



Sub. S.B. 121

124th General Assembly
(As Passed by the Senate)

Sens. Blessing, Fingerhut, Hagan, Robert Gardner, Mallory, Oelslager, Roberts, Brady, Mumper, Mead, Prentiss, Spada

BILL SUMMARY

- Requires the Director of Health to adopt rules specifying the disorders for which screenings of newborn children must be conducted.
- Creates the Newborn Screening Advisory Council to advise the Director and includes the Council in the process the Director uses to adopt rules specifying the disorders for which newborn screenings must be conducted.
- Requires the Director to select a laboratory to perform newborn screenings if the laboratory maintained by the Department of Health is unable to perform screenings for all of the disorders specified by the Director.
- Clarifies the distinction between any fee that is collected for laboratory services in the performance of newborn screenings and the fee that is collected for use in funding programs for individuals with genetic disorders.

CONTENT AND OPERATION

Screenings for disorders in newborn children

(sec. 3701.501)

Current law requires the testing of newborn children for the presence of the following diseases: phenylketonuria, homocystinuria, galactosemia, and hypothyroidism. The Public Health Council is authorized to adopt rules requiring tests for other genetic, endocrine, or metabolic disorders. For a disorder to be included by rule, the following conditions must be met: (1) the Council must

determine that the disorder is treatable and causes disability when undiagnosed and untreated and (2) there must not be a need for taking additional blood samples or specimens. Under this provision, the Council has adopted rules requiring tests for such disorders as sickle cell disease and maple syrup urine disease.¹

The bill eliminates the statutory list of disorders for which testing must be done. Under the bill, which refers to *screening* rather than *testing*, the disorders are to be specified solely through the adoption of rules. Instead of being adopted by the Public Health Council, the rules are to be adopted by the Director of Health with input from the Newborn Screening Advisory Council.²

Newborn Screening Advisory Council

Currently, an ad hoc newborn screening advisory council exists, but the council's duties are not expressed in statute. The bill creates the Newborn Screening Advisory Council in statute and expressly requires it to advise the Director regarding newborn screening. The Council is required to engage in an ongoing review of the newborn screening requirements and to provide recommendations and reports to the Director as requested and as the Council considers necessary. The Director is permitted to assign other duties to the Council as the Director considers appropriate.

The bill requires the Director to appoint the members of the Council. In making appointments, the Director must select individuals and representatives of entities with interest and expertise in newborn screening, including such individuals and entities as health care professionals, hospitals, children's hospitals, regional genetic centers, regional sickle cell centers, newborn screening coordinators, and members of the public.

The bill requires the Department of Health to provide meeting space, staff services, and other technical assistance the Council requires in carrying out its duties. Members of the Council are to serve without compensation, except for reimbursement for actual and necessary expenses incurred in attending Council meetings or performing assignments for the Council.

¹ *Ohio Administrative Code sec. 3701-45-02.*

² *The Public Health Council consists of seven members appointed by the Governor and is part of the Department of Health. It has no administrative duties, but has authority to adopt certain rules and make recommendations to the Director of Health.*

The bill exempts the Council from the existing laws under which a new board or similar entity created by statute must expire after not more than four years, unless the General Assembly acts to extend its existence.³

Determination of disorders to be included

The bill requires the Newborn Screening Advisory Council to evaluate genetic, metabolic, and endocrine disorders to assist the Director in determining which disorders should be included in the required newborn screenings. In determining whether a disorder should be included, the Council must consider all of the following:

- (1) The disorder's incidence, mortality, and morbidity;
- (2) Whether the disorder causes disability if diagnosis, treatment, and early intervention are delayed;
- (3) The potential for successful treatment;
- (4) The expected benefits to children and society in relation to the risks and costs associated with screening for the disorder;
- (5) Whether a screening for the disorder can be conducted without taking an additional blood sample or specimen.

Based on these considerations, the Council is required to make recommendations to the Director for the adoption of rules specifying the disorders to be included. The bill requires the Director to review, promptly and thoroughly, each recommendation the Council submits. If the Director agrees with a recommendation, the Director must adopt rules that correspond with the recommendation. The rules are to be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.).

Standards and procedures for screening

The bill requires the Director to adopt rules in accordance with the Administrative Procedure Act establishing standards and procedures for the screening of newborn children. In some cases, the Director's rules will be similar to or the same as rules that current law requires to be adopted by the Public Health Council. The bill specifies that the Director's rules must include standards and procedures for the following:

³ The existing law is in Revised Code sections 101.82 through 107.87 (not in the bill).

- (1) Causing rescreenings to be performed when initial screenings have abnormal results;
- (2) Designating the person or persons who will be responsible for causing screenings and rescreenings to be performed;
- (3) Giving to the parents of a child notice of the required initial screening and the possibility that rescreenings may be necessary;
- (4) Communicating to the parents the screening and rescreening results;
- (5) Giving notice of the results to the person who caused the child to be screened or rescreened, or another person or government entity when the original person cannot be contacted;
- (6) Referring children with abnormal results to providers of follow-up services.

Laboratories

Current law requires that all newborn screenings be performed by the chemical and bacteriological laboratory maintained by the Ohio Department of Health. The bill continues the requirement that the state laboratory be used, but provides for the use of another laboratory if the Director determines that the state laboratory is unable to perform the screenings for all of the disorders specified in rules adopted under the bill.

If this determination is made, the bill requires the Director to select the laboratory to be used by issuing a request for proposals. The bill permits the Director to select a laboratory located outside Ohio. At the conclusion of the selection process, the Director must enter into a written contract with the selected laboratory. If the Director determines that the laboratory is not complying with the terms of the contract, the Director must immediately terminate the contract. Another laboratory must be selected and contracted with in the same manner.

In the case of rescreenings, current law permits the use of laboratories other than the state laboratory if the Public Health Council adopts rules permitting that use and the laboratory has been approved by the Director for that purpose. The bill eliminates the requirement that rules be adopted permitting the use of other laboratories. Instead, it specifies in statute that rescreenings may be performed by one or more other laboratories designated by the Director. The bill provides that any laboratory the Director considers qualified to perform rescreenings may be designated, including a laboratory located outside Ohio. If more than one laboratory is designated, the bill provides that the person responsible for causing a

rescreening to be performed is also responsible for selecting the laboratory to be used.

Use of fees

(secs. 3701.23 and 3701.501(F))

Current law requires the adoption of rules establishing a fee for newborn screenings of not less than \$14. Of each fee collected, not less than \$10.25 must be deposited in the Genetics Services Fund and not less than \$3.75 must be deposited in the Sickle Cell Fund.

The bill specifies that the fee of not less than \$14 is a fee that is charged and collected in addition to or in conjunction with any laboratory fee that is charged and collected for performing a newborn screening. Under the bill, the rules establishing the additional fee cannot establish a fee that differs according to whether the screening is performed by the state laboratory or another laboratory selected by the Director because the state laboratory is unable to screen for all of the specified disorders.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	05-31-01	p. 607
Reported, S. Health, Human Services and Aging	05-29-02	p. 1844
Passed Senate (33-0)	06-18-02	pp. 1909-1910

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