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Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Health	
Virginia Administrative Code (VAC) citation(s)	12VAC5-66	
Regulation title(s)	Regulations Governing Durable Do Not Resuscitate Orders	
Action title	Amend the Regulations Governing Durable Do Not Resuscitate Orders	
Date this document prepared	December 2015	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Since the inception of the Durable Do Not Resuscitate (DNR) program; the use, understanding of intent and applicability of the acceptable Durable DNR forms have undergone continuous and evolving interpretation. The purpose for amending the definitions in this regulation is to highlight the terminology to provide additional clarity in the honoring of the Durable DNR form by all levels of healthcare providers

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

"Durable Do Not Resuscitate Order" or "Durable DNR Order" means a written physician's order issued pursuant to § 54.1-2987.1 of the Code of Virginia in a form or forms authorized by the board to withhold cardiopulmonary resuscitation from an individual in the event of cardiac or respiratory arrest. For purposes of this chapter, cardiopulmonary resuscitation shall include cardiac compression, endotracheal intubation and other advanced airway management, artificial ventilation, defibrillation, administration of cardiac resuscitative medications, and related procedures. As the terms "advance directive" and "Durable Do Not Resuscitate Order" are used in this article, a Durable Do Not Resuscitate Order or other DNR Order is not and shall not be construed as an advance directive. When used in these regulations, the term "Durable DNR Order" shall include any authorized Alternate Durable DNR jewelry issued in conjunction with an original Durable DNR Order.

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"Emergency Medical Services" or "EMS" means the services rendered by an agency licensed by the Virginia Office of Emergency Medical Services, an equivalent agency licensed by another state or a similar agency of the federal government when operating within this Commonwealth.

"Emergency medical services agency" or "EMS agency" means any agency, licensed to engage in the business, service, or regular activity, whether or not for profit, of transporting and/or rendering immediate medical care to such persons who are sick, injured, wounded or otherwise incapacitated or helpless.

"Other Do Not Resuscitate Order" or "Other DNR Order" means a written physician's order not to resuscitate a patient in the event of cardiac or respiratory arrest on a form other than the authorized state standardized Durable DNR Form under policies and procedures of the health care facility to which the individual who is the subject of the order has been admitted.

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

The Board of Health approved the fast track amendments to the Regulations Governing Durable Do Not Resuscitate Orders 12VAC5-66-10 on March 17, 2016.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

§ 54.1- 2987.1 Durable Do Not Resuscitate Orders state in part, the ability for healthcare practioners to honor the Durable DNR order.

§ 32.1-111.4 Regulations, Emergency Medical Services Personnel and vehicles; Response times; Enforcement provisions; Civil penalties states in part that the Board of Health has authority to promulgate regulations for EMS personnel to follow Do Not Resuscitate Orders pursuant to § 54.1.2987.1.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

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Adding the term of Physicians Orders for Scope of Treatment (POST) within the definition of "DDNR" will clarify to EMS providers and healthcare professionals working at medical facilities that the POST form is a recognized "other Durable DNR" form. The additional terminology is essential to protect the health and welfare of Virginians, in that it will allow another choice concerning end-of-life decisionmaking.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

During the Periodic Review, there were only four submitted comments, all supporting the addition of "POST" to the definition of "other Durable DNR form". No other stakeholders have voiced any opposition to this recommended addition.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

Within 12VAC5-66-10. Definitions, add the following terminology:

Part I. Definitions

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

"Durable Do Not Resuscitate Order" or "Durable DNR Order" means a written physician's order issued pursuant to § 54.1-2987.1 of the Code of Virginia in a form or forms authorized by the board to withhold cardiopulmonary resuscitation from an individual in the event of cardiac or respiratory arrest. For purposes of this chapter, cardiopulmonary resuscitation shall include cardiac compression, endotracheal intubation and other advanced airway management, artificial ventilation, defibrillation, administration of cardiac resuscitative medications, and related procedures. As the terms "advance directive" and "Durable Do Not Resuscitate Order" are used in this article, a Durable Do Not Resuscitate Order or other DNR Order is not and shall not be construed as an advance directive. When used in these regulations, the term "Durable DNR Order" shall include any authorized Alternate Durable DNR jewelry issued in conjunction with an original Durable DNR Order. Durable DNR Order forms ball be completed and signed by a licensed practitioner and signed by the patient or patient's authorized representative.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the

agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

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With the addition of the terminology of "POST", it affords the public a clearer understanding of other acceptable 'Durable Do Not Resuscitate" forms as identified within the *Regulations*. This permits greater flexibility for practioner's and other allied healthcare workers to include the patient and Emergency Medical Services providers in the utilization of documentation that clearly recognizes and acknowledges the patient wishes concerning their end of life decisions. There are no additional advantages to the Commonwealth, and/or disadvantages to the public, agency or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no disproportionate impacts to the citizens or localities of the Commonwealth.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The amended regulations do not impact small business.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

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Projected cost to the state to implement and	No cost
enforce the proposed regulation, including:	
a) fund source / fund detail; and	
b) a delineation of one-time versus on-going	
expenditures	
Projected cost of the new regulations or	No cost
changes to existing regulations on localities.	
Description of the individuals, businesses, or	Healthcare professionals, facilities and patients
other entities likely to be affected by the new	
regulations or changes to existing regulations.	
Agency's best estimate of the number of such	More than 51,00 physicians, nurse practioners, and
entities that will be affected. Please include an	physician assistants
estimate of the number of small businesses	
affected. Small business means a business entity,	Approximately 00 hospitals and 279 nursing
including its affiliates, that:	facilities
a) is independently owned and operated and;	
b) employs fewer than 500 full-time employees or	
has gross annual sales of less than \$6 million.	
All projected costs of the new regulations or	No cost
changes to existing regulations for affected	
individuals, businesses, or other	
entities. Please be specific and include all	
costs including:	
a) the projected reporting, recordkeeping, and	
other administrative costs required for	
compliance by small businesses; and	
b) specify any costs related to the development	
of real estate for commercial or residential	
purposes that are a consequence of the	
proposed regulatory changes or new	
regulations.	
Beneficial impact the regulation is designed	Recognition of other documentation to express a
to produce.	patient's end of life decisions.
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Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

No additional alternatives have been identified.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

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Periodic review and small business impact review report of findings

If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Commenter	Comment	Agency response
Paula Avery Drummer	Section A of Virginia POST form to be Designated as a DDNR The Virginia POST Collaborative Executive Committee is hereby submitting a comment regarding the Regulations Governing Durable Do Not Resuscitate Orders (12 VAC 5-66). We are in agreement with previous comments submitted by Nathan Kottkamp, Ken Faulkner and Lois Shepherd, that the definition of DDNR should be amended to designate Section A of the Virginia POST form as a Durable Do Not Resuscitate order. The Virginia POST form is being used by more and more providers around the state, and this designation as a DDNR will strengthen the clarity and portability of the form. We are, therefore, requesting that Section A of the Virginia POST form be included in 12 VAC5-66 as a Durable Do Not Resuscitate (DDNR) order. We also submit a definition of POST such as: "Physician Orders for Scope of Treatment" ("POST") means a set of portable medical orders (section A of which is a valid DDNR order) resulting from a patient's or a patient's authorized representative's informed decision-making with health care professionals that respects the patient's goals for care regarding the use of medical interventions, is applicable across health care settings, and can be reviewed and revised as needed or desired by the patient or the patient's authorized representative.	Section A of the Virginia POST form to be recognized as a durable DNR form.

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	Thank you for your consideration in this comment and please contact the Virginia POST Collaborative for any additional information.	
Lois Shepherd	I echo the comments of Nathan Kottkamp that the definition of DDNR should be amended to incorporate the POST form.	POST Form to be recognized as a durable DNR form.
Ken Faulkner	Physician Orders for the Scope of Treament (POST) should be included as a full DDNR	Definition of durable DNR should be
	The definition of DDNR should be amended to incorporate the POST form that is being used by more and more providers around the state. POST is a physicians order that enables a patient's wishes and care plan to be established on a common form that is effective regardless of a patient's location. The only edit that appears to be necessary is a revision to the definitions, 12VAC5-66-10, such as: "The term DDNR shall include a Physician Orders for Scope of Treatment (POST) form completed by a licensed practitioner and signed by the patient or patient's authorized representative." Currently, the comprehensive use of the POST form is hindered by the fact that the immunity provided in the the Healthcare Decisions Act (Va. Code 54.1-2988) is not expessly available to	amended to specifically include POST.
	providers.	
	Thank you for considering this comment	
Nathan Kottkamp	POST should be included in the definition of DDNR	Amend the definition of
	The definition of DDNR should be amended to incorporate the POST form that is being used by more and more providers around the state. POST is a physicians order that enables a patient's wishes and care plan to be established on a common form that is effective regardless of a patient's location. The only edit that appears to be necessary is a revision to the definitions, 12VAC5-66-10, such as: "The term DDNR shall include a Physician Orders for Scope of Treatment (POST) form completed by a licensed practitioner and signed by the patient or patient's authorized representative." Currently, the comprehensive use of the POST form is hindered by the fact that the immunity provided in the the Healthcare Decisions Act (Va. Code 54.1-2988) is not expessly available to providers. Thank you for considering this comment.	durable DNR form to include POST.
Barbara Matusiak	Please consider this as public comment on the Virginia Department of Health periodic review of VAC citation: 12VAC5-66 Regulations Governing Durable Do Not Resuscitate Orders specifically on Section 60 Other Do Not Resuscitate Orders. I am requesting that 12VAC5-66-60 Other Do Not Resuscitate Orders be amended to require signed and witnessed informed consent for Do Not Resuscitate (DNR) orders.	The issues presented in this public comment involve an internal challenge not regulated by these set of regulations. The writer has
	In a letter to you dated April 24, 2015 I explained the reason for my request and made recommendations for change. Please include that letter as part of my public comment.	pursued the proper channels to address their concerns. The
	The addition of a requirement for informed consent is not unprecedented as such a requirement exists in other sections	existing regulations

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of Virginia Administrative Code i.e. 12VAC5-20-100; 12VAC35-180-100; 12VAC35-115-70; 6VAC 15-26-10; 6VAC15-45-1560; 6VAC35-170-80; 8VAC20-565-30; 18VAC85-20-350; 22VAC30-40-100; 22VAC30-40-10; 22VAC40-890-50 etc.

The amendment is necessary for the protection of public health, safety and welfare.

The current language can be misinterpreted to mean that signed informed consent is not required because of the specific language that a signature is not required on the order itself. At least one hospital in Richmond does not require signed and witnessed informed consent for DNR orders. There may be other hospitals in Virginia that are doing the same. This must be rectified. As a result of not requiring signed consent a physician at the Richmond hospital wrote a DNR order without the consent of the patient's decision maker. Patients and decision makers must be informed of and agree to a change in code status. The informed consent must be signed and witnessed to ensure that it is properly obtained.

Not requiring signed and witnessed informed consent for a critical life ending DNR order allows practitioners to abuse the use of DNR orders to end the lives of patients and influence the care provided. Although according to the hospital at which this incident occurred a do not resuscitate order indicates only that resuscitative measures will not be initiated if the patient's heart stops or breathing ceases and until that time, the same standard of care applies to all patients, in reality medical care decisions are affected prior to cardiopulmonary arrest by DNR orders. The same patient referenced in my April letter to you was hospitalized at the same hospital in 2008. During that hospitalization the neurologist clearly stated that since she was a full code he had to move her to ICU. If she had been a DNR he would not have transferred her to the ICU and she may not have survived to enjoy the additional five years of life.

Thank you for your consideration of this serious matter.

address the requirement of a signature from the attending physician and the patient or patient representative for the purposes of completing the Durable DNR Order form required by Code. Code of Virginia 54.1-2987.1 does not require that all **Durable DNR** Orders include a physician signature, a patient signature or any evidence that consent has been witnessed. .

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As a result of a periodic review conducted July of 2015, four comments were submitted via Townhall supporting the addition of the definition of the terminology "POST". One submission was a letter outside of the Townhall noting an occurrence from an in-hospital event that was reported to the appropriate agencies to address. The proposed amendment meets the requirements as set forth in Executive Order 17 (2014) as it directly impacts the health, safety and welfare of the public (individual) and is easily written and understood. There is a continued need for this set of regulations as it aids individuals in the legal recognition of their end-of-life decisions. There are no known overlaps or duplications of any federal or state law addressed by this amendment.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children: 2) encourage or discourage

economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

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The amending of these regulations will strengthen the self sufficiency, self-pride, assumption of responsibility for oneself and decision making for the individual as it pertains to their end-of-life decisions.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an <u>emergency</u> regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10		The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:	
		"Agent" means an adult appointed by the declarant under an advance directive, executed or made in accordance with the provisions of § 54.1-2983 of the Code of Virginia to make health care decisions for him.	
		"Alternate Durable DNR jewelry" means a Durable DNR bracelet or necklace issued by a vendor approved by the Virginia Office of Emergency Medical Services. A Durable DNR Order must be obtained by the patient, from a physician, to obtain Alternate Durable DNR jewelry.	
		"Board" means the State Board of Health.	

"Cardiac arrest" means the cessation of a functional heartbeat.

"Commissioner" means the State Health Commissioner.

"Durable Do Not Resuscitate Order" or "Durable DNR Order" means a written physician's order issued pursuant to § 54.1-2987.1 of the Code of Virginia in a form or forms authorized by the board to withhold cardiopulmonary resuscitation from an individual in the event of cardiac or respiratory arrest. For purposes of this chapter, cardiopulmonary resuscitation shall include cardiac compression, endotracheal intubation and other advanced airway management, artificial ventilation, defibrillation, administration of cardiac resuscitative medications. and related procedures. As the terms "advance directive" and "Durable Do Not Resuscitate Order" are used in this article, a Durable Do Not Resuscitate Order or other DNR Order is not and shall not be construed as an advance directive. When used in these regulations, the term "Durable DNR Order" shall include any authorized Alternate Durable DNR jewelry issued in conjunction with an original Durable DNR Order.

"Emergency Medical Services" or "EMS" means the services rendered by an agency licensed by the Virginia Office of Emergency Medical Services, an equivalent agency licensed by another state or a similar agency of the federal government when operating

Durable Do Not Resuscitate Order" or "Durable DNR Order" means a written physician's order issued pursuant to § 54.1-2987.1 of the Code of Virginia in a form or forms authorized by the board to withhold cardiopulmonary resuscitation from an individual in the event of cardiac or respiratory arrest. For purposes of this chapter, cardiopulmonary resuscitation shall include cardiac compression. endotracheal intubation and other advanced airway management, artificial ventilation, defibrillation, administration of cardiac resuscitative medications, and related procedures. As the terms "advance directive" and "Durable Do Not Resuscitate Order" are used in this article. a Durable Do Not Resuscitate Order or other DNR Order is not and shall not be construed as an advance directive. When used in these regulations, the term "Durable DNR Order" shall include any authorized Alternate Durable DNR jewelry issued in conjunction with an original Durable DNR Order. Durable DNR order shall include a Physician Orders for Scope of Treatment (POST) form. Durable DNR Orders including POST forms shall be completed and signed by a licensed practitioner and signed by the patient or patient's authorized representative.

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Rationale:

Recognition of "Physician Orders for Scope of Treatment" as a specific type durable DNR form. POST means a set of portable medical orders resulting from a patient's or a patient's authorized representative's informed decision-making with health care professionals that respects the patient's goals for care regarding the use of medical interventions, is applicable across health care settings, and can be reviewed and revised as needed or desired by the patient or the patient's authorized representative.

within this Commonwealth.

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"Emergency medical services agency" or "EMS agency" means any agency, licensed to engage in the business, service, or regular activity, whether or not for profit, of transporting and/or rendering immediate medical care to such persons who are sick, injured, wounded or otherwise incapacitated or helpless.

"Incapable of making an informed decision" means the inability of an adult patient, because of mental illness, mental retardation, or any other mental or physical disorder that precludes communication or impairs judgment, to make an informed decision about providing, withholding, or withdrawing a specific medical treatment or course of treatment because he is unable to understand the nature, extent, or probable consequences of the proposed medical decision, or to make a rational evaluation of the risks and benefits of alternatives to that decision. For purposes of this article, persons who are deaf or dysphasic or have other communication disorders but who are otherwise mentally competent and able to communicate by means other than speech, shall not be considered incapable of making an informed decision. The determination that the patient is "incapable of making an informed decision" shall be made in accordance with § 54.1-2983.2 of the Code of Virginia.

"Office of EMS" or "OEMS" means the Virginia Office of Emergency Medical Services.

The Virginia Office of Emergency Medical Services is a state office located within the Virginia Department of Health (VDH). Form: TH-04

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"Person authorized to consent on the patient's behalf" means any person authorized by law to consent on behalf of the patient incapable of making an informed decision or, in the case of a minor child, the parent or parents having custody of the child or the child's legal guardian or as otherwise provided by law.

"Physician" means a person licensed to practice medicine in the Commonwealth of Virginia or in the jurisdiction where the treatment is to be rendered or withheld.

"Qualified emergency medical services personnel" means personnel certified to practice as defined by § 32.1-111.1 of the Code of Virginia when acting within the scope of their certification.

"Qualified health care facility" means a facility, program, or organization operated or licensed by the State Board of Health or by the Department of Behavioral Health and Developmental Services (DBHDS) or

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operated, licensed, or owned by another state agency. "Qualified health care personnel" means any qualified emergency medical services personnel and any licensed healthcare provider or practitioner functioning in any facility, program or organization operated or licensed by the State Board of Health or by DBHDS or operated, licensed, or owned by another state agency. "Respiratory arrest" means	
cessation of breathing.	

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