



Sen. Julie A. Morrison

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LRB100 05000 MJP 30604 a

1 AMENDMENT TO SENATE BILL 456

2 AMENDMENT NO. _____. Amend Senate Bill 456 by replacing
3 everything after the enacting clause with the following:

4 "Section 5. The Newborn Metabolic Screening Act is amended
5 by adding Section 3.35 as follows:

6 (410 ILCS 240/3.35 new)

7 Sec. 3.35. Spinal muscular atrophy. In accordance with the
8 timetable specified in this Section, the Department shall
9 provide all newborns with screening tests for the presence of
10 spinal muscular atrophy, beginning on the earlier of the
11 following:

12 (1) January 1, 2019; or

13 (2) within 6 months following the occurrence of all of
14 the following:

15 (A) the establishment and verification of relevant
16 and appropriate performance specifications as defined

1 under the federal Clinical Laboratory Improvement
2 Amendments and regulations thereunder for federal Food
3 and Drug Administration-cleared or in-house developed
4 methods, performed under an institutional review board
5 approved protocol, if required;

6 (B) the availability of quality assurance testing
7 and comparative threshold values for spinal muscular
8 atrophy;

9 (C) the acquisition and installment by the
10 Department of the equipment necessary to implement the
11 initial pilot and statewide volume of screening tests
12 for spinal muscular atrophy;

13 (D) the establishment of precise threshold values
14 ensuring defined disorder identification for spinal
15 muscular atrophy;

16 (E) the development and validation of a reliable
17 methodology for screening newborns for spinal muscular
18 atrophy using dried blood spots and quality assurance
19 testing methodology for such test or the approval of a
20 test for spinal muscular atrophy using dried blood
21 spots by the federal Food and Drug Administration;

22 (F) the authentication of pilot testing achieving
23 each milestone described in subparagraphs (A) through
24 (E) of this paragraph for spinal muscular atrophy; and

25 (G) the authentication of achieving the potential
26 of high throughput standards for statewide volume of

1 spinal muscular atrophy concomitant with each
2 milestone described in subparagraphs (A) through (E)
3 of this paragraph.

4 The Department is authorized to implement an additional fee
5 for the screening no sooner than 6 months prior to beginning
6 the testing in order to accumulate the resources for start-up
7 and other costs associated with the implementation of the
8 screening and thereafter to support the costs associated with
9 screening and follow-up programs for spinal muscular atrophy.
10 The Department may adopt emergency rules in accordance with
11 Section 5-45 of the Illinois Administrative Procedure Act to
12 implement this Section.

13 Section 99. Effective date. This Act takes effect upon
14 becoming law.".