Business Impact Analysis

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

Rule Contact Name and Contact Information:
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Regulation/Packaging Title (a general description of the rules’ substantive content):
Moderate and Deep Sedation and General Anesthesia

Rule Number(s):
4715-5-05, 4715-5-06, 4715-5-07

Date of Submission for CSI Review: 12/2/2021

Public Comment Period End Date: 12/17/2021

Rule Type/Number of Rules:
New/ X__ rules
Amended/ _X_ rules (FYR? ___)
No Change/____ rules (FYR? _X_)
Rescinded/___X_ rules (FYR?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.
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.*

To be Rescinded and New

- **4715-5-05 Use of general anesthesia and deep sedation.** The Board is rescinding this rule and making it a new rule due to being over the 50% amendment threshold. The new rule sets forth the Board’s specific guidelines for the application of a permit and the use of general anesthesia by licensed dentists.

- **4715-5-07 Use of conscious sedation. (To be rescinded)**

- **4715-5-07 Use of moderate sedation. (New)** The Board is rescinding this rule and making it a new rule due to being over the 50% amendment threshold. The new rule sets forth the Board’s specific guidelines for the application of a permit and the use of conscious sedation by licensed dentists.
**Amended**

- **4715-5-06 Reports of Adverse Occurrence** This rule sets forth the specific requirements for an office to report an adverse occurrence. The amendment to this rule is to clarify adverse occurrence, clarify the timeframe, and update the permit name.

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.

**Authorizes by:**

O.R.C 4715.03

**Amplifies:**

O.R.C. 4715.03 Board Organization- exams.

O.R.C. 4715.13 Fees for licenses or permits.

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 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)?

The General Assembly determined that the profession of dentistry required regulation and established a Board to license individuals and enforce the law and rules governing the practice of dentistry in Ohio.

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

The rule is not a quantitative regulation, nor does it impose a measurable (if any) quantitative burden on the licensee. The success of the regulation will be measured by the licensees understanding or legal objections to the rule.

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’s Law and Rules Review Committee holds open meetings throughout the rule review year with the Ohio Dental Association and Dental Hygiene 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.

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 Committee resulted in the changes made to these rules.

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?
No alternative regulations were considered by the agency since it was determined that the rules worked as intended by legislature.

13. 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 Board did not see an application for the rules in this package to be performance-based.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?
The five-year rule review process is conducted with a focus on eliminating obsolete, unnecessary, and redundant rules and avoiding duplication. In addition, meetings with interested parties help to ensure that these rules do not duplicate any existing Ohio regulation.

15. **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 informational presentations to stakeholder organizations and groups of dental personnel to keep the dental profession apprised of current regulations. Stakeholder organizations also ensure that rules are provided to their members through communications and CE. Staff training is conducted for rule changes to ensure that regulations are applied consistently.

**Adverse Impact to Business**

16. **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; and**

   Dentists holding general anesthesia and conscious (moderate) sedation permits and those dentists applying for permits.

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

   Dentists are required to be licensed in Ohio and must apply to obtain permits for providing general anesthesia and/or moderate sedation to citizens of Ohio prior to administration. In order to obtain a general anesthesia/moderate sedation permit, licensed dentists must meet the didactic and clinical education, training and examination requirements set forth by the Board. Additionally, once an application is submitted, a facility evaluation which includes, but is not limited to, an evaluation of appropriate armamentarium, personnel, facility requirements, and emergency protocols along with a clinical evaluation in the administration of general anesthesia/moderate sedation must be successfully completed and graded by an appropriately trained and permitted oral and maxillofacial surgeon.

**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.

Each dentist who wants to obtain a general anesthesia or moderate sedation permit must apply to the Board office. The application fee for each permit is $127 with evaluation fees of $200 for moderate sedation and $400 for general anesthesia. These costs are in addition to the education and training required for the permits. Education and training may be completed during specific dental residency programs such as oral and maxillofacial surgery or pediatric residencies at accredited dental programs or moderate sedation education and training may be completed as a continuing education training provided at an accredited institution.

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

ORC 4715.03 requires the Ohio State Dental Board to regulate eligibility criteria, application procedures, and safe practice standards by a dentist. These rules help to fulfill the Board’s statutory mission of protection of the public.

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 ORC 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?

O.R.C. 4715 does not allow for the implementation of fines or 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 the Ohio Revised and Administrative Codes. Additionally, Board staff regularly respond to inquiries from interested parties.