CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Health

Regulation/Package Title: Chapter 3701-62 – Do-Not-Resuscitate (DNR) Protocol

Rule Number(s): 3701-62-01 to 3701-62-14

Date: August 9, 2018

Rule Type:

- X New
- X Amended
- X 5-Year Review
- X Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulations in plain language.**

The rules set forth in Chapter 3701-62 of the Ohio Administrative Code establish the Do Not Resuscitate ("DNR") Order and Protocol in Ohio pursuant to section 2133.25 of the Ohio Revised Code. The DNR Order and Protocol establish and provide a standardized method of procedure for the withholding of CPR by physicians, emergency medical services personnel, and health care facilities. The rules set forth in Chapter 3701-62 include, but are not limited to, the DNR Order form, Protocol, liability protections, and prohibitions.

Pursuant to the five year review the following rules are being recommended without changes:

3701-62-11– The rule establishes that the death of a person resulting from the withholding or withdrawal of CPR for a person with a valid DNR does not constitute suicide, aggravated murder, murder, or any other homicide.

The following rules are being rescinded and replaced with new rules:

3701-62-05– The rule is being rescinded due to Legislative Service Commission rule drafting requirements for a greater than fifty percent change to the rule content. The rule establishes the DNR Protocol and when it becomes effective. The revisions to the existing rule language make formatting changes for ease of use and flow of information and to clarify the requirements pertaining to documentation of a DNR Order in an individual's record in the absence of a valid DNR form.

- The appendix to this rule establishes the DNR Protocol. The Protocol is being revised to reflect current industry language and standards for congruence with the revised DNR Order form.

3701-62-07– The rule is being rescinded due to Legislative Service Commission rule drafting requirements for a greater than fifty percent change to the rule content. The rule sets forth the requirements for emergency medical services personnel and compliance with the DNR Protocol. The rule authorizes EMS personnel to accept an oral DNR Order from a physician, APRN, or PA and requires verification of issuer's identity. The revisions to the existing rule language incorporate the use of the terms "authorized healthcare provider" and "living will declaration" and to clarify that emergency services personnel are not required to search a person for DNR identification in accordance with section 2133.22 of the Revised Code.

3701-62-09– The rule is being rescinded due to Legislative Service Commission rule drafting requirements for a greater than fifty percent change to the rule content. The rule sets forth the requirement that a transferring health care facility must notify a receiving health care facility of the existence of a person's DNR Order prior to transfer requires an existing oral DNR Order to be written and accompany the person upon discharge. The revisions to the existing rule language provide clarification of the requirement for facilities to notify receiving facilities and transporting personnel of the existence of a DNR when transferring a patient. Furthermore, the revisions clarify that a DNR form or authorized DNR identification must accompany any individual being transferred and provides the specific types of identification that is authorized.

3701-62-10– The rule is being rescinded due to Legislative Service Commission rule drafting requirements for a greater than fifty percent change to the rule content. The rule sets forth the relationship between the DNR, living will declarations, and durable powers of attorney for health care. DNR identification based upon a valid declaration supersedes the authority of a durable power attorney and its named agent(s). A valid durable power of attorney for health care supersedes a DNR based upon an order from a physician, APRN, or PA if that order is inconsistent with the authority of the durable power of attorney for health care. An active living will declaration supersedes DNR identification based upon a previous living will declaration or DNR that is inconsistent with the current declaration. Finally, the to the extent that a known conflict exists between DNR identification based upon a valid DNR Order to which the principal consented, and a valid living will declaration, the more recent document supersedes.

Revisions have been made to:

3701-62-01 – The rule sets forth the definitions used throughout the Chapter, such as "CPR," "do-not-resuscitate order," "do-not-resuscitate protocol," and "cardiac arrest". The rule is being revised to include a new definition for "authorized healthcare provider," include the definition of "comfort care" from section 2133.01 of the Revised Code, to clarify that for the purposes of this Chapter, "declaration" means a "living will declaration," and to include the new definition for "advanced practice nurse" consistent with section 4723.42 of the Revised Code.

3701-62-02 – The rule sets forth the authority and immunities pertaining to DNRs for APRNs and PAs. The rule is being revised to change the existing language specifying Certified Nurse Practitioners and Clinical Nurse Specialists to refer to APRNs consistent with section 4723.42 of the Revised Code. This change incorporates both those specializations as well as Certified Registered Nurse Midwives and Certified Registered Nurse Anesthetists.

3701-62-03 – The rule sets forth immunities from criminal, civil, and professional actions for withholding or withdrawing CPR from a patient with a valid DNR Order for medical, emergency services personnel, and other health care workers. The rule is being revised to replace previous references to physicians, CNP/CNSs, and PAs with the term "authorized healthcare provider."

3701-62-04 – The rule sets forth lists various items that are approved as DNR identification (such as a DNR Order, hospital-type bracelets, necklaces bearing the DNR logo, and wallet cards); establishes when a person is eligible to obtain DNR identification; and states how a person can obtain DNR identification. The rule is being revised to update language to reflect the use of the terms "authorized health care provider" and "living will declaration," clarify that the DNR logo and individual's identifying information must be contained on identification items, and clarify that the DNR Order form shall not be modified in any way or include additional medical instructions that will not be provided immunities under the Chapter. Appendix A to this rule is the State of Ohio DNR Order form. The form is being revised to:

- Streamline the form for easier recognition by individuals and healthcare providers.
- Revise the Protocol to reflect current industry language and standards.
- Include language clarifying immunities granted under Chapter 2133. Of the Revised Code.
- Clarify that a copy of the DNR Order form or authorized identification must accompany the individual during transfers between facilities.

3701-62-06– The rule sets forth ways in which a person may revoke his or her DNR identification, including, but not limited to, destroying the DNR Order form or wallet card; permanently removing DNR jewelry; and revoking a declaration intended to be used as a DNR identification. The rule requires every attending physician, APRN, or PA that issues an order discontinuing a valid DNR Order to ask the patient prior to discharge or transfer whether the patient wants to make another DNR declaration. The rule is being revised to incorporate the use of the terms "authorized healthcare provider" and "living will declaration."

3701-62-08– The rule sets forth the requirement that physicians, CNPs, CNSs, or health care facilities that are unwilling or unable to comply with a person's DNR, to not interfere with the transfer of the person to a provider who will follow the DNR Protocol. The rule is being revised to replace the references to CNPs and CNSs to APRNs.

3701-62-12– The rule sets forth the prohibition for insurance, health benefit plans, and other providers from denying, modifying, or canceling insurance coverage or care plans as a result of a person obtaining a DNR Order. The rule further states, that a provider cannot require a person to rescind a DNR Order to obtain treatment. The rule is being revised to replace the terms CNP and CNS with APRN and clarify that policies in effect and after July 9, 1998 shall not be impacted by an individual's choice to have a DNR.

3701-62-13– The rule sets forth the rights of an individual with a DNR as they pertain to informed consent and declarations pursuant to sections 2133.01 to 2133.15 of the Revised Code. The rule grants an individual the right to make decisions regarding the withholding, or withdrawal of CPR as long as

the person is mentally able to make those decisions. Finally, the rule establishes the fact that a failure to include a specific authorization for the withholding or withdrawal of CPR in a declaration does not preclude the withholding or withdrawal of CPR. The rule is being revised to include the term "living will" with declaration for clarity.

3701-62-14– The rule sets forth the prohibitions pertaining to a DNR Order and DNR identification. The rule prohibits a physician, CNP, or CNS from delaying the transfer of a patient in violation of division (B) of section 2133 of the Revised Code. Additional prohibitions include: falsification and forgery of a DNR for another individual as well as the falsification or forgery of a revocation; defacement, concealment, cancelation or obliteration of another individuals DNR Order without permission; and concealment or withholding knowledge of a DNR revocation with the intent to cause the use, withholding, or withdrawal of CPR for the other person. Pursuant to section 2133.26 of the Revised Code, whoever violates paragraph (A) or (E) of this rule is guilty of a misdemeanor of the third degree. Whoever violates paragraph (B), (C), or (D) of this rule is guilty of a misdemeanor of the first degree. The rule is being revised to include replace the use of CNP and CNS with APRN and to incorporate the use of the term "authorized healthcare provider.".

2. Please list the Ohio statute authorizing the Agency to adopt these regulations.

Ohio Revised Code section 2133.25

3. Do the regulations implement a federal requirement? Are the proposed regulations being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

There are no federal requirements mandating these rules.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable to these rules.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

As required by Ohio Revised Code 2133.25, these rules provide the necessary state-based framework for the Department of Health to provide a standardized method of procedure for the withholding of CPR by physicians, emergency medical services personnel, and health care facilities in the form of the DNR Order and Protocol. Through the DNR Order and DNR Protocol, ODH provides a standardized method to ensure that individual's decisions regarding lifesaving/sustaining measures are clearly expressed and recognized by health care personnel and providers.

6. How will the Agency measure the success of these regulations in terms of outputs and/or outcomes?

The regulations set forth in Chapter 3701-62 of the Ohio Administrative Code are not directly measurable through the standard methods of survey utilized by ODH. ODH is required by statute to make the form available and establish rules, but enforcement of the requirements established in rule, such as the concealment, defacing, or destruction of a valid DNR Order of an individual by

another person without consent are punishable as criminal offenses and would be prosecuted through local or state law enforcement. In the event that ODH received a complaint regarding one of its regulated facilities, programs, or services, ODH would investigate that complaint under the rules regulating the entity, which could result in a survey of the facility. Any violations identified by ODH would be referred to the Ohio Attorney General for further action or relief may be sought by individuals through their local courts. Thus, the "success" of the DNR rules could be determined through the review of related criminal cases in Ohio's courts and the number of complaints received regarding the DNR by the agency itself.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulations.

Ohio Council for Homecare and Hospice
Ohio State Long-term Care Ombudsman
Ohio Department of Aging
Ohio Department of Public Safety
Ohio Hospital Association
Ohio Nurses Association
Ohio State Bar Association
Ohio Adjutant General's Office
Medflight
Leading Age Ohio
City of Cincinnati EMS
City of Dayton EMS
Hospice Alliance of Ohio
Lamusga Law
Ohio Department of Developmental Disabilities
Ohio Health
Cleveland Clinic
Hospice of Dayton
Ohio Osteopathic Association
MedCare Ohio
City of Worthington EMS
Ohio Chapter of the American College of Emergency Physicians
Bioethics Network of Ohio
Nationwide Children's Hospital

8. What input was provided by the stakeholders, and how did that input affect the draft regulations being proposed by the Agency?

Stakeholder participation was the driving force behind the revisions incorporated into the rules, appendices, and the Ohio DNR form. Well attended stakeholder meetings were held on the following dates:

November 28, 2017
March 23, 2018
June 6, 2018
June 28, 2018

In addition to in person stakeholder meetings, ongoing communication of the various stages of the draft rules occurred over the nine months from November 2017 to July 2018 and involved all the identified stakeholders throughout the process. Revisions to the DNR Protocol and Ohio DNR Order form directly reflect input from stakeholders and the final informal review of the drafts by the group in July produced positive comments and support for the revisions.

9. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

The Ohio Department of Health is required to adopt and maintain a standardized method of procedure for the withholding of CPR by health care practitioners and facilities by section 2133.25 of the Revised Code. Alternative regulations to the rules being amended were not considered. The rules reflect the current statutory requirements.

10. **Did the Agency specifically consider performance-based regulations? Please explain.**

A performance based regulation is not appropriate in this instance.

11. **What measures did the Agency take to ensure that these regulations do not duplicate an existing Ohio regulation?**

The agency conducted a thorough review of the Ohio Revised Code and Ohio Administrative Code.

12. **Please describe the Agency's plan for implementation of these regulations, including any measures to ensure that the regulations are applied consistently and predictably for the regulated community.**

ODH makes the DNR Order form, DNR Protocol, and applicable rules available on its agency website for public use. Furthermore, ODH receives and acts upon complaints regarding its regulated entities. The DNR has been in use in Ohio since 1998 and is readily accepted and utilized by healthcare providers and individuals within the state without significant issues.

Adverse Impact to Business

13. **Provide a summary of the estimated cost of compliance with these rules. Specifically, please do the following:**

a. Identify the scope of the impacted business community:

All healthcare providers, to include, but not limited to, healthcare facilities, physicians, nurses, and emergency services personnel.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

The time necessary to complete the form.

c. Quantify the expected adverse impact from the regulation:

The costs associated with these rules remain unchanged from previous versions of the rules. The DNR Order is available for printing from the ODH website. The cost to authorized practitioners is dependent upon the practitioner completing the form; however, the cost would typically be included as part of the fee charged to an individual requesting the DNR Order for a standard office visit or consultation with that provider.

The following are the average wages per service provider type:

Physician: $0.00 to an average of $103.22 per hour*
Nurse Practitioners: $0.00 to an average of $51.68 per hour*
Physician Assistants: $0.00 to an average of $50.37 per hour*

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May 2017, using the codes physicians and surgeons, all others (29-1060), nurse practitioners (29-1171), and physician assistant (29-1071).

14. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

ODH is required to implement section 2133.25 the Ohio Revised Code to provide and maintain a standardized method of procedure for the withholding of CPR by health care practitioners and facilities. The DNR Order is an individual based written document with an insignificant adverse impact for the business community. Businesses, such as ambulatory surgical facilities, routinely include in their informed consent documents, a waiver of a DNR Order by individuals while they are receiving services at the facility thereby eliminating any subsequent issues with upholding the order.

Regulatory Flexibility

15. Does the regulation provide any exemptions or alternative means of compliance for small businesses?

A DNR Order is an individual based written document and there is no identified impact on small businesses.

16. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The agency maintains program staff to assist and provide guidance to individuals and providers regarding the DNR Order form and Protocol. Chapter 2133. of the Ohio Revised Code and Chapter 3701-62 of the Ohio Administrative Code does not provide for the waiver of fines or penalties, thus, section 119.14 of the Revised Code does not apply. Certain Violations of Chapter 3701-62 of the Ohio Administrative Code are punishable as criminal offenses.

17. What resources are available to assist small businesses with compliance of the regulation?

The Ohio Department of Health, Do Not Resuscitate Program provides information and assistance to individuals and providers. Additional information is available at:

http://www.odh.ohio.gov/odhprograms/dspc/dnr/dnr1.aspx