



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio State Dental Board

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Ohio Automated RX Reporting System (OARRS) & Acute Prescribing-Opioids

Rule Number(s): 4715-6-01 and 4715-6-02

Date of Submission for CSI Review: 10/26/2022

Public Comment Period End Date: 11/04/2022

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/ X rules (FYR? Y)

Rescinded/___ rules (FYR?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. **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.**

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

4715-6-01 Standards and procedures for review of “Ohio Automated RX Reporting System” (OARRS)- This rule sets forth the specific requirements and procedures for licenses to follow while checking OARRS.

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.

Amendments to these rules are to correct references and typographical errors.

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.**

Authorized by:

O.R.C. 4715.03 Board organization-examinations.

O.R.C. 4715.302 Dentists review of patient information available through drug database.

O.R.C. 3719.062 Adoption of rules by health-related licensing board regarding opioid analgesics.

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Amplifies:

O.R.C. 4715.30 Disciplinary Actions.

O.R.C. 4715.302 Dentists review of patient information available through drug database.

O.R.C. 3719.062 Adoption of rules by health-related licensing board regarding opioid analgesics.

- 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.

These regulations do not implement a federal requirement, nor were they implemented to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program.

- 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.**

This question is not applicable. The regulations do not implement a federal requirement.

- 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)?**

4715-6-01 - These regulations allow the Board to carry out its statutory mission to ensure protection of the public by setting requirements and procedures for dentists while accessing the OARRS database.

4715-6-02 - 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 quantity 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.

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

4715-6-01 - The success of the regulation will be measured by the licensees understanding or legal objections to the rule.

4715-6-02 - 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.

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- 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.**

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

The Board and the Board's Law and Rule Review Committee hold open meetings throughout the rule review year. Additionally, the Board sends public notices and proposed Rule Review agendas to the Board mailing list, a listing of parties interested in all Board proceedings. Simultaneous with this filing, the Board will be posting/re-posting the Rule and the revised BIA on the Board's website and will be sending these documents out via email to the Board's email list.

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

Discussion by the Board resulted in the conclusion that no input was sought since the amendments were to correct reference errors and non-substantive in nature.

- 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?**

Scientific data was not used to develop the rules as these rules are not data driven.

- 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? *Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

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

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

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.

- 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.**

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The Board will continue to use its website to educate and update licensees on its rules. The Board will work with Stakeholders and licensees to make sure the implementation, or continued implementation process of this rule is smooth and consistent between all parties involved.

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

The rules impact dentists/providers, patients, and insurers throughout the state.

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

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 includes the administrative effort necessary to perform OARRS checks, time to search for diagnosis codes, time to examine patients again to refill a prescription, and to document patient interactions in the system. The dentist may incur cost affiliated with updating a controlled substance electronic prescribing system. Dentists will be required to comply with the prescribing limits to meet the standard of care and maintain licensure. Additional adverse impact may be in disciplinary action by the Board for non-compliance or substandard care to the patients.

If the dentist fails to comply with OARRS reporting requirements or fails to meet the minimum standard of care in complying with the prescribing requirements, the Board may implement disciplinary action in the form of ethics training, continuing education, probation, suspension, or revocation of the dentist's license to practice.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).

There are no changes to the rules that will either reduce or increase a regulatory burden on the business community.

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

The Board believes that the adverse impact to dentists is necessary to enable the Board to carry out its statutory mission of protecting the public by setting requirements and procedures

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for dentists to access and use the OARRS database. Additionally, the Board believes that the regulatory intent of the rules outweighs any adverse impact due to the ongoing opioid epidemic in Ohio.

Regulatory Flexibility

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

These rules do not provide any exemption or alternative means of compliance for small businesses. All licensed dental personnel under R.C. 4715 must have a license or certificate to provide services in Ohio. The law does not differentiate on the size of the business and therefore, these rules apply to all licensed, certified, or registered dental personnel.

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?

ORC 4715. does not allow the imposition of fines or civil penalties. Therefore, this is not applicable.

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

Resources available to assist small businesses/stakeholders with compliance are online access to Chapter 4715 of the Ohio Revised and Administrative Codes. Additionally, Board staff regularly respond to inquiries from interested parties.