

# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

Agency Name: State Medical Board

Regulation/Package Title: Rule 4731-14-01

Rule Number(s): Rule 4731-14-01

Date: \_\_\_\_\_

**Rule Type:**

New

Amended

5-Year Review

Rescinded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 regulation in plain language.**

*Please include the key provisions of the regulation as well as any proposed amendments.*

Rule 4731-14-01 specifies who may pronounce a person dead and who may serve as a competent observer to recite the facts of the person's present medical condition to a physician so that the physician may pronounce the person dead without personally examining

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the body. The rule is significantly amended, therefore, the current rule is being rescinded and a new rule adopted.

**2. Please list the Ohio statute authorizing the Agency to adopt this regulation.**

The rule is authorized by Sections 4731.05 and 4731.053, Ohio Revised Code.

**3. 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.*

The rule is not being adopted pursuant to federal law.

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

Not applicable.

**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)?**

The pronouncement of death of a person is the practice of medicine. Rule 4731-14-01 was originally enacted in 1990 in response to the health care community's concerns after a woman was pronounced dead, but regained consciousness on the embalming table. As a result, then Senator David Hobson convened meetings attended by representatives of paramedic groups, professional associations, the Coroners Association, Funeral Directors Association, and other groups. The outcome of the meetings was the recommendation that the Medical Board promulgate a rule to define who might serve as a "competent observer" to report the facts of a deceased person's medical condition so that a physician could pronounce death without personally examining the body. Section 4731.053, ORC, effective May 16, 2006, required the Medical Board to revise the rule to include a coroner's investigator as a competent observer. Section 4723.36, ORC, effective March 22, 2013, authorizes a certified nurse practitioner, clinical nurse specialist, and registered nurse to pronounce death in specified locations. Section 4730.092, ORC, effective March 22, 2013, authorizes a physician assistant to pronounce death in specified locations.

**6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

Clear and precise language specifying who may pronounce death and who may serve as a competent observer to recite the facts to a physician who cannot observe the body should result in only appropriately trained personnel serving as competent observers or pronouncing death, with no errors being made in pronouncements.

**Development of the Regulation**

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

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

The first step in proposing to revise the current rule was to seek review of proposed language by the Nursing Board, Chiropractic Board, and the Division of Emergency Medical Services. The proposed rule was then submitted to the Physician Assistant Policy Committee (“PAPC”). Pursuant to Section 4730.05, O.R.C., PAPC membership consists of three physician assistants, three physicians (including a physician member of the Medical Board) and a public member. On November 3, 2015, the PAPC recommended that the proposal to rescind the current rule and adopt the proposed new rule be considered by the Medical Board. The Medical Board approved the proposals for circulation to interested parties at its meeting on November 4, 2015. On November 9, 2015, the proposed rules were sent via e-mail to organizations such as, but not limited to, the Ohio Association of Physician Assistants, Ohio State Medical Association, Ohio Academy of Family Physicians, Academy of Medicine of Cleveland and Northern Ohio, Ohio Coroner’s Association, Ohio Podiatric Association, and Ohio Osteopathic Association; governmental affairs representatives for numerous organizations; and state agencies such as the Nursing Board, Chiropractic Board, Division of Emergency Medical Services, and Ohio Department of Health.

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

The original proposal included the requirement that all registered nurses, licensed practical nurses, chiropractors, podiatrists, and all levels of emergency medical technicians hold current certification in advanced cardiac life support (“ACLS”) to serve as a person who can declare death or act as a competent observer to report the body’s condition to a remote physician who then declares death. The Nursing Board, Chiropractic Board, and Division of Emergency Medical Services all provided input that the ACLS certification was not required

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and would have serious adverse impact on the ability of their licensees to provide appropriate service related to the pronouncement of death.

The proposed language for the new rule was sent without any changes to the interested parties on November 9, 2015. Comments were received from the Ohio Board of Nursing; Carol Cunningham, M.D., Medical Director for the Division of Emergency Medical Services; Ohio State Chiropractic Board; Vincent F. DeBono, DC, Dean of the College of Chiropractic, Logan University; Mindy Leah, Senior Director, Registrar, Palmer College of Chiropractic; and Joseph Steifel, DC, President, National University of Health Sciences. All of the commenters stated that the requirement for ACLS certification would have a negative effect on the ability to declare death or serve as a competent observer. The Medical Board removed the requirement from the proposed rule.

**9. 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?**

Some of the amendments to the rule are prompted by legislation that has authorized certified nurse practitioners, certified clinical nurse specialists, registered nurses, and physician assistants to pronounce death in certain situations and other legislation that has created additional types of licenses for physicians (conceded eminence and clinical research faculty).

In recognition of the rigor of podiatric medical education and evolution of the practice, podiatric physicians were added to the listing of professionals who may pronounce death. The practice of podiatric medicine has evolved to require comprehensive education in total body systems, as is evidenced by the statutory authorization for podiatric physicians to perform surgery and prescribe drugs, including controlled substances, and the important role podiatric physicians play in identifying the early signs of systemic diseases so that the patients may be referred for specialist care.

**10. 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?**

No alternative regulations were considered. The rule was originally created at the behest of the medical community and legislators to prevent a repeat of what could have been a horrific tragedy. Since the rule was last reviewed certified nurse practitioners, clinical nurse specialists, registered nurses, and physician assistants were authorized to pronounce death in certain situations. The addition of podiatric physicians reflects evolution of the education and scope of practice of podiatric physicians (as discussed in Questions 9). The holders of

clinical research faculty certificates and conceded eminence certificates were added as they are newly enacted types of licenses for physicians.

**11. Did the Agency specifically consider a performance-based regulation? Please explain.**

*Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

The rule is performance-based in that it does not dictate the process that must be used to achieve compliance.

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

The Medical Board has not found any statutes, other than those referenced in the proposed rule, or additional rules that specify who may pronounce death. Health care facilities, funeral directors, health care professionals, and law enforcement look to Rule 4731-14-01, OAC, to provide guidance on who is authorized to pronounce death or serve as a competent observer. The amendment adds certified nurse practitioners, clinical nurse specialists, and registered nurses in the listing of individuals authorized to pronounce death, not as regulation, but in order to provide a convenient one-stop resource of authorized individuals. It is not duplicative to add physician assistants, to reflect authorization given in statute, or podiatric physicians to the rule because they are regulated only by the Medical Board. The inclusion of chiropractors, registered nurses, licensed practical nurses, emergency medical technicians, paramedics, and coroner's investigators in the listing of competent observers informs everyone of who may observe the body for the purpose of competently reporting the facts so that the physician may pronounce death without being present. The rule does not regulate the listed professions in any way.

In addition, the Medical Board solicited the input of the state agencies that license the pertinent health care professionals who are not licensed by the Medical Board. The Ohio Coroner's Association was informed of the proposed language, but provided no comments.

**13. 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.**

The rule will be distributed to the Coroners Association; Funeral Directors Association; state medical associations; Ohio Hospital Association; Ohio Health Care Association; Ohio Association of Home, Hospice, and Palliative Care; the Chiropractic Board; Division of Emergency Medical Services; Board of Nursing; law enforcement; Ohio Department of

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Health; and other interested parties; posted on the agency's website; included in the newsletter; and sent to licensees.

### **Adverse Impact to Business**

**14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**

**a. Identify the scope of the impacted business community;**

The rule has an adverse impact on business because, except for coroner's investigators, the listed professions require licensure. The impacted business community is made up of the listed professionals.

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

The rule has an adverse impact on business because, except for coroner's investigators, the listed professions require licensure.

**c. Quantify the expected adverse impact from the regulation.**

*The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.*

The adverse impact is the cost of licensure for each profession. Application fees vary: emergency medical technicians and paramedics pay no fee for original application or renewal; chiropractors pay a \$250 original application fee and \$500 biennial renewal fee; certified nurse practitioners and certified nurse specialists pay a \$100 original application fee and \$85 biennial renewal fee; registered nurses pay a \$75 original application fee and \$65 biennial renewal fee; allopathic, osteopathic, and podiatric physicians pay a \$300 original application fee and \$305 biennial renewal fee; physician assistants pay a \$500 original application fee and a \$200 biennial renewal fee; physician training certificate holders pay an original application fee of \$75 and a one-year renewal fee of \$35; physician clinical research faculty certificate holders pay an original application fee of \$375 for a three-year license and three-year renewal fee of \$375; physician special activities certificate holders pay an application fee of \$125, with the certificate non-renewable; and physician certificate of conceded eminence holders pay an original application fee of \$1,000 and a biennial renewal fee of \$1,000.

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

The pronouncement of death and the ability to competently recite the facts of a body's condition in order for a physician to rely upon the recitation to pronounce death require sufficient medical knowledge. Limiting the persons authorized to perform these essential functions to licensed medical personnel and the unlicensed coroner's investigators protects the public from the horrific outcome resulting from the errors caused by non-medically educated or experienced persons.

**Regulatory Flexibility**

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

The regulation provides multiple means for the pronouncement of death, including that the physician need not personally view the body but may rely on the facts reported by one of several professions that fall within the competent observer designation.

**17. 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?**

Violation of the rule is not a paperwork violation.

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

The Medical Board staff will provide customer service, including being available by telephone and mail. The staff may also make presentations when requested.

## Chapter 4731-14 Pronouncement of Death

### 4731-14-01 Pronouncement of death. TO BE RESCINDED

(A) For purposes of this rule, a "physician" refers to an individual holding a current certificate to practice medicine and surgery or osteopathic medicine and surgery.

(B) Only an individual holding a current certificate to practice medicine and surgery or osteopathic medicine and surgery issued under section [4731.14](#) of the Revised Code, a training certificate issued under section [4731.291](#) of the Revised Code, a visiting medical faculty certificate issued under section [4731.293](#) of the Revised Code or a special activities certificate issued under section [4731.294](#) of the Revised Code, in Ohio can pronounce a person dead.

(C) An individual as defined in paragraph (A) of this rule may pronounce a person dead without personally examining the body of the deceased only if a competent observer has recited the facts of the deceased's present medical condition to the physician and the physician is satisfied that death has occurred.

(D) For purposes of this rule a competent observer shall mean:

- (1) A registered nurse holding a current license issued under Chapter 4723. of the Revised Code;
- (2) A licensed practical nurse holding a current license issued under Chapter 4723. of the Revised Code;
- (3) An EMT-B holding a current certificate pursuant to section [4765.30](#) of the Revised Code;
- (4) An EMT-I holding a current certificate pursuant to section [4765.30](#) of the Revised Code;
- (5) A paramedic holding a current certificate pursuant to section [4765.30](#) of the Revised Code;
- (6) A physician assistant holding a current certificate to practice issued under Chapter 4730. of the Revised Code who has met all requirements of Chapter 4730. of the Revised Code;
- (7) A chiropractor holding a current certificate issued under Chapter 4734. of the Revised Code;
- (8) An individual authorized to pronounce a person dead under paragraph (B) of this rule or a person holding a current certificate to practice podiatric medicine and surgery in Ohio.
- (9) A coroner's investigator as referenced in section [313.05](#) of the Revised Code.

Effective: 06/30/2007

R.C. [119.032](#) review dates: 03/23/2007 and 06/30/2011

Promulgated Under: [119.03](#)

Statutory Authority: [4730.07](#), [4731.05](#)

Rule Amplifies: [4731.22](#), [4731.291](#), [4731.293](#), [4731.294](#), [4731.34](#)

Prior Effective Dates: 5/10/90, 5/31/02, 2/28/04

4731-14-01

**Pronouncement of death.**

(A) Only an individual holding one of the following current certificates or licenses may pronounce a person dead:

(1) A certificate to practice medicine and surgery or osteopathic medicine and surgery issued under sections 4731.14 or 4731.29 of the Revised Code;

(2) A training certificate issued under section 4731.291 of the Revised Code;

(3) A clinical research faculty certificate issued under section 4731.293 of the Revised Code;

(4) A special activities certificate issued under section 4731.294 of the Revised Code;

(5) A certificate of authority to practice as a certified nurse practitioner or clinical nurse specialist issued under section 4723.42 of the Revised Code, when the holder acts in compliance with section 4723.36 of the Revised Code;

(6) A license to practice as a registered nurse issued under section 4723.09 of the Revised Code, when the holder acts in compliance with section 4723.36 of the Revised Code.

(7) A license to practice as a physician assistant issued under section 4730.12 of the Revised Code, when the holder acts in compliance with section 4730.202 of the Revised Code;

(8) A certificate of conceded eminence issued under section 4731.297 of the Revised Code;

(9) A certificate to practice podiatric medicine and surgery issued under sections 4731.56, 4731.57, or 4731.571 of the Revised Code.

(B) A physician holding a current certificate to practice medicine or surgery or osteopathic medicine and surgery issued under sections 4731.14 or 4731.29 of the Revised Code may pronounce a person dead without personally examining the body of the deceased only if a competent observer has recited the facts of the deceased's present medical condition to the physician and the physician is satisfied that death has occurred.

(C) For purposes of this rule a competent observer shall mean one of the following:

(1) A licensed practical nurse holding a current license issued under Chapter 4723. of the Revised Code;

(2) An EMT-Basic holding a current certificate issued under section 4765.30 of the Revised Code;

(3) An EMT-Intermediate holding a current certificate issued under section 4765.30 of the Revised Code;

(4) A EMT - Paramedic holding a current certificate issued under section 4765.30 of the Revised Code;

(5) A chiropractor holding a current certificate issued under Chapter 4734. of the Revised Code;

(6) An individual authorized to pronounce a person dead under paragraph (A) of this rule;

(7) A coroner's investigator as referenced in section 313.05 of the Revised Code.