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RULE ADOPTIONS

LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF MEDICAL EXAMINERS

39 N.J.R. 1751(a)

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.

Summary of Public Comments and Agency Responses:

The Board received comments on the proposal from the following:

1. Alan Sori, M.D., Chairman of Surgery, Saint Joseph's Regional Medical Center;

2. Susan Gillespie, Evangelical Covenant Church;

3. Peter Domanico;

4. Henri Fromageot;

5. Colette M. Liddy;

6. Ronald Farina;

7. Rev. Stephen Kaznica;

8. Teresa Fasanello;

9. Renee Michelle Moreau;

10. Adolf Schimpf;

11. Patricia Staley, R.N.;

12. Cecilia Cichon;

13. John Donlan;

14. Patricia Burke;

15. Joseph Maloy;

16. Frank Solis;

17. Michael O'Sullivan;

18. Victoria Manduca;

19. Maureen Ferguson;

20. Joan McLaughlin;

21. Elsie P. Palmer;

22. Peter O'Neill, Irish American Public Action Committee;

23. Marie Heslin, Lifenet;

24. Raymond Nolting;

25. Chris Flaherty;

26. Patrick Pullicino; M.D., Ph.D., New Jersey Medical School, University of Medicine and Dentistry of New Jersey;

27. Thomas and Patricia Gallo, Spotswood Right to Life;

28. Judith Brown, President, American Life League, Inc.;

29. Kenneth Czarnecki;

30. Maryann Schingo, East Brunswick Right to Life;

31. Irene Lenahan;

32. John Carlucci;

33. Ray and Denise Sullivan;

34. Theresa Kenworthy;

35. Kelly Floyd, P.T.;

36. Dr. Seriah L, Rein, Council on the American Family;

37. Robert Goodman;

38. Marie Tasy, New Jersey Right to Life;

39. Douglas Daudelin;

40. Dean Gavaris; Executive Director, Gateway Pregnancy Center;

41. John J. Bogan, Somerset County Right to Life;

42. Marilyn Leiker;

43. Thomas Scibetta;

44. Dorothy M. Scibetta;

45. Courtney Doutel;

46. Helen O'Mullan;

47. Thomas Bojko, M.D., M.S., F.A.A.P., F.C.C.M., Associate Professor and Senior Vice Chair, Clinical Affairs, Department of Pediatrics, Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey;

48. Patricia Murphy, Ph.D., A.P.N., F.A.A.N., Clinical Professor of Surgery, New Jersey Medical School, University of Medicine and Dentistry of New Jersey;

49. Carolyn Torre, R.N., M.A., A.P.N., Director of Practice, New Jersey State Nurses Association;

50. Carl J. Hauser, M.D., Professor of Surgery, Division of Trauma, University of Medicine and Dentistry of New Jersey, Newark;

51. Joseph P. Cummins, New Jersey Committee for Life;

52. Walter Weber, Senior Litigation Counsel, American Center for Law and Justice;

53. Michael Feely, M.D., Atlanticare Regional Medical Center;

54. Jesse Kurtz, The Palimpsest Files;

55. Cornelia and David Tucker;

56. Loretta Aigner, Our Lady of Lourdes Medical Center;

57. Frank Inzano;

58. Patrick S. Smith, New Jersey Right to Life; St. Matthias Church Pro-Life Ministry; Knights of Columbus;

59. James McCormick, LinensNThings;

60. Dr. Daniel Lieuwen;

61. Frances Noronha;

62. Carol Lavis, Pro-Life Networks;

63. Gregory Rokosz, D.O., J.D., F.A.C.E.P., F.A.C.O.E.P, Past Member, New Jersey State Board of Medical Examiners;

64. Carolyn Hughes;

65. Gary Carter, President and CEO, New Jersey Hospital Association;

66. Mary Banasiak-Zizza;

67. Steven Ross, M.D., Professor of Surgery, Director of Trauma, Cooper University Hospital;

68. Scott Chelemer, Medical Director, Critical Care Unit, Virtua-Memorial Hospital;

69. Adrian Fisher, M.D., Associate Professor of Surgery, New Jersey Medical School, Newark;

70. John Jamison, AtlantiCare Regional Medical Center;

71. Michael Nosko, M.D., Ph.D., F.R.C.S., F.A.C.S., Associate Professor and Chief, Division of Neurosurgery, Robert Wood Johnson Medical School University of Medicine and Dentistry; Immediate Past President, New Jersey Neurosurgical Society;

72. Frank and Mary Anne La Cava;

73. Robert Fowler;

74. John Ginty, International Catholic Lawyers Society;

75. M. Niemeyer;

76. Michael Kelly, M.D.,

77. Mary McTigue, R.N.C., M.A.;

78. John Howard;

79. David Knowlton, New Jersey Health Care Quality Institute;

80. Marie Sherry, R.N.;

81. Doris V. Kiney;

82. Joseph P. Weaver;

83. Barbara J. Babington;

84. Frank & Shirley Perry;

85. Suzanne H. Atkins, M.D., Chief of Staff, Associate Dean for Clinical Affairs and Stephen S. Kamin, M.D., Associate Professor & Acting Chair, Department of Neurology & Neurosurgery, University of Medicine and Dentistry of New Jersey- the University Hospital, Newark;

86. Joshua M. Bershad, M.D., Associate Medical Director, Robert Wood Johnson University Hospital;

87. Paul A. Byrne, M.D., Director of Pediatrics & Neonatology, St. Charles mercy Hospital, Oregon, Ohio, Clinical Professor of Pediatrics, Medical University of Ohio, Toledo, Ohio;

88. Raymond E. Cantor, Director of Governmental Affairs, Medical Society of New Jersey;

89. Mary Beth Carrigg, R.N., B.A.,C.N.N.;

90. Patricia Coyle, New Jersey Committee for Life, Inc., State Director;

91. Andrew N. de la Torre, M.D., Assistant Professor of Surgery, Liver Transplant and Hepatobiliary Surgery, New Jersey Medical School, Newark;

92. Robert F. Heary, M.D., Professor and Program Director, Neurological Institute of New Jersey, President, New Jersey State Neurological Society;

93. Eileen Meager;

94. Walter Quense;

95. John S. Radomski, M.D., Chair, Department of Surgery, Our Lady of Lourdes Medical Center;

96. Richard Sautner;

97. Eileen Carrigg Specchio, Ph.D., R.N., Associate Professor of Nursing, College of Saint Elizabeth;

98. Ed and Eileen Spirko;

99. Margaret M. Starkey;

100. Pravin Vasoya, M.D.;

101. Lynne Weiss, M.D., Professor of Pediatrics, Director, Division of Pediatric Nephrology & Hypertension; Lewis Reisman, M.D., Professor of Pediatrics, Director, Pediatric Transplant Program; Hilary Hotchkiss, M.D., Assistant Professor of Pediatrics, Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey;

102. Dominick Zampino, D.O., F.A.C.P., Director, Section of Hospital Medicine, Atlanticare Regional Medical Center; and

103. Edward J. Zampella, M.D., F.A.C.S., Past President, New Jersey Neurosurgical Society.

1. COMMENT: Many of the commenters urged the Board to withhold adoption of the proposed new rules in order to allow the Board more time to study the issues associated with brain death determinations.

RESPONSE: The Board disagrees with the commenters' assertion that the proposed new rules should not be adopted at this time because the Board has had insufficient time to study the issues associated with determining death

on the basis of neurological criteria. The Board undertook a comprehensive review of these issues beginning in the summer of 2005. As part of that review, the Board considered medical references, including recent publications in medical journals, concerning the diagnosis of brain death. In addition, the Board has conducted a thorough review of the concerns and issues raised by the various commenters to this proposal since the close of the public comment period in July of 2006. The Board believes that the proposed new rules are necessary to ensure that the criteria used by its licensees in the declaration of brain death are clinically appropriate and comport with currently accepted medical practice standards. Therefore, the Board believes that it is appropriate to proceed with the adoption of the proposed new rules at this time.

2. COMMENT: Many of the commenters urged the Board to revisit the issue of allowing death to be declared on the basis of neurological criteria. Some of the commenters requested that the Board establish standards by which death may be declared only on the basis of the cessation of respiratory and circulatory system functions.

RESPONSE: The proposed new rules, and the current rules in Subchapter 6A that are being repealed as part of this rulemaking, were proposed following the passage of the New Jersey Declaration of Death Act, set forth at N.J.S.A. 26:6A-1 et seq. The New Jersey Legislature, in enacting the Declaration of Death Act, has expressly provided for the declaration of death in this State on the basis of either cardiorespiratory or neurological criteria. N.J.S.A. 26:6A-2 provides that a person who has sustained irreversible cessation of all circulatory and respiratory functions shall be declared dead, and N.J.S.A. 26:6A-3 provides that a person whose circulatory and respiratory functions can be maintained solely by artificial means, and who has sustained irreversible cessation of all functions of the entire brain, including the brain stem, shall be declared dead. The Board, therefore, is statutorily prohibited from implementing the changes suggested by these commenters.

3. COMMENT: A majority of the commenters opposed the proposed new rules because they believe that the elimination of the current requirement that a second physician be involved in the brain death determination is inappropriate and detrimental to patients. The commenters urged the Board to retain the "two physician requirement," because having a corroborating physician is reasonable in light of the fact that most people are urged to obtain a second physician opinion for most medical diagnoses. The costs associated with obtaining a second physician to confirm a brain death diagnosis are claimed to be marginal when compared to the cost to the patient and his or her family if a single doctor charged with the responsibility to make the brain death determination makes an incorrect assessment. In addition, several commenters believe that the proposed new rules will place an inordinate burden on individual doctors who now will be solely responsible for making brain death determinations.

RESPONSE: The elimination of the current requirement that a second corroborating physician must confirm an attending physician's determination of brain death comports with currently accepted medical standards and practice. The Board notes that certain of the diagnostic tests that are currently available to physicians to confirm a diagnosis of brain death did not exist when the current rules for determining brain death were proposed in 1992.

The Board believes that many of the commenters' concerns with respect to the elimination of the corroborating physician requirement stem from the commenters' misperception about the nature of the requirements for confirmatory testing and the value of the confirmatory testing in the process. Indeed, the Board notes that it would anticipate that the confirmatory tests required will primarily be interpreted by a physician other than the physician who conducts the clinical examination. Because the proposed new rules require the use of objective confirmatory tests to confirm an examining physician's initial assessment of brain death following a comprehensive clinical examination, the Board rejects the commenters' assertion that the second examining physician requirement needs to be retained.

The Board notes that in those rare cases where a confirmatory test cannot be performed because of the extent of the patient's injuries, proposed new rule N.J.A.C. 13:35-6A.4(b)4ii provides that a repeat clinical examination must be performed before a brain death determination can be made. In such a situation, one doctor may be responsible for making the brain death determination because the repeat examination may be performed by the same physician who performed the initial clinical examination. The Board believes that the requirement in the rules that the repeat clinical

examination be performed only following a specified minimum period of observation will safeguard the patient's and family's interests and is confident that after the passage of the referenced time periods, there is no need for a second physician to conduct the examination.

For the foregoing reasons, the Board declines to accept the commenters' suggestion to amend the proposed new rules in order to maintain the current corroborating physician requirement.

4. COMMENT: A majority of the commenters objected to the proposed new rule that would allow a doctor, other than a neurologist or neurosurgeon, to make a brain death determination as inappropriate. Such a requirement would lessen the protections currently afforded patients in the State. The commenters urged the Board not to adopt the proposed new rule that would allow other specialists or physicians who have been granted hospital privileges to make brain death determinations to participate in brain death declarations. The commenters believe that the current requirement that only a neurologist or neurosurgeon be used to make these determinations will continue to ensure that brain death declarations are made by the most qualified physicians available. One commenter claimed that the determination of brainstem death is an acquired skill and that a non-neurologist or non-neurosurgeon cannot be assumed to have such expertise. The commenter also claimed that patient safety dictates that only neurologists or neurosurgeons make this determination.

RESPONSE: The Board disagrees with the commenters' assertions that physicians other than neurologists or neurosurgeons are not qualified to make brain death determinations. Advances in both readily available diagnostic testing and physician training since the current rules on determining brain death, that were originally promulgated in 1992, make the proposed new rules' expansion of the pool of physicians who may participate in brain death determinations both reasonable and beneficial to brain injured patients and their families. Allowing critical care specialists, trauma surgeons and other physicians with the requisite training and experience to make brain death determinations permits those physicians who may be involved in the treatment of the patient and, as a result, familiar to the patient's family, to conduct the clinical examination and to order the necessary confirmatory tests set forth in the proposed new rules.

In addition, the Board believes that the commenters' concerns regarding the qualifications of non-neurologists or non-neurosurgeons, granted privileges by a hospital to participate in the brain death determination process, are unfounded. Hospitals are responsible, under Department of Health and Senior Services rules set forth at N.J.A.C. 8:43G, for credentialing physicians for all procedures performed at their institutions. The Board is confident that hospitals will only credential those physicians to make brain death determinations who have satisfied the criteria established by the institutions for such purposes. Therefore, the Board declines to accept the commenters' suggestions to amend the proposed new rules to permit only neurologists and neurosurgeons to make brain death determinations.

5. COMMENT: Many of the commenters urged the Board not to adopt the proposed new rules because the new rules weaken safeguards originally put in place to protect patients who are unable to speak for themselves. The commenters urged the Board to adopt rules that will respect the sanctity of life in all its stages. Some of the commenters believe that the intent of the new rules is to speed up or streamline the process of organ donation at the expense of severely brain damaged patients who are entitled to appropriate medical care. Several of the commenters are fearful that speeding up the process of making brain death determinations may allow brain injured patients insufficient time to improve or recover. Several of the commenters suggested that treatments currently exist, or are being developed, for brain injured and comatose patients that could allow patients who would otherwise be declared brain dead to recover.

RESPONSE: The Board's intent in proposing the new rules is to ensure that the standards being utilized by physicians in New Jersey to declare death on the basis of neurological criteria are consistent with current clinical practice standards. By so doing, the Board believes that it is safeguarding the welfare of brain injured patients and their families. By ensuring that brain death determinations are made by appropriately trained and experienced examining physicians and that comprehensive clinical examinations are performed and are substantiated by appropriate confirmatory testing, the proposed new rules may help to facilitate the implementation of a patient's, or his or her

family's, wishes. In some cases, this may result in the donation of a patient's organs for transplantation. However, irrespective of a family's decision concerning organ donation, the Board believes that the proposed new rules will assist patients' families in making those decisions in a more timely manner.

6. COMMENT: Several commenters objected to the proposed new rule that would allow any physician granted hospital privileges to declare brain death to make such determinations. Relying on hospital privileging alone, without some other articulated standard of training or competency, is insufficient to provide adequate public trust and assurance of competency. Without such articulated standards, it is unclear how a hospital will grant such privileges to physicians other than neurologists, neurosurgeons, critical care specialists and trauma surgeons. Other commenters urged the Board to consider requiring any non-neurosurgeon or non-neurologist who will be involved in making brain death declarations to pass a State-sanctioned examination aimed at ensuring competency or, in the alternative, requiring mandatory training in brain death determinations as part of examining physicians' residency training.

RESPONSE: As noted in response to Comment 4 above, a hospital's decision to grant a physician privileges to declare death on the basis of neurological criteria must be carried out consistent with Department of Health and Senior Service rules concerning the credentialing of health care facility staff. The Board reiterates that it is confident that a hospital will only credential those physicians to make brain death determinations that have satisfied competency standards imposed by the institution. Similarly, the Board notes that residency training requirements are established by health care institutions and, therefore, are not within the purview of the Board to regulate. The Board rejects the suggestion that a State-sanctioned examination be utilized to ensure competency because the Board believes that the proposed new rules assure that only competent individuals will be permitted to perform brain death determinations.

7. COMMENT: One commenter objected to the language in the proposed new rules that would allow brain death determinations on patients below the age of 12 months to be made by "a pediatric neurosurgeon." The commenter objected to the use of the term because the American Board of Medical Specialties does not recognize "pediatric neurosurgery" as a subspecialty within neurosurgery. The commenter recommended that the proposed new rules be amended to replace all references to "pediatric neurosurgeon" with references to "neurosurgeon."

RESPONSE: The Board's reference to "pediatric neurosurgery" in proposed new rule N.J.A.C. 13:35-6A.3(a)1 and 2 is intended to capture those neurosurgeons who are appropriately trained and credentialed to perform evaluations upon pediatric patients. Use of the term "neurosurgeon" alone, as suggested by the commenter, would not accurately convey the Board's intent that those permitted to perform brain death determinations on patients below the age of 12 months have appropriate training with respect to pediatric patients. The Board notes that the term "pediatric neurosurgeon" is referenced in the current rules. The Board is not aware of any difficulties that currently exist in identifying "pediatric neurosurgeons" or in assuring compliance with this regulatory requirement. Therefore, the Board declines to amend the proposed new rule as suggested by the commenter.

8. COMMENT: One commenter noted that the proposed new rules will have a limited effect in reducing the confusion among patients and their families about brain death determinations. The commenter claims that the Board's attempt to make the declaration of brain death more efficient may make patients' families more distrustful of such determinations.

RESPONSE: The Board disagrees with the commenter's suggestion that the proposed new rules will result in greater confusion and distrust among patients' families. As noted above, the Board believes that the provision in the new rules that will allow critical care specialists, trauma surgeons and other appropriately trained and credentialed physicians to participate in brain death determinations will benefit patients' families. The proposed new rules may allow physicians who are more involved in the treatment of the patient and, as a result, more familiar to the patient's family, to conduct the necessary clinical examination and order the appropriate confirmatory tests. In such cases, families may feel a greater level of comfort in knowing that the brain death assessment is being made by a physician who is more familiar with the patient's particular situation.

9. COMMENT: Many commenters expressed support for the proposed new rules, noting that the rules will bring the process for declaring brain death in New Jersey into conformity with the standards used throughout the country. The commenters stated that New Jersey is one of only two states that have regulations as prescriptive as those currently in place. The elimination of the two physician requirement is proper because no data exists that would suggest that a second assessment by a different doctor reduces error. Eliminating the second physician requirement will eliminate duplication of effort and will reduce the chance of miscommunication.

RESPONSE: The Board thanks the commenters for their support of the proposed new rules.

10. COMMENT: Many commenters noted that the proposed new rules will help to simplify the chain of communication to a patient's family. The proposed new rules will help to ensure the prompt and accurate determination of brain death, which will allow a family to begin making post-mortem decisions without undue delay. The commenters note that the proposed new rules will also help the process of organ donation, which could help countless other persons.

RESPONSE: The Board thanks the commenters for their support of the proposed new rules.

11. COMMENT: Many commenters expressed support for the provision in the proposed new rules that would allow physicians other than neurologists and neurosurgeons to participate in the brain death determination process, noting that families are better served when a physician involved in a patient's care, such as a trauma specialist or a critical care specialist, is also involved in performing the brain death determination. The commenters expressed support for allowing a hospital to make the decision as to which staff members it deems qualified to make brain death determinations. Allowing these other physicians to make brain death determinations will eliminate the delay currently involved in locating neurosurgeons or neurologists for this purpose. New Jersey is facing a shortage of neurologists and neurosurgeons, and locating such physicians in order to make brain death declarations often results in unnecessary and inhumane delays in reaching such determinations. Advances in medical training for physicians have increased skill levels and appropriately trained physicians should not be prohibited from exercising these skills to the benefit of their patients. By broadening the ability of other physicians to determine death on the basis of neurological criteria, the proposed new rules will allow physicians and hospitals to use neurosurgical resources appropriately. One commenter also noted that the proposed new rules would not prohibit a hospital from limiting the performance of brain death determinations to neurologists and neurosurgeons if the hospital so chooses.

RESPONSE: The Board thanks the commenters for their support of the proposed new rules. Although the proposed new rules will allow physicians other than neurologists and neurosurgeons to participate in brain death determinations, the Board does not control hospital credentialing decisions and, thus, agrees that the new rules would not prohibit a hospital from requiring brain death determinations in its facility to be performed only by neurologists and/or neurosurgeons.

12. COMMENT: Several of the commenters asserted that the failure of the proposed new rules to require the use of an electroencephalogram (EEG) to determine brain death will endanger the lives of brain injured patients. The commenters believe that an EEG is the only sure way to establish whether a patient's brain is or is not functioning. The commenters urged the Board to require the use of an EEG in all brain death determinations.

RESPONSE: The Board disagrees with the commenters' assertion that not requiring the use of an EEG will endanger patients. The Board is fully confident that the confirmatory tests set forth in the proposed new rules represent the most objective diagnostic tools currently available for use in determining brain death. The use of these confirmatory tests is consistent with current clinical practice standards and will ensure that a diagnosis of brain death is accurate and reliable.

13. COMMENT: Several of the commenters urged the Board not to adopt the proposed new rules, but to instead respect the personal religious beliefs of brain injured patients. One commenter noted that the proposed new rules would override a patient's desire to be kept alive regardless of a brain death determination. Another commenter inquired

whether any religions maintain that death can only be declared when a person's heart and lungs stop functioning. The commenter also inquired as to what responsibility a physician has in seeking out a patient's personal religious beliefs in such cases.

RESPONSE: The proposed new rules continue to safeguard the personal religious beliefs of patients. Proposed new rule N.J.A.C. 13:35-6A.5 provides that death may not be declared on the basis of neurological criteria if the examining physician has reason to know that such a declaration would violate the patient's religious beliefs. The new rule provides that in such cases, death may only be declared on the basis of cardio-respiratory criteria. The Board notes that this provision is statutorily mandated by the New Jersey Declaration of Death Act, N.J.S.A. 26:6A-5, and is currently in place in the existing rules. The Board is unaware of any evidence to suggest that brain death determinations are being made in contravention of patients' personal religious beliefs. The Board is confident that an examining physician will be made aware of any religious objection by the patient to the pronouncement of brain death through discussions with the patient's family, if such information is not already provided in the patient's available medical records. The Board notes that questions about the beliefs and practices of individual religions with respect to determinations of death are outside the Board's purview.

14. COMMENT: One commenter urged the Board not to allow the protections currently afforded brain injured patients to be weakened by allowing physicians who have a potential vested interest in the patient's death, such as trauma surgeons who are also involved in organ donation, to be responsible for making a brain death determination. The commenter urged that brain death determinations continue to be made by individuals who have no vested interest in the outcome of the patient's assessment.

RESPONSE: The proposed new rules continue to ensure that physicians with potential or actual conflicts of interest with respect to the patient are prohibited from participating in the brain death determination process. Specifically, proposed new rule N.J.A.C. 13:35-6A.5 continues the statutorily-mandated standard set forth at N.J.S.A. 26:6A-4, currently in place in the existing rules, that if the patient is or may be an organ donor, then the examining physician shall not have any role in any contemplated recovery or transplant of that patient's organs. The examining physician is also prohibited from serving in the capacity of an organ transplant surgeon or the attending physician of the organ transplant recipient.

15. COMMENT: One commenter urged the Board not to adopt the proposed new rules because such new procedures are untested. The commenter recommends that the Board not adopt these new procedures until they have been tested in a minimum of 100 cases.

RESPONSE: The procedures set forth in the proposed new rules are not untested. The standards established under the new rules, including the specific confirmatory tests that are to be utilized for brain death determinations, represent the current standard of practice in this area. These procedures are currently utilized by physicians throughout the country in making brain death determinations.

16. COMMENT: One commenter noted that the proposed new rules will require the use of fewer diagnostic procedures to declare a person brain dead. The commenter urged the Board to require the use of sound diagnostic measures, beyond a physician's clinical examination of a patient, to make determinations of brain death.

RESPONSE: The Board disagrees that the proposed new rules will require the use of fewer diagnostic procedures in making brain death determinations. The diagnostic procedures set forth in the proposed new rules are comprehensive and consistent with current clinical practice standards. The Board notes that the proposed new rules provide that brain death determinations can only be made following a clinical examination conducted by an experienced and appropriately trained physician whose findings must be substantiated through the confirmatory tests set forth in the rules. When confirmatory testing cannot be conducted because of the extent of the patient's injuries, a brain death determination can only be made following a repeat clinical examination performed after the passage of a specified minimum period of observation.

17. COMMENT: One commenter expressed support for the elimination of the EEG as a confirmatory test, but noted that the proposed new rules' reliance on transcranial Doppler ultrasound, magnetic resonance angiography (MRA) and computer tomography (CT) angiogram as confirmatory tests is troubling. The commenter also noted that the proposed new rules fail to address how the presence of drugs may confound a clinical examination. The commenter expressed concern that the proposed new rules will turn confirmatory tests into "declarative tests."

RESPONSE: The Board believes that use of the referenced diagnostic tests in brain death determinations is appropriate and consistent with current clinical practice standards. The Board disagrees with the commenter's assessment that the proposed new rules fail to address what impact the presence of certain drugs may have on the clinical examination. Proposed new rule N.J.A.C. 13:35-6A.4(b)2ii and iii specifically directs an examining physician to assess the impact of any neuromuscular blockades and central nervous system (CNS) depressants administered to the patient. The Board also disagrees with the commenter's assertion that the tests set forth in the proposed new rules are being used as declarative tests. The diagnostic tests set forth in the proposed new rules are conducted in order to substantiate or confirm the examining physician's initial clinical examination findings.

18. COMMENT: One commenter noted that it is unlikely that a trauma surgeon, adult critical care specialist or adult neurologist will have any expertise or training to declare brain death in children. The commenter urges the Board to consider allowing physicians who do not specialize in the treatment of children to be involved in declaring brain death in children only on patients above the age of 12. Below this age, a brain death examination should be performed only by a pediatric specialist.

RESPONSE: The standards established in proposed new rule N.J.A.C. 13:35-6A.3(a)3, which authorize neurologists, neurosurgeons, critical care specialists and trauma surgeons to perform brain death assessments on patients older than 12 months of age, are consistent with current clinical practice standards. These practice standards reflect the fact that physicians in these specialties have the requisite training and expertise to perform brain death assessments on individuals of one year of age or greater. The Board, therefore, disagrees with the commenters' assertion that such physicians should not be authorized to examine patients under the age of 12.

19. COMMENT: One commenter expressed concern that the provision in the proposed new rules that references a patient being left off the ventilator for eight to 10 minutes, during which time the patient is observed for respiratory movements, as well as the provision that defines severe hypothermia as core body temperature outside the clinically established age specific range in a child, are too ambiguous. These provisions could lead to misinterpretation of the proposed new rules in practice.

RESPONSE: The Board does not believe that the referenced provisions are ambiguous. The parameters of the clinical examination and the confirmatory tests set forth in the proposed new rules are consistent with current clinical practice standards. The Board is unaware of any evidence to suggest that these diagnostic tools will be misinterpreted by experienced and trained physicians performing brain death evaluations.

20. COMMENT: One commenter objected to the proposed new rules because he believes that the rules will allow a person who is not, in fact, brain dead, to be declared dead. The commenter believes that under proposed new rules N.J.A.C. 13:35-6A.3(a)3 and 13:35-6A.4(b)1, a person may be declared dead where a doctor has only a reasonable basis to suspect brain death. Brain death can be declared, the commenter believes, in cases where a doctor believes that "it is inevitable that brain death will ultimately occur." The commenter also expressed concern that all the clinical criteria that are indicative of brain death, as set forth in the new rules, are not required to be met before a diagnosis of brain death is made.

RESPONSE: The commenter is incorrect in his assessment of the proposed new rules. A brain death declaration under proposed new rule N.J.A.C. 13:35-6A.4 requires, at the onset, that the examining physician have a reasonable basis to suspect brain death. The examining physician must be satisfied that the etiology of the patient's injury is sufficient to cause brain death and that, in his or her professional judgment, the patient's injury is irreversible. The rule

requires the physician to determine whether any complicating medical conditions exist that would confound a clinical assessment of brain death. Once this assessment has been made, the examining physician must then perform the clinical examination of the patient as set forth in the rule. All of the clinical findings set forth in the rule, if present in the patient, are deemed indicative of brain death. The examining physician must then confirm this brain death diagnosis through the use of the confirmatory testing set forth in the rule. In those cases where confirmatory testing is not possible because of the extent of the patient's injuries, the rule requires the examining physician to perform a repeat clinical examination following the passage of a medically-recommended period of observation. It is only following the completion of this process that a physician may declare a patient brain dead.

21. COMMENT: One commenter recommended that the proposed new rules be amended to clarify that pediatric neurologists and pediatric neurosurgeons are specifically included as appropriate examining physicians for patients between the ages of 12 months and 18 years of age.

RESPONSE: Proposed new rule N.J.A.C. 13:35-6A.3(a)3 expressly authorizes neurologists and neurosurgeons, as well as critical care specialists, trauma surgeons and other physicians granted privileges to declare brain death, to perform brain death assessments on patients older than 12 months of age. The standards articulated in the proposed new rules are consistent with current clinical practice standards. The Board notes that pediatric neurologists and pediatric neurosurgeons may declare brain death on individuals between the ages of 12 months and 18 years of age if granted hospital privileges to make such determinations. The Board, therefore, declines to change the proposed new rule as suggested by the commenter.

22. COMMENT: Several commenters expressed support for the proposed new rules, noting that corroboration is still required, whether it be through a second examination or a confirmatory test. The commenters noted that this requirement for corroboration negates the need for a second physician examination. The commenters noted, however, that the proposed new rules would not prohibit a health care institution from requiring a second physician to examine the patient in order for a brain death declaration to be made, if the institution so chooses.

RESPONSE: The Board thanks the commenters for their support of the proposed new rules. As noted previously, the Board does not directly regulate health care institutions and the proposed new rules would not prohibit a health care institution from requiring a second physician to examine the patient prior to permitting a brain death declaration to be made.

23. COMMENT: Several commenters expressed support for the clarification in the proposed new rules that a brain death examination may be initiated if CNS depressants are present, provided they are at or below therapeutic ranges. The commenters believe this clarification will decrease unnecessary delays in performing brain death examinations.

RESPONSE: The Board thanks the commenters for their support of the proposed new rules.

24. COMMENT: Several commenters expressed support for the requirement in the proposed new rules that each initial diagnosis of brain death be confirmed by an objective confirmatory test, or if such testing is not available, a second clinical examination conducted after an appropriate waiting period. The commenters noted that this procedure will ensure the medical certainty of brain death determinations to the highest degree possible.

RESPONSE: The Board thanks the commenters for their support of the proposed new rules.

25. COMMENT: One commenter expressed concern regarding the use of angiography and other blood flow tests to confirm a brain death diagnosis, noting that such tests do not give unequivocal evidence of cessation of all brain function, as is required by New Jersey law.

RESPONSE: The Board disagrees with the commenter's assertions concerning the appropriateness of using the confirmatory tests set forth in the proposed new rules. The standards articulated in the proposed new rules, including the referenced confirmatory tests, are consistent with current clinical practice standards.

26. COMMENT: Two commenters objected to the proposed new rules because they believe the rules require only one brain function to be tested, that is, the brain's control of the in and out motion of the chest, measured through the performance of an apnea test. All other clinical tests to be performed under the proposed new rules concern observance of reflexes, and not functions of the brain. The commenters note that the proposed new rules ignore other functions of the brain, including control of blood pressure, temperature, hormone levels, salt levels, sugar levels, and heart rate. Some commenters noted that comatose organ donors experience a rise in blood pressure and heart rate during the organ removal process. Such brain functions would not be observable if the patient's entire brain could not function. The law in New Jersey requires the cessation of all brain functions for a determination of brain death. Therefore, even if all brain reflexes of a patient have ceased, but the patient has at least one brain function, the patient should not be considered brain dead.

RESPONSE: The confirmatory tests set forth in the new rules, which are interpreted by independent physicians, are reliable, objective indicators of cerebral blood flow. In the absence of cerebral blood flow, there cannot be any brain function.

27. COMMENT: Two commenters noted that most physicians believe use of the apnea test to be unethical and that this test greatly impairs the possible recovery of brain injured patients, possibly even causing death for some patients. The commenters noted that the apnea test is done without the knowledge or consent of the patient's family and that the confirmatory testing required under the proposed new rules is performed after the apnea test. As a result, the confirmatory tests may reflect the dangerous effects of the apnea test.

RESPONSE: The apnea test is designed to be aborted at any sign of cardiac arrhythmia and does not pose a risk for further brain damage to the patient when it is properly performed. The Board notes that the objective tests set forth in the new rules, performed in conjunction with the apnea test, are reliable indicators of cerebral blood flow.

28. COMMENT: One commenter requested that proposed new rule N.J.A.C. 13:35-6A.4(b)4i be amended to require the confirmatory diagnosis of brain death include a finding that "intracranial pressures, as determined by a functioning appropriate intracranial pressure monitoring device, are greater than systolic blood pressure for a period of three hours."

RESPONSE: The Board declines to amend the rule as suggested by the commenter because the objective tests set forth in the rule that are used to determine cerebral blood flow are more reliable and obviate the need to use intracranial pressure monitors.

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.