

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Chapter 25 (16 **Del.C.** Ch. 25)
16 **DE Admin. Code** 4304

PROPOSED

PUBLIC NOTICE

4304 Pre-Hospital Advanced Care Directive

The Division of Public Health, under the Department of Health & Social Services, is proposing regulations which amend Title 16 of the Delaware Code relating to Pre-Hospital Advanced Care Directives. There is a need to address the recognition of Pre-Hospital Advanced Care Directives in conjunction with Advanced Care Directives as provided for in 16 **Del.C.** Ch. 25, in the pre-hospital emergency environment. These regulations require the use of a specific form of individual identification that can be readily recognized and verified during a pre-hospital emergency. The regulations also detail the legislated immunity for certified providers honoring this order. On May 1, 2011, the Division plans to publish the proposed 4304 Pre-Hospital Advanced Care Directives and hold them out for public comment per Delaware law.

Copies of the proposed regulations are available for review in the May 1, 2011 edition of the *Delaware Register of Regulations*, accessible online at: <http://regulations.delaware.gov> or by calling the Office of Emergency Medical Services at (302) 223-1350.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed new regulations must submit same to Deborah Harvey by Tuesday, May 31, 2011 at:

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The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

4304 Pre-Hospital Advanced Care Directive

Purpose:

~~There is a need to update the existing 2003 Pre-Hospital Advance Care Directive ("PACD") regulations (7 Del. Reg. 85, July 1, 2003) to address the recognition of Pre-Hospital Advance Care Directives in conjunction with Advanced Care Directives as provided for advance care directives across all health care settings, including, but not limited to, hospitals, long-term care facilities, hospices, emergency medical transport, and home care. As provided in Chapter 25 of Title 16 of the Delaware Code, advance care directives permit individuals to give instructions about their own health care in Delaware Code Title 16, Chapter 25, in the pre-hospital emergency environment, case they later lack the capacity to do so.~~

~~These regulations require the use of a specific designated form of individual identification that which can be readily recognized and verified during a pre-hospital emergency. The regulations also detail the legislated immunity for certified providers honoring this order an emergency situation. Since the creation of the PACD form, the practice and use of similar forms has evolved in states across the country. The Medical Orders for Life-Sustaining Treatment ("MOLST") form reflects the dominant national trend and is being adopted as an updated version of the PACD form.~~

~~While such legal instruments serve individuals well in clinical settings such as hospitals and Delaware's current PACD loses its authority when a patient changes locations. Patients at the end of life often move from home to hospital to nursing homes, they pose practical problems in life threatening situations when emergency medical home and with each move, forms and orders must be redone.~~

~~Emergency medical services (EMS) individuals are called personnel work under the license of the State EMS Medical Director. In order for assistance EMS personnel to honor an individual's request related to end of life decisions, the EMS must have a medical order. The MOLST form serves both as the summary of the individual's advance care planning~~

decisions and as the medical order.

~~Living wills, power of attorney and other advance directives have material limitations. They are often long and complex, can vary greatly in form and content, are subject to various interpretations, and do not ~~apply to the pre-hospital environment~~ constitute a medical order. Many are hand-written and are impossible to verify on the scene of an emergency. Furthermore, in most states, if an EMS provider is called to the scene, they are legally required to perform life saving techniques (CPR) even if the individual's heart has stopped and they are clinically expired. And, they cannot stop these efforts based on a living will or appointed proxy's request, because advance directives may not apply in EMS related medical emergencies. A Delaware Pre Hospital Advanced Care Directive. In contrast, a Delaware MOLST is a specific order set initiated by the individual and signed by a physician or other authorized health care professional stipulating a specific order set initiated for individual non-resuscitations scope of medical treatment.~~

~~A Pre-Hospital Advanced Care Directive regulation authorizes These MOLST/PACD regulations authorize the Division of Public Health/Office of Emergency Medical Services in conjunction with the Board of Medical Practice Licensure and Discipline, the Delaware Fire Prevention Commission, and other key groups within the State to develop and implement an EMS Pre-Hospital Advanced Care Directive (PACD) a MOLST/PACD protocol for EMS providers. This law and These regulations, protocol, and form standardize the legal ~~advanced~~ advance care directive documentation so EMS ~~that~~ EMS and all health care providers have a readily recognizable format upon which they may make a decision. This would also ~~form~~ form which sets forth the patients' preferences regarding provision of life-sustaining treatments. The MOLST/PACD forms allow EMS and other health care providers both to identify and to honor the an individual's wishes to the greatest extent possible and to grant the individual individuals the dignity, humanity, and compassion they deserve. Consistent with this intent, other health care providers may choose to honor this form.~~

1.0 Definitions

“Advanced Health Care Directive” shall mean an individual instruction or power of attorney for health care, or both.

“Agent” shall mean an individual designated in a power of attorney for health care to make a health care decisions for the individual granting the power.

“Artificial Nutrition And Hydration” means supplying food and water through a conduit, such as a tube or intravenous line where the recipient is not required to chew or swallow voluntarily, including, but not limited to, nasogastric tubes, gastromstomies, jejunostomies and intravenous infusions. Artificial nutrition and hydration does not include assisted feeding, such as spoon or bottle-feeding.

“Capacity” shall mean an individual's ability to understand the significant benefits, risks and alternatives to proposed health care and to make and communicate a health care decision.

“Declarant” shall mean an individual who executes an advance health care directive.

“Division” shall mean the Division of Public Health.

“DNR” shall mean Do Not Resuscitate.

“Emergency Medical Services (EMS) Provider” shall mean individual providers certified by the Delaware State Fire Commission or the Office of Emergency Medical Services, within the Division of Public Health, Department of Health and Social Services or emergency certified medical dispatchers by the National Academy of Emergency Medical Dispatch.

“Emergency Medical Services (EMS) Provider Agency” shall mean a provider agency certified by the Delaware State Fire Prevention Commission or the Office of Emergency Medical Services, or an emergency medical dispatch center under contract with the Department of Public Safety.

“EMS Prehospital Advanced Care Directive Order (PACD)” shall mean an advanced health care directive signed by the individual's physician on forms approved by the Director of the Division of Public Health.

“EMS PACD Program” shall mean the regulations and administrative guidelines promulgated by the Division of Public Health for the administration of this Act.

“Guardian” shall mean a judicially appointed guardian or conservator having authority to make health care decisions for an individual.

“Health Care” shall mean any care, treatment, service or procedure to maintain, diagnose or otherwise affect an individual's physical or mental condition.

“Health Care Decision” shall mean a decision made by an individual or the individual's agent, surrogate or guardian regarding the individual's health care, including:

1. Selection and discharge of health care providers and institutions;
2. Acceptance or refusal of diagnostic tests, surgical procedures, programs of medication ~~and orders not to resuscitate~~ resuscitation; and
3. Directions to provide, withhold or withdraw artificial nutrition and hydration and all other forms of health care.

“Health Care Institution” means an institution, facility or agency licensed, certified or otherwise authorized or permitted by law to provide health care in the ordinary course of business or practice of profession.

“Emergency Medical Services (EMS) Provider” shall mean individual providers certified by the Delaware State Fire Prevention Commission or the Office of EMS, or emergency medical dispatchers certified by the National Academy of Emergency Medical Dispatch.

“Emergency Medical Services (EMS) Provider Agency” shall mean a provider agency certified by the Delaware State Fire Prevention Commission or the Office of EMS, or an emergency medical dispatch center under contract with the Department of Public Safety.

“Individual” means ~~an individual, corporation, business trust, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency or instrumentality or any other legal or commercial entity~~ an individual person, legally adult.

“Individual Instruction” means an individual’s direction concerning a health-care decision for the individual.

“Life-sustaining Procedure” means:

1. Any medical procedure, treatment or intervention that:
 - 4a. Utilizes mechanical or other artificial means to sustain, restore, or supplant a spontaneous vital function; and
 - 2b. Is of such a nature as to afford an individual no reasonable expectation of recovery from a terminal ~~illness condition or permanent unconsciousness.~~
2. Procedures that can include, but are not limited to, assisted ventilation, renal dialysis, surgical procedures, blood transfusions and the administration of drugs, antibiotics and artificial nutrition and hydration.

“Medical Orders for Life-Sustaining Treatment” (“MOLST”) means a specific order set for scope of medical treatment and provided on the MOLST form approved by the Division of Public Health.

“Medically Ineffective Treatment” means that, to a reasonable degree of medical certainty, a medical procedure will not:

1. Prevent or reduce the deterioration of the health of an individual: or
2. Prevent the impending death of an individual.

“Office” shall mean the Office of Emergency Medical Services (EMS) within the Division of Public Health.

“PACD” means an EMS prehospital advanced care directive signed by the individual and the individual’s physician, on forms approved by the Director of Public Health.

“Permanent Unconsciousness” means a medical condition that has existed for at least 4 weeks and that has been diagnosed in accordance with currently accepted medical standards and with reasonable medical certainty as total and irreversible loss of consciousness and capacity for interaction with the environment. The term includes, without limitation, a persistent vegetative state or irreversible coma.

“Physician” means an individual licensed to practice medicine under Chapter 17 of Title 24 of the **Delaware Code**.

“Power Of Attorney For Health Care” means the designation of an agent to make health care decisions for the individual granting the power.

“Primary Physician” or “Attending Physician” shall mean a physician designated by an individual or the individual’s agent, surrogate or guardian to have primary responsibility for the individual’s health care or, in the absence of a designation, or if the designated physician is not reasonably available, a physician who undertakes the responsibility for the individual’s health care.

“Reasonably Available” shall mean readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the individual’s health care needs.

“Supervising Health Care Provider” shall mean the primary physician, or if there is no primary physician or the primary physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual’s health care.

“Surrogate” means an adult individual or individuals who (1) have capacity; (2) are reasonably available; (3) are willing to make health care decisions, including decisions to initiate, refuse to initiate, continue or discontinue the use of a life sustaining procedure on behalf of a ~~individual patient~~ who lacks capacity; and (4) are identified by the ~~individual’s identification~~ attending physician in accordance with ~~this chapter~~ **Del.C. §2507** as the ~~individual person or individuals persons~~ who are to make those decisions ~~in accordance with this chapter.~~

“Terminal Illness Condition” means any disease, illness or condition sustained by any human being for which there is no reasonable medical expectation of recovery and which, as a medical probability will result in

the death of such human being regardless of the use or discontinuance of medical treatment implemented for the purpose of sustaining life or the life processes.

2.0 Right to Self-Determination

An individual, legally adult, who is mentally competent, has the right to refuse medical or surgical treatment if such refusal is not contrary to existing public health laws.

3.0 Medical Prerequisites

- 3.1 Any individual with legal capacity may execute a Medical Order for Life-Sustaining Treatment (MOLST) or a Pre-Hospital Advanced Care Directive (PACD); however, this Directive will not become effective unless, after diagnosis of a terminal condition, or a determination of permanent unconsciousness, it is signed by a physician after diagnosis of a terminal illness or other health care provider permitted by state law.
- 3.2 An Individual with legal capacity, who is able to communicate by some reliable, proven means (i.e. verbally, verbalization, eye blink, finger tap) but is physically unable to sign, may execute a MOLST or PACD through an agent or, surrogate, or guardian. To be effective upon the diagnosis of a terminal illness from a physician in Delaware Conditions that may prevent physical signing of ~~the~~ a MOLST or the PACD include, but are not limited to:
 - 3.2.1 Blindness or illiteracy
 - 3.2.2 Severe arthritis
 - 3.2.3 Amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease)
 - 3.2.4 Quadriplegia
 - 3.2.5 Paralysis of the writing hand
 - 3.2.6 Amputation
- 3.3 An individual who no longer has capacity may be issued a MOLST or PACD through an agent, guardian or surrogate and the individual's physician or authorized health care provider.
 - 3.3.1 Conditions for which a MOLST or PACD may be issued are:
 - 3.3.1.1 Terminal Illness Condition

4.0 Medical Orders for Life-Sustaining Treatment

- 4.1 Medical Orders for Life-Sustaining Treatment may contain the following options
 - 4.1.1 Cardiopulmonary Resuscitation or No Cardiopulmonary Resuscitation (If person has no pulse and is not breathing)
 - 4.1.2 Medical Interventions (If person has a pulse and/or is breathing.)
 - 4.1.2.1 Comfort Measures Only (The use of medications by any route, positioning, wound care, and other measures to relieve pain and suffering. Use of oxygen, oral suctioning and manual treatment of airway obstruction as needed for comfort. Do not transfer to the hospital for life-sustaining treatment. Transfer if comfort needs cannot be met in current location).
 - 4.1.2.2 Limited Additional Interventions. (Includes care described above, IV fluids, and cardiac monitoring as indicated. Do not use intubation or mechanical ventilations. May use non-invasive airway support, [e.g. CPAP, BIPAP]. Transfer to hospital, if indicated.)
 - 4.1.2.3 Full treatment. (Includes care described above, use of intubation, advanced airway interventions, mechanical ventilation, and cardioversion, as indicated. Transfer to hospital, if indicated. Includes intensive care, Additional orders [e.g. dialysis, etc.]
 - 4.1.2.4 Antibiotics
 - 4.1.2.4.1 No antibiotics. Use other measures to relieve symptoms.
 - 4.1.2.4.2 Limited use of antibiotics to provide comfort.
 - 4.1.2.4.3 Use antibiotics to prolong life. (Additional Orders: _____)
 - 4.1.2.5 Artificially administered nutrition: (Always offer food and liquids by mouth, if feasible.)
 - 4.1.2.5.1 No artificial nutrition by tube.
 - 4.1.2.5.2 Defined trial period of artificial nutrition by tube. (Goal: _____)
 - 4.1.2.5.3 Long-term artificial nutrition by tube. (Additional orders: _____)

45.0 Prehospital Advanced Care Directives

- 45.1 Prehospital Advanced Care Directive Options

- 45.1.1 Option A (Advanced Life Support) - “Maximal (Restorative) Care Before Arrest, Then DNR”
- 45.1.1.1 When this option is selected on an EMS PACD, the individual shall receive the full scope of restorative interventions permissible under the Delaware Statewide ALS treatment protocol (including intubation for respiratory distress, cardiac monitoring, synchronized cardioversion for pulse-present ventricular or supra ventricular tachycardia, cardiac pacing for pulse-present symptomatic bradycardia, insertion of IV’s, and drug therapy), in an attempt to forestall cardiac or respiratory arrest (see Delaware Statewide ALS treatment protocol for full description of permissible interventions).
- 45.1.2 Option B (Basic Life Support) – “Limited (Palliative) Care Only Before Arrest, Then DNR”
- 45.1.2.1 Palliative care is defined as supportive care for control of signs and symptoms.
- 45.1.2.1.1 This includes opening the airway using non-invasive means (e.g. chin lift, jaw thrust, finger sweep, nasopharyngeal airway, oropharyngeal airway and abdominal thrust, O2 administration, suctioning, positioning for comfort, control of external bleeding using standard treatments (dressing, elevation, direct pressure, pressure points, cold packs, tourniquets, etc.), immobilize immobilizing fractures, and family or other health care provider administered medications for pain control.
- 45.1.2.1.2 Existing IV lines may be in place and, if so, shall be monitored to the extent possible according to the provider’s level of certification and licensure.
- 45.1.2.2 Inappropriate Care for a Palliative Care Individual includes:
- 45.1.2.2.1 Pacing, cardioversion, and defibrillation
- 45.1.2.2.2 Initiation of IV therapy
- 45.1.2.2.3 EMS Initiated Medications - Except passive oxygen
- 45.1.2.2.4 CPR
- 45.1.2.2.5 Intubation (EOA, endotracheal, nasotracheal, or gastric tube)
- 45.1.2.2.6 Pneumatic anti-shock garment (PASG)
- 45.1.2.2.7 Active ventilatory assistance, unless on an out individual ventilator.
- 45.1.3 Option C (Do Not Resuscitate) – “No Care Administered Of Any Kind”.
- 45.1.3.1 This option permits an individual to reject care of any kind provided there is a signed order clearly stating this course of action. Where this option is in place, no form of life saving efforts, including but not limited to, the opening of the airway, the administration of oxygen, or any other form of life-saving efforts will be administered by EMS personnel under any circumstances, unless the individual provides some form of communication as indicated in Section 3.2.
- 45.1.4 Nothing in this regulation will require an EMS provider to comply with a Pre-Hospital Advanced Care Directive for reasons of conscience.

56.0 Methods of Identification

- 56.1 Provided there is a signed MOLST, PACD, or other approved Division of Public Health signed form, the following are acceptable for implementing methods to identify the EMS existence of a MOLST or PACD form and to implement the MOLST/PACD protocol:
- 56.1.1 Delaware MOLST or EMS PACD Form
- 56.1.2 Delaware MOLST or EMS PACD Wallet Card
- 56.1.3 Delaware MOLST Wrist Bracelet to include Medic-Alert Bracelet or other bracelet approved by the Director of the Division of Public Health.
- 56.1.4 Other State EMS PACD or MOLST Form
- 56.2 Even if a signed PACD, MOLST, or other approved Division of Public Health signed form is present, the following are not acceptable for implementing the EMS PACD or MOLST protocol:
- 56.2.1 Advance directives without an EMS PACD or MOLST form
- 56.2.2 Facility specific PACDs DNR forms
- 56.2.3 Notes in medical records
- 56.2.4 Prescription pad orders
- 56.2.5 PACD stickers
- 56.2.6 Any oral request.
- 56.2.7 Any other device or instrument not listed above as acceptable.

- 56.3 The Delaware MOLST or EMS PACD must be completed for all individuals on a standard form approved by the Division of Public Health, and the form must be present.
- 56.4 If any question exists as to the identity of the individual identified on the Delaware MOLST or EMS PACD form, the EMS provider shall seek to identify the individual through another form of positive identification.
- 56.4.1 If in doubt as to the identification of the individual, the EMS provider shall initiate resuscitative efforts.

67.0 Revocation of MOLST/PACD

67.1 An Revocation by a Patient

7.1.1 A MOLST or EMS PACD may be revoked at any time by: an individual with capacity by:

67.1.1.1 A written cancellation signed by the individual.

67.1.1.2 An oral statement or gesture of any manner by the individual in the presence of two (2) witnesses, one of whom is a health care provider, requesting only palliative care or resuscitation.

7.1.1.3 A new MOLST/PACD constitutes a revocation of a previously dated MOLST/PACD.

7.1.2 If the individual revokes a MOLST form or an EMS PACD orally, the EMS PACD notification devices do not need to be destroyed. EMS providers should thoroughly document the circumstances of the revocation. An oral revocation by an individual is only good for the single response or transport for which it was issued.

7.2 Revocation by an agent, guardian, or surrogate.

67.2.1 During an emergency, when the authorized decision maker is not the individual, this individual decision maker cannot revoke a MOLST order or an EMS PACD. Under no circumstances, can a person or entity, other than the individual, revoke a MOLST order or an EMS PACD during an emergency.

7.2.2 Because of the difficulty in identifying authorized decision makers in emergent situations, it is incumbent upon an authorized decision maker who has authority to revoke a MOLST order or an EMS PACD to do so prior to the emergency if they wish resuscitation for the individual.

78.0 Section Prohibited Conduct

16 Del.C. §2513(b) makes willful concealment, destruction, falsification or forging of an advance directive, without the individual's or authorized decision maker's consent, a class C felony.

89.0 Field Termination

89.1 Nothing in these regulations shall ~~eaffect~~ the power of EMS providers to do the paramedic field termination of resuscitation protocol as approved by the Delaware Board of Medical ~~Practice~~ Licensure and Discipline.

89.2 A life-sustaining procedure may not be withheld or withdrawn from a patient known to be pregnant, so long as it is probable that the fetus will develop to be viable outside the uterus with the continued application of a life-sustaining procedures. (~~70 Del. Laws, c. 392, § 3.~~ 16 Del.C. §2503(i))

910.0 MOLST Protocol

910.1 The Division of Public Health, in consultation with the Board of Medical ~~Practice~~ Licensure and Discipline and the Delaware Fire Prevention Commission, shall develop and publish a protocol for EMS providers to comply with the requirements of this regulation.

10.2 The MOLST form will be available online, in order to maintain continuity throughout Delaware, please copy or print the MOLST form on purple or violet paper.

10.2.3 Faxed copies and photocopies are also valid MOLST forms.

10.2.4 Once this regulation has taken effect and the new MOLST forms are available online, health care providers and patients should no longer use the PACD form, but should use the MOLST form instead.

10.2.4.1 Although new PACD forms should not be created after the MOLST form becomes available, any PACD forms already completed with be honored.

11.0 Periodic Review of the MOLST Form

11.1 The MOLST form does not expire, but it should be reviewed periodically whenever:

11.1.1 The person is transferred from one care setting or care level to another, or

11.1.2 There is a substantial change in the person's health status, or

11.1.3 The person's treatment preferences change.

11.2 To void the MOLST form, draw a line through "Medical Orders" and write "VOID" in large letters. Any changes require a new MOLST.

102.0 Limitations of Liability

102.1 In addition to other immunity that may be provided for in law, 16 **Del.C.** §2510 provides ~~the~~ specific immunity in cases involving the provision, withdrawal, or withholding of care which may be life sustaining in nature.

102.1.1 EMS providers are not subject to criminal prosecution or civil liability or deemed to have engaged in unprofessional conduct as determined by the appropriate licensing, registering, or certifying authority as a result of withholding or withdrawing any healthcare under authorization obtained in accordance with 16 **Del.C.** Ch. 25.

143.0 Data Collection/Program Evaluation

143.1 The Division of Public Health shall provide appropriate information, education and training on the EMS PACD Program to health care providers.

143.2 The Division of Public Health ~~shall provide forms for Delaware licensed physicians and hospices, or other authorized health care providers.~~

143.3 ~~The Division~~ shall monitor the use of MOLST or EMS PACDs as presented to EMS providers.

143.43 The Division shall take such measures as necessary to assure individual confidentiality.

124.0 Reciprocity

124.1 Standardized EMS-Do Not Resuscitate (DNR) or MOLST or POLST (Physician Order for Life-Sustaining Treatment) orders ~~from another State approved by the Director of the Division of Public Health shall be honored.~~

12.2 EMS providers ~~shall treat out-of-state EMS-DNR orders as Limited (Palliative) Care Only Before Arrest PACD individuals, unless otherwise specified by the out-of-~~ validly executed and in compliance with the laws of that state Do Not Resuscitate (DNR) order shall be honored subject to the limitations in these regulations.

7 DE Reg. 85 (7/1/03)

14 DE Reg. 1195 (05/01/11)