LRB-5505/1 KMS:cjs

2023 ASSEMBLY BILL 1057

February 2, 2024 - Introduced by Representatives DITTRICH, DUCHOW, ANDRACA, SUBECK, MURPHY, GUNDRUM, MURSAU, CONLEY, BRANDTJEN, SINICKI and RATCLIFF, cosponsored by Senators JAGLER and TESTIN. Referred to Committee on Health, Aging and Long-Term Care.

AN ACT to create 253.13 (6) of the statutes; relating to: the procedure for adding federal newborn screening recommendations to the state-required newborn screenings, granting rule-making authority, and providing an exemption from emergency rule procedures.

Analysis by the Legislative Reference Bureau

In general, under current law, newborns must be tested for certain congenital and metabolic disorders as specified in rules promulgated by the Department of Health Services. The federal Department of Health and Human Services maintains a list of disorders for which it recommends testing in newborns, known as the federal Recommended Uniform Screening Panel (RUSP).

Under this bill, DHS must evaluate each disorder that is included in the RUSP as of January 1, 2024, to determine whether newborns in this state should be tested for that disorder. This requirement does not apply to any disorder in the RUSP if, as of January 1, 2024, the disorder is already included in the list of disorders for which newborns must be tested in this state. In addition, the bill requires DHS to evaluate any disorder added to the RUSP after January 1, 2024, to determine whether newborns in this state should be tested for that newly added disorder. If DHS determines newborns should not be tested for the disorder, DHS must annually review medical literature and the department's capacity and resources to test for the disorder in order to determine whether to reevaluate the inclusion of the disorder in newborn testing in this state. If, in any of these evaluations or reevaluations, DHS determines that a disorder in the RUSP should be added to the list of disorders for

1

 $\mathbf{2}$

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

which newborns must be tested in this state, the bill requires DHS to promulgate rules to add that disorder.

The requirements for evaluations, reviews, and reevaluations under the bill do not apply to a disorder in the RUSP if DHS is in the process of adding, by rule, the disorder to the list of disorders for which newborns must be tested in this state. However, if the rule-making procedure for that disorder does not result in promulgation of a rule, then DHS must consider the disorder under the review and reevaluation procedures under the bill.

For further information see the state fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

Section 1. 253.13 (6) of the statutes is created to read:

253.13 (6) Federal recommendations; evaluation procedure. (a) *Initial* evaluation. 1. Subject to subd. 2., for any disorder that is added to the federal recommended uniform screening panel approved by the federal Department of Health and Human Services after January 1, 2024, and that is not included in the list of disorders under s. DHS 115.04, Wis. Adm. Code, the department shall do all of the following within 18 months after the addition of the disorder:

- a. Conduct an initial evaluation to determine whether the disorder should be included in the testing required under this section.
- b. If the department determines that the disorder should be included in the testing required under this section, commence rule making to add the disorder to the list under s. DHS 115.04, Wis. Adm. Code.
- 2. This paragraph does not apply to any disorder included in the federal recommended uniform screening panel that will be added to the list of disorders under s. 115.04, Wis. Adm. Code, pending promulgation of a rule for which the department has commenced rule-making procedures as of the effective date of this subdivision [LRB inserts date].

- (b) Annual review. 1. Subject to subd. 2., the department shall do all of the following on an annual basis for any disorder the department determines in an initial evaluation under par. (a) or a reevaluation under par. (c) should not be included in the testing required under this section and for any disorder that was the subject of rule making under par. (a) 2. or 2023 Wisconsin Act (this act), section 2 (2), that did not result in the promulgation of a rule:
- a. Review the medical literature published on the disorder since the initial evaluation or the commencement of rule making under par. (a) 2. or 2023 Wisconsin Act (this act), section 2 (2), to determine whether new information has been identified that would merit a reevaluation of whether testing for the disorder should be included in the testing required under this section.
- b. Determine whether the department has the capacity and resources needed to include testing for the disorder in the testing required under this section.
- 2. This paragraph does not apply to any disorder that is removed from the federal recommended uniform screening panel.
- (c) Reevaluation. If the department finds in an annual review under par. (b) that new information has been identified that would merit a reevaluation of whether testing for a disorder should be included in the testing required under this section or that the department has the capacity and resources needed to include testing for the disorder in the testing required under this section, the department shall do all of the following within 18 months of completing the annual review:
- 1. Conduct a reevaluation to determine whether testing for the disorder should be included in the testing required under this section.

SECTION 1

- 2. If the department determines in the reevaluation that testing for a disorder should be included in the testing required under this section, commence rule making to add the disorder to the list under s. DHS 115.04, Wis. Adm. Code.
- (d) Emergency rule making. The department may use the procedure under s. 227.24 to promulgate a rule under this subsection or 2023 Wisconsin Act (this act), section 2 (1) (b). Notwithstanding s. 227.24 (1) (a) and (3), the department is not required to provide evidence that promulgating a rule under this paragraph as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this paragraph. Notwithstanding s. 227.24 (1) (c) and (2), if the department submits in proposed form a permanent rule to the legislative council staff under s. 227.15 (1) within 15 months of the date the statement of scope of the emergency rule promulgated under this paragraph is published in the register under s. 227.135 (3), the emergency rule remains in effect until the date on which the permanent rule takes effect or the date on which the statement of scope expires under s. 227.135 (5), whichever occurs first.
- (e) *Implementation*. The department shall ensure that testing for any disorder added by rule to the list under s. DHS 115.04, Wis. Adm. Code, in accordance with this subsection begins within 6 months after the date of publication, as defined in s. 227.22 (1), of the rule.

SECTION 2. Nonstatutory provisions.

(1) For any disorder included in the federal recommended uniform screening panel approved by the federal Department of Health and Human Services as of January 1, 2024, that is not included in the list of disorders under s. DHS 115.04, Wis.

1

 $\mathbf{2}$

3

4

5

6

7

8

9

10

11

12

13

14

15

16

- Adm. Code, on the effective date of this subsection, the department of health services shall do all of the following within 18 months of the effective date of this subsection:
- (a) Evaluate whether the disorder should be included in the testing required under s. 253.13 (1).
- (b) If, in its evaluation, the department of health services determines that the disorder should be included in the testing required under s. 253.13 (1), commence rule making to add the disorder to the list under s. DHS 115.04, Wis. Adm. Code.
- (2) Subsection (1) does not apply to any disorder included in the federal recommended uniform screening panel that will be added to the list of disorders under s. DHS 115.04, Wis. Adm. Code, pending promulgation of a rule for which the department of health services has commenced the rule–making procedure as of the effective date of this subsection.
- (3) The department of health services shall ensure that testing for any disorder added by rule to the list under s. DHS 115.04, Wis. Adm. Code, in accordance with sub. (1) begins within 6 months after the date of publication, as defined in s. 227.22 (1), of the rule.

17 (END)