CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: **State Medical Board of Ohio**

Regulation/Package Title: **Delegation Rules**

Rule Number(s): **4731-23-01, 4731-23-02, 4731-23-03, and 4731-23-04**

Date: _____

Rule Type:

- ☐ **New**
- X **Amended**
- X **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- ☐ **Rescinded**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.

   Chapter 4731-23 contains the rules that set the standards by which physician delegation of medical tasks may be made to unlicensed individuals. Unlicensed individuals in a medical

setting may work under a title such as "medical assistant," "patient care assistant," or some similar title.

Rule 4731-23-01 contains definitions for terms used in the Chapter.

Rule 4731-23-02 sets forth the criteria a physician must use when determining whether a medical task may be delegated to an unlicensed person.

Rule 4731-23-03 sets forth the prohibitions applicable to delegation to an unlicensed person.

Rule 4731-23-04 sets forth the provisions of the Ohio Revised Code applicable for purposes of administrative license discipline should Rules 4731-23-02 or 4731-23-03 be violated.

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

   The rules are 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.***

   No, the rules do not implement a federal requirement.

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)?**

   Section 4731.053, Ohio Revised Code, requires the Medical Board to adopt rules that establish standards to be met and procedures to be followed by a physician with respect to the physician's delegation of medical tasks to an unlicensed person or person not specifically authorized by the Ohio Revised Code to perform the medical task.

   Enactment of Section 4731.053 of the Ohio Revised Code on April 10, 2001 was spurred by a formal Opinion issued by Ohio's Attorney General. In the Opinion (OAG 2000-023), the Attorney General declared that "[a] person who is not specifically authorized by statute to administer a drug or medicine is subject to the prohibition in [O.R.C.] 4731.41 against the unauthorized practice of medicine . . . even if such act is performed at the request of, or with the approval of, a licensed physician."

   The rules, therefore, protect the public from the harm that can be caused when a person without the training and education required to secure a license to practice in a health care

field performs a medical task, while at the same time allowing unlicensed personnel to participate in medical care. The rules clarify for physicians, health care licensees, unlicensed persons working in a health care setting, and the public what factors should be considered by a physician in determining whether an unlicensed person may deliver a medical-related task.

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

   The success of the rules will be measured by the number of disciplinary actions taken based on inappropriate delegation.

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 proposed rules were sent on January 15, 2016 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, and Ohio Osteopathic Association; governmental affairs representatives for numerous organizations; attorneys who appear before the Medical Board; and all others persons and organizations who have requested notice of Medical Board rule activity.

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

   No comments were received from any interested party.

   Subsequently it was discovered that terminology and statutes in Rule 4731-23-02 referencing what is now the Ohio Department of Developmental Disabilities needed to be amended to reflect statutory changes. Those amendments were made, but the rule was not re-sent for public comment.

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?**

   The rules reflect the provisions of Section 4731.053, Ohio Revised Code. The provisions can be summarized as requiring that the rules reflect consideration of the condition of the patient, qualifications of the person to whom the physician seeks to delegate, and the nature of the task to be delegated.

   Scientific data was not used to develop the rules. The rules, for which only one amendment is proposed, were written in 2001 and 2002 with the input of the Ohio Nurse's Association,

Ohio State Medical Association, Ohio Hospital Association, Ohio Department of Developmental Disabilities (at the time the name was "Ohio Department of Mental Retardation and Developmental Disabilities) and other interested parties who provided guidance on appropriate criteria and real-world need. At stated in response to Question 8, no comments were received in 2016 on the proposal to continue the rules with the only amendment being to the definition of "task."

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 rules were considered. The current rules have proven to provide the guidance needed for the provision of medical care in a manner that allows lower paid individuals to perform tasks while keeping patient care as the primary concern.

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.***

    Rule 4731-23-02 is a performance-based regulation. The rule defines the criteria to be applied in terms that allow the physician to make the necessary assessment of competency and safety by applying his/her medical judgment.

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

    The rules are required by Section 4731.053, Ohio Revised Code. The Medical Board is the only agency authorized to promulgate rules applicable to physician delegation of tasks to unlicensed persons.

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 only amended language proposed is a clarification of the definition of the word "task." This clarification will make it easier for physician to comply with the rule. The Medical Board will notify all physician licensees of the amendment and continuation of the rules otherwise. The Medical Board has applied the rule consistently and will continue to do so.

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 affected business community is composed of physicians, medical practices, and health care facilities that wish to employ unlicensed persons to perform certain medical-related tasks. The scope also includes individuals who wish to work as unlicensed persons in a medical setting.

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

The impact on physicians, medical practices, and health care facilities that wish to employ unlicensed persons to perform certain medical-related tasks is that the ability to delegate medical task is limited by the criteria that must be applied to determine the appropriateness of delegating the task. The impact on the unlicensed person is that they may not be able to deliver all of the medical services they have been educated to perform. Although the unlicensed person is not required to have completed any formal training, many do. Some training programs for medical assistants, for example, teach the performance of activities that exceed the definition of task or that are clearly prohibited by Rule 4731-23-03(F).

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 U.S. Bureau of Labor Statistics estimates that the average salary of a medical assistant ranges from $28,000 to $32,900. (See http://www.bls.gov/oes/current/oes319092.htm.)

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

It is well accepted in medical practice that an unlicensed person may be trained to competently perform certain medical tasks in order to free the physician and other medical staff (such as nurses) to perform higher-level services. Section 4731.053, Ohio Revised Code, requires the Medical Board to promulgate rules for delegation to unlicensed persons. The rules do not require that unlicensed personnel be used in a medical practice, but facilitate their use.

Regulatory Flexibility

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

No alternates or exemptions are provided. The protection of the public requires that in all medical settings the same standards be used to determine the competency of an unlicensed person to perform a medical task.

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?**

    No paperwork is required to be maintained or submitted to the Medical Board.

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

    The rules will be sent to all licensed physicians and interested parties and be posted on the Medical Board's website. Notice of the rules will be included in the Medical Board's e-newsletter that is emailed to all Medical Board licensees. Medical Board staff members are available to answer questions concerning the rules.

*** DRAFT - NOT YET FILED ***

4731-23-03 **Delegation of medical tasks; Prohibitions.**

(A) A physician shall not delegate the practice of medicine as defined in section 4731.34 of the Revised Code unless specifically authorized to do so in the Revised Code or by an administrative rule adopted pursuant to the Revised Code and which became effective prior to April 10, 2001. Nothing in this chapter of the Administrative Code shall prohibit the performance of emergency medical tasks.

(B) A physician shall not delegate a task to an unlicensed person if the task is beyond that person's competence. In a hospital, as defined in section 3727.01 of the Revised Code, or an ambulatory care center affiliated with the hospital (if the center meets the same credentialing, quality assurance, and utilization review standards as the hospital) wherein unlicensed persons are employed or otherwise authorized by the governing authority of the institution to perform specific medical tasks, one factor the physician shall take into account is the policies by which the employer or the governing authority of the institution seeks to ensure that competent persons will be performing the delegated tasks.

(C) A physician shall not delegate a medical task that is not within the authority of that physician or is beyond the physician's training, expertise, or normal course of practice.

(D) A physician shall not transfer his or her responsibility for supervising an unlicensed person in the performance of a delegated medical task, except to another physician who has knowingly accepted that responsibility.

(E) A physician shall not authorize or permit an unlicensed person to whom a medical task is delegated to delegate the performance of that task to another person.

(F) Except as provided in divisions (D)(4) to (D)(8) of section 4731.053 of the Revised Code, a physician shall not delegate to an unlicensed person the administration of anesthesia, controlled substances, or drugs administered intravenously.

(G) The supervising physician retains responsibility for the manner in which the delegated task is carried out.