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:


(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
(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:


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.”