ORGAN DONATION AFTER CARDIAC DEATH

A LOUISIANA HOSPITAL ETHICS COMMITTEE PERSPECTIVE

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I. INTRODUCTION

Since the performance of the first successful renal transplant procedure in 1954, the story of transplantation medicine has been one of remarkable success. At the end of the twentieth century, the United Network for Organ Sharing reported that more than 200,000 kidney transplants had been done in United States transplant centers. At that time, throughout the United States, there were 891 organ specific transplantation programs in 272 transplant centers, collectively performing thousands of kidney, liver, and heart transplants, and hundreds of lung and kidney-pancreas transplants. The nation’s organ procurement organizations, operating under the framework of the Organ Pro-


2. COMMITTEE ON ORGAN PROCUREMENT AND TRANSPLANTATION POLICY, INSTITUTE OF MEDICINE, ORGAN PROCUREMENT AND TRANSPLANTATION: ASSESSING CURRENT POLICIES AND THE POTENTIAL IMPACT OF THE DHHS FINAL RULE 18, 22, 31 (National Academy Press 1999) [hereinafter INSTITUTE OF MEDICINE, ORGAN PROCUREMENT AND TRANSPLANTATION].
curement and Transplantation Network (OPTN) established by the National Organ Transplant Act of 1984, maintained a waiting list of over 75,000 potential recipients and annually coordinated the transplantation procedures of over 21,000 patients.

In the first decade of the new century, renewed efforts at fostering organ donation and transplantation have included the development of organ donation after cardiac death (DCD) as a means of increasing the supply of donor organs. Current initiatives to increase DCD awareness and utilization include those of accreditation, organ procurement/transplantation, and governmental entities. These initiatives have established new requirements for donor hospitals and transplant center hospitals, and have also increased discussion of the ethical issues raised by organ donation after cardiac death. The Institutional Ethics Committee of the Willis-Knighton Health System recently completed an extensive review of organ donation after cardiac death, culminating in institutional approval of a policy governing the practice of DCD within the health system. This paper details findings developed by our Committee in the completion of that process, and includes discussion of the nature and rationale of organ donation after cardiac death, the statutory basis and regulatory environment pertaining to DCD, and recent initiatives of governmental and non-governmental entities regarding DCD. We also discuss certain principal ethical concerns raised by the practice of


5. Institutional Ethics Committee, Willis-Knighton Health System, Organ Donation After Cardiac Death (DCD) Policy for the Willis-Knighton Health System (2010), [hereinafter the Willis-Knighton Protocol]. (This document is an extensive modification of a template protocol submitted to the Committee by the Louisiana Organ Procurement Agency.) See infra notes 160 & 161.
organ donation after cardiac death and the judgments of our Committee regarding those concerns.

II. What Is Donation After Cardiac Death?

The modern legal construct governing organ donation dates to the promulgation of the first Uniform Anatomical Gift Act (UAGA) by the National Conference of Commissioners on Uniform State Laws (NCCUSL) in 1968. Statutes based on this model law were subsequently adopted in all states, and included provisions regarding persons who may execute an anatomical gift and the manner of executing anatomical gifts. The Act provided that “the gift becomes effective upon the death of the donor” and, although it did not include a definition of death, provided that “the time of death shall be determined by a physician who tends the donor at his death, or, if none, the physician who certifies death.” During this period, death was generally determined by the irreversible cessation of cardiac and respiratory activity.


7. Raymond D. Cotton & Andrew L. Sandler, The Regulation of Organ Procurement and Transplantation in the United States, 7 J. LEGAL MED. 55, 60 (1986). See also Franklin L. Best, Transfers of Bodies and Body Parts Under the Uniform Anatomical Gift Act, 15 REAL PROPERTY PROBATE TRUST J. 806, 806-22 (1980). This article provided a stepwise review of the practical implications of the Act for attorneys of the day, and appended the entire Act, including the prefatory note and comments of the NCCUSL.


9. See Cotton & Sandler, supra note 7, at 61, for a brief discussion of the rationale for omitting a definition of death from the Uniform Anatomical Gift Act.


11. See generally PAUL RAMSEY, On Updating Procedures for Stating that a Man Has Died, THE PATIENT AS PERSON: EXPLORATIONS IN MEDICAL ETHICS 59, 59-112 (Yale Univ. Press 1970) [hereinafter RAMSEY]. Ramsey extensively explored the traditional concept of death as defined by cardiorespiratory manifestations and discussed the tensions that arose when medical advances such as mechanical ventilation and transplantation began to challenge those traditions as the sole determinant of death.
Transplantation generally occurred by utilizing organs taken with consent from living donors or organs urgently retrieved from cadaveric donors after cardiac death had been pronounced. The Advisory Committee of the Human Kidney Transplant Registry reported in 1968 that of 1,741 transplants, 48% were from living related donors, 9% from unrelated living donors, and 43% from cadaveric donors.\(^\text{12}\) A 1967 report of the early kidney transplant experience at the Cleveland Clinic described cadaveric donors:

In general, patients who died suddenly were the best donors. The most suitable cadaver kidneys were from those who died in the Intensive Care Area or in an operating room where close observation was maintained until the time of death. Patients who expired during an open heart operation have provided kidneys comparable to those from living donors, as renal perfusion was maintained by cardiopulmonary bypass with pump oxygenation until recipients could be prepared.\(^\text{13}\)

Thus, at that point in time, cadaveric donors typically were patients who had had an abrupt but monitored in-hospital death by traditional cardiorespiratory criteria, with a rapid organ recovery effort thereafter. This produced significant logistical difficulties in organ procurement. A 1964 discussion elaborated how these difficulties would restrain a cardiac transplant effort:

A set of circumstances would have to exist in which the donor died perhaps from an irreversible noninfective disease of the brain and the recipient was dying of an irremediable coronary lesion such as extensive myocardial infarction. Still more exacting, the patient with irreversible brain disease would have to die at a time immediately prior to the impending death of the prospective recipient.\(^\text{14}\)

However, cases such as the 1963 Newcastle General Hospital case, in which a kidney was removed for transplantation from a patient with a severe traumatic brain injury supported with mechanical respiration, raised controversy as to the pr-

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curement of organs from donors who had not sustained a cardiac death, whether such organ donors were dead, and whether organ procurement caused the death of these donors. The British Medical Journal, in commenting on the Newcastle General Hospital case, provided an early formulation of what later became known as “the dead donor rule” when it advised readers that “to hasten the death of a person whose death (through sickness or previous injury) is already inevitable is homicide in law,” and that “anyone removing organs from an apparently inanimate body (for instance, one retrieved from a serious traffic accident) must first ask himself whether he can positively pronounce the body dead.”
Ultimately, a growing consensus in the medical community regarding a state of neurological death, as codified in the Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, led to an expansion of the tradi-

15. Man Kept Alive as Kidney Donor, THE TIMES (London), July 26, 1963, at 9. The article reported medical testimony in the inquest regarding the death of a 21 year old man who received severe head injuries in a brawl. When the man stopped breathing he was “kept alive for 24 hours on a respiratory machine so that one of his kidneys could be taken for transplanting in another man who was dying of kidney trouble.” Id. After removal of the kidney, the respirator was turned off and no spontaneous breathing or circulation was present. The consultant neurologist testified at the inquest that the patient was dead, prior to removal of the kidney, from brain damage “such that life was impossible.” Id. The Home Office pathologist testified that the patient died from brain damage and that removal of the kidney played “no part in his death.” Id. The jury accepted this testimony and returned a manslaughter verdict against the assailant. Ramsey cited this case as evidence of the “urgent need” to clarify ambiguities in the determination of death. RAMSEY, supra note 11, at 70-72.

16. Moment of Death, BR. MED. J., Aug. 10, 1963, at 394. In more recent years, Youngner et al., declared the dead donor rule to be a fundamental moral requirement governing organ procurement and defined it that “vital organs should only be taken from dead patients, and correlatively, living patients must not be killed by organ retrieval.” Stuart I. Youngner et al., Ethical, Psychosocial, and Public Policy Implications of Procuring Organs From Non-Heart-Beating Cadaver Donors, 269 JAMA 2769, 2771 (1993).

17. Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, A Definition of Irreversible Coma, 205 JAMA 337, 337-340 (1968) [hereinafter the Harvard Report]. The Committee stated that, “An organ, brain or other, that no longer functions and has no possibility of functioning again is for all practical purposes dead.” Id. at 337. The Committee defined the characteristics of irreversible coma and a permanently nonfunctioning brain to include: unreceptivity and unresponsivity, no movements or breathing, no reflexes, and a flat electroencephalogram.
tional definition of death to include brain death criteria. In 1980, the NCCUSL approved the Uniform Determination of Death Act (UDDA), which provided for determination of death by the “irreversible cessation of all functions of the entire brain, including the brain stem” in addition to the traditional common law cardiopulmonary basis for the determination of death. In 1981, The President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research concluded that statutory law should be restated to include a “brain-based standard” to be applied to determine death, in addition to the traditional cardiopulmonary standard, and endorsed the Uniform Determination of Death Act. A recent review of statutory definitions of death found that fourteen states and the District of Columbia have adopted the Uniform Determination of Death Act, eighteen have adopted a modification of the UDDA, fourteen have adopted other statutory provisions defining death, and four have adopted no statute doing so.

Coincident with the acceptance of brain death was the growth of brain dead donors as the predominant source of cada-


19. See generally, PRESIDENT’S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, DEFINING DEATH: A REPORT ON THE MEDICAL, LEGAL, AND ETHICAL ISSUES IN THE DETERMINATION OF DEATH 5-8 (1981) [hereinafter THE PRESIDENT’S COMMISSION REPORT ON DEFINING DEATH] for the conclusions of the report. Regarding a statutory definition of death, the report stated that, “The Commission has concluded that legislatures ought to set the rules for determining human death and that those rules should recognize brain-oriented techniques of establishing death because traditional standards often cannot be employed with patients whose respiration and circulation are artificially maintained.” Id. at 55. The President’s Commission endorsed the Uniform Determination of Death Act on November 7, 1980. Id. at 119.


21. Throughout this paper, the terms “cardiac death” and “brain death” are used to denote death determined by cardiorespiratory criteria and by neurologic criteria, respectively. “Brain dead” refers to the state in which death by neurologic criteria exists. These conditions are all conceived as various manifestations of a singular physiologic state. See discussion infra Part VI.B.
veric organs for transplantation. A 1975 report of the experience with renal transplantation in Louisiana listed causes of death for cadaveric donors to generally include cerebral trauma, cerebral hemorrhage, cerebral thrombosis, brain tumor, drug poisoning, and cerebral anoxia. During this time, the typical cadaveric donor was a patient who had an in-hospital death, usually of neurological cause, with death determined by brain death criteria, who thereby met criteria for withdrawal of life supportive measures. These brain dead donors were sometimes referred to as heartbeating donors, and were distinguished from the older class of cadaveric donors dying from cardiorespiratory causes by description of those donors as non-heartbeating donors. The older practice of retrieval of organs from non-heartbeating donors was largely abandoned, although some centers continued to utilize non-heartbeating donor organs from a carefully selected subset of patients who experienced an expected cardiac death in a monitored environment.

24. See Ralph H. Didlake et al., Utilization and Function of Kidneys Obtained from Nonheartbeating Donors, 38 TRANSPLANTATION 90, 90-91 (1984). The authors defined and utilized the terms “heartbeating” and “nonheartbeating” in a comparison study of the functions of kidneys transplanted from both types of donors.
25. Henri Kreis, Selection of a Donor, in RENAL TRANSPLANTATION: THEORY AND PRACTICE 36, 60-61 (Jean Hamburger, Jean Crosnier, Jean-François Bach, & Henri Kreis eds., 2nd ed., Williams & Wilkins 1981). Kreis noted that, “It is possible to remove kidneys from individuals who have just died under circumstances other than cerebral death.” Id. at 60. But he then discussed the limitations of such efforts, particularly the difficulty in assembling the surgical team and removing the kidney in a time sufficient to prevent irreversible ischemic damage to the organ. He concluded, “As a consequence, most groups throughout the world have given up using these donors, except under exceptional circumstances when there is an urgent need for the donor kidney.” Id. at 61.
26. Didlake et al., supra note 24. These authors reported that kidneys from non-heartbeating (NHB) donors were 8% of their total procurement between 1976 and 1982. They described the nature of these procurements, saying, “Each of these NHB donors was in a controlled environment such as an emergency room, postanesthesia recovery room, or intensive care unit with immediate access to an operating table. In all cases, the referral to the organ recovery team was made prior to the onset of the agonal interval.” Didlake et al., supra note 24, at 90.
During this time, attempts to increase the supply of donated organs generally focused on increasing public acceptance of consent for organ donation, motivating hospital and medical staff to cooperate with organ procurement efforts, and improving the effectiveness of organ procurement agencies.\textsuperscript{27} This framework remained the principal operative focus for expanding the donor supply until the current era, when the shortage of donor organs has rekindled interest in non-heartbeating donors as a source of organs through development of the concept of organ donation after cardiac death.

Although occasionally including the older concept of rapid recovery of organs from uncontrolled cardiac arrest victims, donation after cardiac death in the context of the current discussions is generally what has previously been termed controlled non-heart beating donation. In 1992, the University of Pittsburgh Medical Center, citing as its purpose provision of “an ethically justifiable and auditable policy that respects the rights of the patients to have life support removed and to donate organs if they wish to do so,” adopted a policy governing organ procurement from controlled nonheartbeating donors.\textsuperscript{28} This policy subsequently became known as “the Pittsburgh Protocol.”\textsuperscript{29} In 1997, the Institute of Medicine (IOM) published its report \textit{Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement}, describing the concept of DCD as involving patients who are not brain dead, who are dependant on artificial means of respiratory or circulatory support, and who will have that support discontinued in a controlled manner, allowing a predictable time and process for organ recovery once death ensues.\textsuperscript{30} The pro-
Protocol approved by the Institutional Ethics Committee of the Willis-Knighton Health System strictly constrains the practice of organ donation after cardiac death to controlled non-heartbeating organ donation.  

III. WHY DONATION AFTER CARDIAC DEATH?

The major impetus for the interest in donation after cardiac death has been a growing relative shortage of donor organs amidst changing internal trends in donor supply. Donation rates have not kept pace with the increased demand for solid organs for transplantation. The national trend shows a ten year increase (1996 to 2005) of 57% in the number of donors annually, rising from 9,208 to 14,488. During the preceding decade, in the time period from 1988-1998, the growth rate in the waiting list for organ transplantation was a brisk 300% overall, with ten year percentage increases of 200% for kidney transplant, 1900% for liver transplant, and 300% for heart transplant.

Over the past decade, changes have occurred not only in the demand for donors, but also in the makeup of the donor population. Whereas growth in the number of donors in the late 1990s came almost exclusively from growth in the living donor pool, by 2003 the number of living donors reached a plateau at approx-

31. See the Willis-Knighton Protocol, supra note 5. Our protocol specifies that the potential donor must be a “qualified patient” as defined in the Louisiana Natural Death Act, LA. REV. STAT. ANN. § 40:1299.58.2 PAR. (12) (2008 & Supp. 2011), having been certified in writing as having a terminal and irreversible condition by two physicians who have personally examined the patient, one of whom shall be the attending physician.


33. INSTITUTE OF MEDICINE, ORGAN PROCUREMENT AND TRANSPLANTATION, supra note 2, tbl.1-3, at 20 (quoted percentages are rounded from data in the table).
In 2005, the number of living donors fell from the previous year for the first time in a decade.

Since 1988, approximately 80% of transplanted organs have come from deceased donors. Since 2001, the principal growth in donor supply has also come principally from deceased donors, with the most rapid growth rate in the donation after cardiac death subset. Recent data from the Organ Procurement and Transplantation Network indicates that in 2008, there were 14,196 total donors nationally, of which 44% were living donors and 56% were deceased donors. Of the 7989 deceased donors, 10.6% (846) were DCD donors. National, regional and Louisiana specific data are as follows:

Table 1

<table>
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<tr>
<th></th>
<th>Total</th>
<th>Living</th>
<th>Deceased</th>
<th>DCD</th>
<th>DCD as % of Total</th>
<th>DCD as % of Deceased</th>
</tr>
</thead>
<tbody>
<tr>
<td>National OPTN/UNOS</td>
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<td>6207</td>
<td>7989</td>
<td>846</td>
<td>6.0</td>
<td>10.6</td>
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<tr>
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<td>528</td>
<td>1335</td>
<td>84</td>
<td>4.5</td>
<td>6.3</td>
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<td>218</td>
<td>67</td>
<td>151</td>
<td>12</td>
<td>5.5</td>
<td>7.9</td>
</tr>
</tbody>
</table>

Notes: OPTN/UNOS Region 3 includes Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, and Puerto Rico. DCD indicates donation after cardiac death and is a subset of the deceased.

34. See OPTN/SRTR 2006 Annual Report, supra note 32, tbl.2.8, at 2-29.
35. See id. This downward trend has stabilized in the most recent data. See Organ Procurement and Transplantation Network, Spring 2010 Regional Meeting Data, http://optn.transplant.hrsa.gov/SharedContentDocuments/DataSlides_Spring_2010.pdf (last visited Jan. 29, 2011).
37. See OPTN/SRTR 2006 Annual Report, supra note 32, tbl.2.8, at 2-29 & tbl.2.1, at 2-1. From 2001 to 2006, living donors of any organ rose from 6,607 to 6,895 (a 4.4% increase) while deceased donors of any organ rose from 6,080 to 7,593 (a 24.9% increase).
40. Id.
41. Id.
DHHS Final Rule, the Institute of Medicine noted evidence that the difference in supply and demand of solid organs for transplantation resulted in the deaths of approximately 4,000 Americans yearly. This “gap” between the supply and demand for donor organs has been addressed by the United States Department of Health and Human Services (HHS) with its Gift of Life Donation Initiative designed to increase public awareness and donations, and its Organ Donation Breakthrough Collaborative designed to generate increases in organ donation rates for hospitals and organ procurement organizations. As part of its Public Policy Initiative, the Joint Commission on Accreditation of Healthcare Organizations issued its white paper Health Care at the Crossroads: Strategies for Narrowing the Organ Donation Gap and Protecting Patients with recommendations designed to help create a “tipping point—the point at which things dramatically change—for organ donation and transplantation.” Recently, the Institute of Medicine stated that “to move toward a society where people see organ donation as a social responsibility” is among

42. INSTITUTE OF MEDICINE, ORGAN PROCUREMENT AND TRANSPLANTATION, supra note 2, at 18 (citing 1999 UNOS data).

43. Richard H. Carmona, United States Surgeon Gen., Organ Donation in the 21st Century: National Efforts to Narrow the Gap [prepared remarks], Address at the Joint Commission on Accreditation of Healthcare Organizations (Mar. 10, 2004), http://www.surgeongeneral.gov/news/speeches/JCAHOOrgan_03102004.htm (last visited Jan. 29, 2011). In this speech the Surgeon General indicated that increasing public awareness of the facts of organ donation and the means to indicate wishes regarding organ donation in a simple way were a major focus of HHS initiatives designed to “close the gap” between the 83,000 people who need organs and the donors who can give them.” Id. The discrepancy between the demand and supply of organs for transplantation had been termed a “gap” as early as 1983 in the proceedings of the Surgeon General’s Workshop on Solid Organ Procurement for Transplantation. See C. Everett Koop, Increasing the Supply of Solid Organs for Transplantation, 98 PUB. HEALTH REPS. 566, 567 (1983).


the goals presented in its 2006 report Organ Donation: Opportunities for Action.

Common to all of these initiatives is an effort to expand the practice of donation after cardiac death. The 1997 Institute of Medicine report estimated that expanding the number of controlled DCD donors could potentially increase the number of cadaveric donors by at least 25% and add organs from an additional 1,000 cadaveric donors to the organ supply each year. Clearly, a potential for significant growth of the supply of donor organs is seen in expansion of DCD practice.

IV. THE STATUTORY BASIS AND REGULATORY ENVIRONMENT OF DONATION AFTER CARDIAC DEATH

Organ transplantation in the United States operates upon a statutory basis and within a regulatory environment. The making

46. See discussion Part V infra.

47. Institute of Medicine, Non-Heart Beating Organ Transplantation: Medical & Ethical Issues, supra note 30, at 30. In addition to these estimates, the report also cited data indicating that use of uncontrolled non-heartbeating donors could potentially expand the donor pool by as many as 26,000. Institute of Medicine, Non-Heart Beating Organ Transplantation: Medical & Ethical Issues, supra note 30, at 30. The 2006 Institute of Medicine report arrived at a similar figure of 22,000 by applying a 7.6% donor qualification rate to the 335,000 cardiac arrest victims in the United States annually, Institute of Medicine, Organ Donation, supra note 36, at 156, but noted that such an expansion would require action before consent is obtained from family members by utilization of policies of routine removal of organs or presumed consent for organ donation, Institute of Medicine, Organ Donation, supra note 36, at 133, 205. In the accompanying Report Brief, the Institute of Medicine stated that, "Now is not the time to enact a policy of mandated choice, which would require people to choose whether or not to be an organ donor. Nor should there be any attempt at this time to put into place a presumed-consent policy that would require individuals to specifically opt out of the transplant system if they did not wish to donate their organs. On the other hand, the long term goal should be to create a society so committed to organ donation that such a presumed-consent policy would be acceptable." Institute of Medicine Report Brief, supra note 44, at 3. Such issues and policies have not been reviewed by the Institutional Ethics Committee of the Willis-Knighton Health System. Our adoption of a policy regarding donation after cardiac death, strictly constrained to controlled non-heartbeating donation, in no way implies review of issues of routine removal of organs from deceased patients or presumed consent of deceased patients for organ donation, nor does it in any way imply endorsement or approval of policies regarding uncontrolled non-heartbeating organ procurement or the concept of presumed consent.
of an anatomical gift is generally governed by state laws modeled on the Uniform Anatomical Gift Act and relies on state statutes defining death. Since the 1984 passage of the National Organ Transplant Act, there has been an increasingly active federal involvement in organ transplantation largely centered on regulatory governance of organ procurement. Federal regulations address efficiency in organ procurement operations, equity in organ distribution, quality of organ transplant center operations, and expansion of the donor supply. The modern expansion of organ donation after cardiac death has relied on both the statutory basis of organ donation and the regulatory environment of organ procurement. An understanding of the claims to legitimacy of organ donation after cardiac death requires a careful examination of the statutory basis of organ donation and the regulatory environment of organ procurement in general. Likewise, the Louisiana response to the statutory basis and regulatory environment is framed by these understandings.

A. The Statutory Basis of Organ Donation

No specific statutory authorization of donation after cardiac death as a distinct procedure exists in either federal or Louisiana law. Rather, current donation after cardiac death procedure relies on an existing statutory framework governing the planned withdrawal of life supportive measures in terminally ill patients, the ability of those patients or their families to make an anatomical gift, and the pronouncement of death in those patients by cardi-
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In Louisiana, this statutory framework includes the Louisiana Natural Death Act, the Louisiana Anatomical Gift Act, relevant portions of the Louisiana Motor Vehicle Regulatory Act, and the Louisiana definition of death. These statutes generally provide that persons diagnosed as having a terminal and irreversible condition have a right to control the decision to have life-sustaining procedures withheld or withdrawn, that specified individuals may exercise this right given the incompetence or incapacity of communication of the terminal-ly or irreversibly ill person, that competent individuals may make anatomical gifts to take effect after death, that specified individuals may make anatomic gifts of a decedent’s body or body part, and that death occurs when a person has experienced irreversible cessation of spontaneous respiratory and circulatory functions or an irreversible total cessation of brain function if artificial means of support preclude a determination of death by cardiorespiratory criteria.

The process of organ donation after cardiac death begins with a determination that life-supportive measures will be withdrawn from a terminally ill patient. In Louisiana, this determination is guided by the Louisiana Natural Death Act. The Louisiana Natural Death Act provides two definitions of a terminal and


53. LA. REV. STAT. ANN. § 32:410(B) and (C) (2002 & Supp. 2008).


55. See Michael Vitiello, Louisiana’s Natural Death Act and Dilemmas in Medical Ethics, 46 LA. L. REV. 259, 259-309 (1985) for an early comprehensive review of the Act. As Vitiello points out, the provisions of the Act are explicitly voluntary and illustrative, and do not establish an exclusive means for withholding or withdrawing life-supportive measures. Id. at 263. However, the provisions of the Act have established the de facto governance of these matters in the Willis-Knighton Health System, and are extensively referenced and incorporated into the polices and procedures of the Health System.
irreversible condition: “[A] continual and profound comatose state with no reasonable chance of recovery or a condition caused by injury, disease, or illness which, within reasonable medical judgment, would produce death and for which the application of life-sustaining procedures would serve only to postpone the moment of death.”56 Once these patients have been properly diagnosed as terminally and irreversibly ill and have been certified as a “qualified patient,”57 and presuming that they are comatose, incompetent, or physically or mentally incapable of communication, the individual(s) specified in the Act may then make a declaration concerning the withholding or withdrawal of life-sustaining procedures if the patient has not previously made such a declaration.58 The making of the declaration then allows the controlled

57. See LA. REV. STAT. ANN. § 40:1299.58.2 PAR. (12) (2008 & Supp. 2011), providing that, “‘Qualified patient’ means a patient diagnosed and certified in writing as having a terminal and irreversible condition by two physicians who have personally examined the patient, one of whom shall be the attending physician.”
58. LA. REV. STAT. ANN. § 40:1299.58.5 (A) (2) (2008 & Supp. 2011). The Louisiana Natural Death Act provides that the following individuals, in order of priority, may make a declaration on behalf of a qualified patient: any person or persons previously designated by the patient, while an adult, by written instrument signed by the patient in the presence of at least two witnesses, to have the authority to make a declaration for the patient in the event of the patient’s inability to do so; the judicially appointed tutor or curator of the patient if one has been appointed; the patient’s spouse not judicially separated; an adult child of the patient; the parents of the patient; the patient’s sibling; and the patient’s other ascendants or descendants. LA. REV. STAT. ANN. § 40:1299.58.5(A) (2) & (3) (2008 & Supp. 2011). If there is more than one person in the applicable class, the Act requires that, “[T]he declaration shall be made by all of that class available for consultation upon good faith effort to secure participation of all of that class.” LA. REV. STAT. ANN. § 40:1299.58.5(A) (3) (2008 & Supp. 2011). The Act also specifically allows a competent patient to make a declaration either before or after diagnosis of a terminal and irreversible condition. LA. REV. STAT. ANN. § 40:1299.58.3(A) (2008 & Supp. 2011). Additionally, the Louisiana Motor Vehicle Regulatory Act contains a mandated choice provision as to declarations concerning life-sustaining procedures, requiring that an applicant for a driver’s license “shall be asked at the time of application if he would like to make a declaration concerning life-sustaining procedures or a living will.” LA. REV. STAT. ANN. § 32:410(C)(2) (2002 & Supp. 2010). This Act further provides that a response in the affirmative be recorded on the license, while prohibiting the recording of a negative response. LA. REV. STAT. ANN. § 32:410(C)(1)(a)&(b) (2002 & Supp. 2010). The provisions regarding mandated choice were added by Act 554 of 1995. 1995 La. Acts No. 554, § 1.
withdrawal of life-supportive measures that is the foundation of the donation after cardiac death procedure.

Once the decision to consider withdrawal of life supportive measures has been reached, the donation after cardiac death process then relies on standard organ donation procedures initiated through the execution of anatomical gifts as governed by the Louisiana Anatomical Gift Act. The Louisiana Anatomical Gift Act provides for persons who may make an anatomical gift prior to the death of the donor, stating that “[A]n anatomical gift of a body or part of the donor may be made during his life for the purpose of transplantation, therapy, research, or education” by an adult donor, a minor donor emancipated or authorized under state law to apply for a driver’s license, an agent of the donor, a parent of the donor, or a guardian of the donor. A provision that the persons authorized make an anatomical gift “[m]ay execute the document of gift either after death or immediately before death during a terminal illness or injury” was deleted in the 2010 revisions to the Louisiana Anatomical Gift Act, and the current language is silent as to specific timing of the making of the gift by persons other than the donor when the gift is made prior to death of the donor. The Act further provides for authority to make an anatomical gift of a body or part of a decedent, allowing in order of priority the agent who could have made an anatomical gift immediately prior to the death of the decedent, the surviving spouse, the adult children, the parents, the adult siblings, the adult grandchildren, the grandparents, an adult who exhibited


special care and concern for the decedent, the person acting as guardian of the decedent at the time of death, and any other person having authority to dispose of the body of the decedent.\textsuperscript{62} The patient may also have executed an anatomical gift statement through the Louisiana Department of Public Safety and Corrections. The Louisiana Motor Vehicle Regulatory Act contains a \textit{mandated choice} provision regarding the execution of an anatomical gift statement, requiring that an applicant for a driver’s license “[s]hall be asked at the time of application if he would like to be an organ donor and informed that the gift may be made either to a named donee or without the naming of a donee and the effect thereof as provided in R.S. 17:2354(D).”\textsuperscript{63} The Act provides that an affirmative response regarding execution of an anatomical gift be recorded on the license, while prohibiting the recording of a negative response.\textsuperscript{64}

\textsuperscript{62} \textit{La. Rev. Stat. Ann.} § 17:2354.3(A) (2001 & Supp. 2011). The Act further provides that “[i]f an objection is known, the gift may be made only by a majority of the members of the class who are reasonably available. \textit{La. Rev. Stat. Ann.} § 17:2354.3(B) (2001 & Supp. 2011). Judge Knight has previously called attention to differences in the structure of the classes of individuals who may act on behalf of persons in the Louisiana Natural Death Act and the Louisiana Anatomical Gift Act and has stated, “As a matter of legislative structure, it would seem to be preferable to adopt totally consistent approaches to consent under both these acts unless there is a clearly stated legislative purpose for granting this authority in a different order to somewhat different classes.” Knight, \textit{supra} note 49, at 180.

\textsuperscript{63} \textit{La. Rev. Stat. Ann.} § 32:410(B)(2)(2002 & Supp. 2010). This provision was added by Act 205 of 1983. 1983 \textit{La. Acts} No. 205. For a general discussion of the concept of mandated choice, see \textit{Institute of Medicine, Organ Donation, supra} note 36, at 177-179. Here the Institute of Medicine discusses mandated choice as a strategy to facilitate and promote individual and family decisions to donate, and describes mandated choice as “an approach to donor identification in which all adults are required to state their organ donation preferences,” \textit{id.} at 177. The IOM notes that, “Proposals for models of mandated choice have focused on the incorporation of a set of questions about organ donation into official government documents, such as driver’s license applications, tax returns, or state identification cards (citation omitted).” \textit{Id.}

\textsuperscript{64} \textit{La. Rev. Stat. Ann.} § 32:410(B)(1)(a) & (c) (2002 & Supp. 2010). The statute provides for a “Yes” or “No” check-off box on the license to record the response of the applicant. The statute contains an explanatory rationale for the directive not to record the negative choice of the applicant, stating that, “If the applicant elects not to execute an anatomical gift statement at the time of the application, the statement shall remain blank when presented to the licensee so it can be executed by the licensee at any time after the license is issued.” \textit{La. Rev. Stat. Ann.} § 32:410(B)(1)(c) (2002 & Supp. 2010). These provisions were
Donation after cardiac death thus relies on a statutory basis of two separate testamentary functions—the ability to direct the withdrawal of life supportive measures and the ability to make an anatomical gift—and on the pronouncement of death by statutory criteria. As discussed in Part VI.A infra, it is the novel combination of these statutory functions in the absence of legislative intent that sets the stage for controversy and concern regarding donation after cardiac death as an organ donation process.

B. The Regulatory Environment of Organ Procurement

The Uniform Anatomical Gift Act of 1968 reflected the prevailing social norm that organ donation was an altruistic expression made by an individual (or family) and that its legal construct should be permissive and voluntary.65 The Act did not require the request of an anatomical gift nor did it require the notification of any individual or entity of a potential organ donor. Criticism of the Act on these points subsequently developed in the setting of a growing demand for organs. In its 1985 report Ethical, Legal, and Policy Issues Pertaining to Solid Organ Procurement, the Hastings Center enumerated inadequacies of the voluntary system of organ donation, including “failure to systematically approach family members concerning donation” and “inefficiency on the part of some organ procurement agencies in obtaining referrals of donors.”66 These concerns, among others from the medical and the


65. See Arthur Caplan et al., Increasing Organ and Tissue Donation: What are the Obstacles, What are Our Options? in THE SURGEON GENERAL’S WORKSHOP ON INCREASING ORGAN DONATION: BACKGROUND PAPERS 199, 201-204 (1991) for a discussion of this societal background to the 1968 UAGA.

66. THE HASTINGS CENTER, ETHICAL LEGAL AND POLICY ISSUES PERTAINING TO SOLID ORGAN PROCUREMENT: A REPORT OF THE PROJECT ON ORGAN
bioethics communities, 67 ultimately led to system. 68 Although potentiated by statutes, these changes have been facilitated at the regulatory level, providing two foundational requirements for modern organ procurement—the required request for an anatomical gift from the family of a potential organ donor and the required referral of individuals who have died or whose death is imminent to an organ procurement organization. A third concern relevant to the regulatory framework centers on the definitions of potential donor and imminent death, particularly as they pertain to the application of required request and required referral regulatory provisions to donation after cardiac death.

In addition to the statutory framework regarding withdrawal of life-supportive measures and the execution of anatomical gifts, current donation after cardiac death procedure also relies on these federal and state regulatory frameworks. An understanding of donation after cardiac death necessitates an exploration of these regulatory requirements and how they are now being extended beyond their more traditional applications in order to provide a framework for DCD. And most recently, the Centers for Medicare and Medicaid Services has explicitly addressed the issue of donation after cardiac death in the federal regulatory structure.

1. Required Request for an Anatomical Gift from the Family of a Potential Organ Donor

An early conceptual basis for the regulation of organ procurement was the development of policies mandating the query for an anatomical gift—subsequently termed required request and

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68. A prominent public policy expert wrote, “Hospitals where potential donors die must be identified, critical-care medical personnel must be motivated to cooperate, and families of donors must be persuaded to grant permission for organ removal.” Prottas, supra note 27, at 121.
routine inquiry provisions. Although these terms are sometimes used interchangeably, a “required request” provision typically refers to the mandated query of the family of a deceased patient regarding an anatomical gift, whereas a “routine inquiry” provision refers to the mandated query of a competent patient regarding status as an organ donor.

In April 1986, the Task Force on Organ Transplantation, which had been created in accordance with the National Organ Transplant Act of 1984, noted that the discrepancy between the need for organs and tissues and the supply of donors constituted a “serious gap,” and issued a statement in support of “[t]he enactment of legislation requiring implementation of routine hospital policies and procedures to provide the next-of-kin with the opportunity of donating organs and tissues.” The Task Force made several specific recommendations regarding a required query for an anatomical gift, including recommendations that:

The Health Care Financing Administration incorporate into the Medicare conditions of participation for hospitals certified under subpart U of the Code of Federal Regulations, a condition that requires hospitals to have routine inquiry policies.

All state legislatures formulate, introduce, and enact routine inquiry legislation.

69. See Caplan, supra note 64, for an early description of required request as an option to the “encouraged voluntarism” of the then current system of donor identification.


72. Task Force on Organ Transplantation, U. S. Department of Health and Human Services, Organ Transplantation: Issues and Recommendations, 2 (1986) [hereinafter Task Force Report]. The Task Force on Organ Transplantation had multidisciplinary representation from medicine, law, theology, ethics, allied health, the health insurance industry, the general public, and government, and was charged with conducting “comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation, and to report on these issues within one year,” Task Force Report at 1.
The Commission on Uniform State Laws develop model legislation that requires acute care hospitals to develop an affiliation with an organ procurement agency and to adopt routine inquiry policies and procedures.\textsuperscript{73}

Here, the Task Force used the term “routine inquiry” as a specific type of required request.\textsuperscript{74} Several states had already enacted such “routine inquiry” statues at the time the Task Force issued its recommendation calling upon all states to do so.\textsuperscript{75} These statutes, as well as statutes subsequently enacted, variably included strong and weak required request provisions.\textsuperscript{76} The strong required request laws required hospital administrators to insure that organ donation was queried when a death had been pronounced in a hospital setting, allowed a designated person other than the physician to make the request, and called for documentation that a request was made.\textsuperscript{77} The weak required request laws did not require that the family be asked to donate but did require that the family be informed of the option to donate.\textsuperscript{78} In 1987, the NCCUSL, citing criticisms raised by the Report of the Project on Organ Transplantation, included among amendments to the Uni-

\begin{footnotesize}
\textsuperscript{73} See id. at 3. Subpart U referred to the provisions of 42 C.F.R. governing the End Stage Renal Disease Program. Federal guidelines for provider participation in the renal transplant program were initially contained in this Subpart. 41 Fed. Reg. 22511 (June 3, 1976), redesignated at 42 Fed. Reg. 52826 (Sept. 30, 1977). See also Blumenstein, supra note 48, at 12 & 12 n.9.

\textsuperscript{74} See Task Force Report, supra note 71, at 31-34. The Task Force distinguished a “required request” as a requirement that families be asked to donate, and a “routine inquiry” as a requirement that hospitals offer families the opportunity to donate.

\textsuperscript{75} See generally Task Force Report, supra note 71, Appendix D, 199, 199-213, for a compilation of the then extant routine inquiry statutes of California, Oregon, Indiana, Kentucky, Maine, New York, and Washington.


\textsuperscript{77} This is what the Task Force termed a “required request.” See discussion supra note 73.

\textsuperscript{78} This is what the Task force termed a “routine inquiry.” See discussion supra note 73.
\end{footnotesize}
form Anatomical Gift Act separate sections distinguishing a routine inquiry and a required request. The routine inquiry provision stated that “On or before admission to a hospital, or as soon as possible thereafter, a person designated by the hospital shall ask each patient who is at least [18] years of age: ‘Are you an organ or tissue donor?’” The required request provision stated:

If, at or near the time of death of a patient, there is no medical record that the patient has made or refused to make an anatomical gift, the hospital [administrator] or a representative designated by the [administrator] shall discuss the option to make or refuse to make an anatomical gift and request the making of an anatomical gift pursuant to Section 3(a). The Uniform Anatomical Gift Act (1987) thereby recommended a strong required request provision.

At the federal level, the Omnibus Budget Reconciliation Act of 1986 amended the Social Security Act to require that as a condition of Medicare and Medicaid participation, hospitals must have written protocols to identify potential organ donors, to notify an organ procurement organization of a potential donor, and to “assure that families of potential organ donors are made aware of the option of organ or tissue donation and their option to decline.” Acting under this statutory authority, the Health Care Financing Administration (HCFA) in June 1988 promulgated a final rule addressing provisions relating to organ donation and

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transplantation as hospital conditions of participation in the Medicare and Medicaid programs. As originally codified, these conditions of participation required among several provisions that a hospital must have and implement written protocols that “[a]ssure that the family of each potential organ donor knows of its option either to donate organs or tissues or to decline to do-
... This established a de facto federal requirement that a hospital have at a minimum a weak required request policy. The rule did not establish the timing of the request beyond a general reference that the potential donor must have deceased at the time of discussion with the family. The federal standard was inter-

84. Medicare and Medicaid Programs; Organ Procurement Organizations and Organ Procurement Protocols, 53 Fed. Reg. 6526, 6549 (Mar. 1, 1988) (provision originally codified at 42 C.F.R. § 482.12(c)(5)(i)(A) (1988), removed from Subpart B § 482.12 and superseded by addition of Subpart C § 482.45 (1998) (codified as amended 2010), see Medicare and Medicaid Programs; Hospital Conditions of Participation; Identification of Potential Organ, Tissue, and Eye Donors, 63 Fed. Reg. 33856, 33874-33875 (June 22, 1998)). The structure does not mandate that the family be asked to donate, and makes no mention of a “request.”
85. See Blumenstein, supra note 48, at 16, stating, “Using a hospital’s eligibility to participate in Medicaid or Medicare as the coercive lever, Section 1138 requires all Medicaid or Medicare hospitals to institutionalize a required request policy.” Here Section 1138 refers to Title IX § 1138 of the Social Security Act of 1935, as amended, which was a new section added by the Omnibus Budget Reconciliation Act of 1986, Pub. L. 99-509, § 9318, 100 Stat. 1874, 2009-2010 (1986) (codified at 42 U.S.C. § 1320b-8 (2006)). This provision added several requirements for hospitals and organ procurement organizations regarding organ donation. These include provisions that a hospital may participate in the Medicare and Medicaid programs only of the hospital establishes written protocols meeting specified statutory requirements for identification of organ donors, and that a transplant hospital must be a member of and abide by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) as a condition of participation in Medicare and Medicaid. The Act also provides that organ procurement costs incurred by organ procurement organizations may be payable by Medicare and Medicaid only if the OPO is a “qualified” OPO under the Public Health Service Act § 371(a) (42 U.S.C. 273(b) (2006)) and meets the applicable statutory requirements, and if the OPO meets performance related standards prescribed by the Secretary of Health and Human Services, is a member of and abides by the rules and requirements of the OPTN, and allocates organs in accordance with the medical criteria and policies of the OPTN.
86. This general reference to timing was deleted in the 2006 revisions to 42 C.F.R § 486.302 concerning the issues surrounding the term “potential donor.”
preted as superseding less stringent state provisions but allowing more stringent state requirements, thus leaving room for states to adopt strong required request provisions.87

The Louisiana Anatomical Gift Act was amended in 1986 to include a strong required request provision, specifically mandating that a request be made.88 This provision required that:

When death occurs in a hospital, to a person determined to be a suitable candidate for organ or tissue donation based on accepted medical standards, the hospital administrator or designated representative shall request the appropriate person designated in Subsection H of this Section to consent to the gift of any part of the decedent’s body as an anatomical gift.89 (emphasis added)

A “suitable candidate” was defined as “a patient who is certified by the attending physician, at or immediately before the time of death, to be a suitable donor for any organ or tissue donation based on acceptable medical standards, and who has been released by the coroner in those instances required by law.”90 As
to timing of the request, the Louisiana Act provided that a suitable donor could be identified by the attending physician immediately before death but that the required request would occur when death occurs.\textsuperscript{91} The request was to be a responsibility of the hospital. The “designated representative” of the hospital administrator was not defined in the Act. The Act contained a requirement for documentation of the request, providing that “the person making the request shall complete a certificate of request for an anatomical gift, on a form to be supplied by the secretary of the Department of Health and Human Resources.”\textsuperscript{92}

With Act 99 of 1997, the Louisiana legislature further amended the Louisiana Anatomical Gift Act adding several provisions providing for the designation of a state organ procurement organization, providing for the donation of vascular organs to the Louisiana designated organ procurement organization, and providing restrictions on the donation of vascular organs to out-of-state organ procurement organizations.\textsuperscript{93} Among the provisions was a directive that the Secretary of the Louisiana Department of Health and Hospitals “establish rules concerning the procedures to be employed in making the request” and “establish rules to implement appropriate procedures to facilitate proper coordination among hospitals, organ and tissue banks, and the Louisiana Designated Organ Procurement Organization.”\textsuperscript{94}

In 1998 HCFA, noting the “apparent failure of the current system to convert potential organ donors to actual donors” and the need to improve the hospital/OPO relationship,\textsuperscript{95} and citing the Reinventing Government initiatives of the Clinton-Gore ad-


\textsuperscript{95} Medicare and Medicaid Programs; Hospital Conditions of Participation; Identification of Potential Organ, Tissue, and Eye Donors, (Background), 63 Fed. Reg. 33856, 33857 (June 22, 1998).
administration as its authority, extensively modified the hospital condition of participation regarding identification of potential organ donors. These changes explicitly mandated involvement of the OPO in the required request process and strengthened the required request standard:

(a) Standard: Organ procurement responsibilities. The hospital must have and implement written protocols that:

* * *

(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organ, tissues, or eyes, or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation.

The rule explicitly states that the hospital must designate an individual to “initiate the request to the family,” thereby establishing a strong required request structure. The rule also establishes a federal standard as to who may make the request of the family, and establishes a federal definition of a “designated requestor.” The rule does not specify the timing of a required

96. Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval, (Supplementary Information), 62 Fed. Reg. 66726, 66726 (proposed Dec. 19, 1997).
99. Id.
request of the family of a potential donor, but as discussed in Part IV B.2 infra, the rule does mandate the notification of the OPO when the death of an individual has occurred or is “imminent.”

Citing these provisions, as well as title 17 of the Louisiana Revised Statutes section 17:2354.4(J) as statutory authority, the Secretary of the Louisiana Department of Health and Hospitals in 2002 issued a Rule providing for a “Louisiana/Designated Organ Procurement Organization” which included a strong required request provision similar in structure to that of the federal rule. As subsequently codified in the Louisiana Administrative Code, the Rule referenced the federal regulation and stated:

In order to insure that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate, the department adopts the procedures specified in the federally approved Medicare Conditions of Participation for Hospitals (42 CFR Part 482.45) to be followed by all hospitals in Louisiana. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor.

However, the more stringent Louisiana statutory “shall request” requirement of Act 416 of 1986 also remained in force until removed in the 2010 revisions to the Louisiana Anatomical Gift Act. The removal of the state provision defaulted Louisiana to the “must...ensure” standard of the federal strong required request structure.

The Louisiana administrative rule reinforced the federal imminent death provision regarding the timing of the request,

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103. LA. ADMIN. CODE tit. 48, § 2903(A) (2010).
requiring that all hospitals “must notify in a timely manner, the OPO of individuals whose death is imminent or who have died in a hospital.” The Louisiana rule also incorporated the federal definition of designated requestor. The federal and state rules in effect require that the conduct of the hospital in making the required request be under the supervision or authority of the organ procurement organization.

Thus, as to required request, the Louisiana statutory and regulatory framework has historically been that of a strong required request policy, exceeding the minimum requirements of the federal rule, and establishing a designated requestor framework governed by the Louisiana designated organ procurement agency. However, the 2006 revision of the Uniform Anatomical Gift Act deleted the provisions of the 1987 UAGA pertaining to required request and routine inquiry. The 2010 legislative amendments to the Louisiana Anatomical Gift Act, modeled on the 2006 revisions to the UAGA, deleted Louisiana statutory provisions regarding required request and routine inquiry, thereby defaulting Louisiana to compliance with existing federal law on these matters.

Regulatory provisions regarding required request were developed to help promote the prompt recovery of organs from potential donors, providing that a request for an anatomical gift be made of families by an individual approved by the organ procurement organization when the death of a patient who is judged to be a suitable donor has occurred or is determined to be imminent. The modern practice of donation after cardiac death has developed a similar procedure of routinely requesting an anatom-

ical gift from families of certain individuals not yet deceased but in whom a planned withdrawal of life supportive measures will be made. Although DCD procedures have often appropriated the regulatory framework regarding required request as a matter of policy, our review of the mandates of the required request regulatory structure finds no express intent or explicit requirement that these regulatory provisions be applied in such fashion. The legitimacy of the permissive application of a required request in DCD depends largely on the definitions of potential donor and imminent death, as subsequently explored in Part IV.B.3 infra.

2. Required Referral of an Individual Who Has Died or Whose Death is Imminent to an Organ Procurement Organization

A second conceptual basis for regulation of organ procurement was the development of policies mandating the notification of an organ procurement organization of individuals who have died, or whose death is imminent, for consideration as a potential organ donor. These requirements are termed required referral or routine notification provisions. Until the early 1980’s the referral of a potential organ donor was at the judgment and initiative of the attending or treating physician, and efforts to expand referrals of potential donors centered on educating physicians. However, in 1983 a workgroup of the Surgeon General’s Workshop on Solid Organ Procurement for Transplantation noted that “more organs are available than are being harvested.” The workgroup made note of a pilot study conducted by the Centers for Disease Control “to increase the supply of cadaveric kidneys for transplantation in selected hospitals in Georgia” using “systematic retrieval techniques based on the epidemiologic and public health tools of surveillance and evaluation.” This began a discussion of a more formalized approach to the referral of a po-

109. Nathan et al., supra note 47, at 32.
110. See generally C. Everett Koop, Increasing the Supply of Solid Organs for Transplantation, 98 PUB. HEALTH REP. 566, 566-572 (1983). (This report summarized the proceedings of the 1983 Surgeon General’s Workshop on Solid Organ Procurement for Transplantation, which was convened in response to a request from President Reagan for a “group of experts to discuss ways to increase the supply of organs for transplantation.”) Id. at 566.
111. Id. at 567.
112. Id. at 567 (citing K.J. Beck, et al., Increasing the Supply of Cadaveric Kidneys for Transplantation, 31 TRANSPLANTATION 383, 383-87 (1981)).
potential donor. In 1985, health policy analyst Jeffrey M. Prottas further shifted the concept of donor referral from physician action to hospital function, describing a referral as “obtaining cooperation and information from a hospital.” Prottas proposed to identify the process of obtaining a referral as a core technology in organ procurement.

In its 1986 report, the Task Force on Organ Transplantation noted that “the underlying question confronting the organ procurement system is whether all potential donors are being identified.” The Task Force made several recommendations regarding identification of a potential organ donor, but stopped short of calling for required referral of a potential organ donor to an organ procurement organization. The recommendations included statements suggesting that:

All health professionals involved in caring for potential organ and tissue donors voluntarily accept the responsibility for identifying these donors and for referring such donors to appropriate organ procurement organizations.

Hospitals adopt routine inquiry/required request policies and procedures for identifying potential organ and tissue donors and for providing next-of-kin with appropriate opportunities for donation.

The Joint Commission on Accreditation of Hospitals develop a standard that requires all acute care hospitals to both have an affiliation with an organ procurement agency and have formal policices and procedures for identifying potential organ and issue donors and for providing next of kin with appropriate opportunities for donation.

The Louisiana legislature included a required referral provision in its 1986 amendments to the Louisiana Anatomical Gift Act, with the referral to occur after the family had given consent
to an anatomical gift. This provision also provided that the required referral occur *after* completion of the required request, stating:

> Upon approval of the proper individual specified in Subsection H of this Section, the hospital administrator or designated representative shall notify an appropriate organ or tissue bank, or retrieval organization and cooperate in the procurement of the anatomical gift.\(^\text{117}\)

The 1987 amendments to the Uniform Anatomical Gift Act required hospitals to “establish agreements or affiliations with other hospitals and procurement organizations in the region to coordinate the procurement and utilization of anatomical gifts (Section 9).”\(^\text{118}\) However, the amendments did not require the referral of a potential donor to the organ procurement organization. By 1988, Prottas proposed a policy of routine referral in which hospitals would be required to inform an organ procurement agency (OPA) of the admission of a potential organ donor, “thereby increasing OPA access independently of ICU staff behavior.”\(^\text{119}\)

The 1988 HCFA conditions of participation for hospitals mandated that hospitals must have and implement written protocols that “require that an organ procurement organization designated by the Secretary under § 485.308 of this chapter be notified of potential organ donors.”\(^\text{120}\) The subsequent 1998 HCFA re-

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\(^{120}\) Medicare and Medicaid Programs; Organ Procurement Organizations and Organ Procurement Protocols, 53 Fed. Reg. 6526, 6549 (Mar. 1, 1988) (provision originally codified at 42 C.F.R. § 482.12(c)(5)(i)(C) (1988), removed from Subpart B § 482.12 and superseded by addition of Subpart C § 482.45 (1998), codified as amended 42 C.F.R. § 482.45 (2010), see Medicare and Medicaid Programs; Hospital Conditions of Participation; Identification of Potential
visions to the conditions of participation for hospitals expanded the role of the organ procurement organization into the referral process:

(a) Standard: Organ procurement responsibilities. The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose.

Additionally, the regulation required that the hospital written protocols must ensure that the hospital works cooperatively with the designated OPO in “maintaining potential donors while

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Organ, Tissue, and Eye Donors, 63 Fed. Reg. 33856, 33874-33875 (June 22, 1998).

121. Condition of Participation: Organ, Tissue, and Eye Procurement, 42 CFR § 482.45(a) (1) (2010). Noting that Part 482 does not apply to critical access hospitals (CAH), HCFA added 42 CFR § 485.643 Condition of Participation: Organ, tissue and eye procurement in August 2000 as a new provision for critical access hospitals that “generally parallels the CoP at § 482.25 for all Medicare hospitals with respect to the statutory requirement in section 1138 of the Act concerning organ donation,” Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems, 65 Fed. Reg. 47054, 47101 (Aug. 1, 2000). This rule contains identical provisions to § 482.45(a)(1)& (2) regarding an agreement with an OPO, tissue, and eye bank, timely notification of deaths and imminent deaths, and OPO determination of medical suitability for organ donation. The CAH CoP is distinct from § 482.45(a)(3) in that it only specifies the use of a trained designated requestors (and not an OPO representative) to make the required request of the family. See Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems, 65 Fed. Reg. 47054, 47101 & 47110-47111 (Aug. 1, 2000), and compare 42 C.F.R. § 485.643 (c) (2010) with 42 CFR § 482.45(a)(3) (2010).
necessary testing and placement of potential donated organs, tissues, and eyes takes place.” The 2002 Rule issued by the Secretary of the Louisiana Department of Health and Hospitals required all hospitals in Louisiana to incorporate an agreement with the Louisiana designated OPO and also explicitly restated the federal provisions for a required referral:

D. Under the Medicare Conditions for Participation for Hospitals, the following procedures are to be implemented to facilitate proper coordination among hospitals, the Louisiana designated OPO, and tissue and eye banks.

1. All hospitals will incorporate an agreement with the Louisiana designated OPO, under which it must notify in a timely manner, the OPO of individuals whose death is imminent or who have died in the hospital.

2. The OPO will determine medical suitability for organ donation under this agreement.

Thus, as to required referral, these federal and state regulations, in effect, negated the provisions of Louisiana Act 416 of 1986 that provided for the referral to occur upon the occurrence of death of the patient and after the completion of the required request by the hospital representative, although those provisions remained in Louisiana statutory law until removed in 2010.

The federal and state rules effectively moved the time of the required referral from the prior Louisiana statutory provision (after death) to the current federal provision—when death is imminent or when death has occurred. This construction significantly expanded the referral responsibilities of Louisiana hospitals. However, whether the imminent death and timely notification provisions of the required referral regulatory structure directly apply to the practice of donation after cardiac death, and thus trigger a

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123. LA. ADMIN. CODE tit. 48, pt. 1, § 2903(D) (2010).
required request for organ donation from a potential donation after cardiac death donor, bears further scrutiny with particular attention to the terms potential donor and imminent death.

3. The Definition of the Terms “Potential Donor” and “Imminent Death”

The regulatory environment of organ donation and procurement relies heavily on the concepts of potential donor and imminent death. However, federal definitions of the term “potential donor” have been variable, and no express federal or Louisiana definition of the term “imminent death” exists as to the required request for an anatomical gift or the required referral of a potential organ donor to an organ procurement organization.

a. The Definition of the Term “Potential Donor”

The Omnibus Budget Reconciliation Act of 1986 required that the participation of a hospital in the Medicare program be contingent on the establishment of a written protocol that an OPO “be notified of potential organ donors,” but specified no definition of a potential donor. In promulgating the Final Rule regarding this legislative provision in 1988, HCFA specifically confirmed that the definition of potential donor was to be permissively left to the agreement of the OPO and hospital, addressing this in the Proposed Regulations and Public Comments:

Comment: One commenter questioned the requirement in proposed § 482.12(c)(5)(i)(C) that an OPO designated by the Secretary be notified of potential organ donors. Specifically, the commenter wanted to know whether an OPO should be notified of every potential organ donor regardless of the family’s declination to donate organs. The commenter believed mandatory notification would increase the accuracy of OPO referral statistic and improve the documentation of the potential donor population.

Response: We do not require hospitals to notify an OPO of a potential donor when there is a known family declination. However, we expect relationships between an OPO and hospitals to vary, and we intend to allow the OPO and each hospital to establish a definition of potential donors. We consider it permissible for an OPO that wishes to have more accurate statistics to ask hospitals to include in their reports all potential donors from whom no organs were retrieved for whatever reason.\textsuperscript{126}

Despite this statement, the rule as promulgated specified that the governing body of a hospital must “[i]n accordance with hospital policy...identify potential organ donors as defined in § 485.302 of this chapter....”\textsuperscript{127} 42 C.F.R. § 485.302 provided that “‘Potential donor’ means a person who dies in circumstances (causes and conditions of death and age at death) that are generally acceptable for donation of at least one solid organ if the donor can be identified timely and permission for donation can be obtained.”\textsuperscript{128}

The full context of the 1988 rule as to hospitals seems to indicate that HCFA intended a minimum standard for the definition of a potential donor in the context of a required referral—generally including those medically suitable for donation—but permissively accepted a more expansive definition. This structure allowed a hospital to account for either actual donors or all refer-


rals. However, in all cases it seems clear that the concept of “potential donor” in the 1988 rule intended only the referral of an individual who had died.

In addition to requiring hospital protocols for organ procurement, the Omnibus Budget Reconciliation Act of 1986 also required performance-related standards in order for an organ procurement agency to be a qualified OPO eligible to receive federal Medicare or Medicaid payment with respect to organ procurement costs. In promulgation of the rule pertaining to these performance standards, HCFA made parallel use of its definition of “potential donor.” While using the term in structuring a required referral, HCFA also used the same definition in structuring its regulation of the size of OPO service areas. Here, HCFA required that an OPO have a service area sufficient to yield 50 or more “potential donors” of solid or vascular organs per year.

HCFA subsequently recognized that the “potential donor” term was subject to ambiguity under the permissive structure of the 1988 rule. HCFA revisited this terminology in its comment to the 1998 Hospital Conditions of Participation. Here HCFA seemed to note that the use of the “potential donor” terminology in defining a sufficient service area promoted permissive expansion of the term by the organ procurement organizations:

Generally, a definition for potential donors is designed to cast a wide net by defining potential donors, for example, as all hospital deaths or all patients on ventilators. By making the pool of potential donors so large, OPOs ensure that no medically suitable donors are missed. However, many, if not


130. Medicare and Medicaid Programs; Organ Procurement Organizations and Organ Procurement Protocols (Supplementary Information), 53 Fed. Reg. 6526, 6550 (Mar. 1, 1988) (originally codified at 42 C.F.R. § 485.302, subsequently redesignated § 486.302, then removed in revision of Part 486 Subpart G, see Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs); Final Rule, 71 Fed. Reg. 30982, 31046 (May 31, 2006)).
most, of the potential donors in this large pool will not be medically suitable to be actual donors.\textsuperscript{131}

This confusing and non-uniform state of affairs continued until CMS administratively clarified OPO reporting standards in 2006. At that time, CMS removed the definition of “potential donor” from the regulations. In this revision of the OPO performance standards, CMS initially proposed the terminology “organ donor potential” but later decided upon the term “eligible deaths” for the purposes of outcome measures data for organ procurement organizations.\textsuperscript{132} Although the term “potential donor” remains in common use in reference to an individual patient who may be considered as an organ or tissue donor, since 2006 the federal regulatory structure has left the term subject to a definition as agreed between the hospital and the OPO.

Other organizations have generally followed the federal regulatory precedent. The NCCUSL in promulgating the 2006 Revised Uniform Anatomical Gift Act did not define the term “potential donor,” but continued a multiple use construction of the term. In 2009, the Veterans Health Administration, while noting that its facilities are not required to comply with CMS regulations establishing conditions of participation in the Medicare program, issued a handbook defining procedures for its hospitals to enter into agreements with local organ procurement organizations.\textsuperscript{133} This document includes the definition of “potential donor” to be used in those agreements:

\textsuperscript{131} Medicare and Medicaid Programs; Hospital Conditions of Participation, Identification of Potential Organ, Tissue, and Eye Donors and Transplant Hospitals’ Provision of Transplant-Related Data (Analysis of and Responses to Public Comments), 63 Fed. Reg. 33856, 33862 (June 22, 1998).

\textsuperscript{132} See Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs) (Provisions of the Proposed Regulations), 70 Fed. Reg. 6086, 6090 (proposed Feb. 4, 2005) (proposing that the term “potential donor” should be replaced with a term which would “include specific parameters for the cause and conditions of death that indicate medical suitability for organ donation”) and Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs) (Summary of the Proposed Revisions and Response to Comments), 71 Fed. Reg. 30982, 30985 (May 31, 2006) (designating the term “eligible deaths” to be used for the purposes of outcomes measurement regarding medical suitability for organ donation).

\textsuperscript{133} DEPARTMENT OF VETERANS AFFAIRS, VETERANS HEALTH ADMINISTRATION, VHA HANDBOOK 1101.03-ORGAN, TISSUE, AND EYE DONATION PROCESS 1 (2009). http://www1.va.gov/vhapublications/
The potential donor is an individual who suffers from a condition with terminal prognosis; is at a point where death has occurred or is imminent; and, in the opinion of the attending physician, and in consultation with the procurement coordinator, meets the local donor criteria. A potential donor may also be an individual who has indicated a preference to donate.\textsuperscript{134}

This definition includes both the narrow construction of a deceased patient or a patient near death, as well as the broad “wide net” of the older HCFA construction, and typifies the current practical application of the permissive federal regulatory structure regarding the issue of the “potential donor.” Careful review thus confirms that federal requirements remain permissive as to the concept of “potential donor” and donation after cardiac death. However, similar analysis reveals that federal requirements have been evolving to a more explicit application of the term “imminent death” as it may pertain to DCD.

\textbf{b. The Definition of the Term “Imminent Death”}

The Omnibus Budget Reconciliation Act of 1986 contained no provision referencing \textit{imminent death}. The terminology regarding imminent death, as initially used by HCFA in the 1988 hospital Conditions of Participation and codified in 42 C.F.R. 482.45, was developed in lieu of a definition of a potential donor. HCFA stated in comment to the final rule:

We have not specifically defined potential donor in the final rule because the definition is continually changing, particularly as to the upper age. Instead, we have included the requirement that hospitals routinely refer all deaths and all individuals for whom death is imminent to the OPO, with the assumption that this requirement will, in most communities, lead to better identification of the medi-
cal suitability of the potential donor based on the most recent medical research in transplantation. 135

In discussion of the timely referral provision contained in the 1998 revisions to the Condition of Participation, HCFA seemed to clarify that in the context of requiring the timely referral of individuals whose death is imminent, it was requiring the referral of an individual who had fulfilled brain death criteria and who had not yet been removed from life supportive measures:

The requirement for timely referral at death or when death is imminent means that hospitals must make referrals both before a potential donor is removed from ventilator and while the potential donor’s organs are still viable. Timely referral also means that the hospital must notify the OPO about potential donors early enough in the process to allow sufficient time for the family or the potential donor to make an informed decision about donation. We added these requirements to the final rule to minimize the possibility that organs will be lost to medical complications. One recent study noted that without aggressive support, cardiac arrest occurs in 20 percent of potential donors within 6 hours after the declaration of brain death and in 50 percent of donors within 24 hours. The authors conclude that delays in referrals may reduce the availability of organs since hemodynamic instability and cardiac arrest can develop relatively soon after brain death and emphasize that early identification and intervention are crucial for the successful recovery of organs. 136


136. Medicare and Medicaid Programs; Hospital Conditions of Participation; Identification of Potential Organ, Tissue, and Eye Donors (Analysis of and Responses to Public Comments), 63 Fed. Reg. 33856, 33866 (June 22, 1998) (citation omitted). Here it is clear that timely referral denotes a refinement of the older required referral concept.
HCFA also specifically addressed the non-heartbeating donor at this time, and made it clear that the timely referral language in the regulation was mandatory as to non-heartbeating donors only as “cadaveric potential donors”:

[W]e want to clarify that this rule requires hospitals to notify OPOs or a third party designated by the OPO of individuals whose death is imminent of [sic] who have died in the hospital. Some commenters make reference to “brain death” donors, meaning heart beating donors who have been declared brain dead. This regulation does not exclude the reporting of non-heartbeating deaths. Hospitals must report both brain dead and cadaveric potential donors. 137

It is the belief of our Committee that in distinguishing non-heartbeating donors from brain dead donors, use of the construction “cadaveric potential donors” (as opposed to a possible alternate construction of “potential cadaveric donors”) defines a non-heartbeating donor as a donor who has already died by cardiopulmonary criteria, thus restricting its application to tissue donation and to the uncontrolled non-heartbeating donor scenario. In drawing these distinctions, the structure of this paragraph seems to reserve the term “imminent death” for the class of patients who are or will become a brain dead donor, while classifying the non-heartbeating donor among those “who have died in the hospital.” The scope of this 1998 clarification of the term “imminent death” does not seem to include donor candidates typical of the modern controlled DCD scenario. Controlled DCD patients, although being considered for withdrawal of life supportive measures, are not brain dead, generally are not in urgent danger of brain death, and are not among those who have died in the hospital. They most certainly are not cadavers.

Subsequent guidance from the Centers for Medicare & Medicaid Services (CMS) regarding the timely referral and imminent death provisions has further clarified application to non-

heart beating donors. The CMS Medicare State Operations Manual includes interpretive guidelines for use in state agency surveys that determine certification of health care entities as complying with the standards required by federal regulations in order to be qualified to participate in the Medicare and Medicaid programs. The Medicare State Operations Manual guideline for the provisions of 42 C.F.R. § 482.45(a)(1), most recently updated in 2004, seems to expand the prior construction of imminent death by referring to potential donors as including both patients with impending brain death and those in whom withdrawal of life supportive measures is being contemplated:

Hospitals must notify the OPO of every death or imminent death in the hospital. When death is imminent, the hospital must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor’s organs are still viable. The hospital should have a written policy, developed in coordination with the OPO and approved by the hospital’s medical staff and governing body, to define “imminent death.” The definition for “imminent death” should strike a balance between the needs of the OPO and the needs of the hospital’s care givers to continue treatments of a patient until brain death is declared or the patient’s family has made the decision to withdraw supportive measures.

Further comment in the guideline describes three possible groups of patients who might be included in the definition of imminent death:

138. See generally Ctrs. for Medicare & Medicaid Services, Chapter 1 – Program Background and Responsibilities, in Medicare State Operations Manual (2004), http://www.cms.hhs.gov/manuals/downloads/som107c01.pdf (last visited Jan. 29, 2011), for a discussion of the role of state agencies in the CMS survey and certification process. CMS is the federal agency responsible for monitoring compliance with the Medicare conditions of participation but may have agreements with State agencies to perform this function.

The definition for “imminent death” might include a patient with severe, acute brain injury who:

- Requires mechanical ventilation
- Is in an intensive care unit (ICU) or emergency department; AND
- Exhibits clinical findings consistent with a Glasgow Coma Score that is less than or equal to a mutually-agreed-upon threshold; or
- MD/DOs are evaluating a diagnosis of brain death, or
- An MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family’s decision.

Note that a patient with “severe, acute brain injury” is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity. This construction seems to interject some uncertainty as to whether imminent death referrals must be constrained only to patients who are brain dead or becoming brain dead. However, analysis of the full context of this guideline indicates that what is being proposed is maintenance of the prior 1998 mandatory imminent death reporting structure (those brain dead or in urgent danger of brain death) and permissive expansion to allow imminent death to include other patients subject to agreement between the hospital, its medical staff, and the OPO. These other patients could include severely brain injured patients on the ventilator and severely brain injured patients in whom withdrawal of support is being contemplated. Although not explicitly clarified, it does seem that this guideline permissively allows a controlled donation after cardiac death scenario.

However, in discussion of the timely notification provision, the CMS Medicare State Operations Manual guidelines give further insight regarding what is required in the application of the
term “imminent death.” The timely notification discussion again includes the three groups of patients detailed previously, but then explicitly clarifies that non-heart beating donors (and thus donation after cardiac death) are to be included in the scope of the timely notification regulatory provision:

“Timely notification” means a hospital must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a hospital must notify an OPO while a brain dead or severely brain-injured, ventilator dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart beating donor.  

Unlike the prior permissive expansion of the term “imminent death”, here CMS is expressly mandating timely notification to the OPO of all brain deaths, all ventilated severely brain injured patients, and all “potential non-heartbeating donors.” But importantly, the guidelines also explicitly time the referral of potential non-heartbeating donors to occur after the death of those individuals. The description of this group seems to preserve the original “cadaveric potential donor” construction of 1998. And just as in the 1998 construction, the guideline construction would explicitly apply to tissue donation and to uncontrolled non-heartbeating donors, but leaves unspecified the application of the term “imminent death” within the timely reporting requirement as it might pertain to the current practice of controlled donation after cardiac death.

The fact that the imminent death provisions do not directly pertain to the practice of controlled donation after cardiac death per se is more clearly evidenced in the 2006 CMS comments to its final rule for Medicare and Medicaid conditions for coverage for organ procurement organizations. Here CMS further addresses the issue of the definitions of timely referral and imminent death. And here for the first time CMS directly addresses the distinctive issues of the modern practice of donation after cardiac death.

141.  *Id.*
CMS specifically clarifies that DCD is to be governed within the context of either a separate agreement between a hospital and an OPO, or provisions within a single standard agreement separate and distinct from its provisions regarding imminent death:

We have found that most agreements between OPOs and hospitals are “generic” in nature and do not specify the OPO and hospital roles in the donation process. However, we are requiring OPOs to address the responsibilities of both the OPO and the hospital in implementing §482.45 and §485.643 and include definitions for the terms “imminent death” and “timely referral.”

Many OPOs will need to rewrite their agreements; however, we expect OPOs would develop a standard agreement that addresses OPO and hospital responsibilities and defines “imminent death” and “timely death” [sic] and would ask each of their hospitals to sign the standard agreement. We also expect that OPOs will develop an agreement concerning the responsibilities of both the OPO and the hospital concerning donation after cardiac death for those hospitals that have a donation after cardiac death protocol.

This comment is relevant as the separation was less clear when CMS promulgated this requirement as a standard for an OPO to meet the Process Performance Measures Condition of Coverage in order for organ procurement costs to be reimbursed under the Medicare or Medicaid programs:

§ 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.

(a) Standard: Hospital agreements. An OPO must have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after

cardiac death (if the OPO has a protocol for donation after cardiac death) and the requirements for hospitals at §482.45 or § 485.643. The agreement must specify the meaning of the terms “timely referral” and “imminent death.”

Further guidance regarding a current definition of imminent death can be obtained from the Organ Procurement and Transplantation Network. In adopting definitions for the purposes of OPO data reporting, the OPTN has explicitly constrained imminent death as imminent neurological death:

Imminent Neurological Death is defined as a patient who is 70 years of age or younger with severe neurological injury and requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three brain stem reflexes but does not yet meet the OPTN definition of an eligible death, specifically that the patient has not yet been legally declared brain dead according to hospital policy.

The OPTN presently maintains that the actual medical criteria to specifically satisfy the definition of imminent death remain subject to “clinical triggers” mutually established by the hospital and the OPO. The OPTN Ethics Committee recommends no specific definition of death, holding that death “should


be established using current empirical data and accepted medical standards.\textsuperscript{146}

Upon review of the full context of these sources, our Committee concluded that, with regard to the \textit{imminent death} provision, HCFA (now CMS) did not originally envision that the provision regarding timely notification of individuals whose death is imminent, as promulgated in the hospital Conditions of Participation codified at 42 C.F.R. 482.45, should apply to non-heart beating donors in the modern practice of donation after cardiac death.\textsuperscript{147} We also concluded that the CMS requirement that an OPO agreement with a hospital must define \textit{imminent death} intends mandatory inclusion of donors who meet brain death criteria and patients who are near to and will soon meet brain death criteria, as well as cadaveric potential donors who have already died by cardiopulmonary criteria. The \textit{imminent death} provision may permissively include severely brain injured ventilator patients and severely brain injured patients in whom withdrawal of life supportive measures is being contemplated, subject to agreement between the hospital and OPO. The \textit{timely referral} provisions mandate OPO notification of all brain deaths, all ventilated severely brain injured patients and all “potential non-heartbeating donors” \textit{after the death} of those individuals. Mandatory timely referral of all ventilated severely brain injured patients was developed to capture the referral of patients who might soon meet brain death criteria.

We concluded that the mandatory timely referral and imminent death provisions are not intended to specifically apply to the modern practice of donation after cardiac death. We concluded that it is the intent of CMS that practices regarding donation after cardiac death should be detailed in a separate agreement or in distinctly separate provisions within a single agreement between a hospital and an OPO, and that these donation after cardiac death agreements are permissive as to the definition of the potential controlled donation after cardiac death donor.


\textsuperscript{147} We also extend this conclusion to the parallel provisions of 42 C.F.R. § 485.643 for critical access hospitals.
4. Federal Regulations Explicitly Addressing Donation after Cardiac Death

In its May 31, 2006, Final Rule concerning Medicare and Medicaid conditions of coverage for organ procurement organizations, the Centers for Medicare and Medicaid Services explicitly addressed donation after cardiac death from a regulatory standpoint, stating that “we should not ignore a practice that is becoming increasingly common across the United States and that has the potential to increase the supply of transplantable organs.”148 CMS provided a specific definition of a DCD donor, stating, “[d]onor after cardiac death (DCD) means an individual who donates after his or her heart has irreversibly stopped beating. A donor after cardiac death may be termed a non-heartbeating or asystolic donor.”149

Acting under the broad authority granted under Section 1138 of the Social Security Act,150 as well as new authority granted by the Organ Procurement Organization Certification Act of 2000,151 CMS addressed the donation after cardiac death process by adding provisions under title 42 of the Code of Federal Regulations pertaining to conditions of participation for organ procurement organizations to be qualified to receive payment from the Medicare and Medicaid programs. In so doing, CMS was careful to clarify that it was not mandating the performance of donation after cardiac death by OPOs or hospitals:

We have finalized these requirements to facilitate our oversight of donation after cardiac death, not

148. Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs); Final Rule (Background), 71 Fed. Reg. 30982, 30983 (May 31, 2006).
149. Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs); Final Rule (§ 486.302 Definitions), 71 Fed. Reg. 30982, 31047 (May 31, 2006).
150. See supra note 84 for the statutory reference and for a brief overview of this statutory authority. The relevant authority here is the ability of the Secretary of Health and Human Services to prescribe performance related standards which the OPO must meet in order to qualify for Medicare and Medicaid payment of organ procurement costs incurred by organ procurement organizations.
specifically to encourage OPOs to recover organs from cardiac dead donors.... We must emphasize that these requirements do not mean that an OPO must recover organs from donors after cardiac death. We understand that donation after cardiac death is an evolving practice and is not yet accepted in every area of the country. Some donor hospitals are reluctant to permit donation after cardiac death in their facilities and some transplant surgeons are unwilling to transplant organs from such donors into their patients. Thus, some OPOs are hesitant to advocate donation after cardiac death in their service areas.\textsuperscript{152}

CMS added 42 C.F.R. § 486.324 as a new condition of participation establishing certain requirements for OPO boards and governing bodies. This condition included the provision that, “[t]he OPO’s policies must state whether the OPO recovers organs from donors after cardiac death.”\textsuperscript{153} As noted in Part IV.B.3 supra, CMS also added 42 C.F.R. § 486.322 as a new condition of participation specifying certain relationships between an OPO and hospitals, critical access hospitals, and tissue banks.\textsuperscript{154} This condition included a provision requiring that written agreements between an OPO and Medicare and Medicaid participating hospitals and critical access hospitals “must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after cardiac death (if the OPO has a protocol for donation after cardiac death).”\textsuperscript{155} Finally, CMS added 42

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  \item \textsuperscript{152} Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs); Final Rule (Summary of the Proposed Provisions and Response to Comments on the February 4, 2005 Proposed Rule), 71 Fed. Reg. 30982, 30983 (May 31, 2006). CMS did elect to credit OPOs that perform DCD by allowing a DCD donor to be counted in both the numerator (actual donors) and the denominator (organ donor potential) in calculating the donation rate outcome measure of OPO performance. \textit{Id.} at 31000.
  \item \textsuperscript{153} 42 C.F.R. § 486.324 (g) (2010).
  \item \textsuperscript{154} Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs); Final Rule (Organ Procurement Organization Process Performance Measures, § 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks), 71 Fed. Reg. 30982, 31051 (May 31, 2006), codified at 42 C.F.R. § 486.322 (a) (2010).
  \item \textsuperscript{155} \textit{Id.}
\end{enumerate}
\end{footnotesize}
C.F.R. § 486.344 as a new condition of participation specifying certain requirements for written protocols regarding evaluation and management of potential donors and for organ placement and recovery. CMS specified certain minimum requirements for OPO DCD protocols in this section:

- (f) Donation after cardiac death. If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:
  - (1) Criteria for evaluating patients for donation after cardiac death;
  - (2) Withdrawal of support, including the relationship between the time of consent to donation and the withdrawal of support;
  - (3) Use of medications and interventions not related to withdrawal of support;
  - (4) Involvement of family members prior to organ recovery;
  - (5) Criteria for declaration of death and the time period that must elapse prior to organ recovery.  

Also, among the requirements was a standard requiring the OPO to collaboratively establish with transplant programs protocols defining the roles and responsibilities of the OPO and the transplant program “for all activities associated with the evaluation and management of potential donors, organ recovery, and organ placement, including donation after cardiac death, if the OPO has implemented a protocol for donation after cardiac death.”

Thus, as to explicit federal regulatory requirements regarding donation after cardiac death, CMS has adopted no provision requiring hospitals to participate in donation after cardiac death processes. CMS has adopted a permissive rather than a prescriptive approach regarding the participation of OPOs in DCD. However, if the OPO recovers organs from DCD donors, then CMS has

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156. 42 C.F.R. § 486.344 (f) (2010).
provided requirements for written agreements regarding DCD between the OPO and hospitals, and written protocols regarding DCD between the OPO and transplant programs, and has established specified minimum requirements for the OPO DCD protocol.

C. The Louisiana Response to the Statutory Basis and Regulatory Environment

The Centers for Medicare and Medicaid Services designates only one OPO for each donation service area. The Louisiana Organ Procurement Agency (LOPA), as the Louisiana designated OPO, maintains a standard hospital/OPO agreement that contains a specific timely referral provision providing for the referral to LOPA of patients who meet defined clinical triggers (intubated and connected to a functioning ventilator, with intact cardiac circulation, and a Glasgow Coma Score (GCS) of five or less or other objective evidence of a significant neurologic deficit). The agreement also specifically provides a definition of “imminent death” as a patient who meets the above clinical triggers, who is being evaluated for a diagnosis of brain death, or who is under orders of a physician to have cardiopulmonary sustaining therapies discontinued. The standard agreement does not reference donation after cardiac death. However, by electively extending the imminent death reporting process to patients for whom withdrawal of life supportive therapy is being considered, the agreement in its scope requires referral of all patients suitable for consideration as DCD donors.

The Louisiana Organ Procurement Agency has a separate template donation after cardiac death protocol which specifies provisions governing the anatomical gift process in DCD, provid-

158. 42 C.F.R. § 486.308 (2010). CMS defines a donation service area (DSA) as a geographical area “of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs.” 42 C.F.R. § 486.302 (2010). A DSA may be an entire state, as is the case in Louisiana.


160. See LOPA Agreement, supra note 158.
ing for eligibility and the anatomical gift process in relevant provisions:

The potential DCD donor must be between the ages of 0 years (36 weeks gestation) and 70 years-of-age. It should be determined that the patient is dependent on mechanical/pharmacological support and the removal of such support should result in cardiac death.

The recovery coordinator/family advocate will contact the attending physician to discuss the patient’s clinical situation and develop a plan for presenting the option of organ donation to the family.

If the patient meets criteria for a DCD potential donor, as defined by LOPA policy, the family advocate (after consulting with the attending physician and designated hospital personnel) will approach the legal next-of-kin (LNOK) to present the option of donation and inform the family of the process involved.

The approach for DCD must be separate from the family decision to withdraw life support. The legal next-of-kin/family should be given an opportunity to ask questions and make specific requests regarding when withdrawal of care will occur, who will be present and religious implications during that time.

LOPA personnel will follow hospital policy regarding declaration of death when the patient is being considered for organ donation. For hospitals only requiring one declaration, an additional physician, not a member of the transplant team, will evaluate and determine if the patient’s condition is suitable for the process of organ donation.  

In this protocol, LOPA defines a patient who will be considered as a potential donation after cardiac death donor, stating, “it should be determined that the patient is dependent on mechanical/pharmacological support and that the removal of such support should result in cardiac death.” The LOPA protocol does not explicitly reference the statutory standard for a “terminal and irreversible condition” set forth in Louisiana Revised Statutes section 40:1299.58.2 Par. (15). The LOPA protocol makes no specific mention of a “continual profound comatose state” or of a “condition caused by injury, disease, or illness which, within reasonable medical judgment, would produce death and for which the application of life-sustaining procedures would serve only to postpone the moment of death.” Although the LOPA structure comports with the statute when the provisions for the clinical triggers or imminent death in the template hospital/OPO agreement are harmonized with the DCD policy provisions, we have preferred a more explicit requirement for compliance with the statutory structure. The Willis-Knighton Protocol explicitly references the provisions of the Louisiana Natural Death Act as outlined in Title 40 of the Louisiana Revised Statutes section 40:1299.58.2 as defining necessary conditions for a patient to be considered a DCD candidate in our health system.

Our review finds that the Louisiana Organ Procurement Agency, as the Louisiana designated OPO, has generally followed

162. LOPA Protocol, supra note 160. An earlier version of the LOPA Protocol provided that “the patient must have suffered a non-survivable brain injury or cardiac event such that patient death would be imminent subsequent to the removal of ventilator and vasopressor support.” Louisiana Organ Procurement Agency, Organ Donation after Cardiac Death (DCD) Protocol (February 16, 2004). This version seems more clearly comported to the statutory definition of a “terminal and irreversible condition.” Although the 2004 template document was not published, it was adopted with minimal change by the Louisiana State University Health Sciences Center-Shreveport in June 2005, with recent revision in August 2008 (Louisiana State University Health Sciences Center-Shreveport, Organ Donation after Cardiac Death (DCD) Protocol: Louisiana Organ Procurement Agency (LOPA), (October 1, 2008), available at http://www.sh.lsuhsc.edu/policies/policy_manuals_via_ms_word/hospital_policy/h_5.7.1.pdf (last visited Jan. 29, 2011).


164. However, due to concerns about the application of DCD to conscious patients, the Willis-Knighton Protocol, supra note 5, finds only the presence of a “continual profound comatose state” to be both necessary and sufficient for DCD candidacy in our system. See discussion Part VI.E.4 infra.
a construction in its standard hospital agreements and DCD policies consistent with our analysis of the statutory and regulatory environment of donation after cardiac death.

D. The Statutory Basis and Regulatory Environment of Donation after Cardiac Death – Summary Analysis

Donation after cardiac death practice extensively references the timely referral and imminent death regulatory provisions which were developed to foster the donation of organs from brain-dead donors and the donation of tissues from non-heart beating cardiac death donors. However, analysis of the legislative and regulatory history shows that there is no requirement to provide donation after cardiac death organ recovery, that the mandatory imminent death and timely referral provisions do not apply to donation after cardiac death per se, and that the definition of a potential donor for donation after cardiac death is permissively subject to the agreement of the hospital and the OPO. Mandatory timely referral provisions will capture the severely brain injured ventilated patients who form majority of the DCD population, but this application specifically to DCD is an extrapolation of the original intent of those provisions. Additionally, the circumstances triggering any request for organ donation from a potential donor for the purposes of the practice of donation after cardiac death are subject to the voluntary agreement of the hospital and OPO. For potential donation after cardiac death donors, any organ or tissue donation request is not required by federal or Louisiana statute or regulation until after the death of that donor by cardiac death criteria or unless that donor is also being considered a potential brain death donor. A premortem request may be allowed subject to the voluntary agreement of the hospital, its medical staff, and the OPO. Any request for organ donation after cardiac death must be governed by a written agreement with an OPO subject to certain minimum specifications, and any request for organ donation performed under a donation after cardiac death protocol is subject to the mandatory provisions for a designated requestor common to all organ donation requests. The current standard hospital agreements and DCD policies of the Louisiana designated OPO are generally consistent with the statutory and regulatory environment of DCD.
V. INITIATIVES OF GOVERNMENTAL AND NON-GOVERNMENTAL ENTITIES REGARDING DONATION AFTER CARDIAC DEATH

A. Organ Procurement and Transplantation Entity Initiatives Relating to Donation After Cardiac Death

The most direct and coercive efforts to increase donation after cardiac death activity have come from the organ procurement and transplantation community. In 2003, through its Health Resources and Services Administration (HRSA), the Department of Health and Human Services joined with national leaders and practitioners from the transplantation and hospital communities in the Organ Donation Breakthrough Collaborative. The stated purpose of the Collaborative was to “dramatically increase access to transplantable organs” and to spread “known best practices to the nation’s largest hospitals to achieve organ donation rates of 75 percent or higher in these hospitals.”

A portion of that drive is to increase donation after cardiac death participation. The stated initial HRSA program goal was to “increase the annual number of ‘cardiac death’ donors by 175 until the number of 2,018 ‘cardiac death’ donors is achieved in 2013.” However, given a slower than expected growth in the number of DCD donors, the program performance goal is now for

166. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, Organ Donation Breakthrough Collaborative, in GLOSSARY (2011), http://optn.transplant.hrsa.gov/resources/glossary.asp (last visited Jan. 14, 2011). Here “donation rate” is generally understood as the “number of potential donors that become actual donors.” Centers for Medicare and Medicaid Services, Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations (OPOs); Final Rule (Background), 71 Fed. Reg. 30982-01 (May 31, 2006). This is more technically defined as the “number of eligible donors (actual donors who met the eligibility criteria) as a percentage of the number of eligible deaths.” Id. at 31001.
167. Health Resources and Services Admin., Dept. of Health and Human Services, Fiscal Year 2009 Online Performance Appendix 92 (2009) ftp://ftp.hrsa.gov/about/performanceappendix09.pdf (last visited Jan. 8, 2011). HRSA stated in this report that, “A major focus of the Organ Transplantation Breakthrough Collaborative that was launched in the fall of 2005 is to increase the number of cardiac death donors.” Id.
168. Id. at 91.
10% of deceased donors to be DCD donors by 2013. In order to facilitate this goal, the Organ Procurement and Transplantation Network (OPTN), operating under contract with the United Network for Organ Sharing (UNOS), has conducted a series of initiatives.

In 2004, OPTN/UNOS planned a national conference on donation after cardiac death. The proceedings of this conference, held in Philadelphia in April 2005, were published in the American Journal of Transplantation in 2006. These proceedings stated that “this national conference affirmed the ethical propriety of DCD as not violating the dead donor rule” and that “when a consensual decision is made to withdraw life support by the attending physician and patient or by the attending physician and a family member or surrogate (particularly in an intensive care unit), a routine opportunity for DCD should be available to honor the deceased donor’s wishes in every donor service area (DSA) of the United States.” Among actions suggested by the Conference Work Groups were that OPTN/UNOS require that transplant center and OPO membership criteria be revised to require DCD protocols and that the Joint Commission on Accreditation of Healthcare Organizations revise accreditation standards to require hospitals to implement DCD protocols. Both suggestions were aimed at creating a mandatory culture of compliance with regard to organ donation after cardiac death. The Joint Commission response is reviewed in Part V.C infra. The OPTN/UNOS response has been vigorous and has relied on the regulatory authority of the OPTN as delegated by the Secretary of Health and Human Services.

169. Id. at 92.
170. J. L. Bernat et al., Report of a National Conference on Donation After Cardiac Death, 6 AM. J. TRANSPLANT. 281, 281 (2006) [hereinafter The National Conference Report]. The purpose of the national conference was “to address controversies about the procedure itself, to examine criteria that would predict DCD candidacy following the withdrawal of life support, to advance protocols for recovery, to examine data regarding ischemia time and function of the transplanted organ, to increase DCD and to allocate these organs appropriately.” Id. at 281.
171. Id. at 281.
172. Id. at 281.
173. Id. at 286.
The relationship between UNOS and the OPTN as to regulatory enforcement is complex. The original intent of the relationship was succinctly described by the Department of Health and Human Services in background information to its 1998 Final Rule concerning the OPTN:

The United Network for Organ Sharing (UNOS), a private corporation, operates the OPTN under contract with the Department....

As a private organization, UNOS has by-laws, operating procedures, and membership requirements. They apply only to UNOS members and not to OPTN members. Membership in UNOS is not a requirement for membership in the OPTN. Therefore such procedures are not OPTN procedures, and because they do not bind OPTN members, they are not the subject of this regulation....UNOS may impose conditions for membership in UNOS, but those conditions may not be substituted for, or used to augment, the regulatory requirements for the UNOS-administered OPTN. In contrast, matters relating to the OPTN are encompassed by these regulations; and UNOS, as the OPTN contractor, is required to comply with these regulations and to issue policies consistent with the requirements of these regulations.¹⁷⁴

Nonetheless, UNOS has closely comingled the two organizations. This is directly evidenced by Article II Section 2.11 of the UNOS Bylaws:

Relationship of UNOS Board of Directors and OPTN Board of Directors.

The UNOS Board of Directors shall be elected in parallel with and using the same processes as the OPTN’s Board of Directors, resulting in identical

memberships, if the OPTN Contract provides for such an arrangement. The OPTN is a part of UNOS’ organization and operations. When UNOS operates as the OPTN, it operates the OPTN according to the OPTN Bylaws. This will enable UNOS to perform tasks required by the OPTN Contract under the governance of the OPTN Board of Directors. Activities of the Board of Directors, while constituted as the OPTN Board, shall be limited to activities of the OPTN (i.e., those activities for which costs are reimbursed under the OPTN Contract). To accomplish this, separate agendas or sections within combined agendas shall identify OPTN versus UNOS corporate business. The UNOS Board of Directors shall convene and function as the OPTN Board of Directors for purposes of conducting OPTN affairs and as the UNOS Board of Directors for purposes of conducting UNOS corporate affairs. Consistent with this framework, UNOS Committees are appointed in parallel with OPTN Committees and operate under these same procedures.\textsuperscript{175}

In June 2006, the OPTN/UNOS Board resolved that the organizational bylaws be amended such that OPOs and transplant hospitals "must develop by January 1, 2007 (and once developed must comply with), protocols to facilitate the recovery of organs from DCD donors."\textsuperscript{176} At its December 2006 Board meeting, OPTN/UNOS adopted a set of "model elements” which would be “required to be addressed in OPO and Transplant Hospital DCD Recovery Protocols.”\textsuperscript{177}

\begin{flushleft}
\textsuperscript{175} United Network for Organ Sharing, Bylaws art. II, § 2.11(June 22, 2010), available at http://www.unos.org/docs/Article_II.pdf.

\end{flushleft}
These model elements include sections on suitable candidate selection, consent/approval, withdrawal of life sustaining measures/patient management, pronouncement of death, organ recovery, and financial considerations.\footnote{Organ Procurement and Transplantation Network, Executive Summary of the Minutes OPTN/UNOS Board of Directors Meeting (Dec. 13-14, 2006) 3 (2006), available at http://optn.transplant.hrsa.gov/SharedContentDocuments/Executive_Summary_of_BOD_Meeting_Dec-2006.pdf.} OPTN/UNOS set a required effective date of July 1, 2007 for compliance to this requirement.\footnote{Press Release, United Network for Organ Sharing, OPTN/UNOS Board Addresses Protocols for Donation after Cardiac Death, Standards for Transplant Surgeons and Physicians (Mar. 23, 2007) (on file with author), available at http://optn.transplant.hrsa.gov/news/newsDetail.asp?id=829.} In a press release issued March 23, 2007, Sue V. McDiarmid, president of UNOS and the OPTN and chair of the OPTN/UNOS Board of Directors, stated that “the model elements are meant to give consistent direction for DCD protocols, without attempting to prescribe specific medical practice of organ procurement organizations and hospitals.”\footnote{Organ Procurement and Transplantation Network, OPTN Evaluation Plan (Updated June 30, 2010), at Bylaws-18 (2010), available at http://optn.transplant.hrsa.gov/SharedContentDocuments/Evaluation_Plan_508_093010.pdf.} However, the OPTN Bylaws presently include membership criteria for OPOs and transplant hospitals that require OPOs and transplant hospitals to develop and comply with DCD protocols.\footnote{Id. at 1, 12.} The criteria also require that those protocols “must address the required model elements.”\footnote{Id. at 1, 12.}

Writing in the New England Journal of Medicine, the physician Robert Steinbrook reported the compulsory nature of these actions concerning DCD. He observed that “OPTN/UNOS has required all 257 transplant hospitals and 58 organ procurement organizations in the United States to comply with its new...
OPTN/UNOS has also required all member OPOs and transplant hospitals to supply a certification statement attesting to their implementation of a mandatory DCD organ recovery protocol. As of February 2008 two transplant hospitals had notified UNOS that they would not comply with the mandatory DCD organ recovery protocol on philosophical and ethical grounds. For their noncompliance, these hospitals were subject to the possibility of reprimand and adverse action by OPTN/UNOS.

Given that 42 C.F.R. §§ 486.320 and 482.72 require organ procurement organizations and transplant hospitals respectively to maintain membership in the OPTN, the OPTN bylaws provisions and model elements may seem to have the de facto force of federal regulation.

However, in order for the OPTN bylaws and policies to have actual force of federal regulatory authority, they must first be approved by the Secretary of Health and Human Services and in


185. OPTN/UNOS MEMBERSHIP AND PROFESSION STANDARDS COMMITTEE, REPORT OF THE OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE TO THE BOARD OF DIRECTORS (FEB. 20-21, 2008), at *10 (2008), available at http://optn.transplant.hrsa.gov/CommitteeReports/board_main_Membership&Prof.StandardsCommittee(MPSC)_2_25_2008_13_57.pdf. Two (of 269) transplant hospitals had refused compliance with the mandatory DCD protocol requirement, one due to refusal of the medical staff to approve DCD for their hospital, and the other due to refusal of its physicians to perform DCD after “a bad experience” with a DCD case. OPTN assigned its DCD Advisory Committee to address the issues with the hospitals under threat of an OPTN letter of reprimand or adverse action. Id. A Jan. 2011 search of the OPTN website found no public record of reprimand or adverse action taken against a transplant hospital on grounds of noncompliance to the DCD requirements. http://optn.transplant.hrsa.gov/.

many instances must proceed through a federal rulemaking process.\textsuperscript{187} The Centers for Medicare and Medicaid Services made note of this fact in a comment to its May 31, 2006, final rule regarding conditions for coverage for organ procurement organizations, and clarified the extent of the rulemaking requirement as it pertains to OPTN policies and bylaws:

To be enforced by CMS, rules and requirements of the OPTN (that is OPTN policies and bylaws, which include definitions of terminology used by the OPTN and its members) must be approved formally by the Secretary by being published in the \textit{Federal Register} with an opportunity for the public to comment. However, no policy or bylaw of the OPTN has been approved by the Secretary in this manner. In most instances, we must include the specific language of the OPTN policy or bylaw in order to make it a requirement.\textsuperscript{188}

To date, neither the OPTN bylaws requirements mandating that OPOs and transplant hospitals develop and comply with DCD protocols nor the OPTN Model Elements for Controlled DCD Recovery Protocols have been published in the \textit{Federal Register}. It thus is unclear that any disciplinary action by the OPTN regarding these provisions could be the basis for a loss of Medicare and Medicaid participation. Furthermore, CMS has directly stated that any disciplinary action by the OPTN excluding a transplant hospital from membership is subject to HHS approval. In promulgating 42 C.F.R. § 482.72, concerning maintenance of OPTN membership by transplant hospitals, CMS specifically noted that “No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or of this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to ex-

\textsuperscript{187} OPTN Policies, Secretarial Review and Appeals, 42 C.F.R. § 121.4 (2009).

\textsuperscript{188} Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs); Final Rule (Summary of the Proposed Provisions and Response to Comments on the February 4, 2005 Proposed Rule), 71 Fed. Reg. 30982, 30986 (May 31, 2006).
clude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.\textsuperscript{189}

Thus, our Committee review finds that the OPTN/UNOS position is that adoption of and compliance with a donation after cardiac death protocol is a condition of membership in those organizations for any organ procurement organization or transplant hospital. The DCD protocol must address the OPTN model elements for controlled DCD recovery protocols, although these elements are held as non-prescriptive by OPTN/UNOS. Failure to comply with these requirements places an organ procurement organization or transplant hospital in jeopardy of loss of OPTN membership, but it is unclear as to whether such action by OPTN/UNOS could be derivatively be construed as a de facto basis for federal disciplinary action. Any action by the OPTN to exclude a transplant hospital from membership must be approved by the Secretary of HHS in order to be actionable.

B. Governmental Entity Initiatives Relating to Donation After Cardiac Death

As noted in Parts IV.B.3 & 4 supra, in 2006 the Centers for Medicare and Medicaid Services promulgated federal regulations regarding agreements between hospitals and OPOs concerning DCD. CMS has required that written agreements between an OPO and Medicare and Medicaid participating hospitals and critical access hospitals must describe the responsibilities of both the OPO and hospital concerning donation after cardiac death (if the OPO has a protocol for donation after cardiac death).\textsuperscript{190} CMS has also provided minimum requirements for OPO DCD protocols.\textsuperscript{191} On March 30, 2007, CMS promulgated regulations authorizing the survey and certification of transplant programs.\textsuperscript{192} The final

\begin{thebibliography}{9}
\bibitem{189}Centers for Medicare and Medicaid Services; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants; Final Rule, 72 Fed. Reg. 15198, 15274 (Mar. 30, 2007) (codified at 42 C.F.R. 482.72).
\bibitem{190}Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs); Final Rule, 71 Fed. Reg. 30982, 31051 (May 31, 2006) (codified at 42 C.F.R. §§ 486.322 (a) & 486.344 (f) (2010)).
\bibitem{191}Id.
\bibitem{192}Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants: Final Rule, 72 Fed. Reg. 15198, 15197-15280 (Mar. 30, 2007).
\end{thebibliography}
rule codified requirements for approval and re-approval of transplant entities as conditions of participation in the federal program, and placed Medicare approved transplant centers under the survey and certification enforcement process used for all other providers and suppliers of Medicare services. This rule set forth requirements regarding OPTN membership, certain notifications to CMS, pediatric transplants, data submission, patient and living donor selection, organ recovery and receipt, patient and living donor management, quality assessment and performance improvement, human resources, organ procurement, patient and living donor rights, and certain additional requirement for kidney transplant centers.

The rule required that “a transplant center must be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274).” The rule made no requirement that a hospital have a protocol for donation after cardiac death. However, given the recent OPTN/UNOS Board action to require a DCD protocol as a condition of OPTN membership for OPOs and transplant centers, this rule might be construed to have established a de facto federal mandate for a DCD protocol for OPOs and hospitals with transplant centers.

In comments to the rule, CMS did make specific recommendations regarding informed consent and disclosure for recipients who will receive donation after cardiac death organs. The comment stated that, “the fact that transplantation of certain types of organs (such as ECD or DCD organs) may have an effect on patient or graft survival must be discussed with transplant candidates, as appropriate.”

193. Id.
194. Id.
195. 42 C.F.R. § 482.72 (2010).
196. The enforceability of this interpretation is subject to argument. See discussion Part V.A., supra.
197. Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants: Final Rule, 72 Fed. Reg. 15197, 15240 (Mar. 30, 2007). ECD refers to an extended (or expanded) criteria donor, defined by the OPTN as a donor over age 60 years, or over age 50 years with specified co-morbid medical condi-
There has also been specific federal discussion as to expansion of the defrayment of the costs of donation after cardiac death organ procurement as a means of promoting DCD. In its 2006 Spring Meeting, the Advisory Committee on Organ Transplantation (ACOT) of the US Department of Health and Human Services (DHHS) noted that CMS generally reimburses OPOs for the direct acquisition costs of organ procurement in traditional procurement from brain dead donors beginning at the time of the declaration of brain death. ACOT noted that the timing particular to DCD resulted in a number of costs occurring after the decision to withdraw care and before the declaration of death. These costs are not presently reimbursable by CMS. As the OPTN model elements for DCD protocols require that “OPO policy shall insure that no donation related charges are passed to the donor family” these costs are not generally incurred by the donor family, and are presently the responsibility of the OPO. In November 2006, ACOT recommended to the Secretary of DHHS that the Medicare program allow donation after cardiac death direct organ acquisition expenses to be reimbursable to the organ procurement organization. The recommendation notes that the action would “thereby remove a financial barrier to donation.” To date, this remains unresolved.

Thus, our Committee review finds that specific federal involvement in donation after cardiac death at present remains limited.

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199. OPTN MODEL ELEMENTS, supra note 177, at *2. See also ACOT SPRING 2006 MEETING, supra note 197.


201. Id.
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CMS presently provides no direct federal requirement that a hospital or OPO have a DCD protocol. However, federal rules have required that hospital/OPO agreements address responsibilities concerning DCD if the OPO has a DCD protocol, and have established minimum requirements for OPO DCD protocols. Recent federal rules have also required that transplant centers and OPOs maintain OPTN membership. The OPTN has required as a condition of membership that transplant centers and OPOs adopt a DCD protocol. Federal rules have established minimal requirements regarding informed consent for use of DCD organs. Expanded Medicare funding for DCD procurement expenses remains under advisement.

C. Accreditation Entity Initiatives Relating to Donation after Cardiac Death

The Joint Commission on Accreditation of Healthcare Organizations first required hospitals to have policies and procedures for organ and tissue procurement in 1988. In its 2004 white paper entitled Health Care at the Crossroads: Strategies for Narrowing the Organ Donation Gap and Protecting Patients, the Joint Commission put forward a public policy “action plan” designed to create a culture in which organ donation is a priority, to bring equity, fairness, and safety to the transplantation process, and to take alternative paths to meet the demand for organ donation. Among numerous recommendations in the report was the recommendation that protocols be implemented for the recovery of organs from donors after cardiac death.

In June 2006, the Joint Commission published a modification to its accreditation Leadership Standard LD.3.110, which


204. \textit{Id.} at 9.
pertains to the implementation of policies and procedures for procuring and donating organs and other tissues. Among the revisions was the addition of new language to the Element of Performance 12 by which the Joint Commission scores compliance with the Standard. This language provided that the organization must work with the OPO and tissue and eye banks to “develop a donation policy that addresses opportunities for asystolic recovery, based on an organ potential for donation that is mutually agreed upon by the designated OPO, hospital, and medical staff.”

In May 2007, the Joint Commission clarified that it was not requiring all hospitals to provide donation after cardiac death:

Standard LD.3.110 Element of Performance 12 has been revised to clarify its requirements respecting the procurement and donation of organs and other tissues. EP 12 requires hospitals to have a policy that addresses opportunities for asystolic recovery (often known as “donation after cardiac death”). While the EP does not require hospitals to provide for asystolic recovery, it does require that the policy be mutually agreed upon by the hospital, its medical staff, and its Organ Procurement Organization (OPO)....The EP has been revised to include the following: When the hospital and its medical staff agree not to provide for asystolic recovery and cannot achieve agreement with the designated OPO, the hospital documents its efforts to reach an agreement with its OPO, and the donation policy addresses the hospital’s justification for not providing for asystolic recovery.

Thus, our Committee review finds that the Joint Commission position is that, although a hospital is not required to perform donation after cardiac death organ recovery, a hospital must


206. Id.

207. Joint Commission on Accreditation of Healthcare Organizations, Revised Standard Regarding Procurement and Donation of Organs and Other Tissues, This Month at the Joint Commission, May 2007.
have a policy regarding DCD. That policy could be not to provide DCD. Any policy to provide or not provide donation after cardiac death organ recovery must be mutually agreed by the hospital, the medical staff, and the OPO. The Joint Commission standard provides for the possibility of the inability of the hospital and medical staff to reach an agreement with the OPO regarding a decision not to provide donation after cardiac death organ recovery.

VI. PRINCIPAL ETHICAL CONCERNS RAISED BY DONATION AFTER CARDIAC DEATH

In its 2000 follow-up report on donation after cardiac death, Non-Heart-Beating Organ Transplantation: Practice and Protocols, the Institute of Medicine reported a survey of organ procurement organization contacts regarding impediments to the development of DCD protocols within their organizations. Among the ethical concerns identified were resistance to discontinuing life support, perceived association with physician-aid-in-dying, and medical interventions or determinations of death. The Canadian Council for Donation and Transplantation, in conducting a national forum to discuss whether and how to proceed with DCD in Canada, identified ethical implications of DCD for exploration to include defining death independent of the needs of organ donation and transplantation, interventions on patients before expressed or granted consent, interventions after consent, potential conflicts of interest, and protecting and serving the public. These reports exemplify two distinctively different ethical perspectives—the first maintaining a principal ethical concern that donation after cardiac death be perceived properly, and the second maintaining a principal ethical concern that donation after cardiac death be performed properly.


209. Id. at 14.

The first perspective has already judged the current practice of donation after cardiac death to be medically and legally acceptable. It finds DCD proper at a moral level in that by proceeding with organ donation DCD seeks the good for the terminally ill donor, the donor’s family, the recipient, and society. Ongoing ethical concerns in this perspective are grounded in analogy to arguments developed forty years ago legitimizing organ donation from brain dead donors. These arguments essentially stated that if death has occurred and good may come of it through organ donation, then a societal prohibition of that good is immoral. Modern DCD practice concludes that if death is to occur then a similar good may come, that societal prohibition of that good is immoral, and that societal resistance to that good generates an ethical imperative. Under this perspective, the ethical imperative for DCD practice must center on education of society as to its benefits and promotion of its acceptance.

The second perspective accepts the argument that organ donation from a dead donor is moral, and that patient autonomy in withdrawal of life supportive measures for the terminally ill is ethical, but concludes that linkage of these as the fundamental construct of donation after cardiac death bears exceptional scrutiny since the patient in whom DCD is first contemplated is not yet dead. This perspective seeks the good through focus on the sanctity of the patient’s life and on the integrity of the patient’s autonomy. Under this perspective the ethical imperative for DCD practice is that the sanctity of life and the integrity of autonomy not be violated.

In extensive discussion of a proposed policy governing donation after cardiac death within the Willis-Knighton Health System, the Institutional Ethics Committee judged the second perspective as fundamental in importance. Over a two year period of review, our Committee identified and addressed several principal ethical concerns regarding DCD. These include the extrapolation of existing organ donation statutes and regulations to the practice of donation after cardiac death, the proper determination of cardiac death, the interpretation of the concepts of irreversibility and cessation as they pertain to the determination of death, the proper standard for the determination of death in the practice of organ donation after cardiac death, and practical ethical concerns related to the inviolability of the dead donor rule.
A. The Extrapolation of Existing Organ Donation Statutes and Regulations to the Practice of Donation after Cardiac Death

1. Extrapolation of the Statutory Provisions of the Uniform Anatomical Gift Act

It is fairly certain that at the time of the enactment of organ donation statutes their application was directed at promotion of organ recovery from brain dead donors, but did not intend the current practice of “controlled” donation after cardiac death. Despite concurrent discussions of the right to withdraw life-sustaining treatment and of the issues raised by living wills and the permanently unconscious patient, and despite the contemporaneous enactment of “Natural Death Acts,” statutes developed to promote organ donation did not make reference to organ donation in the context of a withdrawal of life supportive measures in a patient who was terminally ill but not brain dead.\(^{211}\) Likewise, donation after cardiac death, at least in its uncontrolled construction, was clearly a well known practice in the transplant community during this time, but was not incorporated into the development of organ donation statutes and regulations.\(^{212}\)

A review of the documentary history supports the proposition that the statutory framework of organ donation was intended solely for use in brain dead donors, and did not conceive the modern practice of donation after cardiac death. In promulgating the Uniform Anatomical Gift Act of 1968, the NCCUSL declined to define death in the Act. However, in discussion on that point in comment on Section 7 of the Act, the NCCUSL made it clear that it considered death in reference to the Act as inclusive of an irreversible loss of normal brain activity in the presence of supportive measures and that it was demurring on precise criteria defining death in those circumstances:

\(^{211}\) See generally President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Deciding to Forego Life-Sustaining Treatment: A Report on the Ethical, Medical, and Legal Issues in Treatment Decisions (1983) for an extensive exploration of issues surrounding the development of natural Death Acts. At the time of the publication of this report twelve states had enacted a Natural Death Act. See id. fig.1, at 138.

\(^{212}\) See discussion supra Part II regarding contemporaneous descriptions of the practice of donation after cardiac death.
Subsection (b) leaves the determination of the time of death to the attending or certifying physician. No attempt is made to define the uncertain point in time when life terminates. This point is not subject to clear cut definition and medical authorities are currently working toward a consensus on the matter. Modern methods of cardiac pacing, artificial respiration, artificial blood circulation and cardiac stimulation can continue certain bodily systems and metabolism far beyond spontaneous limits. There real question is when have irreversible changes taken place that preclude return to normal brain activity and self sustaining bodily functions. No reasonable statutory definition is possible.\footnote{213}

Section 7 of the UAGA of 1968 became the basis for Louisiana Revised Statutes section 17:2357 as enacted in 1968, appropriating the “time of death” phraseology without further comment to the definition of death:

The time of death shall be determined by the physician who attends the donor at his death, or, if none, the physician who certifies death. The physician shall not be a participant in the procedures for removing the part or transplanting it.\footnote{214}

The contextual inference is that both the Uniform Anatomical Gift Act and, derivatively, the Louisiana Anatomical Gift Act, originally conceived organ donation to occur after an irreversible loss of brain functions. The Task Force on Organ Transplantation also intended organ donation to be applied in brain dead patients, stating this fact more explicitly:

The Task Force finds that a major problem with the current voluntary system of organ donation is that families often are not informed of their option to donate organs and tissues after brain death is determined.\footnote{215}


\footnote{215. TASK FORCE REPORT, supra note 71, at 29.}
Furthermore, the Task Force clearly distinguished between organ recovery from brain dead patients and tissue recovery from other patients, presumably non-heartbeating donors, stating:

Postmortem surgical recovery of organs (but not tissues) requires that death be pronounced under circumstances in which total brain function has ceased, and circulation and lung functions are temporarily mechanically maintained (i.e., a heartbeat-ing cadaver). This condition, defined as brain death, is relatively rare.  

The Task Force on Organ Transplantation thus expressly indicated an understanding that organ donation was to occur in brain dead donors and tissue recovery to occur in a broader group of cadaveric donors, presumably including non-heart beating donors.  

Although the NCCUSL commented that the 1968 UAGA “authorizes the survivors to execute the necessary documents even prior to death,” it is explicitly clear that the actionable gift was not to occur until after death. In the Prefatory Note to the 1968 Uniform Anatomical Gift Act, the NCCUSL identified several “principal legal questions” concerning competing interests in a dead body which the UAGA was designed to address.  

Among these interests were “what is the right of the next of kin, either to set aside the decedent’s expressed wishes, or themselves to make the anatomical gifts from the dead body.”  

This referral to rights exercised postmortem was intended to include donors determined by both brain and cardiac death criteria. However, the historical context makes it clear that the premortem execution of a gift document could apply only in cases of severely brain injured patients with impending brain death. For other patients not yet dead, the next of kin had no legal right to make an anatomical gift. This

219. Id. (emphasis added).
structure was preserved in the 1987 UAGA.\textsuperscript{220} Under this structure, donation after cardiac death would require that the family rapidly make an anatomical gift statement immediately after the pronouncement of death.

Without specifically mentioning donation after cardiac death, Section 4 of the 2006 revision to the Uniform Anatomical Gift Act addressed this limitation, allowing an agent of the donor to make an anatomical gift before the donor’s death.\textsuperscript{221} The NCCUSL also interjected deliberate uncertainty as to provisions of the Act governing the timing of a gift relative to the time of death, allowing at least an interpretive application of its provisions in a manner consistent with the modern practice of controlled organ donation after cardiac death.\textsuperscript{222} The 2006 UAGA codifies in Section 9 the persons who may make an anatomical gift of a decedent’s body or part and sets forth in Section 10 the manner of making of that gift.\textsuperscript{223} The text of the Act specifically indicates that these gifts, known as Section 10 gifts, are to be made of


\textsuperscript{222} REVISED Unif. Anatomical Gift Act (2006) § 9, 8A U.L.A. 91, 91 (Supp. 2011) (emphasis added). The text provides that “Subject to subsections (b) and (c) and unless barred by Section 7 or 8, an anatomical gift of a decedent’s body or part for purpose of transplantation, therapy, research, or education may be made by any member of the following classes of persons....” Id.

a decedent’s body or part. However, the Act defines a “prospective donor” and in comment the NCCUSL clarifies that this term “includes a non-donor individual at or near the time of death with parts that are medically suitable for donation who could become a donor if the individual’s family made an anatomical gift under Section 9.” The Commissioners note that “[p]ersons who can make an anatomical gift under Section 9 often will be consulted whether they would be willing to make a gift when the prospective donor is near death.” In comment to Section 10 the NCCUSL candidly sets forth its purpose, stating:

“This [act] is silent regarding whether a Section 10 gift can be made while a donor or prospective donor is near death or whether the gift can only be made after the donor or prospective donor has died. This is purposeful in order to allow procurement organizations and the person having the priority to make an anatomical gift under Section 9 some latitude as to when to sign a document of gift.”

The 2010 revisions to the Louisiana Anatomical Gift Act contained in title 17 of the Louisiana Revised Statutes closely tracked the provisions of the 2006 UAGA, generally codifying anatomical gift provisions of the 2006 UAGA Section 4 in Louisiana Revised Statutes section 17:2352, Section 9 in section 17:2354.3(A)-(C), Section 10 (a) in section 17:2354.3(D)(1), and also providing a definition of “prospective donor” in Louisiana Revised Statutes section 17:2351 Par. (22).

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Our Committee concluded that neither the NCCUSL in 1968 nor the Task Force on Organ Transplantation in 1986 conceived or interpreted the statutory framework of anatomical gift acts to include the practice of controlled non-heartbeating organ recovery as performed in the modern construction of controlled organ donation after cardiac death. Modern DCD practice has extrapolated the statutory framework of anatomical gift acts beyond original intent. The construction of both the 1968 and 1987 acts could allow controlled DCD only if a gift were executed immediately upon death of the donor. Our Committee has concluded that the 2006 UAGA explicitly allows an agent to make a pre-mortem anatomical gift in a manner that is consistent with modern DCD practice. The explicit structure of the 2006 UAGA otherwise would not contemplate DCD outside the context of a gift executed immediately after death of the donor, although the NCCUSL clearly intended to allow a permissive expansion of its application in a manner that would be consistent with modern DCD practice. The 2010 revisions to the Louisiana Anatomical Gift Act make no specific reference to organ donation after cardiac death, but track the 2006 UAGA provisions.

2. Extrapolation of the Regulatory Structure of Required Request Rules

Review of the historical record finds no indication that the development of required request regulations intended a premortem routine inquiry such as is contemplated in modern donation after cardiac death practice. Professor Arthur Caplan, credited as “the originator of the idea of ‘required request’,” unequivocally set forth in 1988 the time to approach the family of the donor. Describing conditions for required request, he stated, “Strong required request laws are quite specific about the fact that no requests are to be made until death has been pronounced.” All of the state routine inquiry statues recorded in the report of the Task Force on Organ Transplantation referenced an inquiry occurring after death.

234. Caplan, supra note 75, at 36.
235. TASK FORCE REPORT, APP. D, supra note 71, at 199-213. Although termed “routine inquiry” statutes in the Report, these statutes are more proper-
The Task Force itself clearly intended that required request occur only after death had been pronounced, stating in its report:

Given the benefits of organ and tissue donation to both families and recipients, the Task Force believes that trained health professionals either should discuss organ donation with families of all deceased patients who are suitable candidates for organ donation or should refer the patient to a regional organ and/or tissue procurement organization, so that a procurement coordinator will have an opportunity to approach the family.\(^{236}\)

Although current CMS regulations mandate hospitals to conduct a required request of potential donors,\(^{237}\) commentary contemporaneous to the development of required request provisions conceived the potential donor to be a patient with impending brain death.\(^{238}\) Despite the fact that the current regulatory climate allows the term “potential donor” to be subject to definition as agreed between the hospital and the OPO,\(^{239}\) the historical context is that the development of required request regulations conceived a premortem required request for brain dead donors and impending brain-death patients, and did not anticipate the modern practice of donation after cardiac death.

In the current statutory and regulatory environment, the practice of donation after cardiac death has extrapolated statutes and regulations originally designed to facilitate and promote donation of organs and tissues from brain dead individuals, from individuals recently deceased by cardiorespiratory criteria, or from patients whose brain death is “imminent,” to situations in which the patient is not brain dead and is being sustained by life-supportive measures in a terminally ill state, with a planned

\(^{236}\) Task Force Report, supra note 71, at 31-2.
\(^{237}\) Condition of Participation: Organ, Tissue, and Eye Procurement, 42 CFR § 482.45(a)(3) (2010).
\(^{238}\) See discussion Part IV.B.1 supra.
\(^{239}\) See discussion Part IV.B.3 supra.
withdrawal of life supportive measures consistent with a natural death statute. In many DCD cases, death of the patient is “imminent” only because of contemplation of a planned withdrawal of life supportive measures. In most cases, the current practice of DCD applies anatomic gift provisions regarding timely notification, suitability determination, required request, and maintenance of potential donors to patients who are not yet dead and whose death will be “imminent” only after action to withdraw life-supportive measures is taken pursuant to an affirmative decision by the patient or family to do so.

Upon review of the applicable statues and regulations, our Committee concluded that the modern practice of controlled donation after cardiac death is not inconsistent with the provisions of the statutory and regulatory environment. However, we also felt that donation after cardiac death has ventured beyond the original intent of the organ donation statutes and regulations, and exists only by implicit application of the general scope of current organ donation statutes and regulations. This may explain the permissive rather than mandatory approach to donation after cardiac death taken by CMS. Our Committee concluded that that the extrapolation of statutory and regulatory governing authority beyond its original intent clearly warranted a heightened level of scrutiny and oversight to organ donation after cardiac death, both as to policy development and as to ongoing practice.

B. The Proper Determination of Cardiac Death

Because donation after cardiac death donors do not meet criteria for brain death at the time of withdrawal of life-supportive measures, a fundamental early concern raised by the practice of donation after cardiac death was whether the donor was in fact dead. The 1997 Institute of Medicine report succinctly stated that, “Donor patients must not be killed or their death hastened by the taking of organs.” This understanding has historically been the foundation of “the dead donor rule” which, as an internationally recognized norm for organ transplantation,
provides that vital organs without which the donor could not live shall only be taken from a dead person.\textsuperscript{241}

In the practice of organ donation after cardiac death, life supportive measures are withdrawn and the patient is observed for cessation of cardiac and respiratory function. Death is pronounced by cardiorespiratory criteria, and then organ procurement expeditiously begins. DCD explicitly relies on a declaration of death by cardiorespiratory criteria, and involves the removal of vital organs in a compressed time frame following cardiac death. As in cases determined by brain death criteria, if organ procurement were to begin prior to death an unconscionable moral lapse and a criminal act would occur.\textsuperscript{242} Clearly, the proper determination of cardiac death is fundamental to the legal and ethical practice of DCD. A careful re-examination of what constitutes the proper determination of cardiac death is thus imperative.

Prior to the modern development of life-supportive measures, physicians found the determination of death to be intuitively apparent as the termination of life. Both Hippocrates and Osler spoke extensively of conditions ending in death and signs portending death, but neither labored over the determination of death.\textsuperscript{243} The traditional common law, reflecting the practical

\begin{itemize}
  \item \textsuperscript{241} See the discourse of Pope John Paul II, stating “In effect, transplantation presupposes a prior, explicit, free and conscious decision on the part of the donor or of someone who legitimately represents the donor, generally the closest relatives. It is a decision to offer, without reward, a part of one's own body for the health and well-being of another person.... Furthermore, a person can only donate that of which he can deprive himself without serious danger or harm to his own life or personal identity, and for a just and proportionate reason. It is obvious that vital organs can only be donated after death.” His Holiness, Pope John Paul II, Address of His Holiness John Paul II to Participants of the First International Congress of the Society for Organ Sharing (June 20, 1991), http://www.vatican.va/holy_father/john_paul_ii/speeches/1991/june/documents/hf_jp-ii_spe_19910620_trapianti_en.html (last visited Jan. 29, 2011). See also Youngner et al., supra note 16, at 2771.
  \item \textsuperscript{242} See JOHN A. ROBERTSON, THE DEAD DONOR RULE, 29 HASTINGS CEN. REP. 6, 6 (1999). The author states that “laws and norms against homicide forbid killings done for any purpose, including killings done to obtain organs to save the life of others. These laws and norms apply even if the person is unconscious, extremely debilitated, or very near death.” Id.
  \item \textsuperscript{243} See generally HIPPOCRATES, ANCIENT MEDICINE AND OTHER TREATISES (Francis Adams trans., Henry Regnery Co. 1949) and WILLIAM OSLER, THE PRINCIPLES AND PRACTICE OF MEDICINE (D. Appleton and Co. 8th ed. 1912)
\end{itemize}
legal necessity of defining death, incorporated this intuitive sense and centered on cessation of circulatory function. An early text of medical jurisprudence, containing facts “likely to be of practical utility to students of medicine and law” stated, “the verification of death is occasionally a duty thrown on the medical jurist. Certain signs, or indications, have been pointed out as proving that death is real, and not apparent.” First in order of importance among several signs listed was the cessation of circulation and respiration:

The proof of death is the proof of the cessation of the heart’s action for a certain period. The more visible indication of death is the cessation of breathing....The movements of respiration cannot be overlooked by any one who does not choose to overlook them, and the heart never continues to act for more than four or five minutes after respiration has ceased.

However, in 1855 the British physician Thomas Hawkes Tanner presaged modern conceptual discussions of the determination of death, describing death as a unitary generalized physiologic event involving the heart, lungs, and brain:

Death as it occurs in disease is usually complicated; but in all cases, whether it take place suddenly or gradually, or whatever may be the malady, it approaches through one of the three vital organs—the brain, the heart, or the lungs. Life being inseparably connected with the circulation of arterial blood, death takes place directly the action of the heart is completely arrested [sic]; and since the action of the heart is dependant upon the more or less perfect condition of all the vital organs, which stand in a

(1892). Neither of these great physicians, one of antiquity and the other of modernity, found it necessary to define the determination of death in these works of clinical teaching.

244. ALFRED SWAINE TAYLOR, A MANUAL OF MEDICAL JURISPRUDENCE v
(Henry C. Lea, 1873).
245. Id. at 60.
246. Id. at 60.
peculiar relationship to each other, a cessation of the functions of either of the three speedily arrests the remaining two....And so it results that failure in any one of the three links in the chain is fatal.\textsuperscript{247}

As a more practical matter, Dr. Tanner further defined “forms” of death at the level of individual physiologic systems as 
Death by Anaemia (“a want of due supply of blood to the heart”),
Death by Asthenia (“a total failure of the contractile power” of the heart),
Death by Asphyxia (“when the entrance of air into the lungs is in any way stopped”), and
Death by Coma (“the sensibility ceases first, and in consequence of this the movements of the thorax are arrested, as well as the chemical functions of the lungs”).\textsuperscript{248} Having dealt with practicalities, Dr. Tanner then presciently anticipated modern proposals to define death as a failure of a specific physiologic system. He returned the argument to death as a failure of the integrated function of the brain, heart, and lungs:

[I]n death by apnea, the chemical functions of the lungs cease first, and then the circulation of venous blood through the arteries suspend the sensibility; whereas in death by coma, the sensibility ceases first, and in consequence of this the movements of the thorax are arrested, as well as the chemical functions of the lungs. Thus the circulation of venous blood through the arteries is, in the one case the cause, in the other the effect, of the cessation of animal life.\textsuperscript{249}

As modern medical technology developed, the use of the mechanical ventilator and the cardiac pacemaker made it possible to obscure the irreversible cessation of spontaneous respiratory and circulatory functions. The failure of the sensibility described by Dr. Tanner no longer arrested the lungs and heart, and “Death by Coma” became a confused concept. Patients who had sustained the total cessation of brain function could be maintained physio-

\textsuperscript{247} THOMAS HAWKES TANNER, A MANUAL OF CLINICAL MEDICINE AND PHYSICAL DIAGNOSIS 75 (Blanchard and Lea, 2nd ed 1855).
\textsuperscript{248} Id. at 75-6.
\textsuperscript{249} Id. at 76.
logically in a hospital, never meeting the traditional common law cardiorespiratory requirement for death, and becoming what the medical ethicist Paul Ramsey termed “an unburied corpse.”

As courts began to struggle with these issues, early jurisprudence favored continued reliance on the traditional common law cardiorespiratory definition of death. In 1967, the Supreme Court of Kansas, ruling in an estate case, stated that, “Death is the complete cessation of all vital functions without possibility of resuscitation.” Although resuscitative, life-supportive, and transplantation technologies were not at issue in this case, this forceful statement of the pre-eminence of the common law conception of death in the context of the recent development of such technologies drew immediate concern in the medical community. In 1968 Dr. Martin Halley, a Kansas cardiothoracic surgeon and MD/JD, and Professor William F. Harvey, of the Washburn University School of Law, noted that technological advances in supportive therapy and organ transplantation had reopened the question of determination of death and had “resulted in recognition of intrinsic differences between medical and legal definitions of death—an area in which exactitude, uniformity, and agreement are desirable.”

They specifically noted that, although the medical definition and the legal definition both involved cessation of respiration and circulation, the medical definition included insensibility and irreversibility whereas the legal definition included a cessation of “vital functions” and impossibility of resuscitation.

Pressed by these developments, in 1970 Kansas became the first state to adopt a statutory definition of death:

250. RAMSEY, supra note 11, at 64.
253. Id. at 425.
Definition of Death. A person will be considered medically and legally dead if, in the opinion of a physician, based on ordinary standards of medical practice, there is the absence of spontaneous respiratory and cardiac function and, because of the disease or condition which caused, directly or indirectly, these functions to cease, or because of the passage of time since these functions ceased, attempts at resuscitation are considered hopeless; and, in this event, death will have occurred at the time these functions ceased; or

A person will be considered medically and legally dead if, in the opinion of a physician, based on ordinary standards of medical practice, there is the absence of spontaneous brain function; and if based on ordinary standards of medical practice, during reasonable attempts to either maintain or restore spontaneous circulatory or respiratory function in the absence of aforesaid brain function, it appears that further attempts at resuscitation or supportive maintenance will not succeed, death will have occurred at the time when these conditions first coincide. Death is to be pronounced before artificial means of supporting respiratory and circulatory function are terminated and before any vital organ is removed for purposes of transplantation.

These alternative definitions of death are to be utilized for all purposes in this state, including the trials of civil and criminal cases, any laws to the contrary notwithstanding.\textsuperscript{254}

In addition to being the first statutory enunciation of the traditional common law conception of death, the Kansas statute was the first statutory construction to explicitly recognize and define brain death, utilizing as its standard “the absence of spontaneous brain function” conditionally dependent upon

\textsuperscript{254} L. 1970, ch. 378, § 1; L. 1979, ch. 199, § 11 (codified as K.S.A. § 77-202, repealed by, L. 1984, ch. 345, § 4; July 1, codified as K.S.A. § 77-205 (2006)).
“reasonable attempts to either maintain or restore spontaneous circulatory or respiratory function” and upon an appearance that “further attempts at resuscitation or supportive maintenance will not succeed.” The Kansas Supreme Court subsequently noted that the statute “allowed two separate standards to be applied to the single phenomenon of death,” those being “cardiac-respiratory death” and “brain death.” This dual construction was criticized by Professor Ian McColl Kennedy as “the existence in legislative form of what appear to be alternative definitions of death.” The subsequent President’s Commission Report described the Kansas statute as complex and as seeming to create a more lenient standard for the definition of death for potential organ donors.

In response to the general confusion, and also responding to the technical concerns generated by recent medical advances and the moral challenges brought forward by organ donation, Professor Alexander Morgan Capron and Dr. Leon Kass published a proposed model statute defining death “as a single phenomenon measured by different standards” in 1972.

A person will be considered dead if in the announced opinion of a physician, based on ordinary standards of medical practice, he has experienced

255. Id.
256. State v. Shaffer, 574 P.2d 205, 209 (1977). (The Court ruled in this murder case that the application of two separate standards for death was not unconstitutionally vague and that, “There is no constitutional requirement that a single standard be used.”) The 1984 Kansas statute adopted provisions of the Uniform Determination of Death Act, providing that, “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” Kan. Stat. Ann. §77-205 (L. 1984, ch. 345, § 1; July 1, codified as K.S.A. § 77-205 (2006)).
257. Ian McColl Kennedy, The Kansas Statute on Death: An Appraisal, 285 New Eng. J. Med. 946, 947 (1971). (Professor Kennedy went on to say that, “Common sense seems to dictate that death is but of one nature, though its manifestations may vary. It is in no way inspiring of confidence in one’s doctor to learn that there are two types of death.”) Id.
258. The President’s Commission Report on Defining Death, supra note 19, at 63.
an irreversible cessation of spontaneous respiratory and circulatory functions. In the event that artificial means of support preclude a determination that these functions have ceased, a person will be considered dead if in the announced opinion of a physician, based on ordinary standards of medical practice, he has experienced an irreversible cessation of spontaneous brain functions. Death will have occurred at the time when the relevant functions ceased.  

With its initial statement of death by cardiorespiratory criteria, this proposal implicitly relied on the concept of death as a failure of the integrated physiological function of the heart, lungs, and brain, thus preserving the traditional intuitive understanding of death. But the proposal also explicitly addressed the potential modern uncoupling of the manifestations of failure of brain and cardiorespiratory functions in its conditional second statement, allowing a determination of death based on brain criteria when the respiratory and circulatory functions are artificially supported. The proposal explicitly relied on the concept of irreversibility but did not define it, stating instead that “death will have occurred when the relevant functions ceased.”

260. Alexander M. Capron & Leon R. Kass, A Statutory Definition of the Standards for Determining Human Death: An Appraisal and a Proposal. 121 U.PA.L.REV 87, 111. (The authors reported that their article grew out of discussions held by the Research Group on Death and Dying of the Institute of Society, Ethics, and the Life Sciences, and that it reflected the conclusions of the Group’s members but was not the subject of formal approval by the Group. The model statutory language was subsequently termed “the Capron-Kass proposal.”)

261. See Leonard Isaacs, Death, Where is Thy Distinguishing? HASTINGS CEN REP., Feb. 1978, at 5, 7. (Commenting on various model statues, the author notes of the Capron-Kass proposal that, This type of statute preserves the traditional definition for the vast majority of cases but deals with the exceptional cases by providing a clarification of the phenomenon of death in ambiguous situations, rather than suggesting that a new phenomenon of death is involved.”) Id. at 7.

262. However, the authors did note that, “For ordinary situations, the appropriateness of the traditional standard ‘an irreversible cessation of spontaneous respiratory and circulatory functions’ does not require elaboration. Indeed examination by a physician may be a more formal than a real requirement in
In 1975 the American Bar Association proposed a model statute defining death by a brain death standard:

For all legal purposes, a human body with irreversible cessation of total brain function, according to usual and customary standards of medical practice, shall be considered dead. 263

In 1978 the NCCUSL approved the Uniform Brain Death Act, noting that the language “legislates the concept of brain death” 264 and should provide “the basis for whatever inquiry is necessary to fix the time of death,” 265 providing:

For legal and medical purposes, an individual who has sustained irreversible cessation of all functioning of the brain, including the brain stem, is dead. A determination under this section must be made in accordance with reasonable medical standards. 266

The Uniform Brain Death Act was withdrawn from recommendation for enactment when it was superseded in 1980 by NCCUSL approval of the Uniform Determination of Death Act, providing “comprehensive bases for determining death in all situations”. 267 The Act provided that:

An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all func-

determining that most people have died.” See Capron & Kass, supra note 259, at 113.

263. 100 A.B.A. ANN. RPT. 231-32 (1978) (February 1975 mid-year meeting), as reprinted in THE PRESIDENT’S COMMISSION REPORT ON DEFINING DEATH, supra note 19, at 117.


tions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.\textsuperscript{268}

Irreversibility was not addressed by the Commissioners, who noted that, “This Act is silent on acceptable diagnostic tests and medical procedures. It sets the general legal standard for determining death, but not the medical criteria in doing so.”\textsuperscript{269} The 1981 President’s Commission Report noted of the proposed Uniform Determination of Death statute that, “Although it assumes that each dead person became dead at some moment prior to the time of diagnosis, the statute does not specify that moment.”\textsuperscript{270} The Commissioners stated in the Prefatory Note to the Act that, “Time of death is a fact to be determined with all others in each individual case, and may be resolved, when in doubt, upon expert testimony before the appropriate court.”\textsuperscript{271} They clarified their understanding of the construction of the Act in the Prefatory Note by stating 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.”\textsuperscript{272}

These three model statutes show a progression of thought, moving from defining the death of a “human body” to the death of


\textsuperscript{269} National Conference of Commissioners on Uniform State Laws, Prefatory Note to Unif. Determination of Death Act (1980), 12A U.L.A. 778, 779 (2008). However, the Commissioners noted that “Under part (2), the entire brain must cease to function, irreversibly. The ‘entire brain’ includes the brain stem, as well as the neocortex. The concept of ‘entire brain’ distinguishes determination of death under this Act from ‘neocortical death’ or ‘persistent vegetative state.’ These are not deemed valid medical or legal bases for determining death.” Id.

\textsuperscript{270} The President’s Commission Report on Defining Death, supra note 19, at 77.


\textsuperscript{272} Id.
an individual, and moving from brain death as part of a bifurcated conception of death to brain death as part of a “single phenomenon” construction similar to that of the Capron-Kass proposal.

In 1981, the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research concluded that “death is a unitary phenomenon which can be accurately demonstrated either on the traditional grounds of cessation of heart and lung functions or on the basis of irreversible loss of all functions of the entire brain.” The President’s Commission Report listed among its “central conclusions” that recent medical advances necessitated a “restatement of the standards traditionally recognized for determining that death has occurred,” that this restatement “ought preferably to be a matter of statutory law,” that “such a statute ought to remain a matter for state law,” and that “the statutory law ought to be uniform among the several states.” The Report further concluded that the definition of death to be codified in a model statute “ought to address general physiological standards rather than medical criteria and tests, which will change with advances in biomedical knowledge and refinements in technique.”

In 1976, the Louisiana legislature enacted the Louisiana statutory definition of death. The language of the Louisiana definition closely tracked the Capron-Kass proposal:

A person will be considered dead of in the announced opinion of a physician, duly licensed in the state of Louisiana based on ordinary standards of approved medical practice, the person has experienced an irreversible cessation of spontaneous respiratory and circulatory functions. In the event that artificial means of support preclude a determination that these functions have ceased, a person will be considered dead if in the announced opinion of a physician, duly licensed in the state of

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273. THE PRESIDENT’S COMMISSION REPORT ON DEFINING DEATH, supra note 19, at 1.
274. Id.
275. Id.
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Louisiana based on ordinary standards of approved medical practice, the person has experienced an irreversible total cessation of brain function. Death will have occurred at the time when the relevant functions ceased.\textsuperscript{277}

However, the Louisiana statute made important deviations from the Capron-Kass proposal. The statute specified that the physician pronouncing death must be “duly licensed in the state of Louisiana,” thereby providing an explicitly localized governance within the definition of the process.\textsuperscript{278} The statute replaced the Capron-Kass brain death definition of “an irreversible cessation of spontaneous brain functions” with the more rigorous construction of “an irreversible total cessation of brain function.”\textsuperscript{279} This language excluded any confusion arising from debate as to what might constitute “spontaneous” brain function. The Louisiana statutory construction of “irreversible total cessation of brain function” is similar to the “irreversible cessation of all functions of the entire brain, including the brain stem” construction of the Uniform Determination of Death Act.\textsuperscript{280} Both explicitly required a “whole brain” concept for brain death criteria and the use of this

\textsuperscript{277}. LA. REV. STAT. ANN. § 9:111(A) (2008 & Supp. 2011). The Louisiana definition of death herein has not been modified since its original enactment. This original section also contained a specific provision pertaining to transplantation, requiring that, “In any case when organs are to be used in a transplant, then an additional physician, duly licensed in the state of Louisiana not a member of the transplant team, must make the pronouncement of death.” Act 233 of 1976, 1976 La. Acts No. 233, § 1. The 2010 Regular Session of the Louisiana Legislature modified this rule, permissively allowing a hospital to adopt a written policy that “a single physician, duly licensed in the state of Louisiana, not a member of the transplant team, may make the pronouncement of death. In all cases in which a hospital written policy provides that a single physician makes the pronouncement of death, such policy shall also require an opinion by a second physician, not a member of the transplant team, as to the candidacy of the person for the process of organ donation.” Act 937 of 2010 (effective July 1, 2010), sec. 1, 2010 La. Sess. Law Serv. 1937, 1938 (West).


construction disallowed any subsequent use of a “higher brain” or neocortical conception of brain death in Louisiana.281

Thus a review of the relevant history shows that the Louisiana statutory definition of death is based on a unitary construction of the concept of death, recognizing that death is a singular physiologic event occurring at a particular moment in time. At that moment there is irreversible cessation of cardiorespiratory function as either a manifestation of or a cause of irreversible total cessation of brain function.

Upon review of the legislative history, our Committee concluded that it is clear that in the practice of organ donation after cardiac death, wherein life-supportive measures are withdrawn from a terminally ill patient who is not brain dead, a sufficient amount of time must elapse in order to allow a judgment of reasonable ethical, medical, and legal certitude that a unitary death has in fact occurred. In Louisiana, that judgment must be made by physicians acting on ordinary standards of approved medical practice, and that amount of time must insure that there has been not only statutory cardiac death, but also statutory brain death.282

281. Robert Truong, a physician and professor of medical ethics at Harvard Medical School, has argued that the “whole brain” concept of death, by requiring the “loss of vegetative brain functions” is too broad to legitimately allow its application, and that it should be replaced by a “higher brain” standard, allowing brain death to be present in those who have “a permanent loss of consciousness.” R. D. Truog & J. C. Fackler, Rethinking Brain Death, 20 Crit. Care Med. 1705, 1705 (1992). James Bernat, a professor of neurology at Dartmouth Medical School, has replied that the “higher brain” concept of death “would declare dead the thousands of patients in persistent vegetative states and other forms of permanent unconsciousness that are regarded as alive in every society and jurisdiction in the world.” James L. Bernat, A Defense of the Whole-Brain Concept of Death, Hastings Cent. Rep., Mar.-Apr. 1998, at 17. Bernat defended whole-brain death as not requiring “the cessation of functioning of every single neuron” but rather the “[p]ermanent cessation of the clinical functions of the entire brain” thereby affirming death as “the permanent cessation of the critical functions of the organism as a whole.” Id. at 17, 18 (citation omitted).

C. The Interpretation of the Concepts of “Irreversibility” and “Cessation” as they Pertain to the Determination of Death

The President’s Commission on Defining Death established a two-step process for the determination of death. Describing a determination of brain death, the Commission stated, “This is achieved by establishing first that all brain functions have ceased and then by ascertaining that the cessation is irreversible.” Clearly, the same process is required in the determination of death by cardiorespiratory criteria. This two-step sequence was also implicit in the traditional common law understanding of death as “the permanent cessation” of all vital functions.

Donation after cardiac death brings an urgent pressure to reach the earliest possible determination of death, and thus an urgent pressure to reach the earliest possible conclusion of irreversibility in the cessation of spontaneous cardiorespiratory functions and total brain function of the donor patient. However, within the particular constraints of DCD, the earliest possible determination of irreversibility and cessation of these “relevant functions” has proved to be controversial in both concept and practice. Given that Louisiana law defines death of a person by cardiorespiratory criteria as “an irreversible cessation of spontaneous respiratory and circulatory functions” and that the unita-

285. See State v. Johnson, 395 N.E. 2d 368, 372-73 (Ohio Ct. App., Hamilton County 1977) affirmed in part 56 Ohio St. 2d 35 (1978), for a description of the common law understanding of death as a “permanent cessation of all vital functions.” This case was cited as an example of traditional common law doctrine concerning death in The President’s Commission Report on Defining Death (supra note 19, at 135).
286. See Joanne Lynn, Are Patients Who Become Organ Donors under the Pittsburgh Protocol for “Non-Heart Beating Donors” Really Dead?, 3 Kennedy Inst. Ethics J. 167, 167-178 (1993), citing concerns over possible lack of brain death in these donors. See also Renee C. Fox, “An Ignoble Form of Cannibalism”: Reflections on the Pittsburgh Protocol for Procuring Organs from Non-Heart-Beating Cadavers, 3 Kennedy Inst. Ethics J. 231, 231-239 (1993), wherein Dr. Fox termed the Pittsburgh Protocol as “the most elaborately macabre scheme of obtaining organs that I have encountered.” Id. at 232.
ry construction of the Louisiana definition of death requires cardiorespiratory irreversibility to manifest or cause irreversible total cessation of brain function, it follows that the practice of organ donation after cardiac death is entirely dependent on the conceptual interpretation of the terms “irreversibility” and “cessation.”

1. The Concept of Cessation as a Determinant of Death

A discussion of irreversibility and cessation as determinants of death begins with the observation that the Louisiana statute defines the death of a person and not of an organ. The death of a person is defined by the irreversible cessation of the cardiorespiratory functions of the heart and the neurological functions of the brain, and not the necrosis or death of the tissues of those organs. In fact, electrical evidence of tissue function of the heart may persist for periods of several minutes after death. In a 1912 study, the prominent physician George Canby Robinson noted that cardiac electrical activity could be recorded for up to 35 minutes after death. Similarly, pathologic studies of the brains of patients experiencing brain death have shown wide variation in extent of tissue necrosis among various areas of the damaged brain.


289. G. Canby Robinson, A Study with the Electrocardiograph of the Mode of Death of the Human Heart, 16 J. Exp. Med. 291, 291-302 (1912). Dr. Robinson defined death in these patients by noting that, “Clinical death was considered to have occurred when respiration finally ceased, when no heart sounds could be heard, and when muscular relaxation and the general appearance of the patient indicated to the physician that death had occurred. Not until all these conditions were fulfilled was the patient considered dead.” Id. at 292.

290. A. Earl Walker, Pathology of Brain Death, in Brain Death: Interrelated Medical and Social Issues 272, 272-280 (Julius Korein, ed., New York Academy of Sciences, 1978). Reporting a study of 226 brains from the Collaborative Study of Cerebral Death, Dr. Walker described the variable pathologic findings, stating, “Microscopically, there is necrosis of many parts of the brain, particularly the cerebellar folia and the cerebral cortex. The basal ganglia and the diencephalons are less affected than most other areas of the brain.” Id. at 274.
Capron and Kass formulated this understanding into their proposal for a statutory definition of death, stating that “the statute should concern the death of a human being, not the death of his cells, tissues, or organs....”\(^\text{291}\) In its prefatory work on the development of the Uniform Determination of Death Act, the President’s Commission on Defining Death noted that, “The death of a human being—not the ‘death’ of cells, tissues or organs—is the matter at issue. The cessation of vital bodily systems provides the basis for broad standards by which death can be judged to have occurred. But such functional cessation is not of interest in and for itself, but for what it reveals about the status of the person.”\(^\text{292}\) The President’s Commission then used this concept to distinguish the “cessation of function” of the relevant organs from the “loss of activity” or the “organic destruction” of the tissues of those organs:

The phrase "cessation of functions" reflects an important choice. It stands in contrast to two other terms that have been discussed in this field: (a) "loss of activity" and (b) "destruction of the organ."

Bodily parts, and the subparts that make them up, are important for the functions they perform. Thus, detecting a loss of the ability to function is the central aim of diagnosis in this field. After an organ has lost the ability to function within the organism, electrical and metabolic activity at the level of individual cells or even groups of cells may continue for a period of time. Unless this cellular activity is organized and directed, however, it cannot contribute to the operation of the organism as a whole. Thus, cellular activity alone is irrelevant in judging whether the organism, as opposed to its components, is "dead."\(^\text{293}\)

Cessation of function of the individual organ systems, rather than of tissues or cells, then forms the basis for a definition of death. However, the cessation of function of an individual system in and of itself does not constitute death. Rather, the cessation upon which death is defined is a cessation of systemic organ functions that produces a “permanent cessation of the integrated

\(\text{291. Capron & Kass, supra note 259, at 104-105.}\)
\(\text{292. The President’s Commission Report on Defining Death, supra note 19, at 58.}\)
\(\text{293. Id. at 75.}\)
functioning of the organism as a whole.”\textsuperscript{294} As the President’s Commission on Defining Death concluded, death is “that moment at which the body’s physiological system ceases to constitute an integrated whole.”\textsuperscript{295} This understanding of the term “cessation,” as employed in statutory definitions of death requires its foundational application to a unitary construction of the concept of death as discussed in Part VI.B. \textit{supra}, and requires cessation of both circulatory and neurological functions.

2. The Concept of Irreversibility as a Determinant of Death

The second step in the statutory process of determining death is to find that the cessation of functions is irreversible.\textsuperscript{296} The concept of irreversibility has proven to be as controversial as that of cessation in debates over the determination of death. The practice of organ donation after cardiac death, with its urgent pressure for the earliest possible determination of death, has magnified these controversies at both theoretical and practical levels.

An important initial point is that irreversibility is much more subject to variation in definition and interpretation than is cessation of function. Whereas cessation of function is ultimately tied to some physiologic state, irreversibility exists as a situational concept. The early French forensic pathologist Paul Brouardel spoke of the practical realities of this problem over one hundred years ago, noting that in some cases a reversible cessation of relevant functions produces \textit{apparent} death and that even in cases in which death becomes certain, the exact moment of death eludes precise definition:

\begin{quote}
[I]t is sometimes extremely difficult to say whether such and such a person is or is not dead.... Suspension of the heart’s action in particular is not sufficient proof. Nevertheless, in acute diseases, the moment when the heart ceases is evidently, to within a few minutes, the moment of death. But it
\end{quote}

\textsuperscript{294} Capron & Kass, \textit{supra} note 259, at 102. See also \textit{supra} note 280 for a brief description of this principle as it applies to brain death.

\textsuperscript{295} The President’s Commission Report on Defining Death, \textit{supra} note 19, at 33.

has not been shown scientifically that an individual whose heart no longer beats cannot be recalled to life. On the contrary, it is certain that some conditions exist that may be styled the state of apparent death. We might definitely choose some sign as a distinction between life and death, and use it in a conventional way; but I am very much afraid that, however elastic this convention might be, whatever sign might be proposed to denote the moment of death, this sign and this convention will always remain useless in doubtful cases, and we are obliged to acknowledge that we have no sign or group of signs sufficient to determine the moment of death with scientific certainty in all cases.\textsuperscript{297}

The uncertainty generated by a dependence on the situational criteria used in defining death was recognized again in more recent literature when Capron and Kass noted that “the basic concept of death is basically a philosophical matter.”\textsuperscript{298} The Commissioners on Uniform State Laws did not directly address the issue of irreversibility in the promulgation of the UDDA, but did note that their language left such matters subject to interpretation:

\begin{quote}
Time of death, also, is not specifically addressed. In those instances in which time of death affects legal rights, this Act states the bases for determining death. Time of death is a fact to be determined with all others in each individual case and may be resolved, when in doubt, upon expert testimony before the appropriate court.\textsuperscript{299}
\end{quote}

The philosopher David Cole, while critical of the application of irreversibility to the definition of death, has extensively cha-

\textsuperscript{297} P. Brouardel, Death and Sudden Death 17-18 (F. Lucas Benham trans., William Wood & Co. 2nd ed. 1902)
\textsuperscript{298} Capron & Kass, supra note 259, at 102.

racterized its use in that definition.\textsuperscript{300} He has described the use of irreversibility in the definition of death as a modal concept whose force or practical application is subject to one of three construals: a \textit{strong construal}, wherein a lost function cannot be restored by anyone under any circumstances at any time now or in the future; a \textit{weak construal}, wherein a loss of function cannot be reversed by those present at this time; and a \textit{weakest construal}, wherein loss of function is not reversed because those present choose not to intervene.\textsuperscript{301}

The determination of death by circulatory criteria may rely on any of these three construals. A patient found in a condition of rigor mortis is pronounced dead by the strong construal of irreversibility. Under no circumstances could the cessation of cardiopulmonary function be reversed or could the person be resuscitated. A person sustaining a cardiorespiratory arrest in a remote area who fails to respond to bystander cardiopulmonary resuscitation is pronounced dead by the weak construal. In another place or circumstance, the cessation of cardiopulmonary function might have responded to medical attention and the person might well have been successfully resuscitated. A person who has a valid order not to resuscitate in force when they sustain a cardiorespiratory arrest in a hospital is pronounced dead by the weakest construal. The cessation of cardiopulmonary functions could likely be reversed by application of resuscitative measures, but a decision has been made not to do so and thus no effort at reversal is made.

The practice of donation after cardiac death relies on the weakest construal of irreversibility.\textsuperscript{302} After withdrawal of supportive measures, the patient is declared dead at the earliest possible time that the cessation of cardiorespiratory function is deemed to be irreversible, as no attempt at resuscitation is to be


In 2000, the Institute of Medicine, summarizing its prior 1997 conclusion, stated that “death occurs when cardiopulmonary function will not resume spontaneously, and will not be restarted artificially.” The National Conference on Donation After Cardiac Death concluded that “if data show that autoresuscitation (spontaneous resumption of circulation) cannot occur and if there is no attempt at artificial resuscitation, it can be concluded that respiration and circulation have ceased permanently.” Thus, both the National Conference on Donation After Cardiac Death and the Institute of Medicine have linked irreversibility, as well as the definition of death, to the conceptual basis of a lack of cardiac autoresuscitation.

The application of this definition in the practice of organ donation after cardiac death relies on the earliest reliable determination that autoresuscitation of cardiac activity will not occur. The Pittsburgh Protocol set this determination at two minutes of ventricular fibrillation, asystole, or electromechanical dissociation occurring in the setting of pulselessness, apnea, and unresponsiveness. In describing the development of this part of the Pittsburgh Protocol, physicians Michael A. DeVita and James V. Snyder, both specializing in anesthesiology/critical care, noted that “[b]ased upon the little scientific evidence available, a group of intensivists with clinical and research expertise in resuscitation selected two minutes as the duration of pulselessness re-

303. INSTITUTE OF MEDICINE, NON-HEART BEATING ORGAN TRANSPLANTATION: MEDICAL & ETHICAL ISSUES, supra note 30, at 57.

304. INSTITUTE OF MEDICINE, NON-HEART-BEATING ORGAN TRANSPLANTATION: PRACTICE AND PROTOCOLS, supra note 207, at 24. (The IOM remained committed to an irreversibility standard for the cessation of functions as a determinant of death in this report.), Id. at 22-26.

305. The National Conference Report, supra note 169, at 282. (The National Conference Report equated the concepts of permanence and irreversibility in cessation of functions as a determinant of death.), Id. More recently a distinction has been drawn between the standards of permanence and irreversibility in order to justify removal of the heart from DCD donors. See discussion part VI.E.3 infra.


quired for determining death, i.e., the duration after which the likelihood of autoresuscitation is vanishingly small.”

However, the two-minute interval of the Pittsburgh Protocol was contemporaneously criticized as too short to insure a lack of autoresuscitation. Dr. Joanne Lynn, a palliative care expert, noted that “not only do we not have the data that would allow us to predict the potential for spontaneous reversal of cardiac function loss in the dying patients who will be donors under the proposed Pittsburgh protocol, but the evidence we might have from analogous situations is fragmentary and of uncertain applicability.”

In 1997, the Institute of Medicine noted that “shorter intervals between cessation of circulation and determination of death are problematic as to the assurance of irreversibility.” The IOM recommended that an interval of “at least 5 minutes” should elapse after complete cessation of circulatory function before death is pronounced and organ perfusion or removal begins. In a critical review of the limitations of lack of autoresuscitation as the determinant of irreversibility, Youngner, et. al., commented on both time intervals, noting that “there is neither sufficient da-

308. Michael A. DeVita & James V. Snyder, Development of the University of Pittsburgh Medical Center Policy for the Care of Terminally Ill Patients Who May Become Organ Donors after Death Following the Removal of Life Support, 3 KENNEDY INST. ETHICS J. 131, 139 (1993).

309. Lynn, supra note 285, at 172. (Lynn noted that the studies used by the developers of the Pittsburgh Protocol to establish lack of autoresuscitation after loss of cardiac rhythm, and to establish the two minute waiting period for determination of death, relied on data from work with warm ischemia and interventive resuscitation, and that the studies “do not describe autoresuscitation, and they certainly do not provide an argument for the rhythms and time limits proposed.”), Id. at 170. Lynn also noted that studies of arrhythmias in dogs and in humans who were monitored were not analogous to the clinical circumstances of the patients in the Pittsburgh Protocol.), Id. at 170-171.

310. INSTITUTE OF MEDICINE, NON-HEART BEATING ORGAN TRANSPLANTATION: MEDICAL & ETHICAL ISSUES, supra note 30, at 59.

311. Id. The IOM cited “expert information and advice from its senior special experts” in establishing the five minute interval from loss of cardiac rhythm to occurrence of death. Id. The IOM subsequently affirmed the limitations of the autoresuscitation data as originally described by Lynn in 1993. INSTITUTE OF MEDICINE, NON-HEART-BEATING ORGAN TRANSPLANTATION: PRACTICE AND PROTOCOLS, supra note 207, at 22-24.
ta nor compelling reasoning to opt for either of the proposed alternatives.\textsuperscript{312}

Both the Pittsburgh Protocol and the IOM recommendation have been criticized as relying on lack of cardiac autoresuscitation as the sole criterion for irreversibility in the determination of death. Citing concerns that donors under the Pittsburgh Protocol might not reach brain death before organ procurement, Lynn stated that “[t]he proposed Pittsburgh protocol might allow taking organs from persons not yet known to be dead. In fact, it might allow taking organs from persons who are not yet dead, depending upon some specifications of that definition.”\textsuperscript{313} Youngner raised similar concerns regarding the IOM recommendations, finding that “[a]nother criticism of the five-minute rule is that it focuses on cardiopulmonary rather than brain criteria for death.”\textsuperscript{314}

Thus, the construct presently used for the concept of irreversibility in determination of death for the practice of organ donation after cardiac death consists of two questionable components—the use of the weakest construal of irreversibility and the reliance on lack of autoresuscitation as the sole criterion for irreversibility. This construct permits uncertainty as to whether these donors have in fact sustained irreversible cessation of the functions of the entire brain at the time organ procurement begins. It also raises substantive doubt as to whether all of these donors are in fact legally dead prior to the retrieval incision, and introduces pressing questions as to the proper standard for the determination of death in the practice of organ donation after cardiac death.

D. The Proper Standard for the Determination of Death in the Practice of Organ Donation after Cardiac Death

An understanding of the proper standard for the determination of death in the practice of organ donation after cardiac death is of far more than theoretical importance. Despite explicitly clear evidence from the President’s Commission Report on Defining Death that the Uniform Determination of Death Act intended a
unitary construction of death, the actual language promulgated set forth an “either...or” construction for the application of the cardiorespiratory and brain standards. As Professor Capron has noted, this language established a “bifurcated” definition of death, constructionally generating confusion as to whether the Act allowed two separate and independent definitions of death, each based on the cessation of function of a single organ system.

The confusion generated by the bifurcated definition of death in the UDDA has taken deep root in the current culture of organ donation after cardiac death. The 1997 Institute of Medicine Report, citing the UDDA, explicitly accepted the bifurcated definition of death and the reliance on a singular cardiopulmonary standard for death as the foundation for the practice of organ donation after cardiac death:

As noted earlier, the NHBD is a donor whose death is defined by "irreversible cessation of circulatory and respiratory functions" as opposed to "irreversible cessation of all functions of the entire brain, including the brainstem" (Uniform Determination of Death Act, 12 Uniform Laws Annotated 320 [1990 Suppl.]).

315. The report of the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research stated that “death is a unitary phenomenon which can be accurately demonstrated either on the traditional grounds of irreversible cessation of heart and lung functions or on the basis of irreversible loss of all functions of the entire brain.” THE PRESIDENT’S COMMISSION REPORT ON DEFINING DEATH, supra note 19, at 1. This was not clearly reflected in the language of the model statute. See Unif. Determination of Death Act (1980) § 1, 12A U.L.A. 781 (2008), supra note 267 and accompanying text.

316. Alexander Morgan Capron, The Bifurcated Legal Standard for Determining Death: Does It Work?, THE DEFINITION OF DEATH: CONTEMPORARY CONTROVERSIES 117, 117-118 (Stuart J. Youngner, Robert M. Arnold, and Renie Schapiro, eds., Johns Hopkins Univ. Press 1999). Professor Capron emphasized the original intent of the Act, noting that “Bifurcated does not mean that the thing being determined (namely, death) is divided into distinct parts. Rather, it is the method by which death is to be determined that forks into two branches.” Id.

317. INSTITUTE OF MEDICINE, NON-HEART BEATING ORGAN TRANSPLANTATION: MEDICAL & ETHICAL ISSUES, supra note 30, at 23. “NHBD” refers to a non-heart-beating donor in the process of organ donation after cardiac death. The General Counsel to the Department of Human Health and Ser-
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The 2006 report of the National Conference on Donation after Cardiac Death, citing the report of the medical consultants to the President’s Commission on Defining Death, stated that, “A prospective organ donor’s death may be determined by either cardiopulmonary (DCD) or neurologic criteria (donation after brain death [DBD]).”\(^{318}\) The report further concluded that, “Death determination in the DCD patient mandates the use of a cardiopulmonary criterion to prove the absence of circulation. The cardiopulmonary criterion may be used when the donor does not fulfill brain death criteria.”\(^{319}\) Despite this endorsement of the use of the bifurcated standard for determination of death, James L. Bernat, lead author of the report, noted in a separate publication that the “seemingly separate bifurcated criteria are not independent” even when applied in DCD.\(^{320}\) Bernat pointed out that skeptics of DCD question the lack validity of a singular cardiac determination of death by observing that, “If patients could be resuscitated after five minutes of asystole, then clearly they were not dead at that point because the cessation of their brain functions would not have been ‘irreversible,’ a condition that is required by both the concept and statute of death.”\(^{321}\)

\(^{318}\) The National Conference Report, supra note 169, at 281 (citation omitted).

\(^{319}\) Id. at 281.


\(^{321}\) Id. at 123. Bernat went on to note that using a “permanence” standard as opposed to an “irreversibility” standard for determining death by cardiopulmonary criteria could in fact result in removal of organs before there had been irreversible cessation of brain or heart functions. He acknowledged that such a circumstance could result in removal of organs before the donor is unequivocally dead, thereby violating the dead donor rule—a result he termed “a justified exception,” as the donor is “incipiently and unequivocally dying.” Id. at 128-129. Louisiana law explicitly requires an irreversibility standard in the determination of death, LA. REV. STAT. ANN. § 9:111 (2008 & Supp. 2011). This change in standards has important practical consequences as it is being used to justify removal of the heart from a DCD donor.
The application of an explicitly bifurcated construction of the determination of death in organ donation after cardiac death has led to criticism of the ethics of DCD, particularly as to violation of the dead donor rule. Noting doubts about the functional status of the brain in DCD donors, Arnold and Younger noted in 1993 that “[b]y taking advantage of ambiguities in the definition and criteria of death, the Pittsburgh protocol pushes the dead donor rule to the limit.”322 Lynn raised similar concerns, stating, “We do not have reliable evidence of when one could predict global loss of brain function based solely upon the duration of lack of circulation. What evidence we do have is quite clear that the time would be much longer than two minutes.”323

The 1997 IOM Report addressed these concerns when establishing its five minute recommendation, stating that “the interval of absent circulation here will, in a donor with normal body temperature, produce irreversible brain damage.”324 But the longer IOM interval also faced persistent concerns about violation of the dead donor rule. The bioethicist and physician Jerry Menikoff examined the five minute interval of the IOM Report, raising “facts that might suggest the person is still alive” including that “at the time the individual is declared dead, it is quite possible that substantial portions of that person’s brain (including the higher brain, responsible for thoughts and emotions) have not yet permanently ceased to function.”325 John T. Potts, principal investigator for the 1997 IOM Report, responded that:

323. Lynn, supra note 285, at 175.
324. INSTITUTE OF MEDICINE, NON-HEART BEATING ORGAN TRANSPLANTATION: MEDICAL & ETHICAL ISSUES, supra note 30, at 59. The IOM noted that “the shorter intervals between cessation of circulation and determination of death are problematic as to the assurance of irreversibility. Intervals such as 2 minutes are not supported by any experimental data on the probability of autoresuscitation and are too short to support a determination of brain death due to circulatory arrest.” Id. at 59 (citing Lynn, supra note 285).
"[Given the background of severe trauma and/or illness that leads attending medical personnel (with responsible family members) to conclude that death is inevitable and that no further medical intervention is useful or appropriate, it is likely that whole brain death (certainly any higher functions) will occur in the cumulative minutes. . . .

The ethicist James M. DuBois subsequently dissented, concluding that "to move from CR [cardiorespiratory] criteria to brain death, one would have to wait at least ten minutes after CR functions are lost." Our Committee reviewed this controversy and pertinent clinical literature. A clinical overview of cardiac arrest contemporaneous to the 1997 IOM Report seemed to support the five minute interval, stating:

Once cardiac arrest has occurred tissue perfusion ceases. The effects of this are most dramatically seen in the brain. Within 10 – 15 sec of the cessation of cardiac pumping action, loss of consciousness develops because of cerebral hypoxia. Over the next 5 min, neuronal glucose and glycogen stores are progressively depleted and an isoelectric EEG (electroencephalogram) develops. By the end of this time ATP stores are exhausted. At this stage, even if cardiac output is restored, the cerebral injury is likely to be irrecoverable except in certain special circumstances.

A recent study of patients developing cardioinhibitory syncope (a condition with documented transient loss of blood pressure and pulse) found that the electroencephalogram (EEG) became flat on average in less than 30 seconds from the loss of car-

327. James M. DuBois, Non-Heart-Beating Organ Donation: A Defense of the Required Determination of Death, 27 J. L. MED. & ETHICS 126, 127 (1999). (DuBois was arguing for the bifurcated conception of death and that brain death is not essential to a determination of cardiac death.)
328. C. E. Robertson, Cardiac Arrest and Cardiopulmonary Resuscitation in Adults, CAMBRIDGE TEXTBOOK OF ACCIDENT AND EMERGENCY MEDICINE 62, 63 (David Skinner, Andrew Swain, Rodney Peyton & Colin Robertson, eds., 1997).
A classic review of the clinical criteria for brain death found that in cases of presumptive brain death, “the onset of ECS [electrocerebral silence] probably corresponds best with the time of onset of brain death” and that “with only rare transient exceptions” the papillary light, vestibular, oculocephalic, and corneal reflexes were absent in cases of presumptive death.

Likewise, loss of the pupillary reflexes develops very quickly after cardiac asystole.

Upon review of the controversy, our Committee is reasonably certain that electrocerebral silence and loss of brainstem reflexes, signifying a loss of function of the entire brain including the brainstem, develops in less than ten minutes of asystole or ventricular fibrillation and probably in as little as two minutes. We are also reasonably certain that the period of at least five minutes after cardiac asystole prescribed by the IOM Report, although promulgated largely on the grounds of lack of cardiac autoresuscitation, is sufficient to meet the irreversibility standard of the unitary concept of death as to both the cardiorespiratory and neurologic standards in most cases. However, we believe that under these circumstances it is still necessary to ensure clinical evidence of total cessation of brain function prior to the pronouncement of death.

The American Academy of Neurology, in its publication “Practice Parameters: Determining Brain Death in Adults,” noted that “the three cardinal findings in brain death are coma or unresponsiveness, absence of brainstem reflexes, and apnea.” In the practice of controlled donation after cardiac death, our Committee believes that, in the clinical setting of cardiac asystole and respiratory apnea, an irreversible cessation of

329. Fabrizio Ammirati et al., Electroencephalographic Correlates of Vasovagal Syncope Induced by Head-Up Tilt Testing, 29 STROKE 2347, 2347-51 (1998).
331. Franz Aichner & Gerhard Bauer, Cerebral Anoxia, in ELECTROENCEPHALOGRAPHY: BASIC PRINCIPLES, CLINICAL APPLICATIONS, AND RELATED FIELDS 455, 456 (Ernst Niedermeyer & Fernando Lopes da Silva eds., 5th ed. Lippincott Williams & Wilkins 2005).
brain function may be established when the pronouncing physicians document a lack of motor response to supraorbital pressure, the presence of fixed and dilated pupils with lack of a pupillary light reflex, and the absence of corneal reflexes. These are very similar to the criteria advised by the Academy of the Royal Medical Colleges specifically for determination of death in DCD in the United Kingdom.

Our Committee concluded that the physicians pronouncing death must simply follow the governing Louisiana statutory law and pronounce a unitary death by standards of approved medical practice. We chose to impose no arbitrary time for the determination of the irreversible cessation of functions. Our protocol states:

Either the attending physician or a physician designated by the attending (not a member of or associated with the transplant team) will perform the declaration of death in accordance with hospital protocol and Louisiana law. As per La. R.S. 9:111(A), the patient will be considered dead if in the announced opinion of the physician, duly licensed in the state of Louisiana based on ordinary standards of approved medical practice, the patient has experienced an irreversible cessation of spontaneous respiratory and circulatory functions. Furthermore, as specified in La. R.S. 9:111(A), in any case when organs are to be used in transplant, then an additional physician, duly licensed in the state


335. National Health Service, the United Kingdom, Donation After Cardiac Death, Adult—Planning and Withdrawal, at 6, http://www.organdonation.nhs.uk/ukt/about_us/professional_development_programme/pdf/Donation_after_Cardiac_Death_Planning.pdf (last visited Jan. 30, 2011). The Academy advises that these signs be sought after five minutes of continuous asystole. Id.
of Louisiana, not a member of the transplant team, must make the pronouncement of death.336

Under our protocol, after the withdrawal of life-supportive measures a patient may be pronounced dead as soon as there is a reasonable certainty of the irreversible cessation of cardiorespiratory functions and an elapsed time period sufficient to produce signs of irreversible cessation of function of the entire brain, including the brainstem. Depending on the pre-withdrawal neurological status of the patient, we believe that it is possible that such a determination could be made as soon as two minutes after apnea and documented cessation of cardiac function, although such time could conceivably be as long as ten minutes. As the time to irreversible cessation of the entire brain may depend on the baseline neurologic status of the potential donor, we require that any patient to be considered as a potential DCD donor must not be conscious, and, in explicit conformity with the Louisiana Natural Death Act, must be in a “continual profound comatose state with no reasonable chance of recovery.”337

E. Practical Ethical Concerns Related to the Inviolability of the Dead Donor Rule

1. The Need for a Hands-Off Period

Whether a hands-off period should be applied after the determination of death in donation after cardiac death has been a point of disagreement. A hands-off period is generally defined as an elapsed period of time after the donor has been pronounced dead in which no recovery activity by the transplant team is allowed.

The Pittsburg Protocol allowed organ procurement to proceed “immediately after the certification of death.”338 The National Conference on Donation After Cardiac Death stated that when death is declared within two to five minutes of asystole “no fur-

336. The Willis-Knighton Protocol, supra note 5.
ther time is required before recovery events may be initiated. The Institute of Medicine allowed organ perfusion or removal immediately after its recommended determination of death at a time interval of at least five minutes from asystole.

However, the Canadian Council for Donation and Transplantation found in its survey of donation after cardiac death protocols worldwide that a number prescribed a hands-off period of non-intervention to follow the required determination of death. The Council reported that all four reviewed protocols from the United Kingdom required a hands-off period of at least five minutes duration to elapse after the period of time necessary to determine death, while four of the eight United States protocols reviewed did so. The Maastricht Protocol, developed as a result of the First International Workshop on Non-Heartbeating Donors, established a ten minute period of non-intervention after cardiopulmonary arrest.

The principle objections raised to a hands-off period have centered on the contention that such a period is unnecessary to insure that the donor is dead, and on the contention that such a period adversely affects the organs to be harvested. As to the first objection, our Committee has extensively reviewed the issue of elapsed time to reach a unitary definition of death, as discussed in Part VI.D supra, reaching the conclusion that the time to reach a reasonable clinical certainty of neurologic death will generally range from two to five minutes after apnea and cessation of cardiac activity. Understanding that the conception of a unitary death requires reaching a verifiable state of death by neurologic

340. Institute of Medicine, Non-Heart Beating Organ Transplantation: Medical & Ethical Issues, supra note 30, at 59.
342. Id. at 61. This generally resulted in a total interval of ten minutes after asystole before organ procurement could begin.
343. Gauke Kootstra, Statement on Non-heart-beating Donor Programs, 27 TRANSPLANT PROC. 2965 (1995). (Dr. Kootstra has subsequently recognized a five minute “no touch” period after cardiac asystole as established by the Institute of Medicine as “the standard approach.” Gauke Kootstra, History of Non-heartbeating Donation, in ORGAN DONATION AND TRANSPLANTATION AFTER CARDIAC DEATH 1, 4 (David Talbot & Anthony D’Alessandro eds., 2009)).
criteria, we believe that the additional time required by a hands-off period is reasonable to insure the certainty of the required determination of death.\textsuperscript{344}

The second objection to a hands-off period revolves around the concept of “warm ischemia time.” The National Cancer Institute of the U.S. National Institutes of Health defines warm ischemia times as, “In surgery, the time a tissue, organ, or body part remains at body temperature after its blood supply has been reduced or cut off but before it is cooled or reconnected to a blood supply.”\textsuperscript{345} In the practice of donation after cardiac death, warm ischemia time has been subject to various specific interpretations, but is generally considered as the time from cardiac asystole until the time cold perfusion of the donated organ is begun.\textsuperscript{346} The National Conference on Donation After Cardiac Death reported that warm ischemic time for successful transplantation of organs should not exceed 30 minutes for the donated liver and 60 minutes for the donated kidney and pancreas.\textsuperscript{347} Interestingly, upon review of this issue the Canadian Council for Donation and Transplantation concluded that “[i]t seems inherently logical that the duration of warm ischemia is directly related to long-term transplant viability, but no evidence for this supposition could be identified during our review.”\textsuperscript{348} The Institute of Medicine recently examined the issue of warm ischemic time and a requisite hands-off period in the uncontrolled donation after cardiac death scenario, in which DCD is rapidly performed after the cessation of cardiopulmonary resuscitation in patients sustaining sudden cardiac arrest. The IOM concluded that “[i]f one allows a 10-minute hands-off period with an absent heartbeat after the pronouncement of death and the cessation of CPR, the transplantation team would be left with 50 minutes, on average, to perform cannula-

\begin{thebibliography}{9}
\bibitem{344} Dr. Kootsra continues to maintain that such an interval is necessary to insure brain death as a necessary condition in DCD. Kootsra, \textit{History of Non-heartbeating Donation}, supra note 342, at 3.
\bibitem{347} \textit{The National Conference Report, supra} note 169, at 284.
\bibitem{348} \textit{The Canadian Council for Donation and Transplantation, supra} note 340, at 76.
\end{thebibliography}
tion and cooling of the kidneys (which is well within the requisite window of warm ischemic time).\footnote{49}

Believing that it is absolutely essential that the dead donor rule must not be violated, and that the requisite determination of death is that of a unitary death, our Committee chose to require a hands-off period of non-intervention in our protocol. Our protocol specifies that that the transplant recovery team will not be present in the operating room until five minutes after the patient is declared dead, and that cold perfusion preservation and/or recovery of organs will not begin until five minutes after the time that death is pronounced.\footnote{50} We are confident that this interval does not materially impact the quality of the procured organs as compared to those obtained under other protocols.

2. The Use of Extracorporeal Membrane Oxygenation

The adoption of the bifurcated death construction, allowing a patient to be declared dead by circulatory criteria without explicitly requiring death by neurologic criteria, has led to novel practices designed to improve the outcome of transplantation procedures utilizing organs from donation after cardiac death donors. One such practice is the use of whole body extracorporeal membrane oxygenation (ECMO) support for the non-heartbeating donor. As described by Rudich, et. al., this process involves patients with irreversible brain injury who have arterial and venous cannulae placed prior to withdrawal of support.\footnote{51} Upon with-

\footnote{349. Institute of Medicine, Organ Donation, supra note 36, at 156.}
\footnote{350. The Willis-Knighton Protocol, supra note 5. This hands-off period is similar to that of policies previously published by the University of Florida, SHANDS at the University of Florida, Gainseville, Memorandum Number: Pm02-20.01, Subject: Donation After Cardiac Death (Non-Heart Beating Donors Only), reprinted in Institute of Medicine, Non-Heart-Beating Organ Transplantation: Practice and Protocols, App. F, supra note 207, at 121, and the Louisiana State University Health Sciences Center-Shreveport, supra note 161.

351. Steven M. Rudich et al., Extracorporeal Support of the Non-Heart-Beating Organ Donor(Letters to the Editor), 73 Transplantation 158, 158 (2002). ECMO systems typically utilize a reservoir for drainage of venous blood, a roller pump, a membrane exchanger for diffusion of oxygen and carbon dioxide, and a heat exchanger, and are typically used for extracorporeal support in patients with respiratory failure or severe cardiac failure. See Scott K. Alpard & Joseph B. Zwischenberger, ECMO in the Surgical Patient, in Thoracic Trauma}
drawal of life-supportive measures, death is pronounced by cardiorespiratory criteria after five minutes of asystole. The patient is then supported with normothermic ECMO, maintaining hemodynamic support and oxygen delivery as the patient is readied for organ procurement. These authors describe the process as designed “to resuscitate the donor after a formal declaration of cardiac death.” This technique has led some to require more stringent criteria for cardiac death when ECMO is applied.

It is notable that the application of ECMO in patients with prolonged resuscitative efforts after cardiac arrest has resulted in “rescue” of such patients, with a mere 5% incidence of severe neurologic deficit among survivors. Chen, et. al., speculated that “a rapid return of circulation, immediate adequate support, and highly oxygenated blood to the brain by ECMO may be the key to achieving good cerebral resuscitation results, even after prolonged CPR.” Similarly, use of whole-body ECMO may actually preserve cerebral function in DCD donors. Dr. James L. Bernat recently commented on the use of ECMO in organ donation after cardiac death, stating.

Another unconventional protocol used by several hospitals for donation after circulatory death involves providing ECMO to the donor immediately after death is declared. If ECMO adequately provided circulation and oxygenation to the donor’s entire body, it would retroactively negate the death determination by preventing the loss of circulation and respiration from becoming permanent or irreversible, potentially “reanimating” the heart and preventing the progression to brain destruction on which the circulatory criterion of death is predicated.


352. Rudich, et. al., supra note 350, at 158.
353. See Jeff Evans, ECMO Use May Increase Organ Donor Availability, THORACIC SURGERY NEWS, Nov.-Dec. 2008, at 1, 10. Dr. Michael Hines of Wake Forest University is quoted in this article as saying, “To be ultraconservative [in pronouncing death], we wait for 5 minutes after electrical silence of the heart rather than for 5 minutes after pulselessness.” Id. at 10.
355. Id. at 202.
A modification of the ECMO technique, known as EISOR (extracorporeal interval support for organ retrieval) involves placing an occlusion balloon in the thoracic aorta to prevent the oxygenated blood from reaching the heart and the brain, thus avoiding reanimation. Dr. Bernat recently noted that EISOR actively produces destruction of the brain, stating:

A University of Michigan ECMO protocol for procuring abdominal organs apparently avoids this problem. During ECMO, an intracardiac occlusion balloon blocks all blood flow above the diaphragm so that only the abdominal organs are perfused with oxygenated blood. The thoracic organs and brain are isolated from this perfusion circuit and are destroyed by ischemic infarction.

EISOR is deliberately constructed to prevent reversibility of the cessation of brain functions. The Louisiana Natural Death Act, which helps form the statutory basis for the practice of donation after cardiac death in Louisiana law, specifically clarifies its lack of application to clinical practices such as those of EISOR:

Nothing in this Part shall be construed to condone, authorize, or approve mercy killing or euthanasia or to permit any affirmative or deliberate act or omission to end life other than to permit the natural process of dying.

A recent multidisciplinary expert review of the circulatory determination of death in organ donation, convened and funded by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services, concluded that “[t]he use of unmodified extracorporeal membrane oxygenation in the circulatory determination of death donor after death is declared should be abandoned, because by restoring brain circulation, it retroactively negates the previous death determination. Modifications of extracorporeal membrane oxygenation that avoid

358. Bernat, supra note 355, at 671.
this problem by excluding brain circulation are contrived, invasive, and, if used, should require consent of surrogates.\textsuperscript{360}

Our Committee concluded that extracorporeal membrane oxygenation support may preserve cerebral function in patients not yet brain dead when applied as a whole body supportive technique, thus preventing the cessation of total cerebral functions and the occurrence of a unitary death, or may interrupt cerebral circulation in a patient not yet brain dead in the EISOR modification, thereby hastening death. Given our conclusion that a unitary determination death is required in Louisiana law prior to proceeding with organ donation after cardiac death, and given the explicit statement in Louisiana law excluding deliberate acts to end life, we believe that the use of ECMO and EISOR in the DCD donor is inconsistent with Louisiana law. We have concluded that extracorporeal membrane oxygenation in any form shall not be utilized in support of donation after cardiac death donors in the Willis-Knighton Health System.

3. Recovery of the Heart from a Donation after Cardiac Death Donor

Philosophical latitude in the determination of irreversibility has given rise to controversy concerning the possibility of recovery of the heart from a donation after cardiac death donor. The National Conference on Donation After Cardiac Death in 2006 stated that:

[L]imited anecdotal evidence in humans supports the feasibility of cardiac transplantation following DCD, including the first successful heart transplant. Ongoing research involving optimization of the reperfusion technique may enhance immediate functional recovery. Based on the growing numbers of successful non-cardiac solid organ retrievals following DCD, and the ongoing shortage of cardiac donors, especially in the pediatric arena, protocols to develop and optimize heart transplantation fol-

\textsuperscript{360} James L. Bernat, et.al., \textit{The Circulatory-respiratory Determination of Death in Organ Donation}, 38 CRIT. CARE MED. 963, 963 (2010).
Following DCD for pediatric and adult recipients are anticipated.\textsuperscript{361}

In August of 2008, the Denver Children’s Hospital Pediatric Transplant Team reported a series of cardiac transplantation procedures utilizing donor hearts from infants pronounced dead by cardiorespiratory criteria.\textsuperscript{362} The report, citing three transplant procedures, provoked extensive controversy regarding the recovery of a donor heart after a determination of death by cessation of cardiocirculatory function.\textsuperscript{363} The donor infants, all less than 18 months of age, had withdrawal of life supportive measures based upon a determination of “futility of ongoing care and the requirement for life support to maintain viability.”\textsuperscript{364} Life supportive measures were withdrawn in an operating room after “seda-

\textsuperscript{361} The National Conference Report, supra note 169, at 285. Christian Barnard, who performed the first successful cardiac transplantation, did not view the procedure as what would now be understood as a cardiac procurement from a DCD donor. In a 1969 publication, he described the donor as a brain dead donor, reporting that “extensive investigation by neurosurgeons and neurologists indicated that her brain had been so severely damaged that in fact she had come to the stage of brain death.” C. N. Barnard, Human Heart Transplantation, 3 CAN. MED. ASS’N. J. 91 (1969). The neurologic examination of the donor, who had been struck by an automobile, was conducted by Peter Rose-Innis, the senior neurosurgeon on the hospital staff. He found the patient to have two penetrating skull fractures, fixed and dilated pupils, no response to pain, no reflexes, and no activity on an EEG. He declared her dead on neurologic grounds while still maintained on ventilatory support, and before the family was approached about organ donation. See TONY STARK, KNIFE TO THE HEART: THE STORY OF TRANSPLANT SURGERY 61-63 (Macmillan 1996). Barnard turned off the ventilator at the insistence of the anesthesiologist, injected the donor with potassium to produce ventricular fibrillation, declared the patient dead a second time by cardiorespiratory criteria after five minutes, and then proceeded with procurement of the heart. See C. N. Barnard, The Operation, 41 S. Afr. Med. J. 1271, 1271 (1967) and see also DONALD McRAE, EVERY SECOND COUNTS 206-207 (Berkley Pub. Grp. 2007).


\textsuperscript{364} Boucek, et.al., supra note 361, at 710. The average age of the donors was 3.7 days. All were felt to have severe neurological injury. Id. at 712.
tion typical for withdrawal of life support."\textsuperscript{365} Death was declared in the first donor three minutes after cessation of cardiocirculatory function.\textsuperscript{366} In the remaining two donors, the time to pronounce death was shortened to 75 seconds after the cessation of cardiocirculatory function.\textsuperscript{367} All three recipients survived.\textsuperscript{368} The authors concluded that “the experience with these three high-risk patients supports the concept that the heart, like other solid organs, is capable of functioning adequately in a physiologically viable recipient after transplantation, despite cardiocirculatory death of the donor.”\textsuperscript{369}

Commentary accompanying the Denver Children’s Hospital report in the \textit{New England Journal of Medicine} raised serious concerns regarding the practice of cardiac transplantation from a donation after cardiac death donor. Dr. James Bernat, the lead author of the report of the National Conference on Donation After Cardiac Death, wrote:

An unanswered question is whether cardiac transplantation from a donor declared dead according to a circulatory criterion retroactively negates the determination of death. Does the fact that a donor’s heart is restarted in another patient prove that circulatory cessation was not irreversible? Or should the requirement of irreversibility be restricted to circulation within the donor?\textsuperscript{370}

The ethicist Robert Veatch directly challenged the idea that the donor hearts had irreversibly ceased to function:

Virtually all observers have assumed that donation after cardiac death could, in principle, provide any vital organs except hearts. If someone is pro-

\textsuperscript{365} \textit{Id.} at 710. This included the administration of the narcotic analgesic fentanyl in an average dose of 4 micrograms per kilogram and the benzodiazepine sedative lorazepam in an average dose of 0.1 milligrams per kilogram. \textit{Id.}

\textsuperscript{366} \textit{Id.} at 711.

\textsuperscript{367} \textit{Id.} The time from withdrawal of life-supportive measures to pronouncement of death ranged from 11.5 to 27.5 minutes. \textit{Id.} tbl. 1 at 711.

\textsuperscript{368} \textit{Id.} at 712.

\textsuperscript{369} \textit{Id.} at 713.

\textsuperscript{370} Bernat, \textit{supra} note 355, at 671.
nounced dead on the basis of irreversible loss of heart function, after all, it would not be possible for heart function to be restored in another body. Some have suggested defining death as the impossibility of autoresuscitation, which means that the heart cannot restart spontaneously even if could be restarted by means of external stimulation. Calling such a heart “irreversibly stopped” may be defensible if no attempt will be made to restart the heart. However, one cannot say a heart is irreversibly stopped if, in fact, it will be restarted. 371

Ethicists Robert Truog and Franklin Miller, both critics of the dead donor rule, also raised serious doubt as to whether the donors were actually dead:

The cardiac definition of death requires the irreversible cessation of cardiac function. Whereas the common understanding of “irreversible” is “impossible to reverse,” in this context irreversibility is interpreted as the result of a choice not to reverse. This interpretation creates the paradox that the hearts of patients who have been declared dead on the basis of the irreversible loss of cardiac function have in fact been transplanted and have successfully functioned in the chest of another. Again, although it may be ethical to remove vital organs from these patients, we believe that the reason it is ethical cannot convincingly be that the donors are dead. 372

Our Committee noted that concerns that these donors were not dead at the time of the institution of organ recovery may be grounded either in the failure to reach brain death criteria, a concern common to all organ transplantation with donation after cardiac death procurement, or in the failure to reach irreversible cessation of cardiac function as a concern specific to cardiac

transplantation in donation after cardiac death procurement. In either instance, grave questions regarding causation of death arise.

The HRSA multidisciplinary panel of experts recently attempted to dismiss such concerns. The HRSA experts drew a distinction between the irreversibility of cessation of function of the heart as an organ per se and the irreversibility of its circulatory functions within the donor, noting that “circulation, not heartbeat, is the critical function that must be absent when using circulatory-respiratory tests to determine death.”\textsuperscript{373} Their expert report then extended this distinction further by applying a permanence standard for loss of circulatory function—as opposed to an irreversibility standard for loss of cardiac function—to the determination of cessation of functions and the pronouncement of a bifurcated circulatory death, thereby justifying procurement of the heart from a DCD donor. The report noted that “the removal and restarting of the heart elsewhere simply has no impact on the previous determination of the donor’s death because the donor patient remains permanently without circulation in exactly the same way as if his non-beating heart had been left in place.”\textsuperscript{374} This statement, of course, is not exactly true. In the latter case, the deceased donor is permanently without circulation in the

\textsuperscript{373} Bernat, et. al., \textit{supra} note 359, at 968. However, the President’s Commission Report on Defining Death logically and intuitively equated cardiac and circulatory function, stating that, “For patients who are not artificially maintained, breathing and heartbeat were, and are, reliable signs of either systemic integration and/or of continued brain functioning....” \textit{The President’s Commission Report on Defining Death, supra} note 19, at 37. The 2006 Institute of Medicine report proposed that the term \textit{cardiac death} be replaced by \textit{circulatory determination of death}, noting that “[f]urther confusing to families in times of crisis are the terms \textit{brain death} and \textit{cardiac death}. To some, these terms imply that certain organs have died but do not convey that this is a final determination of death.” \textit{Institute of Medicine, Organ Donation, supra} note 36, at 31. The distinction between death of an organ and “cessation of vital bodily systems” was also viewed as important by the President’s Commission, but only as pertaining to the death of the organism as a whole, not as to the particularity of the cessation of function of a single organ or its physiologic system. \textit{The President’s Commission Report on Defining Death, supra} note 19, at 58. Under the President’s Commission construction, defining a patient as dead by circulatory criteria and then removing the heart to function in a recipient would be no more logical or acceptable than defining a patient as dead by neurologic criteria and then removing the brain to function in a recipient.

\textsuperscript{374} Bernat, et. al., \textit{supra} note 359, at 968.
presence of the heart, and in the former case the deceased donor is permanently without circulation in the absence of the heart. In the latter case, the heart of the donor has undoubtedly irreversibly ceased to function, and in the former case the heart of the donor is beating in the chest of the recipient. In the latter case, society may look upon the deceased donor with a firm assurance that death was not hastened, and in the former case it cannot. The nuanced redefinition of cardiac death as circulatory death on a permanence standard seems situational, contrived, and deliberately permissive, but it is efficient. Prompt removal of the heart insures timely certainty of permanent and irreversible cessation of donor circulatory function in a way that no natural death process can replicate.

Society requires that organ transplantation not be done at the expense of the killing of a human being. This social contract requires that the practices of organ donation will include sufficient safeguards to assure that such killing cannot occur. This requirement of the social contract is manifested in the universal application of the dead donor rule in the practice of organ transplantation. The dead donor rule as a practical application of the social contract requires the certainty of the natural death of the donor as a fundamental foundation to organ transplantation from deceased donors.

As noted in Part VI.C.2 supra, the practice of donation after cardiac death relies on determination of death by application of the weakest construal of the irreversibility to the cessation of circulatory and neurologic functions. Death is determined to exist, not because the relevant functions could not be restored, but because a choice has been made not to restore them. The application of the weakest construal is socially allowed precisely because the organs in question are not to be considered for hurried re-

375. See RAMSEY, supra note 11, at 188-197, for a classic moral examination of this proposition.

376. This expectation is a social contract in the general sense that it involves a conditional transfer of power from the people to the political authority in order to give practical structure to a shared fundamental understanding. See Murray Forsyth, Hobbes’s Contractarianism: A Comparative Analysis, in THE SOCIAL CONTRACT FROM HOBBES TO RAWLS 35, 35-39 (David Boucher & Paul Kelly eds., Routledge 1994) for a discussion of the generalities of a social contract.

377. See supra notes 16, 240 & 241 and accompanying text for discussion of this understanding of the requirements of the dead donor rule.
moval from the body of the donor, thus eliminating any uncertainty as to the permanent and irreversible cessation of their functions. 378

The relevant question is not whether in practice a heart may be successfully removed from a DCD donor and transplanted into a recipient. Rather, we must question whether in concept the heart may be removed under the social contract that permits organ transplantation. The application of this conceptual test is not novel, as we apply it in other areas of organ transplantation. For example, allegations that in some countries prisoners have been executed in order to facilitate the removal of their organs have been reviewed by the United States Congress, and in the United States we prohibit any such practice. 379 In this circumstance, there is no doubt that the procurement of the organs is technically feasible, and there is no doubt that good may come of the act of transplanting those organs into needful recipients. The prohibition arises in that the practice involves the killing of a human being. Neither the technical facility of the act nor its resultant good is sufficient to abrogate the social contract. Similarly, neither the technical facility of cardiac procurement in donation after cardiac death, nor the resultant good of these donations, is

378. The President’s Council on Bioethics began to get to this point in its 2008 commentary on donation after cardiac death, stating that “debates about the proper meaning of ‘irreversible’ do not address a more pressing ethical dilemma—the question of whether there is something wrong with rushing to make a determination of death because of external pressures to procure organs as expeditiously as possible.” The President’s Council on Bioethics, Controversies in the Determination of Death 85, 85-86 (2008) available at http://www.thenewatlantis.com/docLib/20091130_determination_of_death.pdf.

379. Allegations of organ harvesting contemporaneous to the execution of Falun Gong prisoners in China have recently been presented to Congress. See Falun Gong: China’s Ongoing War on Human Rights: Hearing Before the Subcommittee on Oversight and Investigations of the H. Comm. On International Relations, 109th Cong. 16-22 (2006) (statement of David Kilgour, Former Member of the Canadian House of Commons), http://commdocs.house.gov/committees/IntRel/hfa30146.000/hfa30146_0f.htm (last visited Jan. 21, 2011). The American Medical Association finds organ donation by a condemned prisoner acceptable only if the decision to donate was made prior to the prisoner’s conviction, and allows tissue to be harvested only after the prisoner has been pronounced dead and the body removed from the death chamber. Council on Ethical and Judicial Affairs, the American Medical Association, Policy E-2.06 Capital Punishment, in Council on Ethical and Judicial Affairs, Code of Medical Ethics of the American Medical Association 20, 21 (2008).
sufficient to overcome the fundamental requirement of the certainty of the natural death of the donor.

More fundamentally, uncertainty between letting the patient die and making the patient die is innate in the application of the weakest construal of the irreversibility standard for the cessation of cardiac function and in the parsed substitution of a permanence standard for cessation of circulatory function in lieu of an irreversibility standard for cessation of cardiac function. Such uncertainty as to causation of death is by no means moot when it exists in cardiac procurement in DCD practice. In distinguishing between the act of ending or refusing lifesaving medical treatment and the act of the causation or assistance of suicide, the United States Supreme Court noted that “the distinction between assisting suicide and withdrawing life-sustaining treatment, a distinction widely recognized and endorsed in the medical profession and in our legal traditions, is both important and logical; it is certainly rational.” The Court further noted that such a distinction “comports with fundamental legal principles of causation and intent.” Our Committee believes that the same rational distinction is fundamentally important in the practice of organ donation after cardiac death, and such a distinction is drawn in particular by the practice of recovery of a heart from a non-heart beating donor.

In discussing a rational basis for the prohibition of physician assisted suicide, the United Supreme Court found that “the State has an interest in protecting vulnerable groups—including the poor, the elderly, and disabled persons—from abuse, neglect, and mistakes.” Our Committee believes that this State interest is not diminished in the final moments of life. The fact that the patient is nearing natural death does not allow or affirm acts that intentionally cause death, nor does it justify a situational redefinition of death.

We note that the American Society of Transplant Surgeons recently demurred on issuing practice guidelines for recovery of cardiothoracic organs in DCD, noting that “[t]here are issues unique to DCD cardiothoracic organ procurement and transplantation.” Our Committee concluded that the removal of a heart from a non-heart beating donor raises serious questions as to the causation of death, the performance of an affirmative act to hasten death, and the lack of compliance with statutory requirements for determination of death. Our Committee has adopted the position that a heart shall not be recovered from a donation after cardiac death donor within the Willis-Knighton Health System. We believe that this prohibition should be adopted wherever donation after cardiac death is practiced.

4. Consent to Donation After Cardiac Death by a Conscious Ventilator-Dependent Patient

The performance of organ donation after cardiac death in a conscious ventilator-dependent patient consenting to the procedure raises obvious concerns regarding the dead donor rule and is not theoretic. Although the common practice of DCD involves a donor who has sustained a severe neurologic injury, some cases have involved donors with advanced disease processes that have left them in a conscious state but dependent upon mechanical ventilatory support such that withdrawal of that support would result in death. In 2000 the Strong Memorial Hospital reported the case of a 28 year old man with posttraumatic quadriplegia who, as a fully conscious and competent patient, was allowed to choose to have his ventilator removed and his organs donated in a DCD procedure. The Institute of Medicine noted that same year that “these requests are rare, but workshop participants reported an occasional request of this kind.”

385. Jeffrey Spike, Controlled NHBD Protocol for a Fully Conscious Person: When Death is Intended as an End in Itself and It has Its Own End, 11 J. CLIN. ETHICS 73, 73-77 (2000).
386. INSTITUTE OF MEDICINE, NON-HEART-BEATING ORGAN TRANSPLANTATION: PRACTICE AND PROTOCOLS, supra note 207, at 42.
the ALS Society has recently detailed the case of a patient with amyotrophic lateral sclerosis (ALS) who directed removal of her ventilator and who was allowed to become a DCD donor under a protocol of the University of California San Francisco Medical Center.³⁸⁷

The 2000 Institute of Medicine Report did not make a recommendation on this issue. The report stated that:

[T]here are limits to consensus on who may be a non-heart-beating donor. For example, opinion is divided on the option of non-heart-beating donation for the patient who is ventilator depended but conscious and who wants to stop life-sustaining treatment.

Consensus on this option was not attempted at the workshop. There are compelling legal and ethical grounds for the right of a conscious person to refuse life-sustaining treatment. However, experience with organ and tissue donation in this situation is too limited to provide a basis for general conclusions and guidelines. Individual cases must be approached with the primary focus on patient comfort and palliative care.³⁸⁸

The National Conference on Donation After Cardiac Death specifically endorsed DCD for these patients, stating that “[c]onditions that may lead to consideration of DCD eligibility include irreversible brain injury, end-stage musculoskeletal disease and high spinal cord injury.”³⁸⁹ The American Society of Transplant Surgeons practice guidelines for DCD have recognized patients with “[c]atastrophic brain injury or other illness such as endstage musculoskeletal disease, pulmonary disease or high spinal cord injury” as candidates for DCD, but importantly also

³⁸⁸. INSTITUTE OF MEDICINE, NON-HEART-BEATING ORGAN TRANSPLANTATION: PRACTICE AND PROTOCOLS, supra note 207, at 42, 49.
recommend that DCD candidates must have “[n]o expectation of meaningful survival, as determined by the patient’s treating physician(s).”

A careful review of the Louisiana statutory structure reveals that the combined provisions of the Louisiana Natural Death Act and the Louisiana Anatomical Gift Act which permissively allow DCD as currently practiced could also conceivably allow DCD to be performed on a conscious patient under specifically constrained circumstances. Such a patient would be “diagnosed and certified in writing as having a terminal and irreversible condition by two physicians who have personally examined the patient, one of whom shall be the attending physician” with a “condition caused by injury, disease, or illness which, within reasonable medical judgment, would produce death and for which the application of life-sustaining procedures would serve only to postpone the moment of death.” There is no specific requirement that such a patient not be conscious. Prior to withdrawal of life-sustaining procedures, such patients could execute a valid anatomical gift under Louisiana Revised Statutes section 17:2352(B), which would take effect after the pronouncement of death.

Whether a conscious person not certified as terminally ill could follow a similar course is less clear. The right of a person to direct their medical care, long established in principles of bodily integrity, autonomy, privacy, and informed consent, is well recognized. The Louisiana Constitution holds that “[e]very person shall be secure in his person...against unreasonable searches, seizures, or invasions of privacy.” In reviewing the right to privacy, the Louisiana Supreme Court in Hondroulis v. Schumacher found that “[t]he decision to obtain or reject medical treatment clearly should be recognized as falling within this cluster of constitutionally protected choices.” The Court then specifically concluded that

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393. LA. CONST. ART. I, § 5.
“also provides for a right to decide whether to obtain or reject medical treatment.”\footnote{395} Louisiana statutory law recognizes the “right of a person eighteen years of age or over to refuse to consent to medical or surgical treatment as to his own person.”\footnote{396} The Louisiana Natural Death Act contains a statement of legislative purposes, findings, and intent which specifies that “all persons have the fundamental right to control the decisions relating to their own medical care, including the decision to have life-sustaining procedures withheld or withdrawn in instances where such persons are diagnosed as having a terminal and irreversible condition.”\footnote{397} In this statement, the Act further specifies that “nothing in this Part shall be construed to be the exclusive means by which life-sustaining procedures may be withheld or withdrawn, nor shall this Part be construed to require the application of medically inappropriate treatment or life-sustaining procedures to any patient or to interfere with medical judgment with respect to the application of medical treatment or life-sustaining procedures.”\footnote{398} Although nowhere explicitly stated, these sources taken in the whole seem to encompass the right of a conscious person not declared terminally ill to exercise a fundamental right to control decisions as to procedures that would be otherwise be considered life-supportive under the Natural Death Act, even if such a decision would result in death. This interpretation would be consistent with the general right to refuse treatment expressed by the Louisiana Supreme Court and codified in Louisiana Revised Statutes section 40:1299.56.

Even if a conscious person (whether terminally ill or not) may decide to forgo life-sustaining treatments and procedures, and even if such person has made a valid anatomical gift statement, our Committee does not believe that there exists an affirmative duty on the part of a physician or hospital to temporarily combine the withdrawal of life-sustaining treatments with the execution of an anatomical gift statement in the practice of organ donation after cardiac death. As detailed in Part IV supra, we find no state or federal statutory or regulatory authority requiring a hospital to perform donation after cardiac death. For those

\footnote{395} Id.
hospitals that choose to provide DCD, the practice is governed by permissive agreement between the OPO and the hospital. There is certainly no requirement that such agreement must allow the practice of DCD in a conscious ventilator-dependent patient who requests it.

The decision whether to do so thus rests on a voluntary and balanced assessment of factors such as respect for the autonomy of the patient, concern for the adequate supply of donor organs, consideration of the well-being of the donor and the integrity of the organ donation process, and apprehension as to public perception of impropriety. In the judgment of our Committee, the rare application of DCD in a conscious ventilator-dependent patient is not a material remedy to the shortage of donor organs. Respect for autonomy of the patient forms the most powerful argument to allow a conscious ventilator-dependent patient to request DCD.

Regarding the principle of patient autonomy, the American Medical Association has held that “[t]he principle of patient autonomy requires that physicians respect the decision to forgo life-sustaining treatment of a patient who possesses decision-making capacity.” However, unbridled autonomy tests the limits of the social contract governing organ donation. In Belgium, the practice of DCD is now occurring in tandem with active euthanasia, and the proponents ask “can a request for organ donation after euthanasia be denied if the patient strongly expresses the will for donation?”

It is clear that our society does not permit unbridled patient autonomy in medical care, and particularly not in organ transplantation. We do not allow patients to sell their organs. We would not allow a living donor to donate a cornea. We require living donors to undergo extensive education as well as cognitive,

399. Council on Ethical and Judicial Affairs, the American Medical Association, Policy E-2.20 Withholding or Withdrawing Life-Sustaining Medical Treatment, in COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION 82, 82-82 (2008).


medical, and psychological evaluations. In a remarkably prescient discussion of these issues in 1970, Paul Ramsey considered the hypothetical case of a father who sacrificially wished to be a living heart donor for his terminally ill son. Noting that “[t]his case, or one like it, will happen one day,” Ramsey reflected that:

Then, the crucial question will be: Are a person’s consent or his spiritual or psychological wholeness the only right-making considerations to be taken into account in deciding such a question? Are violation of a person’s consent or psychological wholeness the only wrong-making features? Are these the only ways to violate a man, or for him to do impermissible violence to himself? Is anything left of the notion that a human being has (or better, is) a bodily integrity, and that out of the respect due also to this there are some actions that must be judged to be wrong—even when they are embraced by a free and informed consent and even when the self-giving of a heart is deemed the only way to avoid intolerable sorrow and may (for all we know) give promise of spiritual benefits in the age to come, and—what is more important still—is the only way successfully to oppose for a time the death of a beloved son?

Our Committee has many concerns as to the interests and well-being of vulnerable patients who may find themselves to be conscious in a ventilator-dependent state due to an endstage musculoskeletal disease, pulmonary disease or high spinal cord injury. The scant evidence available indicates that conscious ventilator-dependent DCD donors express a deeply felt wish that some good be realized from their circumstances. But there are other concerns to be balanced. A 1993 New England Journal of Medicine review of the question of withdrawal of life-supportive therapy in patients with cervical-level quadriplegia, particularly

403. Ramsey, supra note 11, at 190.
soon after injury, found that “while acknowledging that patients with high-level spinal cord injuries have the moral and legal right to refuse treatment, we must also attend to their capacity to make such decisions....[t]he ability of such patients to weigh the factors involved in terminating life support will usually be temporarily diminished to such an extent that they cannot provide informed refusal or consent.”404 It is of substantial concern that in a somewhat analogous population of patients who seek euthanasia or physician-assisted suicide, depression, hopelessness, and a lack of social support are frequent.405 Regarding these patients, the American Medical Association notes that, “Instead of engaging in euthanasia, physicians must aggressively respond to the needs of patients at the end of life. Patients should not be abandoned once it is determined that cure is impossible. Patients near the end of life must continue to receive emotional support, comfort care, adequate pain control, respect for patient autonomy, and good communication.”406

We have no moral or ethical objection to the very carefully performed withdrawal of life-supportive measures in conscious ventilator-dependent patients who request withdrawal in accordance with Louisiana law provided that such patients are thoroughly evaluated for depression and other clinical and social concerns that might impair decision-making capacity. We have no objection to the ability of these patients to become tissue donors by a valid anatomical gift statement, though we would not want such wishes to drive the decision to withdraw life-sustaining therapies. The essential question is whether, in promulgation of

404. David R. Patterson et al., When Life Support is Questioned Early in the Care of Patients with Cervical-Level Quadriplegia, 328 NEW ENGL. J. MED. 506, 507 (1993). The authors concluded that “decisions about life support in an alert patient with a cervical spinal injury should, except in rare circumstances, be delayed until the patient appreciates fully what life will be like after a full course of rehabilitation....It is both possible and medically and ethically acceptable, however, to undertake this process once the patient has completed rehabilitation.” Id. at 508, 509.


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anatomical gift acts, society intended to allow a conscious person to become an organ donor whose death is “imminent” only because of a planned withdrawal of life-supportive measures under a natural death act. We find no evidence that Louisiana has considered these specific matters in legislative debate, and we find no evidence that the legislative history of the Uniform Anatomical Gift Act, the Louisiana Anatomical Gift Act, or Louisiana Natural Death Act indicates such intent.

We have grave concerns about the performance of DCD in a conscious ventilator-dependent patient who would take leave of family, friends, and staff, be transported to the operating room, given sedation, removed from the ventilator, and then be observed to die in preparation for a rushed retrieval of organs. Beyond the highly complex issues of personal and societal good, we believe that there is substantial potential for perceptions of scandal and impropriety within our community and among our staff and patients, with a significant attendant possibility of adverse impact to the integrity of our subsequent organ donation efforts. In careful consideration of all concerns, our Committee has concluded that donation after cardiac death shall not be allowed for a conscious patient within the Willis-Knighton Health System.

Our Committee interpretation of the template LOPA Agreement/Protocol structure is that it could permit DCD to be performed on a conscious competent ventilator-dependent patient who consents to become a DCD donor. Such a patient could be “under orders of a physician to have cardiopulmonary sustaining therapies discontinued” and “dependent on mechanical/pharmacological support and the removal of such support should result in cardiac death.” The Willis-Knighton protocol specifically requires that all potential DCD donors must not be

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407. For a discussion of public scandal that erupted upon initiation of the Cleveland Clinic DCD protocol in 1997, see Wesley J. Smith, CULTURE OF DEATH: THE ASSAULT ON MEDICAL ETHICS IN AMERICA 155, 155-160 (Encounter Books 2000).

408. LOPA Agreement, supra note 158 & LOPA Protocol, supra note 160. Such a patient could have a “condition caused by injury, disease, or illness which, within reasonable medical judgment, would produce death and for which the application of life-sustaining procedures would serve only to postpone the moment of death” as specified in the Louisiana Natural Death Act, LA. REV. STAT. ANN. §§ 40:1299.58.1 to 1299.58.10 (2008 & Supp. 2011).
conscious, and must be in a continual and profound comatose state. 409

VII. CONCLUSION

Over three years ago, the Institutional Ethics Committee of the Willis-Knighton Health System faced the challenge of developing a policy regarding organ donation after cardiac death. We sought to balance societal goods such as the preservation of lives by organ donation and transplantation, the respect for patient autonomy and choice, and the ability of families to gain a sense of benefit in the loss of loved ones, with our responsibility to guard the interests of vulnerable and dying patients and to uphold the highest ethical standards of the medical profession. We conducted an extensive study of the practices of organ donation after cardiac death, including its historical context, its practical impetus, its statutory and regulatory framework, and its ethical challenges. Our conclusions include regulatory and legal interpretation that we believe will be of interest throughout the United States, and ethical positions that we believe should be of interest wherever donation after cardiac death is practiced.

409. The Willis-Knighton Protocol, supra note 5.