CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Standards for Surgery

Rule Number(s): 4731-18-01 (Rescinded); 4731-25-08 (New)

Date: June 27, 2018

Rule Type:

X New

□ Amended

□ 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X Rescinded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 regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.
   The draft rule 4731-25-08 provides general requirements for a surgeon of record in an operative case including patient evaluation for preoperative diagnosis and appropriateness for operation selected; selection of appropriate operation; assuring informed consent; performing or supervising the surgery; and management of post-operative medical care. This rule

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

replaces 4731-18-01with minor grammatical changes. Consequently, rule 4731-18-01 is being rescinded.

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

   R.C. 4731.05 authorizes this regulation.

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?**
   The regulation does not implement a federal requirement, nor is it being adopted in connection with administering or enforcing a federal law or participating in a federal program.

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

   The question is 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 public purpose for this regulation is to protect public safety in the practice of surgery.

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

   The success of this regulation will be measured by the rule being written in plain, understandable language, licensee compliance with the rule, and minimal questions from the licensees about this rule.

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.
   On January 10, 2018, the Medical Board's Policy Committee reviewed and discussed the draft rule at its meeting. The Policy Committee approved the draft rule for initial circulation at this open public meeting.

On January 17, 2018, the draft rule was posted on the Medical Board's website. Subsequently on the same date, Board staff circulated a link to the proposed rule by email to solicit written comments from interested parties which included medical associations; governmental affairs representatives for numerous organizations; attorneys who appear before the Medical Board; and other persons who have requested notice of Medical Board rule activity. A link to the draft rule was also sent to selected licensees including all doctors, physician assistants, and cosmetic therapists. The deadline for submitting comments was February 2, 2018. The Medical Board received one comment on the draft rule.

On March 14, 2018, the Medical Board's Policy Committee and the full Board reviewed and discussed the draft rule and the comment received. Both meetings were open to the public.

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

   A written comment was received from the Ohio Association of Physician Assistants ("OAPA") which suggested changing the draft rule's delegation of aspects of postoperative care to aspects of intra-and perioperative care to expand the rule to reflect additional services that physician assistants perform. In addition, OAPA did not agree with including physician assistants within the term "allied health personnel", and instead suggested adding a separate specific reference to physician assistant in addition to allied health personnel. The suggested changes from this comment were not made to this rule which is focused on the duties and responsibilities of the surgeon of record.

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 Medical Board did not use scientific data to develop the rule or the measurable outcomes of the rule. The draft rule was developed with plain language and common sense to reflect minimum requirements for a surgeon of record.

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?**

    The Medical Board did not consider regulatory alternatives. The draft rule is continuing the requirements of the current rule 4731-18-01 with minor grammatical changes.

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 draft rule is performance based. For example in paragraph (B), it gives the surgeon of record four options to fulfill the surgeon's responsibility to manage postoperative medical care, but does not specify which one it must be.

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

    Medical Board staff reviewed this regulation to ensure that it does not duplicate an existing regulation. The draft rule in 4731-25-08 is replacing the existing rule in 4731-18-01.

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 rules will be posted on the Medical Board's website and notice of the rule will be circulated to the interested parties listed in question 7. Medical Board staff members will be available to answer questions regarding the rule. The Board's investigators and attorneys will be made aware of the rule's provisions so that the rule can be fairly, consistently, and predictably applied to the regulated community.

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 scope of the impacted business community is physicians who are surgeons.

    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
       There is an impact in physician time to fulfill communication requirements with patients about the surgery including evaluation of the patient and assuring that the patient or their representative is able to give informed consent to the surgery.

    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 minimal as the draft rule sets general requirements that a surgeon of record must do in preparation for and performance of surgery as well as for management of postoperative care. These requirements are items that a responsible surgeon would and should do.

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

The Board determined that protecting patient safety justifies the minimal adverse impact to the regulated business community because surgery involves serious invasive procedures that should have some minimal requirements to ensure public safety.

Regulatory Flexibility

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

The public safety requirements of the rule require consistent application and therefore there are no exemptions or alternative means of compliance.

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?

Due process requires the Medical Board to consistently apply this rule to all physicians who are surgeons of record so that all physicians are treated equally under the rule.

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

Medical Board staff members are available to answer questions about this rule.