

Regulatory Analysis Form		This space for use by IRR
(1) Agency Department of Health		RECEIVED 2003 AUG 26 PM 3: 16
(2) I.D. Number (Governor's Office Use) 10-174		INDEPENDENT REGULATORY REVIEW COMMISSION IRRC Number: 335
(3) Short Title Out-of-Hospital Do-Not-Resuscitate Orders		
(4) Pa. Code Cite 28 Pa. 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) <input checked="" type="checkbox"/> Proposed Rulemaking 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 proposed 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 proposed 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 proposed 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 proposed regulations also deal with this component of the DNR Act.		

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

The Department is proposing 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. The proposed rulemaking is being issued pursuant to that requirement.

(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. 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 his or her 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.

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(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 would be required to comply with the regulation. Additionally, there is an indeterminate number of good Samaritans operating AEDs who would be required to comply with the regulations.

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

There are estimated to be 40,000 (in the first year of implementation) patients or surrogates who would choose to initiate an out-of-hospital DNR order with more conservative numbers in subsequent years.

(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.

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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. The Department has received no requests for changes to the regulations since the interim regulations were published in December 2002.

(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 would 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 will also be 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 other states' DNR programs, it is estimated that 40,000 persons would avail themselves of DNR orders and products in the first year of implementation in order to compensate for the previous lack of regulation, with a lower adjustment made for subsequent years. There are 53,336 licensed physicians in PA. It is estimated that approximately 24,000 physicians would 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 40,000 DNR patients, supply costs totaling \$72,400 (in the first year of implementation) would 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 would incur costs for developing written policies and procedures relating to DNR orders. Sample policies and procedures would be provided to the services and service costs would be minimal. The Department will provide technical assistance to licensed ambulance services. Certified EMS personnel would need to attend DNR training; however, the training would 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 would offset other costs incurred in implementing the statute and regulations.

(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.

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County governments may be impacted at their 911 centers. There would 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 will be developed 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.

Cost to State government averages \$26,000 annually for travel, training, and outreach 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 would absorb duties related to providing education and training, handling DNR inquiries, and distributing forms and patient educational materials. In addition, this staff would 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
SAVINGS						
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 SAVINGS	NA	NA	NA	NA	NA	NA
COSTS						
Regulated Community	\$36,200	\$72,400	\$54,300	\$36,200	\$36,200	\$36,200
Local Government	NA	NA	NA	NA	NA	NA

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State Government	\$10,000	\$26,000	\$26,000	\$26,000	\$26,000	\$26,000
TOTAL COSTS	\$46,200	\$98,400	\$80,300	\$62,200	\$62,200	\$62,200
REVENUE LOSSES:						
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:

Previous year is prorated at 50% of FY +1.

Projected volume based on similar state experiences. 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 FY1=40,000 patients, FY2=30,000 pts, FY3=20,000 pts, FY4=20,000 pts, and FY5=20,000 pts.

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 yr. (\$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

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

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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. Under the current regulations, the cost to patients and their families is 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, 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 cost 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?

Forty-four other states have DNR regulations or protocols. The proposed regulations are comparable to other states' regulations.

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. One hospice agency from Youngstown, Ohio, has already requested Pennsylvania out-of-hospital DNR materials.

(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.

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(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 home health section and long term care council at HAP are scheduled for June 10, 2003 and August 15, 2003, respectively.

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 would be required to document the patient's terminal or permanently unconscious condition and include a copy of the patient's signed DNR 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 surrogates with legal authority to act on behalf of the patient, 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 would make it easier for physicians to determine the information they need to provide which, in turn, would 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.

Interim regulations went into effect on March 1, 2003. Comments received by telephone and e-mail were logged and collated for consideration. The Department will consider the comments to the proposed regulations before adopting final regulations. Thereafter, the effectiveness of the regulations will be subject to constant monitoring and review.

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<p>Copy below is hereby approved as to form and legality. Attorney General</p> <p>BY: <u><i>Amy M. Elliott</i></u> DEPUTY ATTORNEY GENERAL AUG 22 2003</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><i>Calvin B. Johnson</i></u> Calvin B. Johnson, M.D., M.P.H.</p> <p>TITLE: <u>Acting Secretary of Health</u></p>	<p>Copy below is hereby approved as to form and legality. Executive or independent Agencies.</p> <p>BY: <u><i>John V. Turner</i></u> 6/17/03</p> <p>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>
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PROPOSED 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 gives notice that it is proposing regulations to facilitate the continued implementation of the Do-Not-Resuscitate Act (DNR Act) (P.L. 409, No. 59) (20 Pa.C.S. §§ 54A01-54A13) enacted by Act 59 of 2002 (Act 59), as assisted by the Department's interim regulations adopted at 32 Pa.B. 6117-6128 (December 14, 2002). The Department is proposing to continue the division of 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), as accomplished by the Department's interim regulations. Subpart A contains regulations the Department has adopted under the Emergency Medical Services Act (EMS Act) (P.L. 164, No. 45) (35 P.S. §§ 6921-6938). The interim regulations made amendments in Subpart A to §§ 1001.1-1001.5, 1003.27, 1005.3, 1005.10 and 1007.7. The interim regulations also adopted Subpart B, which contains Chapter 1051 (relating to out-of-hospital do-not-resuscitate orders). The proposed amendments are set forth in Annex A hereto.

Purpose and Background

To facilitate the prompt implementation of the DNR Act, enacted June 19, 2002, 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 their review by the designated Standing Committees in the House and Senate, and the Independent Regulatory Review Commission (IRRC). The Department adopted interim regulations on December 14, 2002. The interim regulations went into effect on March 1, 2003

Act 59 also requires that following the Department's adoption of interim regulations the Department is to adopt final regulations in accordance with customary rulemaking procedures, by February 18, 2004. The Department is proposing these regulations as a prelude to its adoption of the final regulations by February 18, 2004.

Summary

Subpart A. Emergency Medical Services Systems

The Department proposes to adopt the changes made by the interim regulations to each of the sections affected under Subpart A. Following are the reasons for this decision.

Section 1001.1. Purpose.

When the interim regulations divided Part VII into Subparts A and B, this section was amended to address the purpose of Subpart A rather than the purpose of Part VII. This continues to be appropriate since the Department is proposing to continue the division of its Emergency Medical Services Regulations into two distinct subparts.

Section 1001.2. Definitions.

This section was amended by the interim regulations to provide that the definitions in the section apply throughout Subpart A. The regulation had previously read that the definitions in the section applied throughout Part VII. The preamble to the interim regulations explained that the application of the definitions in this section to all of the regulations in Part VII was no longer practical since some of the terms defined in the section are given different definitions under the DNR Act and the definition section in Chapter 1051 under Subpart B. That explanation continues to apply.

Section 1001.3. Applicability.

This section identified the persons who were affected by Part VII. It had been amended by the interim regulations to identify only persons affected by Subpart A. This limitation remains appropriate.

Section 1001.4. Exceptions.

This section authorized persons to seek exceptions to regulations in Part VII that did not repeat statutory requirements. It was amended by the interim regulations to authorize persons to seek exceptions to only the regulations in Subpart A—that is, to regulations adopted under the EMS Act. Since Subpart A will not apply to the regulations in Subpart B, which are the regulations that facilitate implementation of the DNR Act, this distinction remains appropriate.

Section 1001.5. Investigations.

This section announced that the Department may investigate a possible violation of Part VII. It was amended by the interim regulations to announce that the Department may investigate a possible violation of Subpart A. This distinction remains appropriate for the same reason given in explaining the distinction discussed under the preceding section title

Section 1003.27. Disciplinary and corrective action.

This section addresses the Department's authority to discipline prehospital personnel. Prior to the Department's adoption of the interim regulations, one of the

grounds for discipline was violating a duty imposed by Part VII. Subsection (a)(20) was amended by the interim regulations to provide that discipline may be imposed for violating a duty imposed by Subpart A. This limitation continues to be valid, as the Department's disciplinary authority under the EMS Act does not extend to conduct regulated by the DNR Act and the Department's regulations adopted under that act.

Section 1005.3. Right to enter, inspect and obtain records.

Prior to the Department's adoption of the interim regulations, this section addressed the duty of a ground ambulance service to cooperate with the Department when the Department was investigating a violation of Part VII. It was amended by the interim regulations to substitute "Subpart A" for "Part VII." Under § 1007.1 (relating to general provisions) this amendment was also applicable to air ambulance services. The continued reference to only Subpart A remains appropriate.

Section 1005.10. Licensure and general operating standards.

This section addresses the standards that an entity needs to satisfy to become licensed as a ground ambulance service and continue to operate as a ground ambulance service. It was amended by the interim regulations to require a ground ambulance service to maintain written policies and procedures to implement the requirements of Chapter 1051. The need for this requirement continues. The regulation identifies all of the policies that an ambulance service must keep. When the DNR Act was passed it established procedures that EMS personnel must follow when encountering a person in cardiac or respiratory arrest who displays a DNR order, bracelet or necklace. Ambulance

services need to ensure that their personnel are aware of those procedures as well as the procedures required by the Department's regulations adopted under Act 59.

Section 1007.7. Licensure and general operating standards.

This section addresses the standards that an entity needs to satisfy to become licensed as an air ambulance service and continue to operate as an air ambulance service. It was amended by the interim regulations to require that an air ambulance service maintain written policies and procedures to implement the requirements of Chapter 1051. The need to continue this requirement for ground ambulance services applies as well to air ambulance services.

Subpart B. Matters Ancillary to Emergency Medical Services Systems

Chapter 1051 (relating to out-of-hospital do-not-resuscitate orders) was adopted by the interim regulations to facilitate implementation of the DNR Act. In addition, it assisted the implementation of an Act 59 amendment to the Advance Directive for Health Care Act (P.L. 108, No. 24) (20 Pa.C.S. §§ 5401-5416) that directs emergency medical services (EMS) providers to follow the procedures for implementing an out-of-hospital DNR order when a patient who is experiencing cardiac or respiratory arrest has both an advance declaration issued under the Advance Directive for Health Care Act and an out-of-hospital DNR order issued under the DNR Act.

As explained in the preamble to the interim regulations, there are significant procedural differences between the two processes. Under the Advance Directive for Health Care Act, if a patient has issued an advance declaration that directs that no CPR

be provided in the event of the patient's cardiac or respiratory arrest, 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.

Except as otherwise noted, the Department is proposing to adopt the interim regulations with a few minor revisions. The reasons for this action are as follows.

GENERAL PROVISIONS

Section 1051.1. Purpose.

This section addresses the purposes of the chapter. The primary purpose of the DNR Act and Chapter 1051 of the Department's regulations is to articulate standards for the issuance and revocation of out-of-hospital DNR orders, and compliance with those orders. Nevertheless, one component of the DNR Act departs from this general regulatory scheme. It deals with pregnant patients and establishes special rules that EMS personnel and other health care providers are to follow when dealing with pregnant patients. That section of the DNR Act sets forth specific rules for the administration of out-of-hospital DNR orders issued for pregnant patients. However, it also addresses other types of life-sustaining procedures, other types of orders and directives that address the withholding or withdrawing of life-sustaining procedures, and duties of health care providers (not only EMS personnel) when confronted with such orders. Consequently,

this section was drafted in the interim regulations to announce that the chapter deals with special provisions relating to pregnant patients in addition to the general rules applicable to the issuance and revocation of out-of-hospital DNR orders and compliance with those orders. The reasons for this clarification continue to apply.

Section 1051.2. Definitions.

This section provides definitions for terms used in Chapter 1051. The preamble to the interim regulations discussed definitions in this section that required an explanation as to why they were drafted in the manner adopted. The definitions that were given special attention were the definitions of “attending physician,” “EMS provider,” “EMS personnel,” “health care provider,” “patient,” “prehospital personnel” and “surrogate.” The substance of that discussion is repeated as follows:

Attending physician

“Attending physician” is defined in the interim regulations as it is defined in the DNR Act, except a sentence is added stating that a patient may have more than one attending physician. The Department proposes to retain the additional sentence included in the interim definition for several reasons. First, more than one physician may have primary responsibility for the medical care and treatment of a patient. For example, a patient may use a group practice in which multiple physicians handle the patient’s medical care. It would be difficult to label one physician as the patient’s attending physician if the patient receives services from more than one physician in a group practice. Another example of a patient having more than one primary physician is a

patient who has cancer who sees an oncologist on a regular basis in addition to a primary care physician.

Second, depending upon a variety of circumstances it may be difficult for a physician to conclude that he or she is the “exclusive” attending physician. Also, a physician may believe that he or she is the patient’s attending physician based upon the information the patient or a surrogate provides to the physician, but some information may be forgotten, withheld or not known by the patient or surrogate.

As a practical matter, a physician who is requested to issue an out-of-hospital DNR order for a patient needs to make a good faith judgment as to whether he or she is an attending physician of the patient based upon the medical care the physician provides the patient. If the physician determines that the circumstances of the physician-patient relationship do not enable the physician to make that determination, the physician should attempt to supplement that knowledge with information the physician secures after making reasonable inquiries of the patient or the patient’s surrogate regarding the medical care the patient is receiving from other physicians.

Health care provider, EMS provider, EMS personnel and prehospital personnel

The DNR Act defines “health care provider,” “[EMS] provider,” and “person.” The Department does not construe the term “health care provider” to be restricted to **individuals** who provide health care. The statutory definition of “health care provider” uses the term “person” and includes “personnel recognized” under the EMS Act. The statute’s definition of “person” is not limited to an individual. The Department construes the statute’s definition of “health care provider” to include persons, not limited to

individuals, who are licensed, certified or otherwise authorized under Commonwealth laws to administer health care in the ordinary course of their business or profession. Consequently, it interprets the statutory “health care provider” definition’s reference to “personnel” recognized under the EMS Act, to serve as an example of health care providers and not as a limitation on the definition.

The DNR Act defines “[EMS] provider” to include each health care provider recognized under the EMS Act, and also an individual recognized to use automated external defibrillators (AEDs) under 42 Pa.C.S. § 8331.2 (relating to good Samaritan civil immunity for use of AEDs). Similar to the Department’s interpretation of the statute’s definition of “health care provider,” the Department interprets the statute’s definition of “[EMS] provider” to include a person, not limited to an individual, that provides EMS pursuant to authority granted by the EMS Act. The Department’s interim definitions of “health care provider” and “EMS provider” in this section reflect these interpretations.

Additionally, this section defines the terms “EMS personnel” and “prehospital personnel.” It employs the term “prehospital personnel” in defining “EMS personnel,” and it employs the term “EMS personnel” in defining “EMS provider.” Distinctions between “EMS personnel” and “prehospital personnel” are needed to accommodate the DNR Act’s inclusion of persons who have AED good Samaritan civil immunity as an EMS provider authorized to follow an out-of-hospital DNR order.

“Prehospital personnel” is defined in § 1001.2 (relating to definitions) of the regulations the Department has adopted under the EMS Act, to include ambulance attendants, first responders, EMTs, EMT-paramedics (paramedics), prehospital registered nurses (PHRNs), and health professional physicians. It does not include persons who

have AED good Samaritan civil immunity. These persons are not regulated under the EMS Act. The same definition of “prehospital personnel” is included in this section. These individuals are authorized by the EMS Act to perform various services for ambulance companies.

Some parts of Chapter 1051 address the responsibilities of both prehospital personnel and good Samaritan users of AEDs, and other parts address the responsibilities of prehospital personnel exclusively. The latter provisions deal with the relationship between prehospital personnel and medical command physicians—a relationship that good Samaritan users of an AEDs do not experience. To distinguish between provisions of the regulations that apply to both prehospital personnel and good Samaritan users of AEDs, and those provisions that apply to prehospital personnel only, the Department defined the term “EMS personnel” in the interim regulation to include both types of personnel and uses that term in provisions that apply to both types of personnel. The Department uses the term “prehospital personnel” in provisions that apply to prehospital personnel, but do not apply to good Samaritan users of AEDs.

Patient

The DNR Act defines “out-of-hospital do-not-resuscitate patient” to be an individual for whom an out-of-hospital DNR order has been issued. It defines “patient” to mean the same thing, unless the context indicates otherwise. As used in the DNR Act, “patient” and “out-of-hospital do-not-resuscitate patient” are not interchangeable. “Patient” is employed, for example to refer to an individual who is qualified to receive an out-of-hospital DNR but for whom an out-of-hospital DNR order has not been issued.

The interim regulations' definition of "out-of-hospital [DNR] patient" appears as it does in the statute. The definition of "patient" in the interim regulations applies to an individual who qualifies for an out-of-hospital DNR order by virtue of being in a terminal condition or being in a state of permanent unconsciousness, but who has not received the order. Because this is how the two terms are actually used in the DNR Act, the proposed regulations would continue this distinction.

Surrogate

The DNR Act permits a patient's surrogate to request an out-of hospital DNR order for the patient and to revoke that order. It does not define "surrogate." In the context in which this term is used in the statute, it means a person who has, or persons who jointly have, legal authority to request or revoke an out-of-hospital DNR order. The Department proposes to adopt these definitions and the other definitions in the interim regulation because they continue to be appropriate within the context of the chapter.

§ 1051.3. Applicability.

This section of the interim regulations identifies the major categories of persons to which the chapter applies. It also clarifies that the chapter does not regulate the issuance or implementation of a DNR order executed or to be executed in a hospital, but that it does authorize compliance with an out-of-hospital DNR order in all other settings, including other health care facilities and facilities regulated by other Commonwealth agencies, such as personal care facilities regulated by the Department of Public Welfare. Additionally, it relates that even in a hospital an EMS provider may comply with an out-

of-hospital DNR order if the hospital requests an ambulance service to provide EMS to a patient.

Hospital requests for an ambulance service's assistance occasionally occur when an out-of-hospital DNR patient is receiving services at a hospital site that does not handle emergency patients. Notwithstanding the statutory label of "out-of-hospital [DNR] order," a purpose of the DNR Act is to require EMS providers to withhold the execution of standard life-saving protocols when they are called to handle a patient with an out-of-hospital DNR order, bracelet or necklace who is experiencing respiratory or cardiac arrest. Therefore, the proposed regulations would adopt the same applicability provisions that appear in the interim regulation.

PATIENT AND SURROGATE RIGHTS AND RESPONSIBILITIES

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

The DNR Act identifies the types of patients who qualify to request an out-of-hospital DNR order for themselves. It also provides that even if the patient's surrogate requests the order, the patient may revoke it. The interim regulation incorporates that information. It also includes a statement that the patient for whom an out-of-hospital DNR order has been issued may revoke it regardless of that individual's age or physical or mental condition. This is consistent with the provisions of section 54A05(b) and (c) of the DNR Act (20 Pa.C.S. § 54A05(b) and (c)), which provide that even if the order was secured by a surrogate, the patient may revoke the order regardless of the patient's physical or mental condition. For these reasons, the Department does not propose to change the interim regulation.

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

The DNR Act provides that a patient's surrogate may request an out-of-hospital DNR order for the patient if the patient meets certain criteria, and then may later revoke the out-of-hospital DNR order. The interim regulation includes that information. It also explains that the age or physical or mental condition of the patient does not impact the ability of a surrogate to act on the patient's behalf.

This latter provision may seem confusing at first, especially with respect to age. The key to properly understanding this provision is to focus on the fact that the section only applies to persons who satisfy the definition of "surrogate" at the time of acting on behalf of a patient. This section does not apply if the age of the patient invalidates the authority of another person to act for the patient, because under that circumstance the person would no longer be the patient's surrogate. For example, if the parent of a child acted as a surrogate for the child before the child reached 18 years of age, and by virtue of the child achieving that age the parent or guardian ceases to qualify to serve as the child's surrogate by operation of law, this section would not apply because the parent would no longer be the child's surrogate. However, a parent or guardian of a child would continue to serve as the surrogate of the child after the child reaches 18 years of age if the child has also been adjudicated to be mentally incompetent. In that event the regulation would apply to the parent or guardian, since the parent or guardian would continue to satisfy the definition of "surrogate," and the age of the child would be irrelevant. Also, persons over 18 years of age, when competent, may designate a surrogate to make decisions for them should they later become incompetent and in a terminal condition or permanently unconscious. For example that may occur by the patient issuing an advance

directive for health care that designates another individual to act as the patient's surrogate.

The standards in this regulation continue to be appropriate and, therefore, warrant inclusion in the proposed regulations.

§ 1051.13. Person who loses authority to function as a surrogate.

The responsibilities of a person who loses the authority to function as a patient's surrogate are not addressed in the DNR Act. Subsection (a) of the interim regulation emphasizes that the authority to request an out-of-hospital DNR order for another person, and to revoke that order, is not necessarily an authority that lasts a lifetime. For example, a person may be appointed to act as the guardian of a patient and later be replaced as the patient's guardian.

Subsection (c) of the interim regulation imposes upon a person who has lost the authority to function as a patient's surrogate the duty to make a reasonable effort to contact the physician who issued the out-of-hospital DNR order for the patient to apprise the physician of the change in that person's status and to identify to the physician the patient's new surrogate if there is one. It also requires that person to provide the patient or a replacement surrogate, whomever is appropriate, with the name of the physician and other information to locate the physician. Although the name of the physician would not ordinarily need to be disclosed, since it is on the order, bracelet and necklace, disclosure of the name may need to occur if the DNR items were lost or destroyed. It is proposed that this subsection be advanced to subsection (b).

Subsection (b) of the interim regulation imposes upon a person who has lost the authority to serve as a patient's surrogate the duty to provide the attending physician with information to locate the patient if the physician contacts the former surrogate to advise that the physician misdiagnosed the patient's condition or made an error in determining that the condition was terminal or that the patient was permanently unconscious. This subsection repeats some of the requirements in subsection (b) of the interim regulation and only addresses a former surrogate's duty to cooperate with the patient's attending physician when the physician wants to advise that the physician misdiagnosed the patient's condition or made an error in determining that the condition was terminal or that the patient was permanently unconscious.

The Department proposes to revise this subsection to eliminate the redundancy and broaden its scope. As proposed, a former surrogate would have the duty to provide the physician with information to locate the patient or the patient's current surrogate when the physician contacts the former surrogate for the purpose of providing any information pertinent to the patient. Also, notwithstanding proposed subsection (b)'s requirement that the former surrogate make a good faith effort to contact the attending physician when that person loses surrogate status, the former surrogate may not have made that attempt or the attempt may have failed. This subsection would address the former surrogate's responsibility when contacted by the attending physician under those circumstances. The revised subsection (b) would be moved to subsection (c).

ATTENDING PHYSICIAN RESPONSIBILITIES

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

This section of the interim regulations informs physicians about how they may secure out-of-hospital DNR orders, bracelets and necklaces. It provides that out-of-hospital DNR bracelets and necklaces are to be purchased from a vendor or vendors with which the Department has contracted. It further relates that the Department will publish in the *Pennsylvania Bulletin* a notice identifying the name and address of the vendor or vendors. The section also relates that the Department will publish superseding notices in the *Pennsylvania Bulletin* if and when there is a vendor change.

The procedures in this regulation continue to be the procedures the Department chooses to employ and, therefore, the proposed regulations contain the same procedures. In addition to the use of a *Pennsylvania Bulletin* notice, the Department has also posted at its website, www.health.state.pa.us, a link to a purchase order form attending physicians may use to purchase out-of-hospital DNR orders, bracelets and necklaces.

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

This section of the interim regulations 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 Department continues to believe that the listed duties are appropriate.

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

This section of the interim regulations 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. The regulation does not require the physician to provide

the required information verbally, but the physician is required to ensure that the patient has received and understands all of the required information before issuing an out-of-hospital DNR order requested by the patient. The information the attending physician is required to disclose is available through a link at the Department's website. The Department invites physicians to access and copy that information and provide it to appropriate patients and surrogates. The Department continues to consider the disclosures required by the interim regulation to be appropriate.

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

This section of the interim regulations 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 disclosure required by paragraph (3) of the interim regulation improperly uses the term "health care provider" instead of "EMS provider." Subject to making that substitution, the proposed regulation would not differ from the interim regulation. As previously mentioned, the Department makes the required information available through its website and attending physicians are free to access it and provide it to surrogates.

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

This section of the interim regulations specifies the process the patient's attending physician must follow in deciding the information the physician will provide to the patient when the patient's surrogate requests an out-of-hospital DNR order. The Department continues to believe, as set forth in the regulation, that the physician and

surrogate need to work together to identify the information that should be disclosed to the patient unable to make that decision for himself or herself. A unique decision needs to be made for each patient after considering appropriate factors. However, no order should be issued if the attending physician and surrogate cannot reach an agreement.

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

This section of the interim regulations 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. They require the physician to provide a minimal amount of assistance to enable the patient or surrogate to pursue the matter further with another physician. The Department continues to believe that these procedures are appropriate.

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

This section of the interim regulations prohibits an attending physician's issuance of an out-of-hospital DNR bracelet or necklace without also issuing, or having previously issued, an out-of-hospital DNR order for the patient. The issuance of an order is imperative, since it documents that a qualified person applied for an out-of-hospital DNR order and any other DNR item provided and that the attending physician has made the necessary determinations before providing the item or items. The proposed regulation would not differ from the interim regulation.

§ 1051.28. Documentation.

This section of the interim regulations requires an attending physician to document in an out-of-hospital DNR order whether the physician also provided an out-of-hospital DNR bracelet or necklace for the patient. It also requires the physician to maintain a copy of the order in the patient's medical record. If the physician issues an order and provides the bracelet or necklace at a later time, this section further requires the physician to document in the patient's record the physician's issuance of a bracelet or necklace for the patient. This section is appropriate to retain as it ensures the attending physician's proper documentation and maintenance of pertinent patient information relevant to the physician's issuance of an out-of-hospital DNR item.

§ 1051.29. Duty to contact patient or surrogate.

This section of the interim regulations requires the attending physician to make a reasonable effort to contact the patient or the patient's surrogate, after having issued an out-of-hospital DNR order for the patient, if the physician discovers that the diagnosis of a terminal condition or permanent unconsciousness was in error. The proposed regulation would do the same. The need for this requirement should be obvious. When a physician determines that a medical diagnosis the statute imposes as a precondition to a physician issuing an out-of-hospital DNR order, was made in error, the physician needs to act in a good faith manner to remedy the error by retrieving and destroying the order, and any bracelet or necklace that the physician may have also provided based upon the incorrect diagnosis.

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

This section of the interim regulations addresses a physician's responsibilities when a patient or the patient's surrogate returns or has been requested by the physician to return an out-of-hospital DNR order, bracelet or necklace because the physician has determined that a terminal condition or permanently unconscious diagnosis was in error. In addition to requiring the destruction of a returned DNR item, it also requires that the physician shall not mark his or her records to reflect that the item has been destroyed without having confirmed the destruction of the item. That confirmation may occur without the physician personally destroying or observing the destruction of the item but, in the absence of that, the confirmation of the destruction must be based upon a communication from a reliable person that the item has been destroyed. The proposed regulation would do the same.

EMS PROVIDER RESPONSIBILITIES

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

This section of the interim regulations deals with EMS provider compliance with out-of-hospital DNR orders and the procedures the provider is to follow if uncertain as to whether an out-of-hospital DNR order is valid or has been revoked. Distinctions are made between individual EMS providers who have good Samaritan civil immunity protection for using an AED and individual EMS providers who are prehospital personnel. The distinctions are based upon the interaction prehospital personnel are able to have with medical command physicians and the general lack of access to medical command physicians by persons who use an AED with good Samaritan civil immunity protection. The proposed regulation would maintain these distinctions.

§ 1052.52. Procedure when both advance directive and out-of-hospital DNR order are present.

This section of the interim regulations explains that when an EMS provider observes both an advance directive for health care directing that no CPR be provided in the event of the patient's cardiac or respiratory arrest, and an out-of-hospital order, bracelet or necklace, the provider is to follow the procedure for complying with the out-of-hospital DNR order. The regulations simply repeat the directive under the Act 59's amendment to section 5413 of the Advance Directive for Health Care Act (20 Pa.C.S. § 5413). The Department proposes to adopt the interim regulation with a minor change to correct the incorrect reference to the title of § 1051.51 in the interim regulation.

PREGNANT PATIENTS

§ 1051.61. Pregnant patients.

This section of the interim regulations specifies preconditions to a health care provider complying with an order or direction to not provide nutrition, hydration, CPR and other life-sustaining procedures to a pregnant woman. This section essentially repeats the requirements of section 54A11 of the DNR Act (20 Pa.C.S. § 54A11). The proposed regulation would do the same.

MEDICAL COMMAND PHYSICIAN RESPONSIBILITIES

§ 1051.81. Medical command physician responsibilities.

This section of the interim regulations addresses a medical command physician's responsibilities when communicating with an EMS provider who encounters an out-of-hospital DNR patient who is experiencing cardiac or respiratory arrest. Specific

subsections address the medical command physician's responsibilities when the EMS provider communicates uncertainty as to whether an out-of-hospital DNR order has been revoked, and the medical command physician's responsibilities when the EMS provider advises that the provider has encountered a pregnant out-of-hospital DNR patient who is experiencing cardiac or respiratory arrest. The proposed regulation would do the same. While the DNR Act does not require an EMS provider who observes a displayed DNR order, bracelet or necklace to contact a medical command physician as a precondition to compliance with the DNR item, except when the patient is a pregnant patient, such contact may nevertheless occur, and is required to occur when the EMS provider encounters confusion. This section is necessary to clarify the medical command physician's responsibilities when contact is made.

ORDERS, BRACELETS AND NECKLACES FROM OTHER STATES

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

The DNR Act directs that EMS providers are to comply with out-of-hospital DNR orders issued in another state if that state's orders, bracelets and necklaces are issued in a manner consistent with the laws of the Commonwealth. This section of the interim regulations repeats that responsibility and explains how the Department will apprise EMS providers of the orders, bracelets and necklaces issued in other states that are acceptable in the Commonwealth. The proposed regulation would do the same. The DNR Act requires the bracelets and necklaces to include the printed name and signature of the attending physician, and other information about the attending physician. Due mainly to these requirements, the Department has found no out-of-hospital DNR bracelet or

necklace that is effective in another state and meets the requirements of Pennsylvania law. The Department is continuing to review the laws and out-of-hospital DNR order formats applicable in other states to assess whether they comport with Pennsylvania requirements.

Effective Date

The final regulations will go into effect when adopted, which should occur on or before February 18, 2004, as required by the DNR Act.

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, as well as out-of-hospital DNR bracelets and necklaces. The form physicians are to use to order out-of-hospital DNR forms, bracelets and necklaces is available at a link to the Department's website. A physician may copy the purchase form and send it to the vendor by facsimile or regular mail. Purchase 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 which 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 now required by the interim 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. The proposed regulations would not alter these responsibilities.

Financial Impact

The DNR Act and the proposed 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. 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 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 \$47,060. 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 within 18 months after the effective date of Act 59, which was August 18, 2002.

Regulatory Review

Under section 5(a) of the Regulatory Review Act, the Act of June 30, 1989 (P.L. 73, No. 19) (71 P.S. §§ 745.1-745.15), the Department submitted a copy of these proposed regulations on August 26, 2003, 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. In addition to submitting the proposed regulations, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed regulations within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria which have not been met. The Act specifies detailed procedures for review, prior to final publication of the regulation, by the Department, the General Assembly and the Governor of comments, recommendation or objections raised.

Contact Person

Interested persons are invited to submit comments, suggestions or objections to the proposed regulations to 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, within 30 days after publication of this notice in the *Pennsylvania Bulletin*. Persons with a disability may also submit comments, suggestions or objections to Ms. Trimble in alternative formats, such as by audio, Braille or, for speech or hearing impaired persons, by using V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800) 654-5984[TT]. Persons who require an alternative format of this document should contact Ms. Trimble so that necessary arrangements may be made. The Department will consider the comments it receives in developing final regulations that will be published by February 18, 2004.

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 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.

(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 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 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 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 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.

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 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 a DNR order may 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 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 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.

- (1) The physician shall also explain 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 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 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 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

August 26, 2003

THE SECRETARY

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

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

Dear Mr. Nyce:

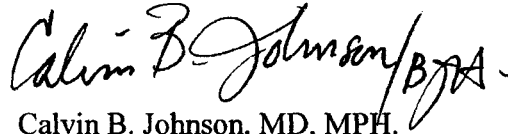
Enclosed is a copy of proposed regulations for review by the Commission pursuant to the Regulatory Review Act (Act) (P.L. 73, No. 19) (71 P.S. §§ 745.1-745.14). If adopted, the proposed regulations will amend the Department's interim regulations promulgated under the Do-Not-Resuscitate Act (P.L.409, No. 59) (20 Pa.C.S. §§ 54A01-54A13).

Section 5(g) of the Regulatory Review Act, 71 P.S. § 745.5(g), provides that the Commission may, within 30 days after the close of the public comment period, convey to the proposing agency and the Standing Committees any comments, recommendations and objections to the proposed regulations. The Department expects the regulations to be published on September 6, 2003. A 30-day comment period is provided.

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, the agency shall submit to the Commission a copy of the agency's response to the 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.

The Department will provide the Committee within 5 business days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the Committee with any assistance it requires to facilitate a thorough review of the proposed regulations. If you have any questions, please contact Dawn Jackson, Director of the Office of Legislative Affairs, at (717) 783-3985.

Sincerely,

A handwritten signature in black ink that reads "Calvin B. Johnson" followed by a stylized monogram "BJA".

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

- X 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 AUG 26 PM 3:16
 INDEPENDENT REGULATORY
 REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
8/26/03	<i>[Signature]</i>	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
8/26/03	<i>[Signature]</i>	
8/26/03	<i>[Signature]</i>	
8-26-03	<i>[Signature]</i>	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
8-26-03	<i>[Signature]</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
8/26/03	<i>[Signature]</i>	LEGISLATIVE REFERENCE BUREAU (for Proposed only)