1	EXPEDITE		
2	■ No hearing set		
	☐ Hearing is set ☐ Date:		
3	Time: Judge/Calendar:		
4	Judge/ Carolicut.		
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6	IN AND FOR THURSTON COUNTY		
7			
	WASHINGTON STATE DENTAL		
8	ASSOCIATION,	No	
9	Petitioner,	PETITION FOR DECLARATORY JUDGMENT AND INJUNCTIVE	
10	vs.	RELIEF PURSUANT TO RCW 34.05	
11	WASHINGTON STATE BOARD OF		
12	DENTURISTS,		
13	Respondent.		
14			
15			
	Petitioner, the Washington State Dental Association ("WSDA"), alleges as follows:		
16	INTRODUCTION		
17			
18	1. This is an action for declaratory relief from improper rulemaking and for other		
19	relief under RCW Ch. 34.05, the Washington Administrative Procedure Act ("APA").		
20	Petitioner is an association whose membership includes more than 4,200 Washington dentists.		
21	The Board of Denturists ("Board"), promulgated the new WAC 246-812-462, effective January		
22	2 22, 2024, that purports to "establish[] the requirements that are to be followed in order for a		
23	licensed denturist to place a prefabricated implant	abutment on an implant for the nurnose of	
24	neensed denturist to place a prefabilicated implant	abutificition an implant for the purpose of	
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26	WSDA PETITION - PAGE 1		
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fabricating, repairing, relining, or rebasing a denture." The new rule exceeds the Board's statutory authority, was adopted without compliance with statutory rule-making procedures, and is arbitrary and capricious. On behalf of its members, WSDA seeks an order declaring the new rule invalid and enjoining the state from implementing it.

JURISDICTION AND VENUE

- 2. The Court has jurisdiction to hear the petition because the new rule, or its threatened application, interferes with or impairs, or immediately threatens to interfere with or impair, the legal rights or privileges of WSDA's members. RCW 34.05.570(2). There is no requirement that WSDA or its members exhaust administrative remedies or take any other action prior to bringing this petition. RCW 35.05.534(1).
 - 3. Venue in this Court is proper under RCW 34.05.570(2).

PARTIES

4. Petitioner, the Washington State Dental Association, is a Washington not-for-profit corporation, with principal offices in Seattle, Washington. WSDA's membership includes more than 4,200 Washington dentists. WSDA's purpose includes advocacy for reduced costs in oral health care; protecting the doctor-patient relationship; and promotion of health and safety of all people in Washington. The mailing address for WSDA is 126 N.W. Canal Street, Suite 300, Seattle, WA 98107.

- WSDA is represented by Emily R. Studebaker and Barbra Z. Nault of
 Studebaker Nault, PLLC, whose mailing address is 11900 N.E. 1st Street, Suite 300, Bellevue,
 WA 98005.
- 6. Respondent, the Board of Denturists, is a board within the Washington State Department of Health that is responsible for regulating the competency and quality of denturists. The mailing address for the Board is PO Box 47852, Olympia, WA 98504-7852.
- 7. There were no adjudicative proceedings before the Board relating to the new rule at issue here.

AGENCY RULE AT ISSUE

8. The agency rule at issue is new rule WAC 246-812-462 that purports to "establish[] the requirements that are to be followed in order for a licensed denturist to place a prefabricated implant abutment on an implant for the purpose of fabricating, repairing, relining, or rebasing a denture," filed on or about December 22, 2023, under WSR 24-02-029 (the "New Abutment Rule"). A true and correct copy of the Rule-Making Order filed in the Office of the Code Reviser is attached hereto as Appendix A.

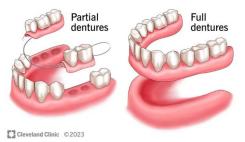
BACKGROUND AND FACTS

9. Enacted in 1994, chapter 18.30 of the Revised Code of Washington establishes denturists as a licensed profession in the State of Washington. At that time, the Board of Denturists was established. The duties of the Board relate solely to education, licensure, and continuing competency of licensed denturists. RCW 18.30.065.

10. Denturists are defined as those who engage in the "practice of denturism." Pertinent to this Petition, the practice of denturism includes (a) "[m]aking, placing, constructing, altering, reproducing, or repairing a denture," (b) "[t]aking impressions and furnishing or supplying a denture directly to a person or advising the use of a denture, and maintaining a facility for the same." RCW 18.30.010(5). The statute defines "denture" as "a *removable* full or partial upper or lower dental appliance to be worn in the mouth to replace missing natural teeth." RCW 18.30.010(2) (emphasis added). "Removable," while not defined in Chapter 18.30, is a common term understood to mean the opposite of "fixed." In oral health, "removable" refers to a device that is removable by the wearer without use of force or specialized tools.

11. The picture below depicts traditional dentures.

Dentures



https://my.clevelandclinic.org/health/treatments/10900-dentures. They can be taken in and taken out by the wearer with their fingers, which is frequently done for purposes of cleaning and comfort. No visit to a practitioner or special tool is needed for their removal.

13. In contrast to the device pictured above, dental implants are medical devices surgically implanted into the jaw to restore a person's ability to chew or their appearance. An implant may be one tooth or may be used to affix an entire arch to the patient's jawbone. Once placed, the patient cannot remove implants with their own fingers. A patient would need to return to a practitioner with the proper tools and skill to remove them. The picture below depicts a dental implant system for individual teeth.

Structure of The Dental Implant System



https://www.fda.gov/medical-devices/dental-devices/dental-implants-what-you-should-know.

Pertinent to this Petition is the middle component called an "abutment," which serves as a support and attachment apparatus, secured to the implant as well as the crown or other prosthesis. There are prefabricated and custom abutments. A prefabricated abutment is a machine-manufactured post that attaches to the superior part of a dental implant and protrudes through the gingival tissues and onto which a crown is fitted.

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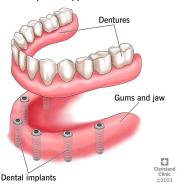
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14. The picture below depicts an entire arch of teeth secured to implant bodies.

Implant Supported Dentures



https://my.clevelandclinic.org/health/treatments/24303-implant-supported-dentures. As with the dental implant system for individual teeth shown above, a patient would need to return to a practitioner with the proper tools and skill to remove the implants.

- 15. Implants and dentures are not the same. Dentures are within the scope of practice of denturists, but implants have never been.
- 16. In February 2018, the Board received and reviewed an inquiry asking if placement of an implant abutment (described above) was within the scope of practice for a licensed denturist. In response, the Board wrote "yes . . . placement of an implant prefabricated abutment is within the scope of practice as listed under RCW 18.30.010(5)." The cited statute is the definition of "practice of denturist."
- 17. The decision sparked great concern in the dental community regarding the safety of the public. Those in opposition include WSDA, the Washington State Society of Prosthodontists, a retired dentist with 42 years of practice, the prosthodontic residency director for the University of Washington and who was formerly the prosthodontic program director for WSDA PETITION - PAGE 6

the US Army and the Prosthodontic Consultant to Surgeon General of the Army, and a fellow of the American College of Prosthodontics. Concerns of the dental community include:

- a. The process of placing implants and abutments is a significant medical process that leaves patients vulnerable to complications and unforeseen circumstances. Treatment of a patient with dental implants requires clinical judgment to determine health of the implant. This includes examination of soft tissues around the implant such as probing with a periodontal probe or visual/digital inspection and assessment of the bony support via radiograph evaluation. Many implant procedures require administration of anesthetics.
- b. Implants are prone to complications during placement and removal, including periimplantitis, occlusal load failure, and lack or loss of implant integration. Implants can also fail or become loose in the bone, and prosthetic components can break or snap.
- c. Proper implant treatment and management requires a comprehensive knowledge of pharmacology, physiology, and biomechanics. There are over 100 medications that affect bone health and the physiology of the oral cavity. Knowledge of these medications is necessary before implant therapy can be recommended.
- d. Implant restoration requires hundreds of hours of dental education and training and includes radiographic and surgical components. Denturist training does not include the skills necessary to safely make necessary assessments and perform all of

these tasks. The description given by denturists is oversimplified to shoehorn the task into denturist scope of practice, and it places the public at risk.

e. Authorization to perform assessments necessary for implants comes from an institution that has been accredited by the American Dental Association's Commission on Dental Accreditation (CODA). CODA explains why accreditation is important:

Accreditation is the ultimate source of consumer protection for prospective students. It is often a prerequisite for governmental funding. Graduation from an accredited program is almost always stipulated by state law and is an eligibility requirement for licensure and/or certification examinations. In short, accreditation of a school or program is a student's most important source of independent validation that the program has at least enough educational value to be "approved" by a credible (expertise-based), independent (free of outside influence), reliable (consistently applied standards) organization that has the U.S. Department of Education's approval."

https://coda.ada.org/. CODA accredits pre-doctoral and post-doctoral education through a vigorous inspection.

f. The requirement that a patient see a dentist for an exam and x-ray twice during the course of treatment in the New Abutment Rule is impractical and impossible to enforce. Most patients will refuse to go through the hassle, which will result in poor patient compliance and poor patient outcomes. There are already examples of poor patient outcomes resulting from a denturist attempting to manage implants.

- g. Implants are not included within the definition of "dentures." The definition of "dentures" is clear and unambiguous and require they be "removable." Implants are not removable. And unlike dentures, implants traverse the gum tissue.
- h. Implant restoration and soft tissue management is not within the clear and unambiguous scope of practice of denturism as defined in RCW 18.30, nor did the legislature intend to include implants when RCW 18.30 was enacted. It is an example of "scope of practice creep." The proper avenue to expand scope of practice is the legislature.
- i. Denturists do not carry the same liability insurance as dentists. If an issue rises, the patient may not have recourse.
- 18. In addition to community members, the Board received notice of concerns from the Washington State Dental Quality Assurance Commission ("DQAC"). DQAC is another Commission within the Department of Health. DQAC is comprised primarily of active, licensed dentists. RCW 18.32.0351. DQAC echoed the concerns of community members and expressed its view that placement of an implant prefabricated abutment is within the practice of dentistry and not within the practice of denturists. The basis for this view was safety of the patient stating that prefabricated abutments are not desirable in all scenarios and whether to use one is a decision that should be made by a licensed dentist. Similarly, the decision whether to use a prefabricated abutment versus a custom abutment is also one that is proper for a licensed dentist.

- 19. Despite being advised by many members of the dental health community that implants and dentures are not the same, that the proposed action would be contrary to law, contrary to decades of industry practice, arbitrary and unlawful, inconsistent with the design of the denturist scope of practice, unsafe for the public, unworkable, and would properly require legislative action, the Board set about to change the legislated and historical scope of the practice of denturists by administratively redefining "denture" to include "prefabricated implant abutments."
- 20. The Board commenced the APA rule-making process on February 15, 2022, WSR 22-05-084. Rather than accurately describe the new rule as changing the denturist's scope of practice, the Board described its proposed rulemaking as "establishing new sections of rule for requirements for prefabricated implant abutments."
- 21. During the APA rule-making process, an agency is required to address certain criteria before adopting significant legislative rules. RCW 34.05.328. Rather than addressing why the New Abutment Rule was needed, the Board ignored the actual Board duties and objectives and instead explained how the new rule answers a question that the Board received. WSR 22-05-084. The Board later stated that the new rule was needed "to set out the requirements that are to be followed in order for a licensed denturist to place an abutment on an implant." WSR 23-19-088. The Board offered no explanation for why such requirements were needed, or why denturists should be placing abutments at all.
- 22. In its comments on the rule, WSDA and several members of the dental community posed a series of questions and concerns intended to prompt a response by the WSDA PETITION PAGE 10

Board consistent with the RCW 34.05.328 requirements, including RCW 34.05.328(1)(d) and (1)(e), which require a determination that the benefit outweighs the cost, and consideration of alternatives. The Board failed to respond. The Board similarly failed to address coordination of the rule with other state laws, such as RCW 18.30.090 (setting forth denturist licensing requirements) and WAC 182-535-1050 (providing a different definition of "dentures" for Medicaid coverage that is now inconsistent). The Board was also ambiguous as to whether it performed a cost-benefit analysis as required by RCW 34.05.328(1)(c). Instead, the Board stated "if" a cost-benefit analysis were done, it would be available by contacting the Board. WSR 24-02-029. The Board therefore failed to sufficiently address the significant legislative rule criteria, and the New Abutment Rule was therefore adopted without compliance with statutory rule-making procedures.

23. During the rule-making process, an agency is also required to comply with the Regulatory Fairness Act, which requires the agency to prepare a small business impact statement, unless an exemption applies. RCW 19.85.025. In one of its filings with the Office of the Code Reviser, the Board stated that the New Abutment Rule was "fully exempt" from the Regulatory Fairness Act. WSR 23-19-088. No explanation was provided. Then in its final Rule-Making Order, WSR 24-02-029, the Board did not address the Regulatory Fairness Act.

Because the dental industry is comprised of both small (less than 50 employees) practices and large groups affiliated with dental service organizations (DSOs), the requisite analysis should have been completed. The New Abutment Rule was therefore adopted without compliance with statutory rule-making procedures.

- 24. Lastly, at the very end of its rule-making process, the Board changed the text of the proposed rule without receiving additional rule-making comments or having another public rule-making hearing. The Board simply changed the text of the proposed rule and implemented it. WSR 24-02-029. The Board therefore again failed to follow rule-making procedures, and the New Abutment Rule was adopted without compliance with statutory rule-making procedures.
- 25. The Board concluded its APA rule-making process on December 22, 2023, with publication of its Rule-Making Order, WSR 24-02-029. The new rule became effective on January 22, 2024. While the Board did not expressly change the definition of "denture" with its rulemaking, the effect of the new rule was exactly that to change the definition of "denture" to include prefabricated implant abutments.
- 26. In correspondence with a dental community member dated January 3, 2024, the Board indicated that failure to comply with the newly promulgated rule would subject denturists to disciplinary action.
- 27. Changing the scope of practice of denturists exceeds the statutory authority of the Board. Changing the definition of "dentures" exceeds the statutory authority of the Board. Adopting the New Abutment Rule exceeds the scope authority of the Board. Adopting the New Abutment Rule was arbitrary and capricious.
- 28. The New Abutment Rule will dramatically expand the activities of denturists without commensurate education and training. For example, despite concerns expressed regarding inadequate denturist training to handle complications during abutment placement, the

Board did not modify denturist education, training, or competency requirements. The New Abutment Rule is therefore arbitrary and capricious.

- 29. The New Abutment Rule will also create significant inefficiencies without any commensurate gain. As an example, the New Abutment Rule requires a dentist to pre-examine and approve the health of the implant before a denturist can attach a prefabricated abutment. In other words, a patient will first need to go visit a dentist, then schedule another appointment with a denturist. As a further complication, these two visits must occur within 90 days of each other. The Board failed to address the inefficiency of this process and did not explain why the dentist should not simply insert the abutment at the same time the dentist performed the pre-examination. This is another basis showing that the New Abutment Rule is arbitrary and capricious.
- 30. The requirement that a dentist pre-examine and "sign-off" on the implant prior to a denturist performing work without dentist oversight also poses substantial risk to the dentist. Should a complication arise when the denturist is working and a dentist is not present, the dentist may still get "blamed" since they signed off on the health of the implant pre-procedure. This exposes dentists to an unnecessary risk and would allow denturists to potentially shift responsibility to a dentist that is not present at the time the complication arises. This is another basis showing that the New Abutment Rule is arbitrary and capricious.
- 31. In sum, expanding the scope of practice of denturists to include placement of prefabricated implant abutments without legislative action exceeds the Board's statutory authority and impairs the rights of WSDA's member dentists. Under the New Abutment Rule,

dentists will be required to take more risk without a commensurate benefit; the New Abutment Rule imposes inefficiencies and delays in treatment without any countervailing benefit to patients; and the expanded scope of practice places the public at increased risk.

- 32. WSDA's members are aggrieved or will be adversely affected by the New Abutment Rule because (i) the Board action has prejudiced or is likely to prejudice the members; (ii) the members' asserted interests are among those the Board was required to consider; and (iii) the judicial relief sought would substantially eliminate the prejudice caused by the Board action.
- 33. WSDA has standing to represent the interests of its members in challenging the New Abutment Rule because (i) its members would otherwise have standing to sue in their own right; (ii) the interests it seeks to protect are germane to the association's purpose; and (iii) neither the claims asserted nor the relief requested require participation of individual members in the lawsuit.

CLAIMS

- 34. The allegations set forth above in paragraphs 1 through 33 are hereby incorporated by reference.
- 35. The New Abutment Rule, or its application, interferes with or impairs or immediately threatens to interfere with or impair the legal rights or privileges of WSDA's members.

- 36. The New Abutment Rule should be declared invalid and its implementation enjoined on the following grounds:
 - a. The New Abutment Rule exceeds the statutory authority of the Board and conflicts with the plain meaning of clear and unambiguous statutes.
 - b. The New Abutment Rule is arbitrary and capricious because it imposes an interpretation and implies a definition that contradicts the meaning of a clear and unambiguous statute, expands denturist responsibilities without a corresponding increase of education and training, exposes dentists to additional risk without being present to see procedures through, and is contrary to historical understanding for the past several decades.
 - c. The rule was adopted without compliance with statutory rule-making procedures by virtue of the Board's failure to adequately to address certain criteria before adopting significant legislative rules, by failing to conduct a cost-benefit analysis, by failing to comply with the Regulatory Fairness Act, and by changing the proposed text without further opportunity for public comment and hearing.

REQUEST FOR RELIEF

Petitioner WSDA respectfully requests the Court enter a judgment and order declaring the New Abutment Rule invalid and enjoining its implementation, and that it be awarded its costs and disbursements as permitted by law.

1	DATED this 2nd day of April, 2024.
2	STUDEBAKER NAULT, PLLC
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25	WSDA PETITION - PAGE 16
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