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S.B. 807: COMMITTEE SUMMARY

Senate Bill 807 (as introduced 10-14-99) Sponsor: Senator John J.H. Schwarz, M.D.

Committee: Health Policy

Date Completed: 10-18-99

## **CONTENT**

The bill would amend the Public Health Code to provide for the retention and disposal of blood specimens taken from a newborn infant for the newborn screening tests required under the Code; allow the blood specimens to be used for medical research under certain conditions; and allow the health professional in charge of a birth, or the hospital, to offer to a newborn's parents a blood sample from the newborn, for future identification purposes.

Currently, under the Code, the health professional in charge of the care of a newborn infant, or the health professional in charge of the birth, must administer to the infant tests for various conditions as prescribed in the Code. The bill provides that the Department of Community Health (DCH), by April 1, 2000, would have to develop a schedule for the retention and disposal of the blood specimens used for the screening tests after the tests were completed. The schedule would have to meet at least all of the following conditions:

- -- Be consistent with nationally recognized standards for laboratory accreditation and Federal law.
- -- Require that the disposal be conducted in compliance with the Code's requirements regarding the disposal of medical wastes.
- -- Require that the disposal be conducted in the presence of a witness (who could be an individual involved in the disposal or any other individual).
- -- Require that a written record of the disposal be made and kept, and that the witness sign the record.

Further, the DCH would have to allow the blood specimens to be used for medical research during the retention period established under the schedule, as long as the medical research was conducted in a manner that preserved the anonymity of the test subjects, and was consistent to protect human subjects from research risks, pursuant to the Code of Federal Regulations.

The bill provides that a health professional in charge of the birth of an infant, or the hospital or other facility in which the birth took place, or both, could offer to draw an additional blood specimen from the infant. The offer would have to be made to the infant's parent, guardian, or person in loco parentis at the time the blood specimens were drawn for the newborn screening tests. If the infant's parent, guardian, or person in loco parentis accepted the offer of an additional blood specimen, it would have to be preserved in a manner that did not require special storage conditions or techniques, including but not limited to lamination. The health professional, or hospital or other facility employee making the offer, would have to explain to the parent, guardian, or person in loco parentis at the time the offer was made that the additional blood specimen could be used for future identification purposes and should be kept in a safe place. The health professional, or hospital or other facility, could charge a fee that was not more than the actual cost of obtaining and preserving the additional blood specimen.

The bill would require the DCH to rewrite its pamphlet explaining the newborn screening requirements when the supply of pamphlets in existence on the bill's effective date was exhausted. When the DCH rewrote the pamphlet, it would have to include at least all of the following information in the pamphlet:

-- The nature and purpose of the testing program required under the Code, including, but not limited to, a brief description of each condition or disorder for which a screening test is required.

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- -- The purpose and value of an infant's parent, guardian, or person in loco parentis retaining a blood specimen in a safe place.
- -- The DCH's schedule for retaining and disposing of blood specimens.
- -- That the blood specimens taken for purposes of conducting the newborn screening tests could be used for medical research.

MCL 333.5431 Legislative Analyst: G. Towne

## **FISCAL IMPACT**

It would appear that additional costs resulting from this bill, if any, would be nominal. Costs to the Department of Community Health would be limited as the required pamphlet would not have to be rewritten until the existing supply of pamphlets had been distributed. Standards already exist for the disposal of biohazardous material and any additional record-keeping would be spread across the 135,000 to 190,000 births each year.

Fiscal Analyst: J. Walker

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