

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Dental Board

Regulation/Package Title: 2017 Acute Prescribing of Opioids

Rule Number(s): O.A.C. 4715-3-01 (Amended) & 4715-6-02 (New)

Date: May 11th 2017

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☐ Rescinded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.

Amendment

- **4715-3-01 Definitions.** This rule creates a category of prescribing terms to the definitions.

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- **4715-6-02 Prescribing Opioid Analgesics for Acute Pain.** This rule sets forth the specific requirements for a dentist to prescribe opioid analgesics for acute pain.
2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**
O.R.C. 4715.03
 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.**
This regulation does not implement a federal requirement nor was it implemented to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate 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.**
This question is not applicable since the regulation does not implement a federal requirement.
 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)?**
Ohio is experiencing an opioid epidemic that greatly impacts public health. The Governor has directed that the state's professional licensing boards adopt rules to affect and improve public health. The purpose of these rules is to reduce the frequency and amount of opioids prescribed for acute pain while preserving the ability for dentists to prescribe beyond the limits imposed when it is appropriate based on the patient's needs and the dentist's clinical judgment.
 6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**
The outcomes from limiting opioid prescribing will be measured by OARRS data and other public health related statistics. Success will be achieved and measured by having clear rules which result in licensee compliance.

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 Board's Law and Rules Review Committee holds open meetings throughout the rule review year. The Committee is comprised of seven (7) members including representatives

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from the Ohio Dental Association and the Ohio Dental Hygienists' Association. Additionally, the Board sends public notices and proposed Rule Review agendas to the Board mailing list, a listing comprised of parties interested in all Board proceedings. The committee met to discuss these rules on April 8, 2017 and May 10, 2017. At both meetings, the committee received and considered public comments from stakeholders. Following the April 8, 2017 Committee meeting, the draft rules were posted on the Board's website and emailed to stakeholders for comment and input. These comments were shared with the Committee when it reviewed the rule on May 10, 2017 and modifications were made to the Rule to reflect the comments received.

The Dental Board discussed the Rule package at its Board meeting on May 10, 2017 and unanimously voted to send the rule to CSI. Simultaneous with this filing, the Board will be re-posting the Rules and the BIA on the Board's website and will be sending these documents out via email to the Board's email list.

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

The Board received support of the new rule (OAC 4715-6-02) from the Ohio Dental Association.

The Board also received written comments from the Ohio Society of Oral and Maxillofacial Surgery and several of its members. These comments expressed concerns over the 30 MED daily limit. In response to these comments and the comments received by individuals who appeared at the April 8, 2017 meeting and the May 10, 2017 meeting, the Board drafted language which allows a prescriber to exceed the 30 MED limit for the 72 hours following the procedure.

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 Board relied on expertise by licensees with relevant experience, professional associations and education providers and scientific data. The GCOAT guidelines and OARRS data were also relied on and used as a scientific data source for the rules.

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 Board did not consider further alternative regulations for this rule package.

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.

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The Board did not propose performance-based regulations in this rule package due to the necessity of setting established processes and standards to achieve its public protection mandate.

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

These measures are being taken in concert with GCOAT, stakeholder Cabinet agencies, other professional licensing board and other stakeholders, including licensees with expertise in their professional specialties. SB 319 granted specific authority for the professional licensing Boards to promulgate rules targeting this issue. Staff reviewed the rules with a focus on eliminating obsolete, unnecessary and redundant rules, correcting typographical errors and avoiding duplication.

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 Board will continue to use its website to educate and update licensees on its rules. Board employees provide information to applicants upon request and for clarification purposes. Staff training is conducted for rule changes to ensure that regulations are applied consistently. Also, the Board will work with professional licensing boards, and the Ohio Dental Association to educate and regulate licensees on Board rules.

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;

Those impacted may include the public, their employers, and individuals licensed by ORC Chapter 4715, education and training programs and other health care providers, employers and entities such as insurers.

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

Individuals are required to have a license meet various conditions for licensure to obtain and renew their licenses. Licenses issued by the Board are required to meet minimal standards of care. If they fail to do so the licensee is subject to possible discipline.

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

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“representative *business*.” Please include the source for your information/estimated impact.

There is no anticipated adverse impact cost attached to these rules.

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

Ohio is suffering from an opioid epidemic. The regulatory intent justifies any impact to business that may be caused by these rules.

Regulatory Flexibility

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

These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and, therefore, they apply to all licensed dentists.

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?

O.R.C. 4715 does not allow for the implementation of fines or penalties. Therefore, this is not applicable.

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

Resources available to assist small businesses with compliance are the Board’s law, rules, and policies online at the Board’s website. Additionally, Board staff respond verbally and in writing to queries from interested parties.