

HB5420



103RD GENERAL ASSEMBLY

State of Illinois

2023 and 2024

HB5420

Introduced 2/9/2024, by Rep. Kimberly Du Buclet

SYNOPSIS AS INTRODUCED:

410 ILCS 240/3.6 new

Amends the Newborn Metabolic Screening Act. Provides for the screening and testing of all newborns for Guanidinoacetate Methyltransferase (GAMT) deficiency. Sets forth requirements that must be met before the screening and testing begin. Authorizes the Department of Public Health to implement an additional fee for the screening prior to beginning testing in order to accumulate resources to implement the amendatory Act.

LRB103 37927 CES 68059 b

A BILL FOR

1 AN ACT concerning health.

2 **Be it enacted by the People of the State of Illinois,**
3 **represented in the General Assembly:**

4 Section 5. The Newborn Metabolic Screening Act is amended
5 by adding Section 3.6 as follows:

6 (410 ILCS 240/3.6 new)

7 Sec. 3.6. Guanidinoacetate Methyltransferase (GAMT)
8 deficiency.

9 (a) In accordance with the timetable specified in this
10 Section, the Department shall provide all newborns with
11 screening tests for the presence of Guanidinoacetate
12 Methyltransferase (GAMT) deficiency. The testing shall begin
13 within 12 months after the occurrence of all of the following:

14 (1) the establishment and verification of relevant and
15 appropriate performance specifications as defined under
16 the federal Clinical Laboratory Improvement Amendments and
17 regulations thereunder for Federal Drug
18 Administration-cleared or in-house developed methods,
19 performed under an institutional review board approved
20 protocol, if required;

21 (2) the availability of quality assurance testing and
22 comparative threshold values for GAMT;

23 (3) the acquisition and installment by the Department

1 of the equipment necessary to implement the initial pilot
2 and statewide volume of screening tests for GAMT;

3 (4) the establishment of precise threshold values
4 ensuring defined disorder identification for GAMT;

5 (5) the authentication of pilot testing achieving each
6 milestone described in items (a) through (d) of this
7 Section for GAMT; and

8 (6) the authentication of achieving the potential of
9 high throughput standards for statewide volume of the GAMT
10 screening test concomitant with each milestone described
11 in items (1) through (4) of this Section.

12 (b) The Department may implement an additional fee for the
13 screening prior to beginning the testing in order to
14 accumulate the resources for start-up and other costs
15 associated with implementation of the screening and thereafter
16 to support the costs associated with screening and follow-up
17 programs for GAMT.