STATE OF NEW JERSEY

NEW JERSEY LAW REVISION COMMISSION

Final Report

Relating to

New Jersey Declaration of Death Act

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INTRODUCTION

In the summer of 1980, the National Conference of Commissioners on Uniform State Laws ("NCCUSL") (now known as the Uniform Law Commission) approved and recommended for enactment in all states the *Uniform Determination of Death Act* ("UDDA"). Over the years, thirty six states, along with the District of Columbia and the U.S. Virgin Islands, have adopted the UDDA. Sources note that all 50 states and the District of Columbia recognize whole brain death as the governing definition of death.[1]

In the course of recent consideration of this uniform law, the Commission learned that New Jersey had already enacted its own determination of death act in 1991, entitled the *New Jersey Declaration of Death Act* ("NJDDA"). Like the UDDA, the NJDDA provides that brain death, as well as the irreversible lack of circulatory and respiratory functions, are determining factors for death declaration. Unlike the UDDA, however, New Jersey's statute provides, among other things, for the: regulation of physicians who make death determinations; protection of these physicians and of other healthcare providers from criminal or civil liability; recognition of religious exceptions to certain death determinations; and the regulation of medical standards for the determination of death.

The Commission recently was asked to consider a proposed change to New Jersey law by representatives of the New Jersey medical community who use the NJDDA in the course of their practice in declaring neurological death. That change would make the NJDDA more consistent with the UDDA by eliminating New Jersey requirements for regulation of the medical standards for death determination.

The Uniform Determination of Death Act

The UDDA provides "comprehensive bases for determining death in all situations" and is based on evolving statutory language that began with a 1970 Kansas statute. According to NCCUSL, the uniform law was influenced by a Model Definition of Death Act drafted by the Law and Medicine Committee of the American Bar Association ("ABA") in 1975, and a Model Determination of Death statute created by the American Medical Association ("AMA") in 1979. Other sources, including the United States Government (see the website http://bioethics.gov/cms/history) state that the UDDA was proposed as a result of the report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research in 1981, but the date of the UDDA promulgation makes this assertion unclear.

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[1] See Melissa Goldstein, J.D., Rapid Public Health Policy Response Project of the GW School of Public Health and Health Services, The George Washington University Medical Center, *Diagnosing Death: Why does it remain "well settled and persistently unresolved?"* (December 2008); Paul W. Armstrong & Robert S. Olick, *Innovative Legislative Initiatives: The New Jersey Declaration of Death and Advance Directives for Health Care Acts*, 16 Seton Hall Legis. J. 177 (1992). See also *Controversies in the Determination of Death*, A White Paper by the President's Council on Bioethics, December 2008, for a thorough discussion of the definition of death.

What is clear is that in the 1970s and early 1980s, the standards for determining death became the subject of lively debate for two reasons: first, because of the advancement of technology which could prolong a person's respiratory and circulatory functions despite the permanent or irreversible cessation of that person's neurological functions; and second, because of the advent of organ donation for transplant.[2]

Under common law, a person was deemed "dead" upon cessation of all vital functions, traditionally demonstrated by an absence of spontaneous respiratory and cardiac functions. According to the UDDA Prefatory Comment, the uniform law addresses the potential disparity between the common law standard of death and the definition of death that has evolved as a result of modern advances in healthcare.

The UDDA provides that[3]:

> An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.

The Prefatory Note states that the "overwhelming majority of cases will continue to be determined according to part (1). When artificial means of support preclude a determination under part (1), the Act recognizes that death can be determined by the alternative procedures." The UDDA purposely does not discuss the medical criteria for determining the death, the time of death, or the liability of persons who make death determinations.[4]

Analysis of New Jersey Law

New Jersey's own law on death determination has evolved over the past thirty-five years.

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[2]See James L. Bermat, *Are Donors After Circulatory Death Really Dead, and Does it Matter? Yes and Yes*, CHEST, Official Publication of the American College of Chest Physicians, 138(1):13-16 (2010). (author states that the UDDA was based on a 1981 Presidential Commission); Steven Laureys, *Death, Unconsciousness and the Brain*, Nature Reviews/Neuroscience, Vol. 6, p. 901, Box 1 (November 2005) ("Although the neurocentric definition of death originated before the advent of multiorgan transplantation . . . the demand for donors has been a major driving factor in the popularization and legalization of brain death."); Stuart J. Youngner and Robert M. Arnold, *Philosophical Debates About the Definition of Death: Who Cares?*, Journal of Medicine and Philosophy, Vol. 26, No. 5, pp. 527-537, 533 (2001).

[3] The act also contains the customary uniform law language which states that the act is to be applied and construed to make uniform the law with respect to the subject of the act among the states enacting it.

[4] As for time of death, the Prefatory Comment states that in those instances where time of death affects legal rights, although the act gives the bases for determining death, time of death is a fact to be determined in each case, and may be resolved, if necessary, upon expert testimony in a court proceeding. There is some controversy on the topic of time of death because when death occurs is directly tied to the definition of "irreversible" for purposes of applying the legal standard. See Stuart J. Youngner and Robert M. Arnold, *Philosophical Debates About the Definitions of Death: Who Cares?*, Journal of Medicine and Philosophy, Vol. 26, No. 5, (2001) at p. 531 ("All laws, clinical criteria and philosophic theories about death insist that the essential functions (whatever they are) must be *irreversibly* lost for death to be declared. But nowhere is irreversible defined.") As for the liability of persons who make death determinations, the Prefatory Comment summarily states that "[t]here is no need to deal with these issues in the text of this Act".

The definition of death was tangentially discussed in *In re Quinlan*, 70 N.J. 10 *cert. den. sub nom. Garger v. New Jersey*, 429 *U.S.* 922 (1976), the seminal New Jersey Supreme Court case involving whether to grant a father's request to discontinue extraordinary medical procedures sustaining the life of his 22-year old, comatose daughter, Karen Ann Quinlan. Having determined that Karen was *not* "brain dead"-- although she had lost all of her cognitive function -- the Court discussed the changing definition of death with the advance of medical technology, stating:

> The determination of the fact and time of death in past years of medical science was keyed to the action of the heart and blood circulation, in turn dependent upon pulmonary activity, and hence cessation of these functions spelled out the reality of death. Developments in medical technology have obfuscated the use of the traditional definition of death.

The Court referred, with approval, to the 1968 report of the Ad Hoc Committee of the Harvard Medical School in describing those standards for determining brain death, including "absence of response to pain or other stimuli, pupilary reflexes, corneal, pharyngeal and other reflexes, blood pressure, spontaneous respiration, as well as 'flat' or isoelectric electro-encephalograms and the like, with all tests repeated 'at least 24 hours later with no change'". The Court further noted that:

> In such circumstances, where all of such criteria have been met as showing 'brain death', the [Ad Hoc] Committee recommends with regard to the respirator [citing from *A Definition of Irreversible Coma*, 205 J.A.M.A. 337-339 (1968)]: 'The patient's condition can be determined only by a physician. When the patient is hopelessly damaged as defined above, the family and all colleagues who have participated in major decisions concerning the patient, and all nurses involved, should be so informed. Death is to be declared and then the respirator turned off. . .'(pp. 18-19; p. 28).

In 1988, however, in *Strachan v. J.F.K. Memorial Hospital*, 109 N.J. 523, 533 (1988), the New Jersey Supreme Court directly addressed the issue of how to define death. Twenty-year old Jeffrey Strachan had shot himself in the head in an apparent suicide attempt, was declared brain dead by an emergency room physician, and then placed on a respirator. That evening, a neurosurgeon at the hospital and one of the attending physicians confirmed brain death and informed the parents that nothing could be done to restore brain function. Because the hospital was actively involved in an organ transplant program, the neurosurgeon asked the family if they would be willing to donate any of their son's organs.

Uncertain of what to do, the parents asked if they could consider the request overnight, during which time their son was continued on life support. The next morning, the parents informed the doctors that they did not wish to donate their son's organs and wanted his life support to be terminated. However, the hospital had no established protocol for responding to such a request. For the next three days, life support was continued while the hospital staff passed off the decision of how to proceed from one person to the next.[5] Only after obtaining the parents' written consent and the results of the

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[5] First the parents were told by a nurse that the hospital administrator needed to order the release of their son's body. Then another neurosurgeon examined their son, confirming, once again, that he was brain dead.

EEGs (which again confirmed brain death), did yet another neurosurgeon make an entry on the third day after Strachan shot himself, indicating: "patient officially brain dead and by hospital regulations we may discontinue respiration c [with] family's permission." The respirator was then disconnected, the death certificate signed, and Jeffrey Strachan's body given to his family for burial.

One of the issues raised in the parents' lawsuit against the hospital administrator and the hospital[6], was whether the hospital acted reasonably in honoring the family's request for their son's body.[7] Having determined that the plaintiffs' right of recovery depended on "when Jeffrey's death occurred," (see p. 531), the Court concluded first that the evidence was overwhelming that Strachan was deemed brain dead considerably earlier than when he was pronounced dead and the death certificate was signed; and second, that "the question comes down to whether our legal definition of death should include brain death". (p. 532).

The Court acknowledged that traditionally death had been defined as the "irreversible cessation of cardiopulmonary function" (citing to *In re Quinlan*, 70 N.J. 10, 26-27, *cert. den. sub nom. Garger v. New Jersey*, 429 U.S. 922 (1976)), but also recognized that this definition had been challenged over time as not reflecting advances in medical technology. Once the brain is dead, however, "no technology exists to restore its function." The court explained the dilemma faced as a result of modern medical advances, as follows:

> For organs to be preserved for transplant, the donor's cardiopulmonary system must continue functioning until the organs can be removed. Under the traditional definition of death, such a donor would be considered as still alive because the heart continues to beat and the lungs continue to perform the respiratory function. In a very real sense, then, a break from the traditional definition of death is a necessary condition to the existence of transplant programs, for otherwise the organ-removal process might be deemed to have 'killed' the donor. (p. 532).

The Court determined that the UDDA provided an appropriate legal definition of death, further supported by the earlier reference in *Quinlan* to "brain death" as an "accepted and prevailing medical standard for death". As a result, the Court found that

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The nursing director and the assistant to the hospital administrator contacted the hospital administrator who consulted with the hospital's general counsel. Counsel then directed that the hospital obtain a signed written consent of the parents for removal of the respirator (which released the hospital and the attending physician from all liability with regard to discontinuance of the life support systems); he further recommended that the hospital conduct two additional EEGs, twenty-four hours apart, "to get a clear understanding of what the boy's condition is", and perhaps seek a court order as an alternative to a medical decision to turn off the respirator. Counsel even suggested the convening of a Prognosis Committee to assist the physicians with their decision to pronounce the patient dead.

[6] The claims against the physicians and the transplant program and its coordinator were dismissed prior to trial.

[7] The Court upheld the Appellate Division's conclusion that the family had a quasi-property right in the body of their dead son, but disagreed with the conclusion that the son was not legally dead until the respirator had been turned off and the death certificate signed (which occurred nearly three days after the son was first declared dead).

there was ample evidence at trial to support the jury conclusion that defendants negligently had held the body of Jeffrey Strachan so as to prevent his proper burial.

The New Jersey Declaration of Death Act

Since 1991, the NJDDA, N.J.S. 26:6A-1, *et seq.*, has set forth the guidelines for determining death in New Jersey. The NJDDA was originally drafted and proposed, along with the *Advance Directives for Health Care Act*, by the New Jersey Bioethics Commission[8]. Both acts were signed into law by Governor James Florio within a few months of each other.

The Bioethics Commission mandate was to provide "a comprehensive and scholarly examination of the impact of advancing technology on health care decisions" in order to enable government and professionals in the fields of medicine, health care, law and science to better understand the issues, the responsibilities of all concerned and the options available. The Commission was also directed to make recommendations on health policy to the legislature, the Governor, and the citizenry of New Jersey. Comprised of 27 appointed members (including representatives of the executive and legislative branches of state government, of statewide professional and health care associations, and of New Jersey's professional and public communities), the Bioethics Commission, over the course of approximately two years, held six public hearings and more than twenty open meetings on the proposed NJDDA and *Advance Directives for Health Care Act*. Both legislative houses also held extensive, open committee hearings and deliberations on the two bills before they were passed with bipartisan support.

The NJDDA provides that an individual, who has sustained irreversible cessation of all circulatory and respiratory functions, as demonstrated in accordance with currently accepted medical standards, shall be declared dead. It also provides that subject to the standards and procedures established in accordance with the NJDDA, an individual whose circulatory and respiratory functions can be maintained solely by artificial means and who has sustained irreversible cessation of all brain function, including the brain stem, also shall be declared dead. The NJDDA has additional features which distinguish it from the UDDA.

New Jersey's law requires the declaration of death be made by a licensed physician professionally qualified by specialty or expertise. To avoid any potential conflicts of interest, if the individual to be declared dead on the basis of neurological criteria is or may be an organ donor, the physician who declares death may not be the organ transplant surgeon, the attending physician of the organ recipient, or otherwise subject to a potentially significant conflict of interest relating to procedures for organ procurement. When the declaration of death is based on neurological criteria, provision is

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[8] The Bioethics Commission (also called the New Jersey Commission on Legal and Ethical Problems in the Delivery of Health Care) was established in November of 1985 as a permanent legislative commission, although it has since been eliminated by statute because of inactivity. See N.J.S. 52:9Y-1 through 52:9Y-6, inclusive, repealed by P.L. 2007, c. 39, §1.

made for determining the time for death. There is a religious or "conscience" exception – unique to New Jersey – which provides that if the physician has a reason to believe on the basis of information in the individual's available medical records or information provided by the family or others that the individual's personal religious beliefs would be violated by the declaration of death upon the basis of the neurological criteria, then the death of the individual shall be declared, and the time of death fixed, solely upon the basis of cardio-respiratory criteria. New York[9] recognizes a similar exception. The NJDDA protects from criminal or civil liability, or discipline for unprofessional conduct, a licensed health care practitioner, hospital or health care provider who acts in good faith and in accordance with currently accepted medical standards to execute the provisions of the NJDDA and any rules or regulations issued pursuant thereto. Finally, the NJDDA precludes the denial of coverage solely because of personal religious beliefs regarding the application of neurological criteria for declaring death and the impairment of insurance or governmental benefits program because of changes in pre-existing criteria for declaration of death effectuated by the legal recognition of modern neurological criteria.

Although the provisions of the NJDDA have not been altered since the law's original enactment in 1991, rules that have been promulgated pursuant to the NJDDA have been amended or readopted several times since the act was first enacted, most recently in 2007. A committee of the State Board of Medical Examiners was recently convened to consider further amendments.

Current regulations 13:35-6A.1 through 13:35-6A.7 of the New Jersey Administrative Code set forth the requirements for physicians authorized to declare death on the basis of neurological criteria, including the physician's qualifications (which are dependent upon the age of the patient upon whom a declaration of brain death is to be made), the physician protocols for pronouncing brain death, the exemption to accommodate personal religious beliefs, and the protections from physician conflict of interest when there is organ donation.

Concerns about authority to regulate medical standards in the NJDDA

Commenters involved in the declaration of neurological death and organ and tissue sharing have suggested revision of section 26:6A-4 of the NJDDA, specifically the elimination of subsection (b)(2) which gives the Department of Health, jointly with the Board of Medical Examiners, the authority to regulate medical standards to govern declarations of death upon the basis of neurological criteria.[10] These commenters advise that this statutory requirement for the adoption and periodic revision of regulations that

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[9] 10 N.Y. A.D.C. 400.16(e) (2009) ("Each hospital shall establish and implement a written policy regarding determinations of death in accordance with paragraph (a)(2) of this section. Such policy shall include . . . a procedure for the reasonable accommodation of the individual's religious or moral objection to the determination as expressed by the individual, or by the next of kin or other person closest to the individual.").

[10] These commenters are Christina W. Strong, Esq., counsel to the New Jersey Organ and Tissue Sharing Network and legal advisor to an *ad hoc* committee of health care professionals concerned with the laws and policies surrounding the declaration of death by neurological criteria; Dr. John Halperin, a neurologist involved in making death declarations; and William Reitsman, R.N., Director of Clinical Services at the NJ Sharing Network.

dictate the clinical diagnosis of brain death are unusual, unnecessary and, in fact, impede the clinical practice of brain death declaration for the purposes of organ donation.

Section 26:6A-4, in its entirety, provides that:

> a. A declaration of death upon the basis of neurological criteria pursuant to section 3 of this act shall be made by a licensed physician professionally qualified by specialty or expertise, in accordance with currently accepted medical standards and additional requirements, including appropriate confirmatory tests, as are provided pursuant to this act.
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> b. Subject to the provisions of this act, the Department of Health, jointly with the Board of Medical Examiners, shall adopt, and from time to time revise, regulations setting forth (1) requirements, by specialty or expertise, for physicians authorized to declare death upon the basis of neurological criteria; and (2) currently accepted medical standards, including criteria, tests and procedures, to govern declarations of death upon the basis of neurological criteria. The initial regulations shall be issued within 120 days of the enactment of this act.
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> c. If the individual to be declared dead upon the basis of neurological criteria is or may be an organ donor, the physician who makes the declaration that death has occurred shall not be the organ transplant surgeon, the attending physician of the organ recipient, nor otherwise an individual subject to a potentially significant conflict of interest relating to procedures for organ procurement.
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> d. If death is to be declared upon the basis of neurological criteria, the time of death shall be upon the conclusion of definitive clinical examinations and any confirmation necessary to determine the irreversible cessation of all functions of the entire brain, including the brain stem.
> L.1991,c.90,s.4.

The commenters contend that although such regulations may have been appropriate in 1991 when the determination of brain death was not part of standard medical training, now, more than twenty years later, "the requirement that medical decision-making be dictated by an administrative body is at best anachronistic and singular, and at worst an impediment to clinical practice and medical judgment." See September 9, 2012 letter from Christina W. Strong, Esq. to John Cannel, (then) Executive Director, New Jersey Law Revision Commission.

The regulations promulgated pursuant to the NJDDA have been amended or readopted several times at the request of physicians, particularly neurologists, neurosurgeons and trauma care physicians. According to Ms. Strong, the process for amending these regulations is time consuming because of the requirement for public comment, the complexity of the subject matter area, and the competing interests of the regulatory bodies involved, i.e., the Department of Health and the State Board of Medical Examiners. The process for the last substantive amendment, according to Ms. Strong, took three years and "culminated in a regulatory amendment which contained a typographical error of key import, which has not been corrected to this day." She concludes that "[e]ven with the focused and good faith response of executive agencies such as the Board of Medical Examiners and the Department of Health, the regulatory process is not the place to prescribe clinical practice. Yet, this is what the statute seemingly requires."

The commenters also argue that because of the application of out-of-date New Jersey regulations that have not kept pace with clinical neurological practices, a person who is determined to be clinically dead by current medical standards may not be deemed "legally" dead in accordance with New Jersey law. This "regulatory practice lag" results in emotional and physical harm to the families of brain dead individuals as well as the possible recipients of their donated organs.

Dr. John Halperin, a neurologist, member of the American Academy of Neurology, and part of a group that rewrote the brain death guidelines for New York State, gave an example of an inherent inconsistency in the New Jersey regulations. Regulation 13:35-6A.4, on the *Standards for declarations of brain death*, sets forth as one of many "complicating medical conditions that may confound the clinical assessment of brain death" the condition of severe hypothermia, defined as a body temperature in adults of 92 degrees Fahrenheit or less. At the same time, the regulation also requires that an apnea test be performed in order to confirm death. Yet this test, as appropriately performed in practice, requires a body temperature of 97 degrees Fahrenheit. Dr. Halperin said there are a handful of similar attempts to interpret the medical literature that make no sense in practice.

Mr. Bill Reitsma, the Director of Clinical Services for the NJ Sharing Network, and a registered nurse, described the dilemma for a family who knows that their loved one is gone but must wait for the completion of a second confirmatory test (also required by state regulations) before the death is pronounced. He explained that during his 33 years of experience, he has not encountered a situation where after the initial clinical examination (properly performed) and the apnea test confirmation of a person's death, a *second* confirmatory examination divulged anything other than that the person was dead.

When asked what standards should be used by New Jersey physicians to make determinations of brain death, these commenters suggest the standards as most recently established by the American Academy of Neurology and seek the addition of language to subsection (a) of N.J.S. 26:6A-4 that states the following (see underscoring below):

> A declaration of death upon the basis of neurological criteria pursuant to section 3 of his act shall be made by a licensed physician professionally qualified by specialty or expertise, <u>based upon the physician's medical judgment</u> and in accordance with currently accepted medical standards <u>that are based upon nationally recognized sources of practice guidelines, including, but not limited to, those adopted by the American Academy of Neurology</u>.

In sum, the commenters have asked this Commission to recommend to the Legislature the elimination of subsection (b) (2) of N.J.S. 26:6A-4 and the corresponding revision of subsection (a) of N.J.S. 26:6A-4. (All proposed changes to the current statute are set forth and discussed later in this report.)

Current views on death determination standards

In the November 2012 issue of the *American Medical Association Journal of Ethics*, Dr. James F. Bartscher, MD and Dr. Panayiotis N. Varelas, MD, PhD, write that recent data show brain death policies are still "remarkably heterogeneous, even amongst some of the nation's most vaunted medication institutions". They state that "urgent attention must be given to consistent application and regular review of our adopted medical and legal standards [for brain death]" for many reasons, including "ensuring accuracy in such an irreversible declaration, securing equitable treatment under the law, and allaying public suspicion and misunderstanding about BD determination." *See* "Determining Brain Death – No Room for Error", Volume 12, Number 11:879-884, p. 879.

In this same article, the authors query whether the "accepted medical standards" to which the UDDA refers truly exist. They ask whether a physician should first consult local hospital policy and, if so, what should occur if that policy conflicts with national guidelines or if no such policy even exists. Arguing for adoption of a national standard "regarding the minimum procedural requirements necessary for a determination of death by neurological criteria," they urge the regular meetings of a "national consensus panel representing expert opinion and knowledge of the published literature" to regularly review and update the national standards as required by evolving medical science and technology. They conclude that the AAN guidelines need more research. (The AAN's most recent "practice guideline" for managing brain death in adult patients was issued in June of 2010. Prior to that, the last guidelines on the subject of brain death were issued in 1995.)

A similar view is expressed in a December 2007 article printed in *Neurology*, wherein the authors evaluated the differences in brain death guidelines in major United States hospitals to determine the existence of any variation from the AAN guidelines.[11] The authors explained that according to the UDDA:

> physicians are required to determine death in accordance with accepted medical standards, which can be national, regional, or local. This allows for broad leeway for physicians practicing at different institutions to create and abide by protocols for brain death determination that may be widely disparate. The determination is often at the discretion of the individual physician, which is fundamentally different from other countries that specify exactly what to test. Despite the fact that the American Academy of Neurology (AAN) published practice parameters for the determination of brain death in adults in 1995, it has been noted that there is still a great variety of practice in US hospitals. (p. 285)

Concerned with the impact on the delivery of care as well as possible confusion about the general understanding of the brain death concept, they found major differences in brain death guidelines among the leading neurologic hospitals in the United States.

[11] *See*, David M. Greer, MD, MA; Panayiotis N. Varelas, MD, Phd; Shamael Haque, DO, MPH; and Eelco F.M. Wijdicks, MD, PhD, "Variability of Brain Death Determination Guidelines in Leading US Neurologic Institutions", *Neurology* 70, January 22, 2008, published ahead of print on December 12, 2007 at www.neurology.org.

They also found that adherence to the AAN guidelines was "variable."[12] and recommended updating of the AAN guidelines (which has since occurred) and the implementation of standards by which institutions are held more accountable for adherence to national guidelines. No such national guidelines or implementation protocol have yet to be put in place.

A small sampling of state guidelines further illustrates the lack of apparent uniformity for brain death determination. Some states, like New York and Texas, do follow the AAN guidelines though there is no provision for this in their statutes. Others, like New Jersey, do not. Virginia, for example, deems a person medically and legally dead if in the opinion of a physician duly licensed and a specialist in the field of neurology, neurosurgery, electroencephalography or critical care medicine, and when based on the ordinary standards of medical practice, determines an absence of brain stem reflexes, spontaneous brain functions and spontaneous respiratory functions, a second physician concurs, and further attempts at resuscitation or continued supportive maintenance would not be successful in restoring these reflexes and functions. Connecticut, Michigan, Ohio and Pennsylvania (along with many states) rely on "accepted medical standards" but do not describe or identify these standards.

Although, in practice, many of these states do adhere to the AAN guidelines, there are no statutory requirements that compel such adherence. As already discussed, hospitals also create their own guidelines, relying on the AAN guidelines, the practice of other hospitals, and the parameters set forth by medical commissions and scholars.

At the same time, this Commission has been advised by representatives of the New Jersey Hospital Association[13] that New Jersey regulations for brain death standards do lag behind the clinical practice. They state that the promulgation of rules dictating clinical practice is counterproductive as they can confuse physicians and delay brain death determinations. These representatives inform the Commission that elimination of the regulations would give hospitals and physicians more flexibility and less fear of applying common sense when making death determinations. And because the physicians

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[12] Although there is nearly uniform acceptance of brain death, variability of the guidelines applied across five categories: (1) guideline performance, where they found a "surprisingly low rate of involvement of neurologists or neurosurgeons in the determination" and the requirement that an attending physician be involved in the determination "conspicuously uncommon"; (2) preclinical testing, where they found that the cause of brain death was not stipulated in a large number of guidelines; (3) clinical examination, where they found the highest degree of (but not unanimous) consistency with the AAN guidelines, most guidelines specifically mentioning aspects of the coma and brainstem examinations; (4) apnea testing, where they found variation in temperature, the proper baseline, and technique for performing the test; and (5) ancillary testing, where specifics for performing such testing were frequently absent.

[13] These representatives are Sarah Lechner, Esq., General Counsel to the New Jersey Hospital Association; Aline Holmes, R.N. and Senior Vice President, Clinical Affairs, New Jersey Hospital Association; and Greg Rokosz, DO., J.D., Chair for the Physicians Executive Constituency Group of the New Jersey Hospital Association and Senior Vice President for Medical and Academic Affairs at St. Barnabas Hospital. Although not a neurologist, Dr. Rokosz primarily is an emergency room physician and familiar with end-of-life issues. Dr. Rokosz also was a member of the State Board of Medical Examiners from 1994 to 2005.

who are permitted to make these determinations are specialists, regulated by the State and required to adhere to the most current standards for their specialties, any resulting harm is not likely.

When asked about the AAN guidelines, the New Jersey Hospital Association representatives advise that these guidelines are the only institutional standards currently available, to which hospitals should be able to adhere.[14] When asked what would happen if the regulations for brain death standards were eliminated, these representatives state that nothing dramatic would change; hospitals would rely upon the AAN guidelines, would examine the medical literature, and would look at what other states were doing, as they do now.

During the time this final report was being prepared, the revised statutory language proposed by Christina Strong, Esq. and submitted to this Commission, was adopted in a legislative bill first introduced on December 10, 2012 by Assemblyman Herb Conaway, Jr. as bill A3586. Bill A3586 was referred to the Assembly Health and Senior Services Committee and a Committee hearing took place on Monday, January 14, 2013, at which time amendments to the bill were approved and released. These amendments, drafted in consultation with Ms. Strong and Commission Staff, will be discussed below in the Post-Hearing Note.

At the request of Assemblyman Conaway's Chief of Staff, a draft of this report was provided to Assemblyman Conaway prior to the hearing. However, because the Commission (at that time) had not yet considered the draft report, the Commission emphasized the following: (1) it supported removal of the statutory authority of the Board of Medical Examiners and the Department of Health to regulate brain death standards; (2) it supported revision of the statute that had the support of the medical community and did not refer to standards that may, in time, become outdated or obsolete; but (3) it had not yet considered the specific statutory language recommended in the draft of this report as it would not be doing so until its January 18th meeting.

Soon before the hearing on A3586, Commission Staff also received a letter from William V. Roeder, Executive Director, New Jersey State Board of Medical Examiners, in response to Staff's request for a public statement regarding the Board's position on possible statutory elimination of the Board's authority to regulate the criteria for declarations of brain death. The January 10th letter states that during its public session on January 9, 2013, the Board discussed this issue and other issues regarding the AAN standards and the Board unanimously decided that:

> it did not perceive a continuing need for the Board to be legislatively required to promulgate regulations defining the criteria for brain death, and the Board

[14] When asked what he thought of the argument that some hospitals could not comply with the AAN standards because they lacked the technology to do so, Dr. Rokosz said that he did not believe this was an issue because if a hospital did not have the technology to perform a confirmatory test -- for example, a brain flow study -- then the hospital should get the technology to do it. Otherwise, the hospital should not be declaring brain death.

therefore does not oppose the legislative proposal to divest the Board from continuing to have that relationship.

The Board further declined to take a position supporting or opposing the inclusion of AAN guidelines in the statutory revision, noting that it had not had an opportunity, through Committee, to study the changes that the AAN had made to its guidelines in 2010. The Board did take the general position, however, that any established criteria "must include adequate and sufficient safeguards to ensure that a declaration of brain death could not be made on a patient who is not in fact brain dead."

A copy of the Board's letter was provided to Assemblyman Conaway and to the Assembly Committee at the time of the hearing.

CONCLUSION

Recognizing that modification to current subsections (a) and (b) (2) of N.J.S. 26:6A-4 is appropriate, the Commission makes recommendations with regard to both subsections as set forth below. Several changes to A3586, however, are recommended for the reasons discussed.

The Commission is persuaded by the information obtained from commenters and the New Jersey Hospital Association that regulations setting forth medical standards to govern declarations of death by neurological criteria do not and cannot keep up with the clinical practice. These regulations may even be harmful in that they may cause delays in brain death determination and lead physicians not to rely upon their own medical judgment. The Commission is persuaded further by the State Board of Medical Examiners' own pronouncement that it does not perceive the continuing need to be required by statute to regulate the standards for declarations of death based upon neurological criteria. Thus, the Commission recommends revision of N.J.S. 26:6A-4 (b) (2) to eliminate from current law the authority of the State Board of Medical Examiners and the Department of Health to regulate brain death standards. However, as will be discussed below, the Commission cannot also recommend the additional language first proposed by commenters (and contained in A3586 prior to its amendment) to qualify current subsection (a) and the last sentence of proposed subsection (b).

Subsection 26:6A-4 (b) (2):

Under current law, the State Board of Medical Examiners and the Department of Health (now the Department of Health and Senior Services) have two types of regulatory authority: (1) regulation of the physicians who declare brain death and (2) regulation of the brain death standards. As already discussed, the Commission agrees that the second type of regulatory authority is no longer necessary and may be counterproductive. Thus, the Commission recommends the removal from the statute of the language that states that the Department of Health and the State Board of Medical Examiners shall adopt and from time to time revise regulations setting forth "currently accepted medical standards,

including criteria, tests and procedures, to govern declarations of death upon the basis of neurological criteria."

However, the initial draft of A3586 suggested adding language to the end of subsection b. that would qualify the first type of regulatory authority given to the Department of Health and the State Board of Medical Examiners. The proposed language would provide that regulations for physicians "not require the use of any specific criteria, test, or procedure in the determination of death by neurological criteria", when there is no such requirement in current law.[15] This proposed language (again prior to the amendment to the bill) is confusing to the Commission and may create doubt about the purpose and intent of the revision of that subsection. The language has since been amended for the purpose of emphasizing that regulatory authority should not be used to dictate that physicians use any specific tests or procedures when declaring death. The Commission acknowledges the purpose of the amendment but does not change its original recommendation.

Subsection 26:6A-4 (a):

The Commission also cannot recommend adding language to subsection (a) that ties accepted medical standards to "nationally recognized sources of practice guidelines, including, but not limited to, those adopted by the American Academy of Neurology."

The AAN guidelines, though arguably the guidelines upon which most hospitals and physicians rely, are not uniformly accepted in the national (or even international) medical community. In addition, no other state brain death statute specifically references the AAN guidelines (or any other particular guidelines). There also appear to be no other "nationally recognized sources of practice guidelines" to guide physicians and hospitals. To the contrary, many medical professionals and scholars decry the lack of national guidelines.

The alternative to the proposed language, though not ideal, is to adopt the UDDA approach which simply requires physicians and hospitals to rely upon "accepted medical standards", or equivalent language. This is the current language used in subsection (a) of the New Jersey statute and is consistent with the approach of other states. From a review of state statutes, the links for which are compiled by the Association of Organ Procurement Organizations (AOPO), current as of 2011, about 31 states reference "in accordance with accepted medical standards" in their statutes, adopting this precise UDDA language. Another six states reference "according to ordinary standards of medical practice" and an additional three states reference "according to usual and customary standards of medical practice." Idaho references in its statute the following language: "in accordance with accepted medical standards which mean the usual and customary procedures of the community in which the determination of death is made." Florida refers to "currently accepted reasonable medical standards."

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[15]Current regulations require the physician authorized to declare death based upon neurological criteria to be plenary licensed and to hold certain qualifications dependent upon the age of the patient for whom the declaration of brain death will be made. See 13:35-6A.3.

The proposed additional language -- that brain death declaration also should be made "based upon the physician's medical judgment" -- does have value and will at least reaffirm what is already understood to be axiomatic for brain death declaration in New Jersey. Since physicians must already adhere to the training standards of their own medical specialties, this additional language hopefully will bolster physician confidence to rely more freely upon training and experience when making brain death determinations. However, the Commission recommends the addition of the qualifier "best" before the terms "medical judgment" to give greater authority to the provision and make it more consistent with other statutory language.

Accordingly, the Commission has modified the language of A3586, and made additions for consistency with other statutes, as follows (Commission changes appear in bold; in the official bill draft proposed deletions from the current statute appear in brackets ([ ]) and proposed additions are underscored; the Commission proposed deletions appear as strikethroughs):

1. Section 4 of P.L.1991, c.90 (C.26:6A-4) is amended to read as follows:

4. a. A declaration of death upon the basis of neurological criteria pursuant to section 3 of this act shall be made by a licensed physician professionally qualified by specialty or expertise, based upon **the exercise of** the physician's **best** medical judgment and in accordance with currently accepted medical standards ~~**[and additional requirements, including appropriate confirmatory tests, as are provided pursuant to this act]**~~ ~~**that are based upon nationally recognized sources of practice guidelines, including, but not limited to, those adopted by the American Academy of Neurology**~~**.**
b. Subject to the provisions of this act, the Department of Health **and Senior Services**, jointly with the State Board of Medical Examiners, shall adopt, and from time to time revise, regulations setting forth ~~[(1)]~~ requirements, by specialty or expertise, for physicians authorized to declare death upon the basis of neurological criteria~~**[; and (2) currently accepted medical standards, including criteria, tests and procedures, to govern declarations of death upon the basis of neurological criteria]. The [initial] regulations shall [be issued within 120 days of the enactment of this act]**~~ ~~**not require the use of any specific criteria, test, or procedure in the determination of death by neurological criteria**~~**.**
c. If the individual to be declared dead upon the basis of neurological criteria is or may be an organ donor, the physician who makes the declaration that death has occurred shall not be the organ transplant surgeon, the attending physician of the organ recipient, nor otherwise an individual subject to a potentially significant conflict of interest relating to procedures for organ procurement.
d. If death is to be declared upon the basis of neurological criteria, the time of death shall be upon the conclusion of definitive clinical examinations and any confirmation necessary to determine the irreversible cessation of all functions of the entire brain, including the brain stem.
(cf: P.L.1991, c.90, s.4)

2. This act shall take effect on the first day of the third month next following the date of enactment, but the Department of Health, jointly with the State Board of Medical

Examiners, may take such anticipatory administrative action in advance thereof as shall be necessary for the implementation of this act.

As already discussed, the Commission does not recommend inclusion of the proposed additional sentence at the end of subsection (1) (b) that limits the requirements for physicians who declare death. That limitation is considered unnecessary and more likely to confuse than clarify the meaning of the overall provision. However, should the Legislature deem it appropriate to amend subsection b. and include the additional language noted in the last sentence, the Commission recommends that the language be made consistent with the remainder of the statute as follows (Commission changes appear in bold):

> b. Subject to the provisions of this act, the Department of Health **and Senior Services**, jointly with the State Board of Medical Examiners, shall adopt, and from time to time revise, regulations setting forth ~~[(1)]~~ requirements, by specialty or expertise, for physicians authorized to declare death upon the basis of neurological criteria~~[; and (2) currently accepted medical standards, including criteria, tests and procedures, to govern declarations of death upon the basis of neurological criteria].~~ The ~~[initial]~~ regulations shall ~~[be issued within 120 days of the enactment of this act]~~ not require the use of any specific criteria, test, or procedure in the **~~determination~~ declaration** of death **~~by~~ upon the basis of** neurological criteria**.**

POST- HEARING NOTE

The amendments to A3586 that were approved in Assembly Committee adopted the changes to subsection (a) of 26:6A-4, suggested by this Commission in this report. The amendments to A3586 that were approved in Assembly Committee did not adopt the preferred changes suggested by this Commission but did adopt the alternative language provided by this Commission with regard to the last sentence of subsection (b) (2) (as noted in this report).