

Department of Legislative Services
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FISCAL AND POLICY NOTE
Revised

House Bill 1315 (Chairman, Health and Government Operations Committee)
(By Request – Departmental – Health and Mental Hygiene)

Health and Government Operations Education, Health, and Environmental Affairs

Maryland Birth Defects Program - Authority to Obtain Medical Information

This departmental bill clarifies the circumstances under which cases with birth defects must be reported and hospital records and other medical information be provided to the Department of Health and Mental Hygiene (DHMH). The bill also eliminates the obsolete term “sentinel” as it applies to birth defects and makes conforming changes.

Fiscal Summary

State Effect: The bill’s provisions could be implemented with existing resources. Enactment of the bill could increase the availability of federal funds for the Maryland Birth Defects Program.

Local Effect: None.

Small Business Effect: DHMH has determined that this bill has minimal or no impact on small business (attached). Legislative Services concurs with this assessment. The attached assessment does not reflect amendments to the bill.

Analysis

Bill Summary: This bill provides that a health care provider must allow DHMH to inspect and obtain copies of medical records of the child through the child’s second year and of the mother’s pregnancy, laboratory test records relating to the birth defect, and any other medical information relating to a child with a birth defect, as long as the information is used for the purposes specified in the bill.

A hospital is required to disclose the identity of a child without a birth defect who is part of a DHMH investigation to the Secretary so the Secretary may protect the public health and provide information to parents of children with birth defects about the birth defects and available services to address the defects. If DHMH shows a need for the individual identity of children without birth defects to conduct an investigation to protect the public health, the hospital must provide the Secretary with a list of children with characteristics that meet the criteria specified for the DHMH investigation. DHMH is required to obtain the informed consent of the parent or guardian of a child with or without a birth defect before obtaining the medical records of the child for any research requiring approval by an institutional board or including the child in any research requiring approval by an institutional board. The Secretary must assure that the identity of a child will not be released outside DHMH without the parent's or guardian's written consent. Any medical information obtained must be kept confidential.

The medical information requested by DHMH must be relevant to:

- the birth defect;
- the quality of reported data;
- providing information or services to the child's family;
- conducting an epidemiological investigation on birth defects; or
- conducting DHMH institutional board-approved research into the causes of birth defects.

The medical information gathered should only be as intrusive as necessary. The bill specifically provides that the release of reports or medical information as specified in this bill is not a violation of the health provider-patient relationship.

A health care provider is immune from civil liability and is not subject to criminal penalties for providing patient information as authorized by the bill. Whenever DHMH is engaged in human research, federal and state laws must be followed regarding protection of human subjects including obtaining appropriate institutional board approval and following the board's protocol.

Current Law: A hospital is required to report on each child who is born live or stillborn in the hospital and has a sentinel birth defect. For a child born outside a hospital, the person filing the birth certificate must make the report. Reports must be submitted by the hospital on a monthly basis. A "sentinel" birth defect is defined as 1 of 12 conditions that may afflict a child at birth. They include anencephaly, spina bifida, cleft palate, specified reduction deformities, Down syndrome, and others.

A hospital must disclose the identity of a child with a birth defect to the Secretary so the Secretary may use the information to protect the public health or provide the parents with

information on sentinel birth defects and the availability of public and private services. If DHMH shows a need for the individual identity of children without sentinel birth defects to conduct a case-control investigation, the hospital must obtain the written consent of the child's parent or guardian to disclose the child's identity. The Secretary must assure that the identity of a child may not be released without the written consent of the child's parent or guardian.

DHMH must assure that information is prepared and periodically updated on sentinel birth defects and the available public and private services for children with these defects. The Secretary must appoint a committee of those specified in statute to determine the components of this required report. The information on sentinel birth defects must be distributed to each hospital. The infant's physician must make the information available to the parents or guardians of infants with sentinel birth defects before the infant is discharged from the hospital with an explanation of the birth defect to the parents or guardians to the extent possible.

The Secretary must send a letter with information about the birth defect and the available services after hospital discharge to the parent or guardian of a child reported as having a sentinel birth defect before the child is six months old. Before the letter is sent, the Secretary must take appropriate steps to ensure that the letter is not sent to the parent or guardian of a child who died. DHMH and the Maryland Department of Environment must jointly develop procedures to monitor data on sentinel birth defects that may be caused by environmental hazards.

Background: According to DHMH, before enactment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), hospitals, and other health care providers routinely provided information to DHMH for its Maryland Birth Defects Program. Hospitals submitted a form with basic birth defects information that had been developed by an advisory committee. If more details were needed, DHMH was granted access to medical and other relevant reports from all types of providers, even without express statutory authorization.

After adoption of federal regulations to implement HIPAA, hospitals and other health care providers became increasingly concerned about confidentiality and exposure to legal action for releasing medical information. Even if the information was needed for public health purposes, providers wanted clear protection in State law from civil or criminal liability for release of that information. The Office of the Attorney General reviewed current law and recommended statutory changes to strengthen disclosure authority. DHMH advises that the bill's changes make the Maryland disclosure provisions more comparable to the birth defect laws in other states.

In recent years, DHMH was unable to carry out investigations of three possible birth defect clusters because the necessary information could not be obtained. Hospitals and other health providers were not willing to confirm a birth defect diagnosis.

The Centers for Disease Control and Prevention (CDC) recently adopted standards for birth defects programs to outline the program's responsibility to obtain health records for quality assurance purposes, and to investigate clusters, trends, and environmental hazards. The Trust for America's Health has evaluated State birth defects programs. In spite of recognition for the quality and timeliness of Maryland's birth defects data and use of the data for services and research, Maryland still received an overall grade of C. According to DHMH, the grade is primarily due to the absence of clear authority for DHMH to access medical information on birth defects to investigate birth defect clusters and environmental hazards, and for quality assurance.

DHMH also advises that it has twice applied and been rejected by CDC for grant funds to improve the birth defects program. In both cases, the State's lack of clear authority to access medical records was emphasized in reviews.

State Fiscal Effect: DHMH advises that the bill's provisions could be implemented with existing resources. Enactment of the bill could increase the availability of federal funds for the Maryland Birth Defects Program. If DHMH could demonstrate that it has clear authority to access medical information, collect missing data, and investigate clusters, DHMH could obtain a CDC grant of about \$100,000 per year for five years. No State match is required for these grants.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene, Department of Legislative Services

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