

**HB0109/673423/1**

BY: Health and Government Operations Committee

AMENDMENTS TO HOUSE BILL 109  
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in line 7, after “Panel” insert “, subject to the approval of the State Advisory Council on Hereditary and Congenital Disorders and the Secretary of Health; establishing certain requirements related to the approval or disapproval of the inclusion of a condition and the implementation of testing for a condition approved for inclusion in the system for newborn screening”; and in line 10, after “Section” insert “13-101 and”.

AMENDMENT NO. 2

On page 1, after line 15, insert:

“13-101.

(a) In this subtitle the following words have the meanings indicated.

**(B) “ADVISORY COUNCIL” MEANS THE STATE ADVISORY COUNCIL ON HEREDITARY AND CONGENITAL DISORDERS.**

**[(b)] (C) “Commission” means the State Commission on Hereditary and Congenital Disorders.**

**[(c)] (D) (1) “Congenital disorder” means a significant structural or functional abnormality of the body that is present at birth.**

(2) “Congenital disorder” does not include a condition that results from:

(i) An intrauterine infection; or

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(ii) A birth injury.

**[(d)] (E)** “Hereditary disorder” means any disorder that:

(1) Is transmitted through the genetic material deoxyribonucleic acid (DNA); or

(2) Arises through the improper processing of the information in the genetic material.”;

after line 16, insert:

**“(A) (1) IN THIS SECTION, “SPECIALIZED TESTING EQUIPMENT” MEANS EQUIPMENT NECESSARY TO RUN A TEST APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION OR A LABORATORY-DEVELOPED TEST.**

**(2) “SPECIALIZED TESTING EQUIPMENT” DOES NOT INCLUDE:**

**(I) TESTING REAGENTS; OR**

**(II) DISPOSABLE LABORATORY EQUIPMENT.”;**

in lines 17 and 21, strike “(a)” and “(b)”, respectively, and substitute “**(B)**” and “**(C)**”, respectively; and in line 24, strike “(d)(2)” and substitute “**(E)(2)**”.

On page 2, in lines 1 and 5, strike “(c)” and “(d)”, respectively, and substitute “**(D)**” and “**(E)**”, respectively; and in line 12, strike “(c)” and substitute “**(D)**”.

On page 3, in lines 4 and 15, strike “(e)” and “(f)”, respectively, and substitute “**(F)**” and “**(H)**”, respectively; in line 4, strike “**NOTWITHSTANDING**” and substitute “**SUBJECT TO THE APPROVAL OF THE SECRETARY AND THE ADVISORY COUNCIL**”.

UNDER PARAGRAPH (2) OF THIS SUBSECTION AND NOTWITHSTANDING"; in line 5, after "EACH" insert "CORE"; strike beginning with "DEPARTMENT" in line 8 down through "PANEL" in line 10 and substitute "SECRETARY AND THE ADVISORY COUNCIL SHALL DETERMINE WHETHER TO APPROVE THE INCLUSION OF A CONDITION IN THE SYSTEM FOR NEWBORN SCREENING"; in lines 10 and 11, strike "2 YEARS" and substitute "1 YEAR"; in line 11, strike "PANEL" and substitute "RECOMMENDED UNIFORM SCREENING PANEL"; after line 11, insert:

"(III) IF THE SECRETARY OR ADVISORY COUNCIL DOES NOT APPROVE THE INCLUSION OF A CORE CONDITION IN THE SYSTEM FOR NEWBORN SCREENING UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH:

1. WITHIN 1 YEAR AFTER THE ADDITION OF THE CONDITION TO THE RECOMMENDED UNIFORM SCREENING PANEL, THE DEPARTMENT SHALL PUBLICLY POST AND SUBMIT TO THE GENERAL ASSEMBLY, IN ACCORDANCE WITH § 2-1257 OF THE STATE GOVERNMENT ARTICLE, A REPORT THAT INCLUDES, AS APPLICABLE, THE SECRETARY'S JUSTIFICATION FOR NOT APPROVING THE INCLUSION AND THE FINAL VOTE OF THE ADVISORY COUNCIL REGARDING THE INCLUSION OF THE CONDITION; AND

2. EACH YEAR AFTER THE INITIAL DISAPPROVAL, THE ADVISORY COUNCIL SHALL:

A. REVIEW THE MEDICAL LITERATURE PUBLISHED ON THE CONDITION SINCE THE INITIAL EVALUATION AND DETERMINE WHETHER SUBSTANTIVE UPDATES HAVE OCCURRED THAT WOULD MERIT FORMAL REEVALUATION OF THE INCLUSION OF THE CONDITION; AND

B. IF THE ADVISORY COUNCIL UPHOLDS ITS DISAPPROVAL OF THE CONDITION, PUBLICLY PUBLISH AND SUBMIT TO THE GENERAL ASSEMBLY, IN ACCORDANCE WITH § 2-1257 OF THE STATE GOVERNMENT ARTICLE, A REPORT ON THE REASON FOR THE DISAPPROVAL."

and after line 14, insert:

(Over)

“(G) (1) IF THE SECRETARY AND THE ADVISORY COUNCIL APPROVE THE INCLUSION OF A CONDITION IN THE SYSTEM FOR NEWBORN SCREENING UNDER SUBSECTION (F) OF THIS SECTION, WITHIN 1 YEAR AFTER THE DATE OF THE APPROVAL, THE DEPARTMENT SHALL:

(I) IF TESTING FOR THE CONDITION CAN BE IMPLEMENTED WITHOUT THE PROCUREMENT OF SPECIALIZED TESTING EQUIPMENT, IMPLEMENT TESTING FOR THE CONDITION; OR

(II) IF THE IMPLEMENTATION OF TESTING REQUIRES THE PROCUREMENT OF SPECIALIZED TESTING EQUIPMENT, SIGN A FINAL PROCUREMENT CONTRACT WITH A VENDOR FOR ALL EQUIPMENT NECESSARY TO IMPLEMENT TESTING.

(2) FOR PROCUREMENTS REQUIRED UNDER PARAGRAPH (1)(II) OF THIS SUBSECTION:

(I) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, THE DEPARTMENT MAY USE EXPEDITED PROCUREMENT UNDER § 13-108 OF THE STATE FINANCE AND PROCUREMENT ARTICLE; AND

(II) THE PROCUREMENT CONTRACT SHALL INCLUDE A CLAUSE AUTHORIZING THE STATE TO TERMINATE THE CONTRACT IF THE VENDOR HAS NOT FULFILLED THE CONTRACT WITHIN 6 MONTHS.”.