Montana Department of
LABOR & INDUSTRY

To: Montana Board of Dentistry
From: Galen Hollenbaugh, Commissioner of Labor
Date: December 15, 2017
Re: Active Supervision of Admin. R. Mont. 24.138.416 and 24.138.2302(1)(j)

I. Introduction

Mont. Code Ann. § 37-1-121 and -122, require the Commissioner of Labor, when necessary, to provide oversight and supervision of the duties and authority of the boards administratively assigned to the Montana Department of Labor & Industry. Pursuant to § 37-1-121(1)(d), the Commissioner shall exercise:

> active supervision authority to approve or disapprove any board action identified by the department as restraining or potentially restraining competition in trade or commerce. Subject to the provisions of 37-1-122(6), the commissioner shall determine if the board action is made or taken pursuant to a clearly articulated state policy and if the restraint or potential restraint of trade or commerce is reasonable and necessary to protect the public health, safety or welfare. Any approval or disapproval under this subsection (1)(d) must be in writing, comply with the provisions in 37-1-122, and set forth the particular reasons supporting the determination. A disapproval may include the commissioner's recommended modifications, if any, for the board's consideration.

Mont. Code Ann. § 37-1-122 sets forth the procedural requirements for active supervision, including the requirement that the Commissioner notify the affected board of the review to be undertaken, permit the board the opportunity to provide written comments and materials regarding the review, and meet with the board.

Pursuant to this statutory authority and obligation, I undertook review of Admin. R. Mont. 24.138.416 and 24.138.2302(1)(j) (the Rules), which are enacted and enforced by the Montana Board of Dentistry (Board). These rules state:

> The board of dentistry interprets 37-29-403(1)(b), MCA, to mean that all partial denture patients shall be referred to a dentist to determine what is needed prior to the denturist starting his services.

Admin. R. Mont. 24.138.416.

> The board defines "unprofessional conduct" as follows: ... (j) fitting, attempting to fit or advertising to fit a prosthesis on or over a dental implant.

Admin. R. Mont. 24.138.2302 (Rule J).

The Board licenses dentists, dental hygienists, and denturists. As of October 2017, there were 650 dentists, 735 dental hygienists, and 18 denturists licensed by the Board.

Based on a thorough review of the documentation and comments received throughout this process as well as careful consideration of the facts at hand, and for the reasons set forth herein, I have determined that both rules are approved.

II. Procedure for Active Supervision

On September 21, 2017, Judy Bovington, Chief Legal Counsel for DLI, on my behalf, notified the Board that supervision of the rules would occur. That notification informed the Board of its opportunity to meet with me and to provide written comments.

In addition, public comment was invited, through publication on October 27, 2017, in the Montana Administrative Register No. 24-2-325. This notice invited comments from the public in person at a hearing on November 3, 2017, and in writing, not later than November 9. Comments were received both orally and in writing, and written comments received after the cutoff date but prior to issuance of this memorandum were considered.

In summary, comments fell into three categories. First, comments from denturists currently in practice in Montana advocated that Rule J be stricken as a result of active supervision. Second, certain comments were received by patients of denturists. These patients spoke highly of the denturists they visited, and believed them capable of placing dentures over implants. Finally, comments were received from the Montana Dental Association, which will be discussed below.

I met with the Denturist Association of Montana (DAM) on October 16. DAM submitted written comment with respect to Rule J. DAM's written comments argued that Rule J should be stricken or modified on review. DAM noted that other states, most particularly Oregon, permit the practice of denturitry, and therefore that it should be equally permitted here. DAM recommended that Rule J be modified to create a referral process between denturists and dentists and to create an eight hour education requirement for denturists prior to their being permitted to place dentures over implants. In addition, DAM stated that implant retained dentures were relatively simple—the denture, once made, simply snapped onto the implants which had been placed by an oral surgeon, and the process was complete. Finally, DAM submitted course summaries from George Brown College for Implant Retained Removable Prosthodontics and Implant Prosthodontics II, as exemplars of the training undergone by denturists prior to the start of practice.

Further, I met on October 30 with the Board. The Board also provided various written submissions. Board members stated that the intention of Rule J had nothing to do with financial interests, but were instead simply to protect the public. The Board stated that, while a denture

could be snapped onto an implant, as argued by DAM, such was an incomplete picture of the placement of an implant over a denture. The Board argued that only dentists are properly trained to evaluate the proper placement of an implant in a jaw, and that they are able to diagnose issues which might arise with the implant—whether it was properly placed or not. The Board noted that half of dental implants have some problem, and nearly ten percent fail completely. As a result, the Board argued that the ability to diagnose and treat problems with the implants is important. The Board further argued the importance of being able to take and utilize a full medical history for the patient, since medical and lifestyle issues impact the success and failure of dental implants.

At that meeting, I also requested further information regarding the standard of care for dental implants following their placement.

I met with the Montana Dental Association (MDA) on November 17. MDA advocated that Rule J be retained as written. MDA further provided written comments for consideration. The MDA restated several of the points made by the Board. In addition, they emphasized the high failure rate of dental implants, and thus argued the importance of a dentist being permitted to diagnose and treat problems which might arise. MDA argued that the proposal submitted by DAM for a referral process and educational minimums was insufficient to protect the public. Finally, MDA noted that dentists are involved in the creation of a treatment plan for patients who might receive implants. They stated that dentists consider whether implants are likely to be successful, based on medical history. Then, they determine the proper location for the placement of implants to be inserted by an oral surgeon. Both steps, they argued, are outside the scope of practice and educational background for a denturist—with or without Rule J. However, they noted, incorrect placement of a dental implant could lead to severe problems.

Separate from the above, I note that the practice of denturitry in Montana has been the subject of a varied and litigious history. In 1984, the creation of the Board of Denturitry appeared, by citizen initiative, on the general election ballot as I-97. Soon thereafter, the Board of Denturitry was combined into the Board of Dentistry due a lack of denturitry licensees. Since that time, there have been numerous suits brought by denturists against the Board, attempting to invalidate placement of denturitry with the Board and rules enacted by the Board.

III. Analysis

As outlined above, I strove to receive comment from all those affected by the rule. I met with advocacy groups on each side of the issue, received comment from the Board and the public, and I reviewed the documentation submitted by all, including medical explanations based on current research on the issue, training materials for denturitry, and legal background. This analysis is based upon this thorough review of the subject matter, though it does not describe exhaustively every item received or reviewed.

The issues relating to Admin. R. Mont. 24.138.416 are rather simply resolved. At base, the rule operates as a restatement and minor clarification of the Board's understanding of the purpose of Mont. Code Ann. § 37-29-403, regarding the necessity of referral prior to the

placement of partial dentures. As such, the Legislature made the determination that such referral was required—the rule does little beyond what is required by the Legislature. Because the Board does not have discretion with regard to that rule, I affirm it here here.

The remainder of this analysis will focus on Rule J.

A. Medical Issues

Over many years, numerous academic papers studying the potential for medical harm relating to dental implants have been published. These studies were exhaustively documented and explained by the Board in their submission to me for consideration. In addition to reviewing that submission, I reviewed particular papers applicable to the question presented.

Of primary import, risk associated with dental implants are extensive and myriad. *See Clinical complications with implants and implant prostheses*, Goodacre, Charles J. *et al.*, The Journal of Prosthetic Dentistry, August 2003, pp 121-132. This article is a study of studies relating to dental implants, and therefore provides a broad, summary view of the risks associated with implants. Loss of implants is not uncommon:

> Data regarding implant loss with maxillary fixed complete dentures were provided in 9 studies with a mean loss of 10% (443 of 4559 implants). In the mandible, a 3% mean loss was recorded (255 of 9991 implants) from the combined data of 14 studies. With implant overdentures, the mean maxillary implant loss was 19% (206 of 1103 implants), and the mean mandibular implant loss was 4% (242 of 5683 implants). With both implant fixed complete dentures and implant overdentures, the implant loss in the maxilla was much greater than the mandibular implant loss.
>
> With implant fixed partial dentures, the maxillary and mandibular implant loss rates were the same. A mean loss of 6% was recorded in the maxilla (213 of 3297 implants) and a mean loss of 6% in the mandible.

Id. at 123 (internal citations removed). Goodacre summarized identified complications as follows:

> The literature identified the following 6 categories of complications associated with implant prostheses: surgical complications, implant loss, bone loss, peri-implant soft tissue complications, mechanical complications, and esthetic/phonetic complications. The most common surgical complications associated with implants were hemorrhage-related complications (24%), neurosensory disturbance (7%), and mandibular fracture (0.3%).

Id. at 127.

Put simply, it is not the case that, once placed, an implant need not be further monitored and studied. Instead, given the many and not uncommon varieties of complications relating specifically to dental implants, it is important that an individual trained, and able to diagnose and treat, with respect to the implant carefully monitor any changes.

Montana's Legislature, however, has determined that denturists are not able to "diagnose or treat any abnormalities, except that a licensed denturist may apply tissue conditioning agents." Mont. Code Ann. § 37-29-402(3). As such, while problems are common, Montana's Legislature has determined that denturists are unable to recognize or treat those problems. It is not the province of the Commissioner of Labor to second-guess the determinations made by the Legislature.

For this reason, it is my opinion that Rule J is necessary to protect the public's health and safety and that it must remain in full force and effect. Further, the rule stems from reasonably articulated state policy as set forth in the statutes cited above, as well as the more general obligations of the Board to protect the public and to set and enforce standards for practice under its purview. *See generally* Mont. Code Ann. § 37-1-131.

B. The referral process proposed by DAM is inadequate

Proposed by the Denturist Association of Montana was the enactment of a rule requiring referral of denture patients to dentists, and that simultaneously the Board enact a rule requiring educational standards for denturists. Based on my review of the proposal as well as the documents and comments received throughout this process, this proposal does not adequately protect the public from the potential medical harms outlined above.

As discussed, the risk of harm from dental implants comes not simply from the problematic creation and placement of a denture over the implant which could result in improper tensions and pressures on the implants themselves, but also from the general failure rate of the dental implants themselves. That is, even were the denture properly made, the implant itself might fail in the ways outlined above. Because denturists have been prohibited by the Legislature from diagnosing and treating problems which might arise relating to the implants, a mere referral requiring a dentist to review the work in the creation of the denture is insufficient.

It might be argued that post-insertion problems with implants are so obvious that, with or without medical training, a denturist can recognize the need to refer the patient to see a doctor. While certainly accurate in some circumstances, there are instances where the problem does not become readily apparent at a time when treatment can adequately be undertaken. In the anecdotal example provided by the Board during the meeting regarding active supervision, a board member noted that, while an implant appeared without problem and the patient did not describe pain, probing of the tissue revealed a severe issue. Without the ability to probe for such a concern, denturists are unable to protect the public from such problems.

C. Laws of other states

Finally, Montana's prohibition on the placement of dentures over implants is not out of step with regulations and restrictions of other states. First, only six states in the United States license the practice of denturitry, as distinct from dentistry: Arizona, Idaho, Maine, Montana, Oregon, and Washington. As such, it is uncommon at this time for denturists to be licensed at all—let alone to practice in the ways considered here.

Second, of the six states which license denturists, only two, Washington and Oregon, permit denturists to place dentures over implants. The remainder vary somewhat in the limitations of the practice. Arizona, for example, falls at the other end of the spectrum--requiring a denturist to work under the general supervision of a dentist, who must review all denture work, perform initial examinations, and review the completed dentures—such must be certified by both the dentist and the denturist and retained in the patient file. *See* Ariz. Rev. State. § 32-1294.

As such, Montana appears to have taken a more middle-of-the-road approach to the regulation of denturists—permitting their independent operations, but restricting practice where necessary to protect the public broadly.

Third, much has been argued regarding the Oregon Court of Appeal's ruling considering the practice of denturitry. *Or. St. Denturist Ass'n. v. Bd. of Dentistry*, 19 P.3d 986 (Or. Ct. App. 2001). DAM argues that the case should be of particular import to this Active Supervision because of the similarities between the Oregon and Montana statutes and definitions. However, the case is inapposite. In *Oregon*, the Court considered whether the Oregon Board of Dentistry's declaratory ruling regarding the definition of dentures was unduly restrictive. *Id.* at 987. The Court, applying principles of statutory construction, concluded that the ruling should be stricken. *Id.* at 991.

By contrast, the Montana Supreme Court has previously ruled that Rule J is permissible based on Montana's laws. *See Denturist Association of Mont. v. State of Mont., Dep't of Labor & Indus.*, 2016 MT 119, ¶ 15 (holding that the challenge to Rule J was invalid because it had already ruled on the question of authority for promulgation: "*Wiser I* and *II* denturists who made the same challenge that Brisendine now makes: the Board's promulgation of Admin. R. M. 24.138.2302(1)(j) is invalid because it conflicts with statute.") This prior litigation determined, among other things, that the Board exercised its authority pursuant to state policy, in enacting the rules here. It is not the purpose, nor would it be proper, for active supervision to attempt to relitigate a matter already concluded or reconsider an order of the Supreme Court. In Montana, the law is settled that the Board has the authority through its statutes to enact Rule J. The question remaining is solely whether the Board's enactment was necessary to protect the public's safety and health. That question was neither raised nor addressed by the Oregon Court of Appeals. As such, the decision has no bearing on the outcome here.

IV. Conclusion

For the foregoing reasons, I conclude that both rules subject to my supervision at this time should remain in force.

Issued this 15th day of December, 2017.

Galen Hollenbaugh, Commissioner of Labor