

SB0067



103RD GENERAL ASSEMBLY

State of Illinois

2023 and 2024

SB0067

Introduced 1/20/2023, by Sen. Laura Fine

SYNOPSIS AS INTRODUCED:

410 ILCS 240/3.5 new

Amends the Newborn Metabolic Screening Act. Requires the Department of Public Health to provide all newborns with screening tests for the presence of metachromatic leukodystrophy. Requires the testing to begin within 6 months following the occurrence of specified milestones. Allows the Department to require payment of an additional fee for the provision of metachromatic leukodystrophy screening tests. Contains other provisions.

LRB103 04485 CPF 49491 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 3.5 as follows:

6 (410 ILCS 240/3.5 new)

7 Sec. 3.5. Metachromatic leukodystrophy.

8 (a) The Department shall provide all newborns with
9 screening tests for the presence of metachromatic
10 leukodystrophy. The testing shall begin within 6 months after
11 the occurrence of all of the following milestones:

12 (1) Unless the federal Food and Drug Administration
13 approves a screening test for metachromatic leukodystrophy
14 using dried blood spots, the development and validation of
15 a reliable methodology for screening newborns for
16 metachromatic leukodystrophy using dried blood spots and a
17 methodology for conducting quality assurance testing of
18 the screening test.

19 (2) The availability of any necessary reagent for a
20 metachromatic leukodystrophy screening test.

21 (3) The establishment and verification of relevant and
22 appropriate performance specifications as defined under
23 the federal Clinical Laboratory Improvement Amendments and

1 regulations thereunder for Federal Drug
2 Administration-cleared or in-house developed methods,
3 performed under an institutional review board approved
4 protocol, if required.

5 (4) The availability of quality assurance testing and
6 comparative threshold values for metachromatic
7 leukodystrophy screening tests.

8 (5) The acquisition and installation by the Department
9 of equipment necessary to implement metachromatic
10 leukodystrophy screening tests.

11 (6) The establishment of precise threshold values
12 ensuring defined disorder identification of metachromatic
13 leukodystrophy.

14 (7) The authentication of pilot testing indicating
15 that each milestone described in paragraphs (1) through
16 (6) has been achieved.

17 (8) The authentication of achieving the potential of
18 high throughput standards for statewide volume of each
19 metachromatic leukodystrophy screening test concomitant
20 with each milestone described in paragraphs (1) through
21 (4).

22 (b) To accumulate the resources for the costs, including
23 start-up costs, associated with metachromatic leukodystrophy
24 screening tests and any follow-up programs, the Department may
25 require payment of an additional fee for administering a
26 metachromatic leukodystrophy screening test under this

1 Section. The Department may not require the payment of the
2 additional fee prior to 6 months before the Department
3 administers metachromatic leukodystrophy screening tests under
4 this Section.