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Bill Analysis
Legislative Service Commission

S.B. 121

124th General Assembly
(As Introduced)

Sen. Blessing

BILL SUMMARY

- Requires the Public Health Council to adopt rules identifying the disorders for which screenings of newborn children must be conducted.
- Allows initial screenings to be performed by laboratories other than the laboratory maintained by the Ohio Department of Health.

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 be no need for taking additional blood samples or specimens. Under this provision, the Council has adopted rules requiring tests for sickle cell disease and other hemoglobinopathies.¹

The bill continues the testing of newborn children for genetic, endocrine, or metabolic disorders, but the list of specific diseases for which testing must be done is eliminated. Instead, the bill requires the Public Health Council to adopt rules

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

that identify the disorders for which screening must be conducted.² The rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.). In identifying the disorders, the Council is required to consider the following criteria:

- (1) Whether the disorder causes disability if diagnosis, treatment, and early intervention are delayed;
- (2) Characteristics of the disorder, including incidence, morbidity, and mortality;
- (3) Potential for successful treatment;
- (4) The specimen type required to conduct a screening;
- (5) Characteristics of the screening, including sensitivity, specificity, feasibility for mass screening, and cost;
- (6) Expected benefits to children and society in relation to the risks and costs associated with screening for the disorder.

Notice of results

In addition to requiring that notice of proposed screenings and their results be given to the parents of a child, current law requires the Public Health Council to adopt rules that prescribe a method for giving notice of proposed screenings and their results to any of the following, as determined appropriate in the rules: the person who caused the child to be screened, employees designated in the rules of the hospital of birth, or the local health commissioner. Under the bill, the rules may require that the additional notice be given to any of those listed in current law or to (1) employees of any other facility at which a birth occurs or (2) a person or government entity responsible for providing medical or nursing follow-up care to the child. The bill provides that when notice of results is given to the persons and government entities specified in either current law or the bill parental consent is not necessary.

Laboratories

Current law requires that all newborn screenings be performed by the chemical and bacteriological laboratory maintained by the Ohio Department of

² "Screening," the term used by the bill in place of "testing," is defined by the bill as a process by which an individual undergoes a procedure to indicate whether the individual is at a greater or lesser risk of having a specific condition.

Health. The Public Health Council is authorized to adopt rules permitting other laboratories approved by the Director of Health to perform rescreenings when abnormal results are obtained from initial screenings.

The bill allows initial screenings and any rescreenings to be conducted either by the state laboratory or by a laboratory with valid certificate issued pursuant to the federal Clinical Laboratories Improvement Act (CLIA) authorizing the laboratory to perform examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease.

Use of fees

(secs. 3701.23 and 3701.502)

Current law requires the adoption of rules establishing a fee for newborn screenings of not less than \$14. Under current rules, the fee for performing a newborn screening is \$27 and the fee for a hemoglobin pattern is \$10.³ 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 provides that the fee established by the Public Health Council is an *initial* fee and that deposits in the Genetics Services Fund and Sickle Cell Fund come from payments of the initial fee. The bill specifies that the minimum disbursements to these funds must be made whether the initial fee is paid directly to the Department of Health or transmitted to the Department after being paid to a hospital, free standing birthing center, or other person.

The bill provides that any amount charged by the state laboratory that exceeds the initial fee must be deposited in the existing Laboratory Handling Fee Fund. Any amount charged by a CLIA certified laboratory that exceeds the initial fee must be paid to the CLIA certified laboratory.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	05-31-01	p. 607

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³ *Ohio Administrative Code sec. 3701-49-011(A)(4).*