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RULE ADOPTIONS
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF MEDICAL EXAMINERS**

Adopted Repeal and New Rules: N.J.A.C. 13:35-6A

Declarations of Death Upon the Basis of Neurological Criteria

Purpose; Definition of Brain Death; Requirements for Physicians Authorized to Declare Death on the Basis of Neurological Criteria; Standards for Declaration of Brain Death; Organ Donation; Exemption to Accommodate Personal Religious Beliefs; Pronouncement of Death

Proposed: May 15, 2006 at 38 N.J.R. 2021(a).

Adopted: January 10, 2007 by the Board of Medical Examiners, Sindy M. Paul, M.D., President.

Filed: March 26, 2007 as R.2007 d.120, without change.

Authority: N.J.S.A. 26:6A-1, specifically 26:6A-4 and 45:9-2.

Effective Date: May 7, 2007.

Expiration Date: March 17, 2010.

Federal Standards Statement

A Federal standards analysis is not required because the adopted repeal and new rules are governed by N.J.S.A. 26:6A-1 et seq. The adopted repeal and new rules are not subject to any Federal requirements or standards.

Full text of the adopted new rules follows:

SUBCHAPTER 6A. DECLARATIONS OF DEATH UPON THE BASIS OF NEUROLOGICAL CRITERIA

13:35-6A.1 Purpose

(a) The rules in this subchapter are established pursuant to N.J.S.A. 26:6A-1 et seq. (P.L. 1991, c. 90), the New Jersey Declaration of Death Act, and set forth:

1. Requirements, by specialty or expertise, for physicians authorized to perform a clinical brain death examination and declare death upon the basis of neurological criteria; and
2. Accepted medical standards, including criteria, tests and procedures, to govern declarations of death upon the basis of neurological criteria.

13:35-6A.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise.

"Apnea" means the absence of respiration and a terminal PCO₂ greater than 60 mmHG or a terminal PCO₂ at least 20 mmHg over the initial normal baseline PCO₂.

"Brain death" means the irreversible cessation of all functions of the entire brain, including the brainstem.

"Examining physician" means a physician who performs a clinical brain death examination and meets the qualifying criteria set forth at N.J.A.C. 13:35-6A.3. The term "examining physician" may refer to one or more physicians

involved in the clinical brain death examination.

13:35-6A.3 Requirements for physicians authorized to declare death on the basis of neurological criteria

(a) A physician performing a clinical brain death examination shall be plenary licensed and shall hold the following qualifications, dependent on the age of the patient upon whom a declaration of brain death is to be made:

1. Age below two months: When declarations of brain death are to be made upon children below two months of age, the examining physician shall be a specialist in neonatology, pediatric neurology or pediatric neurosurgery.
2. Age between two months and 12 months: When declarations of brain death are to be made upon children at or above two months of age, and at or below 12 months of age, the examining physician shall be a specialist in pediatric critical care, pediatric neurology or pediatric neurosurgery.
3. Age greater than 12 months: When declarations of brain death are to be made upon patients above 12 months of age, the examining physician shall be duly qualified by training and experience to declare brain death. For purposes of this section, neurologists, neurosurgeons, critical care specialists and trauma surgeons shall be deemed to be duly qualified physicians. In addition, any physician who has been granted privileges by a hospital to declare brain death may serve as the examining physician pursuant to this subchapter.

13:35-6A.4 Standards for declaration of brain death

(a) Declarations of brain death shall be made in accordance with accepted medical standards. A patient may be pronounced dead if a physician meeting the requirements set forth in N.J.A.C. 13:35-6A.3 determines in accordance with the criteria set forth in this section that brain death has occurred.

(b) The examining physician who is to pronounce brain death shall:

1. Determine a reasonable basis to suspect brain death. Brain death may be declared where the etiology of the insult or injury is sufficient to cause brain death and, in the judgment of the examining physician, is irreversible;
2. Exclude complicating medical conditions that may confound the clinical assessment of brain death, including:
 - i. Severe hypothermia, defined as core body temperature at or below 92 degrees Fahrenheit in adults, or outside the clinically established age specific range in a child;
 - ii. The effects of neuromuscular blockade(s). In the event a neuromuscular blockade was used to treat the patient, the examining physician shall establish that the effects of the blockade are reversed prior to performing clinical examinations for brain death;
 - iii. The effects of CNS depressants. If CNS depressants are present and serum blood level is therapeutic or below the therapeutic range, a clinical examination may be initiated. If serum blood levels are not available, above the therapeutic range or unknown, or there is an overdose or toxic exposure of an unknown agent, a brain death evaluation may proceed without reliance on clinical examination if, in the judgment of the examining physician, the injury or cause of coma is non-survivable. In such event, an objective measure of intracranial circulation shall be used as a confirmatory test;
 - iv. Severe metabolic imbalances, unless in the judgment of the examining physician any such imbalances do not confound the clinical assessment of brain death; and
 - v. Mean arterial pressure less than 60 mmHg in an adult or outside the clinically established age specific range in a child;
3. Perform a clinical examination to evaluate the patient for the presence of brain death. The following clinical findings, if present, are indicative of brain death:

- i. A determination that supraspinal motor response(s) to pain is absent;
- ii. A determination that brainstem reflexes are absent, which determination may be established by ascertaining all of the following:
 - (1) No pupillary response to light;
 - (2) No deviation of the eyes to irrigation of each ear with 50 ml of cold water. The tympanic membrane shall be determined to be intact;
 - (3) No corneal reflex; and
 - (4) No response to stimulation of the posterior pharynx and/or no cough response to tracheobronchial suctioning; and
- iii. The presence of apnea, which shall be established in accordance with the following testing procedure:
 - (1) Arterial PCO₂ is normalized to greater or equal to 40 mmHg;
 - (2) 100 percent oxygen is delivered via the ventilator for 10 minutes prior to starting the test;
 - (3) A baseline arterial blood gas is drawn;
 - (4) A pulse oximeter is connected and the ventilator is disconnected;
 - (5) 100 percent oxygen is delivered into the trachea via cannula in the ET tube, at six liters/minute;
 - (6) If tolerated, the patient is left off the ventilator for eight to 10 minutes and the patient is observed carefully for respiratory movements. Another blood gas is drawn at the end of the eight to 10 minutes and the ventilator is reconnected;
 - (7) The length of the apnea test and the PCO₂ at the end of the test are documented in the patient record; and
 - (8) If the patient does not tolerate the apnea test, as evidenced by significant drops in blood pressure and/or oxygen saturation, or the development of significant arrhythmias, the test shall be discontinued and either repeated or supplanted with a confirmatory test.
- iv. When, in the judgment of the examining physician, a clinical examination cannot be performed due to the nature of injuries, intoxication, patient instability, electrolyte imbalances or any other reason, a confirmatory test such as an intracranial blood flow, four vessel cerebral angiography, radionuclide angiography, transcranial Doppler ultrasound, CT angiogram, or MR angiogram shall be substituted for the clinical examination; and

4. Confirm the diagnosis with a confirmatory test or by a repeat clinical examination, consistent with the following:

- i. When a clinical examination of a patient shows the absence of all supraspinal and brain stem reflexes as established by the criteria in (b)3 above, the examining physician shall confirm the diagnosis of brain death with an objective confirmatory test measuring intracranial circulation such as an intracranial blood flow, four vessel cerebral angiography, radionuclide angiography, transcranial Doppler ultrasound, CT angiogram or MR angiogram.
- ii. In the event confirmatory testing is not available or is clinically precluded, the examining physician shall repeat the clinical examination after a period of observation, which period shall be not less than 48 hours for patients below the age of two months, not less than 24 hours for patients between the ages of two months to one year, and not less than six hours for patients greater than one year of age.

13:35-6A.5 Organ donation

If the person to be declared dead upon the basis of neurological criteria is or may be an organ donor, then the

examining physician shall not have any responsibility for any contemplated recovery or transplant of that person's organs, and shall not serve in the capacity of organ transplant surgeon, the attending physician of the organ recipient, or otherwise an individual subject to a potentially significant conflict of interest relating to procedures for organ procurement.

13:35-6A.6 Exemption to accommodate personal religious beliefs

Death shall not be declared on the basis of neurological criteria if the examining physician has reason to believe, on the basis of information in the patient's available medical records, or information provided by a member of the patient's family or any other person knowledgeable about the patient's personal religious beliefs, that such a declaration would violate the personal religious beliefs of the patient. In these cases, death shall be declared, and the time of death fixed, solely upon the basis of cardio-respiratory criteria.

13:35-6A.7 Pronouncement of death

The examining physician shall document within the patient record the results of all tests performed and shall sign the chart. After a clinical examination and a confirmatory test or examination have been completed and documented on the patient's chart, and if the examining physician has been able to make all requisite determinations consistent with N.J.A.C. 13:35-6A.5, then the examining physician may authorize the pronouncement of death. The actual pronouncement of death may thereafter be made by the examining physician or any plenary licensed physician acting upon the authorization of the examining physician.