

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

Form #5

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2015 AUG -3 P 1:57
OFFICE WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF AGENCY ADOPTION OF A PROCEDURAL OR INTERPRETIVE RULE
OR A LEGISLATIVE RULE EXEMPT FROM LEGISLATIVE REVIEW**

AGENCY: Department of Health and Human Resources/Bureau for Public Health TITLE NUMBER: 64

CITE AUTHORITY: W. Va. Code §§ 29A-3-1 et. seq.

RULE TYPE: PROCEDURAL _____ INTERPRETIVE X

EXEMPT LEGISLATIVE RULE _____

CITE STATUTE(S) GRANTING EXEMPTION FROM LEGISLATIVE REVIEW

AMENDMENT TO AN EXISTING RULE: YES _____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 101

TITLE OF RULE BEING PROPOSED: USE OF THE E-DIRECTIVES REGISTRY BY EMERGENCY MEDIC SERVICES

THE ABOVE RULE IS HEREBY ADOPTED AND FILED WITH THE SECRETARY OF STATE. THE EFFECTIVE DATE OF THIS RULE IS September 3rd, 2015


Authorized Signature

**TITLE 64
INTERPRETIVE RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH**

FILED

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

SERIES 101

USE OF THE E-DIRECTIVES REGISTRY BY EMERGENCY MEDICAL SERVICES

§64-101-1. General.

1.1. Scope. -- This interpretive rule is intended to give direction to emergency medical services (EMS) personnel and agencies in the performance of cardiopulmonary resuscitation and level of medical intervention when a Do Not Resuscitate order or Physician Orders for Scope of Treatment form is located on the e-Directive registry.

1.2. Authority. -- The Bureau for Public Health promulgating this interpretive rule pursuant to the provisions of *W. Va. Code* §§ 29A-3-1 *et. seq.*

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Summary. -- The Bureau for Public Health is promulgating this interpretive rule to set forth the Bureau's interpretation of the provisions of *W.Va. Code* §§16-30-10, 13 &25 and 16-30C-5 & 7 and the applicability of advance directives and medical orders (do not resuscitate or Physician Orders for Scope of Treatment (POST)) electronically stored in the e-Directive Registry. The Bureau interprets the provisions of *W.Va. Code* §§ 16-30-10, 13 &25 and 16-30C-5 & 7, that require emergency medical services personnel to comply with advance directives and medical orders contained in a do-not-resuscitate order or POST form, to also include information accessed from a do-not-resuscitate order or POST form electronically stored on the e-Directive Registry, and communicated to emergency medical services personnel by a Medical Command Center during on-line medical direction.

1.6 Applicability. -- This interpretive rule is intended by Bureau for Public Health to provide information or guidance to the public regarding the agency's interpretation of the provisions of the West Virginia Health Care Decisions Act (*W. VA Code* §§16-30-1 *et. seq.*), specifically §§16-30-10, 13 &25, and the Do Not Resuscitate Act (*W.Va. Code* §§ 16-30C-1 *et. seq.*), specifically *W.Va. Code* §§ 16-30C-5 & 7.

1.7. Purpose. -- It is the purpose of this interpretive rule to ensure that the right of a person to self-determination relating to CPR and level of medical intervention is protected. This interpretive rule is intended to give direction to emergency medical services personnel in the performance of CPR and level of medical intervention when a DNR order or Physician Orders for Scope of Treatment form is located on the e-Directive registry. This interpretive rule is intended only to provide information or guidance to the public regarding the agency's interpretations, policy or opinions on the provisions of the West Virginia Health Care Decisions

Act (*W. Va. Code* §§16-30-1 *et. seq.*, specifically §§16-30-10, 13 & 25) and Do Not Resuscitate Act (*W. Va. Code* §§ 16-30C-1 *et. seq.*), specifically *W. Va. Code* §§ 16-30C-5 & 7, and is not intended to be determinative of any issue affecting constitutional, statutory or common law rights, privileges or interests.

§64-101-2. Definitions.

2.1. "Cardiopulmonary resuscitation" or "CPR" means those measures used to restore or support cardiac or respiratory function in the event of a cardiac or respiratory arrest.

2.2. "Do not resuscitate order" or ("DNR order") means an order issued by a licensed physician that CPR should not be administered to a particular person.

2.3. "e-Directive Registry" means the electronic database, established and maintained by the West Virginia Center for End-of-Life Care (WVCEOLC) through the West Virginia Health Information Network (WVHIN), that electronically stores and makes available to treating health care providers advance directive forms, do not resuscitate cards, and POST forms.

2.4 "Level of medical intervention" means the order on a Physician Orders for Scope of Treatment (POST) form in Section B for comfort measures, additional limited interventions, or full interventions.

2.5. "Medical Command Center" means a designated facility staffed by paramedic communications specialists, operating under medical supervision, who provide on-line advice and direction to emergency medical services personnel regarding treatment, triage and destination decisions under the guidelines of the medical direction system.

2.6. "On-Line Medical Direction" means the medical direction given by personnel at an approved Medical Command Center to emergency medical services personnel at the time of an emergency medical services incident, by voice or other means, as established by Office of Emergency Medical Services protocol and guidelines.

2.7. "Physician orders for scope of treatment form" or "POST" means a standardized form containing orders by a qualified physician that details a person's life-sustaining wishes.

§64-101-3. Background.

West Virginia Health Care Decisions Act.

The West Virginia Health Care Decisions Act ("the Health Care Decisions Act")(*W. Va. Code* §§ 16-30-1 *et. seq.*), is intended to ensure that a patient's right to self-determination in health care decisions be communicated and protected; and to set forth a process for private health care decision making for incapacitated adults, including the use of advance directives, which reduces the need for judicial involvement and defines the circumstances under which immunity will be available for health care providers and surrogate decision makers who make health care decisions. *W. Va. Code* § 16-30-2. In enacting the Health Care Decisions Act, the Legislature

sought to establish an effective method for private health care decision making for incapacitated adults, and to provide that the courts should not be the usual venue for making decisions. *Id.*

Physicians, licensed health care professionals, health care facilities or their employee may not be subject to criminal or civil liability for good-faith compliance with or reliance upon the directions of the medical power of attorney representative in accordance with the Health Care Decisions Act. *W.Va. Code* §16-30-10. Additionally, a health care provider, health care facility or employee may not be subject to criminal or civil liability for good-faith compliance with or reliance upon the orders in a POST form. *Id.*

If a person with an order to withhold or withdraw life-prolonging intervention is transferred from one health care facility to another, the existence of the order must be communicated to the receiving facility prior to the transfer and the written order shall accompany the person to the receiving facility and remain effective until a physician at the receiving facility issues admission orders. *W.Va. Code* § 16-30-13.

When a person with a POST form is transferred from one health care facility to another, the health care facility initiating the transfer must communicate the existence of the POST form to the receiving facility prior to the transfer. *Id.* The POST form must accompany the person to the receiving facility and will remain in effect. *Id.*

Do Not Resuscitate Act

The Do Not Resuscitate Act ("the DNR Act") (*W.Va. Code* §§ 16-30C-1 *et. seq.*), was enacted by the Legislature to protect the right of a person to self-determination relating to CPR. The intent of the Act is to give direction to emergency medical services personnel and other health care providers in regard to the performance of CPR.

The DNR Act provides that every person "shall be presumed to consent to the administration of CPR in the event of cardiac or respiratory arrest", unless a health care provider has actual knowledge of a DNR order or a completed POST form. *W.Va. Code* §16-30C-5. "Actual knowledge" means the possession of information of the person's wishes communicated to the health care provider *orally or in writing* by the person, the person's medical power of attorney representative, the person's health care surrogate or other individuals resulting in the health care provider's personal cognizance of these wishes. *W.Va. Code* §16-30-3(a). (*italics added*).

When presented with a DNR order or POST form, emergency medical services personnel must comply with the contents of the order or form. *W.Va. Code* §16-30C-7. The DNR Act also provides for the revocation of a previous request for or consent to a DNR order when the person makes a written, oral or other act of communication to a physician or other professional staff of the health care facility, or destroys the order or POST form and removes any do not resuscitate identification. *W.Va. Code* §16-30C-8(a) & (b).

A health care provider is not subject to criminal prosecution or civil liability for carrying out, in good faith, a do-not-resuscitate order or for actions taken in compliance with the standards and procedures contained in the Act. *W.Va. Code* §16-30C-9(a). Additionally, a health care provider who witnesses a cardiac or respiratory arrest may not be subject to criminal prosecution or civil

liability for providing CPR to a person for whom a DNR order has been issued, provided that the health care provider is:

- (1) Reasonably and in good faith unaware of the issuance of a DNR order; or
- (2) Reasonably and in good faith believed that consent to the DNR order had been revoked or canceled. *W.Va. Code §16-30C-9(b)*.

The e-Directive Registry

The e-Directive Registry is an electronic registry of advance directives and medical orders established and maintained by the West Virginia Center for End-of-Life Care (WVCEOLC) through the West Virginia Health Information Network (WVHIN). With the permission of patients or their legal agents, the electronic registry stores and makes available to treating health care providers advance directive forms, do-not-resuscitate cards, and POST forms, submitted to the registry.

The e-Directive Registry is a password-protected, Health Insurance Portability and Accountability Act (HIPAA) compliant on-line registry that makes accurate, relevant information about patients' advance directives and medical orders available in a medical crisis. It is accessible 24 hours a day, 7 days a week to health care providers, and ensures that patients' wishes will be respected throughout the continuum of health care settings.

Applicability of e-Directive Registry to the DNR Act

Neither the Health Care Decisions Act nor the DNR Act include a reference to the e-Directive Registry nor do they appear to contemplate an on-line database of advance directives and medical orders that is accessible by emergency medical services personnel while responding to an emergency medical services incident. Thus, there is a concern that the lack of an explicit acknowledgement in either Act, that information ascertained from documents stored on the e-Directive Registry and then communicated to emergency medical services personnel during on-line medical direction, constitutes actual knowledge of a DNR order or an order regarding level of medical intervention on a completed POST form.

Because there is a presumption that a person consents to the administration of CPR in the event of cardiac or respiratory arrest unless a health care provider has actual knowledge of a DNR order or a completed POST form, emergency medical services personnel have a duty to perform CPR unless he or she is in possession of information that results in the emergency medical services personnel's personal cognizance of the person's wishes regarding the patient's desire to be resuscitated and for level of medical intervention. As noted above, the definition of "actual knowledge" provides that a person's wishes regarding their desire to be resuscitated be communicated to the health care provider "orally or in writing." Consequently, it is unclear as to whether storage on the e-Directive Registry of a DNR order or a completed POST form, which is accessed by the Medical Command Center and orally communicated to emergency medical service personnel, constitutes "actual knowledge" for the purposes of the Health Care Decisions Act or the DNR Act.

§64-101-4. Interpretive Rule

As it is the intent of the Health Care Decisions Act and the DNR Act to give direction to emergency medical services personnel and other health care providers with regard to the performance of CPR and compliance with the orders on a POST form, the Bureau for Public Health interprets the provisions of *W. Va. Code* §§16-30-10, 13 & 25 and *W. Va. Code* §§16-30C-5 & 7, to include DNR orders or POST forms electronically stored on the e-Directive Registry. Therefore, information contained in a patient's DNR order or completed POST form that is:

- electronically stored on the e-Directive Registry;
- accessed by the Medical Command Center; and
- orally communicated to emergency medical service personnel,

constitutes "actual knowledge" for the purposes of the Health Care Decisions Act and the DNR Act.



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH

Earl Ray Tomblin
Governor

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Karen L. Bowling
Cabinet Secretary

August 3, 2015

Dr. Alvin H. Moss, MD, Professor of Medicine
WVU Robert C. Byrd Health Sciences Center
Center for Health Ethics and Law
1195 Health Sciences North
Post Office Box 9022
Morgantown, West Virginia 26506-9022

Re: Interpretive rule *W.Va. Code R. 64-101-1 et seq. - Use of the E-Registry by
Emergency Medical Services.*

Dear Dr. Moss:

Thank you for your letter dated July 20, 2015, and your comments regarding proposed
interpretive rule *W.Va. Code R. 64-101-1 et seq. - Use of the E-Registry by Emergency Medical
Services.*

I will attach your comments to the interpretive rule when it is filed with the Office of Secretary of
State with the notice of the agency's adoption of the final rule.

Sincerely,

A handwritten signature in black ink, appearing to read "BJS", written over a horizontal line.

Brian J. Skinner,
Bureau for Public Health General Counsel

pc: Dr. Michael R. Mills, OEMS Medical Director
Barbara Taylor, Deputy Commissioner
Rahul Gupta, Commissioner



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH

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Karen L. Bowling
Cabinet Secretary

July 31, 2015

Dr. Alvin H. Moss, MD, Executive Director
West Virginia Network of Ethics Committees
1195 Health Sciences North
Post Office Box 9022
Morgantown, West Virginia 26506-9022

Re: Interpretive rule *W.Va. Code R. 64-101-1 et seq. - Use of the E-Registry by
Emergency Medical Services.*

Dear Dr. Moss:

Thank you for your letter dated July 23, 2015, and your comments regarding proposed
interpretive rule *W.Va. Code R. 64-101-1 et seq. - Use of the E-Registry by Emergency Medical
Services.*

I will attach your comments to the interpretive rule when it is filed with the Office of Secretary of
State with the notice of the agency's adoption of the final rule.

Sincerely,

A handwritten signature in black ink, appearing to read "BJS", with a long horizontal line extending to the right.

Brian J. Skinner,
Bureau for Public Health General Counsel

pc: Dr. Michael R. Mills, OEMS Medical Director
Barbara Taylor, Deputy Commissioner
Rahul Gupta, Commissioner



West Virginia University
ROBERT C. BYRD HEALTH SCIENCES CENTER

July 20, 2015

**Proposed Interpretive Rule Title 64, Series 101: Use of the West Virginia e-Directive Registry by
Emergency Medical Services**

Dear Mr. Skinner:

I write in support of this interpretive rule to give direction to emergency medical services personnel and agencies in the performance of cardiopulmonary resuscitation and level of medical intervention when a do not resuscitate order or Physician Orders for Scope of Treatment form is located on the West Virginia e-Directive Registry portal of the West Virginia Health Information Network. Persons complete advance directives, do not resuscitate orders, and Physician Orders for Scope of Treatment so that their wishes for medical treatment can be known and respected at a time when they no longer possess decision-making capacity and are in an emergency medical situation.

This interpretive rule states that a person's advance directives, do not resuscitate order, and/or Physician Orders for Scope of Treatment stored in the e-Directive Registry constitute, "actual knowledge," and when treating health care providers including emergency medical services have actual knowledge of a person's advance directives, do not resuscitate order, or Physician Orders for Scope of Treatment they are required to respect them.

It is my hope that the Office of Emergency Medical Services will develop protocols for Medical Command Centers to access the West Virginia e-Directive Registry. It is most important when they are transporting patients who lack decision-making capacity and are in an emergency medical situation. These people cannot speak for themselves, but through the documents in the Registry the person's wishes for medical treatment can be known and respected by emergency medical services and throughout our West Virginia health care system.

Thank you for considering my comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Arvin H. Moss, MD'.

Arvin H. Moss, MD
Professor of Medicine

Center for Health Ethics and Law

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Equal Opportunity/Affirmative Action Institution



West Virginia Network of Ethics Committees

July 23, 2015

**Proposed Interpretive Rule Title 64, Series 101:
Use of the West Virginia e-Directive Registry by Emergency Medical Services**

Dear Mr. Skinner:

The West Virginia Network of Ethics Committees is composed of 53 institutional members including hospitals, nursing homes, hospice, and home health agencies. On behalf of the West Virginia Network of Ethics Committees, I write in support of this interpretive rule. Persons complete advance directives, do not resuscitate orders, and Physician Orders for Scope of Treatment so that their wishes for medical treatment can be known and respected at a time when they no longer possess decision-making capacity and are in an emergency medical situation.

This interpretive rule states that a person's advance directives, do not resuscitate order, and/or Physician Orders for Scope of Treatment stored in the e-Directive Registry constitute, "actual knowledge," and when treating health care providers including emergency medical services have actual knowledge of a person's advance directives, do not resuscitate order, or Physician Orders for Scope of Treatment they are required to respect them.

The implementation of this interpretive rule will enable people who at the moment cannot speak for themselves to be able to give voice to their wishes for treatment through their documents in the West Virginia e-Directive Registry. The West Virginia Network of Ethics Committees is pleased that West Virginians will be able to retain control over the end-of-life treatment they receive through use of the West Virginia e-Directive Registry by emergency medical services and other treating health care providers.

Thank you for considering the comments of the West Virginia Network of Ethics Committees.

Sincerely,

Alvin H. Moss, MD
Executive Director



July 24, 2015

Brian J. Skinner, Director
Public Health Regulations
West Virginia DHHR
Bureau for Public Health
350 Capitol St. Room 702
Charleston, WV 25301

RE: *Interpretative Rule Title 64 Series 101 - Use of the E-Directive Registry by Emergency Medical Services*

Dear Mr. Skinner,

On behalf of the membership of the West Virginia EMS Coalition (EMS Coalition), I am submitting comments on *Interpretative Rule Title 64 Series 101* regarding the use of the E-Directive Registry by Emergency Medical Services. After careful review by our membership, we are requesting the rule be withdrawn to allow for further collaboration and development with the emergency medical services community in developing the rules.

We wish to note at the outset of these comments our great disappointment with being placed in a position of opposing a newly proposed rule that has already been formally issued for comment. Particularly when responding to a rule that attempts to provide some clarity to an issue as important as the usage of the E-Directive Registry by Emergency Medical Services.

We have found through past experience that being given the opportunity to work with the Bureau, providing operational-experienced input during the initial drafting process nearly always results in a superior product. Further, when dealing with matters of new substance creating potential operational impacts on our licensed agencies, such as that contained in this proposed rule, the proactive collaboration we have enjoyed in the past has typically also allowed for a more efficient consideration of the proposal once it was formally released.

We welcome the proposed rule's intention to provide interpretative guidance regarding state code provisions relating to the Health Care Decisions Act, the Do Not Resuscitate (DNR) Act, and the use of the e-Directive Registry. Each of these code provisions has raised important questions that our membership must address every day in carrying out the public duty and responsibility we have been trained for and entrusted to perform. In order to provide some context of the WV EMS Coalition's familiarity with these matters, a recent

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estimate by one of our members determined that in over half of their run responses they arrive to a find a patient unresponsive, with no pulse and/or respiration, and in need of immediate resuscitation.

Further, also noted was the frequency in these runs with which it was already dealing with DNRs, physician orders for scope of treatment (POST) forms, and advance directives, often doing so within a confusing and sometimes conflicting tableau of input from Medical Command, family members, medical powers of attorney, medical surrogates, and others with myriad questions or directives related to treatment decisions, the amount of intervention warranted or desired, patient comfort measures to be provided, destination decisions, etc. While we welcome further interpretative guidance, our experience leads us to conclude that the 'broad strokes' of guidance contained in the proposed rule do not provide that. Consequently, the proposal is not one we can support without significant changes to clarify how our operations and more importantly the needs of our clients might be impacted

In the relative short amount of time the formal rule making process provided us, we did gather specific comments on some of the more troubling provisions of the proposed rule. Because so much of the proposed rule's substance is contained within the background section at 64-101-3 we have tried to identify in our comments specific questions where we believe situational interpretation would be helpful. These are briefly identified and discussed below.

Please note that some concerns we have identified cannot be addressed without further legislative guidance. *Consequently, in addition to withdrawal of the proposed rule, we believe any new rule dealing with the sensitive matters this proposal attempts to address should be issued as a Legislative rule and not the Interpretative rule as it is currently proposed.*

With regard to some of our specific areas of concern we offer the following comments/questions:

- **64-101-2.1 and 2.2** - In practical terms, the administration of cardiopulmonary resuscitation (CPR) initially includes re-establishment of an airway. In situations in which a responding squad has 'actual knowledge' of the existence of a verified DNR, does provision of this simple measure - which often alone may restore the patient to a level of consciousness enabling communication - run counter to the DNR and Health Care Decisions Acts?

The proposed rule generally addresses only CPR. In situations where it is clearly evident to a responding squad that another intervention, e.g. the administration of Narcan to counter an accidental overdose of a prescribed opioid medication to restore a patient's functioning, does the injection constitute a violation of the DNR Act? If, in this situation, the squad has been provided 'actual knowledge' of a verified DNR being ordered or a POST form written, is the naloxone injection in compliance with the contents of the order or form?

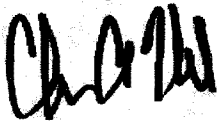
Similarly, a squad arrives at an accident scene where a victim with a compound fracture of the femur and related femoral artery bleed must be quickly treated in order to avoid fatal blood loss. Is treatment of the bleed consistent with the proposed rule if a DNR is verified? How should the injury, presenting condition, and subsequent intervention in this example be handled in a compliant manner when it is clear they are unrelated to the condition on which the DNR was written?

- **64-101-3** - The above are but a few of many examples where we believe additional guidance would be helpful. The proposed rule however, lacks the specificity we believe is needed to comfortably carry out our responsibilities in compliance with the code sections referenced in this section.
- **E-Directive Registry** – We have supported the development of the Registry as an important source of information for our members. We wish to comment though that use of the Register is not always possible and creates serious operational concerns. The rural nature and the severe topography in much of the state present situations where communication with Medical Command to gain information that may be contained in the Registry is significantly constrained. While we note and appreciate references in the proposed rule which seem to imply an expectation of ‘good faith efforts’ to comply, we have concerns over how such efforts may ultimately be interpreted. In the absence of access to the Registry, squads are faced with decisions that must be made quickly and efficiently.

Even when the Registry can be accessed squads are faced with compliance concerns related to the proposed rule. Accident scenes are typically chaotic. Personal belongings included identification may be strewn throughout the accident scene or unavailable. Attempting to ‘match’ an identity of an accident victim to that of an individual with a DNR entered in the Registry can be difficult and to do so confidently may be impossible. Our members are therefore interested in further guidance being made available that addresses these situations.

We appreciate the opportunity to submit these comments and are very interested in a continued dialogue on these matters.

Sincerely,



Chris Hall, Executive Director
WV EMS Coalition



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH

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Karen L. Bowling
Cabinet Secretary

July 29, 2015

Chris Hall, Executive Director
WV EMS Coalition
206 Capitol Street, 3rd Floor
Charleston, West Virginia 25301

Re: Interpretive rule *W. Va. Code R. 64-101-1 et seq. - Use of the E-Registry by
Emergency Medical Services.*

Dear Mr. Hall,

Thank you for your letter dated July 24, 2015, and your comments regarding proposed interpretive rule *W. Va. Code R. 64-101-1 et seq. - Use of the E-Registry by Emergency Medical Services.*

After giving your comments careful review, I have concluded that there is some confusion about the nature of the proposed interpretive rule and what it is intended to accomplish. An interpretive rule is intended to provide information or guidance to the public regarding the agency's interpretation, policy, or opinion of a law enforced or administered by it and is not intended to be determinative of any issue affecting private rights, privileges or interests. In other words, an interpretive rule is a rule issued by an administrative agency that is only intended to clarify or explain existing laws or regulations. It does not have the force of law.

In this case, the Bureau for Public Health is simply providing the public with the Bureau's interpretation of the provisions of the West Virginia Health Care Decisions Act (*W. Va. Code* §§ 16-30-10, 13 & 25) and the Do Not Resuscitate Act (*W. Va. Code* §§ 16-30C-5 & 7), and the applicability of advance directives and medical orders (do not resuscitate (DNR) or Physician Orders for Scope of Treatment (POST)) electronically stored in the e-Directive Registry. As you are aware, the provisions of West Virginia Health Care Decisions Act and the Do Not Resuscitate Act, require emergency medical services personnel to comply with advance directives and medical orders contained in a DNR order or POST. The Bureau found it necessary to promulgate the interpretive rule since neither Act makes reference to advance directives stored, maintained and accessed electronically.

By promulgating the interpretive rule, the Bureau is informing the public that it interprets both Acts to also include information accessed from a DNR order or POST that is electronically stored

Chris Hall, Executive Director
July 29, 2015
Page 2

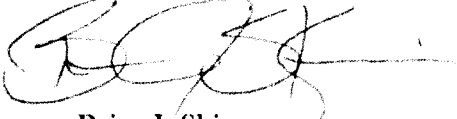
on the e-Directive Registry, and communicated to emergency medical services personnel by a Medical Command Center during on-line medical direction. In essence, the Bureau is simply saying that it believes that a DNR order or POST form stored on the e-Directive Registry should be treated in the same manner as a DNR order or POST form attached to a patient's refrigerator.

The interpretive rule is not intended to provide guidance or impose requirements effecting the operation of agencies that you represent. However, the interpretive rule may result in an evaluation of current procedures, policies and protocols regarding the use of the e-Directive Registry by emergency medical services.

The goal of the interpretive rule is to ensure that a person's wishes for medical treatment contained in advance directives, DNR orders, and POST, can be known and respected at a time when he or she no longer possess decision-making capacity and are in an emergency medical situation. The implementation of the interpretive rule will enable West Virginians to retain control over the end-of-life treatment they receive through the use of the West Virginia e-Directive Registry by emergency medical services and other treating health care providers.

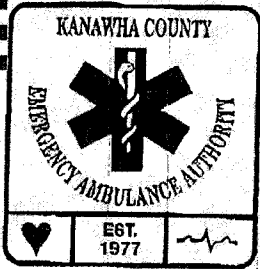
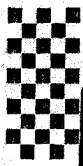
Thank you again for your comments and I hope this letter clears up any confusion regarding the proposed interpretive rule.

Sincerely,



Brian J. Skinner,
Bureau for Public Health General Counsel

pc: Dr. Michael R. Mills, OEMS Medical Director
Barbara Taylor, Deputy Commissioner
Rahul Gupta, Commissioner



601 BROOKS STREET
CHARLESTON, WV 25301

Kanawha County Emergency Ambulance Authority

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July 24, 2015

Brian J. Skinner, Director
Public Health Regulations
West Virginia DHHR
Bureau for Public Health
350 Capitol St. Room 702
Charleston, WV 25301

RE: *Interpretative Rule Title 64 Series 101 - Use of the E-Directive Registry by Emergency Medical Services*

Dear Mr. Skinner:

After careful review, we are requesting the rule be withdrawn to allow for further collaboration and development with the emergency medical services community in developing the rules.

We have found through past experience that being given the opportunity to work with the Bureau during the initial drafting process nearly always results in a superior product. Further, when dealing with matters of new substance creating potential operational impacts, such as that contained in this proposed rule, the proactive collaboration we have enjoyed in the past has typically also allowed for a more efficient consideration of the proposal once it was formally released.

We welcome the proposed rule's intention to provide interpretative guidance regarding state code provisions relating to the Health Care Decisions Act, the Do Not Resuscitate (DNR) Act, and the use of the e-Directive Registry. Each of these code provisions has raised important questions that our team must address every day in carrying out the public duty and responsibility we have been trained for and entrusted to perform.

Further, also noted was the frequency in these runs with which it was already dealing with DNRs, physician orders for scope of treatment (POST) forms, and advance directives, often doing so within a confusing and sometimes conflicting tableau of input from Medical Command, family members, medical powers of attorney, medical surrogates, and others with

myriad questions or directives related to treatment decisions, the amount of intervention warranted or desired, patient comfort measures to be provided, destination decisions, etc. While we welcome further interpretative guidance, our experience leads us to conclude that the 'broad strokes' of guidance contained in the proposed rule do not provide that. Consequently, the proposal is not one we can support without significant changes to clarify how our operations and more importantly the needs of our clients might be impacted

With regard to some of our specific areas of concern we offer the following comments/questions:

- **64-101-2.1 and 2.2** – In practical terms, the administration of cardiopulmonary resuscitation (CPR) initially includes re-establishment of an airway. In situations in which a responding squad has 'actual knowledge' of the existence of a verified DNR, does provision of this simple measure - which often alone may restore the patient to a level of consciousness enabling communication – run counter to the DNR and Health Care Decisions Acts?

The proposed rule generally addresses only CPR. In situations where it is clearly evident to a responding squad that another intervention, e.g. the administration of Narcan to counter an accidental overdose of a prescribed opioid medication to restore a patient's functioning, does the injection constitute a violation of the DNR Act? If, in this situation, the squad has been provided 'actual knowledge' of a verified DNR being ordered or a POST form written, is the naloxone injection in compliance with the contents of the order or form?

Similarly, a squad arrives at an accident scene where a victim with a compound fracture of the femur and related femoral artery bleed must be quickly treated in order to avoid fatal blood loss. Is treatment of the bleed consistent with the proposed rule if a DNR is verified? How should the injury, presenting condition, and subsequent intervention in this example be handled in a compliant manner when it is clear they are unrelated to the condition on which the DNR was written?

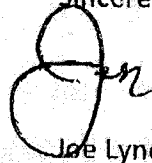
- **64-101-3** - The above are but a few of many examples where we believe additional guidance would be helpful. The proposed rule however, lacks the specificity we believe is needed to comfortably carry out our responsibilities in compliance with the code sections referenced in this section.
- **E-Directive Registry** – We have supported the development of the Registry as an important source of information for our members. We wish to comment though that use of the Register is not always possible and creates serious operational concerns. The rural nature and the severe topography in much of the state present situations where communication with Medical Command to gain information that may be contained in

the Registry is significantly constrained. While we note and appreciate references in the proposed rule which seem to imply an expectation of 'good faith efforts' to comply, we have concerns over how such efforts may ultimately be interpreted. In the absence of access to the Registry, squads are faced with decisions that must be made quickly and efficiently.

Even when the Registry can be accessed squads are faced with compliance concerns related to the proposed rule. Accident scenes are typically chaotic. Personal belongings included identification may be strewn throughout the accident scene or unavailable. Attempting to 'match' an identity of an accident victim to that of an individual with a DNR entered in the Registry can be difficult and to do so confidently may be impossible. Our members are therefore interested in further guidance being made available that addresses these situations.

We appreciate the opportunity to submit these comments and are very interested in a continued dialogue on these matters.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Lynch". The signature is stylized with a large, looped initial "J" and a cursive "Lynch".

Joe Lynch
Executive Director

JL/th



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH

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Governor

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Karen L. Bowling
Cabinet Secretary

July 29, 2015

Joe Lynch, Executive Director
Kanawha County Emergency Ambulance Authority
Post Office Box 292
Charleston, West Virginia 25321

Re: Interpretive rule *W. Va. Code R. 64-101-1 et seq. - Use of the E-Registry by
Emergency Medical Services.*

Dear Mr. Lynch,

Thank you for your letter dated July 24, 2015, and your comments regarding proposed interpretive rule *W. Va. Code R. 64-101-1 et seq. - Use of the E-Registry by Emergency Medical Services.*

After giving your comments careful review, I have concluded that there is some confusion about the nature of the proposed interpretive rule and what it is intended to accomplish. An interpretive rule is intended to provide information or guidance to the public regarding the agency's interpretation, policy, or opinion of a law enforced or administered by it and is not intended to be determinative of any issue affecting private rights, privileges or interests. In other words, an interpretive rule is a rule issued by an administrative agency that is only intended to clarify or explain existing laws or regulations. It does not have the force of law.

In this case, the Bureau for Public Health is simply providing the public with the Bureau's interpretation of the provisions of the West Virginia Health Care Decisions Act (*W. Va. Code* §§ 16-30-10, 13 & 25) and the Do Not Resuscitate Act (*W. Va. Code* §§ 16-30C-5 & 7), and the applicability of advance directives and medical orders (do not resuscitate (DNR) or Physician Orders for Scope of Treatment (POST)) electronically stored in the e-Directive Registry. As you are aware, the provisions of West Virginia Health Care Decisions Act and the Do Not Resuscitate Act, require emergency medical services personnel to comply with advance directives and medical orders contained in a DNR order or POST. The Bureau found it necessary to promulgate the interpretive rule since neither Act makes reference to advance directives stored, maintained and accessed electronically.

By promulgating the interpretive rule, the Bureau is informing the public that it interprets both Acts to also include information accessed from a DNR order or POST that is electronically stored

Joe Lynch, Executive Director
July 29, 2015
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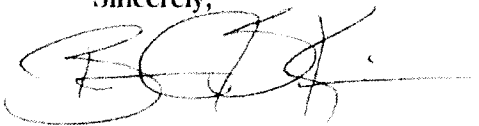
on the e-Directive Registry, and communicated to emergency medical services personnel by a Medical Command Center during on-line medical direction. In essence, the Bureau is simply saying that it believes that a DNR order or POST form stored on the e-Directive Registry should be treated in the same manner as a DNR order or POST form attached to a patient's refrigerator.

The interpretive rule is not intended to provide guidance or impose requirements effecting your agency's operations. However, the interpretive rule may result in an evaluation of current procedures, policies and protocols regarding the use of the e-Directive Registry by emergency medical services.

The goal of the interpretive rule is to ensure that a person's wishes for medical treatment contained in advance directives, DNR orders, and POST, can be known and respected at a time when he or she no longer possess decision-making capacity and are in an emergency medical situation. The implementation of the interpretive rule will enable West Virginians to retain control over the end-of-life treatment they receive through the use of the West Virginia e-Directive Registry by emergency medical services and other treating health care providers.

Thank you again for your comments and I hope this letter clears up any confusion regarding the proposed interpretive rule.

Sincerely,

A handwritten signature in black ink, appearing to read "B. J. Skinner", with a horizontal line extending to the right.

Brian J. Skinner,
Bureau for Public Health General Counsel

pc: Dr. Michael R. Mills, OEMS Medical Director
Barbara Taylor, Deputy Commissioner
Rahul Gupta, Commissioner