

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Dental Board

Regulation/Package Title: 2015 – Chapter 20

Rule Number(s) 4715-20-03

Date: December 7, 2015

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 Rescinded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.

No Change

- **4715-20-03 Disposal of sharps.:** This rule sets forth the guidelines for the disposal of sharps in the dental office. Amendments to the rule allow the Board the flexibility to set forth the disposal methods by policy.

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

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

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

- 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.

The proposed amendment does not implement a federal requirement or being amended 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 proposed amendment 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)?**

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. ORC 4715.03(C)(1)(b) and (C)(2) mandate that the Board adopt rules that establish and define universal blood and body fluid precautions in the dental practice.

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

Success will be measured by having a clear rule written in plain language, by licensees compliance with the rule, and minimal questions from licensees regarding requirements of the 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.

The Board's Law and Rules Review Committee (Committee) holds open meetings throughout the rule review year. The Committee is comprised of eleven (11) members including representatives of the Board, 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 of parties interested in all Board proceedings. The Committee met with the opportunity to discuss these rules in July, September, and December 2014.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

8. 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 and by the full Board resulted in the conclusion that this rule is working as intended by the legislature and that the only changes made were to provide flexibility by the Board to set forth the disposal methods by policy.

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?

ORC 4715.03(C)(1)(b) and (C)(2) require the Board to adopt rules to establish and define universal blood and body fluid precautions including handwashing, disinfection and sterilization of equipment, handling and disposal of needles, gloves, and other garments and devices. These rules were first put into place in 1987, are considered a model for other state boards to follow, and are based on Food and Drug Administration (FDA) and Centers for Disease Control (CDC) standards.

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 regulations were considered by the agency since it was determined that the rule worked as intended by legislature.

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 Board did not see an application for the rule to be performance-based.

12. 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.

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 and social media links to educate and update licensees on its rules. Board employees provide informational presentations to stakeholder organizations and groups of dental personnel in an effort to keep the dental profession apprised of current regulations. Stakeholder organizations also ensure that rules, particularly

amended rules are provided to their members through communications and CE opportunities. Staff training is conducted for rule changes to ensure that regulations are applied consistently.

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;

OAC Chapter 4715-20 impacts licensees by mandating that the minimum infection control procedures and appropriate disposal of sharps within the dental practice.

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

The nature of the adverse impact of the rule is in the purchase of proper containers for the disposal of sharps and the cost of disposal and in the handling of sharps.

Additionally, if a licensee is not in compliance with the infection control law and rule and it comes to the attention of the Board, the licensee may, if the violation is not corrected, be subject to discipline by the Board.

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 cost to the licensee to comply varies depending on cost as set forth by manufacturers of sharps disposal containers and the entities who provide disposal services. Additionally, the cost for any violation of this infection control rule is the could be only a time commitment to as much as obtaining continuing education in infection control and ethics that would be in addition to complying with the original continuing education requirements. There may also be time involved to complete any Board-ordered additional continuing education.

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

The Board is solely responsible for ensuring that only competent and safe practitioners are permitted to practice dental radiography in Ohio. Therefore, following infection control protocols ensures protection of the public.

Regulatory Flexibility

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

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

These rules do not provide any exemptions 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, applies to all licensed, certified, or registered providers.

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?

ORC 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/stakeholders with compliance are online access to the Ohio Revised and Administrative Codes. Additionally, Board staff regularly respond to inquiries from interested parties.

PATIENT AND PERSONAL PROTECTION

4715-20-03 DISPOSAL OF SHARPS.

All sharps items must be disposed of in containers specifically designed and manufactured for the management and/or disposal of sharps in accordance with the requirements established by ~~local and state environmental agencies~~ board policy.