

Common Sense Initiative

Mike DeWine, Governor Jon Husted, Lt. Governor Joseph Baker, Director

Business Impact Analysis

Agency, Board, or Commission Name: <u>Ohio Department of Health</u>
Rule Contact Name and Contact Information: <u>Olivia Igel and Cole Weidman 614-995-5945</u>
Regulation/Package Title (a general description of the rules' substantive content): Chapter 3701-62 Do-Not-Resuscitate (DNR) Protocol
Rule Number(s): <u>3701-62-01 through 3701-62-14</u> 1 st Posting 11/12 to 12/12/2024
CHANGES MADE AFTER FIRST POSTING HIGHLIGHTED IN YELLOW
Date of Submission for CSI Review: <u>11/12/2024</u>
Public Comment Period End Date: <u>12/12/2024</u>
Rule Type/Number of Rules:
New/rules No Change/rules (FYR?)
Amended/X_rules (FYR?_X_) Rescinded/rules (FYR?)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Reason for Submission

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
- **b.** \Box Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- c. Requires specific expenditures or the report of information as a condition of compliance.
- d.
 Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

Regulatory Intent

2. Please briefly describe the draft regulation 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.

ODH's recommended new rules are set forth as follows:

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". Amendments include removing regulatory restrictions in accordance with SB 9 of the 134th General Assembly and the definition change of "hospital" as part of the definition of "Health care facility" is now defined in section 3722.01 of the ORC.

Changes made to remove "audible" in (D) per stakeholder request:

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(D) "Cardiac arrest" means the loss of discernible audible and palpable pulse, with or without the loss of cardiac action/rhythm if on a cardiac monitor, or the sudden abrupt loss of heart function.

3701-62-02

The rule sets forth the authority and immunities pertaining to DNRs for APRNs and PAs. The rule allows the department to remove the additional physician's signature on Appendix A, and an APRN now has authority to sign off on an Ohio DNR form without a physician's signature per ORC 2133.21 and 2133.26.

Changes made:

• Changes made to reinstate the use of "and" in paragraph (A) and (B) of OAC 3701-62-02 per stakeholder request.

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.

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. Amendments include removing regulatory restrictions in accordance with SB 9 of the 134th General Assembly. Appendix A to this rule is the State of Ohio DNR Order form. The form is being revised to:

- Remove the requirement for a physician's signature in addition to an APRN and PAs to match current revised code of ORC 2133.211.
- Reorganizing language which includes moving language from the bottom of the form to the top of the form that restricts writing any other medical orders than what's on the form. Stakeholders requested this as this was an identified issue and doing so will be easier to identify for providers.
- Updating language to allow for clear language for providers and patients filling out the form.

Changes made:

- Based on stakeholder's comments, the word "Optional" has been added to Appendix A under "Patient or Authorized Representative's Signature."
- Changes made to (A)(6) per stakeholder request:

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(A)(6) A wallet card bearing the logo and the individual's identifying information as depicted in appendix D to this rule. If the person is a "DNR Comfort Care - Arrest" patient as specified in rule 3701-62-05 of the Administrative Code, the wallet card will also include the word "arrest". This card may be reproduced as needed; and

• Changes made to grammatical and technical errors on Appendix A per stakeholder request.

3701-62-05

The rule establishes the DNR Protocol and when it becomes effective. Amendments include removing regulatory restrictions in accordance with SB 9 of the 134th General Assembly. The appendix to this rule establishes the DNR Protocol.

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 to issue 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. Amendments include removing regulatory restrictions in accordance with SB 9 of the 134th General Assembly.

3701-62-07

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. Amendments include removing regulatory restrictions in accordance with SB 9 of the 134th General Assembly.

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, do not interfere with the transfer of the person to a provider who will follow the DNR Protocol. Amendments include removing regulatory restrictions in accordance with SB 9 of the 134th General Assembly.

3701-62-09

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. Amendments include removing regulatory restrictions in accordance with SB 9 of the 134th General Assembly.

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• Changes made to (C)(2)(b) and (c) per stakeholder request:

(b) A transparent hospital-type bracelet with an insert containing the logo and identifying information as depicted in appendix B to rule 3701-63-04 of the Administrative Code. If the person is a "DNR Comfort Care - Arrest" patient as specified in rule 3701-62-05 of the Administrative Code, the bracelet will also include the word "arrest";

(c) A wallet card bearing the logo and identifying information as depicted in appendix D to rule 3701-62-04 of the Administrative Code. If the person is a "DNR Comfort Care - Arrest" patient as specified in rule 3701-62-05 of the Administrative Code, the bracelet will also include the word "arrest"; or

3701-62-10

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, 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, in which the more recent document supersedes.

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.

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 because 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 on and after July 9, 1998, will not be impacted by an individual's choice to have a DNR. Amendments include removing regulatory restrictions in accordance with SB 9 of the 134th General Assembly.

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 if 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.

3701-62-14

The rule sets forth the prohibitions pertaining to a DNR Order and DNR identification. The rule prohibits a physician, APRN, or PA 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 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. Amendments include removing regulatory restrictions in accordance with SB 9 of the 134th General Assembly.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

ORC § 2133.25

4. Does the regulation implement a federal requirement? Is the proposed regulation 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? *If yes, please briefly explain the source and substance of the federal requirement.*

There are no federal requirements mandating these rules.

5. If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

6. 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.

7. How will the Agency measure the success of this regulation 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.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

Not applicable.

Development of the Regulation

9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

The Ohio Department of Health (ODH) held two in-person stakeholder meetings to discuss the five-year review of Do-Not-Resuscitate (DNR) Protocol Chapter 3701-62 as well as phone calls and emails with stakeholders by executive leadership. The first in-person meeting was held on January 24th, 2024, and the second meeting was both in-person and virtual and was held on May 14th, 2024. Each session had participants from various stakeholders, including:

Ohio Council for Homecare and Hospice

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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 State University Wexner Medical Center Palliative Care Council 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 Ohio Medical Board Ohio Board of Nursing Greater Columbus Pro-Life MedCare Ohio TriHealth Mercy Health Ohio Chapter of the American College of Emergency Physicians **Bioethics Network of Ohio** Ohio Department of Medicaid Nationwide Children's Hospital

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

In addition to in person stakeholder meetings, ongoing communication of the various stages of the draft rules occurred over the nine months from January 2024 to September 2024 and involved all the identified stakeholders throughout the process. Revisions to the DNR Protocol and Ohio DNR Order form are direct results of communications with stakeholders. Due to a lack of consensus on the Ohio DNR Order form, no substantive changes were made, and only necessary items were changed such as the removal of a physician's signature in addition to an APRN or PA's signature, and the reorganizing of language from the bottom of

the form to the top to avoid an identified issue in meetings of the providers writing other medical orders other than what's on the form.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Not applicable.

12. 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.

13. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

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

14. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is 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

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

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

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

The time necessary to complete the form.

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:

Physicians, All Other: \$130.31 per hour* Nurse Practitioners: \$59.07 per hour* Physician Assistants: \$57.67 per hour*

Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May 2023, using the codes physicians and all others (29-1229), nurse practitioners (29-1171), and physician assistant (29-1071).

16. Are there any proposed changes to the rules that will <u>reduce</u> a regulatory burden imposed on the business community? Please identify.

Not applicable.

17. 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

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

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

19. 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.

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

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