn screening required pursuant to [section 136A.5](#).

18 4. Notwithstanding any provision to the contrary, the
19 results of each newborn's critical congenital heart disease
20 screening shall only be reported in a manner consistent with
21 the reporting of the results of ~~metabolic~~ newborn screenings
22 pursuant to [section 136A.5](#) if funding is available for
23 implementation of the reporting requirement.

24 EXPLANATION

25 The inclusion of this explanation does not constitute agreement with
26 the explanation's substance by the members of the general assembly.

27 This bill relates to newborn screenings.

28 The bill establishes, in Code, the congenital and inherited
29 disorders advisory committee (advisory committee), which
30 currently is established in administrative rules. The bill
31 provides, as is provided in administrative rules, that the
32 advisory committee is established to assist the center for
33 congenital and inherited disorders (center) and the department
34 of public health (DPH) in matters relating to genetic
35 and genomic health care services for all Iowans, that the

1 members of the advisory committee shall be appointed by the
2 director of public health, that the members shall include
3 persons with relevant expertise and interest including parent
4 representatives, and that one of the duties of the advisory
5 committee is to assist the center and DPH in designating the
6 conditions to be included in the newborn screening and in
7 regularly evaluating the effectiveness and appropriateness of
8 the newborn screening.

9 The bill specifically requires that beginning July 1,
10 2022, the advisory committee shall ensure that all conditions
11 included in the federal recommended uniform screening panel as
12 of January 1, 2022, are included in the newborn screening. The
13 bill requires that within 12 months of the addition of a new
14 condition to the federal recommended uniform screening panel,
15 the advisory committee shall consider and make a recommendation
16 to DPH regarding inclusion of the new condition in the newborn
17 screening, including current newborn screening capacity to
18 screen for the new condition and the resources necessary to
19 screen for the new condition going forward. If the advisory
20 committee recommends inclusion of a new condition, DPH shall
21 ensure that the new condition is included in the newborn
22 screening within 18 months of receipt of the recommendation.

23 The bill requires DPH to submit an annual status report to
24 the general assembly by December 31, regarding the current
25 conditions included in the newborn screening, any new
26 conditions currently under consideration or recommended by the
27 advisory committee for inclusion in the newborn screening, any
28 new conditions considered but not recommended by the advisory
29 committee in the prior 12-month period and the reason for not
30 recommending any such conditions, any departmental request for
31 additional newborn screening program capacity or resources
32 necessitated by the inclusion of a recommended new condition
33 in the newborn screening, and any delay and the reason for
34 the delay by the advisory committee or DPH in complying with
35 the specified time frames for considering and recommending or

1 adding a new condition to the newborn screening.

2 The bill requires the state hygienic laboratory to establish
3 the newborn screening fee schedule in a manner sufficient to
4 support the newborn screening system of care.

5 The bill also changes references to "newborn metabolic
6 screening" or "metabolic newborn screening" to "newborn
7 screening".