DENTAL BOARD OF CALIFORNIA
MEETING MINUTES
March 14, 2022

NOTE: In accordance with Government Code Section 11133 and Governor Gavin Newsom's Executive Order N-1-22, the Dental Board of California (Board) met on March 14, 2022, via teleconference/WebEx Events, and no public locations or teleconference locations were provided.

Members Present:
Alan Felsenfeld, MA, DDS, President
James Yu, DDS, MS, Vice President
Sonia Molina, DMD, MPH, Secretary
Steven Chan, DDS
Lilia Larin, DDS
Meredith McKenzie, Esq., Public Member
Angelita Medina, Public Member
Alicia Montell, DDS
Steven Morrow, DDS, MS
Rosalinda Olague, RDA, BA
Joanne Pacheco, RDH, MAOB

Members Absent:
Mark Mendoza, Public Member

Staff Present:
Sarah Wallace, Interim Executive Officer
Tina Vallery, Chief of Administration and Licensing
Jessica Olney, Anesthesia Unit Manager
Wilbert Rumbaoa, Administrative Services Unit Manager
Paige Ragali, Acting Dentistry Licensing and Examination Unit Manager
Mirela Taran, Administrative Analyst
David Bruggeman, Legislative and Regulatory Specialist
Kristy Schieldge, Regulatory Counsel, Attorney IV, Department of Consumer Affairs (DCA)
Tara Welch, Board Counsel, Attorney III, DCA

12:00 p.m., Monday, March 14, 2022

Agenda Item 1: Call to Order/Roll Call/Establishment of a Quorum
The Board President, Dr. Alan Felsenfeld, called the meeting to order at 12:05 p.m. The Board Secretary, Dr. Sonia Molina, called the roll; 11 Board Members were present, and a quorum was established.

Agenda Item 2: Public Comment on Items Not on the Agenda
Dr. Maura Tuso voiced concerns in relation to her California dentist license. Dr. Tuso was advised that her inquiries will be responded to by the Board's Interim Executive Officer.

Agenda Item 3: Discussion and Possible Action on February 10-11, 2022 Board Meeting Minutes
Ms. Sarah Wallace, Interim Executive Officer, requested an amendment to the meeting minutes on page 5 of the meeting materials, Agenda Item 4, first paragraph, first line, to add "he" before "attended".

Motion/Second/Call (M/S/C) (Yu/Pacheco) to approve the February 10-11, 2022 meeting minutes as revised.

Ayes: Chan, Felsenfeld, Larin, McKenzie, Medina, Molina, Montell, Morrow, Olague, Pacheco, Yu.
Nays: None.
Abstentions: None.
Absent: Mendoza.
Recusals: None.

The motion passed. The Board received public comment. Dr. Tuso inquired whether public comments are noted formally at Board meetings and how she would go about presenting a question. Dr. Felsenfeld responded that they are not and that topics can be brought up at any meeting to be requested as an agenda item at a future Board meeting.

Agenda Item 4: Discussion and Possible Action to Consider Comments Received During the 45-Day Comment Period and Proposed Responses Thereto for the Board's Rulemaking to Amend California Code of Regulations, Title 16, Sections 1021, 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, 1043.8, 1044, 1044.1, 1044.2, 1044.3, and 1044.5, 1070.8, Adopt Sections 1017.1, 1043.8.1, and 1043.9, 1043.9.1, 1043.9.2, and Repeal Section 1044.4 Relating to the SB 501 (Anesthesia and Sedation) Rulemaking
Regulatory Counsel, Ms. Kristy Schieldge, went over the rulemaking process and provided a brief explanation of where the Board is in this process and where the Senate Bill (SB) 501 rulemaking is headed. She provided members with a chart that is produced by the Office of Administrative Law to explain the rulemaking process. The Office of Administrative Law (OAL) is the agency that is responsible for reviewing and approving all regulations for state agencies in the state, including the Board. OAL will review regulations based on six standards, which include: authority, clarity, consistency, non-duplication, reference, and necessity.

Ms. Schieldge provided a brief background of the initiation of the rulemaking process, including the Board's action at its November 2021 Board meeting where it authorized the Executive Officer to initiate a rulemaking to implement these changes. Pursuant to that directive, the following documents were posted on the Board's website and sent to interested parties: Notice of Proposed Rulemaking; Initial Statement of Reasons; and the Proposed Text. Changes to proposed text are required by law to be shown in underline for addition of new text and strikethrough for deletion of existing text.

The notice was published by OAL, and the proposed text noticed for a 45-day written public comment period, which ended on February 15, 2022; there was also a hearing held on February 16, 2022, to take additional public comments. Ms. Schieldge advised the members that they are required to consider and respond to all comments received in response to the Board's proposal. The meeting materials contain the public comments received on the Board's proposal, including those provided at the public hearing held on February 16, 2022. She reminded the members that public comment closed at the February 16, 2022 hearing, and therefore her recommendation was that the Board does not entertain any new comments on this agenda item. Doing so would require the Board to re-open the public comment period. She advised the Board that this Board meeting item was simply to discuss the comments already received and whether to accept the comments and make further modifications to the proposed text or reject them.

If the Board agreed that changes should be made in response to comments, Ms. Schieldge advised the Board that it had a couple of options. If the comments are nonsubstantial (grammatical, technical or does not substantially affect a right or responsibility under the law) or substantial, sufficiently related (meaning a reasonable member of the public could have determined from the notice that these changes to the regulation could have resulted), then changes may be made after 15-day notice to the public is provided. Generally, the Board would look at what was struck out or underlined in the originally proposed regulatory language for guidance on this. If not sufficiently related (meaning it raised a new topic not covered by the original proposal – OAL refers to it as "major changes"), then the rulemaking would need to be re-started.

Mr. David Bruggeman, Legislative and Regulatory Specialist, provided the report, which is available in the meeting materials. He presented each comment and staff's recommendations to the written public comments on the proposed regulations and the comments that were made at the February 16, 2022 regulatory hearing:

A. Email, dated January 23, 2022, from Lois Richardson

Comment Summary: The commenter proposed edits to proposed California Code of Regulations (CCR), title 16, sections 1043(b), 1043.9(b), and 1044(a). The commenter noted that the Joint Commission on Health Care Organizations now operates under the name "The Joint Commission" (Comment No. 1), and the agency responsible for licensing hospitals in the State of California is the California Department of Public

Health, not the California Department of Health Services (Comment No. 2). She also recommended substituting the word “that” for the word “which” when it follows the phrase “treatment facility” in sections 1043, 1043.9(b), and 1044 (Comment No. 3).

Staff Recommended Response:

Accept Comments: Under Government Code section 11346.8(c), the Board may make changes to the originally proposed regulatory language that are not related to the original proposal without further notice if the proposed changes are nonsubstantial or solely grammatical in nature. At the time that the existing regulatory language was adopted in sections 1043(b) and 1044(a), the relevant accrediting body for general acute care hospitals was titled, “Joint Commission on Health Care Organizations,” but has apparently changed since that time to “The Joint Commission” (see attached “The Joint Commission 70-Year Historical Timeline,” published by the Joint Commission). The originally proposed regulatory language in proposed section 1043.9(b) mirrors the existing text, for consistency, found in sections 1043(b) and 1044(a). As a result of the renaming/branding of The Joint Commission, the Board proposes to accept Comment No. 1 as a nonsubstantial change and will amend the term in sections 1043, 1044, and 1043.9.

Comment No. 2 relates to the transfer of authority over health facilities (including general acute care hospitals) from the California Department of Health Services (the agency responsible for licensure of these hospitals at the time the regulation was adopted) to the California Department of Public Health (see Health & Saf. Code, §§ 20, 1250 and 131050) effective July 1, 2007. As a result, the Board considers changing of the name from “Health Services” to “Public Health” to be nonsubstantial and proposes to modify the text as recommended. The Board considers Comment No. 3 to be solely grammatical and agrees with the change, and therefore accepts the comment. As a result of the foregoing, the Board proposes to make the changes proposed by the commenter for sections 1043(b), 1043.9(b), and 1044(a).

B. 1. Mary Wilson, anesthesia nurse with the Indio Surgery Center, written comments dated January 24, 2022

Comment Summary: The commenter argued that many ambulatory dental surgery centers treat thousands of pediatric patients every year under general anesthesia, that many of these centers treat patients in an underserved demographic, and there are a limited number of pediatric dental offices accepting Medi-Cal and Denti-Cal. In light of these and other considerations, the commenter requested the Board take into consideration the language of “outpatient” as solely a dental office, thus leaving ambulatory centers exempt from the regulatory requirements.

The commenter did not cite to specific regulatory sections or proposals, but existing text at section 1043(b) defines “outpatient” for the purpose of determining when a general anesthesia permit is required, as follows:

(b) For purposes of this article, “outpatient” means a patient treated in a treatment facility which is not accredited by the Joint Commission on Health Care Organizations or licensed by the California Department of Health Services as a “general acute care hospital” as defined in subdivision (a) of Section 1250 of the Health & Safety Code.

Staff Recommended Response:

Reject Comment: Government Code section 11346.8(c) prohibits a state agency from adopting changes to originally noticed text, unless the change or modification is sufficiently related to the original text previously made available to the public that the public was adequately placed on notice that the change could result from the originally proposed action. A change is considered to be sufficiently related if "a reasonable member of the directly affected public could have determined from the notice that these changes to the regulation could have resulted." (Cal. Code Regs., tit. 1, § 42.)

Section 1043(b) was noticed without any changes to the originally adopted text (i.e., changes were not shown in underline and strikeout). As set forth in the Notice of Proposed Regulatory Action, the purpose of the current proposal is to implement the new requirements of Senate Bill 501 (Glazer, Chapter 929, Statutes of 2018). Although some provisions of that bill became effective on January 1, 2019, provisions governing the use of minimal, moderate, and deep sedation and general anesthesia became effective on January 1, 2022. Business and Professions Code section 1646.1(a), which section 1043(b), implements, requires, in pertinent part the following:

(a) A dentist shall possess either a current license in good standing and a general anesthesia permit issued by the board or a permit under Section 1638 or 1640 and a general anesthesia permit issued by the board in order to administer or order the administration of deep sedation or general anesthesia on an **outpatient basis** for dental patients. (Emphasis added.)

This requirement for a dentist to obtain a general anesthesia permit from the Board to order or administer general anesthesia on an outpatient basis was first enacted as part of the Dental Practice Act in 1979 (see Stats.1979, c. 886, p. 3071, § 1). As specified above, SB 501 does not alter that requirement. The current regulations have also not been amended since 2006 and the Board has previously rejected similar requests to exempt surgery clinics from the outpatient definition (see more detailed response below in response to comment H. below).

Since the commenter makes suggestions for changes not sufficiently related to the originally noticed regulatory proposal, Board Regulatory Counsel advises that any substantial changes to Section 1043(b) would require the Board to begin the regulatory process over again if the Board wanted to consider changes to that section. Business and Professions Code section (BPC) section 1646.11 provides:

> A general anesthesia permitholder who has a permit that was issued before January 1, 2022, may follow the terms of that existing permit until it expires. Any permit issued or renewed pursuant to this article on or after January 1, 2022, shall require the permitholder to follow the new requirements of this article.

In the interests of existing and new general anesthesia permitholders and the public, it is therefore critically important that the Board complete the rulemaking process as expeditiously as possible. The Board therefore declines to make any changes to section 1043(b) at this time.

B. 2. Mary Wilson, anesthesia nurse with the Indio Surgery Center, written comments received at the hearing on February 16, 2022

Comment Summary:

Comment 1: The commenter renewed her request to revise the "outpatient" definition to include an exemption for an accredited/Medi-Cal certified ambulatory surgery center and that the "outpatient" definition refer solely to the dental office.

Comment 2: The commenter also requested that an accredited/Medi-Cal certified ambulatory surgery center "be included within the acute care facilities in section 2827 [presumably of the Business and Professions Code] in reference to CRNA's."

Staff Recommended Response:

Reject Comments:

Comment 1: For the reasons set forth above under the response to the B.1. comments above, the Board rejects this comment.

Comment 2: BPC section 2827 provides the following in the Nursing Practice Act:

> The utilization of a nurse anesthetist to provide anesthesia services in an acute care facility shall be approved by the acute care facility administration and the appropriate committee, and at the discretion of the physician, dentist or podiatrist. If a general anesthetic agent is administered in a dental office, the dentist shall hold a permit authorized by Article 2.7 (commencing with Section 1646) of Chapter 4 or, commencing January 1, 2022, Article 2.75 (commencing with Section 1646) of Chapter 4.

However, this provision is not part of the Dental Practice Act, relates to the provision of anesthesia services by nurse anesthetists in acute care facilities, and simply addresses the requirements for administration in a dental office, which is only one type of outpatient setting. According to Board Regulatory Counsel, this provision does not expressly or impliedly supersede the requirements in BPC section 1646.1. To the extent

the commenter is suggesting amendments to existing section 1043(b) or changes to BPC section 1646.1, the comments are rejected as neither not sufficiently related to this rulemaking or requiring statutory changes that are beyond the authority for the Board to address in this rulemaking.

C. Letter, dated January 27, 2022, via email from Tammy Kegler, from Kenneth D. Pierson, co-owner of Hapy Bear Surgery Center, LLC

Comment Summary: The commenter stated that an ambulatory surgical center should be allowed to contract with any properly licensed anesthesia provider, be that a dentist with an anesthesia permit from the Dental Board of California, a Medical Anesthesiologist with or without an anesthesia permit from the Dental Board of California, or a Certified Registered Nurse Anesthetist licensed in the state of California. The commenter requested that state licensed ambulatory surgical centers be exempted from SB 501.

Staff Recommended Response:

Reject Comments: As explained in the response to comments B.1. and B.2. above, to the extent the commenter is requesting amendments to existing section 1043(b) or BPC section 1646.1, the request is rejected as either not sufficiently related to this rulemaking or requiring statutory changes that are beyond the authority of the Board to address in this rulemaking.

D. Letter, dated January 31, 2022, from Jeremy Pierson, CEO and co-owner of Hapy Bear Surgery Center, LLC

Comment Summary: The commenter restated arguments raised in comment C. above. In addition, the commenter stated that the regulations associated with Senate Bill 501 that are being written at this time are attempting to allow the Board to overstep its regulatory limits by determining the necessary licenses needed by anesthesia professionals working in their ambulatory surgery center (ASC). The commenter further strongly requested that ASCs as outpatient treatment centers be exempted from these regulations.

The commenter argued that the Dental Board of California should have regulatory oversight for dental offices but not over ASCs that the commenter states are held to a much higher standard for patient safety by their own regulatory entities. The commenter stated that any dentist working in an ASC would be under the purview of the Dental Board but the ASC is not. He further asserted that if ASCs are not exempted from the regulations for SB 501, it will significantly impact the number of patients that are able to be seen due to the severe lack of anesthesia providers who have anesthesia permits from the Board.

Staff Recommended Response:

Reject Comments: The Board is not asserting, through this rulemaking, authority to regulate ASCs. The Board agrees with the commenter that "[a]ny dentist working in an ASC would be under the purview of the [Board] . . . ." The Board has statutory authority over dentists ordering the administration of or administering general anesthesia or deep sedation, moderate sedation, oral conscious sedation (adults), and pediatric minimal sedation to dental patients on an outpatient basis, which includes treatment at ASCs that are not general acute care hospitals and are considered an outpatient setting by law (see BPC, §§ 1646.1, 1647.2, 1647.19, and 1647.31; current Cal. Code Regs., tit. 16, § 1043(b); Health and Safety Code (HSC), §§ 1248.1(a), (f)).

Although the Board does not regulate ASCs directly, the Board's statutory authority to require an onsite inspection and evaluation of the licentiate and the facility, equipment, personnel, and procedures utilized by the licentiate to administer or order the administration of anesthesia or sedation is established in BPC sections § 1646.4(a) (general anesthesia and deep sedation), and 1647.7(a) (moderate sedation). Further, in response to a complaint submitted to the Board alleging that a dentist or dental assistant has violated any Board law or regulation, the Board may inspect the books, records, and premises of any California licensed dentist, regardless of practice location, and the licensing documents, records, and premises of any dental assistant. (BPC, § 1611.5(a).)

With respect to the commenter's request for exemption of ASCs from the Board's regulations, the Board notes that existing section 1043(b) establishes that outpatient treatment does not include treatment in a general acute care hospital accredited by the Joint Commission on Health Care Organizations or licensed by the California Department of Health (in-patient facilities), and the regulatory proposal does not affect the current application of the Board's regulations to dentists working at ASCs. As explained in the response to comments B.1., B.2., and C. above, to the extent the commenter is suggesting amendments to existing section 1043(b) or BPC section 1646.1, it is rejected as either not sufficiently related to this rulemaking or requiring statutory changes that are beyond the authority for the Board to address in this rulemaking. The Board therefore rejects this comment.

E. Letter, dated January 31, 2022, from Alan J. Vallerine, CEO of the Fresno Dental Surgery Center (FDSC), via email from Chelsea Parreira,

Comment Summary: The commenter raised concern that the regulatory proposal could have a major negative impact on access to care if not amended. The commenter noted that FDSC treats the underprivileged and special needs patients referred to them by over 500 conventional dental offices in the surrounding area, and patients are referred to FDSC only after all attempts have been made and documented to try and complete the patient's dental treatment in a conventional setting. The commenter argued that any disruption of dental services at FDSC would have a dramatic increase

in children being referred to emergency rooms that are already overwhelmed. The commenter requested that their state licensed and accredited ASCs be exempt from the proposed regulation, proposed amended language, and the current law.

Staff Recommended Response:

Reject Comments: With respect to the comment requesting exemption from regulations, the Board presumes the comment is directed to possible changes to Section 1043(b). As explained in the response to comments B.1., B.2., C., and D. above, to the extent the commenter is suggesting amendments to existing section 1043(b) or BPC section 1646.1, it is rejected as either not sufficiently related to this rulemaking or requiring statutory changes that are beyond the authority for the Board to address in this rulemaking.

F. Letter, dated January 28, 2022, from John Bonutto, Indio Surgery Center (received on 2/3/22), follow-up email as sent via Lori Dean on 2/11/22 with a modified letter, and an additional email sent via Lori Dean on 2/15/22 with proposed text)

Comment Summary: The commenter indicated that some provisions of the proposed regulations seem ambiguous. The commenter stated that in general, there does not seem to be any differentiation between a standard dental office and a licensed and accredited ASC. The commenter reiterated ASC safety, protocol, and oversight comments made in comments B.1., B.2., C., D., and E. above. The commenter stated that "[w]ithout exemption from Bill-501, specifically their ability to utilize CRNAs [certified registered nurse anesthetists] as part of our Surgical Team, our operations would be drastically effected." The commenter also noted the difficulty finding dental and medical anesthesiologist with a dental general anesthesia permit. The commenter requested that SB 501 be modified to reflect the following:

> (A) Accredited/Medicare certified ASCs should be exempt from the provisions of SB 501 (Comment No. 1) and the definition of outpatient should be solely dental offices (Comment No. 2); and, (B) Accredited ASCs should be included with acute care facilities in section 2827 addressing the use of certified nurse anesthetists. (Comment No. 3.)

Staff Recommended Response: The Board rejects these comments for the following reasons.

Comment No. 1, 2: For the reasons set forth above under the response to comments B.1., B.2., C., and D. above, the Board rejects this comment.

Comment 3: BPC section 2827 provides the following in the Nursing Practice Act:

> The utilization of a nurse anesthetist to provide anesthesia services in an acute care facility shall be approved by the acute care facility administration and the appropriate committee, and at the discretion of the physician, dentist or podiatrist. If a general anesthetic agent is administered in a dental office, the dentist shall hold a permit authorized by Article 2.7 (commencing with Section 1646) of Chapter 4 or, commencing January 1, 2022, Article 2.75 (commencing with Section 1646) of Chapter 4.

However, this provision is not part of the Dental Practice Act, relates to the provision of anesthesia services by nurse anesthetists in acute care facilities, and simply addresses the requirements for administration in a dental office, which is only one type of outpatient setting. This provision does not expressly or impliedly supersede the requirements in BPC section 1646.1. The Board, pursuant to BPC section 1614, has the authority to issue regulations concerning the provisions of the Dental Practice Act. As BPC section 2827 is not part of the Act, the Board lacks authority to make the suggested change. To the extent the commenter is suggesting amendments to existing section 1043(b) or changes to BPC section 2427, the comments are rejected as neither not sufficiently related to this rulemaking or requiring statutory changes that are beyond the authority of the Board to address in this rulemaking.

G. Letter, dated February 13, 2022, from Robert Orr, CRNA, MS, MBA, BSN, Orr Anesthesia Services

Comment Summary: The commenter indicated that he is an anesthesia provider that has been providing pediatric dental cases for many years and thousands of cases. The commenter indicated that the new SB 501 needs clear language for all groups and stakeholders especially the children. He indicated that dental offices need the same safety for the children that hospitals and ASCs provide, and there is a huge difference in the way a dentist office is regulated as compared to hospitals and surgery centers that deal with agencies like CMS. The commenter indicated FDSC has done over 59,000 patients since September 2012, without any patient transfer to a higher level of care for a medical or dental complication. The commenter indicated that there is a misconception that CRNAs (certified registered nurse anesthetists) are not capable of taking care of these cases and that there is not enough anesthesiologist or pediatric anesthesiologists to do cases, much less do strictly pediatrics dental cases. The commenter urged the Board to thoughtfully consider all stakeholders in the wording of this and future legislative actions and that thousands of kids can be impacted by SB 501, and it won't be in a good way.

Staff Recommended Response: The Board rejects these comments for the following reasons. It is unclear from this comment what specific area the commenter recommends be amended or addressed. It appears that the comment advocates for the Board to authorize CRNAs to perform general anesthesia for pediatric dental patients in an ASC. However, the Board’s authority to authorize the order or administration of general anesthesia to pediatric patients is limited to dentists and physicians licensed by

the Medical Board of California (BPC, §§ 1646.1, 1646.9). This comment must therefore be rejected as beyond the authority of the Board to address in this rulemaking.

To the extent the commenter is suggesting amendments to existing section 1043(b) or changes to BPC section 2427, the comments are rejected as neither not sufficiently related to this rulemaking or requiring statutory changes that are beyond the authority for the Board to address in this rulemaking.

H. Letter, dated February 14, 2022, from Elizabeth DeBouyer, Executive Director, California Ambulatory Surgery Association (CASA)

General Background Comment Summary: The commenter explained there currently are approximately 64 ASCs in California providing some form of dental services with a small amount of those facilities providing dental procedures. The commenter noted that ASCs are regulated under a variety of state and federal requirements, and an ASC can perform procedures on patients if it meets one of three criteria:

> 1.) Licensed by the California Department of Public Health (CDPH) as a "surgical clinic" pursuant to Health and Safety Code Section 1204(b)(1); 2.) Accredited as an "outpatient setting" by one of the five accrediting bodies approved by the Medical Board of California (MBC) pursuant to Health and Safety Code Section 1248; or 3.) Certified by the Medicare Program as an "ambulatory surgical center."

The commenter stated that under these regulatory scenarios, either CDPH, MBC, and/or accrediting bodies, or CMS and/or their contracting entity can take corrective action against the facility. The commenter stated that the Board has no statutory or regulatory authority to regulate these facilities, regardless of the level of sedation and anesthesia being provided nor the types of dental procedures that are being performed. The commenter argued that the only authority the Board has is over the licensed dentists performing these procedures in these "outpatient" settings. The commenter argued that the proposed regulations appear to miss the mark on the definition of "outpatient" and "outpatient setting."

The commenter attached a memo, dated September 10, 2019, to the Board from attorneys Jeanne Vance and Jennifer Nguyen of the law firm Salem and Green, in which the following opinions were rendered:

> (1) California Business and Professions code section 1646.18 does not apply to services performed in a Medicare-certified ambulatory surgery center;
> (2) A dental ambulatory surgery center is not subject to the jurisdiction of the Dental Board if it is an outpatient setting subject to general anesthesia requirements under the Health and Safety Code;
> (3) the dental anesthesia permit requirements set forth in Section 1646.1 do not apply to services provided outside of a dental office; and,

(4) CRNA's may deliver general anesthesia at a Medicare-certified ambulatory surgery center by dentist's order without having a dental anesthesia permit.

Summary of Comment No. 1: The commenter recommended the Board revise the definition for "outpatient setting" in the proposed regulations, as follows:

For purposes of this article, "outpatient setting" means a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

Staff Recommended Response to Comment No. 1: Reject the comment. The Board's current authority for mandating a permit to order or administer anesthesia or sedation is based upon whether the dentist is performing the procedure on an "outpatient basis" (see BPC, §§ 1646.1, 1647.2, 1647.19, and 1647.31). The words "outpatient setting" occur in existing text in Article 5 (without definition) and as a proposed additional definition to Article 5.5, section 1044(b) for "outpatient basis" as follows:

(a) "Outpatient basis" means "outpatient setting" as used in Health and Safety Code Sections 1248 and 1248.1 and means all settings where oral conscious sedation is being provided to dental patients with the exception of a treatment facility which is accredited by the Joint Commission on Health Care Organizations or licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

The Board's current proposal adds the words "outpatient setting" to the definition of "outpatient basis" at section 1044(a) to conform to the terminology used in HSC sections 1248 and 1248.1, which are already cross-referenced in section 1044(a). The commenter's proposal would expand the scope of the original rulemaking to include this new definition, which exceeds the scope of the Board's original rulemaking and, in the opinion of Board Regulatory Counsel, would require the Board to restart the rulemaking to consider these changes.

In addition, HSC section 1248.1 lists eight different types of permissible outpatient settings that may operate in California, including an ASC that is certified to participate in the Medicare program. However, nowhere in that section does it indicate that operation of these settings automatically exempts dentists or other personnel from complying with licensure requirements contained in the Dental Practice Act.

On the contrary, since the Board last reviewed this provision, HSC section 1248.1 still requires dentists and physicians to comply with the relevant portions of the Dental Practice Act in that outpatient setting. Section 1248.1 provides, in pertinent part:

> No association, corporation, firm, partnership, or person shall operate, manage, conduct, or maintain an outpatient setting in this state, unless the setting is one of the following:
> . . .
>
> (f) **Any outpatient setting to the extent that it is used by a dentist or physician and surgeon in compliance with** Article 2.7 (commencing with Section 1646) or Article 2.8 (commencing with Section 1647) of Chapter 4 of **Division 2 of the Business and Professions Code**. (Emphasis added.)
>
> . . .
>
> Nothing in this section shall relieve an association, corporation, firm, partnership, or person from complying with all other provisions of law that are otherwise applicable.

The suggested definition by the commenter therefore appears inconsistent with the more exhaustive list of outpatient settings set forth in HSC section 1248.1 and the express legislative directive to comply with all other provisions of law that are otherwise applicable. This section specifically contemplates compliance with the relevant article of the Dental Practice Act (at the time, Article 2.7) dealing with requirements for obtaining a general anesthesia permit and which applies to "any outpatient setting to the extent that it is used by a dentists or physician." For the aforementioned reasons, the Board rejects this comment.

Summary of Comment No. 2: The commenter requested that these outpatient settings (referenced in the above definition) must be exempt from the regulations and any regulatory oversight by the Board. Otherwise, the commenter asserted that what the Board is promulgating will be considered an "underground regulation" by creating barriers to access to care without proper enabling statue authorizing the Board regulatory oversight of these facilities.

Staff Recommended Response to Comment No. 2: Reject the comment. The Board is not asserting, through this rulemaking, authority to regulate ambulatory surgical center settings. The Board regulates dentists' administration of anesthesia and sedation on an "outpatient basis," which includes under existing regulation, administration in settings other than a general acute care hospital (see current subsections 1043(b) and 1044(a)). The Board's regulatory action to implement relevant statutory provisions is not "underground" but rather existing law and regulation. The Board has statutory and regulatory authority over dentists administering or ordering the administration of general anesthesia or deep sedation, moderate sedation, oral conscious sedation (adults), and pediatric minimal sedation to dental patients on an

outpatient basis, which includes treatment at ASCs that are considered an outpatient setting by law (see BPC, §§ 1646.1, 1647.2, 1647.19, and 1647.31; current Cal. Code Regs., tit. 16, §§ 1043(b) and 1044(a); and HSC, §§ 1248.1(a), (f)).

The Board's statutory authority to require an onsite inspection and evaluation of the licentiate and the facility, equipment, personnel, and procedures utilized by the licentiate to administer or order the administration of anesthesia or sedation is established in BPC sections § 1646.4(a) (general anesthesia and deep sedation) and 1647.7(a) (moderate sedation). Further, in response to a complaint submitted to the Board alleging that a dentist or dental assistant has violated any Board law or regulation, the Board may inspect the books, records, and premises of any California licensed dentist, regardless of practice location, and the licensing documents, records, and premises of any dental assistant. (BPC, § 1611.5, subd. (a).) The Board therefore rejects this comment.

With respect to the comment requesting exemption from regulations, the Board presumes the comment is directed to possible changes to sections 1043(b) or 1044(a). As explained in the response to comments B.1., B.2., C., and D. above, to the extent the commenter is suggesting amendments to existing sections 1043(b) or 1044, it is rejected as not sufficiently related to this rulemaking. The regulatory proposal to add new subsection 1043.9(b) simply restates the Board's existing authority for pediatric patients receiving oral conscious sedation at section 1044(a). For the reasons discussed in more detail below, the Board wishes to retain this long-standing interpretation of outpatient basis for the newly titled "pediatric minimal sedation permit" (previously pediatric oral conscious sedation permit) that the Board believes has worked well to ensure public protection and to maintain consistency with the "outpatient" and "outpatient basis" definitions contained in sections 1043 and 1044. Consideration of possible changes to section 1043.9 and not the others would lead to inconsistent regulatory oversight. For these reasons, the comments are rejected.

Summary of Comment No. 3: The commenter recommended repealing the existing definition of "outpatient" in section 1043(b) and replacing it with the following (as represented in double underline):

> (b) For purposes of this article, "outpatient" means a patient treated in a treatment facility which is not a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.) or licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health & Safety Code.

Staff Recommended Response to Comment No. 3: Reject the comment. As explained in the response to comments B.1., B.2., C., and D. above, this proposed

comment is not sufficiently related to this rulemaking. The Board also considers the following substantive legal and policy issues regarding this existing regulatory definition.

Surgical clinics licensed by the California Department of Public Health are specialty clinics defined under HSC section 1204(b)(1) as ”a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours.” The licensing and regulations covering these facilities are less stringent than those for general acute care hospitals, which are obligated to provide more services, be available 24 hours a day, and handle inpatient procedures. As a result, the Board’s existing regulation at section 1043(b) recognizes that “outpatient basis” does not include accredited or licensed general acute care hospitals within the definition of “outpatient” because those health care facilities provide “staff that provides 24-hour **inpatient care**, including the following basic services: medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services . . .” (emphasis added) as specified in HSC section 1250(a).

HSC section 1225(c)(2) requires surgical clinics (as defined in HSC section 1204(b)) to comply with the federal certification standards for ASCs found in Code of Federal Regulations, title 42, sections 416.1 through 416.54. It is the Board’s understanding that these standards are not equivalent to those required for Joint Commission accreditation as a hospital, or for licensure as a “general acute care hospital” by the California Department of Public Health.

In addition, the commenter’s proposed amendment appears to conflict with the HSC section 1248(b)(1) definition of an “outpatient setting,” which states:

> “Outpatient setting” means any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, as defined in Section 1250, and where anesthesia, except local anesthesia or peripheral nerve blocks, or both, is used in compliance with the community standard of practice in doses that, when administered have the probability of placing a patient at risk for loss of the patient’s life-preserving protective reflexes.

The Board’s current definition at section 1043(b) incorporates the definition in HSC section 1248.1, which includes the exemption, by law, for a general acute care facility, which is defined in HSC section 1250(a) as a general acute care hospital. The Board’s current definition therefore is consistent with the definitions for outpatient settings noted above and contemplated by current HSC standards.

Finally, when the Board last considered revisions to section 1043(b) in 2006, the Board was asked by the California Association of Nurse Anesthetists (CANA) to consider a similar issue and exempt facilities accredited by an accrediting entity approved by the Medical Board of California (see p. 3 of Exhibit “E” Final Statement of Reasons attached to written comments provided by Andrew Kugler) and was advised by Board counsel at

the time that the requested changes would be inconsistent with the statute. Current Board Regulatory Counsel does not disagree with that assessment and advises that revising the definition for "outpatient" as recommended would require amendments to the Dental Practice Act.

For all of the foregoing reasons, this comment is rejected.

Summary of Comment No. 4: The commenter recommended repealing the existing introductory sentence in section 1043.3 as follows (as represented in double strikethrough):

> All offices in which general anesthesia, deep sedation, or ~~conscious~~ moderate sedation is conducted under the terms of this article shall, unless otherwise indicated, meet the standards set forth below. In addition, an office may in the discretion of the board be required to undergo an onsite inspection. ~~For the applicant who administers in both an outpatient setting and at an accredited facility, the onsite must be conducted in an outpatient setting.~~ The evaluation of an office shall consist of three parts:

Staff Recommended Response to Comment No. 4: Reject this comment. This comment appears related to the commenter's position that the Board has no regulatory oversight over the premises, other than a dental office, in which a dentist administers general anesthesia to a patient. For the reasons set forth above under response to comment no. 2 for this commenter, the Board rejects this argument. In addition, the proposed requirement that an applicant who administers anesthesia in both an outpatient setting and at an accredited facility have their onsite inspection at an outpatient setting focuses the onsite inspection on the area where practice would occur and where an accurate assessment of the standards required for the permit may be made in an environment with possibly less stringent oversight than would be required for an accredited facility. The Board considers the existing requirement consistent with its consumer protection mission and therefore declines to make any modifications to the existing regulation.

Summary of Comment No. 5: The commenter recommended deleting the definition proposed by the Board for "outpatient basis" in section 1043.9(b) relating to pediatric minimal sedation permits, and replacing it with the following (as shown in double-underline):

> (b) "Outpatient basis" as used in Section 1647.31 of the Code means all settings where pediatric minimal sedation is being provided to dental patients with the exception of a treatment facility which is a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security

Act (42 U.S.C. Sec. 1395 et seq.) or licensed by the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

Staff Recommended Response to Comment No. 5: Reject this comment. The Board hereby incorporates the substantive legal and policy issues discussed in response to this commenter's comment no. 3 above for this comment response. For the reasons discussed in that response, the Board wishes to retain this long-standing interpretation of outpatient basis for the newly titled "pediatric minimal sedation permit" (previously pediatric oral conscious sedation permit) that the Board believes has worked well to ensure public protection and to maintain consistency with the "outpatient" and "outpatient basis" definitions contained in sections 1043 and 1044. Consideration of possible changes to section 1043.9 but not the other sections would lead to inconsistent regulatory oversight. For these reasons, the comment is rejected.

Summary of Comment No. 6: The commenter recommended adding the following to the proposed 1043.9.1 requirements, as follows (as shown in double-underline):

(a) A licensed dentist who desires to administer or order the administration of pediatric minimal sedation on an outpatient basis is not required to apply to the Board for a pediatric minimal sedation permit if they possess another sedation permit from the Board and in compliance with Business and Professions Code 2725(b)(2).

Staff Recommended Response to Comment No. 6: Reject this comment. BPC section 2725(b)(2) is a provision in the Nursing Practice Act relating to the scope of practice for nursing. This provision does not relate to and is not referenced in any existing section of the Dental Practice Act. As the proposed regulations section is specific to the ability of a dentist to administer or order pediatric minimal sedation on an outpatient basis in compliance with the Dental Practice Act, this proposed change is unrelated to the current proposal and beyond the scope of the Board's current authority to consider for this rulemaking proposal. For these reasons, the comment is rejected.

Summary of Comment No. 7: The commenter recommended repealing the existing definition of "outpatient basis" in Section 1044(a) and replacing it with the following (as shown in double-underline):

(a) "Outpatient basis" means a dental office where oral conscious sedation is being provided to dental patients with the exception of a treatment facility which is a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.) or licensed by the

California Department of Health Services as a “general acute care hospital” as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

Staff Recommended Response to Comment No. 7: Reject the comment. The Board hereby incorporates the reasons set forth above in response to comment no. 3 for this commenter, in response to this comment. BPC section 1647.19 contains no such limitation on the provision of oral conscious sedation to only dental offices, but similar to other provisions of the Dental Practice Act, requires a permit for sedation on an “outpatient basis.” HSC section 1248.1(f) does not limit outpatient settings for dentists to only a “dental office.” On the contrary, subsection (f) indicates that compliance with Dental Practice Act requirements relates to “any outpatient setting.” The Legislature has been aware of this requirement since 2005 and has chosen to not act to limit the scope of the required permit to a specific outpatient setting as it has done for other types of permits (see BPC, § 1646.9(a) limiting the requirement for a physician to obtain a general anesthesia permit from the Board to administer anesthesia to the office of a licensed dentist).

When the Board last considered revisions to section 1044 in 2006, the Board was asked to consider a similar issue. It was suggested that the definition of “outpatient basis” be amended to include “a treatment facility which (that) is accredited as an office-based surgery facility by the Joint Commission on the Accreditation of Health Care Organizations…”

The Board considered the suggested language and agreed with the comment that an evaluation of the Joint Commission’s standards may be needed. The Board opted not to make the suggested change at that time to maintain consistency with the language for oral conscious sedation for minors. The Board also noted the review of Joint Commission standards would delay implementation of the regulations and impact the ability of patients to seek care. The Board did not make the change and requested staff research the issue and report back to the Board.

Board staff notes that further delaying implementation of the regulations at this time would lead to a lapse in permits for dental general anesthesia and sedation. A formal review of the current standards could be done, but staff recommends that such a review not delay implementation of the regulations. For these reasons, this comment is rejected.

Summary of Comment No. 8: The commenter proposed changes to BPC section 1647.2(c), including the requirement that a dentist be physically present in the treatment facility while the patient is sedated when receiving treatment at a surgical clinic.

Staff recommended response to Comment No. 8: Reject the comment. As the commenter acknowledges, the proposed change is to statute. Such a change is beyond the scope of this rulemaking process.

I. Letter, dated February 15, 2022, from Mary McCune on behalf of the California Dental Association

Ms. McCune offered several comments, which are summarized and responded to below:

Comment No. 1 Summary: Form PE-1 (NEW 05/2021), titled "Documentation of Deep Sedation and General Anesthesia or Moderate Sedation Cases for Pediatric Endorsement" appears to be missing the title and the fee information. The commenter believes this is intended to be the application form for the Pediatric Endorsement. The commenter also believes the form is missing a certification of training where the applicant certifies that they have completed the training specified in statute for moderate sedation of patients under age 13.

Staff recommended response to Comment No. 1: Reject this comment. The Board has considered the comment and has decided to make no changes to the text based thereon for the following reasons.

The proposed new regulatory section 1043.8.1 outlines the requirements for an application to the Board for a pediatric endorsement for a general anesthesia permit (in subsection (a)) and a pediatric endorsement for a moderate sedation permit (in subsections (b) and (c)). Those requirements include, among other things, completing Form PE-1, paying the appropriate application fee listed in section 1021, submitting a certificate of completion or other evidence showing completion of the training required by BPC section 1646.2 or 1646.9 (for pediatric endorsement of a general anesthesia permit), or BPC section 1647.3 (for pediatric endorsement of a moderate sedation permit).

Form PE-1 is for documenting the necessary cases required for the pediatric endorsement. The application for that endorsement consists of all items listed in the relevant portion of regulations section 1043.8.1. There is no specific form required for the endorsement application, only for the documentation of the cases required for the endorsement. Similarly, there is no certification by the applicant that they have completed the necessary training, applicants must submit proof of this training as part of their application.

Comment No. 2 Summary: The commenter would like the Board to include criteria for the board-approved training in pediatric life support and airway management consistent with BPC section 1601.8. Such criteria are not in the proposed regulations. The commenter's organization has developed recommendations for such a course that they consider more appropriate for dental providers than the Pediatric Advanced Life Support (PALS) certification that applicants for the pediatric endorsement must complete.

Staff recommended response to Comment No. 2: Reject this comment. The Board has considered the comment and has decided to make no changes to the text based thereon for the following reasons.

The Board does not consider it necessary to put the specific course requirements for an alternative board-approved training in regulation. BPC section 1601.8 states that the Board "may approve a training standard" in lieu of PALS certification if a board-approved training standard is "an equivalent or higher level of training for pediatric dental anesthesia-related emergencies than PALS certification that includes, but is not limited to, pediatric life support and airway management." The Board cited the American Red Cross, the American Hospital Association and the American Health and Safety Institute as these organizations work to establish and maintain standards in advanced cardiac life support and pediatric advanced life support. The Board does not feel that it could improve on the standards set by these organizations by developing its own criteria for alternative courses at this time.

Comment No. 3 Summary: Echoing concerns over the definition of "outpatient" and "outpatient facility," the commenter believes the existing definition of "outpatient" in section 1043(b) of the regulations that is not proposed to be changed in this proposed regulatory action is inconsistent with definitions of "outpatient setting" found in HSC sections 1248 and 1248.1. The commenter suggests revising the definition of "outpatient" in section 1043(b) to include the definition of "outpatient setting" found in HSC sections 1248 and 1248.1.

Staff recommended response to Comment No. 3: Reject this comment. The Board has considered the comment and has decided to make no changes to the text based thereon for the following reasons.

As stated above, this proposed change is to existing text and not a change noticed required to implement SB 501. As a result, any possible changes to section 1043(b) would require the Board to start the regulatory process over to address these changes.

In addition, as explained in response to comments provided in H. above, the Board believes that its definitions of "outpatient" and "outpatient basis" are consistent with HSC sections 1248 and 1248.1 and the definition of "outpatient setting" used therein.

Comment No. 4 Summary: The commenter seeks clarity as to whether a dentist may order the administration of deep sedation/general anesthesia within their scope of practice in an outpatient setting as described in HSC section 1248.15(3). The commenter noted that the Board may not be able to speak to the authority of a dentist to order the administration of deep sedation/general anesthesia by a certified registered nurse anesthetist given pending legislation (SB 889).

Staff recommended response to Comment No. 4: Reject this comment. The Board has considered the comment and has decided to make no changes to the text based thereon for the following reasons.

The Board believes the commenter seeks clarity about whether a dentist is within their scope of practice to order the administration of deep sedation/general anesthesia in an outpatient setting by a certified registered nurse anesthetist. While there is pending legislation as of this writing that may change the ability of certified registered nurse anesthetists to administer anesthesia in dental settings, the Board can only speak to the laws and regulations in effect at the present time and to the proposed regulations at issue in this proceeding.

The Dental Practice Act at BPC sections 1646.1 and 1646.9, as enacted by SB 501, currently restricts the issuance of a general anesthesia permit (which would include deep sedation under the proposed regulations) to licensed dentists and physicians and surgeons (licensed by the Medical Board of California) who file an application and meet the necessary requirements. There currently is no provision in the Act for the Board to grant an anesthesia permit to a certified nurse anesthetist. The proposed changes to section 1043.1(b) would remove the reference to administration of general anesthesia by a nurse anesthetist to conform the current regulations to the requirements of SB 501, which were effective January 1, 2022.

While HSC section 1248.15(3) would allow the outpatient setting, in its discretion, to permit anesthesia service by a certified registered nurse anesthetist, a dentist could not, within their scope of practice, order a certified nurse anesthetist to administer deep sedation or general anesthesia.

Comment No. 5 Summary: The commenter suggested that the Board define equivalency standards for training in pediatric moderate sedation for inclusion on the form MSP-2 (Certification of Moderate Sedation Training). The commenter further suggested that the statutory requirement of 20 cases of moderate sedation in patients under BPC section 1647.3(d)(2) should be considered training equivalent to a Commission on Dental Accreditations (CODA) accredited pediatric residency.

Staff recommended response to Comment No. 5: Reject this comment. The Board has considered the comment and has decided to make no changes to the text based thereon for the following reasons.

The commenter seeks a statutory change, which is beyond the scope of this regulatory proceeding and confounds the competency demonstration requirements with the training requirements. BPC section 1647.3(d) sets out four requirements for a pediatric endorsement for a moderate sedation permit for which applicants must confirm **all** of the following:

- Completion of a Commission on Dental Accreditation (CODA) accredited residency in pediatric dentistry or the equivalent training in pediatric moderate sedation, as determined by the Board;
- Successful completion of at least 20 cases of moderate sedation to patients under 13 years of age;
- If providing sedation to patients under seven years of age, completion of 20 cases of moderate sedation for children under seven in the 24-month period preceding application or renewal; and
- Current certification in Pediatric Advanced Life Support and airway management or other board-approved training in these areas.

The statute requires all four requirements to be met, so absent a statutory change, it would not be permitted to substitute the 20 cases demonstration of *competency* requirement for the CODA-accredited residency in pediatric dentistry or the equivalent *training* requirement.

Comment No. 6 Summary: The commenter believes that Form PE-1 is the application for the pediatric endorsement and recommends Form PE-1 be retitled and a certification form added document training received as specified in BPC section 1647.2 for moderate sedation of patients under age 13.

Staff recommended response to Comment No. 6: Reject this comment. For the reasons set forth in response to comment no. 1 for this commenter, the Board rejects this comment. There is no form required but rather the requirements for application are contained in proposed section 1043.8.1.

Comment No. 7 Summary: The commenter believes that a certification of training form is missing from the application for the use of oral conscious sedation for adult patients. They recommended borrowing relevant language from forms OCS-2 and OCS-3 and using that language to replace form OCS-C. The purpose of such a form would be to ensure compliance with BPC Section 1647.20.

Staff recommended response to Comment No. 7: Accept this comment. The Board has considered the comment and has decided to make the following changes:

Currently proposed Form OCS-C (new 05/2021) was intended to cover all requirements for adult conscious sedation and incorporate all existing regulatory or statutory requirements. Upon review of this comment, it was discovered that the criteria for OSC-1 and OSC-4 were not captured on this new proposed form. As a result, the Board accepts this comment and the text of OSC-C will be modified to request that applicants identify which one of the four requirements listed in BPC section 1647.20 they meet, and to include evidence to demonstrate compliance with that requirement.

In addition, section 1044.4 will be retained, **and not repealed**. Applicants seeking to meet the requirement of BPC section 1647.20(d) – 10 cases or oral conscious

sedation satisfactorily performed by the applicant within any three-year period ending no later than December 31, 2005 – can still use Form OCS-4 (03/07) to document those cases.

J. Letter, dated February 15, 2022, from Alan Vallarine, DDS, Fresno Dental Surgery Center, Larry Church, DDS, Indio Surgery Center, Pankaj Patel, DMD, Bay Area Dental Surgery Center, Devin Larson, Blue Cloud Pediatric Surgery Centers, and Marcus Kasper, All Kids Dental Surgery Center

Comment Summary: The commenters recommended exempting certain facilities from the definition of "outpatient" in existing section 1043(b) and "outpatient basis" in existing section 1044(a) and the proposed "outpatient basis" definition contained in section 1043.9(b) (Comment No. 1). These revisions are consistent with the proposed changes recommended by another commenter in comment H. above. In addition, the commenters recommended striking the word "offices" or "office" and replacing it with "outpatient setting," as follows (Comment No. 2):

> **1043.3. Onsite Inspections**
> All ~~offices~~ outpatient settings in which general anesthesia, deep sedation, or moderate sedation is conducted under the terms of this article shall, unless otherwise indicated, meet the standards set forth below. In addition, an ~~office~~ outpatient setting may in the discretion of the board be required to undergo an onsite inspection. For the applicant who administers in both an outpatient setting and at an accredited facility the onsite must be conducted in an outpatient setting. The evaluation of an ~~office~~ outpatient setting shall consist of three parts:

Staff recommended response to Comment No. 1: Reject the comment. For the reasons set forth above in response to comment H. above, the Board rejects this comment.

Staff recommended response to Comment No. 2: Reject the comment. The Board believes the term "office" is more commonly understood by dentists to include the premises or facility where general anesthesia services are provided and is a term used throughout the Dental Practice Act (see e.g., BPC sections 1646.1, 1646.9, 1647.16), and therefore declines to make this change.

K. Letter, dated February 15, 2022, from Jeanne Vance, on behalf of ASCs and other healthcare providers

Comment Summary: The commenter stated that application of minimum standards for the delivery of anesthesia intended for dental offices to the highly sophisticated operations of an ASC would run contra to the success of ASC, which have provided a less expensive alternative to hospital care with a similar surgical outcome. The commenter requested that the Board amend the proposed regulations to clarify sections 1043(b), 1043.3, 1043.9(b) and 1044 consistent with comment J. above.

Staff recommended response to Comments: Reject the comments. For the reasons set forth above in response to comment J. above, the Board declines to make the changes recommended by this commenter.

L. Letter, dated February 16, 2022, from Andrew Kugler on behalf of the California Association of Nurse Anesthetists

Comment Summary: The commenter stated that for more than 30 years, it was commonly understood that the definition of outpatient in section 1043(b) did not extend to patients treated at ASCs, meaning that dentists could order the administration of general anesthesia by a qualified provider (be it a CRNA or anesthesiologist) in an ASC, even if they did not hold an anesthesia permit, just as they do in acute care hospitals. However, the commenter understood that the Board has recently taken a contrary position that a dentist must hold a permit when ordering anesthesia in an ASC.

The commenter proposed changes to section 1043(b), 1043.9, and 1044(a) to exclude the following new types of facilities from the definition of “outpatient” and “outpatient setting”: (1) licensed by the California Department of Public Health as a “surgical clinic” pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health & Safety Code; (2) accredited by an accrediting agency approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with section 128); or (3) certified to participate in the Medicare Program as an ambulatory surgical center pursuant to Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

Staff recommended response to comments: Reject this comment. The Board has considered the comment and has decided to make no revisions to the text thereon for the reasons set forth in responses to comments provided to the commenter under subsection H. above.

Oral and Written Comments Received at the Board’s February 16, 2022 Regulatory Hearing

A hearing was requested by several parties and was held via WebEx teleconferencing services on February 16, 2022, at 1:30 p.m., Pacific time.

Seven individuals offered comments, either on behalf of themselves or representing organizations. In many cases the same individuals had also provided written comments to the Board. In some cases, individuals who spoke at the hearing provided a copy of their remarks to the Board.

Repeated comments:

(1) Comments requesting further exemption for anesthesia and sedation in outpatient settings that include ambulatory surgery centers: Jeanne Vance, Bryan Docherty,

Monica Miller, Mary Wilson, Michael Warda, and Ken Pierson each echoed the suggestion found in many written comments that ASCs be exempted from the regulations defining outpatient or outpatient settings.

Proposed Staff Response: Reject the comments. As noted above, the Board has decided not to make the suggested change, in part because it considers the definitions of outpatient and outpatient basis in current and proposed regulations are consistent with the statutory definition of "outpatient setting" in HSC sections 1248 and 1248.1. Please see the analysis in response to comment H. above.

(2) Bruce Whitcher spoke on behalf of the California Dental Association, summarizing the written comments the organization submitted. (See comment F. for those comments and proposed Board responses.)

(3) Bryce Docherty, representing the California Ambulatory Surgery Association, summarized the written comments the organization submitted. (See comment E. for those comments and proposed Board responses.)

(4) Monica Miller, presenting the California Association of Nurse Anesthetists, referenced the written comments submitted by her association and emphasized their agreement with previous comments about the status of ASCs. (See comment L. for those comments and proposed Board responses.)

(5) Mary Wilson echoed the written comments she submitted, suggesting that ASCs be included as acute care facilities in BPC section 2827. (See comments B.1 and B.2 above for those comments and proposed Board responses.)

Dr. Felsenfeld invited counsel to provide any further guidance on the issues presented. Ms. Schieldge addressed the largest comment concern, the definition of outpatient or outpatient basis, that has been brought forward by public commenters in this rulemaking. She stated that the issue is a statutory authority issue. Ms. Schieldge noted in the meeting materials [see page 436], the first iteration of the Board's authority to issue general anesthesia permits was enacted in 1979 and that outpatient-basis authority existed then and has continued to exist for the next 40 plus years. The Board can adopt rules related to profession, but they have to be grounded in reality. Ms. Schieldge stated the reality is that facilities mentioned in the public comments are in fact providing services on an outpatient basis and therefore dentists administering anesthesia and sedation in those settings are required to have a permit. Ms. Schieldge noted the dictionary definition of "outpatient" is a patient who receives medical treatment without being admitted to a hospital and stated that the Board's existing regulations follow that commonly understood meaning. She also noted the Health and Safety Code provisions that are currently cross-referenced in the Board's regulations are consistent with the Health and Safety Code's definition of outpatient setting. Ms. Schieldge does not think the Board can make the legal argument to OAL that the Board has the power to carve out exceptions to different outpatient settings and cherry-pick which dentists have to comply in which setting. She stated that would be something before the

Legislature and the Board would want discussed on a policy basis, she stated that she did not believe that this rulemaking is the appropriate place for that discussion.

Dr. Felsenfeld commented that the Board needs to move forward with these regulations to protect those who are providing anesthesia services; if the rulemaking gets further bogged down, there will be fewer anesthesia providers. In addition, Dr. Felsenfeld stated there will be discussion on the role of nurse anesthetists and ambulatory surgical centers at a future Board meeting.

(M/S/C) (Chan/Yu) to direct staff to proceed as recommended to accept or reject comments as specified and provide the responses to the comments as indicated in the meeting materials.

Dr. Felsenfeld requested public comment before the Board acted on the motion.

The Board received public comment. Elizabeth DeBouyer, Executive Director of the California Ambulatory Surgery Association (CASA), noted that CASA strongly believes that these proposed regulations miss the mark on the definition of outpatient and outpatient setting. CASA has identified five specific areas of the regulations that need to be amended in order to comport with existing law. Additionally, it recommends one section of the Business and Professions Code (BPC) that needs to be amended in order to comport with existing law. Ms. DeBouyer stated the regulations as presented create a significant access to care issue particularly for the children served by Medi-Cal. CASA believes that the definitions and exemptions in these regulations need to be specific to an ambulatory surgery center (ASC) that is accredited, Medicare certified, and/or state licensed.

Ms. Jeanne Vance, a healthcare attorney with the law firm Weintraub Tobin. Ms. Vance stated the purpose of this law was to increase the standards for providing anesthesia in dental offices, which were not regulated settings. She stated there is nothing unique about dental anesthesia that makes it more inherently dangerous than anesthesia provided in other settings. Ms. Vance noted that she submitted comments at the February 16, 2022 public hearing that would have clarified that these general anesthesia permit requirements would not apply in settings that are highly regulated outside of dental offices merely because the patients have an issue in their mouth. Ms. Vance verbalized that staff for the bill recommended clarifying the definition of outpatient basis to provide that it does not include the services of a general acute hospital, even if the services were provided in an outpatient department of a general acute care hospital on outpatients, and the Board adopted this regulation. Weintraub Tobin believes it was adopted in error. Ms. Vance stated that the original statute did not contain any such exemption or clarification, but the Dental Board appropriately determined it was in its discretion to define what outpatient basis means. They believe that discretion needs to be exercised to further clarify that these rules do not apply to ASCs. ASCs are Medi-care certified and licensed. While there was a comment that ASCs' licensing standards being less than a general acute care hospital, which is true

from a licensing standpoint. But that ignores the fact that they are subject to Medi-care certification and accreditation standards, which are very extensive and is the reason the Board's meeting package is so lengthy, because it includes the Medi-care standards that apply to ASCs.

Dr. Bruce Whitcher thanked the Board for the presentation. Dr. Whitcher stated that although ASCs do provide a high level of care, it should be recognized that the topic discussed is a regulatory legal issue, and what many of the commentors have requested is to try to amend statute through regulation, which is not allowed and would cause the rulemaking to be rejected. He urged the Board to adopt staff recommendations and move this forward in order for the Board to issue new permits. He stated that if anything will affect access to care, it is the Board's inability to issue new sedation and anesthesia permits, which is hinging on this particular motion.

Mr. Michael Warda, attorney, indicated that under the BPC, the use of a nurse anesthetist can operate and be directed by a physician, dentist, or podiatrist in a hospital; ASCs have the same procedures in place to protect patients with respect to the anesthesia procedure. Mr. Warda asked the Board to address this issue and help modify state law. Mr. Warda verbalized that he believes the Board has been tasked by the Office of Oral Health (OOH) to implement rules, part of which is to assess dental needs by race, ethnicity, geography, and income. Mr. Warda stated that kids being treated at ASCs need access to this care, and if a nurse anesthetist by statute can work in a hospital under the direction of a doctor or dentist who does not carry an anesthesia permit, a dentist should not be treated differently; he should be treated as a doctor. Mr. Warda stated the Board should protect dentists and state that the Board wants dentists to have the ability to use anesthesia the same way a dentist can in a hospital, provided that the dentist is in a certified facility. Mr. Warda urged the Board to work with this group and the communities to immediately get the issue resolved. He stated the issue is critical, will move in that directly anyway, and it is important for the Board to be involved.

Dr. Tuso stated her appreciation of how in-depth this entire presentation was about using general anesthesia in the dental offices and the Board policing or ensuring that the public safety is preserved. She went on to inquire on how to have her prior statements and concerns addressed officially at a Board meeting. Dr. Felsenfeld stated that Dr. Tuso's comments were off-topic.

Dr. Felsenfeld called for the vote on the proposed motion. Dr. Molina took a roll call vote on the proposed motion as follows:

Ayes: Chan, Felsenfeld, Larin, McKenzie, Medina, Molina, Montell, Morrow, Olague, Pacheco, Yu.
Nays: None.
Abstentions: None.
Absent: Mendoza.
Recusals: None.

The motion passed.

Agenda Item 5: Discussion and Possible Action to Consider Adoption of Proposed Amendments to California Code of Regulations, Title 16, Sections 1021, 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, 1043.8, 1044, 1044.1, 1044.2, 1044.3, 1044.5, 1070.8, 1017.1, 1043.8.1, 1043.9, 1043.9.1, 1043.9.2, and 1044.4 Relating to the SB 501 (Anesthesia and Sedation) Rulemaking

Mr. Bruggeman provided the report, which is available in the meeting materials. He reviewed the proposed modified text and emphasized that he will be referring to modifications being made to the proposed regulations. Mr. Bruggeman mentioned that modifications to the originally proposed regulatory language are shown in double underline for new text and double strikethrough for deleted text and would be in yellow highlight.

(M/S/C) (Chan/Montell) to approve the proposed modified text and documents added to the rulemaking file and direct staff to take all steps necessary to complete the rulemaking process, including sending out the modified text with these changes and notice of the addition of documents added to the rulemaking file for an additional 15-day comment period. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulation, and adopt the proposed regulations (including the decision not to repeal section 1044.4) as described in the modified text notice for 16 CCR sections 1017.1, 1021, 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, 1043.8, 1043.8.1, 1044, 1044.1, 1044.2, 1044.3, 1044.4, 1044.5,1070.8, 1043.9, 1043.9.1 and 1043.9.2.

Dr. Felsenfeld requested public comment before the Board acted on the motion. The Board received public comment. Dr. Tuso asked for clarification on how she can get her concerns fully addressed at a meeting. Dr. Felsenfeld advised Dr. Tuso her comments were out of order unless directed to the agenda item. Dr. Tuso made no comments on this specific agenda item.

Dr. Felsenfeld called for the vote on the proposed motion. Dr. Molina took a roll call vote on the proposed motion as follows:

Ayes: Chan, Felsenfeld, Larin, McKenzie, Medina, Molina, Montell, Olague, Pacheco, Yu.
Nays: None.
Abstentions: None.
Absent: Mendoza, Morrow (due to technical difficulties).
Recusals: None.

The motion passed.

At 2:13 p.m., the Board recessed for a break.

At 2:30 p.m., the Board reconvened.

Agenda Item 6: Discussion and Possible Action to Initiate an Emergency Rulemaking, Adopt Regulations and a Finding of Emergency, and Initiate a Regular Rulemaking to Adopt California Code of Regulations, Title 16, Section 1066 Relating to Dentists Initiating and Administering Vaccines

Mr. Bruggeman provided the report, which is available in the meeting materials. Ms. Schieldge explained the differences between an emergency rulemaking and a regular rulemaking. Emergency regulations are a process for adopting regulations on a temporary basis in response to a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, or general welfare, or if a statute deems a situation to be an emergency under the Administrative Procedure Act, as it does in this case under BPC section 1625.6. Because emergency regulations are intended to avoid serious harm and require immediate action, the emergency rulemaking process is substantially abbreviated compared to the regular rulemaking process that was just discussed, including the notice, comment period and the time within which OAL has to review (10 calendar days after filing).

Board Member, Dr. Lilia Larin, raised concerns that dentists who want to volunteer in administering vaccines in the future might have the impression that they must apply these written regulations when doing so. She inquired how this rulemaking would apply to dentists who are volunteering at another facility that is not their own. Ms. Schieldge replied that the statute states that in addition to the actions authorized under BPC section 1625, a dentist may independently prescribe and administer influenza and COVID-19 vaccines approved or authorized by the United States Food and Drug Administration (FDA). Dr. Larin asked if this would be sufficient wording to eliminate any confusion posed on volunteering dentists. Ms. Schieldge indicated that she does not want to presume that there is an ulterior meaning in “independently prescribe.”

Dr. Larin expressed concern that volunteering dentists, as they are acting independently, may think that this rulemaking also applies to them. Ms. Schieldge replied that it does apply to them wherever they practice; it is independent in the sense that they are doing it pursuant to their current scope. Dr. Larin noted that her concerns lay with recordkeeping. Ms. Schieldge responded that the dentist is in compliance as long as the administration of vaccination is recorded. The rulemaking is simply making it specific to the dental practice; however, it does not change the fact that dentists must have documentation somewhere of that information. The one difference is that the documentation of immunization training would have to be on premises. Dr. Larin stated that volunteering dentists would not have that documentation on premises. Ms. Schieldge replied that the training requirements is for training certificates, which have to

be readily retrievable during normal business operating hours. Wherever the information is stored, it has to be available to the Board for inspection.

Board Counsel, Ms. Tara Welch, pointed out that this rulemaking is primarily for the administration of vaccines in a dental office and not on voluntary terms. To the extent that dentists have been voluntarily administering the COVID-19 vaccination, they have likely been doing so under an executive order. In the event that dentists continue to voluntarily administer the COVID-19 vaccine, they would be doing so under a different law, rather than the Dental Practice Act (DPA). Ms. Welch specified that these regulations are only fleshing out the new authority under the DPA to administer vaccines in the dental office. Dr. Larin asked if it is possible to clarify this verbiage somewhere in the rulemaking. Ms. Schieldge replied that the question to be addressed would be whether dentists are independently administering vaccines or whether they are doing it under someone else's supervision. Ms. Welch clarified that dentists who were administering COVID-19 vaccines were doing so under Department of Consumer Affairs (DCA) waiver orders, which have already expired or will be expiring once the state of emergency comes to an end. As such, Ms. Welch stated there are no statutes to cross-reference, because the current authority is under executive or DCA waiver orders. Going forward with voluntary administration, if there is any authority to administer these vaccines, it likely would be under the Health and Safety Code, which staff have not researched because they are solely focused on implementing the new bill that centers the administration of these vaccines in the dental office. She advised that it would be beneficial to get moving with this rulemaking. If dentists want to continue to voluntarily administer vaccines, Ms. Welch stated that would be a different question for the Legislature and would no longer fall under the executive orders. Dr. Chan indicated that he does advocate initiating this emergency rulemaking and suggested the Board do this initial format and initial rulemaking and modify the format as it moves forward and the shortfalls become apparent.

(M/S/C) (Chan/Morrow) to (1) direct staff to take all steps necessary to complete the emergency rulemaking process, including the filing of the emergency rulemaking package with the Office of Administrative Law (OAL), authorize the Executive Officer to make any non-substantive changes to the proposed regulations, and adopt the finding of emergency and the proposed regulatory language as written in the Order of Adoption; if no adverse comments are received and the text is approved by OAL, authorize re-adoption as needed and authorize the staff to take all steps necessary to complete the regular rulemaking process to make the regulations permanent and adopt the proposed regulations at Title 16, CCR Section 1066 as noticed; and (2) if OAL or another control agency disapproves the emergency rulemaking, direct staff to submit the proposed text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review and if no adverse comments are received, authorize the Executive Officer to take all steps necessary to initiate the regular rulemaking process, make any non-substantive changes to the package, and set the matter for a hearing, if requested; if no adverse comments are received during the 45-day public comment period and no hearing is requested, authorize the Executive Officer

to take all steps necessary to complete the rulemaking and adopt the proposed regulations at Title 16, CCR Section 1066 as noticed.

Dr. Felsenfeld took public comment on the proposed motion. The Board received public comment. Dr. Whitcher, on behalf of the California Dental Association (CDA), disclosed that they are in support of this proposal and thanked the Board for bringing this forward and conducting the rulemaking so promptly. Dr. Tuso presented comments regarding an enforcement case. Dr. Tuso was advised that her comments did not pertain to the agenda item.

Dr. Felsenfeld called for the vote on the proposed motion. Dr. Molina took a roll call vote on the motion as follows:

Ayes: Chan, Felsenfeld, Larin, McKenzie, Medina, Molina, Montell, Morrow, Olague, Pacheco, Yu.
Nays: None.
Abstentions: None.
Absent: Mendoza.
Recusals: None.

The motion passed.

Agenda Item 7: Adjournment
Dr. Felsenfeld adjourned the meeting at 3:01 p.m.