CHAPTER 227

AN ACT concerning research in sudden death in infancy and early childhood and amending and supplementing P.L.2000, c.24.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. Section 2 of P.L.2000, c.24 (C.52:17B-88.10) is amended to read as follows:

C.52:17B-88.10 Standardized protocols for autopsies of suspected SIDS victims.

2. a. The State Medical Examiner, in consultation with the Commissioner of Health and Senior Services, shall develop standardized protocols for autopsies performed in those cases in which the suspected cause of death of a child under one year of age is sudden infant death syndrome and in which the child is between one and three years of age and the death is sudden and unexpected.

b. The State Medical Examiner shall establish a Sudden Child Death Autopsy Protocol Committee to assist in developing and reviewing the protocol. The committee shall include, but shall not be limited to, the State Medical Examiner or his designee, the Assistant Commissioner of the Division of Family Health Services in the Department of Health and Senior Services or his designee, the Director of the Division of Youth and Family Services in the Department of Human Services or his designee, the director of the SIDS Resource Center established pursuant to P.L.1987, c.331 (C.26:5D-4), an epidemiologist, a forensic pathologist, a pediatric pathologist, a county medical examiner, a pediatrician who is knowledgeable about sudden infant death syndrome and child abuse, a law enforcement officer, an emergency medical technician or a paramedic, a family member of a sudden infant death syndrome victim and a family member of a sudden unexpected death victim who was between one and three years of age at the time of death.

The committee shall annually review the protocol and make recommendations to the State Medical Examiner to revise the protocol, as appropriate.

c. The protocols shall include requirements and standards for scene investigation, criteria for ascertaining the cause of death based on autopsy, criteria for specific tissue sampling, and such other requirements as the committee deems appropriate. The protocols shall take into account nationally recognized standards for pediatric autopsies.

The State Medical Examiner shall be responsible for ensuring that the protocols are followed by all medical examiners and other persons authorized to conduct autopsies in those cases in which the suspected cause of death is sudden infant death syndrome or in which the child is between one and three years of age and the death is sudden and unexpected.

d. The protocols shall authorize the State Medical Examiner, county medical examiner or other authorized person to take tissue samples for research purposes, as provided in section 2 of P.L.2005, c.227 (C.52:17B-88.11).

e. The sudden infant death syndrome autopsy protocol shall provide that if the findings in the autopsy are consistent with the definition of sudden infant death syndrome specified in the protocol, the person who conducts the autopsy shall state on the death certificate that sudden infant death syndrome is the cause of death.

C.52:17B-88.11 Protocol for participation of medical examiners in certain research activities concerning SIDS.

2. The Legislature finds and declares that: advances in genetics, biochemistry and other areas of medical research are yielding new information about the specific causes of sudden death in infancy and early childhood; these findings are of great importance because the largest subgroup of these deaths, Sudden Infant Death Syndrome, remains a "rule-out" diagnosis for which the family learns what did not, rather than what did, cause the death of their child; without knowing the actual cause, families are not able to determine if there is a genetic basis that places their other children at risk, and physicians are not able to prevent a death by prospectively diagnosing and treating a potentially fatal medical problem; and if the State is to meet its public health goal of reducing infant mortality, it is in the public interest to accelerate efforts to identify actual causes of death in infants and young children.

a. The State Medical Examiner, in consultation with the Commissioner of Health and Senior Services and the Sudden Child Death Autopsy Protocol Committee established pursuant to

section 2 of P.L.2000, c.24 (C.52:17B-88.10) shall establish, pursuant to this section, a protocol for participation by medical examiners in research activities concerning deaths of children three years of age and younger. The protocol shall be revised as necessary. The research shall include all autopsies in which the suspected cause of death of a child under one year of age is sudden infant death syndrome and the suspected cause of death of a child three years of age and younger is not considered a violent death pursuant to subsection a. of section 9 of P.L.1967, c.234 (C.52:17B-86).

The protocol shall authorize the State Medical Examiner, county medical examiner or other authorized person to take and transfer tissue samples to an approved research project prior to obtaining the consent of the parent or legal guardian of the deceased infant or young child, but the research project shall not be permitted to use the tissue prior to its obtaining consent as provided in paragraph (3) of this subsection.

Notwithstanding the provisions of this section to the contrary, the protocol shall provide that no tissue sample shall be taken from a deceased infant or young child whose parent or legal guardian has objected to an autopsy because it is contrary to the religious beliefs of the deceased, in accordance with section 2 of P.L.1983, c.535 (C.52:17B-88.2).

The protocol shall, at a minimum, stipulate that:

(1) the research project first be approved by the institutional review board of the facility at which the research shall be conducted, then by the Sudden Child Death Autopsy Protocol Committee, and finally by the Institutional Review Board of the New Jersey Department of Health and Senior Services. If a research project is submitted by the Department of Health and Senior Services, the final review of the project shall be conducted by an independent review board;

(2) the research project delineate the information, other than the tissue sample, that will be required from the investigation of the death of the infant or young child;

(3) the research project develop a plan for the release by the State Medical Examiner or county medical examiner, as applicable, of a decedent's tissue, as well as obtaining written consent for the use of the tissue and other identifying information from the parent or legal guardian of the deceased infant or young child;

(4) the research project develop a plan for the disposal of a decedent's tissue in the event that the parent or guardian does not give consent for use of the tissue, and in cases in which consent is given, upon completion of the research. The plan shall incorporate accepted procedures for disposal of surgical biopsies and biohazardous materials, and shall include procedures to inform the parent or guardian and the Sudden Child Death Autopsy Protocol Committee of the disposal plan;

(5) the research project reimburse the State Medical Examiner, county medical examiner or other authorized person participating in the research for reasonable costs incurred in taking storing and providing tissue samples for the project. The estimated costs subject to reimbursement shall be reviewed and approved by the State Medical Examiner;

(6) the research project provide the State Medical Examiner and the Sudden Child Death Autopsy Protocol Committee with periodic updates on the status of the project; and

(7) the Sudden Child Death Autopsy Protocol Committee may terminate a research project that is not in compliance with the research project as approved pursuant to this subsection.

b. Upon receiving notification from the research project that the research project has obtained written consent from the parent or legal guardian of the deceased infant or young child for the use of tissue samples and identifying information, the State Medical Examiner, county medical examiner or other authorized person, as applicable, shall provide the research project with copies of the autopsy reports and any reports generated by the State Medical Examiner or county medical examiner concerning the subject of the research.

c. The information and tissue samples provided by the State Medical Examiner, county medical examiner or other authorized person to the research project shall be used by the research project only for the purposes approved by the Sudden Child Death Autopsy Protocol Committee and as specified in the protocol, and shall not otherwise be divulged or made public so as to disclose the identity of any person to whom they relate. The information provided to the research project shall not be considered a public record pursuant to P.L.1963, c.73 (C.47:1A-1

et seq.) or P.L.2001, c.404 (C.47:1A-5 et al.).

d. The Sudden Child Death Autopsy Protocol Committee shall oversee the approved research projects.

e. The State Medical Examiner, county medical examiner, their employees and other persons authorized by the State Medical Examiner to provide tissue samples and identifying information to the research project, and the members of the Sudden Child Death Autopsy Protocol Committee shall not be liable for civil damages as the result of any actions or omissions performed in good faith and in accordance with the provisions of this act.

3. This act shall take effect on the 60th day after enactment.

Approved September 22, 2005.