

HOUSE BILL No. 5950

November 12, 2014, Introduced by Rep. Poleski and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled "Public health code," by amending section 5430 (MCL 333.5430), as added by 2006 PA 31, and by adding section 5431a.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 Sec. 5430. (1) The newborn screening quality assurance
2 advisory committee is created in the department. The newborn
3 screening quality assurance advisory committee ~~shall consist~~
4 **CONSISTS** of 10 members ~~and~~ **TO** be appointed by the department as
5 follows:

6 (a) One individual representing a Michigan nonprofit health
7 care corporation **OR A NONPROFIT MUTUAL DISABILITY INSURER.**

8 (b) One individual representing the Michigan health and
9 hospital association.

1 (c) One individual representing the Michigan state medical
2 society.

3 (d) One individual representing the Michigan osteopathic
4 association.

5 (e) One individual representing the department's medical
6 services administration.

7 (f) One individual representing the department's public health
8 administration.

9 (g) One individual who is a neonatologist with experience and
10 background in newborn screening.

11 (h) One individual representing health maintenance
12 organizations.

13 (i) Two individuals representing the general public.

14 (2) The newborn screening quality assurance advisory committee
15 shall meet annually to review the list of newborn screening tests
16 required under ~~section~~**SECTIONS 5431 AND 5431A** and under department
17 rules, regulations, and guidelines. The newborn screening quality
18 assurance advisory committee shall, on an annual basis, submit a
19 written report to the department regarding the appropriateness of
20 the existing list of required newborn screening tests. The newborn
21 screening quality assurance advisory committee shall also include
22 in the report recommendations to revise the list to include
23 additional newborn screening tests that are nationally recognized
24 in the scientific literature or national standards for conditions
25 that can be ameliorated or treated if identified by a newborn
26 screening test and to remove certain tests that are no longer
27 supported in the scientific literature or national standard as

1 being effective for ameliorating or treating conditions that can be
2 identified by newborn screening.

3 (3) The newborn screening quality assurance advisory committee
4 shall conduct a financial review of any recommended changes to the
5 list of newborn screening tests and shall include in the written
6 report required under subsection (2) a recommendation for the
7 increase or decrease in the amount charged ~~pursuant to~~ **UNDER**
8 section 5431 for newborn screening tests. The recommended change
9 shall not exceed any net change in the amount of the actual cost of
10 any proposed additional tests and follow-up minus savings from any
11 proposed deleted tests and follow-up.

12 (4) Within 30 days after the department has received the
13 report required under subsection (2), the department may approve or
14 reject the recommendations of the newborn screening quality
15 assurance advisory committee. If the department does not reject the
16 recommendations or fails to act within the 30 days, then the
17 recommendations shall be forwarded to the standing committees in
18 the senate and house of representatives that consider issues
19 pertaining to public health for approval.

20 (5) Within 45 days after the recommendations are forwarded and
21 received, the legislature shall approve or reject those
22 recommendations without amendment by concurrent resolution adopted
23 by both standing committees of the senate and house of
24 representatives that consider issues pertaining to public health
25 and both houses of the legislature by recorded vote. If the
26 proposed recommendations are not submitted on a legislative session
27 day, the 45 days commence on the first legislative session day

1 after the recommendations are submitted. The 45 days shall include
2 not less than 9 legislative session days. If the recommendations
3 are not rejected within the 45-day period, the recommendations
4 ~~shall be~~ **ARE** considered approved, shall be adopted by the
5 department, and ~~shall~~ take effect 6 months after the
6 recommendations are adopted by both houses of the legislature or
7 considered approved as provided under this subsection.

8 **SEC. 5431A. (1) BEGINNING ON THE DATE ESTABLISHED IN AN ORDER**
9 **DESCRIBED IN SUBSECTION (3), IN ADDITION TO THE TESTS REQUIRED**
10 **UNDER SECTION 5431, A HEALTH PROFESSIONAL IN CHARGE OF THE CARE OF**
11 **A NEWBORN INFANT OR, IF NONE, THE HEALTH PROFESSIONAL IN CHARGE AT**
12 **THE BIRTH OF AN INFANT SHALL ADMINISTER OR CAUSE TO BE ADMINISTERED**
13 **TO THE INFANT A TEST FOR THE PRESENCE OF CERTAIN LYSOSOMAL STORAGE**
14 **DISORDERS KNOWN AS KRABBE, POMPE, GAUCHER, FABRY, AND NIEMANN-PICK.**
15 **A TEST ADMINISTERED UNDER THIS SECTION IS CONSIDERED A TEST**
16 **REQUIRED UNDER SECTION 5431(1) AND IS SUBJECT TO THE REQUIREMENTS**
17 **OF AND ENTITLED TO THE PROTECTIONS PROVIDED IN SECTION 5431.**

18 **(2) THE DEPARTMENT SHALL MONITOR AND DETERMINE WHEN ALL OF THE**
19 **FOLLOWING REQUIREMENTS HAVE BEEN MET WITH REGARD TO THE TESTING**
20 **REQUIRED UNDER SUBSECTION (1):**

21 **(A) THE NECESSARY REAGENTS ARE REGISTERED WITH THE FEDERAL**
22 **FOOD AND DRUG ADMINISTRATION.**

23 **(B) THE NECESSARY REAGENTS ARE AVAILABLE FROM THE CENTERS FOR**
24 **DISEASE CONTROL AND PREVENTION.**

25 **(C) A QUALITY ASSURANCE TESTING METHODOLOGY IS AVAILABLE FOR**
26 **THE PROCESSES INVOLVED IN THE TESTING.**

27 **(3) UPON DETERMINING THAT THE REQUIREMENTS IN SUBSECTION (2)**

1 HAVE BEEN MET, THE DEPARTMENT SHALL DO BOTH OF THE FOLLOWING:

2 (A) ACQUIRE AND INSTALL THE EQUIPMENT NECESSARY TO IMPLEMENT
3 THE TESTING REQUIRED UNDER SUBSECTION (1).

4 (B) ISSUE AN ORDER ESTABLISHING A DATE THAT THE TESTING
5 REQUIRED UNDER SUBSECTION (1) WILL BEGIN, WHICH DATE SHALL BE
6 WITHIN 6 MONTHS AFTER THE DEPARTMENT MAKES ITS DETERMINATION UNDER
7 SUBSECTION (2).