SOUTH DAKOTA STATE BOARD OF DENTISTRY PUBLIC HEARING JUNE 2, 2023

Judge Williamson called the Public Hearing to order at 10:08 a.m. on Friday, June 2, 2023 and noted that this was the time and place for the South Dakota State Board of Dentistry Public Hearing to consider changes to the administrative rules as provided in the Notice of Public Hearing to Adopt Rules.

Hearing Officer: Judge Catherine Williamson

Members of the Board: Dr. Nick Renemans, Zona Hornstra, Dr. Tara Schaack, Dr. Brian Prouty, and Dr. Harold Doerr.

Board staff: Brittany Novotny and Lisa Harsma.

Legal Counsel: Shelly Munson.

Others: Paul Knecht, South Dakota Dental Association; Mike Mueller, Delta Dental of South Dakota; Tasha Wendel and Hailey Bruggeman, South Dakota Dental Hygienists' Association; Dr. Lamar Koistinen, Horizon Healthcare, Inc.; Dr. Denis Miller, Siouxland Oral Surgery; Shana Davis, iData Research; Martin Saperstein, Ph.D, Saperstein Associates, Inc.; and Madris Kinard, Device Events.

Judge Williamson noted that statements made during the hearing were being recorded in the minutes, that due notice of this public hearing was published in three South Dakota newspapers, and that copies of the affidavits of publication are available for those in attendance. Judge Williamson noted that the proposed rules had been edited for compliance with the requirements for form, style and legality as required by the South Dakota Legislative Research Council pursuant to SDCL 1-26.

Judge Williamson invited Dr. Renemans to provide the rule package.

Dr. Renemans provided a summary of the project history and process to date, along with an overview of the proposed changes:

Summary of Project History and Process:

- The Board released an initial draft of administrative rules, solicited stakeholder feedback, and reviewed that feedback at its public meeting on June 24, 2022. Revisions were made to the draft rules, based on stakeholder feedback.
- The Board released a second draft of the administrative rules, solicited stakeholder feedback, and reviewed that stakeholder feedback at the public board meeting on October 21, 2022. Additional revisions were made to the draft rules based on stakeholder feedback.

- The Board released a third draft of the rules, solicited stakeholder feedback, and reviewed that feedback at the public board meeting January 13, 2023. Revisions were again made to the draft based on stakeholder feedback.

Dr. Renemans thanked stakeholders and licensees for providing feedback on multiple drafts of the rules over the course of the last year, noting that the Board has significantly changed the rule proposal from where it began in June of 2022, based on stakeholder feedback that was received.

Summary of Proposed Changes:

- Clinical Competency Examinations: 20:43:03:01 20:43:03:02 20:43:03:04 20:43:03:08 20:43:03:09 and 20:43:03:10 focus on updating the clinical competency examination language for dental and dental hygiene licensure to include psychomotor examinations that utilize a simulation format, noting there has been a monumental shift in the examination formats since COVID-19. As the examination format, technology, and terminology continues to evolve, the proposed changes are necessary to allow the Board the authority to continue accepting the clinical competency examinations, which ensures continued license portability for applicants.
- Nitrous Oxide: 20:43:09:06 updates supervision requirements for the administration of nitrous oxide by dental hygienists with a permit and registered dental assistants with a permit. This update allows for the administration of nitrous oxide to occur under indirect supervision for all patients. Additionally, this update allows a dental hygienist to administer nitrous under general supervision if the safety requirements outlined in rule are met.
- Local Anesthesia: Similarly, 20:43:09:06.01 updates the supervision requirements for the administration of local anesthesia by dental hygienists with a permit. This update allows for the administration to occur under indirect supervision for all patients. Additionally, this update allows a dental hygienist to administer local anesthesia under general supervision if the safety requirements outlined in rule are met. These changes will help increase access to care.
- Collaborative Supervision Service Reporting: 20:43:10:05 removes a reporting requirement for collaborative supervision services that is no longer needed. When collaborative supervision was implemented in 2012, stakeholder organizations requested that the Board serve as a central repository and collect information regarding services provided under collaborative supervision. Since that time, the organizations utilizing collaborative supervision have set up their own processes to capture this information internally. Therefore, these stakeholder organizations have requested that the reporting requirement now be removed because it is duplicative.
- Advertising: 20:43:04:01 and 20:43:04:01.01 pertain to advertising and advertising as a specialist. Dr. Renemans noted that the Board worked with stakeholders on all sides of this issue throughout the last year in an effort to identify language that would provide a regulatory framework that all sides could agree upon. Unfortunately, that effort was met with limited success. Additionally, recognizing this is an area that has generated litigation in other states, he noted the Board has worked closely with general counsel to mitigate that risk where possible, and has communicated with the Office of Risk Management and the Department of Health throughout this project. Dr. Renemans asked Shelly Munson to provide a summary.

Shelly Munson noted that the Board learned of litigation in other states where similar rules to the existing rule were held unconstitutional due to blind reliance by the dental boards on trade organizations, like the American Dental Association, to establish a specialty practice. She noted that the litigation in other states has been largely driven by a private trade organization known as the American Academy of Implant Dentistry (AAID). AAID has forced other state boards to amend their specialty advertising rules through actual or threatened litigation. In response, states have taken varying approaches in defining who qualifies as a specialist. Shelly Munson noted that the Board is doing the same by amending the current administrative rule. She highlighted that to date, no other states have adopted a rule like South Dakota's proposed rule, which eliminates reliance on special interest trade organizations altogether. This reliance on trade organizations was the crux of the issues noted by courts in other states. South Dakota instead has proposed a fair and straightforward approach that is consistent with public opinion and the majority of licensees - that is, a licensee becomes a specialist by completing a two year residency program. All feedback received was in support of this rule, except the trade organization that would stand to benefit by allowing its organization's members to become specialists through membership in its organizations and completion of its continuing education. Shelly Munson noted that she met several times with the specialty trade organization, AAID, and corresponded several times with their attorney in an effort to gain consensus. She noted that based on review and analysis of the court decisions in other states, the proposed rule has eliminated the previous constitutional violations and is now constitutionally sound, directly advances the substantial governmental interest of protecting the public from misleading advertising, and is no more extensive than is necessary to serve that interest.

Written Testimony: Judge Williamson entered into the record the following letters that were received prior to the hearing:

- A. Paul Knecht (South Dakota)
 - a. Proponent representing the South Dakota Dental Association.
- B. Dr. Scott Van Dam (South Dakota)
 - a. Proponent
- C. Drs. Miller, George, and Leet (South Dakota)
 - a. Proponents representing Siouxland Oral and Maxillofacial Surgery.
- D. Justin Winthrow and Colin Callahan (Ohio, Pennsylvania, and North Carolina)
 - a. Opponents representing the American Academy of Implant Dentistry (AAID).
- E. Kimber Cobb, Dr. Mark Armstrong, and Alexander Vandiver (Arizona, Maryland, and North Carolina)
 - a. Proponents representing the Commission on Dental Competency Assessments (CDCA), Western Regional Examining Board (WREB) & Council of Interstate Testing Agencies (CITA).
- F. Tasha Wendel (South Dakota)
 - a. Proponent representing the South Dakota Dental Hygienists' Association.
- G. Miranda Drake (South Dakota)
 - a. Proponent representing the University of South Dakota Department of Dental Hygiene.

Verbal Testimony: Judge Williamson took Verbal Testimony. Verbal Testimony was presented by the following:

- Dr. Denis Miller (South Dakota Representing himself as practicing oral and maxillofacial surgeon and Siouxland Oral and Maxillofacial Surgery)
 - o Proponent, testified in support of the proposed specialty advertising rule. An outline of verbal testimony provided by Dr. Miller is attached.
- Dr. Lamar Koistinen (South Dakota Representing Horizon Healthcare, Inc.)
 - o Proponent, testified in support of the proposed local anesthesia and nitrous oxide rules, noting the changes will increase access to care.
- Paul Knecht (South Dakota Representing the South Dakota Dental Association)
 - o Proponent, testified in support of all proposed rules. Mr. Knecht thanked the Board for the open and transparent process used to review all drafts and the diligence of the Board throughout the project.
- Tasha Wendell (South Dakota Representing the South Dakota Dental Hygienists' Association)
 - Proponent, testified that the SDDHA Board supports all of the proposed rules, but specifically wanted to highlight support for the local anesthesia and nitrous oxide rules, noting the changes will increase access to care.
- Mike Mueller (South Dakota Representing Delta Dental of South Dakota)
 - o Proponent, testified in support of the proposed repeal of the collaborative supervision reporting rule, noting that rule is no longer necessary.

There were no additional testifiers. There was no opponent verbal testimony presented.

Judge Williamson called for collateral witnesses.

Shelly Munson called Shawna Davis with iData Research to testify and established her identity, profession, pertinent experience, research and methodology. It was established that iData research was contracted to conduct research and did so using appropriate methodologies. Exhibit 5 was entered into the record. The witness was released from her subpoena.

Shelly Munson called Martin Saperstein, Ph.D. with Saperstein and Associates, Inc. to testify and established his identity, profession, pertinent experience, South Dakota and Ohio Survey results, and methodology. It was established that Saperstein and Associates conducted a survey in South Dakota using appropriate methodologies. The results of this survey indicate that a significant majority of the South Dakota residents surveyed believe that a person advertising as specialist has completed an accredited residency, a significant majority of the South Dakota residents surveyed believe that a person advertising as specialist would be more qualified than general dentist, and a significant majority of the South Dakota residents surveyed would be less inclined to choose a dentist advertising as specialist if the individual found out the dentist did not complete a residency. Mr. Saperstein confirmed these results were consistent with a survey previously conducted in Ohio, highlighting that each survey validates the findings of the other and the results are compelling. Exhibits 1 and 2 were entered into the record. The witness was released from his subpoena.

Shelly Munson called Madris Kinard with Device Events to testify and established her identity, profession, pertinent experience, research and methodology. It was established that the dental implant adverse event data used in her research was collected from the FDA's MAUDE database, the primary data source the FDA uses, and includes reports recently made public by the FDA. Exhibit 3 and 4 were entered into the record. The witness was released from her subpoena.

The following Exhibits were entered into the record:

- Exhibit 6 Advanced Dental Implant Programs in the United States published by the AAID in 2017.
- Exhibit 7 Ohio State Dental Board Antitrust Referral Analysis from 10/31/18 referencing Ohio survey results.
- Exhibit 8 Effects of the Florida Statutory Disclaimer on Consumers and Providers of Implant Dentistry article regarding use of disclaimers and confusion created by disclaimers.
- Exhibit 9 Evidence on the Effects of Mandatory Disclaimers in Advertising article regarding use of disclaimers and confusion created by disclaimers.
 - Shelly Munson noted that the Board solicited feedback on an earlier draft of the specialty advertising rules that included disclaimers but ultimately there was a consensus among stakeholders and the Board that disclaimers were confusing and misleading, which is consistent with these reports.

Shelly Munson called Dr. Miller to answer questions regarding his presentation materials and posters. The following exhibits were entered into the record:

- Exhibits 10 through 31 – Information and illustrations that pertain to the testimony provided by Dr. Miller.

Judge Williamson again called for any opponent verbal testimony. There was no opponent verbal testimony presented.

Judge Williamson closed testimony and opened the public hearing to Board Discussion and/or action.

The Board noted that it has spent significant time and undertaken a year-long review process leading up to this hearing that has included many opportunities to submit feedback and many revisions made pursuant to that feedback. The Board highlighted that throughout this process case law from other states was reviewed; meetings were held with stakeholders on all sides of this issue, including the American Board of Oral Implantology (ABOI) and AAID, to review feedback; research regarding various state models was conducted; and revisions were made based on all of the stakeholder feedback, research, and information obtained throughout the process. The Board thanked stakeholders for participating in the lengthy process.

Dr. Doerr spoke in support of the rule proposal, highlighting the compelling survey data that supports the current rules proposal. He noted the limitations of the failure rate information and cautioned against drawing conclusions. He felt the information presented, along with the

feedback provided by stakeholders, supports the rule proposal and highlighted that the simplicity of the proposal strikes a balance and does not overregulate.

Dr. Schaack spoke in support of the rules, noting that the Board has done significant research as it worked with stakeholders to identify the appropriate path forward that includes a regulatory model that upholds the statutory obligation of the Board to protect the public from misleading advertising and does so in the least restrictive manner, all while balancing very diverse perspectives in this area.

Zona Hornstra spoke in support of the proposed rules and thorough review process, highlighting the Board's charge to protect the public. She highlighted the two surveys presented that support the proposed rules.

Dr. Renemans spoke in support of the proposed rules and highlighted the thorough review process that was undertaken.

Dr. Prouty noted that this decision is difficult, given his many years of experience with implants and the quality training programs that are available outside of formal residencies. He highlighted that the rules before the Board pertain only to who can advertise as a specialist, noting that the rules do not prevent anyone from maintaining or developing a reputation as someone that does a great job with implants. He supported Dr. Doerr's remarks regarding the limitations of the failure rate information.

Doerr moved that the South Dakota State Board of Dentistry approve the adoption of the amended rules ARSD §§ 20:43:03:01; 20:43:03:02; 20:43:03:04; 20:43:03:08; 20:43:03:09; 20:43:03:10; 20:43:04:01; 20:43:04:01.01; 20:43:09:06; 20:43:09:06.01; 20:43:10:05 as presented, including the LRC edits for compliance with the requirements for form, style and legality. Second by Hornstra. Motion carried.

There being no further business, the public hearing was adjourned at 11:53 a.m.

Zora L'Horrstra Zona Hornstra, Secretary