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INDEPENDENT REGULATORY
REVIEW COMMISSION

PENNSYLVANIA HOSPICE NETWORK

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PA EMS OFFICE

Ms. Margaret E. Trimble
Director of Emergency Services Offices
Department of Health
1032 Health & Welfare Building
P.O. Box 90
Harrisburg, PA 17108

Dear Ms. Trimble:

The Pennsylvania Hospice Network, state association of Hospice organizations in the Commonwealth of Pennsylvania, is concerned about the impact of certain language in the proposed rulemaking in the Pennsylvania Bulletin of September 6, 2003 regarding Out-Of-Hospital Do-Not-Resuscitate orders. The language in question is contained in subsection (a) of § 1051.51:

“When an EMS provider observes an out-of-hospice 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.”

While recognizing the importance of an EMS provider’s ability to verify the authenticity of a DNR order, the requirement of an original signature may unnecessarily complicate the operation of such an order in critical situations, during which the expedient recognition and operation of a DNR order is most crucial.

Further, Act 59 of 2002 (Do-Not-Resuscitate Act), which requires and authorizes these regulations, omits language requiring “(a)n original declaration, signed by the declarant or other authorized person” to make a DNR operative. This omitted language is replaced by a general rule requiring EMS providers to comply with the instructions of the “medical command physician.” The “medical command physician” may instruct EMS providers to “withhold or discontinue cardiopulmonary resuscitation for a declarant whose advance directive has become operative under section 5405 (relating to when declaration becomes operative).” Under section 5405, this advance directive becomes operative when the attending physician is provided with a copy. The legislative intent of Act 59 of 2002 appears to be to allow copied documents to suffice to make the order operative, which is contrary to the effect of the language in question in the proposed rules.

The language in the proposed rules can be amended to allow EMS providers to verify the order’s authenticity and render the order operative, honoring the patient’s intent, by adding the clause “or an unaltered copy thereof.” The amended language would read:

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

Please consider these comments an attempt to preserve the intent of the original legislation as well as that of the patient. Thank you for your consideration.

Sincerely,



Lonna H. Donaghue
Executive Director



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Pennsylvania Academy of
FAMILY PHYSICIANS

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INDEPENDENT REGULATORY
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October 6, 2003

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Director of the Emergency Medical Services Office

Pennsylvania Department of Health

1032 Health and Welfare Building

PO Box 90

Harrisburg, PA 17108

VIA FACSIMILIE AND U.S. MAIL

Dear Ms. Trimble:

On behalf the over 4,800 members of the Pennsylvania Academy of Family Physicians (PAFP) I am writing in response to the Department of Health's (Department) proposed rulemaking to continue the implementation of 20 Pa. C.S. §§ 54A01—54A13 (relating to Do-Not-Resuscitate Act) (DNR Act), which would supplant the Department's current interim regulations adopted in December 2002.

The PAFP continues to believe that the patient would be better served by taking responsibility that the Department suggests as an imposition on physicians in some instances, and explicitly mandates in others, and transfer that responsibility to the patient. The PAFP believes that the patient should have the responsibility to destroy the DNR necklace or bracelet (as indicated by the DNR Act) and that the patient should also be granted the opportunity to purchase the DNR necklace or bracelet directly from the Department. The Department's proposed rulemaking requires physicians to pre-purchase the brochures, necklaces and bracelets and have these items at-the-ready on patient demand. These issues are financially and administratively burdensome and increase liability for physicians, when the patient would be best served by taking action upon himself or herself, to facilitate the best course of obtaining and maintaining the order and the corresponding bracelet or necklace.

The PAFP believes that the Department could better implement the DNR Act to achieve increased patient satisfaction and decreased physician burden, by adopting the ideas set forth in earlier testimony by the Pennsylvania Medical Society. The PAFP concurs with the Society's concept of the Department issuing a pamphlet disclosing the pertinent information to patients for physician use with their patients. Using this same simplistic and patient-friendly order form, the Department could accompany the disclosure items to include a section for physician signature and patient necklace or

2704 Commerce Drive ■ Suite A ■ Harrisburg, PA 17110-9365

VOICE 717.564.5365

TOLL FREE 800.648.5623

FAX 717.564.4235

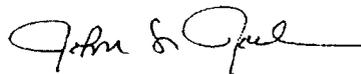
www.pafp.com

bracelet ordering information. Further, the patient would be served most efficiently by being able to obtain the ordering form and disclosure brochure on the Department's website to download the material and take it with them to their physician's office.

Finally, the PAFP believes that §1051.26 (2) should be stricken in its entirety. Beyond being overly burdensome, the PAFP contends that this section could be interpreted to require physicians to counsel patients on receiving a second medical opinion, and implicitly declare their own medical judgment suspect. Any patient in the Commonwealth is already permitted to choose his or her own physician, and a physician should not be made responsible under any circumstances to require that his or her patient be referred to another physician for a second medical opinion.

Thank you for this opportunity to express the PAFP's concerns. The PAFP would be receptive to any assistance within its means that the Department would need in adopting the ideas and changes it would like to see implemented to this proposed rulemaking. Should you need further clarification regarding these comments, please do not hesitate to contact me direct at 1-800-648-5623.

Sincerely,



John S. Jordan, CAE
Executive Vice-President

cc: Wanda D. Filer, MD – President, PAFP
Kent D.W. Bream, MD – Chair, PAFP Public Policy Commission
Charles I. Artz, Esq. – General Counsel, PAFP
Andrew Sandusky – Director of Governmental Affairs, PAFP

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PA EMS OFFICE

213 Market Street
9th Floor
P.O. Box 11844
Harrisburg, PA 17108-1844
717.234.5988
Fax 717.236.3777

Franklin L. Kury
Direct Phone: 717.257.3045
Email: fkury@reedsmith.com

INDEPENDENT REGULATORY
REVIEW COMMISSION

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October 3, 2003

Ms. Margaret E. Trimble
Director of Emergency Services Offices
Department of Health
1032 Health & Welfare Bldg.
P. O. Box 90
Harrisburg, PA 17108

Re: Proposed Rulemaking
Out-Of-Hospital Do-Not-Resuscitate Orders

Dear Ms. Trimble:

As counsel to Vitas Healthcare Corporation, a provider of Hospice services in five southeastern Pennsylvania counties, we are submitting this letter as a comment to the proposed rulemaking published in the Pennsylvania Bulletin of September 6, 2003, dealing with Out-Of-Hospital Do-Not-Resuscitate orders.

Vitas objects to the last sentence in subsection (a) of §1051.51, Implementation of out-of-hospital DNR order as written, to wit:

“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.”

The requirement for honoring an order only if it contains original signatures is not authorized by Act 59 and creates unnecessary difficulties for EMS providers.

There is no language in Act 59 requiring that EMS providers act only if they have an order with “original signatures.”

To the contrary, Act 59 deleted a provision in the prior law that EMS providers are authorized to implement orders only if:

“(1) An original declaration, signed by the declarant or other authorized person, is presented to the emergency services personnel. The emergency medical services personnel must immediately notify the medical command decision of the presence of the declaration.”

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Ms. Margaret E. Trimble
October 3, 2003
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See pages 2 and 3 of Act 96 (Printer's No. 3930) which became Act 59. This deleted language is replaced by the following:

“§5413 Emergency medical services

(a) General rule. An emergency medical services provider shall, in the course of providing care to a declarant, at all times comply with the instructions of an authorized medical command physician to withhold or discontinue cardiopulmonary resuscitation for a declarant whose advance directive has become operative under section 5405 (relating to when declaration becomes operative).”
20 Pa.C.S.A. §5413.

An advance directive becomes operative when a copy is provided to the attending physician. 20 Pa.C.S.A. §5405 (underlining added). If a copy of the declaration to the physician is sufficient to make it operative, a copy to the EMS provider should be sufficient to carry out the order.

Section 5413, cited above, is applicable only in those instances where an out of hospital DNR order is not in effect under Act 59 (Chapter 54A), Section 54A04(a).

Under section 54A10(a), emergency service providers are authorized to comply with an order if made aware of the order by the examining a bracelet, a necklace, or the order itself. The phrase “the order itself” is silent as to whether it can be a copy or must be the original. Considering that removal of the original signature provisions under §5413, we believe it the legislative intent that original signatures not be required.

Moreover, requiring the order with an original signature could cause delays in carrying out the order, a prospect which puts added pressure on the EMS personnel and frustrates the patient's intent.

We recognize the necessity for an EMS provider to be confident that an order is genuine and still operative. We, therefore, suggest that the sentence in question be amended by adding to it the clause “or an unaltered copy thereof” so that the sentence would read:

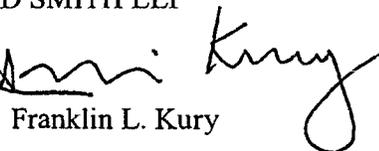
“When an EMS provider observes an out-of-hospital DNR order without also observing an out-of-hospital DNR bracelet or necklace, the EMS provider shall implement the out-of-hospital DNR order only if it contains original signatures or an unaltered copy thereof.” (Underlining to show new language.)

We, therefore, respectfully submit these comments and will be pleased to respond any questions you may have. Thank you for your consideration.

Very truly yours,

REED SMITH LLP

By


Franklin L. Kury

FLK:ngw

cc: Ms. Denise Harris (Pennsylvania Hospice Network)
Mr. Mark Bailey (Vitas Healthcare Corporation)



Pennsylvania MEDICAL SOCIETY®

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INDEPENDENT REGULATORY
REVIEW COMMISSION

October 6, 2003

Ms. Margaret E. Trimble, Director
Office of Emergency Medical Services
Department of Health
1032 Health and Welfare Building
P.O. Box 90
Harrisburg, Pennsylvania 17108

Re: Department of Health Proposed Regulations Regarding Out-of-Hospital
Do-Not-Resuscitate Orders

Dear Ms. Trimble:

I am writing as President of the Pennsylvania Medical Society to offer comments on behalf of the Society concerning the above captioned regulations.

The Society has appreciated the opportunity to be involved in the discussions with the Department over the implementation of the Do-Not-Resuscitate Act. (DNR)

Generally, the Society is in support of the draft regulations. The Society still, however, objects to the additional responsibilities placed on the attending physician. The proposed regulations place the burden on the physician of securing DNR bracelets and necklaces in significant quantities. The proposed regulations also permit the patient to revoke the DNA order without the physician's knowledge. Finally, the attending physician shall offer to assist the patient or surrogate to secure the services of another physician if the attending physician is unwilling to issue an out-of-hospital DNR.

With respect to the securing of bracelets and necklaces, why should the physician have to purchase the items? There are sources available for bracelets and necklaces for other conditions. As long as the physician completes the DNR form and instructs the patient or surrogate regarding its use, whether or not the patient chooses to display a bracelet or necklace, should not be the concern of the physician.

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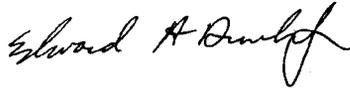
The patient or surrogate should be required to notify the issuing physician whenever the DNR order is to be revoked. Otherwise, the physician will have no knowledge of the revocation and in an emergency may act contrary to the wishes of the patient.

With respect to assisting the patient or surrogate in finding a physician willing to issue a DNR order when the attending is unwilling to do so, the requirement is too open ended. The physician should not be obligated to do more than would be done when making any referral to another physician.

During public hearings and in correspondence, the Society recommended that to the extent possible, the procedure for initiating the DNR order should parallel the process to become a uniform organ donor. The Society also suggested that any bracelets and necklaces offered should be directly through the patient.

The Pennsylvania Medical Society appreciates the opportunity to comment on these proposed regulations.

Sincerely,

A handwritten signature in cursive script, appearing to read "Edward H. Dench, Jr.", written in black ink.

Edward H. Dench, Jr., MD
President

Cc: Secretary of Health
Independent Regulatory Review Commission
Pennsylvania Academy of Family Physicians
Pennsylvania Chapter, American College of Emergency Physicians