DENTAL HYGIENE BOARD

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Mobile Dental Hygiene Clinics; Issuance of Approval; and Registered Dental Hygienist in Alternative Practice, Physical Facility Registration.

Section(s) Affected: Sections 1116 and 1116.5 of Title 16 of the California Code of Regulations (CCR).

Updated Information

The Informative Digest and Initial Statement of Reasons are included in the rulemaking file and incorporated as though set forth herein.

No public hearing was originally set for this proposal and none was requested. Board staff noticed the proposed rulemaking on January 31, 2024, with a 45-day comment period ending on March 19, 2024. The Board received two (2) comments which are summarized below.

On April 25, 2024, the Board noticed the modified text to persons specified in subdivisions (a)(1) through (4) of Section 44 of Title 1 of the CCR. The comment period concluded on May 11, 2024. The Board received one (1) comment which is summarized below as well.

The Board reviewed the comments at its July 19-20, 2024, Full Board meeting. The Board approved the responses to the comments, directed staff to take all steps necessary to complete the rulemaking, and adopted the proposed regulations at Sections 1116 and 1116.5 as noticed.

The modified text after the 45-day comment period included the following amendments:

A. Addition of "dental hygiene care" after "written" and before "plan" in subdivision (a)(8) of section 1116.

Business and Professions Code section 1908(a) states: "The practice of dental hygiene includes dental hygiene assessment and development, planning, and implementation of a dental hygiene care plan. It also includes oral health education, counseling, and health screenings." Therefore, the Board determined to mirror the law and add "dental hygiene care" to "plan" to provide a clear and consistent definition for the type of "plan" utilized by a registered dental hygienist in alternative practice (RDHAP) within the language to prevent misinterpretation by the reader.

B. Addition of "dental hygiene care" after "written" and before "plan" in subdivision (a)(9) of section 1116.5.

The Board incorporates by reference its response to Amendment A.

The modified text and forms after submission to the Office of Administrative Law, included the following:

C. Nonsubstantive Changes

Further changes without regulatory effect were made to the regulation text and forms incorporated by reference after the July 19-20, 2024, Board meeting. These changes included:

- Reordering the definition terms to follow alphabetical order.
- Revising and including cross references where appropriate.
- Non-substantially revising language concerning submitting an application through the BreEZe.
- Revising "Authority" and "Reference" citations.
- Minor revision to grammar and punctuation.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which it was proposed or would be as effective and less burdensome to affected private persons than the adopted regulations or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The Board incorporates by reference the alternatives identified in its Initial Statement of Reasons and did not receive any comments that altered its findings.

Incorporation of Documents by Reference

All forms incorporated by reference in this rulemaking would be cumbersome, unduly expensive and otherwise impractical to publish in the CCR. All forms incorporated by reference that are being adopted, amended, or repealed in this rulemaking were available on the Board's website and hardcopies will be available from the Board upon request.

Objections or Recommendations/Responses

The Board received two (2) comments (Comments) during the 45-day comment period on the Board's proposed language of sections 1116 and 1116.5.

A. January 31, 2024 letter from Lisa Schnoor, RDH.

Comment A-1 Summary

Ms. Schnoor states "Acceptance of the proposal for extended functions and mobile clinics have my voice. It's a long needed area of hygiene that should have service."

Response:

The Board acknowledges and appreciates the support for the regulation.

B. January 18, 2024 letter from Tooka Zokaie, Sr. Health Policy Analyst, on Behalf of the California Dental Association (CDA).

Comment B-1 Summary

Ms. Zokaie states CDA appreciates the opportunity to review and comment on the proposed mobile dental hygiene clinic (MDHC) regulations. She states while the proposed language creates the ability for the Dental Hygiene Board of California (DHBC, Board) to regulate MDHCs, CDA believes several clarifications and additions would enhance patient safety. Additionally, she states CDA requests the following concerns be addressed to fully support DHBCs proposed regulatory language for MDHCs to ensure clear communication with patients, including disclosures and consent that are equal to those required in brick-and-mortar settings.

Response:

The Board acknowledges and thanks the CDA for their comments. However, the Board believes that the anticipated benefits of the proposed regulations for issuing approvals for Mobile Dental Hygiene Clinics and Physical Facility Registrations outweigh any of the concerns cited in this letter, and these items will be discussed in more detail below.

Comment B-2 Summary

Ms. Zokaie states CDA strongly recommends removing the requirement for MDHCs to adhere to CDC drinkable water guidelines, and instead requiring applicants to comply with infection control guidelines governing all licensees of the Dental Board of California and DHBC as currently referenced in California Code of Regulations (CCR), Title 16 section 1116(d)(3)(D).

She states CDA believes licensees should be held to the standards set in section 1005, the dental setting infection control regulations evaluated and maintained collaboratively by DBC and DHBC. She states these regulations reflect many guidelines, including those published by CDC, and that that singling out CDC guidelines solely for MDHCs will establish conflicting standards within dentistry with no measurable benefit for patient safety.

Response:

The Board thanked the commenter, however, the Board rejects this comment for the following reasons:

First, the Board determined to include and clarify the Dental Board of California's (DBC) regulatory requirement of "potable water" for Mobile Dental Clinics in 16 CCR section 1049(c)(3)(C) which states: "Have ready access to an adequate supply of potable water, including hot water." By ensuring water quality guidelines are established to comply with the "Guidelines for Infection Control in Dental Health-Care Settings – 2003" from the Centers for Disease Control and Prevention (CDC), in addition to the "Safe Drinking Water Act." (42 U.S.C. Sec. 300f et seq.), the Board believes the regulation adequately ensures safe water standards for use in MDHCs and PFs.

Second, the Board requires MDHCs and Physical Facilities (PFs) to adhere to infection control requirements of 16 CCR section 1005 in section 1116(d)(3)(A) and 1116.5(c)(3)(A), respectively. Additionally, section 1133 requires licensees to comply with the minimum standards for infection control as set forth in section 1005. Furthermore, 16 CCR section 1005 does not address water quality within the regulation.

Therefore, the Board believes there is no conflict with the minimum standards for infection control as set in 16 CCR section 1005, and accordingly, the Board is making no changes to the regulations in response to this comment.

Comment B-3 Summary

Ms. Zokaie states the proposed regulations do not explicitly call for Registered Dental Hygienists in Alternative Practice (RDHAPs) operating an MDHC to obtain patient consent for services. She states that RDHAPs are required by the code of ethics to obtain patient consent for treatment and that CDA believes that obtaining consent in non-bricks-and-mortar settings should be appropriately applied to MDHCs.

Ms. Zokaie stated that asking the patient when they last received care from a dentist and requesting the dentist's contact information should be included as this will support the RDHAP's collaboration with the patient's dental home to coordinate comprehensive dental treatment and assist in obtaining a complete health history and maintaining an accurate dental treatment record.

Ms. Zokaie suggested the addition of a section 1116.5(h) consent for services and language to support this section.

Response:

The Board thanked the commenter, however, the Board rejects this comment for the following reasons:

First, Ms. Zokaie erroneously cited section 1116.5 which is for physical facilities. Section 1116 is the proposed language for MDHCs.

Second, as Ms. Zokaie states, RDHAPs are required by the code of ethics to obtain patient consent prior to treatment.

The Board requires all licensees to satisfactorily complete an examination in California law and ethics as prescribed by the dental hygiene board prior to licensure [Bus. & Prof. Code §1917, subd. (d)].

The Board defines “Ethics” and incorporates the California Dental Hygienists' Association's Code of Ethics for Dental Hygienists (“CDHA Code of Ethics”) in 16 CCR section 1100(k) which states:

“(k) “Ethics” for the purposes of the examination required by section 1917(d) of the Business and Professions Code, means an act or acts in accordance with the California Dental Hygienists' Association's (CDHA's) Policy Manual, Chapter 2, Code of Ethics for Dental Hygienists (Amended HOD 2015), which is hereby incorporated by reference, or the American Dental Hygienists' Association's (ADHA's) Bylaws and Code of Ethics (Adopted June 23, 2014), which is hereby incorporated by reference, and ADHA Policy Manual, pages 7-12, (Adopted June 22, 2015), which is hereby incorporated by reference.”

The “Core Value” of “Individual Autonomy and Respect for Human Beings” in the “CDHA’s Code of Ethics” speaks to “Informed Consent” as it states:

“People have the right to be treated with respect. They have the right to informed consent prior to treatment, and they have the right to full disclosure of all relevant information so that they can make informed choices about their care.”

Additionally, in the “Standards of Professional Responsibility,” the section regarding “To Clients” of the “CDHA’s Code of Ethics”, it states:

“Provide clients with the information necessary to make informed decisions about their oral health and encourage their full participation in treatment decisions and goals.”

As RDHAPs are bound by their professional code of ethics, the Board determined adding this requirement to the regulation would be duplicative and unnecessary.

Accordingly, the Board is making no changes to the regulations in response to this comment.

Comment B-4 Summary

Ms. Zokaie states professional ethics require that patients receive minimal radiographic exposure and when radiographs are taken, those images be evaluated and used for treatment planning purposes and the patient be advised of the results. She states these patient protections regarding radiographic exposure are not included in the proposed text.

She states sections 1116(d)(1)(F) and 1116.5(c)(1)(E) only specify a radiographic operatory must be used that complies with California Radiation Control Regulations. She adds “to ensure that these concerns are explicitly addressed, and radiographs exposed by MDHCs are utilized by a dentist for comprehensive diagnosis and treatment planning whenever appropriate.”

Response:

The Board thanked the commenter, however, the Board rejects this comment for the following reasons:

First, registered dental hygienists (RDHs) and RDHAPs are educated in radiation safety and radiography techniques in dental hygiene educational programs as prescribed by the Board in 16 CCR section 1105.2(d)(4), which includes the required topics of radiation protection, radiation safety, and principles of radiographic exposure.

Second, Business and Professions Code (BPC) 1921 authorizes an RDHAP to perform any of the duties or functions authorized to be performed by an RDH. Additionally, BPC section 1913 states: “Unless otherwise specified in this chapter, a registered dental hygienist may perform any procedure or provide any service within the scope of their practice in any setting under the appropriate level of supervision required by this article, if the registered dental hygienist has completed the appropriate education and training required to perform the procedure or provide the service.” As BPC section 1925 authorizes an RDHAP to practice as an independent contractor or as a sole proprietor of an alternative dental hygiene practice, the RDHAP is therefore not bound by dentist supervision requirements with regard to radiographic exposures.

Third, BPC section 1908(a) states: “The practice of dental hygiene includes dental hygiene assessment and development, planning, and implementation of a dental hygiene care plan. It also includes oral health education, counseling, and health screenings.” Radiographs are a necessary dental hygiene assessment tool in order to develop a complete and accurate dental hygiene care plan.

Finally, BPC section 1931(a) allows an RDHAP to provide services to a patient without

obtaining written verification that the patient has been examined by a dentist or physician and surgeon licensed to practice in this state. However, it is the standard of care for RDHAPs to provide patients with copies of treatment records, including radiographs, upon request, as well as in proposed sections 1116(j)(4) and 1116.5(g)(4), the Board requires the RDHAP that within fifteen (15) days of receipt of a written request by the patient, the owner shall provide for the transfer of copies of the patient's treatment records, including radiographs, to the succeeding provider or to the patient, as specified by the patient.

Accordingly, the Board is making no changes to the regulations in response to this comment.

Comment B-5 Summary

Ms. Zokaie states the proposed regulations do not provide guidance for accessible dental and official records. She states MDHCs should be required to keep official records at their place of business and available for inspection and copying upon Board request.

Response:

The Board thanked the commenter, however, the Board rejects this comment for the following reasons:

Proposed section 1116(d)(5) states: "An RDHAP operator shall provide access during business hours to the RDHAP's *records* and facility to the Board, or its authorized representative(s), to review the MDHC for compliance with all laws, regulations, and standards applicable to MDHCs including, but not limited to, the BPC, CCR, CDC, and HIPAA."

As the proposed regulation already addresses records access, the Board determined there is no need for additional language and accordingly, the Board is making no changes to the regulation in response to this comment.

Comment B-6 Summary

Ms. Zokaie states to promote transparency, communication, and patient safety, the MDHC operator should be required to provide the patient with an information sheet reflecting the services provided during the visit, the limitation of the services that RDHAPs can provide, a recommendation to receive a comprehensive examination by a licensed dentist, and contact information for follow-up services or dental emergencies. She states if the patient has provided consent to an institutional facility or dental office to access the patient's dental health records, the institution shall also be provided with a copy of the information sheet.

Response:

The Board thanked the commenter, however, the Board rejects this comment for the following reasons:

It is the standard of care for RDHAPs to provide patients with after dental hygiene care information, including contact information for follow-up services or dental emergencies. Additionally, subdivision (d)(1)(A) requires the MDHC owner have a written procedure that specifies the means of obtaining emergency follow-up care for patients treated in the MDHC, as well as subdivision (d)(1)(A) requiring the MDHC owner to maintain a telephone number where patients are able to contact the MDHC owner or provider with questions, concerns, or emergency needs. Furthermore, section (d)(1)(B) requires an MDHC owner to maintain a relationship with at least one licensed dentist located in California for referral, consultation, and emergency services.

As stated before, RDHAPs are bound by their professional code of ethics.

In the “Standards of Professional Responsibility” regarding “To Clients” in the CDHA’s “Code of Ethics,” itstates in part:

- Provide oral health care utilizing high levels of professional knowledge, judgment, and skill.
- Serve as an advocate for the welfare of clients.
- Provide clients with the information necessary to make informed decisions about their oral health and encourage their full participation in treatment decisions and goals.
- Refer clients to other healthcare providers when their needs are beyond our ability or scope of practice.
- Educate clients about high-quality oral health care.

Additionally, in the “To the Community and Society” section in the CDHA’s “Code of Ethics,” it states in part:

- Recognize and uphold the laws and regulations governing our profession.
- Comply with local, state, and federal statutes that promote public health and safety.
- Promote access to dental hygiene services for all, supporting justice and fairness in the distribution of healthcare resources.

As RDHAPs are bound by their professional code of ethics, the Board determined adding this requirement to the regulation would be duplicative and unnecessary.

Accordingly, the Board is making no changes to the regulations in response to this comment.

Comment B-7 Summary

Ms. Zokaie states the definition of portable equipment is unclear. She states: “Section 1116(1) (*sic*) identified that MDHCs shall not include equipment used and transported by licensed registered dental hygienists. Conversely, Section 1116(11)(b) (*sic*) states that an RDHAP who wishes to operate an MDHC in any setting authorized in Cal. Bus. & Prof. Code Sect. 1926 would include such equipment.” She states the conflict between these sections creates confusion as to whether RDHAPs’ portable equipment is included or excluded from MDHCs.

Response:

The Board thanked the commenter, however, the Board rejects this comment for the following reasons:

Section 1116(a)(1) defines an MDHC as “*any self-contained facility* in which dental hygiene services are rendered that may be moved, towed, or transported from one location to another.” Section 1116(a)(1) also states this term shall not include *equipment* used and transported by licensed RDHAPs in discharging their duties in locations or settings authorized by BPC section 1926. Additionally, section 1116(a)(3) then defines “*equipment*” to mean any tool, instrument, or device used by an RDHAP to provide dental hygiene services.

BPC section 1926.3(b)(1) requires RDHAPs utilizing “portable equipment to practice dental hygiene” to register the PF where the “portable equipment” is maintained. Section 1116.5 specifically addresses the requirement for registration of “portable equipment.” Additionally, section 1116.5(a)(4) provides the definition for “portable equipment” to mean “any tool, instrument, or device used by an RDHAP to provide dental hygiene services designed for and capable of being carried or moved from one location to another.”

Therefore, the Board believes there is no conflict between the definitions as they are addressed within their respective sections and accordingly, the Board is making no changes to the regulations in response to this comment.

Comment B-8 Summary

Ms. Zokaie states the “written plan” developed by the RDHAP, as referenced in Section 1116(8) (*sic*), is unclear. She states section 1116(8) (*sic*) identifies the “patient of record” as a patient “who has had a medical and dental history completed and evaluated, had oral conditions assessed and documented, and had a written plan developed by the RDHAP.” She states this section fails to specify what elements should be included in the plan, or if it refers specifically to a dental hygiene treatment plan. Ms. Zokaie CDA urges DHBC to include additional language to ensure all parties understand the obligations and limitations of this requirement.

Response:

The Board thanked the commenter and accepts this comment for the following reason:

The Board added “dental hygiene care” to “plan” to provide a clear and consistent definition for the type of “plan” utilized by an RDHAP within the language to prevent misinterpretation by the reader.

Comment B-9 Summary

Ms. Zokaie states “Section 1116(a)(10), “Patient Treatment Records,” states that patient treatment records include “dental hygiene evaluation(s), dental hygiene diagnosis(es), dental hygiene procedures and treatment, and response to dental hygiene treatment ...”. She states as it is written, it is unclear what distinguishes a dental hygiene “procedure” from dental hygiene “treatment” or the advantage of using these two terms.

Response:

The Board thanked the commenter, however, the Board rejects this comment for the following reasons:

The Merriam Webster dictionary defines a procedure as “a particular way of accomplishing something or of acting.” whereas the Merriam Webster dictionary defines treatment as “a therapeutic agent, therapy, or *procedure* used to treat a medical condition.”

For example, probing [utilizing an instrument that is placed between the patient’s gingiva (gums) and tooth to determine how attached the gingiva is to the tooth] is an assessment *procedure*. Probing provides necessary data to assist in determining the extent of a patient’s periodontal (gum) disease, but does not provide any *treatment* of the periodontal disease.

However, scaling and root planing [using specialty dental instruments with blades to remove calculus (tartar) from teeth] results in the removal of calculus irritating the patient’s gingiva, causing a decrease in gingival inflammation, and ultimately the *treatment* of the patient’s periodontal disease.

Therefore, as treatment and procedures are two distinct categories, the Board has determined there is no clarity issue and accordingly, the Board is making no changes to the regulations in response to this comment.

Comment B-10 Summary

Ms. Zokaie states CDA appreciates the opportunity to share these concerns and recommendations with DHBC. She states on behalf of CDA members, they are also

advocating for these provisions to be included in DBC mobile dental regulations so all dental professionals who operate mobile clinics will be held to the same standards of care. She adds addressing concerns regarding infection control guidelines, patient consent, and follow-up care will protect patient safety and ensure patients are educated regarding the treatment they receive.

Response:

Again, the Board acknowledges and thanks the CDA for their comments.

Comments and Responses to 15-Day Amended Language Comment Period

The Board received comments during the 15-day comment period on the Board's amended language of sections 1116 and 1116.5. Below is the Board's response to the comments made therein.

C. May 1, 2024 letter from Rose M. Johnson

Ms. Johnson states "It will be a good idea to approve this Bill, registering Mobile Dental Hygiene. It will clearly inform patients, protect those whom we RDHAP serve."

Response:

The Board acknowledges and appreciates the support for the regulation.