Regulatory Analysis

Notice of Intended Action to be published: 641—Chapter 142
"Out-of-Hospital Do-Not-Resuscitate Orders"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 144A.7A
State or federal law(s) implemented by the rulemaking: Iowa Code section 144A.7A

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 6, 2024 10 a.m.	Microsoft Teams Meeting ID: 268 876 122 100 Passcode: QXqezE

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

These proposed rules direct EMS providers and service programs on the processes for the recognition of out-of-hospital do-not-resuscitate (OOH DNR) orders or identifiers and implementation of the OOH DNR protocol. In addition, these rules set forth guidelines for consideration by health care providers and organizations to help ensure uniform and orderly understandings, processes and procedures for the use and implementation of OOH DNR orders consistent with the provisions of Iowa Code chapter 144A.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

There are no costs associated with this rulemaking.

- Classes of persons that will benefit from the proposed rulemaking:

Iowans with terminal conditions who desire to have OOH DNR orders in place will benefit.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

The OOH DNR form is open and accessible for public use. It is unknown how many Iowans utilize the OOH DNR order. EMS providers comply with orders when in use.

- Qualitative description of impact:

The OOH DNR order provides Iowans who do not want to be resuscitated an option to let EMS providers know their wishes. EMS providers comply with OOH DNR orders according to this administrative rule.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

Personnel and other administrative costs will be borne by the Department.

- Anticipated effect on state revenues:

There will be no impact on state revenues.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

Without this guidance for health care providers, Iowans who do not want to be resuscitated may not have the opportunity to have their wishes fulfilled.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

No, the rulemaking is appropriate and required by law.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

No other methods were considered.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

The statute directs the Department to promulgate rules.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

There is no impact on small business.

Text of Proposed Rulemaking

ITEM 1. Rescind 641—Chapter 142 and adopt the following **new** chapter in lieu thereof:

CHAPTER 142
OUT-OF-HOSPITAL DO-NOT-RESUSCITATE ORDERS

641—142.1(144A) Definitions. For the purpose of these rules, the following definitions apply:

"Adult" means an individual 18 years of age or older.

"Attending physician" means a physician selected by, or assigned to, the patient who has primary responsibility for the treatment and care of the patient.

"Attending physician assistant" means the physician assistant selected by, or assigned to, the patient who has primary responsibility for the treatment and care of the patient.

"Comfort care" means care within the scope of the health care provider's training and certification to alleviate pain and suffering but does not include resuscitative measures.

"Emergency medical care" means such medical procedures as:

1. Administration of intravenous solutions.
2. Intubation.
3. Performance of cardiac defibrillation and synchronized cardioversion.
4. Administration of emergency drugs as provided by rule by the department.
5. Any other medical procedure approved by the department, by rule, as appropriate to be performed by emergency medical care providers who have been certified in that procedure.

"EMS provider" means an emergency medical care provider as defined in Iowa Code section 147A.1.

"Health care provider" means a person, including an emergency medical care provider, who is licensed, certified, or otherwise authorized or permitted by the law of this state to administer health care in the ordinary course of business or in the practice of a profession.

"Hospital" means any hospital licensed under the provisions of Iowa Code section 135B.1.

"Life-sustaining procedure" means any medical procedure, treatment, or intervention, including resuscitation, which utilizes mechanical or artificial means to sustain, restore or supplant a spontaneous vital function, and when applied to a patient in a terminal condition, would serve only to prolong the dying process. "Life-sustaining procedure" does not include the provision of nutrition or hydration except when required to be provided parenterally or through intubation or the administration of medication or performance of any medical procedure deemed necessary to provide comfort care or to alleviate pain.

"Medical direction" means direction, advice, or orders provided by a medical director or supervising physician.

"Medical director" means any physician licensed under Iowa Code chapter 148 who is responsible for overall medical direction of the service program and who has completed a medical director workshop, sponsored by the department, within one year of assuming duties.

"Online medical direction" means immediate medical direction provided directly to service program emergency medical care providers, in accordance with written parameters and protocols, by the medical director or supervising physician, either on scene or by any telecommunications system.

"Out-of-hospital do-not-resuscitate identifier" or *"OOH DNR identifier"* means a durable yet easily removable unique identification approved by the department and worn by a patient who has an out-of-hospital do-not-resuscitate order.

"Out-of-hospital do-not-resuscitate order" or *"OOH DNR order"* means a written order on a form approved by the department, signed by an attending physician, executed in accordance with the requirements of Iowa Code section 144A.7A and issued consistent with Iowa Code section 144A.2, that directs the withholding or withdrawal of resuscitation when an adult patient in a terminal condition is outside the hospital.

"Out-of-hospital do-not-resuscitate protocol" or *"OOH DNR protocol"* means the statewide protocol approved by the department and intended to avoid unwarranted resuscitation by emergency medical care providers when a valid out-of-hospital do-not-resuscitate order or identifier is encountered.

"Patient" means any individual who is sick, injured, or otherwise incapacitated.

"Physician" means any individual licensed under Iowa Code chapter 148.

"Physician assistant" or *"PA"* means an individual licensed pursuant to Iowa Code chapter 148C.

"Qualified patient" means any patient who is an adult as defined in Iowa Code section 144A.2.

"Registered nurse" or *"RN"* means an individual licensed pursuant to Iowa Code chapter 152.

"Resuscitation" means any medical intervention that utilizes mechanical or artificial means to sustain, restore, or supplant a spontaneous vital function, including but not limited to chest

compression, defibrillation, intubation, and emergency drugs intended to alter cardiac function or otherwise to sustain life.

"Service program" or *"service"* means any medical care ambulance service or nontransport service that has received authorization by the department.

"Supervising physician" means any physician licensed under Iowa Code chapter 148.

"Terminal condition" means an incurable or irreversible condition that, without the administration of life-sustaining procedures, will, in the opinion of the attending physician, result in death within a relatively short period of time or a state of permanent unconsciousness from which, to a reasonable degree of medical certainty, there can be no recovery.

641—142.2(144A,147A) Responsibilities of the department.

142.2(1) *OOH DNR physician or physician assistant order.* The department designates the OOH DNR order form contained in Appendix A as the uniform OOH DNR order form to be used statewide. If an attending physician or attending physician assistant issues an OOH DNR order for a qualified patient, the physician or physician assistant must use the form contained in Appendix A.

142.2(2) *OOH DNR personal identifier.* The department designates the identifier supplied by MedicAlert® as the uniform personal identifier to be used for mobile qualified patients statewide. Instructions for obtaining a uniform personal identifier are contained in Appendix A.

142.2(3) *OOH DNR protocol.* The department designates the OOH DNR protocol contained in Appendix B as the uniform protocol to be used by EMS providers in implementing an OOH DNR order.

142.2(4) *Appendix A and Appendix B forms.* Forms referenced in subrules 142.3(1) through 142.3(3) are available through the department's website or by request.

641—142.3(144A,147A) EMS providers.

142.3(1) *Uniform protocol.* EMS providers shall act in accordance with the department's OOH DNR protocol when implementing an OOH DNR order. EMS service programs shall incorporate the OOH DNR protocol as part of their service protocols and, using educational materials consistent with the curriculum developed and approved by the department, shall inform and educate EMS providers on the protocol's requirements as well as the requirements of Iowa Code chapter 144A and these rules.

142.3(2) *Responsibility of the EMS provider.* The EMS provider responding outside a hospital as a member of a service program shall:

a. Evaluate the patient's status and needs through an assessment consistent with the provider's training and certification.

b. Determine the existence of an OOH DNR order or that the patient is wearing an OOH DNR identifier.

c. Honor the OOH DNR order or OOH DNR identifier worn by the patient.

d. Discontinue resuscitation if the OOH DNR order or OOH DNR identifier worn by the patient is discovered after resuscitation has begun.

e. Follow the OOH DNR protocol.

f. Provide comfort care to the patient at all times.

g. Contact on-line medical direction for further instructions as necessary to provide appropriate patient care.

h. If uncertainty exists regarding the validity or applicability of the OOH DNR order or identifier, the EMS provider shall provide the necessary and appropriate resuscitation.

i. Document compliance or noncompliance with the OOH DNR order and the reasons for not complying with the order, including evidence that the order was revoked or uncertainty regarding the validity or applicability of the order.

641—142.4(144A) Guidelines for non-EMS health care providers, patients, and organizations. In order to encourage understanding and implementation of OOH DNR orders and protocols throughout

Iowa and honor a qualified patient's wishes and intent regarding the provision of life-sustaining procedures in an out-of-hospital setting consistent with the requirements of Iowa Code chapter 144A, the following guidelines should be considered.

142.4(1) *Attending physicians or attending physician assistants who issue OOH DNR orders.* The attending physician or attending physician assistant should ensure that the following are accomplished:

a. Establish that the patient is qualified because the patient:

(1) Is an adult; and

(2) Has a terminal condition.

b. Explain to the patient or the individual legally authorized to act on the patient's behalf the implications of an OOH DNR order.

c. If the qualified patient or individual legally authorized to act on the patient's behalf decides that the patient should not be resuscitated, the attending physician or attending physician assistant may issue the OOH DNR order on the prescribed uniform order form. The order will direct health care providers to withhold or withdraw resuscitation.

d. Explain to the qualified patient or the individual legally authorized to act on the patient's behalf how the OOH DNR order is revoked.

e. Include a copy of the order in the qualified patient's medical record.

f. Provide a copy of the order to the qualified patient or the individual legally authorized to act on the patient's behalf.

142.4(2) *Qualified patients or legally authorized persons.* A qualified patient or a person legally authorized to act on a qualified patient's behalf should:

a. Make an informed decision concerning resuscitation in the face of a terminal condition.

b. Ensure that the qualified patient's family members are aware of this decision and inform them of the location of the OOH DNR order and the purpose of an OOH DNR identifier.

c. Understand the process for revocation as described in rule 641—142.5(144A).

142.4(3) *Non-EMS health care providers.* A non-EMS health care provider contemplating resuscitation for a patient should:

a. Evaluate the patient's status and needs through an assessment consistent with the provider's training, certification and licensure.

b. Determine that the presenting condition is within the scope of the patient's terminal condition and is not the result of a motor vehicle collision, fire, mass casualty or other cause of a sudden accident or injury.

c. Determine the existence of an OOH DNR order or that the patient is wearing an OOH DNR identifier.

d. Honor the OOH DNR order or OOH DNR identifier worn by the patient.

e. Discontinue resuscitation if the OOH DNR order or OOH DNR identifier worn by the patient is discovered after resuscitation has begun.

f. Provide comfort care to the patient at all times.

g. If uncertainty exists regarding the validity or applicability of the OOH DNR order or identifier, the health care provider shall provide the necessary and appropriate resuscitation.

h. Document compliance or noncompliance with the OOH DNR order and the reasons for not complying with the order, including evidence that the order was revoked or uncertainty regarding the validity or applicability of the order or OOH DNR identifier.

142.4(4) *Hospitals.* A hospital:

a. Is not precluded from honoring an OOH DNR order entered in accordance with this chapter and in compliance with established hospital policies and protocols.

b. Should, to avail itself of the immunities provided within Iowa Code chapter 142, establish such policies and protocols to address an OOH DNR order or identifier encountered on a person who presents to the emergency department or in any other area within the facility if the person presents as a patient or visitor.

c. Should integrate policies and procedures with the OOH DNR protocol for hospital-based ambulance service programs, if present.

142.4(5) *Other health care organizations.* A nursing home, home health care agency, hospice, or other health care organization should establish policies and protocols consistent with these rules to address admitted patients who have OOH DNR orders.

641—142.5(144A) Revocation of the out-of-hospital do-not-resuscitate order. An OOH DNR order is deemed revoked at any time that a patient, or an individual authorized to act on the patient's behalf as designated on the OOH DNR order, is able to communicate in any manner the intent that the order be revoked, without regard to the mental or physical condition of the patient. A revocation is only effective as to the health care provider upon communication to that provider by the patient, an individual authorized to act on the patient's behalf as designated in the OOH DNR order, or by another person to whom the revocation is communicated by the patient.

641—142.6(144A) Personal wishes of family members or other individuals who are not authorized to act on the patient's behalf. The personal wishes of family members or other individuals who are not authorized in the order to act on the patient's behalf cannot supersede a valid OOH DNR order.

641—142.7(144A) Transfer of patients.

142.7(1) An attending physician or attending physician assistant who is unwilling to comply with an OOH DNR order or who is unwilling to comply with the provisions of Iowa Code section 144A.7A shall take all reasonable steps to effect the transfer of the patient to another physician or physician assistant.

142.7(2) If the policies of a hospital, nursing home, home health care agency, hospice or other health care organization preclude compliance with the OOH DNR order of a qualified patient, the provider shall take all reasonable steps to effect the transfer of the patient to an organization in which the provisions of Iowa Code section 144A.7A can be carried out.

641—142.8(144A) Application to existing orders.

142.8(1) An OOH DNR order or similar order executed prior to September 10, 2003, is valid and shall be honored in accordance with the then-applicable provisions of the law.

142.8(2) Health care providers may honor an OOH DNR order or identifier from another state if it can be validated and applied in a manner consistent with the OOH DNR order or identifier prescribed in these rules. In cases where there is uncertainty, clarification should be sought through on-line medical direction or resuscitation efforts should be initiated.

These rules are intended to implement Iowa Code sections 144A.7A and 147A.4.

APPENDIX A

Iowa Department of Health and Human Services
OUT-OF-HOSPITAL DO-NOT-RESUSCITATE ORDER
(Please type or print)

Date of Order: _____/_____/_____
Patient Information:
Name: (Last)_____(First)_____(Middle)_____
Address: _____(City)_____(Zip)_____
Date of Birth: _____/_____/_____ Gender (Circle): M or F
Name of Hospice or Care Facility (if applicable): _____

Attending Physician or Physician Assistant Order

As the attending physician or attending physician assistant for the above-named patient, I certify that this individual is over 18 years of age and has a terminal diagnosis. After consultation with this patient (or the patient's legal representative), I hereby direct any and all health care providers, including qualified emergency medical services (EMS) personnel, to withhold or withdraw the following life-sustaining procedures in accordance with Iowa law (Iowa Code chapter 142A):

- Cardiopulmonary Resuscitation/Cardiac Compression (Chest Compressions).
- Endotracheal Intubation/Artificial or Mechanical Ventilation (Advance Airway Management).
- Defibrillation and Related Procedures.
- Use of Resuscitation Drugs.

This directive does NOT apply to other medical interventions for comfort care.

_____ _____/_____/_____
Signature of Attending Physician (MD, DO) or Attending Physician Assistant **Date**

_____ (_____)_____-_____
Printed Name of Attending Physician or Attending Physician Assistant **Physician's or Physician Assistant's Telephone (Emergency)**

To the extent that it is possible, a person designated by the patient may revoke this order on the patient's behalf. If the patient wishes to authorize any other person(s) to revoke this order, the patient MUST list those persons' names below:

Name: _____
Name: _____
Name: _____
Name: _____

Patients, please note: Directions for obtaining a uniform identifier are listed on the back of this form. The uniform identifier is the key way the health care provider and/or EMS personnel can quickly recognize that you have an Out-of-Hospital Do-Not-Resuscitate order. If you are not wearing an identifier, the health care provider and/or EMS personnel may not realize that you do not want to be resuscitated.

Physicians or physician assistants, please note: Information regarding the completion of an Out-of-Hospital Do-Not-Resuscitate order is on the back of this form.

APPENDIX A

Directions for obtaining a uniform identifier:

The uniform identifier may be obtained through MedicAlert®[1], which requires:

1. A completed MedicAlert® application, which is available in physician or physician assistant offices or through MedicAlert® by phoning (800)432-5378 or the website www.medicalert.org, and fee.
2. A copy of this completed OOH DNR order, which must accompany the MedicAlert® application or be sent to MedicAlert® prior to the identifier's being mailed.

[1]MedicAlert® is a nonprofit 501C membership organization.

Suggested guidelines for physicians or physician assistants:

1. Please review the Iowa Out-of-Hospital Do-Not-Resuscitate order and related protocol with the patient/patient's legal representative(s). The following points may be helpful:

- Patient/patient's legal representative(s) listed on this order must understand the significance of this order, that in the event the patient's heart or breathing stops or malfunctions, the anticipated result of this order is death.
- Patient/patient's legal representative(s) listed on this order may revoke this directive at any time. However, the desire to revoke must be communicated to the EMS or other health care professionals at the scene.
- It is important to emphasize that this order does not apply to medical interventions to make the patient more comfortable.
- The importance of wearing the uniform identifier for those qualified patients who would benefit from the mobility this offers should be stressed. It is also helpful to walk patients through the process they must follow to acquire the identifier.

2. Provide a copy of this order to the patient/patient's legal representative(s) listed on this order and place the original in the patient's medical records.

The OOH DNR Order form is available through the department's website.

APPENDIX B

EMS OUT-OF-HOSPITAL DO-NOT-RESUSCITATE PROTOCOL

Purpose: This protocol is intended to avoid unwarranted resuscitation by emergency care providers in the out-of-hospital setting for a *qualified patient*.[1] There must be a valid Out-of-Hospital Do-Not-Resuscitate (OOH DNR) order signed by the qualified patient's attending physician or physician assistant or the presence of the OOH DNR identifier indicating the existence of a valid OOH DNR order.

No resuscitation: Means withholding any medical intervention that utilizes mechanical or artificial means to sustain, restore, or supplant a spontaneous vital function, including but not limited to:

1. Chest compressions,
2. Defibrillation,
3. Esophageal/tracheal/double-lumen airway; endotracheal intubation, or
4. Emergency drugs to alter cardiac or respiratory function or otherwise sustain life.

Patient criteria: The following patients are recognized as qualified patients to receive no resuscitation:

1. The presence of the uniform OOH DNR order or uniform OOH DNR identifier, or
2. The presence of the attending physician or attending physician assistant to provide direct verbal orders for care of the patient.

The presence of a signed physician or physician assistant order on a form other than the uniform OOH DNR order form approved by the department may be honored if approved by the service program EMS medical director. However, the immunities provided by law apply only in the presence of the uniform OOH DNR order or uniform OOH DNR identifier. When the uniform OOH DNR order or uniform OOH DNR identifier is not present, contact must be made with on-line medical control and on-line medical control must concur that no resuscitation is appropriate.

Revocation: An OOH DNR order is deemed revoked at any time that a patient, or an individual authorized to act on the patient's behalf as listed on the OOH DNR order, is able to communicate in any manner the intent that the order be revoked. The personal wishes of family members or other individuals who are not authorized in the order to act on the patient's behalf shall not supersede a valid OOH DNR order.

Comfort Care (♥): When a patient has met the criteria for no resuscitation under the foregoing information, the emergency care provider should continue to provide that care which is intended to make the patient comfortable (a.k.a. **♥Comfort Care**). Whether other types of care are indicated will depend upon individual circumstances for which medical control may be contacted by or through the responding ambulance service personnel.

♥Comfort Care *may include but is not limited to:*

1. *Pain medication.*
2. *Fluid therapy.*
3. *Respiratory assistance (oxygen and suctioning).*

[1]*Qualified patient* means an adult patient determined by an attending physician or attending physician assistant to be in a terminal condition for which the attending physician or attending physician assistant has issued an Out-of-Hospital DNR order in accordance with the law. (Rule 641—142.1(144A), definitions)