TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS
DIVISION 10. DENTAL BOARD OF CALIFORNIA

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Senate Bill (SB) 501, Anesthesia and Sedation

Sections Affected: California Code of Regulations (CCR), Title 16, Sections 1017.1[New], 1021, 1043, 1043.1, 1043.2, 1043.3, 1043.4, 1043.5, 1043.6, 1043.7, 1043.8, 1043.8.1 [New], 1043.9 [New], 1043.9.1 [New], 1043.9.2 [New], 1044, 1044.1, 1044.2, 1044.3, 1044.5, & 1070.8 and a new Article 5.1.
(Note: The Board originally noticed repeal of 1044.4 but it no longer is contemplated or affected by this proposal as described below.)

Updated Information:

The Initial Statement of Reasons is included in the file. The information contained therein is updated as follows:

The 45-day public comment period began on December 31, 2021 and ended on February 15, 2022. The Dental Board of California (Board) received written comments as described below. A hearing was not scheduled as part of the initial notice of this rulemaking, but several parties requested a hearing, which took place over teleconference in accordance with Government Code section 11133 and Governor Gavin Newsom's Executive Order N-1-22, on February 16, 2022. A transcript of the hearing is included in the regulatory file. The Board received additional verbal and written comments at the February 16, 2022 hearing, which are described below. The comments as well as the responses to those comments are summarized in the "Objections or Recommendations/responses" section below. The Board considered the comments at its March 14, 2022 meeting and authorized modified text changes as follows.

Modified Text

On its own motion and in response to some of the comments received (see comments "accepted"), the Board made changes to the noticed proposed regulations as described below.

1. The Board made non-substantial clarifying changes to the introduction to the proposal including adding the word "and', adding titles for the existing chapter 4 and

article title references to the introduction to the regulatory proposal so that the regulated community has notice of where section 1017.1 is located.

2. The proposed regulations as originally noticed would have repealed CCR section 1044.4 Documentation of 10 Cases. On review it was determined that this section should not be repealed as the underlying authority was not repealed.

3. Amended section 1044.1 to repeal outdated forms and to consolidate requirements for the adult conscious sedation permit. Existing form OCS-1 would be repealed as the underlying authority for that form was repealed under the provisions of SB 501. OCS-1 is being added to the rulemaking file with a watermark to show "repeal" of that form consistent with the proposed text and to further demonstrate to the public the need to repeal and replace that form with the new OCS-C form.

4. Revised Form OCS-C (New 05/21), "Application for Use of Oral Conscious Sedation on Adult Patients" to list each of the four requirements in Business and Professions Code section 1647.20 for applicants to demonstrate sufficient education and/or experience in oral conscious sedation as currently provided in OCS-3, which is being added to the rulemaking file (with a "repealed" watermark) to show the transfer and consolidation of requirements from that form to the new OCS-C form. The OCS-C form has been amended to list each of the requirements and to have applicants check a box corresponding to the requirement that they are demonstrating compliance with by attaching relevant evidence as specified. In the Board's experience, these questions and the applicable documentation requirements (including proof of academic completion via a diploma or certificate of completion) provide the Board with sufficient verification of the educational experience requirements for this permit. Cross-references have been added to the existing text from the originally adopted Form OCS-3 to further clarify the Board's existing educational requirements and provide notice to the applicants of the educational criteria necessary to qualify for the permit.

5. Removed reference to Form OCS-3 (Rev. 03/07), "Application for Adult Oral Conscious Sedation Certificate," in section 1044.1. As removing the reference effectively repeals the form, the Board is providing additional notice of that fact to the public by including in the rulemaking file a copy of Form OCS-3, with "Repealed" watermark.

6. A copy of the Form OCS-4 (Rev 03/07) "Documentation of Oral Conscious Sedation Cases" incorporated by reference in section 1044.4 was added to the rulemaking file to further justify and explain the Board's decision not to repeal that form as originally noticed.

7. Struck the reference in the introduction to the proposed repeal of section 1044.4 of Article 5.5 of Chapter 2, which, as discussed above, the Board opted to retain.

8. As discussed below, proposed section 1043.8.1 strikes and renumbers subsection (c). As a result, the existing cross-reference in section 1017.1(a) was renumbered to match 1043.8.1, as follows:

> (a) As a condition of renewal, each licensee who holds a general anesthesia permit with a pediatric endorsement shall provide documentation to the Board showing completion of twenty (20) cases of general anesthesia to pediatric patients as provided in Section 1043.8.1, subsections (c)-(ed).

9 Business and Professions Code sections 1646.2, and 1647.3 contain a 24-month currency of knowledge requirement that was inadvertently not reflected in the pediatric endorsement renewal requirements for moderate sedation permit holders in proposed section 1017.1(b)(1)-(2). In addition, the word “under” was inadvertently left out of the originally proposed regulatory language posted and mailed to the public in subsection (b)(3). To correct this omission, the Board made the following changes to proposed section 1017.1(b):

> (b) As a condition of renewal, each dentist licensee who holds a moderate sedation permit with a pediatric endorsement shall confirm to the Board in writing the following as part of the permit renewal requirements in Section 1043.8 (“application”):
>
>> (1) Whether the licensee completed at least twenty (20) cases of moderate sedation for children under thirteen years of age in the 24-month time period immediately preceding application for their current permit renewal either independently and/or under the direct supervision of another permit holder;
>>
>> (2) Whether the licensee completed at least twenty (20) cases of moderate sedation for children under seven years of age in the 24-month time period immediately preceding application for their current permit renewal either independently and/or under the direct supervision of another permit holder, and;
>>
>> (3) If applicable, if the licensee lacks sufficient cases, whether the licensee is administering moderate sedation to patients under

seven years of age only under the direct supervision of a permit holder who meets the qualifications of 1647.3 of the Code.

10. Amended section 1021 to add references to fees for physicians and a nonsubstantial change to correct the introductory title to properly reflect the types of licensees covered in the following fee schedule. Section 1021 currently refers to fees for “dentist examination and licensure by the board**.” This section includes the fees for anesthesia and sedation permits that can be held by physician licensees or other licensees, and the introductory text should accurately reflect the existing and proposed fees contained therein. The text would be modified to state:

§ 1021. Examination, Permit and License Fees for Dentists.
The following fees are set for dentist examination and licensure by the board**, and for other licensee, registrant or applicant types specified below:

(s) General A~~a~~nesthesia (for dentist and physician licensees) or ~~conscious~~Moderate S~~s~~edation P~~p~~ermit renewal fee	$325

…

(ag) Application for Pediatric Endorsement for General Anesthesia Permit (for dentist and physician licensees)	$532

11. Made nonsubstantial changes in response to public comments received to update outdated references in sections 1043(b), 1044(a), and 1043.9(b), as follows:

Section 1043(b): For purposes of this article, “outpatient” means a patient treated in a treatment facility ~~which~~ that is not accredited by the Joint Commission ~~on Health Care Organizations~~ or licensed by the California Department of Public Health ~~Services~~ as a “general acute care hospital” as defined in subdivision (a) of Section 1250 of the Health & Safety Code.

Section 1043.9(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~~ that is accredited by the Joint Commission ~~on Health Care Organizations~~ or licensed by the California Department of Public Health ~~Services~~ as a “general acute care hospital” as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

Section 1044(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~~ that is accredited by the Joint Commission ~~on Health Care Organizations~~ or licensed by the California Department of Public Health ~~Services~~ as a “general acute care hospital” as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

12. Amended section 1043.3 to clarify a reference to an onsite inspection. In the third sentence of the first paragraph of this section text currently reads “the onsite must be conducted in an outpatient setting.” The section concerns onsite inspections, and adding the word “inspection” after onsite in this sentence would provide additional clarity. The text would be modified to state:

> **§ 1043.3. Onsite Inspections.**
> 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 inspection must be conducted in an outpatient setting. The evaluation of an office shall consist of three parts:

13. Amended section 1043.6(b)(2) to include that the applicant given Conditional Approval will be considered to have passed the evaluation if they have corrected deficiencies within the 15-day period following receipt of notice of those deficiencies. The text would be modified to state:

> (2) Conditional Approval for failing to have appropriate equipment, proper documentation of controlled substances, or proper recordkeeping. “Conditional approval” means the applicant must submit written proof of correcting the deficiencies to the Board within fifteen (15) days of receiving notice of the deficiencies by showing the action taken by the applicant, including retention of proper equipment or documentation, to correct the deficiencies before the applicant will be considered to have passed the evaluation and before a permit is issued; or

14. Amended section 1043.6(c) to replace the “retested” in the last sentence with the word “reevaluated.” As the section concerns evaluations rather than tests, this substitution would make the language more consistent. The text would be modified to state:

(~~b~~c) ~~An applicant who has failed the evaluation may appeal that decision to the board and request a reevaluation. This appeal must be made in writing to the board stating the grounds for the appeal within thirty (30) days after the date on which the evaluation results were mailed. However,~~ ~~p~~Pursuant to ~~s~~Sections 1646.4(a), 1646.9(d) and 1647.7(a) of the ~~c~~Code, the permit of any applicant who has failed an onsite inspection and evaluation shall be automatically suspended 30 days after the date on which the board notifies the applicant of the failure unless, within that time period, the applicant has retaken and passed an onsite inspection and evaluation.

~~Upon receipt of the appeal request and an additional evaluation fee, the board will schedule an independent reevaluation of the appellant~~. If an applicant has failed two evaluations, the board will decide the matter and may grant or deny a permit or request further evaluation of the appellant with a board member or other board appointed representative being present. The applicant must successfully complete remedial education in a subject within the scope of the onsite inspection and evaluation as determined by the Board prior to being ~~retested~~ reevaluated if a third onsite inspection and evaluation is granted or prior to the issuance of a new permit.

15. Amended section 1043.8.1(b) to renumber subsections (6) and (7). This section currently has no subsection (5), so subsections (6) and (7) should be renumbered to (5) and (6), respectively.

16. Deleted section 1043.8.1(c) as the text in this section (outlining the requirements for submitting case documentation for the pediatric endorsements for general anesthesia and moderate sedation) is already addressed in section 1043.8.1(b)(3) and on the PE-1 form. As a result, this subsection is not necessary and duplicative of those requirements. Subsections (d) and (e) would be relettered to (c) and (d), respectively.

17. Amended introductory text of section 1043.9.2 to include equipment standards for maintenance, testing and inspection as well as the appropriate size of equipment, medication, and resuscitation capabilities for a pediatric population. This addition would be consistent with the language on the PMSP-1 form and the language for equipment standards for other anesthesia and sedation types. The text would be modified to state:

All equipment should be maintained, tested and inspected according to the manufacturers' specifications. In an office where minimal sedation services are to be provided to pediatric patients, the required equipment, medication and resuscitative capabilities shall be appropriately sized for use on a pediatric population.

18. Amended section 1043.9.2 to delete the requirement that equipment must be maintained in good operating condition. Because other proposed changes (explained in item 16 above) would add the requirement that equipment be maintained, tested, and inspected according to manufacturers' specifications (i.e., "good operating condition" standards), the language in this section is not necessary. The text would be modified to state:

> (c) Ancillary equipment must include the following~~, and be maintained in good operating condition~~:

19. Rescinded the repeal of section 1044.4 (Documentation of 10 Cases) and removed references to that repeal in the modified text. In the process of responding to comments it was determined that the Board lacks statutory authority to repeal section 1044.4, which implements BPC section 1647.20. Form OCS-4 (03/07), the form the Board currently uses to implement section 1647.20 would also not be repealed. While staff note that this is an outdated pathway not typically used by recent applicants, repeal of that pathway would require a statutory amendment.

20. Amended section 1044.5(b) to delete the requirement that equipment must be maintained in good operating condition. Because other proposed changes would add the requirement that equipment be maintained, tested, and inspected according to manufacturers' specifications, the language in this section is not necessary. The text would be modified to state:

> (b) Ancillary equipment, which must include the following~~, and be maintained in good operating condition~~:

Modifications to Forms:

21. Amended the GAP-1 Form introductory text to update language referring to which state agencies may share taxpayer information with the Board and under what circumstances an unpaid tax obligation may result in a denied application or suspended permit. These changes would clarify the relevant section of the Business and Professions Code that applies and reflect recent changes to that section. The text would be modified to state:

> * Under Business and Professions Code sections 31 and 494.5, the ~~State Board of Equalization (BOE)~~ California Department of Tax and Fee Administration (CDTFA) and the Franchise Tax Board (FTB) may share taxpayer information with the Board. You are required to pay your state tax obligation. This application may be denied or your permit may be suspended if you have a state tax obligation and the state tax obligation is

not paid and your name appears on ~~either~~ the ~~BOE~~ State Board of Equalization, the CDTFA or FTB certified list of top 500 tax delinquencies.

22. Amended the GAP-1 Form to add a "to" before "pediatric patients" in the text section labelled "Facilities and Equipment Requirements" for the purposes of clarity. The text would be modified to read:

> **FACILITIES AND EQUIPMENT REQUIREMENTS -** ALL EQUIPMENT SHOULD BE MAINTAINED, TESTED, AND INSPECTED ACCORDING TO THE MANUFACTURERS' SPECIFICATIONS. IN AN OFFICE WHERE SEDATION SERVICES ARE TO BE PROVIDED TO PEDIATRIC PATIENTS, THE REQUIRED EQUIPMENT, MEDICATION AND RESUSCITATIVE CAPABILITIES SHALL BE APPROPRIATELY SIZED FOR USE ON A PEDIATRIC POPULATION.

23. Amended the GAP-1 Form to remove the phrase "as medically required" from the end of Question 23. This change would make the question more consistent with the language of section 1043.3(b)(1) of the regulations. The text would be modified to state:

> 23. ADEQUATE MEDICAL HISTORY AND PHYSICAL EVALUATION RECORDS UPDATED PRIOR TO EACH ADMINISTRATION OF DEEP SEDATION AND GENERAL ANESTHESIA. SUCH RECORDS SHALL INCLUDE BUT ARE NOT LIMITED TO THE RECORDING OF THE AGE, SEX, WEIGHT, PHYSICAL STATUS (AMERICAN SOCIETY OF ANESTHESIOLOGISTS CLASSIFICATION), MEDICATION USE, ANY KNOWN OR SUSPECTED MEDICALLY COMPROMISING CONDITIONS, RATIONALE FOR SEDATION OF THE PATIENT, AND AN EVALUATION OF THE AIRWAY, AND AUSCULTATION OF THE HEART AND LUNGS ~~AS MEDICALLY REQUIRED~~.

24. Amended the GAP-1 Form Question 26 to move the "or" after the phrase "if the patient is a minor" to before that same phrase. This would add clarity to whom may provide consent on behalf of the patient and under what circumstances they may do so. The text would be modified to state:

> 26. WRITTEN INFORMED CONSENT OF THE PATIENT, OR, AS APPROPRIATE, PATIENT'S CONSERVATOR, OR THE INFORMED CONSENT OF A PERSON AUTHORIZED TO GIVE SUCH CONSENT FOR THE PATIENT, OR IF THE PATIENT IS A MINOR, ~~OR~~ HIS OR HER PARENT OR GUARDIAN, PURSUANT TO BUSINESS AND PROFESSIONS CODE SECTION 1682(e).

25. Amended the GAP-1 Form section at the end of the form that reproduces section 1043.8.1 for the convenience of the applicants and make corresponding changes to proposed section 1043.8.1 consistent with the amendments discussed above in item 15.

26. Amended the language of section 1043.8.1(a), (b) and (c) on the MSP-1 Form to reflect the changes made to that language in regulation and also to delete an inadvertent insertion of text ~~"Advanced Cardiac Life Support (ACLS) and"~~ in subsection (a)(4). This change would make the regulatory language included with the form consistent with the modified text of the regulations.

27. Amended the MSP-1 Form introductory text to update language referring to which state agencies may share taxpayer information with the Board and under what circumstances an unpaid tax obligation may result in a denied application or suspended permit. These changes would clarify the relevant section of the Business and Professions Code that applies and reflect recent changes to that section. The text would be modified to state:

> ***** Under Business and Professions Code sections 31 and 494.5, the ~~State Board of Equalization (BOE)~~ California Department of Tax and Fee Administration (CDTFA) and the Franchise Tax Board (FTB) may share taxpayer information with the Board. You are required to pay your state tax obligation. This application may be denied or your permit may be suspended if you have a state tax obligation and the state tax obligation is not paid and your name appears on ~~either~~ the ~~BOE~~ State Board of Equalization, the CDTFA or FTB certified list of top 500 tax delinquencies.

28. Amended the MSP-1 Form to add a “to” before “pediatric patients” in the text section labelled “Facilities and Equipment Requirements” for the purposes of clarity. The text would be modified to state:

> **FACILITIES AND EQUIPMENT REQUIREMENTS -** ALL EQUIPMENT SHOULD BE MAINTAINED, TESTED, AND INSPECTED ACCORDING TO THE MANUFACTURERS' SPECIFICATIONS. IN AN OFFICE WHERE SEDATION SERVICES ARE TO BE PROVIDED TO PEDIATRIC PATIENTS, THE REQUIRED EQUIPMENT, MEDICATION AND RESUSCITATIVE CAPABILITIES SHALL BE APPROPRIATELY SIZED FOR USE ON A PEDIATRIC POPULATION.

29. Amended the MSP-1 Form Question 26 to move the “or” after the phrase “if the patient is a minor” to before that same phrase. This would add clarity to whom may provide consent on behalf of the patient and under what circumstances they may do so. The text would be modified to state:

> 26. WRITTEN INFORMED CONSENT OF THE PATIENT, OR, AS APPROPRIATE, PATIENT'S CONSERVATOR, OR THE INFORMED CONSENT OF A PERSON AUTHORIZED TO GIVE SUCH CONSENT FOR THE PATIENT~~, OR~~ IF THE PATIENT IS A MINOR, OR HIS OR HER PARENT OR GUARDIAN, PURSUANT TO BUSINESS AND PROFESSIONS CODE SECTION 1682(e).

30. Amended the MSP-2 Form in the first paragraph of question 4 to correct the spelling of Administration. It is missing the second “i". The text would be modified to state:

> THIS DENTIST IS APPLYING FOR A MODERATE SEDATION PERMIT TO ADMINISTER OR ORDER THE ADMINISTRATION OF MODERATE SEDATION IN A DENTAL OFFICE IN CALIFORNIA. IN ORDER TO QUALIFY FOR A PERMIT, THE APPLICANT IS REQUIRED TO PROVIDE PROOF OF COMPLETION OF TRAINING IN MODERATE SEDATION. PLEASE CHECK

THE APPROPRIATE BOXES BELOW RELATING TO THE TRAINING THE ABOVE-NAMED APPLICANT COMPLETED AT YOUR EDUCATIONAL INSTITUTION.

31. Amended the PE-1 Form introduction to clarify the pediatric permit renewal requirements for general anesthesia permit holders with a pediatric endorsement and moderate sedation permit holders with a pediatric endorsement consistent with the requirements in section 1017.1. In addition, this proposal would make changes to correct an error in cross-reference to section 1043.8.1. The proposed modifications are as follows:

> This document shall be completed in its entirety as part of the initial application for a pediatric endorsement (for both general anesthesia and moderate sedation permits) or as a condition of the renewal application for ~~either~~ a general anesthesia ~~or moderate sedation~~ permit that includes a pediatric endorsement as provided in Section 1017.1 of Title 16 of the California Code of Regulations (16 CCR) or your application may be rejected as incomplete. The requirements for a completed initial application for a pediatric endorsement to a general anesthesia permit or a moderate sedation permit are listed in 16 CCR section 1043.~~1.8.~~8.1.

32. Amended the PE-1 Form to modify question 4 in order to better ensure applicants for pediatric endorsements of their moderate sedation permits provide required information. The question would add language to emphasize the need to complete the following section of the form and refer them to the notice statement on the form for additional requirements. The text would be modified to state:

> 4. **FOR APPLICANTS FOR A MODERATE SEDATION PERMIT ONLY, PLEASE COMPLETE THIS SECTION (**see requirements in the notice statement above for providing moderate sedation to children under seven years of age):

33. Amended the PE-1 Form to change the language requesting specific information about the anesthesia or moderate sedation cases being documented to comply with the requirements for the pediatric endorsement. The language would form a new question 5 and be revised to emphasize that all applicants need to complete the question and to clarify that the case information can be provided on the form or in attachments to the form. The text would be modified to state:

> 5. FOR ALL APPLICANTS, PLEASE PROVIDE ALL THE FOLLOWING INFORMATION ON THIS FORM OR IN ATTACHMENTS TO THIS FORM BY CASE NUMBER:
> (1) Pediatric patient's sex, age, and weight;
> (2) Date of general anesthesia or moderate sedation procedure;
> (3) Type of dental procedure performed and duration of general anesthesia or moderate sedation;
> (4) A description of the method, amount, and specific general anesthesia or moderate sedation agent administered;
> (5) A statement on how the pediatric patient was monitored and by whom; and,
> (6) Pediatric patient's condition at discharge.

34. Amended the PE-1 Form to renumber the last question and references to other questions on the form. Inserting a new question 5 requires that the existing question 5 be renumbered to 6 and that references to questions 4A and 5A be renumbered 5A and 6A, respectively.

35. Added the word "immediately" to the introductory sentence on page 3 of the form to more accurately describe the currency of knowledge requirements set forth in BPC sections 1646.2, and 1647.3. The proposed change would be as follows:

> APPLICANTS MUST PROVIDE THE FOLLOWING FOR EACH CASE OCCURRING WITHIN 24 MONTHS IMMEDIATELY PRECEDING APPLICATION FOR THE PEDIATRIC ENDORSEMENT.

36. Amended the PMSP-1 Form introductory text to update language referring to which state agencies may share taxpayer information with the Board and under what circumstances an unpaid tax obligation may result in a denied application or suspended permit. These changes would clarify the relevant section of the Business and Professions Code that applies and reflect recent changes to that section. The text would be modified to state:

> ***** Under Business and Professions Code sections 31 and 494.5, the ~~State Board of Equalization (BOE)~~ California Department of Tax and Fee Administration (CDTFA) and the Franchise Tax Board (FTB) may share taxpayer information with the Board. You are required to pay your state tax obligation. This application may be denied or your permit may be suspended if you have a state tax obligation and the state tax obligation is not paid and your name appears on ~~either~~ the ~~BOE~~ State Board of Equalization, the CDTFA or FTB certified list of top 500 tax delinquencies.

37. Amended the PMSP-1 Form text section labelled "Facilities and Equipment Requirements" to replace the word "anesthesia" with the phrase "minimal sedation" and add a "to" before "pediatric patients" for the purposes of clarity. The text would be modified to state:

> **FACILITIES AND EQUIPMENT REQUIREMENTS -** ALL EQUIPMENT SHOULD BE MAINTAINED, TESTED, AND INSPECTED ACCORDING TO THE MANUFACTURERS' SPECIFICATIONS. IN AN OFFICE WHERE ~~ANESTHESIA~~ MINIMAL SEDATION SERVICES ARE TO BE PROVIDED TO PEDIATRIC PATIENTS, THE REQUIRED EQUIPMENT, MEDICATION AND RESUSCITATIVE CAPABILITIES SHALL BE APPROPRIATELY SIZED FOR A PEDIATRIC POPULATION.

38. Amended the PMSP-1 Form in question 14 to replace the word "factility" with the word "facility."

39. Amended the PMSP-2 Form in question 4 to correct the spelling of Administration in the first paragraph. It is missing the second "i." In the same question the period following the phrase "clinical case" should be removed for clarity. The text would be modified to state:

> 4. MINIMAL SEDATION TRAINING VERIFICATION:

THIS DENTIST IS APPLYING FOR A PEDIATRIC MINIMAL SEDTION PERMIT TO ADMINISTER OR ORDER THE ADMINISTRATION OF PEDIATRIC MINIMAL SEDATION IN A DENTAL OFFICE IN CALIFORNIA. IN ORDER TO QUALIFY FOR A PERMIT, THE APPLICANT IS REQUIRED TO PROVIDE PROOF OF COMPLETION OF TRAINING IN PEDIATRIC MINIMAL SEDATION. PLEASE CHECK THE APPROPRIATE BOXES BELOW RELATING TO THE TRAINING THE ABOVE-NAMED APPLICANT COMPLETED AT YOUR EDUCATIONAL INSTITUTION.

THE APPLICANT LISTED ON THIS FORM SUCCESSFULLY COMPLETED THIS INSTITUTION'S EDUCATIONAL PROGRAM IN MINIMAL SEDATION THAT INCLUDES EITHER OF THE FOLLOWING:

☐ AT LEAST 24 HOURS OF PEDIATRIC MINIMAL SEDATION INSTRUCTION IN ADDITION TO ONE CLINICAL CASE, AND TRAINING IN PEDIATRIC MONITORING, AIRWAY MANAGEMENT, AND RESUSCITATION AND PATIENT RESCUE FROM MODERATE SEDATION, OR,

40 Rescinded the repeal of Form OSC-4. The form is incorporated by reference in section 1044.4. As the modified text would no longer repeal that section, Form OSC-4 would no longer be repealed.

41. Amended the OSC-C Form introductory text to update language referring to which state agencies may share taxpayer information with the Board and under what circumstances an unpaid tax obligation may result in a denied application or suspended permit. These changes would clarify the relevant section of the Business and Professions Code that applies and reflect recent changes to that section. The text would be modified to state:

> * Under Business and Professions Code sections 31 and 494.5, the State Board of Equalization (BOE) California Department of Tax and Fee Administration (CDTFA) and the Franchise Tax Board (FTB) may share taxpayer information with the Board. You are required to pay your state tax obligation. This application may be denied or your permit may be suspended if you have a state tax obligation and the state tax obligation is not paid and your name appears on either the BOE State Board of Equalization, the CDTFA or FTB certified list of top 500 tax delinquencies.

42. Amended the OCS-C Form to add a question 10 on how applicants are qualifying for the permit under Business and Professions Code section 1647.20 in response to comments submitted by the California Dental Association. This section describes four requirements for an applicant to demonstrate either education or experience that would satisfy the Board as to the applicant's qualifications to administer oral conscious sedation and are needed to implement the educational qualifications provisions of BPC section 1647.20. These questions are being moved from existing application OCS-3, which the Board previously adopted to implement these requirements (which remain unchanged from SB 501). Applicants can satisfy this section by meeting one of the four requirements, and would indicate which one they meet on Form OCS-C. In the Board's

experience, these questions, and the applicable documentation requirements (including proof of academic completion via a diploma) provide the Board with sufficient verification of the educational experience requirements for this permit. Cross-references have been added to the existing text from Form OCS-3 to further clarify the Board's existing educational requirements and provide notice to the applicants of the educational criteria necessary to qualify for the permit. The text would be modified to state:

> 10. **QUALIFICATION** – INDICATE UNDER WHICH METHOD LISTED BELOW YOU QUALIFY FOR AN ORAL CONSCIOUS SEDATION CERTIFICATE FOR ADULTS AND ATTACH APPROPRIATE DOCUMENTATION AS SET FORTH BELOW.
>
> ☐ SUCCESSFUL COMPLETION OF A POSTGRADUATE PROGRAM IN ORAL AND MAXILLOFACIAL SURGERY APPROVED BY THE COMMISSION ON DENTAL ACCREDITATION OR A COMPARABLE ORGANIZATION APPROVED BY THE BOARD AS PROVIDED IN TITLE 16, CALIFORNIA CODE OF REGULATIONS (CCR) SECTION 1044.2. APPLICANT MUST PROVIDE A COPY OF HIS OR HER DIPLOMA.
>
> ☐ SUCCESSFUL COMPLETION OF A PERIODONTICS OR GENERAL PRACTICE RESIDENCY OR ADVANCED EDUCATION IN A GENERAL DENTISTRY POST-DOCTORAL PROGRAM ACCREDITED BY THE COMMISSION ON DENTAL ACCREDITATION THAT MEETS THE DIDACTIC AND CLINICAL REQUIREMENTS OF CCR SECTION 1044.3. APPLICANT MUST PROVIDE A COPY OF HIS OR HER DIPLOMA.
>
> ☐ SUCCESSFUL COMPLETION OF A BOARD-APPROVED EDUCATIONAL PROGRAM ON ORAL MEDICATIONS AND SEDATION MEETING THE REQUIREMENTS IN CCR SECTION 1044.3.
>
> ☐ DOCUMENTATION OF 10 SUCCESSFUL CASES OF ORAL CONSCIOUS SEDATION PERFORMED BY THE APPLICANT ON ADULT PATIENTS IN ANY THREE-YEAR PERIOD ENDING NO LATER THAN DECEMBER 31, 2005 AS PROVIDED IN BPC SECTION 1647.20(d)). ATTACH FORM OCS-4 WITH COPY OF TREATMENT RECORDS.

43. Amended the OCS-C Form to renumber the questions following the new question 10. The current questions numbered 10 through 25 will be renumbered 11 through 26, respectively.

44. Amended the OCS-C Form in question 21 to remove the reference to the maintenance of ancillary equipment. This change would be consistent with other suggested changes and reflect the same standards as modified language related to onsite inspections. The text would be modified to state:

> ~~20~~21. DO YOU HAVE ANCILLARY EQUIPMENT ~~AND IS ALL ANCILLARY EQUIPMENT AT THE FACILITY MAINTAINED IN GOOD OPERATING CONDITION~~? FOR THE PURPOSES OF THIS QUESTION, ANCILLARY EQUIPMENT" MUST INCLUDE ALL OF THE FOLLOWING:

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A summary of the responses received at the hearing and in writing, along with the Board's responses, is included below.

The Board issued a Notice of Modified Text on March 18, 2022 to make these changes, and that public comment period closed on April 4, 2022. One adverse comment was received on April 4, 2022; however, the comment was subsequently withdrawn on April 7, 2022. Copies of the comment letter and the subsequent withdrawal is included in this rulemaking file.

On March 14, 2022, the Board delegated to the Executive Officer the authority to adopt the proposed modified text, as written, if no adverse comments were received and delegated to the Executive Officer the authority to make any technical or non-substantive changes that may be required in completing the rulemaking file.

Second Modified Text

In response to review by the Office of Administrative Law, the Board made changes to the noticed proposed regulations as described below:

Modifications of Regulatory Text

1. Change the word "should" in the first sentence of section 1043.3(a) to shall. This would make the language consistent with language in section 1044.5 and correctly reflect the original intent that the equipment maintenance requirement is mandatory rather than discretionary. The resulting change would read as follow:

All equipment ~~***should***~~***shall*** be maintained, tested and inspected according to the manufacturers' specifications.

2. Change the word "should" in the second sentence of the introductory paragraph in section 1043.9.2 to shall. This would make the language consistent with the rest of that paragraph and language in section 1044.5 and correctly reflect the original intent that the equipment maintenance requirement is mandatory rather than discretionary. The resulting change would read as follows:

All equipment ~~***should***~~***shall*** be maintained, tested and inspected according to the manufacturers' specifications.

3. Amend section 1043.9.2(d)(4) to further explain the documentation requirements for adequate supply of drugs. OAL seeks greater clarity on the phrase “adequate supply” with respect to the documentation for drugs maintained at the facility ,and therefore the following modifications (additions are in double underline, double strikethrough and bold) were made to the text:

(4) Documentation that all drugs maintained at the facility are checked at least ***once a*** quarter~~ly~~ for expired drugs and an adequate supply ***of drugs based upon patient demographics*** for the patient population served, ***which includes the number of patients served at the facility and the age of patients served at the facility. For the purposes of compliance with this subsection, documentation of adequate supply shall include a written explanation of how the adequate supply was calculated by the facility.***

4. Amend the forms incorporated by reference to add clarity to the consequences of an incomplete application. In each of the forms included in this rulemaking package (General Anesthesia Permit/GAP-1, Application for Moderate Sedation Permit/MSP-1, Certification of Moderate Sedation Training/MSP-2, Documentation of Deep Sedation and General Anesthesia or Moderate Sedation Cases for Pediatric Endorsement/PE-1, Application for Pediatric Minimal Sedation Permit/PMSP-1, Certification of Pediatric Minimal Sedation Training/PMSP-2, Application for Use of Oral Conscious Sedation on Adult Patients/OSC-C) there is language that states the form or application must be completed or the application “may be rejected as incomplete.”

OAL indicated that the language does not appear to precisely reflect what would actually happen (that staff would provide the opportunity to address any deficiencies before an application is considered ‘abandoned’ per the Board’s current regulations at Title 16, California Code of Regulations (16 CCR) section 1004). As a result, staff recommend replaced the language “may be rejected as incomplete” with “will not be processed (16 CCR section 1004).” This will clarify that the application will not be processed if deficiencies are not addressed in accordance with the Board’s abandonment regulations at 16 CCR section 1004.

5. Amend the introductory language concerning Facilities and Equipment Requirements in three of the forms incorporated by reference. Change the word should to shall in the first sentence of the introductory matter in the Facilities and Equipment Requirements section of the Application for Moderate Sedation Permit/MSP-1, the Application for Pediatric Minimal Sedation Permit/PMSP-1, and the Application for Use of Oral Conscious Sedation on Adult Patients/OSC-C. This would make the language consistent with sections 1043.3 and 1043.9.2. The resulting change would read as follows:

ALL EQUIPMENT ~~***SHOULD***~~***SHALL*** BE MAINTAINED

6. Change the language in Question 25(A) of the Application for Use of Oral Conscious Sedation on Adult Patients/OSC-C to align with section 1044.5(d). The text of Question 25 (A) should be amended to read as follows:

THE NECESSARY AND APPROPRIATE ~~***EMERGENCY***~~ DRUGS AND ***AGE- AND*** SIZE-APPROPRIATE EQUIPMENT TO RESUSCITATE A NONBREATHING AND UNCONSCIOUS PATIENT AND PROVIDE CONTINUOUS SUPPORT WHILE THE PATIENT IS TRANSPORTED TO A MEDICAL FACILITY.

A summary of the responses received in writing, along with the Board's responses, is included below.

The Board issued a Notice of Second Modified Text on June 28, 2022 to make these changes, and that public comment period closed on July 14, 2022. Three comments were received on July 1, 2022 from one individual as described in the "Objections or Recommendations/Responses" section below. However, those comments were not directed at changes noticed in the second modified text and were therefore not considered by the Board. Another individual submitted three comments by email on July 17, 2022, outside of the comment period. (The commenter indicated that a hard copy had been mailed to the Board earlier. While the Board does not have record of receiving that hard copy within the notice period, it has prepared responses to those comments out of an abundance of caution.) The comments were also not directed at the changes noted in the second modified text and were therefore not considered by the Board.

On June 28, 2022, the Board delegated to the Executive Officer the authority to adopt the proposed second modified text, as written, if no adverse comments were received and delegated to the Executive Officer the authority to make any technical or non-substantive changes that may be required in completing the rulemaking file. At the request of the Office of Administrative Law, the Board made further technical or non-substantive changes to the Order of Adoption as specified below.

Local Mandate Determination

The proposed mandate does not impose a mandate on local agencies or school districts.

Small Business Impact:

The Board has determined that the proposed regulations would not affect small businesses. Although small businesses owned by licensees of the Board and small businesses that employ licensees of the Board may be impacted, the Board estimates that the fiscal impact would be minor as described in the Business Impact statement in

the Initial Statement of Reasons. The Board does not maintain data relating to the number of percentage of licensees who own a small business; therefore, the number or percentage of small businesses that may be impacted cannot be predicted.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board as part of public comments received or at the Board's meetings would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective or less burdensome to affected private persons than the proposed regulation, or would be more cost-effective to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. All recommendations provided during this rulemaking were considered by the Board and accepted or rejected as discussed below.

The Board is mandated by statute to develop these regulations and there is no other method of developing the requirements for the issuance of the general anesthesia, moderate sedation, pediatric minimal sedation, and oral conscious sedation for adults permit and necessary forms.

One possible alternative would be to delay or not promulgate these regulations. This is not feasible because the statute provides that the existing permits and requirements will be repealed effective January 1, 2022. Failure to promulgate the proposed regulations will result in the Board being unable to issue the general anesthesia, moderate sedation, pediatric minimal sedation, and oral conscious sedation for adults permit, and the pediatric endorsement required for the administration of sedation and anesthesia in California in compliance with the Dental Practice Act. The proposal would require a general anesthesia and moderate sedation permit holder with a pediatric endorsement to document continued competency in the administration of sedation and anesthesia in a dental office which would greatly benefit the public, specifically pediatric dental patients.

Rejected: The Board's highest priority is the protection of the public while exercising its licensing, regulatory, and disciplinary functions. These proposed regulatory changes provide the Board with the means to ensure that dentists and physicians who administer anesthesia and sedation in dental office settings meet minimum standards for health and safety thereby ensuring dental patients are afforded the appropriate levels of safety and care and there are no alternatives to making this occur.

Objections or Recommendations/Responses:

Summary and Response to Comments Received During 45-Day Comment Period

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

Comment Summary: The commenter proposes the following edits to sections 1043(b), 1043.9(b) and 1044(a). The commenter notes that the Joint Commission on Health Care Organizations now operates under the name "The Joint Commission" (Comment No. 1) and that the agency responsible for licensing hospitals in the State of California is the California Department of Public Health and not the California Department of Health Services (Comment No. 2). She also recommends substituting the word "that" for the word "which" when it follows the phrase "treatment facility" in regulations sections 1043(b), 1043.9(b) and 1044 (Comment No. 3).

Board Response: The Board accepted the 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 amended 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 modified the text as recommended.

The Board considers Comment No. 3 to be solely grammatical and agrees with the change, and therefore accepted the comment. As a result of the foregoing, the Board made 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 argues 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 requests 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 does 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."

Board Response: The Board rejected the 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 declined 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 renews 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 requests 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."

Board Response: The Board rejected the 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 states 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 requests that state licensed ambulatory surgical centers be exempted from AB 501.

Board Response: The Board rejected the 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 restates arguments raised in comment C. above. In addition, the commenter states 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 requests that ASCs as outpatient treatment centers be exempted from these regulations.

The commenter argues 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 states that any dentist working in an ASC would be under the purview of the Dental Board but the ASC is not. He further asserts 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.

Board Response: The Board rejected the 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, <u>regardless of practice location</u>, 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 raises 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 argues 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 requests that their state licensed and accredited ASCs be exempt from the proposed regulation, proposed amended language, and the current law.

Board Response: The Board rejected the 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 indicates that some provisions of the proposed regulations seem ambiguous. The commenter states that in general, there does not seem to be any differentiation between a standard dental office and a licensed and accredited ASC. The commenter reiterates ASC safety, protocol, and oversight comments made in comments B.1., B.2., C., D., and E. above. The commenter states 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 notes the difficulty finding dental and medical anesthesiologist with a dental general anesthesia permit. The commenter requests 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.)

Board Response: The Board rejected 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 indicates that he is an anesthesia provider that has been providing pediatric dental cases for many years and thousands of cases. The commenter indicates that the new SB 501 needs clear language for all groups and stakeholders especially the children. He indicates 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 indicates 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 indicates 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 urges 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.

Board Response: The Board rejected 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 explains 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 notes 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 states 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 states 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 argues that the only authority the Board has is over the licensed dentists performing these procedures in these “outpatient” settings. The commenter argues that the proposed regulations appear to miss the mark on the definition of “outpatient” and “outpatient setting.”

The commenter attaches 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 are 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 recommends 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.)."

Board Response to Comment No. 1: The Board rejected 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" <u>means "outpatient setting"</u> 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 requests 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 asserts 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.

Board Response to Comment No. 2: The Board rejected 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 1044(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 recommends 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.

Board Response to Comment No. 3: The Board rejected 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 recommends 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:

Board Response to Comment No. 4: The Board rejected 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 recommends 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.

Board Response to Comment No. 5: The Board rejected 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 recommends 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)."

Board Response to Comment No. 6: The Board rejected 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 recommends 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."

Board Response to Comment No. 7: The Board rejected 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 proposes 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.
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Board response to Comment No. 8: The Board rejected 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.

Board response to Comment No. 1: The Board rejected 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.

Board response to Comment No. 2: The Board rejected 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.

Board response to Comment No. 3: The Board rejected 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). Commenter notes 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).

Board response to Comment No. 4: The Board rejected 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 suggests 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 suggests 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.

Board response to Comment No. 5: The Board rejected 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.

Board response to Comment No. 6: The Board rejected 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 recommend 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.

Board response to Comment No. 7: The Board accepted 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 recommend 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 recommend 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:

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

Board response to Comment No. 2: The Board rejected 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 states 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 requests that the Board amend the proposed regulations to clarify sections 1043(b), 1043.3, 1043.9(b) and 1044 consistent with comment J. above.

Board response to Comments: The Board rejected 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 states 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 understands that the Board has recently taken a contrary position that a dentist must hold a permit when ordering anesthesia in an ASC.

The commenter proposes 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.).

Board response to comments: The Board rejected 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.

Board Response: The Board rejected 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 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 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 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 Board responses.)

Summary and Response to Comments Received During First 15-Day Comment Period for Modified Text

As noted above, comments were received on April 4 and subsequently withdrawn on April 7 by the California Association of Nurse Anesthetists. As the comments were withdrawn and the commenter noted that the Board's previous response to their comments was sufficient, the Board did not respond to those comments.

Summary and Response to Comments Received During Second 15-Day Comment Period for Second Modified Text

Letter and written comments from Steven Ganzberg, DMD, MS, Past Chair, Section of Dental Anesthesiology UCLA School of Dentistry, dated July 1, 2022.

1. Summary of Comment No. 1: In the originally proposed text at section 1043.3(a)(7), the text at subdivision (K) was recommended to be deleted and the following text added:

(K) Capnograph for all patients receiving moderate sedation, deep sedation or general anesthesia.

(i) For deep sedation or general anesthesia, when capnography is precluded or invalidated by the nature of the patient, procedure, or equipment, a pre-tracheal/precordial stethoscope must be used.
(ii) For moderate sedation, when capnography is precluded or invalidated by the nature of the patient, procedure, or equipment, bidirectional communication with the patient must be maintained.

Response to Comment No. 1: As these comments do not address the changes noticed in the Second Modified Text, the Board did not respond to these comments.

2. Summary of Comment No. 2: In the originally proposed text at section 1043.3(a)(7), the commenter suggests adding the following new subsection:

(L) Body temperature measuring device which must be used when triggering agents for malignant hyperthermia are administered.

Response to Comment No. 2: As these comments do not address the changes noticed in the Second Modified Text, the Board did not respond to these comments.

3. Summary of Comment No. 3: In the originally proposed text at section 1043.3(b), the commenter suggests revising the existing proposal to include the following:

(2) Moderate sedation, deep sedation, and/or general anesthesia records which shall include a time-oriented record with preoperative, intraoperative, and postoperative documentation of the continuous monitoring of:

(i) oxygen saturation by pulse oximetry (at least every 15 minutes intraoperatively and post-operatively);
(ii) respiratory rate (at least every 15 minutes intraoperatively);
(iii) end tidal carbon dioxide (at least every 15 minutes intraoperatively);
(iv) body temperature (at least every 15 minutes intraoperatively, if used);
(v) heart rhythm by electrocardiography (at least every 15 minutes intraoperatively for general anesthesia and deep sedation);
(vi) heart/pulse rate (intraoperatively, at least every 5 minutes for general anesthesia and deep sedation and at least every 10 minutes for moderate sedation; postoperatively, at least every 15 minutes); and
(vii)the continual monitoring of blood pressure (intraoperatively, at least every 5 minutes for general anesthesia or deep sedation and at least every 10 minutes for moderate sedation; postoperatively, as needed); and

drugs [amounts administered and time administered], length of the procedure, any complications of general anesthesia or sedation and a statement of the patient's

condition at time of discharge.

Response to Comment No. 3: As these comments do not address the changes noticed in the Second Modified Text, the Board did not respond to these comments.

Email and written comments from Lenny Naftalin, DDS, DABDA, President-elect, American Society of Dentist Anesthesiologists, sent July 17. 2022 (In his email, Dr. Naftalin indicates a hard copy was mailed to the Board).

1. Summary of Comment No. 1. Commenter indicates that the current documentation of cases requirement for a pediatric endorsement would be better handled by submitting copies of case records with patient names redacted. Commenter goes further to indicate if case information is not being reviewed that an attestation would be sufficient.

Response to Comment No.1. As these comments do not address the changes noticed in the Second Modified Text, the Board did not respond to these comments.

2. Summary of Comment No. 2. Commenter suggests that the requirements for documentation in section 1043.3(b)(2) are inconsistent with the standard of care as it pertains to pulse oximetry readings. Additionally, commenter suggests there should be a requirement for documentation of capnography readings and cardiac rhythm via electrocardiography at least every 15 minutes.

Response to Comment No. 2. As these comments do not address the changes noticed in the Second Modified Text, the Board did not respond to these comments.

3. Summary of Comment No. 3. Commenter suggests that the requirements in 1043.3(a)(7)(K) for capnography and temperature devices do not make sense for patients in deep sedation/general anesthesia. Commenter suggests the standard should be to require capnography for all patients in deep sedation, moderate 44edation or general anesthesia.

Response to Comment No. 3. As these comments do not address the changes noticed in the Second Modified Text, the Board did not respond to these comments.

<u>**Incorporated by Reference:**</u>

The following forms ("forms") have been incorporated by reference:

1. "Application for General Anesthesia Permit" Form GAP-1 (New 05/2021)

2. “Application for Moderate Sedation Permit” Form MSP-1 (New 05/2021)
3. “Certification of Moderate Sedation Training” Form MSP-2 (New 05/2021)
4. “Documentation of Deep Sedation and General Anesthesia or Moderate Sedation Cases for Pediatric Endorsement” Form PE-1 (05/2021)
5. “Application for Pediatric Minimal Sedation Permit” PMSP-1 (New 05/2021)
6. “Certification of Pediatric Minimal Sedation Training” Form PMSP-2 (New 05/2021)
7. “Application for Use of Oral Conscious Sedation on Adult Patients” Form OCS-C (New 05/2021)

The incorporation by reference method was used because it would be impractical and cumbersome to publish these forms in the California Code of Regulations (CCR). The Board requires the applications (GAP-1, MSP-1, PMSP-1, OCS-C) and accompanying documents (Forms MSP-2, PE-1, PMSP-2) to evaluate whether applicants meet qualifications for issuance or renewal of a permit or pediatric endorsement as outlined in Sections 1646.2, 1646.9, 1647.2, 1647.3, 1647.31 and 1647.32 of the Dental Practice Act (Business and Professions Code sections 1600 and following). Since these sections do not explicitly prescribe the contents of these forms or any required documentation, these forms provide a convenient and simple way for applicants to understand these requirements to obtain or maintain Board approval. If the applications and supporting documentation was incorporated into the CCR, the various check boxes and questions needed to be answered to implement the aforementioned sections of the Dental Practice Act would be difficult to reprint in the CCR, and therefore could cause confusion for the users. These forms were made available to the public and were posted along with the proposed regulatory language on the Board’s website.

Technical Cleanup

In preparing the final rulemaking file, it was noted that the numbering in sections 1044.5 (b), (c), and (d) for the modified text were changed to be continuous with the numbering in section 1044.5(a) – each new subsection started with the number following the last number in the prior subsection. As part of the technical cleanup authority granted the Board Executive Officer, the numbering has been changed to reflect the proper sequential numbering found in these regulations in the original proposed changes.

As the file was under review by the Office of Administrative Law, several nonsubstantive changes were identified by OAL that would provide additional clarity to the rulemaking and improve the consistency of language used throughout the regulations. Aside from changes in capitalization and formatting, these changes included the following:

- Change references from conscious sedation to moderate sedation in Sections 1017(e), 1017(j)(2), 1017(j)(3), 1017(p) and 1018.1(a)(1) to reflect the change of the Conscious Sedation Permit to the Moderate Sedation Permit.
- Change references to “permit holder” or “applicant” in Sections 1043.5 and 1043.6 to “permittee or applicant” to better reflect that inspections can be done at facilities where both permittees and applicants would be using anesthesia or sedation.
- Change reference to Section 1043.1 in Section 1043.3(b) to refer to the Application for General Anesthesia Permit, Form GAP-1 (New 05/2021). This reflects a change in Section 1043.1 that is no longer relevant to the text in Section 1043.3.(b).
- In the forms that address collection of the Social Security number (Application for General Anesthesia Permit, Form GAP-1 (New 05/2021), Application for Moderate Sedation Permit, Form MSP-1 (New 05/2021), Application for Pediatric Minimal Sedation Permit, PMSP-1 (New 05/2021), and Application for Use of Oral Conscious Sedation on Adult Patients, Form OCS-C (New 05/2021), reference to the Individual Taxpayer Identification number was included to be consistent with Business and Professions Code sections 30 and 494.5.