

Regulatory Analysis Form		This space for use by ERRC
(1) Agency Department of Health		RECEIVED 2003 DEC -5 PM 2:32
(2) I.D. Number (Governor's Office Use) 10-174		ERRC Number: 3355
(3) Short Title Out-of-Hospital Do-Not-Resuscitate Orders		
(4) Pa. Code Cite  28 Pa. Code Chs. 1001, 1003, 1005, 1007 and 1051	(5) Agency Contacts & Telephone Number  Primary Contact: Margaret E. Trimble, Director of the Emergency Medical Services Office, Department of Health, 1032 Health and Welfare Building, P.O. Box 90, Harrisburg, PA 17108, (717) 787-8740  Secondary Contact: Kenneth Brody, Chief Counsel's Office, Department of Health, 825 Health and Welfare Building, P.O. Box 90, Harrisburg, PA 17108, (717) 783-2500	
(6) Type of Rulemaking (Check One)  Proposed Rulemaking <input checked="" type="checkbox"/> Final Order Adopting Regulation  Final Order, Proposed Rulemaking Omitted	(7) Is a 120-Day Emergency Certification Attached?  <input checked="" type="checkbox"/> No Yes: By the Attorney General  Yes: By the Governor	
(8) Briefly explain the regulation in clear and non-technical language. The final regulations will assist the implementation of an Act 59 of 2002 (Act 59) amendment to the Advance Directive for Health Care Act (20 Pa.C.S. §§ 5401-5416) that directs emergency medical services (EMS) providers to follow the procedures for implementing an out-of-hospital DNR (no-resuscitation) order instead of an advance directive when both are present with the patient. An out-of-hospital DNR order issued under the DNR Act directs that no cardiopulmonary resuscitation (CPR) be provided by an EMS provider to a patient who experiences cardiac or respiratory arrest. The final regulations will also aid the Department in its implementation and administration of the DNR Act (20 Pa.C.S. §§ 54A01-5413). A primary purpose of the DNR Act enacted by Act 59, and Chapter 1051 of the final regulations, is to articulate standards for the issuance, revocation and compliance with out-of-hospital DNR orders. However, a component of the DNR Act deals with pregnant patients. That component sets forth specific rules for the administration of out-of-hospital DNR orders issued to pregnant patients. Also, it addresses other types of life-sustaining procedures, other types of orders and directives that address the withholding or withdrawing of life-sustaining procedures from pregnant patients, and duties of health care providers when confronted with such orders. The final regulations also deal with this component of the DNR Act.		

## Regulatory Analysis Form

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The Department is adopting final regulations to facilitate implementation of the DNR Act pursuant to section 6 of Act 59. That section gave the Department authority to adopt interim regulations (exempt from standing committee and IRRC review), but further provided that after the interim regulations were adopted the Department would be required to adopt final regulations by February 18, 2004, through customary rulemaking procedures.

(10) Is the regulation mandated by any federal or state law or court order or federal regulation?

If yes, cite the specific law, case or regulation, and any deadlines for action.

Yes. The regulations are mandated by section 6 of Act 59.

Act 59 went into effect on August 18, 2002. It required that the interim regulations be adopted within 120 days thereafter. Interim regulations were published December 14, 2002. Proposed regulations were published on September 6, 2003. Section 6 requires that final regulations be promulgated no later than 18 months after August 18, 2002.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Prior to the passage of Act 59 and the Department's adoption of the interim regulations, patients who suffered from a terminal illness or became permanently unconscious, and who desired to die naturally if they experienced cardiac or respiratory arrest, had difficulty having their wishes satisfied when EMS personnel were called to the scene. EMS personnel would follow standard resuscitation practices unless directed otherwise by a medical command physician. The General Assembly enacted the Advance Directive for Health Care Act to assist a patient who becomes terminally ill or permanently unconscious in having the patient's health care wishes implemented when the patient is no longer competent to communicate those wishes. However, the procedures for EMS personnel to comply with those wishes were too cumbersome to be practical. The DNR Act was enacted to simplify the process for EMS personnel not providing CPR to terminally ill or permanently unconscious patients when the patient or the patient's surrogate makes the decision to reject CPR when the patient experiences cardiac or respiratory arrest. These regulations are needed to facilitate the smooth implementation of the DNR Act.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

Every competent adult has the legal right to decide whether to accept or reject medical care, even emergency and life-saving care. Prior to Act 59, there was no good statutory means for EMS practitioners to permit these choices. The Advance Directive for Health Care Act attempted to aid patients in making these choices when the EMS system was triggered, but the procedures it employed were too cumbersome and complicated to be effective. Absent regulations to aid in the administration of the DNR Act, that act would not be implementable or not be implementable in the manner contemplated by the General Assembly.

## Regulatory Analysis Form

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Any patient with a terminal illness who wishes to avoid CPR in the event of cardiac or respiratory arrest, as well as a patient who is permanently unconscious, but who made the decision to avoid CPR in an advance directive, while conscious and competent, would benefit from these regulations. Prevention of unnecessary pain and suffering is an obvious, but not quantifiable benefit. Monetary costs per patient include related ambulance fees, undesired hospitalization, and possible intensive care admissions resulting from resuscitative efforts that may only serve to prolong suffering and not improve the quality of life in the terminally ill patient. The Department of Veteran Affairs Geriatrics and Extended Care Strategic Healthcare Group reports a range of \$24,512 to \$41,206 in costs for an individual's terminal care in the last 6 months of life.

Such costs affect patients, their families, and the health care industry, since they are forced to bear the expense of the lack of supportive regulation allowing patients the right to choose not to be resuscitated. EMS practitioners and the medical community would also benefit from the regulation by being granted the ability to provide appropriate and compassionate health care for dying patients, as chosen by the patient or the patient's surrogate with the assistance of the patient's attending physician, instead of imposing unwanted extraordinary measures that are not likely to result in a positive patient outcome. Under the Advance Directive for Health Care Act, if a patient has issued an advance declaration that directs that no CPR be provided, the EMS provider cannot follow that directive until the provider contacts a medical command physician, the medical command physician determines that the declaration is operative, and the medical command physician directs the EMS provider to withhold or discontinue CPR. Under the DNR Act, the EMS provider is empowered to withhold CPR upon observing an out-of-hospital DNR order, bracelet or necklace displayed with the patient; the EMS provider is not required to contact a medical command physician to secure approval.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

No one should be adversely affected by these regulations. Some physicians who qualify as the attending physician may not want to provide an out-of-hospital DNR order for a patient who qualifies for the order. The proposed regulations would not force a physician to issue the order if the physician does not want to do so, but the regulations would require the physician to assist the patient or the patient's surrogate to obtain that service from another physician.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

There are approximately 50,000 currently certified EMS practitioners who will be required to comply with the regulations. Additionally, there is an indeterminate number of good Samaritans operating AEDs who will be required to comply with the regulations.

There are 53,336 licensed physicians in PA. It is estimated that approximately 24,000 physicians will be involved in issuing DNR orders for patients.

There are estimated to be 10,000 (in the first year of implementation) patients or surrogates who will choose to initiate an out-of-hospital DNR order, with similar numbers in subsequent years.

## Regulatory Analysis Form

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

In developing the interim regulations the Department conferred with the State Advisory Council and Commonwealth agencies such as the Department of Aging, the Department of Education, the Department of Public Welfare, and the Pennsylvania Emergency Management Agency. It also convened a public hearing on the interim regulations on September 12, 2002, prior to which it distributed a preliminary draft of the interim regulations to persons who requested the preliminary draft. Notice of the public hearing was published at 32 Pa. B. 4208 (August 24, 2002). In adopting the interim regulations the Department considered the comments of the State Advisory Council, the Department's sister agencies, and all other persons who have provided comments to the Department. This input was also considered by the Department in developing the proposed regulations. A 30-day comment period was provided. Five persons, including IRRC, commented. The Department considered each of the comments in developing its final regulations.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures that may be required.

It is estimated that physicians will incur minimal costs for ordering DNR forms and DNR bracelets and necklaces. These products cost \$0.35 for bracelets, \$1.35 for necklaces, and \$0.11 for DNR order.

Patient and physician information has been developed and distributed by the Department. Educational materials are also available on the Department's web site. Patient educational material will reduce the need for physician resources to inform patients, families and caregivers on out-of-hospital DNR orders.

Based on the Department's experience in 2003 including the limitations for patient eligibility imposed by Act 59, it is estimated that 10,000 persons will avail themselves of DNR orders and products annually. There are 53,336 licensed physicians in PA. It is estimated that approximately 24,000 physicians will be involved in DNR orders with their patients. This number is based on data reported on the annual hospital questionnaire for the period ending June 1998 on physicians with clinical privileges in cardiology, colon/rectal, family practice, internal medicine, neurological surgery, oncology, otolaryngology, surgery and thoracic surgery.

For 10,000 DNR patients, supply costs totaling \$18,100 (in the first year of implementation) will be absorbed by an estimated 24,000 physicians, or those physicians, or some of them, may choose to pass the cost to their patients.

Licensed ambulance services will incur costs for developing written policies and procedures relating to DNR orders. Sample policies and procedures will be provided to the services and service costs will be minimal. The Department will provide technical assistance to licensed ambulance services. Certified EMS personnel will need to attend DNR training; however, the training will be approved for continuing education (CE), an existing regulatory requirement for certified EMS personnel.

It is expected that the overall net cost savings in reducing expensive and undesired end-of-life care will offset other costs incurred in implementing the statute and regulations.

## Regulatory Analysis Form

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures that may be required.

County governments may be impacted at their 911 centers. There will be minimal or no costs associated with minor adjustments that may be needed for medical dispatch protocols.

Local and county governments operating licensed ambulance services will be required to establish policies and procedures relating to DNR; however, minimal costs are anticipated as model policies and procedures have been developed by the Department and provided to all licensed services. As part of the continuing education requirement for certified EMS personnel, no additional costs are anticipated for employees to receive DNR training.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulations, including legal and accounting or consulting procedures that may be required.

Costs to state government averages \$26,000 annually for clerical support, travel costs for training, outreach and technical assistance to support the program.

Initial expenses were incurred to develop a DNR training module and disseminate information to regional EMS council staff, training institutes, and accredited CE sponsors who deliver DNR training. Existing staff have and will continue to absorb duties related to providing education and training, handling DNR inquiries, and distributing forms and patient educational materials. In addition, this staff will assist in collecting information for vendor specifications, as well as monitor vendor compliance for production and distribution of DNR supplies.

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government and state government for the current year and five subsequent years.

	Previous FY (2002)	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
<b>SAVINGS</b>						
Regulated Community	NA	NA	NA	NA	NA	NA
Local Government	NA	NA	NA	NA	NA	NA
State Government	NA	NA	NA	NA	NA	NA
<b>TOTAL SAVINGS</b>	NA	NA	NA	NA	NA	NA

## Regulatory Analysis Form

<b>COSTS</b>						
Regulated Community	\$0	\$18,100	\$18,100	\$18,100	\$18,100	\$18,100
Local Government	NA	NA	NA	NA	NA	NA
State Government	\$13,000	\$26,000	\$26,000	\$26,000	\$26,000	\$26,000
<b>TOTAL COSTS</b>	\$13,000	\$44,100	\$44,100	\$44,100	\$44,100	\$44,100
<b>REVENUE LOSSES:</b>						
Regulated Community	NA	NA	NA	NA	NA	NA
Local Government	NA	NA	NA	NA	NA	NA
State Government	NA	NA	NA	NA	NA	NA
Total Revenue Losses	NA	NA	NA	NA	NA	NA

(20a) Explain how the cost estimates listed above were derived.

Regulated community:

Projected volume based on a monthly average of the Department's experience to date in 2003. Every patient who wants a DNR order is required to obtain a written DNR order, however, they may *choose* whether to secure a bracelet, necklace, or both in order to identify themselves to EMS practitioners. The actual costs of these are \$0.35 for bracelets and \$1.35 for necklaces, and \$0.11 per DNR form. Thus, budget estimates are based on an average of \$1.81 per patient for DNR order and supplies. Estimated volumes are 10,000 patients annually based on the Department's experience in 2003, which includes limitations for patient eligibility imposed by Act 59.

State Government:

Development and revision of training materials, information and educational materials.  
 Clerical support and travel costs for training, outreach, and technical assistance (\$16,000).  
 Training costs for 16 EMS regions X 2 training sessions per year (\$10,000).

(20b) Provide the past three-year expenditure history for programs affected by the regulation.

Program			
	1999-00	2000-01	2001-02
(Health) General Government	\$24,250,000	\$27,453,000	\$29,353,000

## Regulatory Analysis Form

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

Without personal experience to draw upon, no one can relate to terminally ill patients and their families in the final days of life. Many of these patients feel helpless to determine their own course of treatment. Such suffering cannot be expressed in measurable terms. Without the regulations, the cost to patients and their families will be measured in anguish and pain that simply serves to prolong life, not improve its quality. Simply put, there is no benefit in that. In addition, without the regulations family members can incur increased financial burden when terminally ill patients are subjected to care they do not want that potentially results in prolonged hospitalization following successful resuscitative efforts.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

There are no non-regulatory alternatives. The statute sets the standards and directs the Department to adopt regulations to help implement the DNR Act.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

One alternative was for the Department to bear the costs of bracelets and necklaces. Every patient who wants a DNR order is required to obtain a written DNR order, however, they may *choose* whether to secure a bracelet, necklace, or both in order to identify themselves to EMS practitioners. The actual costs of the DNR order, bracelet, and necklace are \$1.81 per patient. Thus, budget estimates are based on an average per patient for DNR order and supplies. The Department rejected the option of paying for these DNR items because the costs to physicians and patients are small. However, the cost to the Department could be great if the Department assumed the expense of providing these items throughout the Commonwealth.

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

There are no federal regulations or standards for DNR orders.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

The Department is aware of patients who cancelled travel plans to the Commonwealth when informed that their DNR order from their home state could not be implemented or followed by EMS practitioners in Pennsylvania. The DNR Act accommodates DNR orders issued in other states under laws equivalent to Pennsylvania law. Forty-four other states have DNR regulations or protocols. The Department is currently evaluating one-third of these forty-four states for regulations consistent with PA. The primary barrier to consistency is related to the requirement by Act 59 that the patient has a terminal condition or suffers from a state of permanent unconsciousness. Another significant barrier is that PA law requires the signature of the attending physician on each out-of-hospital DNR item the physician issues.

One hospice agency from Youngstown, Ohio, requested Pennsylvania out-of-hospital DNR materials but was deemed ineligible because it was unable to identify an attending physician licensed to practice medicine in PA.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The regulation does not affect other agency regulations.

## Regulatory Analysis Form

(27) Will any public hearings or information meetings be scheduled? Please provide the dates, times, and locations, if available.

A public hearing was advertised in the *Pennsylvania Bulletin* and held on September 12, 2002. Informational meetings will be held with regional EMS councils and within the Statewide Advisory Council's committee structure. The first briefing was held September 25, 2002 with the PEHSC Medical Advisory Committee.

An informational session was held for the 16 regional EMS councils and the Statewide Advisory Council on February 13, 2003 and the Hospital and Healthsystems Association of PA (HAP) on March 5, 2003. Additional sessions with the Council of Hospital Home Health Agencies of HAP and HAP's Council of Long-Term Care Providers were provided on June 10, 2003 and August 15, 2003.

Briefings and information materials will be provided to Statewide professional associations, including Operation Heartbeat.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports that will be required as a result of implementation, if available.

Physicians will be required to document the patient's terminal or permanently unconscious condition and include a copy of the patient's signed out-of-hospital DNR order form within the patient's medical records.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

Special provisions are written into the regulations to define and permit persons with legal authority to act on behalf of the patient (surrogates), including minors, to request an out-of-hospital DNR order or to revoke that order. Consideration is also given to pregnant patients suffering from a terminal condition. The DNR Act imposes additional criteria before a DNR order may be implemented by a health care provider for a pregnant patient and the regulations repeat those standards. The proposed regulations include disclosures that attending physicians must provide to patients and their surrogates to assist them in making a decision on whether to request an out-of-hospital DNR order. The information provided in these disclosures is not set forth in the DNR Act. Including them in the regulations will make it easier for physicians to determine the information they need to provide which, in turn, will make it easier for a patient or the patient's surrogate to make an informed decision.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The statutory deadline for adoption of final regulations is February 18, 2004. The Department anticipates that it will adopt final regulations before that date.

(31) Provide the schedule for continual review of the regulation.

The effectiveness of the regulations will be subject to constant monitoring and review.



**OUT-OF-HOSPITAL DNR  
COMMENTERS**

Mr. Edward H. Dench, Jr., MD  
President  
Pennsylvania Medical Society  
777 East Park Drive  
P.O. Box 8820  
Harrisburg, PA 17105-8820

Ms. Lonna H. Donaghue  
Executive Director  
Pennsylvania Hospice Network  
P.O. Box 60636  
128 State Street  
Harrisburg, PA 17106-0636

Mr. John S. Jordan, CAE  
Executive Vice-President  
Pennsylvania Academy of Family Physicians  
2704 Commerce Drive  
Suite A  
Harrisburg, PA 17110-9365

Mr. Franklin L. Kury  
Reed Smith LLP  
213 Market Street  
9<sup>th</sup> Floor  
P.O. Box 11844  
Harrisburg, PA 17108-1844

**OUT-OF-HOSPITAL DNR  
COMMENTERS REQUESTING COPIES OF  
THE FINAL FORM REGULATIONS**

Mr. Franklin L. Kury  
Reed Smith LLP  
213 Market Street  
9<sup>th</sup> Floor  
P.O. Box 11844  
Harrisburg, PA 17108-1844

**ADDITIONAL REQUEST FOR  
COPIES OF  
THE FINAL FORM REGULATIONS**

Ms. Cheri L. Rinehart  
Vice President  
Integrated Delivery Systems  
The Hospital & Healthsystem Association of Pennsylvania  
4750 Lindle Road  
P.O. Box 8600  
Harrisburg, PA 17105-8600

FACE SHEET  
FOR FILING DOCUMENTS  
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED

2003 DEC -5 PM 2:32

REVIEW COMMISSION

DO NOT WRITE IN THIS SPACE

#2355

<p>Copy below is hereby approved as to form and legality. Attorney General.</p> <p>BY _____ DEPUTY ATTORNEY GENERAL</p> <p>DATE OF APPROVAL _____</p> <p><input type="checkbox"/> Check if applicable. Copy not approved. Objections attached.</p>	<p>Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:</p> <p><u>DEPARTMENT OF HEALTH</u> (AGENCY)</p> <p>DOCUMENT/FISCAL NOTE NO. <u>10-174</u></p> <p>DATE OF ADOPTION: _____</p> <p>BY: <u>Calvin B. Johnson</u> Calvin B. Johnson, M.D., M.P.H.</p> <p>TITLE: <u>Secretary of Health</u></p>	<p>Copy below is hereby approved as to form and legality. Executive or independent Agencies.</p> <p>BY: <u>Tanya C. G... ..</u></p> <p><u>12/4/03</u> DATE OF APPROVAL</p> <p>(Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title)</p> <p><input type="checkbox"/> Check if applicable. No Attorney General approval or objection within 30 days after submission.</p>
--	---	--

FINAL REGULATIONS

TITLE 28. HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA CODE CHS. 1001, 1003, 1005, 1007, 1051]

Out-of-Hospital Do-Not-Resuscitate Orders

The Department of Health (Department) hereby adopts final regulations dividing 28 Pa. Code Part VII (relating to emergency medical services) into Subpart A (relating to emergency medical services systems) and Subpart B (relating to matters ancillary to emergency medical services systems), amending §§ 1001.1-1001.5, 1003.27, 1005.3, 1005.10 and 1007.7, and adding Chapter 1051 (relating to out-of-hospital do-not-resuscitate orders), as set forth in Annex A hereto.

***Purpose and Background***

To enable the prompt implementation of 20 Pa.C.S. §§ 54A01-54A13 (relating to Do-Not-Resuscitate Act) (DNR Act), enacted by the act of June 19, 2002 (P.L. 409, No. 59 (Act 59), effective August 18, 2002, Act 59 required that the Department adopt interim regulations by December 16, 2002. To expedite adoption of the interim regulations Act 59 exempted those regulations from review by the designated standing committees in the House and Senate, and by the Independent Regulatory Review Commission (IRRC). The Department adopted interim regulations on December 14, 2002. They went into effect on March 1, 2003.

Act 59 requires the Department to adopt final regulations in accordance with customary rulemaking procedures following the Department's adoption of interim regulations through the abbreviated rulemaking process. After its adoption of the interim regulations, and in accordance with standard rulemaking procedures, the Department proposed amendments to the regulations. Proposed rulemaking was published at 33 Pa.B. 4450 (September 6, 2003). A 30-day comment period was provided.

These final regulations continue the changes to the Department's regulations made by the interim rulemaking process, with a few revisions. This includes the division

of 28 Pa. Code Part VII into Subparts A and B; the amendments the interim regulations made to §§ 1001.1-1001.5, 1003.27, 1005.3, 1005.10 and 1007.7a, which are regulations originally adopted under the Emergency Medical Services Act (EMS Act) (P.L. 164, No. 45) (35 P.S. §§ 6921-6938); and the addition of Chapter 1051. The Department's proposed rulemaking announced the Department's intention to adopt as final regulations, with few changes, the same provisions the Department had previously adopted as interim regulations. The Department received comments from five sources, including IRRC, and thoroughly reviewed and considered those comments before adopting these regulations.

***Summary***

The proposed regulations to which no comments were addressed are adopted for the reasons given in the preamble to the proposed regulations. Notwithstanding the absence of comments to those proposals, the Department reevaluated them for the purpose of determining whether revisions should be made in final rulemaking. The only regulations that are discussed in this preamble are those that have been revised or to which comments were addressed in their proposed form.

**Subpart A. Emergency Medical Services Systems**

**§ 1005.3. Right to enter, inspect and obtain records.**

This section was originally promulgated under the EMS Act to aid in the implementation of 35 P.S. § 6932(k), which gives the Department both the right and the responsibility to periodically inspect ambulance services as it deems appropriate and necessary.

***Comment***

The preamble to the proposed regulations states the Department's intention to include a reference to Subpart A of Part VII in this section. The reference was not included in this section. Was it the Department's intention to include the reference to Subpart A in the subsections of the section?

***Response***

The Department has made no change to the regulation based on this comment.

Prior to the adoption of the interim regulations, this regulation addressed the duty of an ambulance service to cooperate with a Department inspection when the Department was investigating a violation of regulations it had adopted under the EMS Act. At that time, Part VII of the Department's regulations was comprised exclusively of regulations the Department had promulgated under the EMS Act. However, when the Department adopted the interim regulations, which were not adopted pursuant to the EMS Act, but, rather, pursuant to the DNR Act, the Department divided Part VII into two subparts— Subpart A, which contains the regulations adopted under the EMS Act, and Subpart B, which contains the regulations adopted under the DNR Act. Because some of the regulations that were placed in Part A included a reference to Part VII instead of Subpart A, it became necessary to change the reference in those sections.

This change was made in the interim regulations. The reference to this "part" in subsection (a) was changed to "subpart." The proposed regulations proposed to retain that change and that change is retained in this final regulation.

**Subpart B. Matters Ancillary to Emergency Medical Services Systems**

**§ 1051.3. Applicability.**

This section identifies the persons to whom this chapter is applicable. No comments were received pertaining to this section. However upon further review of subsection (b), the Department has decided to revise that subsection to clarify that in a hospital an EMS provider shall comply with an out-of-hospital DNR order in the course of providing care to or transportation of an out-of-hospital DNR patient on behalf of an ambulance service.

**§ 1051.11. Patient qualifications to request and revoke out-of-hospital DNR order.**

This section addresses a qualified patient's right to request and revoke an out-of-hospital DNR order and the other out-of-hospital DNR items.

**§ 1051.12. Surrogate's authority to request and revoke out-of hospital DNR order.**

This section addresses a surrogate's right to request and revoke an out-of-hospital DNR order and the other out-of-hospital DNR items, and the patient's right to revoke an out-of-hospital DNR order issued upon a surrogate's request. The following comment applies to both §§ 1051.11 and 1051.12.

***Comment***

If the patient or surrogate makes the decision to revoke an out-of-hospital DNR order, the patient or surrogate, not the physician, should have the responsibility to destroy the DNR items.

***Response***

The Department has made no change to the regulations based upon this comment.

The Department agrees with the comment. These two regulations do not provide otherwise. The only circumstance under which a physician is required to destroy the DNR items issued by the physician is when they are returned to the physician, pursuant to the physician's request, if the physician determines that his or her diagnosis that the patient is in a terminal condition or permanently unconscious was in error. See § 1051.30(a) (relating to physician destruction of out-of-hospital DNR order, bracelet or necklace). Even when the physician communicates such a misdiagnosis and requests the return of the out-of-hospital DNR items on that basis, if the patient or surrogate does not honor the physician's request to return the items, the physician is relieved of the duty to destroy them. Under those circumstances, the physician is simply precluded from making an entry in the patient's record that the order has been destroyed without having confirmed the destruction of the DNR items issued by the physician. See § 1051.30(b).

**§ 1051.13. Duties when person loses authority to function as a surrogate.**

This section addresses responsibilities to the patient and to the attending physician of a replaced and replacement surrogate when a surrogate is replaced.

***Comment***

Should responsibilities similar to those the regulations place on former surrogates be placed on replacement surrogates?

***Response***

Some responsibilities should be placed on a replacement surrogate. The Department has revised the regulation by adding a subsection (d) to require a replacement surrogate to make a reasonable effort to notify the physician of the change in surrogates if the new surrogate is made aware of the out-of-hospital DNR order, is provided



information regarding the physician who issued it, and has not already confirmed that the physician was apprised of the change in surrogates by the prior surrogate. Due to the addition of this subsection, which expands the scope of the matters addressed by the section, the Department has also changed the title from “Person who loses authority to function as a surrogate” to “Duties when person loses authority to function as a surrogate.”

***Comment***

Does an out-of-hospital DNR order remain valid if a surrogate who is subsequently replaced requested it? If so, how could the new surrogate become aware of an existing out-of-hospital DNR order?

***Response***

In response to this comment, the Department is adding language to subsection (b) (previously subsection (c)) to require a former surrogate to apprise a new surrogate of the out-of-hospital DNR order if the former surrogate is able to do so. The text in subsection (b) is moved to subsection (c).

To answer the questions, if a person has authority to function as a patient’s surrogate at the time that person requests an out-of-hospital DNR order for the patient, and the attending physician issues the order, the order remains in effect regardless of whether the person later loses the authority to act as the patient’s surrogate. Thereafter, the order may be revoked only by a subsequent surrogate, if there is one, or by the patient. For some patients, such as a patient who is competent and under 18 years of age when the order is secured by a parent, but later reaches 18 years of age, there will be no replacement surrogate. However, for some patients a prior surrogate will be replaced by

a new one. There are numerous circumstances under which this might happen. In some instances, the former surrogate will be able to apprise the new surrogate of the order. In other instances, such as when a former surrogate dies, or does not possess the capacity to communicate due to a disability such as a coma, the former surrogate will not be able to communicate the information to the replacement surrogate. However, the Department is amending the regulation to require a former surrogate to communicate the information to a succeeding surrogate when the circumstances permit.

It should be noted that if the out-of-hospital DNR items were issued at the request of a patient's former surrogate, these items would have the former surrogate's signature on them, not the signature of the replacement surrogate. From a legal perspective, the items continue to be effective and the new surrogate is also empowered to revoke the out-of-hospital DNR order. Nevertheless, as a practical matter an EMS provider is likely to hesitate complying with an attempted revocation by the replacement surrogate because the replacement surrogate's signature is missing on the out-of-hospital DNR item observed by the EMS provider. Consequently, the Department recommends that the replacement surrogate pursue the issuance of replacement out-of-hospital DNR items for the patient, containing the replacement surrogate's signature, to best ensure his or her ability to effectively exercise revocation authority.

***Comment***

Proposed subsections (b) and (c) require a former surrogate to help the physician locate "the patient or the patient's current surrogate." If the patient is unable to communicate it may be difficult for the physician to locate the current surrogate. Should the word "or" be replaced by "and?"

***Response***

The Department has made the recommended revision. The Department agrees that the former surrogate should provide the physician with any information he or she may have to help the physician locate the patient and the patient's current surrogate if the patient has a current surrogate. As previously discussed, not all patients will need to continue to have a surrogate. The Department has amended the regulation to require the former surrogate, when he or she loses surrogate status, and if capable of doing so, to provide the physician with any information he or she may have to help the physician locate the patient and the patient's current surrogate if the patient has a current surrogate.

**§ 1051.21. Securing out-of-hospital DNR orders, bracelets and necklaces.**

This section provides that only physicians or their agents may secure out-of-hospital DNR order forms, bracelets and necklaces.

**§ 1051.22. Issuance of out-of-hospital DNR order.**

This section states that an attending physician may issue an out-of-hospital DNR order and specifies various duties the physician is required to perform before issuing the order. The following comments apply to both §§ 1051.21 and 1051.22.

***Comment***

The patient would be better served by obtaining an out-of-hospital DNR order, bracelet and necklace directly from the vendor, than from the patient's attending physician. The responsibility of the attending physician in this regard should be to examine the patient to determine that the patient is qualified to receive the out-of-hospital DNR items, and then to issue an order authorizing the patient or the patient's surrogate to procure the item or items from the vendor.

***Response***

The Department has made no change to the regulations based upon this comment.

The DNR Act is clear on this matter. It provides for only a qualified patient's attending physician to "issue" an out-of-hospital DNR order and the other out-of-hospital DNR items. 20 Pa.C.S. § 54A04(a)-(d). It makes no provision for a patient or a patient's surrogate to secure any of these items from any source other than the patient's attending physician, and it makes no provision for a person other than a patient's attending physician to issue any of the items.

In addition to the statutory requirement that only an attending physician may issue the DNR items, the requirement that the necklace, bracelet and order include the dated signature of the physician (*see* 20 Pa.C.S. § 54A04(b), (c) and (d)) makes it impractical for any of the items to be provided by a person other than the attending physician.

The attending physician's issuance of these items, after signing and dating the order, and signing and dating a tab the physician encloses and seals in the bracelet or necklace pendant, also makes it far more difficult for someone to create and use an unauthorized, illegal out-of-hospital DNR item. Direct physician control over the issuance of these items is a safeguard. It reduces the opportunity for a person to secure original unsigned out-of-hospital DNR items and insert a forged signature of a purported patient or surrogate on an out-of-hospital DNR order, or a forged and dated signature of a physician on any of the items.

***Comment***

Physicians should not be required to pay for out-of-hospital DNR items, should not be required to purchase these items in bulk, and should not be required to stock these items so that they are available on demand.

***Response***

The Department has made no change to the regulations based upon this comment. The Department has, however, amended the regulation to clearly state that physicians are responsible for purchasing out-of-hospital DNR orders.

Nothing in the regulations requires physicians to bear the ultimate cost of these items. They may charge the patient or the patient's surrogate for providing the service, including the cost of the DNR items they issue, which currently ranges from \$.11 for the order to \$1.35 for the necklace.

The DNR Act provides for the Department to make the out-of-hospital DNR items available to physicians to issue to their patients. 20 Pa.C.S. § 54A04(b), (c) and (d). Section 6 of Act 59 provides that the Department may contract with any public or private entity to facilitate any of its responsibilities under Act 59. However, Act 59 made no appropriation of funds to the Department for the purpose of providing out-of-hospital DNR items to physicians and is silent regarding who is to pay for the out-of-hospital DNR items. Section 1051.21 (relating to securing out-of-hospital DNR orders, bracelets and necklaces) explains that physicians may purchase the DNR items from the vendor with whom the Department has contracted, whose name the Department will publish in a notice in the *Pennsylvania Bulletin*. The Department has published the name of the

vendor. Additionally, the Department has posted on its website, [www.health.state.pa.us](http://www.health.state.pa.us), a link to a purchase order form attending physicians may use to purchase the items.

The vendor with whom the Department has made arrangements requires that the items be purchased in lots of 50 due to the low cost of each item negotiated with the Department. Nothing prevents physicians from jointly purchasing these items directly or through an agent, but at least one attending physician must be identified on the purchase order.

The comment that the proposed regulations would require an attending physician to have the out-of-hospital DNR items in stock, ready to provide to a patient or the patient's surrogate upon demand, is not correct. No such requirement was set forth in the interim or proposed regulations, and no such requirement is imposed by the final regulations. It is up to the physician to determine whether to secure these items in advance of a request or to wait until a request is made. Moreover, § 1051.26 (relating to physician refusal to issue an out-of-hospital DNR order) acknowledges that it is permissible for an attending physician to choose not to provide this service for qualified patients.

***Comment***

Patients would be served more efficiently by being able to obtain the form to order out-of-hospital DNR items with the other out-of-hospital DNR materials the Department places on its website. Patients could then download the form and take it with them to their attending physicians.

***Response***

The Department has made no change to the regulations based upon this comment.

The regulations place upon the physician the responsibility to order the out-of-hospital DNR items. The Department's vendor requires purchases of each out-of-hospital DNR item in lots of 50. Once a physician makes one order there will likely be a considerable passage of time before another purchase needs to be made. Prior to that time, the physician would have no need to use each individual purchase order form brought to a physician by a patient or the patient's surrogate if the Department were to revise the regulations as suggested by the comment.

The Department could make different arrangements with a vendor and insist that the vendor permit physician purchases of out-of-hospital DNR items individually. However, this would simply take more time, involve more paperwork, increase mailing, and add more costs for patients or physicians.

Furthermore, it is likely that many of the patients who seek out-of-hospital DNR items will be elderly and need assistance in the process, or may have diminished capacity due to the condition that qualifies them for out-of-hospital DNR items, or may not have access to the internet or even know how to use a computer to accomplish what the comment suggests. These people should be able to rely upon and secure assistance from their attending physicians and the staffs of those physicians.

**§ 1051.23. Disclosure to patient requesting out-of-hospital DNR order.**

This section identifies the information a patient's attending physician must disclose to the patient before issuing an out-of-hospital DNR order requested by the patient.

**§ 1051.24. Disclosure to surrogate requesting out-of-hospital DNR order.**

This section identifies the information a patient's attending physician must disclose to the patient's surrogate before issuing an out-of-hospital DNR order requested for the patient by the surrogate. The following comments apply to both §§ 1051.23 and 1051.24.

***Comment***

The Department could better implement the DNR Act by developing a pamphlet for physicians to provide to their patients and patient surrogates, which discloses the pertinent information the regulations require the patient's attending physician to disclose to the patient or the patient's surrogate, as the case may be, before issuing an out-of-hospital DNR order for the patient.

***Response***

The Department has made no change to the regulations based upon this comment.

The Department agrees that it would simplify physician compliance and assist both patients and their surrogates if the Department prepared materials containing the suggested information. As announced in the preamble to the proposed regulations, the Department has already done that. The information is available to read and copy through the Department's website. The preamble to the proposed regulations expressly invited physicians to access and copy that material to distribute to their patients and surrogates. The Department repeats that invitation here. The Department believes that this is a better approach than the Department printing pamphlets for a variety of reasons. First, it is less costly. Act 59 did not appropriate funds to the Department to print and distribute informational pamphlets. Second, the information is available to any person who has



access to the internet and wants to review it. Further, patients for whom an out-of-hospital DNR order has been issued and their surrogates may easily access the information at any time if they have access to the internet, but could lose or misplace a pamphlet provided to them. Also, the Department may easily add to or clarify information available through its website, but would need to reprint and distribute new pamphlets to accomplish the same result if it elected to distribute pamphlets. Coupled with the amendment of the interim regulations made through this final rulemaking, the Department is also amending the information it provides through its website.

***Comment***

A patient who revokes an out-of-hospital DNR order should be required to apprise the attending physician who issued the order that the order has been revoked.

***Response***

The Department has made no change to the regulations based upon this comment.

The DNR Act provides that the patient or surrogate may revoke an order at any time, “and in any manner, including verbally or by destroying or not displaying the order, bracelet or necklace.” 20 Pa.C.S. § 54A05(c). The statute does not make revocation contingent upon the patient or surrogate notifying the patient’s attending physician, and the Department may not impose such an additional requirement by regulation.

The Department agrees that a patient or the patient’s surrogate should keep the attending physician informed of decisions made to revoke the order, but this is not always feasible or practical. A patient or surrogate may decide to revoke the order one day by not displaying any of the out-of-hospital DNR items or by simply declaring that the order is revoked, and then change his or her mind the next day. As long as the patient or

surrogate does not destroy all of the out-of-hospital DNR items that have been issued by the attending physician, that person may reinstate the order simply by displaying one of the items again. Certainly, however, nothing prevents the issuing physician from advising the patient and surrogate that he or she should contact the physician if the decision is made to revoke the order.

***Comment***

Whether or not the patient chooses to display a bracelet or necklace should be of no concern to the attending physician.

***Response***

The Department has made no change to the regulations based upon this comment.

The Department agrees. In the context of these regulations this should not be a concern of the physician. The regulations impose no requirement on the physician to keep abreast of whether the patient is or is not wearing or displaying a DNR item.

***Comment***

Why do proposed §§ 1051.23(9) and 1051.24(5) not require the attending physician to apprise the patient and surrogate that the physician will contact the patient or surrogate if the physician discovers that the diagnosis of a terminal condition was in error? If the premise for an out-of-hospital DNR order is in error, a mere “attempt” to notify the patient or surrogate, as would be required by the proposed regulations, may not sufficiently protect the patient. This comment also applies to § 1051.29 (relating to duty to contact patient or surrogate).

### ***Response***

In response to this comment, the Department has amended §§ 1051.23(9) and 1051.24(5) to require the physician to disclose that the physician will make every reasonable effort to contact the patient or surrogate in the event the physician discovers that he or she erred in diagnosing the patient to be permanently unconscious or in a terminal condition. The Department has also amended § 1051.29 to impose the “every reasonable effort” standard upon the attending physician with respect to the physician contacting the patient or surrogate when the physician determines that he or she erred in making the diagnosis of the patient’s condition.

The “every reasonable effort standard” is the same standard section 5409(a) of the Advance Directive for Health Care Act imposes on an attending physician to assist a patient to find another physician who will follow the patient’s advance directive when the attending physician cannot in good conscience comply with the advance directive. The regulation cannot require the physician to apprise the patient or surrogate that the physician will contact the patient because the physician may not be able to make contact despite the physician’s best efforts.

### ***Comment***

Proposed § 1051.23(5) requires the attending physician to apprise a patient that an out-of-hospital DNR order is not effective when the patient is in a hospital, except under limited circumstances, and to also apprise the patient that a DNR order may be issued for the patient in a hospital in accordance with other procedures. The Department should specify what these procedures are by cross-referencing them, or delete the phrase “in accordance with other procedures” from this subsection.

***Response***

The Department has left the phrase in the regulation and has not cross-referenced other procedures. However, the Department has added language to clarify the purpose of the disclosure, which is to convey to the patient that although EMS providers will generally not be able to comply with an out-of-hospital DNR order in a hospital, other avenues to secure a DNR order may exist in a hospital. There are no statutory or regulatory provisions to cross-reference at this time. That does not mean that no such provisions will exist in the future. It is possible that a patient's advance directive in a declaration for health care issued under the Advance Directive for Health Care Act may direct that a DNR order be issued that would be effective in a hospital, but the Department has no authority to assert that in its regulations.

**§ 1051.26. Physician refusal to issue an out-of-hospital DNR order.**

This section prescribes the procedures an attending physician is to follow when the physician is not willing to issue an out-of-hospital DNR order for a patient who qualifies for the order. Under these circumstances the section requires the physician to make every reasonable effort to assist the patient or surrogate to pursue the matter further with another physician.

***Comment***

Paragraph (2) should be stricken in its entirety. Beyond being overly burdensome, this section could be interpreted to require physicians to counsel patients on receiving a second medical opinion, which implicitly suggests to the patient that the attending physician's opinion should be treated as being suspect. Any patient in the Commonwealth is already permitted to choose his or her own physician, and a physician

should not be made responsible under any circumstances to require that his or her patient be referred to another physician for a second medical opinion.

*Response*

The Department has not removed the paragraph, but in response to the comment has revised the regulation to clarify that there is no duty to refer the patient to another physician when the reason the physician will not issue the order is that the person is not qualified to request it, or the physician had determined that the patient is not in a terminal condition or permanently unconscious.

Proposed paragraph (2) was not intended to convey the message described in the comment. The Department believes that nothing in the proposed paragraph suggests that a physician refer a patient to another physician for a second opinion if the physician determines that the patient is not permanently unconscious or in a terminal condition. However, the Department has revised the regulation to clarify this. Also, expressly excluded from the referral provision is any duty to refer when the patient's surrogate and the attending physician cannot agree on the information the physician is to provide to the patient when the surrogate has requested the order.

The regulation conveys that the attending physician may, for any reason, choose not to issue an out-of-hospital DNR order for a patient who qualifies for the order. The physician may have a conscientious objection to issuing an out-of-hospital DNR order for a patient notwithstanding the physician's diagnosis that the patient is permanently unconscious or in a terminal condition, or there may be some other reason. The regulation does not seek to limit the reasons for an attending physician's decision not to issue an out-of-hospital DNR order for a patient who is qualified to receive the order.

Nevertheless, the Department believes an attending physician has a responsibility to the patient that goes beyond a refusal to issue an out-of-hospital DNR order. If the patient or the patient's surrogate comes to the physician for the purpose of seeking an order, and the physician determines the patient is qualified to receive the order but the physician is unwilling to issue it, the Department believes that the physician should refer the patient or patient's surrogate to another physician who will issue the order requested.

It is rare for a statute to limit a patient's right to secure a service from only the patient's attending physician. Due to this extraordinary feature, some patients who qualify for an out-of-hospital DNR order may not know how to next proceed if the patient's attending physician refuses to issue the order, or may incorrectly believe that the only way to secure such an order is to discontinue the physician-patient relationship with that physician and seek a new exclusive attending physician.

The Department believes that a physician who refuses to issue an out-of-hospital DNR order for a patient who is qualified to receive the order has a fiduciary responsibility to the patient to explain why the patient will not be able to secure the order from the physician, and to advise that the patient may secure the service from another physician who qualifies as the patient's attending physician. The Department further believes that the physician's fiduciary responsibility to the patient requires the physician to offer the physician's assistance in finding another physician who will provide a service to which the patient is entitled by statute, but which that physician is unwilling to provide. This type of fiduciary duty is expressly imposed upon an attending physician under the Advance Directive for Health Care Act when the attending physician refuses to

comply with the patient's health care choices in a declaration containing an advance directive for health care. That provision states as follows:

If an attending physician...cannot in good conscience comply with a declaration...the attending physician shall so inform the declarant...The attending physician...shall make every reasonable effort to assist in the transfer of the declarant to another physician...who will comply with the declaration. 20 Pa.C.S. § 5409(a).

A patient's attending physician should have no less responsibility when the physician is unwilling to comply with a patient's or surrogate's choice that the physician issue an out-of-hospital DNR order for the patient when the patient qualifies for the order.

***Comment***

To what degree is a physician required to assist a patient to obtain an out-of-hospital DNR order from another physician? Will a referral be sufficient?

***Response***

In response to this comment the regulation has been amended to impose the same standard for referral as 20 Pa.C.S. § 5409(a) imposes upon an attending physician who refuses to comply with advance directives for health care a patient makes in a declaration prepared under the Advance Directive for Health Care Act.

**§ 1051.30. Physician destruction of out-of-hospital DNR order, bracelet or necklace.**

This section addresses an attending physician's duty to destroy out-of-hospital DNR items returned to the physician following a physician's disclosure to the patient or the patient's surrogate that the physician made an error in the diagnosis, or to confirm the destruction of the out-of-hospital DNR items if the physician is unable to retrieve the items following the disclosure.

***Comment***

The preamble to the proposed regulations stated that the physician needs to secure confirmation of the destruction of the out-of-hospital DNR items from a reliable person before recording the revocation of the out-of-hospital DNR order in the patient's medical record. However, the word "reliable" was not included in the text of the proposed regulation. The final regulation should be revised to prohibit physician notation of the revocation in the patient's record unless the physician destroys the items or secured confirmation of the revocation from a "reliable" source, and the term "reliable person" should be defined in the definitions section.

***Response***

The Department agrees with the comment as it relates to this section and has revised the regulation as suggested. The Department has not added the definition of "reliable person" in § 1051.2 (relating to definitions). The attending physician will need to make the determination, on a case-by-case basis, of whether the destruction of the items has been confirmed by a reliable person. That determination will be somewhat subjective since it will apply the physician's own value system as to who the physician can depend upon to provide the physician with a truthful confirmation that the out-of-hospital DNR items have been destroyed.

**§ 1051.51. Implementation of out-of-hospital DNR order.**

This section deals with EMS provider compliance with out-of-hospital DNR orders.



***Comment***

Why is an EMS provider required to follow only a DNR item that includes the original signature of the attending physician? Also, how can the EMS provider readily determine if the items contain original signatures? The last sentence of subsection (a) should be revised as follows:

When an EMS provider observes an out-of-hospital DNR order without also observing an out-of-hospital DNR bracelet or necklace, the EMS provider shall implement the out-of-hospital DNR order only if it contains original signatures or an unaltered copy thereof.

The requirement for honoring an order only if it contains original signatures is not authorized by the act and creates unnecessary difficulties for the EMS providers.

Act 59 omitted a provision in section 5413 of the Advance Directive for Health Care Act requiring “(a)n original declaration, signed by the declarant or other authorized person” to make a DNR order operative. This omitted language is replaced by a general rule requiring EMS providers to comply with the instructions of the medical command physician. The medical command physician may instruct EMS providers to “withhold or discontinue cardiopulmonary resuscitation for a declarant whose advance directive has become operative under section 5405 (relating to when the declaration becomes operative).” Under section 5405, this advance directive becomes operative when the attending physician is provided with a copy. The legislative intent appears to allow copied documents to suffice to make the order operative.

***Response***

The Department disagrees with this interpretation of the DNR Act and the assessment of legislative intent demonstrated by Act 59, and rejects the recommendation.

The DNR Act requires that the order must contain the signature of the patient or the patient's surrogate and the signature of the attending physician. 20 Pa.C.S. § 54A04(b). The DNR Act also authorizes and requires EMS providers to comply with an out-of-hospital DNR order only "if made aware of the order" by examining the bracelet, necklace or "the order itself." 20 Pa.C.S. § 54A10(b)(1). This language "the order itself" makes it clear that if the bracelet or necklace is not present, to comply with the out-of-hospital DNR order the EMS provider must observe the original order, not a copy of the order.

The statutory construction argument fails to support a disregard of the unambiguous language in 20 Pa.C.S. § 54A10(b)(1). That argument is based upon amendments to the Advance Directive for Health Care Act, not the DNR Act. Nevertheless, nothing about the Act 59 amendments to the Advance Directive for Health Care Act suggests that an EMS provider should be able to comply with an out-of-hospital DNR order by seeing a copy of that order instead of the original.

The amendments to the Advance Directive for Health Care Act removed one of the two processes that had previously existed under that statute for EMS personnel to follow an advance declaration for health care (which may include all types of health care directives and need not include a DNR directive), and it modified the other process. The removed process was the process authorizing the EMS practitioner to comply with an advance directive after personally observing the original declaration signed by the declarant or an authorized representative and then contacting a medical command physician to secure approval to comply with the advance directive. The amendments did not substitute for this process or amend the second process to permit an EMS provider to

act on a copy of an advance directive—it removed an EMS provider’s ability to act on any advance directive for health care document, an original or a copy, based upon the provider’s observation of the document. This change to the Advance Directive to Health Care Act cannot be construed to demonstrate a legislative intent that the Act 59 language “examining...the order itself” in the DNR Act means anything other than what it clearly states.

The policy argument that the EMS practitioner’s reliance on a copy makes it easier for the EMS practitioner also fails. As written, the regulation provides that if the EMS practitioner observes the order, bracelet or necklace the practitioner is to accept that item as a DNR order and follow it. Compliance is made easy; the assessment is simple—if only an order is present comply with it if there is an original dated signature of the physician and do not comply with it if there is no original signature. If the regulation provides that the EMS practitioner does not need to observe an order with an original signature, and may follow an order with an “unaltered copy” of the signature, how would the EMS practitioner determine that a copy of the physician’s signature (or even a copy of the patient’s or surrogate’s signature) is legitimate and has not been impermissibly inserted? Furthermore, what does an “unaltered signature” mean in the context of the regulation? How would the EMS practitioner make the determination that a signature is “unaltered” without observing the original signature? The introduction of the additional language would complicate, not simplify the EMS provider’s determination as to whether the provider should or should not comply with the order.

More importantly, the requirement that the signature be an original protects the patient or surrogate in ensuring that that person’s wishes are followed—particularly when,

after the order is secured, the patient or surrogate has a change of heart. A patient or surrogate may revoke an out-of-hospital DNR order by simply destroying it or removing it from sight. 20 Pa.C.S. § 54A05(c). The patient or surrogate need not apprise anyone else of the revocation. In some circumstances, such as when a patient is alone and decides to revoke an out-of-hospital DNR order immediately before losing consciousness, the patient may have no opportunity to communicate that decision to another person.

If there is only one effective order, and the patient or surrogate conceals or destroys it, there is far less opportunity for a mistake to be made than when there are multiple copies that could be relied upon, not all of which the patient or surrogate has destroyed. If copies are available, there is a possibility that someone will intentionally or unwittingly substitute a copy when the original cannot be located because it was revoked, or not remove a copy after the revocation because the person did not know that the order was revoked by the destruction or concealment of the original.

Moreover, it seems clear that the Legislature crafted the DNR Act to protect patients from unscrupulous persons who might seek to hasten a patient's death against the patient's wishes by falsifying or forging an order and signature or hiding the revocation of the order. The DNR Act makes such conduct a criminal homicide if the conduct causes the hastening of the patient's death by the withholding or withdrawal of life-sustaining treatment with the intent to do so contrary to the wishes of the patient. 20 Pa.C.S. § 54A12.

If the patient or the patient's surrogate destroys the original order, and the original order is the only copy of the order that can direct an EMS provider to withhold CPR in the event the patient experiences cardiac or respiratory arrest, it may not be impossible

for another person to create a forged original order, but it is certainly more difficult to do that than to illegally manufacture a purported copy of the order or substitute a true copy of the order the patient or the surrogate has acted to revoke.

***Effective Date/Sunset Date***

The regulations are effective upon publication in the *Pennsylvania Bulletin* as final regulations. No sunset date is imposed. The Department will monitor the regulations to ensure that they meet needs that are within the scope of the Department's authority to address through regulations adopted under Act 59.

***Paperwork***

The Department, pursuant to a duty imposed upon it by the DNR Act, has already developed an out-of-hospital DNR order form, and the specifications for out-of-hospital DNR bracelets and necklaces, for attending physicians to issue for patients who qualify for those orders. A sample order form may be reviewed by using a link at the Department's website. However, to prevent persons other than physicians from securing the order forms, the website version has been marked as a sample. It cannot be copied and used as an order form. Physicians must secure out-of-hospital DNR order forms from the Department's contracted vendor.

The Department has also developed both an electronic and paper process for physicians to use to secure from the Department's contracted vendor out-of-hospital DNR order forms, bracelets and necklaces. The purchase order form physicians are to use to order out-of-hospital DNR forms, bracelets and necklaces is available through a link to the Department's website. A physician may copy the purchase order form and send it to the vendor by facsimile or regular mail. Purchase order forms may also be

secured directly from the vendor. The Department anticipates that it will continue to employ these procedures.

The Department has already completed the paperwork required to contract with a vendor to produce and provide the orders, bracelets and necklaces, and it has contracted with a vendor. It will need to repeat the process from time to time—whenever a contract is about to expire and the Department needs to enter into a new contract or contracts.

The Department has published a notice in the *Pennsylvania Bulletin* identifying the vendor from whom attending physicians may procure out-of-hospital DNR order forms, bracelets and necklaces. The Department will also need to publish new notices if a new vendor or vendors are chosen in the future. The Department will also need to publish notices in the *Pennsylvania Bulletin* identifying states that provide out-of-hospital DNR orders, bracelets and necklaces that EMS providers are to follow, and describing the acceptable out-of-hospital DNR items.

Physicians are required by the regulations to maintain information in patient medical records regarding the issuance of out-of-hospital DNR items, and they are also required to prepare the paperwork to enable them to secure and provide out-of-hospital DNR items for patients.

### ***Financial Impact***

While the purpose of the DNR Act and Chapter 1051 is to enable a patient in a terminal condition, or the patient's surrogate, to communicate a decision that directs EMS providers to permit the patient to die with dignity, significant health care cost-savings will often be a collateral benefit. The DNR Act and the regulations will save patients and their families, as well as insurers, the costs of paying for continued patient care when

patients who are in a terminal condition or who are permanently unconscious receive unwanted but successful CPR following a cardiac or respiratory arrest, that continues and perpetuates, and sometimes worsens, the patient's poor quality of life. These end-of-life costs can continue to burden the family for several years following a patient's death.

The average annual cost the DNR Act and Chapter 1051 impose over 5 years to the regulated community (attending physicians, patients, and surrogates) is projected to be \$18,100. This includes the cost of procuring DNR orders, bracelets, and necklaces for distribution in attending physician offices. The current costs are \$.11 for an out-of-hospital DNR order form, \$1.35 for an out-of-hospital DNR necklace, and \$.35 for an out-of-hospital DNR bracelet, plus taxes and shipping costs. A minimum order of 50 of an order, bracelet or necklace is required. The average annual costs over 5 years for State government is projected to be \$26,000, which includes development and printing costs for educational materials, training, outreach, and travel needed to assist regional EMS councils and practitioners in the implementation of the statute and the regulations.

It is expected that the overall cost-savings in reducing expensive and undesired end-of-life care will offset other costs incurred in implementing the statute and regulations.

#### ***Statutory Authority***

Section 6 of Act 59 provides that the Department shall publish final regulations to assist in the implementation of the DNR Act.

#### ***Regulatory Review***

Under Section 5(a) of the Regulatory Review Act (Act), the Act of June 30, 1989 (P.L. 73, No. 19) (71 P.S. §§ 745.1-745.15), on January 29, 1999, the Department submitted a copy of proposed rulemaking, published at 33 Pa. B. 4450, to the

Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee for review and comment. In compliance with section 5(c) of the Act, the Department also provided IRRC and the Committees with copies of all comments received, as well as other documentation.

In compliance with section 5.1(a) of the Act, the Department submitted a copy of the final-form regulations to IRRC and the Committees on \_\_\_\_\_. In addition, the Department provided IRRC and the Committees with information pertaining to commentators and a copy of a detailed Regulatory Analysis Form prepared by the Department. A copy of this material is available to the public upon request.

In preparing these final-form regulations the Department considered all comments received from IRRC, the Committees and the public.

These final regulations were deemed approved by the House Health and Human Services Committee and the Senate Public Health and Welfare Committee on \_\_\_\_\_. IRRC met on \_\_\_\_\_, and approved the regulations in accordance with section 5.1(e) of the Act. The Office of Attorney General approved the regulations on \_\_\_\_\_.

***Contact Person***

Questions regarding these final regulations may be submitted to Margaret E. Trimble, Director, Emergency Medical Services Office, Department of Health, 1032 Health and Welfare Building, P.O. Box 90, Harrisburg, PA 17108-0090, (717) 787-8740. Persons with disabilities may submit questions in alternative formats, such as by audiotape or Braille. Speech or hearing impaired person may use V/TT (717) 783-6514, or the Pennsylvania AT&T Relay Services at 1-800-654-5984 [TT].



Persons with disabilities who would like to obtain this document in an alternative format (that is, large print, audiotape, or Braille) should contact Ms. Trimble so that necessary arrangements may be made.

***Findings***

The Department finds:

- (1) Public notice of intention to adopt the regulations adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§1201 and 1202), and the regulations thereunder, 1 Pa. Code §§7.1 and 7.2.
- (2) A public comment period was provided as required by law and all comments were considered and forwarded to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare.
- (3) The adoption of the final-form regulations is necessary and appropriate for the administration of the authorizing statute.

***Order***

The Department, acting under the authorizing statute, orders that:

- (a) The regulations of the Department, 28 Pa. Code, Part VII. Emergency Medical Services, are amended by dividing 28 Pa. Code Part VII (relating to emergency medical services) into Subpart A (relating to emergency medical services systems) and Subpart B (relating to matters ancillary to emergency medical services systems), amending §§ 1001.1-1001.5, 1003.27, 1005.3, 1005.10 and 1007.7, adding Chapter 1051 (relating to out-of-hospital do-not-resuscitate orders), and adding §§ 1051.1-1051.101, as set forth in 33 Pa.B. 4450 and Annex A hereto.

(b) The Secretary of Health shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(c) The Secretary of Health shall submit this order, Annex A and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for their review and action as required by law.

(d) The Secretary of Health shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

# **ANNEX A**

## **TITLE 28. HEALTH AND SAFETY**

### **PART VII. EMERGENCY MEDICAL SERVICES**

#### **SUBPART A. EMERGENCY MEDICAL SERVICES SYSTEM**

##### **CHAPTER 1001. ADMINISTRATION OF THE EMS SYSTEM**

###### **§ 1001.1. Purpose.**

The purpose of this subpart is to plan, guide, assist and coordinate the development of regional EMS systems into a unified Statewide system and to coordinate the system with similar systems in neighboring states, and to otherwise implement the Department's responsibilities under the act consistent with the Department's rulemaking authority

###### **§ 1001.2. Definitions.**

The following words and terms, when used in this subpart, have the following meanings, unless the context clearly indicates otherwise:

\*\*\*

###### **§ 1001.3. Applicability.**

This subpart affects regional EMS councils, the Council, other entities desiring to receive funding from the Department or the regional EMS councils for the provision of EMS, ALS and BLS ambulance services, QRSs, instructors and institutes involved in the training of prehospital personnel including EMTs, EMT-paramedics, first responders, ambulance attendants and health professionals, and trauma centers and local governments involved in the administration and support of EMS.

#### **§ 1001.4. Exceptions.**

(a) The Department may grant exceptions to, and departures from, this subpart when the policy objectives and intentions of this subpart are otherwise met or when compliance would create an unreasonable hardship, but would not impair the health, safety or welfare of the public. No exceptions or departures from this subpart will be granted if compliance with the standard is required by statute.

(b) Requests for exceptions to this subpart shall be made in writing to the Department. The requests, whether approved or not approved, will be documented and retained on file by the Department. Approved requests shall be retained on file by the applicant during the period the exception remains in effect.

(c) A granted request will specify the period during which the exception is operative. Exceptions may be reviewed or extended if the reasons for the original exception continue.

(d) An exception granted may be revoked by the Department for just cause. Just cause includes, but is not limited to, failure to meet the conditions for the exception. Notice of the revocation will be in writing and will include the reason for the action of the Department and a specific date upon which the exception will be terminated.

(e) In revoking an exception, the Department will provide for a reasonable time between the date of the written notice or revocation and the date of termination of an exception for the holder of the exception to come into compliance with this subpart. Failure to comply after the specified date may result in enforcement proceedings.

(f) The Department may, on its own initiative, grant an exception to this subpart if the requirements of subsection (a) are satisfied.

**§ 1001.5. Investigation.**

The Department may investigate any person, entity or activity for compliance with the act and this subpart.

\*\*\*

**CHAPTER 1003. PERSONNEL**

**§ 1003.27. Disciplinary and corrective action.**

(a) The Department may, upon investigation, hearing and disposition, impose upon prehospital personnel who are certified or recognized by the Department one or more of the disciplinary or corrective measures in subsection (c) for one or more of the following reasons:

\*\*\*

(20) Violating a duty imposed by the act, this subpart or an order of the Department previously entered in a disciplinary proceeding.

\*\*\*

**CHAPTER 1005. LICENSING OF BLS AND ALS GROUND AMBULANCE SERVICES**

\*\*\*

**§ 1005.3. Right to enter, inspect and obtain records.**

(a) Upon the request of an employe or agent of the Department during regular and usual business hours, or at other times when that person possesses a reasonable belief that violations of this subpart may exist, a licensee shall:

\*\*\*

**§ 1005.10. Licensure and general operating standards.**

\*\*\*

(l) *Policies and procedures.* An ambulance service shall maintain written policies and procedures addressing each of the requirements imposed by this section, as well as the requirements imposed by §§ 1001.41, 1001.42, 1001.65, 1005.11 and Chapter 1051 (relating to out-of-hospital do-not-resuscitate orders), and shall also maintain written policies and procedures addressing infection control, management of personnel safety, substance abuse in the workplace, and the placement and operation of its ambulances.

\*\*\*

**CHAPTER 1007. LICENSING OF AIR AMBULANCE SERVICES—ROTORCRAFT**

**§ 1007.7. Licensure and general operating standards.**

\*\*\*

(n) *Policies and procedures.* An air ambulance service shall maintain written policies and procedures addressing each of the requirements imposed by this section, as well as the requirements imposed by §§ 1001.41, 1001.42, 1001.65 (relating to data and information requirements for ambulance services; dissemination of information; and cooperation) and Chapter 1051 (relating to out-of-hospital do-not-resuscitate orders) and shall also maintain written policies and procedures addressing infection control, management of personnel safety, substance abuse in the workplace, and the placement and operation of its air ambulances.

**SUBPART B. MATTERS ANCILIARY TO EMERGENCY**

**MEDICAL SERVICES SYSTEMS**

**CHAPTER 1051. OUT-OF-HOSPITAL DO-NOT-RECUSCITATE ORDERS**

**GENERAL PROVISIONS**

**§ 1051.1. Purpose.**

This chapter provides standards for the issuance and revocation of out-of-hospital DNR orders and compliance with those orders. An additional purpose of this chapter is to address how health care providers are to deal with orders or directions to not provide life-sustaining treatment, CPR, nutrition or hydration to a pregnant woman.

**§ 1051.2. Definitions.**

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

*Advance directive*—A directive for health care in a declaration issued pursuant to 20 Pa.C.S. Chapter 54 (relating to the Advance Directive for Health Care Act).

*Attending physician*—A physician who has primary responsibility for the medical care and treatment of a patient. A patient may have more than one attending physician.

*CPR--Cardiopulmonary resuscitation*—Cardiac compression, invasive airway techniques, artificial ventilation, defibrillation and other related procedures used to resuscitate a patient or to prolong the life of a patient.

*Declarant*—As defined in 20 Pa.C.S. § 5403 (relating to definitions).

*Declaration*—As defined in 20 Pa.C.S. § 5403.

*Department*—The Department of Health of the Commonwealth.

*DNR*—Do not resuscitate.

*EMS personnel--Emergency medical services personnel*—Prehospital personnel and individuals given good Samaritan civil immunity protection when using an automated external defibrillator under 42 Pa.C.S. § 8331.2 (relating to good Samaritan civil immunity for use of automated external defibrillators).

*EMS provider--Emergency medical services provider*—EMS personnel, a medical command physician and, as defined in § 1001.2 (relating to definitions), an advance life support service medical director, medical command facility medical director, medical command facility, ambulance service and quick response service.

*Health care provider*—A person who is licensed, certified or otherwise authorized to administer health care in the ordinary course of a business or practice of a profession. The term includes EMS providers.

*Invasive airway technique*—Any advanced airway technique, including endotracheal intubation.

*Life-sustaining treatment*—

- (i) A medical procedure or intervention that, when administered to a patient, will serve only to prolong the process of dying or to maintain the patient in a state of permanent unconsciousness.
- (ii) The term includes nutrition and hydration administered by gastric tube or intravenously or any other artificial or invasive means if the order of the patient so specifically provides.

*Medical command physician*—A physician who is approved by a regional emergency medical services council to provide medical command.

*Out-of-hospital DNR bracelet*—A bracelet which signifies that an out-of-hospital DNR order has been issued.

*Out-of-hospital DNR necklace*—A necklace which signifies that an out-of-hospital DNR order has been issued.



*Out-of-hospital DNR order*—A written order, the form for which is supplied by the Department or its designee pursuant to this chapter, that is issued by an attending physician and directs EMS providers to withhold CPR from the patient in the event of cardiac or respiratory arrest.

*Out-of-hospital DNR patient*—A patient for whom an attending physician has issued an out-of-hospital DNR order.

*Patient*—One of the following:

- (i) An individual who is in a terminal condition.
- (ii) A declarant whose declaration has become operative under 20 Pa.C.S. § 5405(2) (relating to when declaration becomes operative) and which provides that no CPR shall be provided in the event of the declarant's cardiac or respiratory arrest if the declarant becomes permanently unconscious, or designates a surrogate to make that decision under those circumstances

*Permanently unconscious*—

- (i) A medical condition 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.
- (ii) The term includes, without limitation, a persistent vegetative state or irreversible coma.

*Person*—An individual, corporation, partnership, association or Federal, State or local government or governmental agency.

*Physician*—An individual who has a currently registered license to practice medicine or osteopathic medicine in this Commonwealth.

*Prehospital personnel*—The term includes any of the following prehospital practitioners:

- (i) Ambulance attendants.
- (ii) First responders.
- (iii) Emergency medical technicians (EMTs).
- (iv) EMT-paramedics.
- (v) Prehospital registered nurses.
- (vi) Health professional physicians.

*Surrogate*— An individual who has, or individuals who collectively have, legal authority to request an out-of-hospital DNR order for another individual or to revoke that order.

*Terminal condition*—An incurable and irreversible medical condition in an advanced state caused by injury, disease or physical illness which will, in the opinion of the attending physician, to a reasonable degree of medical certainty, result in death regardless of the continued application of life-sustaining treatment.

**§ 1051.3. Applicability.**

(a) This chapter applies to the following:

- (1) Health care providers.
- (2) Attending physicians.
- (3) Patients.
- (4) Surrogates.

(b) This chapter neither compels nor prohibits health care provider compliance with an out-of-hospital DNR order in a hospital—~~In~~, EXCEPT THAT IN a hospital, an EMS provider shall comply with an out-of-hospital DNR order ~~only if responding on behalf of an ambulance service to a call the hospital makes for ambulance service assistance~~ IN THE COURSE OF

PROVIDING CARE TO OR TRANSPORTATION OF AN OUT-OF-HOSPITAL DNR  
PATIENT ON BEHALF OF AN AMBULANCE SERVICE.

(c) This chapter does not regulate the issuance of or compliance with a DNR order issued in a hospital to be followed in that hospital.

(d) This chapter permits EMS providers to comply with out-of-hospital DNR orders in all settings other than a hospital, except as set forth in subsection (b), including personal care facilities and all other health care facilities.

**PATIENT AND SURROGATE RIGHTS AND RESPONSIBILITIES**

**§ 1051.11. Patient qualifications to request and revoke out-of-hospital DNR order.**

(a) *Patient requesting an out-of-hospital DNR order.* A patient may request and receive an out-of-hospital DNR order from the patient's attending physician if the patient has a terminal condition and the patient is at least 18 years of age, has graduated from high school, has married or is emancipated.

(b) *Patient revoking an out-of-hospital DNR order.* An out-of-hospital DNR patient, regardless of age or physical or mental condition, may revoke an out-of-hospital DNR order issued for the out-of-hospital DNR patient whether the order was issued pursuant to the request of the patient or the patient's surrogate.

**§ 1051.12. Surrogate's authority to request and revoke out-of-hospital DNR order.**

(a) *Surrogate requesting an out-of-hospital DNR order.* The surrogate of a patient may request and receive from the patient's attending physician an out-of-hospital DNR order for the patient, regardless of the patient's age or other physical or mental condition.

(b) *Surrogate revoking an out-of-hospital DNR order.* A patient's surrogate may revoke an out-of-hospital DNR order for the patient if the out-of-hospital DNR order was issued at the request of a surrogate.

**§ 1051.13. ~~Person who~~ DUTIES WHEN PERSON loses authority to function as a surrogate.**

(a) *No authority to revoke out-of-hospital DNR order.* A person who acted as a patient's surrogate when requesting an out-of-hospital DNR order for the patient may not revoke the out-of-hospital DNR order if the person loses the legal authority to serve as the patient's surrogate.

(b) [*Duty when contacted by physician.* If a person who acted as the patient's surrogate when the out-of-hospital DNR order was issued for the patient, is not qualified to act as the patient's surrogate when a physician contacts that person pursuant to § 1051.30(b) (relating to physician destruction of out-of-state DNR order, bracelet or necklace), the person shall apprise the physician that the person is no longer the patient's surrogate and provide the physician any information the person has to help the physician locate the patient.

(c)] *Duty when person loses surrogate status.* A IF CAPABLE OF DOING SO, A person who loses the authority to act as a patient's surrogate after the person obtained an out-of-hospital DNR order for the patient shall APPRISE A REPLACEMENT SURROGATE, IF ANY, OF THE PATIENT'S OUT-OF-HOSPITAL DNR ITEMS AND OF OTHER PERTINENT INFORMATION RELATING TO THOSE ITEMS. THE FORMER SURROGATE SHALL ALSO PROVIDE TO THE REPLACEMENT SURROGATE OR TO THE PATIENT IF THE PATIENT IS NO LONGER REPRESENTED BY A SURROGATE, THE NAME OF THE PHYSICIAN WHO ISSUED THE OUT-OF-HOSPITAL DNR ORDER AND ANY INFORMATION THE PERSON HAS TO HELP THE PATIENT OR NEW SURROGATE LOCATE THE PHYSICIAN. THE FORMER SURROGATE, IF CAPABLE OF DOING SO,

SHALL ALSO make a reasonable effort to apprise the physician who issued the out-of-hospital DNR order of the change in that person's status, as well as the name of the person, if any, who replaced that person as the patient's surrogate and any information the former surrogate has to help the physician locate the patient or AND the patient's current surrogate. ~~A person who loses the authority to act as a patient's surrogate shall also provide to the patient if the patient is no longer represented by a surrogate, or to the replacement surrogate if there is one, the name of the physician who issued the out-of-hospital DNR order and any information the person has to help the patient or the patient's surrogate locate the physician.~~

(c) Duty when contacted by physician. If a patient's former surrogate did not attempt to contact the patient's attending physician as required by subsection (b), or made the attempt but was unsuccessful, and is contacted by the patient's attending physician for the purpose of communicating information regarding the patient, the patient's former surrogate shall apprise the physician that the person is no longer the patient's surrogate and provide the physician any information the former surrogate has to help the physician locate the patient or the patient's current surrogate.

**(D) DUTY OF REPLACEMENT SURROGATE.** A PERSON WHO REPLACES ANOTHER PERSON AS THE PATIENT'S SURROGATE AFTER AN OUT-OF-HOSPITAL DNR ORDER HAS BEEN ISSUED FOR THE PATIENT, AND WHO IS MADE AWARE OF THE ORDER AND GIVEN INFORMATION REGARDING THE ATTENDING PHYSICIAN WHO ISSUED THE ORDER, SHALL MAKE A REASONABLE EFFORT TO CONTACT THE PHYSICIAN TO APPRISE THE PHYSICIAN OF THE CHANGE IN SURROGATES UNLESS THE NEW SURROGATE IS ABLE TO CONFIRM THAT THE FORMER SURROGATE HAS ALREADY MADE THE DISCLOSURE.

## ATTENDING PHYSICIAN RESPONSIBILITIES

### § 1051.21. Securing out-of-hospital DNR orders, bracelets and necklaces.

(a) *Securing order forms.* A physician or the physician's agent may secure out-of-hospital DNR order forms from the Department unless the Department has contracted with a vendor to provide the order forms, in which case the physician shall secure the order forms BY PURCHASING THEM from the contracted vendor.

(b) *Securing bracelets and necklaces.* A physician may secure out-of-hospital DNR bracelets and necklaces by purchasing them from the vendor or vendors with which the Department has contracted to produce the bracelets and necklaces.

(c) *Vendors.* The Department will publish in a *Pennsylvania Bulletin* notice the name and address of the vendors with which it has contracted under this section and publish superseding *Pennsylvania Bulletin* notices when there are vendor changes.

### § 1051.22. Issuance of out-of-hospital DNR order.

(a) *Authority to issue.* A patient's attending physician shall issue an out-of-hospital DNR order for the patient if the patient who is qualified to request the order under § 1051.11(a) (relating to patient qualifications to request and revoke out-of-hospital DNR order) or the patient's surrogate requests the attending physician to issue an out-of-hospital DNR order for the patient and the attending physician determines that the patient has a terminal condition or is permanently unconscious.

(b) *Review of order before signing.* Before completing, signing and dating an out-of-hospital DNR order, a patient's attending physician shall ensure that the patient is identified in the order, that all other provisions of the order have been completed, and that the patient or the patient's surrogate, as applicable, has signed the order.

(c) *Order form.* A patient's attending physician shall issue an out-of-hospital DNR order for the patient only on a form provided by the Department or its designee.

**§ 1051.23. Disclosures to patient requesting out-of-hospital DNR order.**

When a patient qualified under § 1051.11(a) (relating to patient qualifications to request and revoke out-of-hospital DNR order) requests an out-of-hospital DNR order, the attending physician shall disclose the following information to the patient before issuing an out-of-hospital DNR order for the patient:

(1) The diagnosed condition is a terminal condition.

(2) An out-of-hospital DNR order directs an EMS provider to withhold providing CPR to the patient in the event of the patient's cardiac or respiratory arrest.

(3) The attending physician may also issue an out-of-hospital DNR bracelet or necklace for the patient, and that the necklace and bracelet also direct an EMS provider to withhold providing CPR in the event of the patient's cardiac or respiratory arrest.

(4) An out-of-hospital DNR order, bracelet or necklace requested by a patient is effective only when the patient possesses and displays the order, bracelet or necklace.

(5) An out-of-hospital DNR order is not effective when the patient is in a hospital, unless an EMS provider has been dispatched to provide EMS to the patient in the hospital, but IT MAY BE POSSIBLE FOR a DNR order ~~may~~ TO be issued for the patient in a hospital in accordance with other procedures.

(6) The patient may revoke the out-of-hospital DNR order; the patient may do so without the physician's approval or knowledge; revocation may be accomplished by destroying or not displaying the order, bracelet or necklace, or by conveying the decision to revoke the out-of-hospital DNR order verbally or otherwise at the time the patient experiences respiratory or

cardiac arrest; and neither the patient's physical nor mental condition will be considered to void the patient's decision to revoke the out-of-hospital DNR order if that decision is clearly communicated in some manner.

(7) The possibility exists that the EMS provider may administer CPR in the event of the patient's cardiac or respiratory arrest if an EMS provider is uncertain regarding the validity or applicability of the out-of-hospital DNR order, bracelet or necklace.

(8) An EMS provider who complies with the patient's out-of-hospital DNR order may provide other medical interventions to the patient to provide comfort or alleviate pain.

(9) The physician will ~~attempt~~ MAKE EVERY REASONABLE EFFORT to contact the patient to ask the patient to return the out-of-hospital DNR order, bracelet and necklace to the physician, for destruction by the physician, if the physician discovers that the diagnosis of the terminal condition was in error.

(10) If the patient is female, there are additional procedures that an EMS provider will need to follow to implement an out-of-hospital DNR order if the patient is pregnant at the time of cardiac or respiratory arrest. If the patient is pregnant or requests information regarding the additional procedures, the physician shall explain the requirements of § 1051.61 (relating to pregnant patients).

**§ 1051.24. Disclosures to surrogate requesting out-of-hospital DNR order.**

Before issuing an out-of-hospital DNR order for a patient that is requested by the patient's surrogate, the attending physician shall disclose the following information to the surrogate:

(1) The diagnosed condition is a terminal condition or that the physician has diagnosed the patient to be permanently unconscious.



(2) The disclosures required by § 1051.23(2), (3), (5), (7) and (8) (relating to disclosures to patient requesting out-of-hospital DNR order).

(3) An out-of-hospital DNR order, bracelet or necklace requested by the surrogate is effective only when the order, bracelet or necklace is displayed with the patient or the surrogate presents the order to the [health care] EMS provider at the time the patient experiences cardiac or respiratory arrest.

(4) The patient or surrogate may revoke the out-of-hospital DNR order; the patient or surrogate may do so without the physician's approval or knowledge; revocation may be accomplished by destroying or not displaying the order, bracelet or necklace, or by conveying the decision to revoke the out-of-hospital DNR order verbally or otherwise at the time the patient experiences cardiac or respiratory arrest; and neither the physical nor mental condition of the patient will be considered to void the decision of the patient or surrogate to revoke the out-of-hospital DNR order if that decision is clearly communicated in some manner. The physician shall also apprise the surrogate, if it seems appropriate under the circumstances, that the power of the surrogate to revoke the out-of hospital DNR order for the patient will terminate if the surrogate loses the legal authority to make that decision.

(5) The physician will ~~attempt~~ MAKE EVERY REASONABLE EFFORT to contact the surrogate to ask the surrogate to return the out-of-hospital DNR order, bracelet and necklace to the physician, for destruction by the physician, if the physician discovers that the diagnosis of the terminal condition or that the patient is permanently unconscious was in error.

(6) If the patient is female, there are additional procedures that an EMS provider will need to follow to implement an out-of-hospital DNR order if the patient is pregnant at the time of cardiac or respiratory arrest. If the patient is pregnant or the patient's surrogate requests

information regarding the additional procedures, the physician shall explain the requirements of § 1051.61 (relating to pregnant patients).

**§ 1051.25. Disclosures to patient when surrogate requests out-of-hospital DNR order.**

Before issuing an out-of-hospital DNR order for a patient that is requested by the patient's surrogate, the attending physician shall disclose to the patient the information in § 1051.23 (relating to disclosures to patient requesting out-of-hospital DNR order) that the physician in good faith believes the patient needs to have to make a future decision to revoke or not revoke the order. In making this assessment, the physician shall consult with the patient's surrogate and consider factors such as the reason the patient is not able to request an out-of-hospital DNR order, the patient's ability to comprehend and retain the information, and the patient's age and maturity. The attending physician shall refuse to issue the order if the physician and surrogate cannot agree to the information that is to be disclosed to the patient by the physician.

**§ 1051.26. Physician refusal to issue an out-of-hospital DNR order.**

An attending physician who is not willing to issue an out-of-hospital DNR order for a reason other than described in § 1051.25 (relating to disclosures to patient when surrogate requests out-of-hospital DNR order) shall explain the reason to the patient or the patient's surrogate, as appropriate. IF THE REQUEST IS MADE BY A PATIENT'S SURROGATE, OR BY A PATIENT WHO QUALIFIES TO MAKE THE REQUEST UNDER § 1051.11 (RELATING TO PATIENT QUALIFICATIONS TO REQUEST AND REVOKE OUT-OF-HOSPITAL DNR ORDER), AND THE PHYSICIAN DETERMINES THAT THE PATIENT IS QUALIFIED TO RECEIVE AN OUT-OF-HOSPITAL DNR ORDER, THE PHYSICIAN SHALL ALSO DO THE FOLLOWING:

- (1) ~~The physician shall also explain~~ EXPLAIN TO THE PATIENT OR SURROGATE that an out-of-hospital DNR order may be issued only by a physician who has primary responsibility for the treatment and care of a patient.
- (2) ~~The physician shall offer~~ MAKE EVERY REASONABLE EFFORT to assist the patient or surrogate to secure the services of another physician who is willing to issue an out-of-hospital DNR order for the patient and who will undertake primary responsibility for the treatment and care of the patient in addition to or instead of the attending physician, as the patient or surrogate chooses.

**§ 1051.27. Providing out-of-hospital DNR bracelet or necklace.**

(a) *Bracelet and necklace.* A patient's attending physician may provide to the patient, or to the patient's surrogate for the patient, an out-of-hospital DNR bracelet or necklace, or both, if the physician has issued or is issuing an out-of-hospital DNR order for the patient and the patient or the surrogate requests the item or items.

(b) *Order also required.* A patient's attending physician may not provide an out-of-hospital DNR bracelet or necklace for the patient without also issuing, or having issued, an out-of-hospital DNR order for the patient.

(c) *Department vendor.* A patient's attending physician may provide to or for the patient only an out-of-hospital DNR bracelet or necklace produced by a vendor with which the Department has contracted to produce the bracelet or necklace.

**§ 1051.28. Documentation.**

An attending physician who issues an out-of-hospital DNR order for a patient shall maintain a copy of that order in the patient's medical record and shall document in that order whether the physician also provided an out-of-hospital DNR bracelet or necklace, or both. If the attending physician provides an out-of-hospital DNR bracelet or necklace after issuing the out-of-hospital DNR order, the physician shall document the patient's medical record to reflect that the bracelet or necklace was also provided for the patient.

**§ 1051.29. Duty to contact patient or surrogate.**

If a physician who issued an out-of-hospital DNR order for the patient, subsequently determines that the diagnosis that the patient is in a terminal condition or is permanently unconscious was in error, the physician shall make ~~a good faith~~ EVERY REASONABLE effort to promptly contact the patient or the patient's surrogate to disclose the error. The physician shall also request the return of the order, and the bracelet and necklace if the physician provided those items.

**§ 1051.30. Physician destruction of out-of-hospital DNR order, bracelet or necklace.**

(a) *Destruction of order, bracelet and necklace.* A physician shall destroy an out-of-hospital DNR order, bracelet or necklace returned to the physician under §1051.29 (relating to duty to contact patient or surrogate), as follows:

(1) The physician shall shred or otherwise destroy beyond identification the original order and mark all copies of the order in the physician's possession as having been revoked.

(2) The physician shall cut the bracelet or necklace pendant in half or take other action that renders the bracelet or necklace incapable of being again used as an out-of-hospital DNR bracelet or necklace.

(b) *Documentation of order when items not destroyed.* A physician who requests the return of an out-of-hospital DNR order, bracelet or necklace under §1051.29 may not mark copies of the order in the physician's possession as having been revoked without having destroyed, or confirmed FROM A RELIABLE PERSON the destruction of the original out-of-hospital DNR order and any out-of-hospital DNR bracelet or necklace the physician provided for the patient.

### **EMS PROVIDER RESPONSIBILITIES**

#### **§ 1051.51. Implementation of out-of-hospital DNR order.**

(a) *Display of order, bracelet or necklace.* An EMS provider may not provide CPR to a patient who is experiencing cardiac or respiratory arrest if an out-of-hospital DNR order, bracelet, or necklace is displayed with the patient or the patient's surrogate presents the EMS provider with an out-of-hospital DNR order for the patient, and neither the patient nor the patient's surrogate acts to revoke the order at that time. When an EMS provider observes an out-of-hospital DNR order without also observing an out-of-hospital DNR bracelet or necklace, the EMS provider shall implement the out-of-hospital DNR order only if it contains original signatures.

(b) *Discovery after CPR initiated.* If after initiating CPR an EMS provider becomes aware of an out-of-hospital DNR order that is effective pursuant to subsection (a), the EMS provider shall discontinue CPR.

(c) *Prehospital practitioner uncertainty.* If a prehospital practitioner is uncertain as to whether an out-of-hospital DNR order has been revoked for a patient who is experiencing cardiac or respiratory arrest, the prehospital practitioner shall provide CPR to the patient subject to the following:

(1) If the prehospital practitioner is in contact with a medical command physician prior to initiating CPR, the prehospital practitioner shall initiate or not initiate CPR as directed by the medical command physician.

(2) If the prehospital practitioner is in contact with a medical command physician after initiating CPR, the prehospital practitioner shall continue or not continue CPR as directed by the medical command physician.

(d) *Discontinuation of CPR not initiated by prehospital practitioner.* If CPR had been initiated for the patient before a prehospital practitioner arrived at the scene, and the prehospital practitioner determines that an out-of-hospital DNR order is effective pursuant to subsection (a), the prehospital practitioner may not discontinue the CPR without being directed to do so by a medical command physician.

(e) *AED good Samaritan.* If an individual who is given good Samaritan civil immunity protection when using an automated external defibrillator (AED) under 42 Pa.C.S. § 8331.2 (relating to good Samaritan civil immunity for use of automated external defibrillators) is uncertain as to whether an out-of-hospital DNR order has been revoked for a patient who is experiencing cardiac arrest, the individual may provide CPR to the patient as permitted by 42 Pa.C.S. § 8331.2, but shall discontinue CPR if directed by a medical command physician directly or as relayed by a prehospital practitioner.

(f) *Providing comfort and alleviating pain.* When a prehospital practitioner complies with an out-of-hospital DNR order, the prehospital practitioner, within the practitioner's scope of practice, shall provide other medical interventions necessary and appropriate to provide comfort to the patient and alleviate the patient's pain, unless otherwise directed by the patient or the prehospital practitioner's medical command physician.

**§ 1051.52. Procedure when both advance directive and out-of-hospital DNR order are present.**

If a patient with cardiac or respiratory arrest has both an advance directive directing that no CPR be provided and an out-of-hospital DNR order, an EMS provider shall comply with the out-of-hospital DNR order as set forth in § 1051.51 (relating to compliance with an out-of-hospital DNR order).

**PREGNANT PATIENTS**

**§ 1051.61. Pregnant patients.**

Notwithstanding the existence of an order or direction to the contrary, life-sustaining treatment, CPR, nutrition and hydration shall be provided to a pregnant patient by a health care provider unless, to a reasonable degree of medical certainty as certified on the patient's medical record by the patient's attending physician and a second physician who is an obstetrician who has examined the patient, life-sustaining treatment, nutrition and hydration will have one of the following consequences:

- (1) They will not maintain the pregnant patient in such a way as to permit the continuing development and live birth of the unborn child.
- (2) They will be physically harmful to the pregnant patient.
- (3) They will cause pain to the pregnant patient which cannot be alleviated by medication.

**MEDICAL COMMAND PHYSICIAN RESPONSIBILITIES**

**§ 1051.81. Medical command physician responsibilities.**

(a) *Compliance with out-of-hospital DNR order.* If a medical command physician is in contact with a prehospital practitioner when the prehospital practitioner is attending to a patient in cardiac or respiratory arrest and the prehospital practitioner is made aware of an out-of-hospital

DNR order for the patient by examining an out-of-hospital DNR order, bracelet or necklace, the medical command physician shall honor the out-of-hospital DNR order. If appropriate, the medical command physician shall direct the prehospital practitioner to provide other medical interventions within the practitioner's scope of practice to provide comfort to the patient and alleviate the patient's pain, unless the prehospital practitioner is otherwise directed by the patient.

(b) *Prehospital practitioner uncertainty.* If a medical command physician is in contact with a prehospital practitioner when the prehospital practitioner is attending to a patient in cardiac or respiratory arrest and the prehospital practitioner communicates uncertainty as to whether an out-of-hospital DNR order for the patient has been revoked, the medical command physician shall ask the prehospital practitioner to explain the reason for the uncertainty. Based upon the information provided, the medical command physician shall make a good faith assessment of whether the described circumstances constitute a revocation, and then direct the prehospital practitioner to withdraw or continue CPR based upon whether the physician determines that the out-of-hospital DNR order has been revoked or not revoked.

(c) *Pregnant patient.* If a medical command physician is in contact with a prehospital practitioner when the prehospital practitioner is attending to a pregnant patient in cardiac or respiratory arrest, and the prehospital practitioner is made aware of an out-of-hospital DNR order for the pregnant patient by examining an out-of-hospital DNR order, bracelet or necklace for the patient, and apprises the medical command physician of the out-of-hospital DNR order, the medical command physician shall direct the prehospital practitioner to ignore the out-of-hospital DNR order unless the medical command physician has knowledge that the patient's attending physician and a second physician who is an obstetrician had examined the patient, and both



certified in the patient's medical record that, to a reasonable degree of medical certainty, life-sustaining treatment, nutrition, hydration and CPR will have one of the following consequences:

(1) They will not maintain the pregnant patient in such a way as to permit the continuing development and live birth of the unborn child.

(2) They will be physically harmful to the pregnant patient.

(3) They will cause pain to the pregnant patient which cannot be alleviated by medication.

(d) *Inconsistencies.* Subsections (a) and (b) apply when the patient is a pregnant patient, except to the extent they are inconsistent with subsection (c).

#### **ORDERS, BRACELETS AND NECKLACES FROM OTHER STATES**

##### **§ 1051.101. Recognition of other states' out-of-hospital DNR orders.**

(a) *Validity of orders, bracelets and necklaces from other states.* An out-of-hospital DNR order, bracelet or necklace valid in a state other than this Commonwealth is effective in this Commonwealth to the extent the order, bracelet or necklace is consistent with the laws of this Commonwealth.

(b) *Department acceptance.* The Department will review the applicable laws of other states, and the out-of-hospital DNR orders, bracelets and necklaces provided in other states, and list in a notice in the *Pennsylvania Bulletin* the states that provide out-of-hospital DNR orders, bracelets and necklaces that are consistent with the laws of the Commonwealth. The notice will also include, for each state listed, a description of the out-of-hospital DNR order, bracelet and necklace the state issues consistent with the laws of the Commonwealth. The Department will update the list and descriptions, as needed, in a superseding notice in the *Pennsylvania Bulletin*.

(c) *Compliance by EMS providers.* An EMS provider shall comply with §§ 1051.51, 1051.52, 1051.61 and 1051.81 when encountering a patient with an apparently valid out-of-hospital DNR order, bracelet or necklace issued by another state listed in a notice in the *Pennsylvania Bulletin* issued under subsection (b).

# Commonwealth of Pennsylvania



DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

December 5, 2003

Robert E. Nyce  
Executive Director  
Independent Regulatory Review Commission  
14th Floor, Harrisstown II  
333 Market Street  
Harrisburg, PA 17101

Re: Department of Health – Final Regulations No. 10-174  
Out-of-Hospital Do-Not-Resuscitate Orders

Dear Mr. Nyce:

Enclosed are final-form regulations for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§ 745.1-745.15). These regulations will facilitate the continued implementation of the Do-Not-Resuscitate Act (20 Pa.C.S. §§ 54A01-54A13).

Section 5.1(a) of the Regulatory Review Act, 71 P.S. § 745.5a(a), provides that upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to the Commission a copy of the agency's response to comments received, the names and addresses of the commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

A list of the names and addresses of the commentators who requested a copy of the final-form regulations is enclosed. Their comments were previously forwarded to the Commission by the Department.

Section 5.1(e) of the Regulatory Review Act, 71 P.S. § 745.5a(e), provides that the Commission may have until its next scheduled meeting which occurs no less than 30 days after receipt of these regulations, to approve or disapprove the final-form regulations.

December 5, 2003

The Honorable Robert E. Nyce

Page 2

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact Dawn Jackson, Director of Policy and Legislative Affairs, at (717) 783-3985.

Sincerely,

A handwritten signature in black ink, appearing to read "C. Johnson", written in a cursive style.

Calvin B. Johnson, MD, MPH  
Secretary of Health

Enclosures

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE  
REGULATORY REVIEW ACT**

I.D. NUMBER: 10-174  
 SUBJECT: Out-of-Hospital Do-Not Resuscitate Orders  
 AGENCY: Department of Health

**TYPE OF REGULATION**

Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation

a. With Revisions

b.

Without Revisions

RECEIVED  
 2003 DEC -5 PM 2:33  
 INDEPENDENT REGULATORY REVIEW COMMISSION

**FILING OF REGULATION**

DATE	SIGNATURE	DESIGNATION
12/5	<i>Carol Rucker</i>	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
12/5	<i>N. Thompson</i>	
12/5/03	<i>K. Kruse</i>	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
12/5/03	<i>L. Calie</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
_____	_____	ATTORNEY GENERAL (for Final Omitted only)
_____	_____	LEGISLATIVE REFERENCE BUREAU (for Proposed only)

December 4, 2003