

**TITLE 16. DENTAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS**

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing has been scheduled for the proposed action.

Subject Matter of the 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, 1044.4, 1044.5, & 1070.8 and a new Article 5.1.

Specific Purpose of Each Adoption, Amendment, or Repeal:

1. Background and Statement of the Problem:

The Dental Board of California (Board) licenses and regulates dentists, registered dental assistants, and registered dental assistants in extended functions. In addition, the Board is responsible for setting the duties and functions of approximately 50,000 unlicensed dental assistants. The Board's highest priority is the protection of the public when exercising its licensing, regulatory, and disciplinary functions. The Board assures the initial and continued competence of its licensees through licensure, investigation of complaints against its licensees, and discipline of those found in violation of the Dental Practice Act (Act), monitoring licensees whose licenses have been placed on probation, and managing the Diversion Program for licensees whose practice may be impaired due to abuse of dangerous drugs or alcohol.

The Act governs the use of general anesthesia, conscious sedation, and oral conscious sedation for pediatric and adult patients. In February 2016, Senator Jerry Hill, Chair of the Senate Committee on Business, Professions, and Economic Development, was made aware of a tragedy in which an otherwise healthy child died after receiving general anesthesia at a dentist's office. He notified the Board of his concern about the rise in the use of anesthesia for young patients and asked the Board to investigate whether California's present laws, regulations, and policies are sufficient to protect the public. In response, the Board President appointed a two-person subcommittee to work with staff to research this issue and conduct a study; the study was expanded to include review of incident reports related to all levels of pediatric sedation including conscious sedation, oral conscious sedation, and general anesthesia as well as administration of local anesthetic in California for a six year-period (2010-2015).

The Board released its study and the findings of its subcommittee ("subcommittee") in December 2016 entitled "Pediatric Anesthesia Study" ("the Study"). The Study found

that California dental sedation and anesthesia laws are similar to laws in other states and differ primarily in the area of personnel requirements. Approximately half of other states specify the number of staff who must be present, in addition to the dentist, when general anesthesia or moderate sedation is administered.

California policies, laws and regulations were found to be generally consistent with professional dental association guidelines with the exception of a recommendation in the American Academy of Pediatrics-American Academy of Pediatric Dentistry Guidelines for a person dedicated to the monitoring and administration of deep sedation and general anesthesia. The Board recommended updating terminology, staffing requirements, educational requirements, and monitoring standards in an effort to improve the safety of pediatric dental anesthesia and sedation.

As enacted, SB 501 (Glazer, Chapter 929, Stats. of 2018), beginning January 1, 2022, establishes new provisions in the Act governing the use of deep sedation and general anesthesia, moderate sedation, and pediatric minimal sedation for dental patients in Articles 2.75 (commencing with Section 1646 of the Business and Professions Code (BPC)), Article 2.84 (commencing with Section 1647 of the BPC), and Article 2.87 (commencing with Section 1647.30 of the BPC) of the Act. Among other requirements, the Act will require dentists to possess either a current license in good standing and a general anesthesia permit, or other specified credentials in order to administer or order the administration of deep sedation or general anesthesia on an outpatient basis. (Bus. & Prof. Code, §§ 1646.1 and 1646.2.) The Act will also authorize a licensed physician and surgeon to administer deep sedation or general anesthesia if that physician and surgeon meets certain requirements, including holding a valid general anesthesia permit and a pediatric endorsement, if applicable. (Bus. & Prof. Code, § 1646.9.)

The Act will require dentists to possess a pediatric endorsement of their general anesthesia permit to administer or order the administration of deep sedation or general anesthesia to patients under 7 years of age and will require dentists to be present in the dental office during the ordering and administration of general anesthesia or deep sedation. (Bus. & Prof. Code, § 1646.1, subd. (b).) The Act requires the presence of the operating dentist and at least 2 additional personnel for patients under 13 years of age for procedures involving deep sedation or general anesthesia and requires that certain personnel be present throughout the procedure and to maintain current certification in pediatric life support and airway management, as specified. (Bus. & Prof. Code, § 1646.1, subd. (d).) Dentists applying for a pediatric endorsement for the general anesthesia permit will have to provide proof of successful completion of an accredited or equivalent residency training program, and a certain number of cases of deep sedation or general anesthesia for patients under 7 years of age, along with current certification in specific life support training. (Bus. & Prof. Code, § 1646.2, subd. (c).)

Presently, the Act prohibits a dentist from administering or ordering the administration of conscious sedation, as defined, on an outpatient basis unless the dentist meets certain licensing criteria. (Bus. & Prof. Code, § 1647.19.) Effective January 1, 2022, changes to

the Act under SB 501 will repeal existing provisions relating to the use of conscious sedation. The term “conscious sedation” will be replaced with “moderate sedation,” meaning a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands and meets other criteria. (Bus. & Prof. Code, § 1647.1.) The Act will authorize dentists to administer or order the administration of moderate sedation on an outpatient basis to a dental patient if the dentist meets specified licensing criteria and has applied to the Board, submitted an application fee, and shown successful completion of training in moderate sedation. (Bus. & Prof. Code, § 1647.2.)

The Act will require a dentist who orders the administration of moderate sedation to be physically present in the treatment facility while the patient is sedated and would require the presence of additional specified personnel for sedation of patients 13 years of age or younger. (Bus. & Prof. Code, § 1647.2, subd. (c)(1).) Training in the administration of moderate sedation will be acceptable if it consists of a certain number of instructional hours and completion of cases and complies with certain guidelines for teaching pain control and sedation. (Bus. & Prof. Code, § 1647.3, subd. (c).) The Act will require a dentist to obtain a pediatric endorsement on the moderate sedation permit prior to administering moderate sedation to a patient under 13 years of age, except as specified, and will require a dentist to obtain specified training and apply on a form prescribed by the Board to receive a pediatric endorsement. (Bus. & Prof. Code, § 1647.3, subd. (d).)

The Act also requires, as a condition of renewal, under amendments enacted by SB 501 (Chapter 929, Stats. of 2018), and effective January 1, 2022, that specified permit holders establish continuing competency to administer general anesthesia, deep sedation (“anesthesia”) or moderate sedation (“sedation”) by completing 20 cases of anesthesia or sedation for specified pediatric populations within the 24-month period immediately preceding each permit renewal period (Bus. & Prof. Code, §§ 1646.2, 1647.3.) Existing regulations do not specify how the Board will determine compliance with these new requirements. This proposal would specify these compliance requirements for permit holders who seek to administer anesthesia and sedation as provided under the Act.

The Act will establish new requirements for dentists administering or ordering the administration of minimal sedation, defined as a drug-induced state during which patients respond normally to verbal commands. (Bus. & Prof. Code, § 1647.30.) Dentists may administer or order the administration of minimal sedation on pediatric patients under 13 years of age if the dentist possesses specified licensing credentials and follows certain procedures. (Bus. & Prof. Code, 1647.31.) Any dentist who desires to administer or order the administration of minimal sedation must apply on a form prescribed by the Board and submit an application fee. (Bus. & Prof. Code, § 1647.32.)

In addition to the foregoing changes, SB 501 amended, added to, and repealed portions of Business and Professions Code sections 1601.8, 1646-1646.10, 1647-1647.9.5,

1682, 1724, and 1750.5. The Board needs to make significant regulatory updates to the current anesthesia and sedation permit program regulations to implement the foregoing statutory changes and ensure minimum standards for the professions are met, including adding new forms, permit requirements, and fees, making revisions to renewal requirements, onsite inspection and evaluation standards, facility and equipment standards, Board-approved educational requirements for dentists and dental sedation assistants; and, repealing oral conscious sedation case documentation requirements.

In this rulemaking proposal, the Board proposes to:

- Adopt section 1017.1 and a new title “Continued Competency Requirements for Renewal of Permits with Pediatric Endorsements,” to replace a prior repealed regulation entitled “Processing Times.” This change would prescribe the requirements to maintain continued competency in the administration of deep sedation, general anesthesia, and moderate sedation to patients under the age of 13 by prescribing the documentation or written confirmation general anesthesia and moderate sedation permit holders with pediatric endorsements must provide the Board at license renewal.
- Amend section 1021 to (1) provide grammatical changes and other non-substantive changes to add references to the “Business and Professions Code” or the “Code” to existing subsections (a)-(p); (2) strike references to “conscious sedation” and replace with references to “moderate sedation” in subsections (q), (s), and (u) (re-lettered from current (t)); and (3) establish fees for the following:
 - (q) an application for general anesthesia (dentist or physician) or moderate sedation permit (\$524),
 - (s) application for pediatric minimal sedation permit (\$459),
 - (t) pediatric minimal sedation permit renewal (\$182),
 - (ae) application for adult oral conscious sedation certificate (\$459),
 - (af) adult oral conscious sedation certificate renewal (\$168),
 - (ag) application for pediatric endorsement for general anesthesia permit (dentist or physician) (\$532); and,
 - (ah) application for pediatric endorsement for moderate sedation permit (\$532).
- Amend section 1043 to add the words “deep sedation” wherever the words “general anesthesia” are used, and strike the word “conscious” wherever it is used and replace it with “moderate” before the word “sedation” in the definitions section applicable to deep sedation and moderate sedation. This proposal would also capitalize the “C” in “code” throughout this section.
- Amend section 1043.1 to establish permit application requirements for general anesthesia permits (which will include deep sedation) and moderate sedation permits and the requirements to pay a fee to process those applications as set forth in Section 1021. The regulation will incorporate by reference the “Application for General Anesthesia Permit” Form GAP-1 (New 05/2021) and

“Application for Moderate Sedation Permit” Form MSP-1 (New 05/2021). The regulation will incorporate by reference a “Certification of Moderate Sedation Training” Form MSP-2 (New 05/2021) which must accompany the “Application for Moderate Sedation Permit.” The regulation will also require applicants who wish to administer or order the administration of deep sedation or general anesthesia to patients under seven years of age to separately apply for a pediatric endorsement to their permit and receive approval from the Board. The regulation will require applicants who wish to administer or order the administration of moderate sedation to patients under 13 years of age to separately apply for a pediatric endorsement to their permit and receive approval from the Board.

- Amend section 1043.2 to establish the number and qualifications of evaluators required to evaluate applicants for the issuance or renewal of general anesthesia and moderate sedation permits. Proposed amendments to section 1043.2(a) would require two or more persons for each evaluation team for the first evaluation or in the event an applicant has failed an evaluation; all subsequent evaluations would only require one evaluator. Proposed amendments to subsections (b) and (c) would add the words “deep sedation” wherever the words “general anesthesia” are used, and strike the word “conscious” wherever it is used and replace it with “moderate” before the word “sedation.” This proposal would also capitalize the “C” in “code” in subsection (b). In subsection (d), this proposal would require evaluators to possess a current, active, and unrestricted license from the Board or, the Medical Board of California for applicants qualifying under Section 1646.9 of the Code. For purposes of this section, “unrestricted” would mean not subject to any disciplinary action such as revocation, suspension, or probation.
- Amend section 1043.3 to revise facilities, equipment, records, and drug requirements for dental offices administering general anesthesia, deep sedation, or moderate sedation to adult and pediatric patients. This proposal would add the words “deep sedation” wherever the words “general anesthesia” are used and strike the word “conscious” wherever it is used and replace it with “moderate” before the word “sedation.”

Subsection (a): The office facilities and equipment maintenance requirement to be in “good operating condition” will be struck and replaced with a requirement that equipment be maintained, tested and inspected according to manufacturer specifications. For pediatric patients, equipment, medication and resuscitative capabilities would be required to be appropriately sized for use on pediatric patients.

Subsection (a)(7)(K): Existing requirements will be struck and replaced with a requirement that patients receiving moderate sedation, deep sedation or general

anesthesia shall have ventilation continuously monitored during the procedure by at least two of three specified methods.

Subsection (b)(3): This new subsection would require that records include: the category of the provider (as defined in BPC 1680(z)(3)) responsible for sedation oversight, the category of the provider delivering sedation, the category of the provider monitoring the patient during sedation, and whether the person supervising the sedation performed one or more of the procedures.

Subsection (b)(4): This proposal would revise the current requirements to include written consent of the patient's conservator, or the informed consent of a person authorized to give such consent for the patient pursuant to BPC section 1682(e).

- Amend section 1043.4 to add the words "deep sedation" wherever the words "general anesthesia" are used and strike the word "conscious" wherever it is used and replace it with "moderate" before the word "sedation". This proposal would also capitalize the "C" in "code" wherever it occurs in this section.
- Amend section 1043.5, and 1043.7 to replace "conscious" with "moderate" as SB 501 eliminates the use of term "conscious." This proposal would also capitalize the "C" in "code" wherever it occurs in section 1043.5.
- Amend section 1043.6 to prescribe the grades evaluators will be required to use to recommend to the Board for inspections and evaluations of applicants for the general anesthesia and moderate sedation permits, which would include: (1) "Passed Evaluation" (met all required components of the onsite inspection and evaluation), (2) "Conditional Approval" (for failing to have appropriate equipment, proper documentation of controlled substances, or proper recordkeeping and must submit written proof, as specified, of correcting the deficiencies within fifteen (15) days of receiving notice), (3) "Failed Simulated Emergency" (Permit holder failed one or more simulated emergency scenario(s) required for the on-site inspection and evaluation); or, (4) "Failed Evaluation" (Permit holder failed due to multiple deficient components required for the on-site inspection and evaluation or failed to comply with the conditions for issuance of a conditional approval as specified).

The proposal would delete references to appeal procedures to the full board after failing an evaluation and also the process for requesting an independent reevaluation upon payment of an additional evaluation fee.

This proposal would require applicants (who have failed two previous inspections) to 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 if a third onsite inspection and evaluation is granted or prior to

the issuance of a new permit. The proposal would also make other technical changes to add a relevant cross-reference to Section 1646.9(d) (relating to physician and surgeon qualifications) and capitalize the “C” in Code wherever it appears in this section.

- Amend section 1043.8 to replace “conscious” with “moderate” and cross-reference section 1017 and 1017.1’s continuing competency requirements, and section 1021 for the required fees for the permits.
- Adopt section 1043.8.1 to establish the requirements for completed applications for pediatric endorsements to the general anesthesia and moderate sedation permits. The regulation will incorporate by reference the “Documentation of Deep Sedation and General Anesthesia or Moderate Sedation Cases for Pediatric Endorsement” Form PE-1 (New 05/2021). The section would require an applicant for a pediatric endorsement who seeks to use general anesthesia or moderate sedation in the treatment of pediatric patients under 13 years of age or seven years of age to submit to the Board information to document each of the 20 cases of deep sedation and general anesthesia or moderate sedation required by Sections 1646.2 and 1647.3 of the Code on Form PE-1.

This section would further authorize the Board to require, upon request by the Board in any investigation of the information provided on Form PE-1, that applicants also provide documentation or patient records for each deep sedation and general anesthesia or moderate sedation pediatric case listed on Form PE-1, including preoperative evaluation, medical history, monitoring of vital signs throughout the procedure, and condition at discharge.

Finally, this proposal would require applicants to submit legible copies of the information required by this section with pediatric patient identifying information redacted.

- Adopt Article 5.1 and title “Pediatric Minimal Sedation” to establish a new article for the regulations relating to the pediatric minimal sedation permit.
- Adopt section 1043.9 to establish definitions for Article 5.1 relating to the pediatric minimal sedation permit, including definitions for “another sedation permit”, “outpatient basis”, and “pediatric patient,” as specified.
- Adopt section 1043.9.1 to establish who must apply for the pediatric minimal sedation permit for the purposes of BPC section 1647.31 and 1647.32. The regulation will incorporate by reference the “Application for Pediatric Minimal Sedation Permit” PMSP-1 (New 05/2021) and the “Certification of Pediatric Minimal Sedation Training” Form PMSP-2 (New 05/2021) that must accompany the application and applicable fee as set by Section 1021. This proposal would create an exemption for a licensed dentist who desires to administer or order

minimal sedation if they possess another sedation permit from the Board (as defined in section 1043.9). This section would also require that the office in which the pediatric minimal sedation is administered meet the facilities and equipment standards set forth in Section 1043.9.2.

- Adopt section 1043.9.2 to establish the facility, equipment (including ancillary equipment as specified), emergency cart or kit, emergency drugs, and records requirements applicable to facilities in which pediatric minimal sedation is administered to patients.
- Amend section 1044 to delete references to superseded articles and references to oral conscious sedation for minors, and clarify definitions applicable to “outpatient basis” (means “outpatient setting” as referenced in Health and Safety Code section 1248) in regulations in Article 5.5, for oral conscious sedation.
- Amend section 1044.1 to delete current references to current forms for applications for certificates for adult (OCS-1 (Rev. 01/05) or minor (OCS-3 Rev. 03/07) conscious sedation and establish and incorporate by reference the “Application for Use of Oral Conscious Sedation on Adult Patients” Form OCS-C (New 05/2021). This proposal would also remove references to requirements for dentists who possess only an adult oral conscious sedation permit and oral conscious sedation certificate for minor patients references. This proposal would also replace the word “conscious” with the word “moderate” before the words “sedation permit.”
- Amend section 1044.2 to make non-substantive, clarifying amendments including to remove an outdated reference to section 16147.12(b), add a reference to “of the Code” (short form reference for Business and Professions Code) and capitalize the “B” in the word “board.”
- Amend section 1044.3 to eliminate reference to the administration of and program coursework related to oral conscious sedation on minors since this is now replaced by pediatric minimal sedation. This section would further be amended to shorten a reference to the Business and Professions Code to “Code,” strike a reference to “conscious” sedation and replace it with “moderate” sedation, and strike a reference to “the American Academy of Pediatric Dentistry.”
- Repeal section 1044.4 relating to requirements for documentation of 10 cases of oral conscious sedation based on its reference to an outdated experience pathway for applicants administering oral conscious sedation.
- Amend section 1044.5 to revise facility, equipment, records, and drug requirements applicable to facilities in which oral conscious sedation is

administered to patients. This proposal would add requirements for all equipment to be maintained, tested, and inspected according to the manufacturers' specifications. This proposal would add requirements for obtaining the patient's conservator, or the informed consent of a person authorized to give such consent for the patient and strike a reference to "the parent or legal guardian of the patient" (as this section no longer pertains to minors).

- Amend section 1070.8 to revise course requirements for the dental sedation assistant permit to include references to deep sedation, moderate sedation (and striking references to "conscious sedation") and adding a requirement that didactic instruction include resuscitation of pediatric patients. The proposal would also include minor, technical and grammatical changes to the text for consistency of use of terms throughout the Division.

2. Anticipated Benefits from this Regulatory Action:

This regulatory proposal will afford maximum protection to pediatric patients who receive sedation and anesthesia services in California. The regulations will create an orderly process for applicants to obtain pediatric endorsements to the general anesthesia permit and moderate sedation permits. The application process will ensure that the Board grants permits and endorsements to only those applicants who are qualified to provide sedation and anesthesia services. The renewal process will ensure permit holders possess continued competency in the administration of deep sedation or general anesthesia, by requiring general anesthesia permit holders to submit documentation of completion of twenty (20) cases of general anesthesia to pediatric patients in order to maintain continued competency. This proposal will also require moderate sedation permit holders to submit documentation of completion of twenty (20) cases of moderate sedation to pediatric patients in order to maintain continued competency. Pediatric patients are our States most vulnerable patients and these requirements will ensure dentists possess competency at the time of renewal.

The adoption of the forms incorporated by reference in this proposal will assist staff in ensuring an applicant meets the training requirements for the administration of general anesthesia, deep sedation, moderate sedation, pediatric minimal sedation, oral conscious sedation for adults and training requirements applicable to pediatric endorsements.

The amendments to the regulations governing onsite inspections and evaluations will ensure that evaluators are properly qualified and utilize appropriate standards. The regulations will provide clarity to regulated professionals about how these evaluations are graded and reviewed by the Board's onsite inspection team, and how to remedy areas in which they receive failing grades.

The fees established and amended in this proposal will ensure the Board has sufficient resources to process applications and ensure applicants meet legal requirements for permits and endorsements.

This proposal will also amend requirements for dental sedation assistant permit courses including instruction requirements. These amendments will ensure those obtaining this permit will be properly trained in all categories of anesthesia and sedation in the Act as established by SB 501 and will properly monitor patients during procedures.

Factual Basis/Rationale:

The Board proposes the following:

Amend Section 1017.1. Continued Competency Requirements for Renewal of Permits.

Title of the regulation

The Board proposes to adopt a new title of the regulation to reflect it contains continuing competency requirements for renewal of permits for accuracy and ease-of-reference.

Subdivision (a)

The Board proposes to adopt subdivision (a) to establish that, as a condition of renewal, each licensee who holds a general anesthesia permit with a pediatric endorsement must 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)-(e).

This amendment is necessary to implement BPC section 1646.2(c)(2) which provides that a deep sedation or general anesthesia permit applicant must provide proof of at least 20 cases of deep sedation or general anesthesia to patients under seven years of age in the 24-month time period directly preceding application for a pediatric endorsement to establish competency, both at the time of initial application and at renewal. BPC section 1646.9(e) makes this requirement applicable to physician and surgeon licensees as well.

This subdivision is placed in section 1017.1 to locate requirements for continued competency in one place, to provide notice to affected licensees of the Board's requirements for establishing continuing competency at the time of renewal, and to help ensure that the licensee provides the requisite documentary "proof" needed to establish competency as required by BPC sections 1646.2 and 1646.9. Placing the

same requirements on the licensee at the time of renewal ensures that the licensee continues to meet the same rigorous documentary standards that they met at time of initial application considering the fact that the permit authorizes administration of deep sedation or general anesthesia (an induced, reversible and controlled loss of consciousness), which creates the most potential risk of harm to a patient if minimum standards are not met.

Subdivision (b)(1)-(3)

The Board proposes to adopt subdivision (b) to set forth the information a moderate sedation permitholder must provide to the Board as a condition of renewal.

The Board proposes to add subdivisions (b)(1) and (b)(2) to reflect the requirements set forth in section 1647.3(d)(2) and (d)(3). Section 1647.3(d)(2) requires permitholders to maintain and provide proof for up to three renewal periods of at least 20 cases of moderate sedation to patients under 13 years of age to establish competency in pediatric moderate sedation. Section 1647.3(d)(3) requires dentists who wish to provide moderate sedation to children under seven years of age establish and maintain current competency by completing 20 cases of moderate sedation for children under seven years of age for each permit renewal period.

BPC 1647.3 offers several possible pathways for establishing compliance with the above-mentioned requirements. BPC section 1647.3(d)(2) and (d)(3) provide that a dentist shall establish competency for the moderate sedation permit on renewal by “successful completion” or by “completion” of 20 cases of moderate sedation to patients under 13 years of age and under 7 years of age, respectively (“independently” administer). However, subdivisions (f) and (g) of BPC section 1647.3 also permit exceptions for applicants and permitholders who lack sufficient cases of administration to pediatric patients under 13 years of age and/or under 7 years of age to continue to qualify for the permit. BPC section 1647.3(g) permits a permitholder who lacks sufficient cases of independent administration to pediatric patients under 7 pursuant to subdivision (d)(3) to “administer moderate sedation to patients under seven years of age under the direct supervision of a permitholder who meets those qualifications.” As a result, on initial and renewal of the permit, licensees have a variety of pathways to establish competency and qualify for the permit.

This means that an applicant for initial and renewal of the permit may have a range of cases to establish competency. Permitholders may have as few as 20 cases to qualify for the permit (if patients are all under 7) or as many as 40 cases to qualify for the permit (if some patients are under 13 but over 7 years of age and the rest are under 7 years of age), or have a mix of cases in between the range of 20-40 to qualify for the permit. Further, competency may be established independently (for patients under 13 years of age) or by allowing the permitholder to perform under the direct supervision of another permitholder who qualifies under BPC section 1647.3 (for patients under 7 years of age) if they lack the 20 cases required for renewal. This presents some

challenges in how to request information from and establish competency for the permit and cover all the different types of factual scenarios.

The Board proposes to simplify the process for establishing compliance on renewal for a moderate sedation permit in the following manner. Licensees will be asked to confirm in writing to the Board on renewal all of the following under proposed subsections (b)(1)-(3):

- (1) Whether they completed at least twenty (20) cases of moderate sedation for children under thirteen years of age either independently and/or under the direct supervision of another permit holder (to cover the total number of cases completed for patients under 13 generally as required by BPC section 1647.3(d)(2) (recognizing the under 7 patients are a subset));
- (2) Whether the licensee completed at least twenty (20) cases of moderate sedation for children under seven years of age either independently and/or under the direct supervision of another permit holder (to cover the total number of cases completed for patients under 7 (as required by BPC section 1647.3(d)(3)); 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 (to verify whether the permitholder qualifies under an exception to the subsection (d)(3) requirements per BPC section 1647.3(g)).

This information will be sufficient for the Board to determine whether minimum competency is established or whether further investigation may be required to determine whether minimum standards continue to be met. These requirements are also placed in section 1017.1 to locate requirements for continued competency in one place, to provide notice to affected licensees of the Board's requirements for establishing continuing competency at the time of renewal, and to help ensure that moderate sedation permitholders provide the requisite documentary "proof" needed to establish competency as required by BPC section 1647.3 in the 24-month period immediately preceding each permit renewal period.

Amend Section 1021. Examination, Permit and License Fees for Dentists.

Subdivisions (a) through (d)

Currently, section 1000 of the Board's regulations defines "Code" to mean "Business and Professions Code" whenever it is used in Division 10 of Title 16 of the California Code of Regulations. For ease of reference for the Board's staff and regulated community, the Board proposes to re-state "of the Business and Professions Code (the Code)" for the first fee category in this fee schedule and add "of the Code" at the end of each the fee categories in subsections (b)-(d). These amendments also convey to the

reader, in a simple way, that the statutory sections and authorities for the various applications are in the Business and Professions Code.

Subdivisions (g) and (h)

The Board proposes to capitalize “code” for consistency throughout the regulations and consistency with the definition contained in Section 1000(f).

Subdivision (j), (k), (m), (n), (o), (p), (u)

Proposed edits to initial capitalize the following words, which currently are in lower case:

- (j) & (k): “Additional Office Permit,”
- (m): “Name Permit,”
- (n): “Renewal,”
- (o): “Fictitious Name,” “Fictitious Name Permit,”
- (p): “Education Registered Provider”,
- (u): “Sedation Onsite Inspection,” and, “Evaluation.”

The Board proposes to capitalize the initial letter of various terms (initial capitalize) in these subdivisions for consistency throughout this section and to emphasize the subject matter description of the fees, making it easier for the reader to identify the type of fee and corresponding amount required by this section. The capitalization will also apply to the names of the application and/or renewal fees for the listed permits issued by the Board.

Subdivision (q): Application for General Anesthesia or Moderate Sedation Permit Fee

The Board proposes to amend this subdivision to add “Application for,” replace “conscious” with “moderate,” and initial capitalize the terms in the subdivision. The Board also proposes to increase the current application fee from \$500 to \$524 to recover its costs for processing this application. BPC section 1724(o) and (q) authorizes fees for general anesthesia permits and moderate sedation permits, respectively, of up to \$1,000 as necessary for carrying out the Board’s responsibilities required by the Act. In addition, in order to recover its costs for processing applications related to administration by a physician in a dental office, BPC section 1646.9(b), as amended by SB 501 provides, in pertinent part:

“A physician and surgeon who desires to administer deep sedation or general anesthesia as set forth in subdivision (a) shall apply to the board on an application form prescribed by the board and shall submit all of the following:

- (1) The payment of an application fee prescribed by this article. . . .”

A Workload Cost Analysis was completed, which determined that the total cost to the Board to process both the Application for General Anesthesia Permit (whether for a dentist or a physician and surgeon applicant) and Application for Moderate Sedation Permit is \$524. See workload cost calculations showing each task associated with processing the applications in Fee Workload Cost Analysis of the Underlying Data. These fees are necessary for the Board to implement its responsibilities for licensing only qualified applicants as prescribed by the Act and to recover its costs of processing these applications.

The Board adds “Application for” to clarify and provide additional notice to the regulated community that the fee is required for either application for the General Anesthesia or Moderate Sedation permits and not the permits themselves.

The Board replaces “conscious” with “moderate” because the Act, under statutes enacted by SB 501, repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board will capitalize the terms in the subdivision for consistency throughout this section.

Subdivision (r): Deletion of “Oral Conscious Sedation Certificate Renewal”; Addition of Application for Pediatric Minimal Sedation Permit and Fee

The Board proposes to replace “Oral Conscious Sedation Certificate Renewal” with “Application for Pediatric Minimal Sedation Permit.” The Board proposed to adopt a fee of \$459 for the application. BPC section 1724 authorizes the Board to establish charges and fees as is necessary for the purpose of carrying out the responsibilities under the Act as it relates to dentists. A Workload Cost Analysis was completed which determined that the total cost to the Board to process an Application for Pediatric Minimal Sedation Permit is \$459. See workload cost calculations showing each task associated with processing the application in the Fee Workload Cost Analysis of the Underlying Data.

SB 501 replaces the oral conscious sedation permit (OCSP) with the pediatric minimal sedation permit. The Board will no longer issue the OCSP for minors. BPC section 1647.35 provides that “a permitholder who has a [OCSP] that was issued before January 1, 2022, that authorized the permitholder to administer or order the administration of oral conscious sedation for minor patients under prior Article 2.85 (commencing with Section 1647.10) 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 requirements of this article.” This amendment is necessary because, effective January 1, 2022, the Board will issue the pediatric minimal sedation permit and need to charge a new fee to recover its costs for processing the application.

Subdivision (s): General Anesthesia or Moderate Sedation Permit Renewal Fee Title

The Board proposes to replace “conscious” with “moderate,” and capitalize the terms in the subdivision.

The Board replaces “conscious” with “moderate” because the Act, under statutes enacted by SB 501, repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board will capitalize the terms in the subdivision for consistency throughout this section.

Subdivision (t): Pediatric Minimal Sedation Permit renewal fee

The Board proposes to create a fee category and title for a pediatric minimal sedation permit renewal fee and establish a fee of \$182. BPC section 1724 authorizes the Board to establish charges and fees as is necessary for the purpose of carrying out the responsibilities under the Act as it relates to dentists. A Workload Cost Analysis was completed which determined that the total cost to the Board to for the Pediatric Minimal Sedation Permit renewal is \$182. See cost in Fee Workload Cost Analysis of the Underlying Data.

SB 501 repealed the authority for the oral conscious sedation permit for minor patients and replaced it with the pediatric minimal sedation permit under the provisions of Article 2.87 of the Act (Bus. & Prof. Code, §§ 1647.30 et seq.), which necessitates a fee for a renewal thereof. (Bus. & Prof. Code, § 1647.35.)

Revise tile and re-letter section as subdivision (u): “General Anesthesia or Moderate Sedation Onsite Inspection and Evaluation Fee”

Due to the addition of new subdivision (t), the Board proposes to re-letter existing section (t) to (u) and make the following changes. The Board proposes to replace “conscious” with “moderate,” and capitalize the terms in the subdivision.

The Board replaces “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board will capitalize the terms in the subdivision for consistency throughout this section.

Former subdivisions (t) through (ad)

The Board proposes to renumber former subdivisions (t) through (ad). This amendment is necessary because of the creation of a new subdivision (t).

New subdivision (ae): Application for Adult Oral Conscious Sedation Certificate Fee

The Board proposes to add “Application for,” strike “minor,” capitalize the terms in the subdivision, and raise the fee from \$368 to \$459. BPC section 1724(r) authorizes a fee of up to \$1,000 as necessary for carrying out the Board’s responsibilities required by the Act. A Workload Cost Analysis was completed which determined that the total cost to the Board to process an Application for Adult Oral Conscious Sedation Certificate is \$459. See the Board’s workload costs in the Fee Workload Cost Analysis of the Underlying Data. This fee increase is therefore necessary to ensure the Board is fully reimbursed its administrative costs for the workload associated with this application.

The Board proposes to add “Application for” to clarify that the fee must accompany the application for an oral conscious sedation certificate. The Board strikes “minor” because the Act, through amendments enacted by SB 501, replaces the Oral Conscious Sedation Permit for minor patients with the pediatric minimal sedation permit for minors, so the current reference is no longer necessary. (Bus. & Prof. Code, § 1647.35.)

The Board will capitalize the terms in the subdivision for consistency throughout this section.

Move and revise current title of subdivision (r) to subdivision (af): Adult Oral Conscious Sedation Certificate Renewal Fee (Keep Existing Fee Amount)

The Board proposes to move the current fee category and fee for an oral conscious sedation certificate renewal from subdivision (r) to a new subdivision (af) and add the word “adult” to the description for convenience so that all provisions relating to adult oral conscious sedation are in one location. . The Board previously adopted a fee of \$168 for

this fee category (which included both minors and adults) based on the result of a rulemaking action that was approved by the Office of Administrative Law and filed with the Secretary of State on August 24, 2017.

The Board proposes to add the word “Adult” to the title of this fee category so that it would read “Adult Oral Conscious Certificate Renewal”. This is necessary because the Act, as amended by SB 501, replaces the oral conscious sedation certificate for minors with the pediatric minimal sedation permit for minors, which is currently proposed to be added at subdivision (t). (Bus. & Prof. Code, § 1647.35.) Accordingly, the Board must create a new title solely applicable to adults. The workload has not changed for this fee category, so the Board does not propose to change the current fee of \$168 that is being charged for this renewal.

New subdivision (ag): Application for Pediatric Endorsement for General Anesthesia Permit

The Board proposes to create a fee category for an application for pediatric endorsement for general anesthesia permit and establish a fee of \$532 for the application to recover its costs for the workload associated with processing an application for the pediatric endorsement. Not all applicants who desire to administer or order general anesthesia seek to serve the pediatric population, and those who do must, in addition to obtaining the general anesthesia permit, “apply for a pediatric endorsement for the general anesthesia permit” as provided in BPC section 1646.2(c). BPC section 1724 authorizes the Board to establish charges and fees as is necessary for the purpose of carrying out the responsibilities required by the Act as it relates to dentists. In addition, in order to recover its costs for processing applications related to administration by a physician in a dental office, BPC section 1646.9, as amended by SB 501 provides, in pertinent part:

“A physician and surgeon who desires to administer deep sedation or general anesthesia as set forth in subdivision (a) shall apply to the board on an application form prescribed by the board and shall submit all of the following:

(1) The payment of an application fee prescribed by this article. . . .”

(e) A physician and surgeon who additionally meets the requirements of paragraphs (2) and (3) of subdivision (c) of Section 1646.2 may apply to the board for a pediatric endorsement to provide deep sedation or general anesthesia to a child under seven years of age.

A Workload Cost Analysis was completed which determined that the total cost to the Board to process an Application for Pediatric Endorsement for General Anesthesia Permit (whether for a dentist or physician and surgeon applicant) is \$532. See the Board’s total workload cost in the Fee Workload Cost Analysis of the Underlying Data. This fee is therefore necessary to ensure the Board is fully reimbursed its administrative

costs for the workload associated with this application and that only applicants who plan to order or administer general anesthesia to the pediatric population pay for the costs associated with this endorsement.

This is necessary because the Act, as amended by SB 501, requires dentists to possess a pediatric endorsement of their general anesthesia permit to administer or order the administration of deep sedation or general anesthesia to patients under 7 years of age. (Bus. & Prof. Code, § 1646.1, subd. (b).)

New subdivision (ah): Application for Pediatric Endorsement for Moderate Sedation Permit

The Board proposes to create a fee category for an application for pediatric endorsement for moderate sedation permit and establish a fee of \$532 to recover its costs for the workload associated with processing an application for the pediatric endorsement. Not all applicants who desire to administer or order moderate sedation seek to serve the pediatric population, and those who do must, in addition to obtaining the moderate sedation permit, “may apply for a pediatric endorsement “ as provided in BPC section 1647.3(d). BPC section 1724 authorizes the Board to establish charges and fees as is necessary for the purpose of carrying out the responsibilities required by the Act as it relates to dentists. A Workload Cost Analysis was completed which determined that the total cost to the Board to process an Application for Pediatric Endorsement for Moderate Sedation Permit is \$532. See the Board’s total workload cost in the Fee Workload Cost Analysis of the Underlying Data. This fee is therefore necessary to ensure the Board is fully reimbursed its administrative costs for the workload associated with this application and that only applicants who plan to order or administer moderate sedation to the pediatric population pay for the costs associated with this endorsement.

This is necessary because the Act, as amended by SB 501, requires a dentist to obtain a pediatric endorsement on the moderate sedation permit prior to administering moderate sedation to a patient under 13 years of age. (Bus. & Prof. Code, § 1647.3, subd. (d).)

Note:

The Board proposes to add BPC sections 1646.2, 1647.3, 1647.20, 1647.23, 1647.32, 1647.33 to the Reference section. This is necessary because this regulation implements, interprets or makes these statutes specific.

The Board proposes to delete BPC section 1647.12 and 1647.15 from the Reference section. This is necessary because this regulation does not implement, interpret, or make these statutes specific.

Section 1043. Definitions.

Subdivisions (a) and (c)(1)

The Board proposes to add “deep sedation” to subdivision (a).

BPC section 1646, effective January 1, 2022,¹ establishes the term “deep sedation.” Section 1646.1 provides that a general anesthesia permit must be obtained to administer or order the administration of deep sedation or general anesthesia. Accordingly, the amendment to subdivision (a) is necessary so the applicant for a general anesthesia permit is aware of the levels of anesthesia which can be administered to dental patients and the type of permit required. According to BPC 1682(a), it is unprofessional conduct for a dentist to have more than one patient undergoing moderate sedation, deep sedation, or general anesthesia unless the patient is monitored on a one to one ratio by a dentist or another licensed health professional authorized to administer moderate sedation, deep sedation, or general anesthesia.

The Board proposes to add “deep sedation” to subdivision (c)(1) because BPC section 1682(a), to which this subdivision refers, uses the term “deep sedation” in providing what conduct is unprofessional under section 1682(a). Accordingly, the amendment is necessary to conform the regulation with the amendments to the statute, effective January 1, 2022.

Subdivision (c)

The Board proposes to capitalize “code” for consistency throughout the regulations.

Subdivision (c)(2)

The Board proposes to replace “conscious” with “moderate” in subdivision (c)(2) because the Act, as amended by SB 501, repeals existing provisions relating to the use of conscious sedation. The Act replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

¹ Each of the statutes cited herein as part of SB 501 is effective January 1, 2022. For brevity, the Board eliminates “effective January 1, 2022” in future references herein to statutory amendments effected by SB 501 but by reference the Board means to apply the versions of these statutes effective January 1, 2022.

Subdivision (d)

The Board proposes to capitalize “s” in “Section” and replace “conscious” with “moderate” and add “deep sedation” to subdivision (d).

The Board capitalizes “section” to emphasize sections of the Business and Professions Code and for consistency throughout the regulations.

The Board replaces “conscious” with “moderate” because the Act, as amended by SB 501, repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board adds “deep sedation” to the subdivision because statutory changes enacted by SB 501 amend BPC section 1682(b) to include “deep sedation.” Accordingly, the amendments are necessary to conform the regulation with the amendments to the statute, effective January 1, 2022.

Section 1043.1. Permit Application Requirements.

Title of regulation

The Board proposes to add “Application” to the title of regulation because the amended regulation incorporates applications for the general anesthesia and moderate sedation permits. This change is necessary for ease-of-reference and to make the information on permit applications more accessible to staff and the regulated community.

Subdivision (a)

The Board proposes to replace “conscious” with “moderate” and add “deep sedation” and “or sedation” to subdivision (a).

The Board replaces “conscious” with “moderate” because the Act, as amended by SB 501, repeals existing provisions relating to the use of conscious sedation. The Act replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board adds “deep sedation” as BPC section 1646.1(a) requires that a dentist must possess a general anesthesia permit in or to administer or order the administration of deep sedation or general anesthesia. Section 1043.1(a) and BPC section 1646.9(a) will allow a dentist who does not possess a general anesthesia or moderate sedation permit to hire or contract with a permit holder to administer deep sedation, general anesthesia, or moderate sedation to their dental patients. Accordingly, the amendments are necessary to conform the regulation with the amendments to the statute, effective January 1, 2022. The addition of the word “sedation” is necessary to make it easier to understand that the regulation applies to both anesthesia “or sedation.”

Subdivision (b)

The Board proposes to amend subdivision (b) to provide the process by which dentists, and physicians and surgeons may apply for a permit to administer deep sedation and general anesthesia pursuant to BPC sections 1646.2 and 1646.9.

BPC section 1646.2(a) provides a dentist who desires to administer or order the administration of deep sedation or general anesthesia must apply to the board on an application form prescribed by the board. Section 1646.9 provides a physician and surgeon may administer deep sedation or general anesthesia in the office of a licensed dentist for dental patients if they meet the conditions set forth in the statute. Therefore, it is necessary for the Board to cite these statutes to provide context for the permit application incorporated by reference in subdivision (b).

The Board will incorporate by reference the “Application for General Anesthesia Permit” Form GAP-1 NEW (05/2021). This is the application by which dentists, and physicians and surgeons may apply for a permit to administer deep sedation or general anesthesia. It also states that the application must be accompanied by the fee provided in section 1021(q). These requirements are necessary for the Board to administer this permit program as required by the Act and recover its costs of administration as set forth in the changes to Section 1021 described above.

The form referenced in this subdivision would be cumbersome, unduly expensive and otherwise impractical to publish in the California Code of Regulations.

FORM GAP-1, APPLICATION FOR GENERAL ANESTHESIA PERMIT

- Application fee box with notice that application fees are nonrefundable. The Board established a fee of \$524 for the application in section 1021(q). The application fee is non-refundable because the Board incurs staff hours and resources to review the application regardless of whether the application is approved or denied. These statements are necessary to provide notice to the applicants of these requirements.

- Instructions:

- This application for a permit to administer deep sedation or general anesthesia (“general anesthesia permit”) must be completed in its entirety or the application may be rejected as incomplete. Attach additional sheets if necessary.

This statement is necessary to provide notice to the applicant that the entirety of the application must be completed, or it will be rejected and to give direction on how to provide additional sheets of information to the Board to complete the application. This helps to ensure the applicant completes the application and the application is processed by staff expeditiously.

- Any material misrepresentation of any information on the application is grounds for denial or subsequent revocation of the permit.

This statement is necessary to provide notice to the applicant that any material misrepresentation of any information on the application is grounds for denial or subsequent revocation of the permit. (Bus. & Prof. Code, § 498 [“A board may revoke, suspend, or otherwise restrict a license on the ground that the licensee secured the license by fraud, deceit, or knowing misrepresentation of a material fact or by knowingly omitting to state a material fact.”].) This helps to provide notice to the applicants of these potential grounds for denial or discipline and to ensure the applicant provides truthful information to the Board.

- Under BPC sections 31 and 494.5, the State Board of Equalization (BOE) 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 or FTB certified list of top 500 tax delinquencies.

This statement is necessary to provide to an applicant that the application may be denied or permit suspended if the applicant fails to pay state tax obligations. This notice is required by BPC section 31 and is necessary to give proper notice to the applicants of the possible consequences for failure to pay their state tax obligations as set forth in BPC sections 31 and 494.5.

- Item 1: The form requires the applicant to disclose a social security number, or individual taxpayer identification number as required by BPC section 30(a)(1).
- Items 2-9: Items 2-9 seek identifying information about the applicant, including birth date, name, mailing address (address of record, which may be a p.o. box under the provisions of BPC section 27(a)), primary practice location (physical address), email address (optional), telephone number, fax number (optional), and dental or medical

license number. These items of information are necessary to verify the applicant's identity and eligibility (already have to be licensed with the board or the Medical Board of California), ensure accuracy in the processing of the application, and enable the Board to communicate more efficiently with the applicant.

- Item 10 (Applicant Residency Training): The form requires the dentist and physician and surgeon applicants to provide information regarding the completion of the applicant's residency program. (Bus. & Prof. Code, §§ 1646.2, 1646.9.) For ease of use and comprehension, the Board has separated the two types of eligible licensees into two separate sets of questions: subdivision "A" for dental licensees, and subdivision "B" for physician and surgeon licensees.

Subdivision "A" Dental Licensees

This section asks whether dental licensees have completed a residency program in general anesthesia accredited by the American Dental Association's Commission on Dental Accreditation (CODA) or a residency program in oral and maxillofacial surgery accredited by the CODA. This is necessary because BPC section 1646.2(a) requires an applicant to show they have successfully completed a minimum of one year of advanced training in anesthesiology and related academic subjects approved by the board, or equivalent training or experience approved by the board, beyond the undergraduate school level. The Board accepts residency programs which have been approved by CODA in anesthesiology and oral and maxillofacial surgery as they are a national accrediting agency for United States predoctoral dental programs, and advanced education training programs which are accepted for licensure in California under BPC sections 1628, 1634, 1635.5, and 1647.20. These standards are also currently reflected in subdivisions (b)(1) and (b)(2) of this section and are being relocated to the form as questions for ease of reference and use by the applicants.

To verify that this requirement has been met, the form requests the applicant provide a certificate of completion, which is typically issued by programs as a form of recognition that the residency has been completed. The Board has received "other documentary evidence" of completion in the past, such as letters from a program, which it would also accept in lieu of a certificate of completion.

Subdivision "B" Physician and Surgeon Licensees

This section asks whether physician and surgeon licensees have completed a postgraduate residency training program in anesthesiology that is recognized by the American Council on Graduate Medical Education. This is necessary to verify whether this requirement has been met because BPC section 1646.9(b)(2) requires that the applicant has successfully completed a postgraduate residency training program in anesthesiology that is recognized by the American Council on Graduate Medical Education. (Bus. & Prof. Code, § 1646.9, subd. (b)(2).) Consistent with BPC section 2079's requirements, applicants who answer "yes" to this question are also directed to

submit a completed copy of this application to the Medical Board of California to enable this Board to verify that the applicant has completed the required training. This is necessary to ensure all applicable statutory qualifications are met prior to issuance of the permit and for the Board to assist the applicant with complying with BPC section 2079.

- Item 11: The form asks the applicant to indicate whether they are applying for a pediatric endorsement to the general anesthesia permit. If the applicant answers yes, the applicant is instructed that they must complete a separate application for a pediatric endorsement and meet the requirements referenced in section 1043.8.1. The applicant may apply for the pediatric endorsement at the same time as the general anesthesia permit or at a later date. This item also directs applicants to attached copies of BPC sections 1646.1 and 1646.2, and section 1043.8.1 to explain the monitoring requirements to licensees. The applicant is required to check the box if they want the application for the pediatric endorsement and general anesthesia permit processed along with this application. This is necessary so staff can try to process both the permit and endorsement applications at the same time so both can be tracked contemporaneously for the convenience of the applicant.
- Item 12: The form asks the applicant to indicate whether the applicant is currently or has served in the U.S. military as required by BPC section 114.5.
- Item 13: The form asks the applicant whether the applicant is requesting the expediting of the initial application for members of the U.S. Armed Forces who have been honorably discharged. This question is necessary to determine whether an applicant is applying for expedited review and processing per BPC section 115.4. The item then asks the applicant to scan and attach a copy of a certificate of release from active duty (DD-214, which is the Department of Defense's standard report of separation for members of the U.S. Armed Forces that includes the necessary information for the Board to process such requests) or other evidence showing the date and type of discharge to receive expedited review. To date, the Board has not received any other type of evidence in lieu of the DD-214 but includes this possibility should it be submitted in the future to help ensure that applicants have other options for demonstrating they qualify. This information is necessary to determine whether the applicant has provided satisfactory evidence that meets the requirements for expedited processing per BPC 115.4.
- Item 14: The form asks the applicant whether they already hold a valid license or comparable authority to practice dentistry in another U.S. state or territory, and whether their spouse or domestic partner is an active duty member of the U.S. Armed Forces and is assigned to a duty station in California under official orders. The question is necessary to determine whether an applicant meets the requirements for expedited review and processing under BPC section 115.5. If the applicant answers yes, the form states that their application will receive an expedited review, consistent with BPC section 115.5.

The form asks the applicant to provide documentary evidence to support the request including: (1) a certificate of marriage or certified declaration/registration of domestic partnership filed with the Secretary of State or other documentary evidence of legal union with an active-duty member of the Armed Forces; (2) a copy of the applicant's current dental license in another state, district, or territory of the United States; and (3) a copy of the military orders establishing your spouse or partner's duty station in California. These documents are necessary to verify and ensure the applicant meets the statutory requirements for expediting the licensure process by requesting official government documents, licenses and military records to substantiate the information provided to the Board. To date, the Board has not received any other type of evidence in lieu of a certificate of marriage or certified declaration/registration of domestic partnership but includes this possibility of "other documentary evidence" should it be submitted in the future to help ensure that applicants have other options for demonstrating they qualify.

- Item 15: The form asks the applicant to indicate whether: (1) the applicant was admitted to the United States as a refugee pursuant to section 1157 of Title 8 of the United States Code; or (2) the applicant was granted asylum by the Secretary of Homeland Security or the Attorney General of the United States pursuant to section 1158 of Title 8 of the United States Code; or, (3) the applicant has a special immigrant visa and was granted a status pursuant to section 1244 of the Public Law 110-181, Public Law 109-163, or section 602(b) of Title VI of division F of Public Law 111-8 [relating to Iraqi and Afghan translators/interpreters of those who worked for or on behalf of the United States government]. These questions are necessary to determine whether the applicant qualifies for expediting of the initial application for refugees, asylees, and holders of special immigrant visas as required by BPC section 135.4(a)'s criteria for expediting these types of applications.

If the applicant answers yes, the Board requests they attach official documents commonly issued by federal agencies or the courts for the categories of individuals listed in section 135.4 as evidence of their status as a refugee, asylee, or special immigrant visa holder which includes:

- Form I-94, arrival/departure record, with an admission class code such as "re" (refugee) or "ay" (asylee) or other information designating the person a refugee or asylee.
- Special immigrant visa that includes the "si" or "sq."
- A permanent resident card (Form I-551), commonly known as a "green card," with a category designation indicating that the person was admitted as a refugee or asylee.
- An order from a court of competent jurisdiction or other documentary evidence that provides reasonable assurances to the Board that the applicant qualifies for expedited licensure per BPC section 135.4.

These documents are necessary to verify and ensure the applicant meets the statutory requirements for expediting the initial application process. Copies of official government documents will help ensure the accuracy of the information provided by the applicants to the Board.

- Statement before Item 16: The form states: Facilities and Equipment Requirements - All equipment must be maintained, tested, and inspected according to the manufacturers' specifications. In an office where sedation services are to be provided pediatric patients, the required equipment, medication, and resuscitative capabilities shall be appropriately sized for use on a pediatric population. This statement is necessary to educate the applicant regarding the legal requirements applicable to facilities and equipment in accordance with the required standards for all offices where deep sedation or general anesthesia is conducted under section 1043.3.
- Item 16: The form asks the applicant whether the facility has an operating theater large enough to adequately accommodate the patient on a table or in an operating chair and permits an operating team consisting of at least three individuals to freely move about the patient. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(1).
- Item 17: The form asks whether the facility has an operating table or chair that permits the patient to be positioned so the operating team can maintain the airway, quickly alter patient position in an emergency, and provides a firm platform for the management of cardiopulmonary resuscitation. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(2).
- item 18: The form asks whether the facility have a lighting system that is adequate to permit evaluation of the patient's skin and mucosal color and a backup lighting system which is battery powered and of sufficient intensity to permit completion of any operation underway at the time of general power failure. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(3).
- Item 19: The form asks whether the facility has suction equipment that permits aspiration of the oral and pharyngeal cavities and a back-up device that can operate at the time of a general power failure. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(4).
- Item 20: The form asks whether the facility has an oxygen delivery system with adequate fullface masks and appropriate connectors that is capable of allowing the

administering of greater than 90% oxygen at a 10 liter/minute flow at least sixty minutes (650 liter “e” cylinder) to the patient under positive pressure, together with an adequate backup system that can operate at the time of general power failure. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(5).

- Item 21: The form asks whether the facility has a recovery area that has available oxygen, adequate lighting, suction and electrical outlets and states it can be the operating theatre. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(6).
- Item 22: The form asks whether the facility has the listed ancillary equipment maintained in good operating condition. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(7).
- Question before Item 23: The form asks whether the applicant maintains the records listed in items 23 through 26. This question is used to verify that the standards for records retention contained in section 1043.3(b) are met.
- Item 23: The form requires the applicant to indicate whether the applicant maintains an adequate medical history and physical evaluation records which are updated prior to each administration of deep sedation or general anesthesia which include 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 visual examination of the airway, and auscultation of the heart and lungs as medically required. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(b)(1).
- Item 24: The form asks the applicant whether the applicant maintains general anesthesia or deep sedation records which include a time-oriented record with preoperative, multiple intraoperative, and postoperative pulse oximetry (every 5 minutes intraoperatively and every 15 minutes postoperatively for general anesthesia or deep sedation) and blood pressure and pulse readings, (both every 5 minutes intraoperatively for general anesthesia or deep sedation), drugs [amounts administered and time administered], length of the procedure, any complications of anesthesia or sedation and a statement of the patient's condition at time of discharge. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(b)(2).
- Item 25: The form asks whether the applicant maintains records which include the category of the provider responsible for sedation oversight, the category of the provider delivering sedation, the category of the provider monitoring the patient

during sedation, and whether the person supervising the sedation performed one or more of the procedures. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(b)(3).

- Item 26: The form asks whether the applicant maintains the written informed consent of the patient, or appropriate, patient's conservator, or the informed consent of a person authorized to give consent for the patient, or if the patient is a minor, his or her guardian pursuant to Business and Professions Code section 1682(e). This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(b)(4).
- Item 27: The form asks the applicant if they maintain the listed emergency drugs at all times in connection with the administration of deep sedation or general anesthesia. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(c).
- Item 28: The form asks if the applicant is competent to treat all of the listed emergencies. This question is necessary so the Board can determine whether the applicant satisfies the requirements for acceptable knowledge of how to treat the listed emergencies as set forth in section 1043.4(c). This helps ensure that the Board has some evidence prior to issuance of the permit that the applicant is aware of these issues and the need to be knowledgeable in these areas to practice competently and safely for the protection of the public.
- Item 29: The form asks whether the applicant's dental office personnel directly involved with the care of the patients undergoing deep sedation or general anesthesia certified in basic cardiac life support (CPR). This is necessary because it is unprofessional conduct for any dentist with patients who are undergoing moderate sedation to have dental office personnel directly involved with the care of those patients who are not certified in CPR and recertified biennially. (Bus. & Prof. Code, § 1682, subd. (d).) This question is necessary to determine prior to issuance of the permit, and for the protection of the public, whether this standard is met.
- Item 30: The form asks the applicant to provide the addresses of all locations where the applicant will administer or order the administration of deep sedation or general anesthesia. If the applicant is a physician and surgeon, they are directed to provide the names of any hospitals where they have membership on the medical staff. This question is necessary so the Board can identify the locations where administration will occur for the purposes of future investigation and inspection and verify that the legal requirements set forth in sections 1043.3 and 1043.4 are met at each location.
- Certification under penalty of perjury: The form requires the applicant acknowledge and certify under penalty of perjury under the laws of the State of California, that the information including any attached statements is true and correct by providing a

signature and date. The Board relies upon applicants' self-reported information in evaluating applications. This requirement helps ensure that the representations on the form are accurate and made in good faith.

- Information Collection and Access section: The form includes the required notices and disclosures to the applicant for the Board's collection of personal information in compliance with Civil Code section 1798.17.

Subdivisions (b)(1) and (b)(2)

The Board proposes to delete these subdivisions as the requirements established for the general anesthesia permit will be set forth in Form GAP-1.

New subdivision (c)

The Board proposes to add this subdivision to explain that applicants wishing to administer or order the administration of deep sedation or general anesthesia to patients under seven years of age must apply for a pediatric endorsement to their general anesthesia permit as set forth in section 1043.8.1 and receive approval from the Board. This subdivision is necessary to explain the process to applicants for obtaining a pediatric endorsement to a general anesthesia permit and that it must be separately approved by the Board.

New subdivision (d)

The Board proposes to revise former subdivision (c) to provide the process by which a dentist may apply for a moderate sedation permit for the purposes of BPC sections 1647.2 and 1647.3. The Board replaces "conscious" with "moderate" because the Act, as amended by SB 501, repeals existing provisions relating to the use of conscious sedation. The Act replaces the term "conscious sedation" with "moderate sedation."

BPC section 1647.2(a) provides the requirements for a dentist to administer or order the administration of moderate sedation on an outpatient basis for a dental patient. Section 1647.3(a) provides a dentist who desires to administer or to order the administration of moderate sedation shall apply to the board on an application form prescribed by the board. Therefore, it is necessary for the Board to cite these statutes to provide context for the permit application incorporated by reference in subdivision (d). References to the requirements of BPC section 1647.3 and the requirement for an individual to be a licensed dentist in California will be deleted as those requirements will be addressed on the new application proposed to be incorporated by reference discussed below.

The Board will incorporate by reference the "Application for Moderate Sedation Permit" Form MSP-1 NEW (05/2021). This is the application by which dentists may apply for a moderate sedation permit. It also states that the application must be accompanied by the fee provided in section 1021(q).

The form referenced in this subdivision would be cumbersome, unduly expensive and otherwise impractical to publish in the California Code of Regulations.

FORM MSP-1, APPLICATION FOR MODERATE SEDATION PERMIT

- Application fee box with notice that application fees are nonrefundable. The Board established a fee of \$524 for the application in section 1021(q). The application fee is non-refundable because the Board incurs staff hours and resources to review the application regardless of whether the application is approved or denied. These statements are necessary to provide notice to the applicants of these requirements.
- Instructions:
 - This application must be completed in its entirety or the application may be rejected as incomplete. Attach additional sheets if necessary.

This statement is necessary to provide notice to the applicant that the entirety of the application must be completed, or it will be rejected and to give direction on how to provide additional sheets of information to the Board to complete the application. This helps to ensure the applicant completes the application and is processed by staff expeditiously.

- Any material misrepresentation of any information on the application is grounds for denial or subsequent revocation of the permit.

This statement is necessary to provide notice to the applicant that any material misrepresentation of any information on the application is grounds for denial or subsequent revocation of the permit. (Bus. & Prof. Code, § 498 [“A board may revoke, suspend, or otherwise restrict a license on the ground that the licensee secured the license by fraud, deceit, or knowing misrepresentation of a material fact or by knowingly omitting to state a material fact.”].) This helps to ensure the applicant provides truthful information to the Board and provides notice to the applicants of these potential grounds for discipline.

- Under BPC sections 31 and 494.5, the State Board of Equalization (BOE) 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 or FTB certified list of top 500 tax delinquencies.

This statement is necessary to provide to an applicant that the application may be denied or permit suspended if the applicant fails to pay state tax obligations. This notice is required by BPC section 31 and is necessary to give proper notice to the applicants of

the possible consequences for failure to pay their state tax obligations as set forth in BPC sections 31 and 494.5.

- Item 1: The form requires the applicant to disclose a social security number, or individual taxpayer identification number as required by BPC section 30(a)(1).
- Items 2-9: Items 2-9 seek identifying information about the applicant, including birth date, legal name, mailing address (address of record, which may be a p.o. box under the provisions of BPC section 27(a)), primary practice location (physical address), email address (optional), telephone number, fax number (optional), and dental license number. These items of information are necessary to verify the applicant's identity and eligibility (licensee in good standing per BPC sections 1647.2, 1646.9) and ensure accuracy in the processing of the application and enable the Board to communicate more efficiently with the applicant.
- Item 10: The form asks the applicant whether they have successfully completed training in moderate sedation. The form then sets forth a definition for "training" on the form that sets forth each of the requirements for training as provided in BPC section 1647.3(c)(1)-(3). This question is necessary for the Board to verify that the applicant has met the requirements for moderate sedation training as set forth in BPC section 1647.3.

If the applicant answers "Yes", the form then requires the applicant to provide information regarding the completion of the training in moderate sedation. This information is necessary because the applicant is required under BPC section 1647.3(a) to produce "evidence" that he or she has successfully completed training in moderate sedation as required in BPC section 1647.3(c). The item directs the applicant to fill out a completed "Moderate Sedation Training" (MSP-2 (New 05/2021) with the application, (which is incorporated by reference at section 1043.1(d)(1)). This form provides the Board with a consistent method for verifying that the requirements of BPC section 1647.3 have been met. (See further explanation of necessity under MSP-2.)

- Item 11: The form asks the applicant to indicate whether they are applying for a pediatric endorsement to the moderate sedation permit. If the applicant answers yes, the applicant is notified that they must complete a separate application for a pediatric endorsement and meet the requirements in section 1043.8.1. These provisions help the applicant get clear instruction on how to apply for a pediatric endorsement to the moderate sedation permit and allows staff to easily track which applicants need to fulfill additional application requirements to obtain both the permit and the endorsement. The applicant may apply for the pediatric endorsement at the same time as the general anesthesia permit or at a later date. To provide notice and help ensure the applicants are fully informed about the requirements, this item also directs applicants to attached copies of BPC sections 1647.2 and 1647.3, and

section 1043.8.1 to explain the monitoring requirements to licensees. The applicant is required to check the box if they want the application for the pediatric endorsement and general anesthesia permit processed along with the moderate sedation permit application. This is necessary so staff can try to process both the permit and endorsement applications at the same time so both can be tracked contemporaneously for the convenience of the applicant.

- Item 12: The form asks the applicant to indicate whether the applicant is currently or has served in the U.S. Military as required by BPC section 114.5.
- Item 13: The form asks the applicant whether the applicant is requesting the expediting of the initial application for members of the U.S. Armed Forces who have been honorably discharged. This question is necessary to determine whether an applicant is applying for expedited review and processing per BPC section 115.4. The item asks the applicant to scan and attach a copy of a certificate of release from active duty (DD-214, which is the Department of Defense's standard report of separation for members of the U.S. Armed Forces that includes the necessary information for the Board to process such requests) or other evidence showing the date and type of discharge to receive expedited review. To date, the Board has not received any other type of evidence in lieu of the DD-214 but includes this possibility should it be submitted in the future to help ensure that applicants have other options for demonstrating they qualify. This information is necessary to determine whether the applicant has provided satisfactory evidence that meets the requirements for expedited processing per BPC 115.4.
- Item 14: The form asks the applicant whether they already hold a valid license or comparable authority to practice dentistry in another U.S. state or territory, and whether their spouse or domestic partner is an active duty member of the U.S. Armed Forces and is assigned to a duty station in California under official orders. The question is necessary to determine whether an applicant meets the requirements for expedited review and processing under BPC section 115.5. If the applicant answers yes, the form states that their application will receive an expedited review, consistent with BPC section 115.5.

The form asks the applicant to provide documentary evidence to support the request including: (1) a certificate of marriage or certified declaration/registration of domestic partnership filed with the Secretary of State or other documentary evidence of legal union with an active-duty member of the Armed Forces; (2) a copy of the applicant's current dental license in another state, district, or territory of the United States; and (3) a copy of the military orders establishing your spouse or partner's duty station in California. These documents are necessary to verify and ensure the applicant meets the statutory requirements for expediting the licensure process by requesting official government documents, licenses and military records to substantiate the information provided to the Board. To date, the Board has not received any other type of evidence in lieu of a certificate of marriage or certified declaration/registration of domestic

partnership but includes this possibility should it be submitted in the future to help ensure that applicants have other options for demonstrating they qualify.

- Item 15: The form asks the applicant to indicate whether (1) the applicant was admitted to the United States as a refugee pursuant to section 1157 of Title 8 of the United States Code; or (2) the applicant was granted asylum by the Secretary of Homeland Security or the Attorney General of the United States pursuant to section 1158 of Title 8 of the United States Code; or, (3) the applicant has a special immigrant visa and was granted a status pursuant to section 1244 of the Public Law 110-181, Public Law 109-163, or section 602(b) of Title VI of division F of Public Law 111-8 [relating to Iraqi and Afghan translators/interpreters of those who worked for or on behalf of the United States government]. These questions are necessary to determine whether the applicant qualifies for expediting of the initial application for refugees, asylees, and holders of special immigrant visas as required by BPC section 135.4(a).

If the applicant answers yes, they have to attach official documents commonly issued by federal agencies or the courts for the categories of individuals listed in section 135.4 as evidence of their status as a refugee, asylee, or special immigrant visa holder which includes:

- Form I-94, arrival/departure record, with an admission class code such as “re” (refugee) or “ay” (asylee) or other information designating the person a refugee or asylee.
- Special immigrant visa that includes the “si” or “sq.”
- A permanent resident card (Form I-551), commonly known as a “green card,” with a category designation indicating that the person was admitted as a refugee or asylee.
- An order from a court of competent jurisdiction or other documentary evidence that provides reasonable assurances to the Board that the applicant qualifies for expedited licensure per BPC section 135.4.

These documents are necessary to verify and ensure the applicant meets the statutory requirements for expediting the initial application process. Copies of official government documents will help ensure the accuracy of the information provided by the applicants to the Board.

- Statement before Item 16: The form states: Facilities and Equipment Requirements - All equipment must be maintained, tested, and inspected according to the manufacturers’ specifications. In an office where sedation services are to be provided pediatric patients, the required equipment, medication and resuscitative capabilities shall be appropriately sized for use on a pediatric population. This statement is necessary to educate the applicant regarding the legal requirements applicable to facilities and equipment standards for all offices where moderate sedation is conducted per section 1043.3.

- Item 16: The form asks the applicant whether the facility has an operating theater large enough to adequately accommodate the patient on a table or in an operating chair and permits an operating team consisting of at least three individuals to freely move about the patient. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(1).
- Item 17: The form asks whether the facility has an operating table or chair that permits the patient to be positioned so the operating team can maintain the airway, quickly alter patient position in an emergency, and provides a firm platform for the management of cardiopulmonary resuscitation. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(2).
- Item 18: The form asks whether the facility have a lighting system that is adequate to permit evaluation of the patient's skin and mucosal color and a backup lighting system which is battery powered and of sufficient intensity to permit completion of any operation underway at the time of general power failure. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(3).
- Item 19: The form asks whether the facility has suction equipment that permits aspiration of the oral and pharyngeal cavities and a back-up device that can operate at the time of a general power failure. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(4).
- Item 20: The form asks whether the facility has an oxygen delivery system with adequate fullface masks and appropriate connectors that is capable of allowing the administering of greater than 90% oxygen at a 10 liter/minute flow at least sixty minutes (650 liter "e" cylinder) to the patient under positive pressure, together with an adequate backup system that can operate at the time of general power failure. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(5).
- Item 21: The form asks whether the facility has a recovery area that has available oxygen, adequate lighting, suction and electrical outlets and states it can be the operating theater. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(6).
- Item 22: The form asks whether the facility has the listed ancillary equipment maintained in good operating condition. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(a)(7).

- Question before Item 23: The form asks whether the applicant maintains the records listed in items 23 through 26. This question is used to verify that the standards for records retention contained in section 1043.3(b) are met.
- Item 23: The form requires the applicant to provide information as to whether the applicant maintains an adequate medical history and physical evaluation records which are updated prior to each administration of moderate sedation which include 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 visual examination of the airway. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(b)(1).
- Item 24: The form asks the applicant whether the applicant maintains moderate sedation records which include a time-oriented record with preoperative, multiple intraoperative, and postoperative pulse oximetry (every 5 minutes intraoperatively), drugs [amounts administered and time administered], length of the procedure, any complications of sedation and a statement of the patient's condition at time of discharge. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(b)(2).
- Item 25: The form asks whether the applicant maintains records which include the category of the provider responsible for sedation oversight, the category of the provider delivering sedation, the category of the provider monitoring the patient during sedation, and whether the person supervising the sedation performed one or more of the procedures. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(b)(3).
- Item 26: The form asks whether the applicant maintains the written informed consent of the patient, or appropriate, patient's conservator, or the informed consent of a person authorized to give consent for the patient, or if the patient is a minor, his or her guardian pursuant to Business and Professions Code section 1682(e).. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(b)(4).
- Item 27: The form asks the applicant if they maintain the listed emergency drugs at all times in connection with the administration of moderate. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.3(c).
- Item 28: The form asks if the applicant is competent to treat all of the listed emergencies. This question is necessary so the Board can determine whether the applicant satisfies the requirements for acceptable knowledge of how to treat the listed emergencies as set forth in section 1043.4(c). This helps ensure that the

Board has some evidence prior to issuance of the permit that the applicant is aware of these issues and the need to be knowledgeable in these areas to practice competently and safely for the protection of the public.

- Item 29: The form asks the applicant whether the dental office personnel who are directly involved with the care of patients undergoing moderate sedation are certified in basic cardiac life support (CPR). This is necessary because it is unprofessional conduct for any dentist with patients who are undergoing moderate sedation to have dental office personnel directly involved with the care of those patients who are not certified in CPR and recertified biennially. (Bus. & Prof. Code, § 1682, subd. (d).) This question is necessary to determine prior to issuance of the permit, and for the protection of the public, whether this standard is met.
- Item 30: The form asks the applicant to provide the addresses of all locations where the applicant will administer or order the administration of moderate sedation. If the applicant is a physician and surgeon, they are directed to provide the names of any hospitals where they have membership on the medical staff. It states that all offices must meet the standards set forth in the Board's regulations in Article 5 (commencing with section 1043) of Title 16 of the California Code of Regulations. This question is necessary so the Board can identify the locations where administration will occur for the purposes of future investigation and inspection and verify that the legal requirements set forth in sections 1043.3 and 1043.4 are met at each location.
- Certification under penalty of perjury: The form requires the applicant acknowledge and certify under penalty of perjury under the laws of the State of California, that the information including any attached statements is true and correct by providing a signature and date. The Board relies upon applicants' self-reported information in evaluating applications. This requirement helps ensure that the representations on the form are accurate and made in good faith.
- Information Collection and Access section: The form includes the required notices and disclosures to the applicant for the Board's collection of personal information in compliance with Civil Code section 1798.17.

New subdivision (d)(1)

The Board proposes to add this subdivision to enable the applicant to comply with BPC section 1647.3(a). BPC section 1647.3(a) provides that an applicant must "produce evidence showing that he or she has successfully completed training in moderate sedation that meets the requirements of subdivision (c)." (Bus. & Prof. Code, § 1647.3, subd. (a).) Section 1647.3(c) provides that training must: (1) include at least 60 hours of instruction; (2) satisfactory completion of at least 20 cases of administration of moderate sedation for a variety of dental procedures; and (3) compliance with the requirements of

the Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students of the American Dental Association, including, but not limited to, certification of competence in rescuing patients from a deeper level of sedation than intended, and managing the airway, intravascular or intraosseous access, and reversal medications.” (Bus. & Prof. Code, § 1647.3, subd. (c)(1)-(3).)

Subdivision (d)(1) would require applicants to submit a completed form incorporated by reference, Certification of Moderate Sedation Training” Form MSP-2 (New 05/2021) The certification training form will enable staff to verify completion of the required training and will be required to accompany the Form MSP-1.

The form referenced in this subdivision would be cumbersome, unduly expensive, and otherwise impractical to publish in the California Code of Regulations. The form will be available on the Board’s website and from the Board upon request.

FORM MSP-2, CERTIFICATION OF MODERATE SEDATION TRAINING

- Notice to Applicants:
 - This completed form must be submitted to the Dental Board of California (Board) with your application for a moderate sedation permit as required by Title 16, California Code of Regulations (CCR) section 1043.1 or your application may be rejected as incomplete. The information requested on this form is mandatory pursuant to BPC section 1647.3 and Title 16 CCR section 1043.1. The information provided will be used to determine qualification for a moderate sedation permit.

This statement is necessary to provide notice to the applicant that MSP-2 must be submitted with Form MSP-1 or the application for a moderate sedation permit may be rejected as incomplete. The form instructs the applicant that the information requested is mandatory. This helps to ensure the applicant completes the application and is processed by staff expeditiously. This information is also required to be provided to affected individuals in accordance with Civil Code section 1798.17, subdivisions (a), (c), (d), and (e), which require the Board to include with this form notice of the following: the name of the agency requesting the information, the authority (statute or regulation) which authorizes maintenance of the information, whether submission of the information is mandatory, and the consequences of not providing the requested information.

- The information may be provided to other governmental agencies, or in response to a court order, subpoena, or public records request. You have a right of access to records containing personal information unless the records are exempted from disclosure. Individuals may obtain information regarding the location of their records by contacting the Board’s Executive Officer at 2005 Evergreen Street, Suite 1550, Sacramento, CA 95815,

Executive Officer, 916-263-2300.

This statement is necessary to comply with the Section 1798.17 of the Civil Code which requires the Board to notify the applicant that the information they provide on this form of the uses of their personal information, as well as provide other disclosures in accordance with Civil Code section 1798.17, subdivisions (b), (f), (g) and (h).

- Instructions to applicants and educational institution: The form instructs applicants they must complete questions 1-3 and educational institutions must complete question 4. This is necessary to communicate to the applicant that they must seek information from their educational institution in order to complete the form.
- Items 1-3: Items 1-3 seek identifying information about the applicant, including legal name, license number, and name of school/educational institution. These items of information are necessary to verify the applicant's identity and to ensure accuracy in the processing of the certification and enable the Board to communicate more efficiently with the applicant.
- Item 4: For ease of comprehension in filling out the certification and to increase likelihood of accuracy in the process, the form includes an introduction before the question that notifies the educational institution of the following:

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.

The form directs the educational institution to indicate that the permit applicant has successfully completed the institution's educational program in moderate sedation that includes a list of all of the training requirements for the moderate sedation permit listed in BPC section 1647.3, subdivision (c)(1)-(3). This provides a simple and convenient way for the applicant to show "evidence", as required by BPC section 1647.3, that they have met the training requirements for the moderate sedation permit. Also, this form provides educational institutions with the information needed to assist their students in completing the requirements for permit issuance.

- Certification: The certification would require an official from the education institution to sign, date, print their name and title, and certify under penalty of perjury under the laws of the State of California, that the information provided on the certification is true and correct, confirm that according to the institution's records the applicant

satisfactorily completed the above referenced training at the education institution, the type of program that applicant was enrolled in, the beginning and end date that the applicant was enrolled in the program, and an education program seal. This helps ensure that the information the educational institution provides is truthful and accurate, that the Board meets its obligations to obtain evidence of training for the issuance of this permit in compliance with BPC section 1647.3, and to help ensure minimum standards are met for the protection of the public. In addition, the provision of the personal information of the educational institution, including the school official's name, title, and telephone number would allow the Board to confirm and investigate the accuracy of the representations in the certification and authenticate the information provided.

- Seal: The form asks the educational institution to use their seal to ensure that it is the educational institution providing the information. This is necessary so the Board knows that their information comes from the educational institution and is accurate.

New subdivision (d)(2)

The Board proposes to add subdivision (d)(2) to provide that the fee for the moderate sedation permit application is set forth in section 1021. This subdivision is necessary to cite where the fee may be found for ease of reference for the reader and ensure that the applicant submits the applicable fee as well as meeting the other requirements for this section.

Repeal of existing (d)

The Board will strike former subdivision (d) because 16 CCR 1061 has been repealed, effective June 21, 2021.

New subdivision (e)

The Board proposes to add subdivision (e) to inform applicants of the process for applying for a pediatric endorsement to a moderate sedation permit and receiving Board approval. This is necessary to help ensure that the applicants meet the minimum standards for the permit as prescribed in Section 1043.8.1 and comply with those requirements to obtain Board approval. Newly added section 1043.8.1, to which this subdivision refers, sets forth the information the applicant must submit to obtain the pediatric endorsement for patients under 13 years of age. (Newly added section 1043.8.1, subd. (b).)

Note:

The Board proposes to add BPC sections 1646.1 and 1647.2 to the Reference section. This is necessary because this regulation implements, interprets or makes these statutes specific.

Section 1043.2. Composition of Onsite Inspection and Evaluation Teams.

Subdivision (a)

Existing regulation requires an onsite evaluation team to consist of two or more persons for each evaluation. The Board proposes to amend this subdivision to limit the requirement for two or more evaluators. The amendment provides that the team will consist of two or more persons chosen and approved by the board for the first evaluation, or in the event that an applicant has failed an evaluation. For each subsequent evaluation only one evaluator shall be required.

Board staff has faced a challenge in coordinating the onsite inspection and evaluations as they must be conducted by two subject matter experts (SME) who are practicing dentists and physicians in California who are contracted by the Board as evaluators. In a review of evaluations conducted in fiscal years 2017/2018, 2018/2019, and 2019/2020 the Board found cases in which the two evaluators did not agree on the result in less than 1% of evaluations completed. Therefore, Board staff found it was not necessary to have two evaluators in every case. Board staff presented a proposal to the Board on May 18, 2018, to change the number of evaluators required for the onsite inspections and evaluations which they voted to accept and direct Board staff to prepare proposed regulatory language to initiate a rulemaking.

Subdivision (b)

The Board proposes to amend this subdivision to replace “subdivision” with “subsection,” and capitalize “section” and “code.” These amendments are necessary for consistency throughout the regulations.

The Board proposes to replace “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board adds “deep sedation” to subdivision (b). This is necessary because the SME appointed to conduct the onsite inspection and evaluation should be familiar with the levels of sedation and anesthesia as defined in BPC sections 1646(a) and (b), and 1647.1(a) that may be administered by the applicant to a dental patient for the purposes of completing the onsite inspection and evaluation. This is necessary to help ensure that the Board’s reviewers are qualified to review all of the anesthesia and

sedation methods administered by the subject of the inspection and can render an expert opinion on compliance.

Subdivision (c)

The Board proposes to replace the term ‘conscious’ with ‘moderate’ because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term ‘conscious sedation’ with ‘moderate sedation,’ meaning ‘a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.’ (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board proposes to add ‘deep sedation’ because the SME appointed to conduct the onsite inspection and evaluation should be familiar with the levels of sedation and anesthesia as defined in BPC sections 1646(a) and (b), and 1647.1(a) that may be administered by the applicant to a dental patient for the purposes of completing the onsite inspection and evaluation. This is necessary to help ensure that the Board’s reviewers are qualified to review all of the anesthesia and sedation methods administered by the subject of the inspection and can render an expert opinion on compliance.

New subdivision (d)

The Board proposes to add subdivision (d) to require evaluators to possess a current, active, and unrestricted license from the Board or, the Medical Board of California for applicants qualifying under Section 1646.9 of the Code. For purposes of this section, ‘unrestricted’ means not subject to any disciplinary action such as revocation, suspension, or probation.

This subdivision is necessary because BPC section 1646.9(c) requires that at ‘least one of the persons evaluating the procedures utilized by the physician and surgeon must be a licensed physician and surgeon expert in outpatient deep sedation or general anesthesia who has been authorized or retained under contract by the board for this purpose.’ Subdivision (d) makes these requirements specific by further providing that the evaluator must possess a current, active and unrestricted license from the Board, or the Medical Board of California. This requirement is necessary because the possession of a current, active, and unrestricted license means that the evaluator has met competency requirements and the license is not restricted in any way that may be the result of disciplinary action. This provides assurances to the Board that the evaluator has a current knowledge and experience base, is minimally competent to perform their duties, and is not limited in their competency or restricted in any manner from discharging those duties. This helps the Board ensure only a competent, experienced, and credible pool of expert evaluators are used for an onsite

inspection team. The Board adds a definition for the meaning of discipline, consistent with the types of actions the Board is authorized to take under the Act. This is provided for ease of comprehension and to provide notice to those affected by these regulations of the standards by which an evaluation team will be selected.

Re-numbering of former subdivision (d)

The Board proposes to re-number this subdivision from (d) to (e) based on the adoption of a new subdivision (d).

Note:

The Board proposes to add BPC section 1646.9 to the Reference section. This is necessary because this regulation implements, interprets, or makes this statute specific.

Section 1043.3. Onsite Inspections.

Preface

The Board proposes to add “deep sedation” to the preface of the regulation. This amendment is necessary because this regulation governs onsite inspections, and SB 501 authorizes the Board to require onsite inspections of a licensee before the issuance or renewal of a general anesthesia/deep sedation permit. Therefore, it is necessary to amend the regulation to include this category of sedation. (Bus. & Prof. Code, § 1646.4, subd. (a).)

Subdivisions (a)(7)(A), (a)(7)(B), (a)(7)(E), (a)(7)(G), (c)(4), (c)(5), (c)(9), & (c)(11)

The Board proposes to replace “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

Subdivision (a)

The Board proposes to add “All equipment should be maintained, tested and inspected according to the manufacturers’ specifications. In an office where anesthesia 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,” to this subdivision. This amendment is necessary because the size and age of patients

vary and equipment to accommodate patients treated must be available in order to ensure that the appropriate equipment is used to ensure the health and safety of the patients served. Also, in the Board's experience, ensuring the equipment is maintained, tested, and inspected according to the manufacturers' specifications is the minimum standard needed to ensure that the equipment used is operated safely for the protection of the public.

The Board proposes to delete "and shall be maintained in good operating condition." This is necessary because this statement is no longer needed because the addition at the beginning of the subdivision addresses the maintenance requirement.

Subdivision (a)(7)(K)(i)-(iii)

The capnograph is a device used to monitor a patient during the anesthesia or sedation procedure in order to prevent adverse events. The Board proposes to delete "A capnograph and temperature measuring device are required for the intubated patient receiving general anesthesia. (This equipment is not required for conscious sedation.)" and add "Patients receiving moderate sedation, deep sedation, or general anesthesia shall have ventilation continuously monitored during the procedure by two of the following three methods:" and then list the requirements set forth in BPC section 1682(c).

These amendments are necessary because BPC section 1682(c) provides that it is unprofessional conduct for a dentist with patients who are undergoing deep sedation, general anesthesia, or moderate sedation to fail to have these patients continuously monitored during a dental procedure with a pulse oximeter or similar or superior monitoring equipment and ventilation continuously monitored using at least two of the three following methods: (1) auscultation of breath sounds using a precordial stethoscope; (2) monitoring for the presence of exhaled carbon dioxide with capnography; (3) verbal communication with a patient under moderate sedation. This method shall not be used for a patient under deep sedation or general anesthesia. The Board proposes to place these methods in regulation, so dentists are aware of the affirmative requirement that they monitor patients with at least two of these methods. This helps keep licensees informed about these requirements in advance of any issues being identified that may subject them to discipline by the Board while ensuring minimum standards are being implemented for the protection of the public.

The Board deletes the first sentence of subdivision (a)(7)(K) because the capnograph and temperature device should be used as a monitoring device for all patients who are administered deep sedation, general anesthesia, and moderate sedation consistent with the amendments to the Act under SB 501. The existing language does not address those amendments and instead uses what will become outdated references to conscious sedation instead of moderate sedation. Therefore, the language is being deleted and replaced with revised text for the reasons set forth above. In addition, updated language that clarifies that the verbal communication method "shall not be

used for a patient under deep sedation or general anesthesia" has been added. This requirement is necessary because the verbal communication method is not appropriate or effective to monitor a patient's ventilation due to the high level of sedation for the patient in the administration of deep sedation or general anesthesia. A patient who has been administered deep sedation or general anesthesia may not be easily aroused and may require positive pressure ventilation.

Subdivision (b)(1)

The Board proposes to delete "general anesthesia or conscious sedation" and replace it with "moderate sedation, deep sedation, or general anesthesia," and add "deep sedation" to the second sentence of the regulation. These amendments are necessary because SB 501 replaces "conscious" with "moderate" and adds the new category of "deep sedation." (Bus. & Prof. Code, § 1646, 1646.1, & 1647.1.) BPC section 1646.3 requires dentists administering deep sedation or general anesthesia to maintain medical history, physical evaluation, deep sedation, and general anesthesia records as required by board regulations. BPC section 1647.6 requires dentists administering moderate sedation to maintain records of the physical evaluation, medical history, and moderate sedation procedures used as required by board regulations. This regulation makes these statutory requirements specific by prescribing the types of records dentists must maintain.

Currently, this subdivision requires recording in the medical records of "auscultation of the heart and lungs as medically required." The Board proposes to delete "as medically required" from the second sentence of the subdivision. Auscultation is the process of listening to body sounds, usually with a stethoscope. This amendment is necessary because, in the Board's opinion, the auscultation of the heart and lungs should be completed before deep sedation or general anesthesia is administered to dental patients in every case to help check the circulatory system and airways of the patient before administration of anesthesia or sedation. Further, the Board believes that by the permit holder performing the auscultation of the heart and lungs before each administration of deep sedation, or general anesthesia that this can help to detect abnormalities, and prevent adverse events for the dental patient that could occur if these abnormalities were not detected prior to administration.

Subdivision (b)(2)

The Board proposes to delete "General anesthesia and/or conscious sedation" and add "Moderate sedation, deep sedation, and/or general anesthesia." These amendments are necessary because SB 501 replaces "conscious" with "moderate" and adds the new category of "deep sedation." (Bus. & Prof. Code, § 1646, 1646.1, & 1647.1.) BPC section 1646.3 requires dentists administering deep sedation or general anesthesia to maintain medical history, physical evaluation, deep sedation, and general anesthesia records as required by board regulations. BPC section 1647.6 requires dentists administering moderate sedation to maintain records of the physical evaluation,

medical history, and moderate sedation procedures used as required by board regulations. This regulation makes these statutory requirements specific by prescribing the types of records dentists must maintain.

The Board proposes to delete “interoperative” and replace it with “intraoperative.” This amendment is necessary because using “interoperative” is a typographical error.

Newly added subdivision (b)(3)

The Board proposes to add a new subdivision (b)(3) to state “Records shall include the category of the provider responsible for sedation oversight, the category of the provider delivering sedation, the category of the provider monitoring the patient during sedation, and whether the person supervising the sedation performed one or more of the procedures. Categories of providers are defined in Section 1680(z)(3) of the Code.”

This amendment is necessary in order for the permit holder to help ensure the permit holder provides a complete and accurate report to the Board regarding adverse events as specified in BPC section 1680(z) and has accurate documentation of those primarily involved in patient sedation or anesthesia administration and care. BPC section 1680(z) makes it unprofessional conduct for a licensee to fail to report in writing to the Board within 7 days any of the following:

- (A) the death of the licensee’s patient during the performance of any dental procedure;
- (B) the discovery of the death of a patient whose death is related to a dental procedure performed by the licensee; or,
- (C) the removal to a hospital or emergency center for medical treatment of any patient to whom oral conscious sedation, conscious sedation, or general anesthesia was administered.

Subdivision (z)(2) of BPC section 1680 requires the licensee to report, among other things, the category of the provider responsible for sedation oversight; the category of the provider delivering sedation; the category of the provider monitoring the patient during sedation; and, whether the person supervising the sedation performed one or more of the procedures when any of the foregoing adverse events happen. This requirement is necessary to ensure that this critical information is retained in the permit holder’s records in every case so it is available for inspection, to confirm minimum standards regarding administration are met, and ensure information is communicated accurately to the Board in the event of an adverse event. In addition, to ensure accurate and complete documentation and reporting of information, the Board is adding a provision that defines what a category of provider means, as follows: “Categories of providers are defined in Section 1680(z)(3) of the Code.”

Re-numbered subdivision (b)(4)

The Board re-numbers this subdivision from (b)(3) to (b)(4). This is necessary because the Board proposes a new subdivision (b)(3).

The Board proposes to add after “patient,” or, as appropriate, patient’s conservator, or the informed consent of a person authorized to give such consent for the patient,” and “pursuant to Section 1682(e) of the Code.” The Board amends the categories of person who can provide written consent to more broadly reflect the legal representatives who could be providing consent on behalf of the patient.

The Board adds a “patient’s conservator” because conservators may be appointed for a person who is unable to provide properly for his or her personal needs for physical health, food, clothing, or shelter. (Prob. Code, § 1801, subd. (a).) The Board adds a catch-all category for other persons “authorized to give such consent for the patient” to refer to other persons who are authorized to make healthcare decisions, such as those possessing an advance health care directive. (Prob. Code, § 4701.)

The Boards adds a cross-reference to BPC section 1682(e) which provides it is unprofessional conduct for “[a]ny dentist to fail to obtain the written informed consent of a patient prior to administering moderate sedation, deep sedation, or general anesthesia. In the case of a minor, the consent shall be obtained from the child’s parent or guardian.” This ensures the regulation is interpreted consistently with the statute governing the same subject matter.

Section 1043.4. Evaluation Standards.

Subdivision (a)

The Board proposes to add “deep sedation, “or sedated,” and “or sedation” to this subdivision. This amendment is necessary because SB 501 adds a new category of “deep sedation.” This regulation establishes evaluation standards for purposes of BPC sections 1646.4 which provides that “[p]rior to the issuance or renewal of a permit for the use of deep sedation or general anesthesia, the board may, at its discretion, require an onsite inspection and evaluation of the licentiate and the facility, equipment, personnel, and procedures utilized by the licentiate.” Because this statute applies to both deep sedation and general anesthesia, it is necessary to add “deep sedation” to subdivision (a).

The Board proposes to capitalize “section” and “Code” for consistency throughout the regulations.

Subdivision (b)

The Board proposes to replace “conscious” with “moderate” because the Act, as amended by SB 501, repeals existing provisions relating to the use of conscious

sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board proposes to capitalize “section” and “code” for consistency throughout the regulations.

Section 1043.5. Cancellation of an Onsite Inspection and Evaluation.

Subdivision (a)

The Board proposes to replace “conscious” with “moderate” because the Act, as amended by SB 501, repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

Subdivision (c)

The Board proposes to capitalize “code” for consistency throughout the regulations.

Section 1043.6. Grading of Inspection and Evaluation.

Newly added subdivision (b)

The Board proposes to add a new subdivision (b) to establish the types of grades an evaluation team must recommend.

Existing regulation establishes that a grade shall be determined by the board but does not specify how that grade is titled or what it means. This amendment is necessary to establish the types of grades a permit holder may receive from the Board based on the recommendation of the evaluators. This amendment establishes simple, fair and consistent review terms, a description of those terms and a grading system by which an evaluator will assess a permittee and make recommendations to the Board after an onsite inspection of an office in which general anesthesia, deep sedation or moderate sedation is performed. This will provide notice to the permit holder and the public regarding whether the licensee passed or failed the evaluation and under what conditions a permit would be issued following an inspection.

Newly added subdivision (b)(1)

The Board proposes to add “Passed Evaluation. Permit holder met all required components of the onsite inspection and evaluation as provided in sections 1043.3 and 1043.4; or” as a new subdivision (b)(1).

This amendment is necessary to establish the requirements to receive a pass on an evaluation and provide notice of that standard to the regulated community. A permit holder passes when they have demonstrated competency in the requirements of sections 1043.3(a) and 1043.4 in the administration of deep sedation, general anesthesia, or moderate sedation. As a result, they will not be required to complete another evaluation for at least five years for general anesthesia or deep sedation permitholders pursuant to BPC sections 1646.4(a) and 1646.9(d), and at least six years for moderate sedation permitholders per BPC section 1647.7(a).

Newly added subdivision (b)(2)

The Board proposes to add “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 a permit is issued; or” as a new subdivision (b)(2).

This amendment is necessary because the permit holder is required to pass the onsite inspection pursuant to BPC section 1646.4(a), section 1646.9(c), and section 1647.7(a) which includes the demonstration of deep sedation, general anesthesia, or moderate sedation. The SME will evaluate the permit holder and make a recommendation to the Board whether the permit holder met the requirements of the section. If a permit holder demonstrates competency in the administration of deep sedation, general anesthesia, or moderate sedation but needs to make corrections to equipment, documentation of controlled substances, or recordkeeping, the Board will give the permit holder the opportunity to make those corrections. This grading option is necessary because it allows the applicant to meet the statutory requirements listed above, correct typically minor deficiencies, and not fail the entire evaluation. Corrections are typically made by, for example, purchasing the missing equipment or making edits to the sedation record template. Permit holders will be given 15 days to correct deficiencies from when they receive notice. In the Board’s experience, this is sufficient time for a permit holder to address the deficiency, e.g., provide proof of purchase or a corrected document. The Board considers these types of deficiencies easily remediated and would not affect competency and the quality of patient care. As a result, allowing deep sedation, general anesthesia or moderate sedation to continue while in this “conditional approval” status would not generally jeopardize patient health and safety. This interim grade and process therefore is needed to allow the permitholder to meet the standard while

pending final review and possible passage of the evaluation by the Board. Board staff have determined that 15 days is a sufficient number of days for the permit holder to make corrections to forms, acquire or purchase missing or expired items and submit proof to the Board for review. The recommendation of a conditional pass would be made by the subject matter expert who is an expert in the delivery of anesthesia and sedation services. The subject matter expert would determine if the missing equipment or documentation would pose an immediate risk to the public or create an issue for patients to access to care.

Newly added subdivision (b)(3)

The Board proposes to add “Failed Simulated Emergency. Permit holder failed one or more simulated emergency scenario(s) required for the on-site inspection and evaluation; or” as a new subdivision (b)(3).

This amendment is necessary because the onsite inspection and evaluation verifies a permit holder is able to demonstrate competency in the administration of deep sedation, general anesthesia, or moderate sedation, maintains the proper equipment and drugs on site, and can demonstrate with staff that they are able to demonstrate competency in 13 simulated emergency scenarios in order to prevent adverse events when administering deep sedation, general anesthesia or moderate sedation. The SME will evaluate the permit holder and make a recommendation to the Board whether they have met the requirements of the section but there can be degrees of failure that are not captured by a simple “fail” description and grading system. This amendment is necessary to accurately convey how the Board will assess when a failure of occurs in one area of the review, but not the entire evaluation necessarily. This “failed simulated emergency” grade is necessary because if a permit holder has demonstrated competency in the administration of deep sedation, general anesthesia, or moderate sedation and maintains the proper equipment and drugs, but has failed to demonstrate competency in one or more simulated emergency scenario, the Board may give the permit holder per subsection (d) of this section the opportunity to retake the simulated emergencies portion of the evaluation and not fail the entire evaluation.

Newly added subdivision (b)(4)

The Board proposes to add “Failed Evaluation. Permit holder failed due to multiple deficient components required for the on-site inspection and evaluation or failed to comply with the conditions for issuance of a conditional approval as provided in subsection (b)(2) of this section” as a new subdivision (b)(4).

This amendment is necessary to provide notice of how the Board will issue a failing grade and under what conditions the Board will consider an applicant to have failed an evaluation. The permit holder is required to meet the requirements of sections 1043.3(a) and 1043.4 which includes the demonstration of deep sedation, general anesthesia, or moderate sedation. The SME will evaluate the permit holder and make a

recommendation to the Board. If the SME finds the permit holder has demonstrated they are not competent in multiple components involving the administration of deep sedation, general anesthesia, or moderate sedation, for example that the permit holder is missing multiple drugs, or equipment, or has not complied with the conditions for issuance of a conditional approval referenced in subsection (b)(2) of this section, they can recommend a failure to the Board. Upon review, the Board may fail the permit holder and require that they complete a second onsite inspection and evaluation or be automatically suspended per subsection (c). These standards are necessary to ensure that the permit holders meet the minimum standards for competence in administration of sedation or anesthesia for the protection of the public. As a result, an inability to pass an evaluation or correct deficiencies noted in the evaluation (that resulted in a conditional approval) presents a risk of harm to the public and for which a failing grade on the evaluation is warranted.

Re-numbered subdivision (c)

The Board proposes to re-number former subdivision (b) to subdivision (c). This is necessary based on the establishment of a new subdivision (b).

The Board proposes to delete:

- “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,;” and
- “Upon receipt of the appeal request and an additional evaluation fee, the board will schedule an independent reevaluation of the appellant.”

The Board proposes to add:

“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 if a third onsite inspection and evaluation is granted or prior to the issuance of a new permit.”

The Board eliminates the appeal process because the appeal is not necessary based on the amendments to the subdivision. Current language states that the permit holder may appeal to request a reevaluation. By removing the appeal language this will allow the Board to work with the permit holder to schedule a reevaluation in a timely manner to demonstrate competency in the administration of deep sedation, general anesthesia, and moderate sedation. In the Board’s experience, the appeal process only added further delay and typically resulted in reevaluation to resolve the issues raised by the prior evaluation. Further, the licensee could contest this decision under current law if they ultimately cannot successfully pass an evaluation after two or more opportunities

for reevaluation after service of any notice by the Board purporting to discipline any license or permit for these failures (see Bus. & Prof. Code, § 1646.7, 1647.9, and Gov. Code, §§ 11500 et seq.)

The new language establishes a remedial education requirement before an applicant can be retested. This will give the applicant a greater chance of success before a third reevaluation or being issued a new permit by taking additional courses in the areas in which they did not demonstrate competency. The helps ensure the Board meets its goal is to ensure qualified, competent individuals are permitted to administer deep sedation, general anesthesia, and moderate sedation.

The Board proposes to capitalize “pursuant” and add a citation to BPC section 1646.9(d). This amendment is necessary based on the deletion of “However” and for clarity because BPC section 1646.9 because this section provides that “[t]he permit of a physician and surgeon who has failed an onsite inspection and evaluation shall be automatically suspended 30 days after the date on which the board notifies the physician and surgeon of the failure unless within that time period the physician and surgeon has retaken and passed an onsite inspection and evaluation.” As subdivision (c) of the regulation addresses suspension of permits after a failed inspection and evaluation, it is necessary to cite the statute that addresses inspections of physicians and surgeons seeking deep sedation or general anesthesia permits. (Bus. & Prof. Code, § 1646.9, subds. (a) and (d).)

The Board proposes to capitalize “section” and “code” for consistency throughout the regulations.

Re-numbered subdivision (d)

The Board proposes to re-number former subdivision (c) to subdivision (d). This is necessary based on the establishment of a new subdivision (b).

Section 1043.7. Manner of Giving Notice of Evaluation.

The Board proposes to replace “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

Section 1043.8. Renewal.

The Board proposes to replace “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board proposes to “add continuing competency” because section 1017.1 now includes continued competency requirements at section 1017.1(a) and (b).

The Board proposes to add citations to section 1017.1 and 1021 of the regulations. These amendments are necessary for clarity. They convey to the reader where educational and continuing competency requirements and applicable fee may be found.

Section 1043.8.1. Application for Pediatric Endorsement; Documentation of 20 General Anesthesia or Moderate Sedation Cases; Additional Requirements for Applicant Investigation; Legible Copies of Records.

Subdivision (a) and New Title

The Board proposes to add this subdivision requiring submission of a completed application to the Board for a pediatric endorsement that includes a list of items, and a title to establish the application requirements for the pediatric endorsements to the general anesthesia permit under BPC section 1646.2(c) and 1646.9. This subdivision is necessary to inform applicants for the pediatric endorsements what must be submitted to satisfy the requirements in section 1646.2(c) and 1646.9(e), provide a complete list of requirements in one convenient location for applicants, and help ensure the Board only receives completed applications for processing the pediatric endorsement. The title is being added for ease of reference and to help guide affected readers to the location of these provisions for better organization of this Article.

Subdivision (a)(1)

The Board proposes to add this subdivision to obtain the name of the applicant, mailing address or address of record, physical address, dental or medical license number, and applicant’s general anesthesia permit number, if any. These items of information are necessary to verify the applicant’s identity and eligibility (meets the requirements in BPC section 1646.1, 1646.9) and ensure accuracy in the processing of the application and enable the Board to communicate more efficiently with the applicant.

Subdivision (a)(2)

The Board proposes to add this subdivision to require the applicant to submit a certificate of completion or other documentary evidence showing completion of a residency training program as required by section 1646.2 for a dental licensee or Section 1646.9 for a physician and surgeon licensee.

This subdivision is necessary to ensure and verify that dental applicants meet the Act's statutory requirements for a pediatric endorsement because section 1646.2 requires an applicant to show they completed a Commission on Dental Accreditation (CODA)-accredited or equivalent residency training program that provides competency in the administration of deep sedation and general anesthesia on pediatric patients. (Bus. & Prof. Code, § 1646.2, subd. (c)(1).) Section 1646.9 requires a physician and surgeon applicant to successfully complete a postgraduate residency training program in anesthesiology that is recognized by the American Council on Graduate Medical Education, as set forth in section 2079. As a result, this requirement is necessary to ensure and verify that a physician and surgeon applicants meet the Act's statutory requirements for issuance of a pediatric endorsement. The Board has received other evidence of completion in the past, such as letters from a program, which it would also accept in lieu of a certificate of completion. Therefore, adding "or other documentary evidence" allows flexibility for the applicants in meeting this requirement.

Subdivision (a)(3)

The Board proposes to add this subdivision to provide that an applicant must submit a completed "Documentation of Deep Sedation and General Anesthesia or Moderate Sedation Cases for Pediatric Endorsement" Form PE-1 NEW (05/2021), which is incorporated by reference, in order to obtain a pediatric endorsement. This form is necessary to provide a convenient way for applicants to document compliance with the requirements in BPC sections 1646.2(c)(2) and 1646.9 for documenting 20 cases of deep sedation or general anesthesia.

The form referenced in this subdivision would be cumbersome, unduly expensive, and otherwise impractical to publish in the California Code of Regulations. The form will be available on the Board's website and from the Board upon request.

FORM PE-1, DOCUMENTATION OF DEEP SEDATION AND GENERAL ANESTHESIA OR MODERATE SEDATION CASES FOR PEDIATRIC ENDORSEMENT

- Page One, instructions and notices:
 - Instructions:

The form directs the applicant to complete the application if they are applying for either a general anesthesia or moderate sedation permit that includes a pediatric endorsement as or renewing a general anesthesia permit that includes a pediatric endorsement as provided in section 1017.1 or the application may be rejected as incomplete. The form advises applicants that the requirements for a completed initial application for a pediatric endorsement to a general anesthesia permit or a moderate sedation permit may be found in 16 CCR section 1043.1.8. To help ensure the applicant provides complete information and for ease of use, the Board instructs the applicant that additional sheets may be attached to the form as necessary.

This instruction is necessary to ensure the applicant fills out the form in its entirety, understands that the questions are mandatory and where the authority for the information may be found in law and regulation, and helps ensure expeditious processing by the Board. These disclosures also comply with the notice requirements of subdivisions (a), and (e) of Civil Code section 1798.17.

The form advises that any material misrepresentation of any information on this form is grounds for denial or subsequent revocation of the permit. This statement is necessary to provide notice to the applicant that any material misrepresentation of any information on the application is grounds for denial or subsequent revocation of the permit. (Bus. & Prof. Code, § 498 [“A board may revoke, suspend, or otherwise restrict a license on the ground that the licensee secured the license by fraud, deceit, or knowing misrepresentation of a material fact or by knowingly omitting to state a material fact.”].) This helps to ensure the applicant provides truthful and accurate information to the Board.

The second paragraph of the introduction includes the additional required notices and advisements consistent with the requirements of Civil Code section 1798.17. The first sentence states that the information requested on the form is mandatory pursuant to BPC sections 1646.2 and 1647.3 and Title 16 CCR section 1043.1.8

This advisement complies with subdivision (c) and (d) of Civil Code section 1798.17 and is necessary to place applicants on notice of the legal requirements applicable to applying for a general anesthesia permit or a moderate sedation permit. This assists applicants in marshalling the necessary information for the application.

The form advises that the information may be provided to other governmental agencies, or in response to a court order, subpoena, or public records request and the applicant has a right of access to records containing personal information unless the records are exempted from disclosure. The form advises that individuals may obtain information regarding the location of their records by contacting the Board’s Executive Officer at 2005 Evergreen Street, Suite 1550, Sacramento, CA 92815, Executive Officer, 916-263-2300.

This statement is necessary to comply with the Section 1798.17 of the Civil Code which requires the Board to notify the applicant that the information they provide on this form of the uses of their personal information, as well as provide other disclosures in accordance with Civil Code section 1798.17, subdivisions (b), (f), (g) and (h).

- Notices:

The Board provides notices to applicants for general anesthesia or moderate sedation permits regarding the legal requirements applicable to the permit applications. For general anesthesia permit applicants seeking a pediatric endorsement or renewal of endorsement, the notice identifies the statutory requirements for patient monitoring and staffing in BPC section 1646.1 and quotes the provisions relating to documentation of 20 cases of deep sedation or general anesthesia to patients under 7 years of age in BPC section 1646.2. For moderate sedation permit applicants seeking a pediatric endorsement, the notice identifies the statutory requirements for patient monitoring and staffing in BPC section 1647.2, and quotes the provisions relating to documentation of 20 cases of moderate sedation in BPC section 1647.3 (including the experience pathways that qualify an applicant for a permit). These notices are necessary to place applicants on notice of the legal requirements applicable to applying for or renewing a general anesthesia permit or a moderate sedation permit. This assists applicants in marshalling the necessary information for the documentation needed to complete their application.

- Items 1 & 2:

These items request the applicant's full legal name and medical or dental license number. These items of information are necessary to verify the applicant's identity and eligibility and ensure accuracy in the processing of the application and enable the Board to communicate more efficiently with the applicant.

- Item 3:

This item requires the applicant to state whether they are applying for a pediatric endorsement to administer or order the administration of deep sedation or general anesthesia to pediatric patients under the age of 7, or whether the applicant is applying for a pediatric endorsement to administer or order the administration or moderate sedation to pediatric patients under the age of 13. This enables the Board to determine the type of permit the applicant is applying for and to determine what education and experience requirements apply to the application.

- Item 4:

BPC section 1647.3 requires two different sets of competency qualifications for dental licensees to meet. BPC section 1647.3(d)(2) requires documentation of at least 20

cases of moderate sedation to patients under thirteen (13) years of age, and BPC section 1647.3(d)(3) requires documentation of 20 cases of moderate sedation to patients under seven (7) years of age.

As a result of the foregoing, the Board has created a separate qualifications section on this form to allow the Board to efficiently collect information relevant to these requirements and determine whether the minimum case requirements for each age group (20 cases of administration to under 13 and 20 cases of administration under 7) have been met. Recognizing that qualifying experience could range from a minimum of 20 cases (e.g., all cases might be under 7 years of age) to 40 cases or more (combination of age groups under 13 and under 7), the Board directs the applicant to complete this section and provide attachments for each case by case number that includes the listed information. This item informs the applicant that they will need to provide the following information in attachments 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.

BPC section 1647.3(d)(2), and (d)(3) require an applicant to provide the Board with documentation of 20 pediatric cases to show competency in the administration of deep sedation or general anesthesia to pediatric patients, including patients under 13 years of age and under 7 years of age. This information is therefore necessary for the applicant to easily and efficiently document competency in the administration of the anesthesia or sedation in the age groups for which they seek the permit.

The criteria will assist the Board in determining whether the procedures were performed competently based upon the criteria listed in this section (Item Nos. 1-5). The Board will need to determine if the documentation provided demonstrates that the applicant has administered moderate sedation to pediatric patients in the age category in which they are applying for a pediatric endorsement. In the Board's experience, these criteria will help the Board determine on a case-by-case basis whether the applicant met minimum standards for competent administration in the profession. In particular, item nos. 1 and 4 are important factors in determining competent administration as differences in age, weight, and sex can greatly impact the corresponding efficacy and safety administration considerations and the selection of the method, amount, and agent used for the particular procedure. Item nos. 3, 5, and 6 will inform the Board regarding whether proper administration and safety protocols were followed, allow the Board to evaluate patient outcomes and whether proper post procedure care or patient management occurred. The required information will also assist the Board in identifying individual cases for further review and investigation as personal identifying information of the dental patient will be omitted under this proposal.

Item 4A asks whether the applicant is seeking to provide moderate sedation to children under thirteen years of age. If the applicant says yes, the form asks the applicant to check all of the boxes at Item 4B that apply, which include:

- Whether they completed at least 20 cases of moderate sedation for children under thirteen years of age as noted on this form or related attachments.
- Whether they completed at least 20 cases of moderate sedation for children under thirteen years of age under direct supervision by another permit holder as noted on this form or related attachments.
- Whether they completed at least 20 cases of moderate sedation for children under thirteen years of age both independently and under direct supervision by another permit holder as noted on this form or related attachments.

The first question is necessary for the Board to collect this information to establish eligibility for the permit because BPC section 1647.3(d)(2) requires moderate sedation permit applicants to show successful completion of at least 20 cases of moderate sedation to patients under 13 years of age to establish competency in pediatric moderate sedation at the time of the initial application. (Bus. & Prof. Code, § 1647.3, subd. (d)(2).) This question establishes factually whether the experience was gained independently to help the Board determine whether this criterion was met through this pathway.

The second and third questions are necessary because BPC section 1647.3(f) allows applicants for a pediatric endorsement to qualify under another pathway. Those who otherwise qualify for the pediatric endorsement but lack sufficient cases of moderate sedation to patients under 13 years of age may satisfy this requirement by administering moderate sedation to patients under 13 years of age under the direct supervision of a general anesthesia or moderate sedation permit holder with a pediatric endorsement, instead of independently (or both through independent practice or under direct supervision). The applicant is allowed to count these cases toward the 20 required in order to qualify for the applicant's pediatric endorsement. (Bus. & Prof. Code, § 1647.3, subd. (f).) The third question is necessary to determine whether the applicant is relying on both independently performed cases and those performed under the direct supervision of a permit holder with a pediatric endorsement and allow for the applicant to qualify using a combination of experience as authorized under BPC section 1647.3. These questions will allow the Board to collect relevant information to determine whether the applicant qualifies for the permit under the Act.

- Item 5:

This item asks the applicant whether they are seeking to provide moderate sedation to children under seven years of age. If the applicant says yes, the form asks the applicant to check all of the items at Item 5B that apply, which include:

- Whether they completed at least 20 cases of moderate sedation for children under seven years of age as noted on this form or related attachments.
- If they did not complete at least 20 total cases of moderate sedation for children under seven years of age independently but administer moderate sedation to patients under seven years of age under the direct supervision of a permitholder who meets those qualifications.

The first question is necessary because BPC section 1647.3(d)(3) requires moderate sedation applicants who wish to provide moderate sedation to children under seven years of age to establish and maintain current competency for this pediatric population by completing 20 cases of moderate sedation for children under seven years of age in the 24-month period immediately preceding application for the pediatric endorsement. (Bus. & Prof. Code, § 1647.3, subd. (d)(3).)

The second question is necessary because BPC section 1647.3(g) allows applicants for a pediatric endorsement seeking to provide moderate sedation to children under seven years of age, but who lack sufficient cases of moderate sedation to patients under seven years of age may administer moderate sedation to patients under seven years of age under the direct supervision of a permitholder who meets those qualifications. (Bus. & Prof. Code, § 1647.3, subd. (g).) These questions will allow the Board to collect relevant information to determine whether the applicant qualifies for the permit under the Act.

- Cases 1-20:

To easily collect and verify whether minimum eligibility criteria are met, applicants for a general anesthesia or moderate sedation permit are required to provide specified information for each case occurring within the 24 months preceding application for the pediatric endorsement consistent with the requirements in BPC sections 1646.2(c)(2), 1646.9(e), and 1647.3(d)(2)-(3). The listed information includes: (1) the date of procedure, (2) the type of anesthesia/sedation administered (deep sedation, general anesthesia, or moderate sedation), (3) the type of procedure, (4) the pediatric patient age, (5) the pediatric patient sex, (6) pediatric patient weight, (7) a brief description of the method, amount, and specific sedation agent administered, who administered the sedation, who monitored the patient, and who performed the procedure on the pediatric patient, and (8) a description of the pediatric patient's condition at the time of discharge. Discharge planning can help in recovery and reduce the risks of adverse events. A description of the pediatric patient's condition at the time of discharge serves as an important document of what treatment the patient has received.

BPC sections 1646.2(c)(2), 1646.9(e), and 1647.3(d)(2)-(d)(3) require an applicant to provide the Board with documentation of experience administering sedation or anesthesia of pediatric cases at time of application and renewal to show competency in the administration of deep sedation or general anesthesia to pediatric patients. This

information is therefore necessary for the applicant to easily and efficiently provide documentation of competency in the administration of the anesthesia or sedation in the age groups for which they seek the permit as part of their initial application or renewal.

The required information will assist the Board in determining whether the applicable procedures were performed competently based upon the criteria listed in this section (Item Nos. 1-8). This will also help the Board to determine if the documentation provided demonstrates that the applicant has administered general anesthesia, deep sedation, or moderate sedation to pediatric patients in the age category in which they are applying for a pediatric endorsement. In the Board's experience, these criteria will help the Board determine on a case-by-case basis whether the applicant met minimum standards for competent administration in the profession. In particular, the patient-specific data (age, sex, and weight) are important factors in determining competent administration as differences in age, weight, and sex can greatly impact the corresponding efficacy and safety administration considerations and the selection of the method, amount, and agent used for the particular procedure. The other items will help inform the Board regarding whether proper administration and safety protocols were followed, allow the Board to evaluate patient outcomes and whether proper post procedure care or patient management occurred. The required information will also assist the Board in identifying individual cases for further review and investigation as other personal identifying information of the dental patient will be omitted under this proposal.

- Certification under penalty of perjury: The form requires the applicant certify under penalty of perjury under the laws of the State of California that the foregoing information including all attachments is true and correct by providing a signature and date. The Board relies upon applicants' self-reported information in evaluating applications. This requirement helps ensure that the representations on the form are accurate and made in good faith.

Subdivision (a)(4)

The Board proposes to add this subdivision to require an applicant to provide a certificate or other documentation of current certification in Advanced Cardiac Life Support (ACLS) and Pediatric Advanced Life Support (PALS) as provided by the American Red Cross (ARC), the American Heart Association (AHA), or the American Safety and Health Institute (ASHI).

This is necessary because BPC section 1646.2 requires a dentist applying for a pediatric endorsement for the general anesthesia permit to provide proof of successful completion of current certification in Advanced Cardiac Life Support (ACLS) and Pediatric Advanced Life Support (PALS) or other board-approved training in pediatric life support and airway management, pursuant to Section 1601.8, for the duration of the permit. (Bus. & Prof. Code, § 1646.2, subd. (c)(3).) The Board has chosen the ARC, AHA, and ASHI as these organizations are nationally recognized providers whose courses in advanced cardiac life support for both adult and pediatric patients are taught

by experts in the field who develop and maintain standards for the ACLS, and PALS courses accepted by healing arts boards, hospitals, and universities throughout the United States.

Subdivision (a)(5)

The Board proposes to add this subdivision to require applicants to pay the fee specified in section 1021 to apply for the pediatric endorsement to administer or order to administration of deep sedation or general anesthesia to pediatric patients.

This subdivision is necessary to provide notice to the applicant that the required fee must accompany the application. It is cross-referenced here for ease of reference. Please also see justification provided for the fee in the discussion regarding section 1021(ag).

Subdivision (a)(6)

The Board proposes to add this subdivision to require the applicant to certify under penalty of perjury that the information on the application is true and correct.

This is necessary because the Board relies upon applicants' self-reported information in evaluating applications. This requirement helps ensure that the representations on the form are accurate and made in good faith.

Subdivision (b)

The Board proposes to add this subdivision to establish the application requirements for the pediatric endorsements to the moderate sedation permit under BPC section 1646.7.3(d) and to provide all application requirements in one convenient list. This subdivision is necessary to inform applicants for the pediatric endorsements what must be submitted to satisfy the requirements in section 1647.3(d), including what the Board considers to be a completed application.

Subdivision (b)(1)

The Board proposes to add this subdivision to obtain the name of the applicant, mailing address or address of record, physical address, dental license number, and applicant's moderate sedation permit number, if any. These items of information are necessary to verify the applicant's identity and eligibility and ensure accuracy in the processing of the application and enable the Board to communicate more efficiently with the applicant.

Subdivision (b)(2)

The Board proposes to add this subdivision to require the applicant to submit a certificate of completion or other documentary evidence showing completion of a residency training program as required by section 1647.3 for a dental licensee.

This subdivision is necessary to verify an applicant's eligibility because section 1647.3 requires an applicant to show they successfully completed a residency in pediatric dentistry accredited by the Commission on Dental Accreditation (CODA) or the equivalent training in pediatric moderate sedation, as determined by the board. (Bus. & Prof. Code, § 1647.3, subd. (d)(1).) The Board has accepted other evidence of completion in the past, such as letters from a program, which it would also accept in lieu of a certificate of completion. Therefore, adding "or other documentary evidence" allows flexibility for the applicants in meeting this requirement.

Subdivision (b)(3)

The Board proposes to add this subdivision to provide that an applicant must submit a completed Form PE-1 as provided in this section. This requirement is necessary to ensure that applicants for a moderate sedation permit complete the Form PE-1 as part of their application for a moderate sedation permit and to verify their competency in the administration of moderate sedation as required by BPC section 1647.3(d)(2)-(d)(3).

Please see additional justification provided for the form in the discussion regarding subdivision 1043.8.1(a)(3).

Subdivision (b)(4)

The Board proposes to add this subdivision to require an applicant to provide a certificate or other documentary evidence of current certification in Pediatric Advanced Life Support (PALS) as provided by the American Red Cross (ARC), the American Heart Association (AHA), or the American Safety and Health Institute (ASHI).

This is necessary because BPC section 1647.3 requires to verify that an applicant has current certification in Pediatric Advanced Life Support (PALS) and airway management or other board-approved training in pediatric life support and airway management, adopted pursuant to Section 1601.8. (Bus. & Prof. Code, § 1647.3, subd. (d)(4).) The Board has chosen the ARC, AHA, and ASHI as these organizations are nationally recognized providers whose courses in advanced cardiac life support for both adult and pediatric patients are taught by experts in the field who develop and maintain standards for the ACLS, and PALS courses accepted by healing arts boards, hospitals, and universities throughout the United States. Due to the variety of ways in which completion may be documented, the Board allows the applicant to provide proof of completion through "other documentary evidence" other than providing a certificate of completion from one of these providers.

Subdivision (b)(5)

The Board proposes to add this subdivision to require applicants to pay the fee specified in section 1021 to apply for the pediatric endorsement to administer moderate sedation to pediatric patients.

This subdivision is necessary to provide notice to the applicant that the required fee must accompany the application for the Board to consider it complete. It is cross-referenced here for ease of reference. Please also see justification provided for the fee in the discussion regarding section 1021(ah).

Subdivision (b)(6)

The Board proposes to add this subdivision to require the applicant to certify under penalty of perjury that the information on the application is true and correct.

This is necessary because the Board relies upon applicants' self-reported information in evaluating applications. This requirement helps ensure that the representations on the form are accurate and made in good faith.

Subdivision (c)

The Board proposes to add subdivision (c) to provide an applicant for a pediatric endorsement who seeks to use general anesthesia or moderate sedation in the treatment of pediatric patients under 13 years of age or seven years of age shall submit to the Board information to document each of the 20 cases of deep sedation and general anesthesia or moderate sedation required by Sections 1646.2 and 1647.3 of the Code on Form PE-1 which is hereby incorporated by reference.

This is necessary because the form will provide information in order to determine if the applicant has completed the minimum number of cases required as well as demonstrate competence in the administration of deep sedation, general anesthesia, or moderate sedation to be approved for a pediatric endorsement to administer deep sedation, general anesthesia, or moderate sedation to pediatric patients under the age of seven or under the age of 13. This section ensures that the Board adopts a requirement to information is provided to document the 20 cases required by BPC sections 1646.2 and 1647.3 on the Form PE-1 established by this section so that if an applicant does not document as required by this subsection, the Board may deny the application for failure to comply with this section.

Subdivision (d)

The Board proposes to add subdivision (d) to provide that upon request by the Board in any investigation of the information provided on Form PE-1, applicants shall also

provide documentation or patient records for each deep sedation and general anesthesia or moderate sedation pediatric case listed on Form PE-1, including preoperative evaluation, medical history, monitoring of vital signs throughout the procedure, and condition at discharge.

This is necessary because if, for instance, the Board has cause to believe that any of the information is incorrect, has been misrepresented or needs further clarification, this provision would allow the Board to require an applicant to submit the underlying information used to complete the PE-1. This enables the Board to examine the underlying records to determine whether the information provided on the form was correct or what additional information may be needed to determine competency of administration.

Subdivision (e)

The Board proposes to add subdivision (e) to provide applicants shall submit legible copies of the information required by this section with pediatric patient identifying information redacted.

This is necessary because this subdivision complements subdivision (d) in enabling the Board to investigate the veracity of the information provided on the form. Requiring the copies to be legible ensures the Board can decipher the information provided and therefore receive a truly complete application. Requiring the pediatric patient identifying information to be redacted helps to ensure the patient's privacy rights are protected while ensuring the Board still obtains what it needs (as provided in this section) to verify competency.

Note:

The Board proposes to add BPC section 1614 to the Authority section. This is necessary because this statute authorizes the Board to adopt regulations in the subject matter.

The Board proposes to add BPC sections 27, 108, 1611.5, 1646.1, 1646.2, 1647.2, 1647.3, and 1646.9 to the Reference section. This is necessary because this regulation implements, interprets or makes these statutes specific.

New “Article 5.1 Pediatric Minimal Sedation”

The Board proposes to add a new Article 5.1 to state that the following regulations relate to pediatric minimal sedation. This will enhance the clarity of the subdivision and provide better organization of the regulations.

Section 1043.9. Definitions.

The Board proposes to add this subdivision to provide a definitions section for terms used in Article 5.1.

Subdivision (a)

The Board proposes to add a definition for “Another sedation permit” which means “a current permit for deep sedation or general anesthesia, a current moderate sedation permit with pediatric endorsement, or a current permit that is described in subdivision (a)(2) of Section 1647.31 of the Code.”

This is necessary because section 1043.9.1 uses the term “another sedation permit” in explaining that dentists who desire 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. The definition is necessary to clarify section 1043.9.1 since the Act permits these other permit holders to perform these services without obtaining an additional pediatric minimal sedation permit as provided in BPC section 1647.31 (a)(2) and therefore would help inform affected licensees of this exception.

Subdivision (b)

The Board proposes to add a definition for “Outpatient basis,” which as used in Section 1647.31 of the Code, will mean “all settings where pediatric minimal 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.”

This is necessary because section 1043.9.1 provides “[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.” Defining the term “outpatient basis” clarifies, for purposes of section 1043.9.1(a), when a dentist is not required to apply for a pediatric minimal sedation permit.

Subdivision (c)

The Board proposes to add a definition for “Pediatric patient,” which will mean “a patient who is under 13 years of age.”

This is necessary because this definition clarifies in Article 5.1 when specified legal requirements apply under the Act. This is necessary because the commonly understood meaning of “pediatric” (child under 18 years of age) does not apply in this context and without this clear definition the term’s use may confuse the affected applicant regarding what patient population is covered by the regulations.

Note:

The Board proposes to add BPC section 1614 to the Authority section. This is necessary because this statute authorizes the Board to adopt regulations in the subject matter.

The Board proposes to add BPC sections 1647.31 to the Reference section. This is necessary because this regulation implements, interprets or makes these statutes specific.

Section 1043.9.1. Requirements; Standards.

Subdivision (a)

The Board proposes to add subdivision to provide “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.”

This is necessary because BPC 1647.31 provides that a dentist may administer or order the administration of pediatric minimal sedation on an outpatient basis for pediatric dental patients under 13 years of age, if the dentist holds a current permit for deep sedation and general anesthesia, or holds a current permit for moderate sedation with a pediatric endorsement, or obtains a pediatric minimal sedation permit. (Bus. & Prof. Code, § 1647.31, subd. (a)(1).) Under section 1043.9, “another sedation permit” means “a current permit for deep sedation or general anesthesia, a current moderate sedation permit with pediatric endorsement, or a current permit that is described in subdivision (a)(2) of Section 1647.31 of the Code.” The Board inserts this provision in this regulation for to help inform applicants that they need not submit the application set forth in subdivision (b) if subdivision (a) applies to them. This will result in fewer unnecessary work and costs for both the applicants and the Board.

Subdivision (b)

The Board proposes to add this subdivision to provide that “[f]or the purposes of Sections 1647.31 and 1647.32 of the Code, an applicant for a pediatric minimal sedation permit shall submit a completed ‘Application for Pediatric Minimal Sedation Permit’ PMSP-1 (New 05/2021), which is hereby incorporated by reference, to the Board and shall be accompanied by the applicable fee as set by Section 1021. The application shall be accompanied by a ‘Certification of Pediatric Minimal Sedation Training’ Form PMSP-2 (New 05/2021), which is hereby incorporated by reference.” These forms provide applicants with a simple, straightforward method of demonstrating that they qualify for the pediatric minimal sedation permit, and meet the requirements in BPC sections 1647.31, 1647.32 and section 1043.9.2 (facility, recordkeeping and

equipment standards). This subdivision also notifies applicants of the requirements for submitting a completed application, including completion of these forms and submission of the fee set forth in section 1021. Please refer to the explanation in section 1021(r) for the rationale for prescribing the initial application fee.

The forms referenced in this subdivision would be cumbersome, unduly expensive and otherwise impractical to publish in the California Code of Regulations.

FORM PMSP-1, APPLICATION FOR PEDIATRIC MINIMAL SEDATION PERMIT

- Application fee box with notice that application fees are nonrefundable. The Board established a fee of \$459 for the application in section 1021(r). The application fee is non-refundable because the Board incurs staff hours and resources to review the application regardless of whether the application is approved or denied. These statements are necessary to provide notice to the applicants of these requirements.
- Instructions:
 - This application must be completed in its entirety or the application may be rejected as incomplete. Attach additional sheets if necessary.

This statement is necessary to provide notice to the applicant that the entirety of the application must be completed, or it will be rejected. It is also necessary to explain that the applicant may attach additional sheets if necessary. This helps to ensure the applicant completes the application, provides all applicable information, and the form is processed by staff expeditiously.

- Any material misrepresentation of any information on the application is grounds for denial or subsequent revocation of the permit.

This statement is necessary to provide notice to the applicant that any material misrepresentation of any information on the application is grounds for denial or subsequent revocation of the permit. (Bus. & Prof. Code, § 498 [“A board may revoke, suspend, or otherwise restrict a license on the ground that the licensee secured the license by fraud, deceit, or knowing misrepresentation of a material fact or by knowingly omitting to state a material fact.”].) This helps to ensure the applicant provides truthful information to the Board and provides notice to the applicants of these potential grounds for discipline.

- Under BPC sections 31 and 494.5, the State Board of Equalization (BOE) 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 or FTB certified list of top 500 tax delinquencies.

This statement is necessary to provide to an applicant that the application may be denied or permit suspended if the applicant fails to pay state tax obligations. This notice is required by BPC section 31 and is necessary to give proper notice to the applicants of the possible consequences for failure to pay their state tax obligations as set forth in BPC sections 31 and 494.5.

- Please include your “Certification of Pediatric Minimal Sedation Training” (Form PMSP-1 (new 05/2021) and fee with this application.

This statement is necessary to ensure the applicant has completed the required training and residency under BPC 1647.32(c)(1) and (c)(2) and help ensure the Board receives a completed application, including the fee. Please see justification for this certification under Form PMSP-2.

- Item 1: The form requires the applicant to disclose a social security number, or individual taxpayer identification number as required by BPC section 30(a)(1).
- Items 2-9: Items 2-9 seek identifying information about the applicant, including birth date, legal name, mailing address (address of record which may be a p.o. box under the provisions of BPC section 27(a)), primary practice location, email address (optional), telephone number, fax number (optional), and dental license number. These items of information are necessary to verify the applicant’s identity and eligibility (licensee in good standing per BPC section 1647.32(a)) and ensures accuracy in the processing of the application and enable the Board to communicate more efficiently with the applicant.
- Item 10: The form asks the applicant to indicate whether the applicant is currently or has served in the U.S. military as required by BPC section 114.5.
- Item 11: The form asks the applicant whether the applicant is requesting the expediting of the application for members of the U.S. Armed Forces who have been honorably discharged. This question is necessary to determine whether an applicant is applying for expedited review and processing as required by BPC section 115.4. The item asks the applicant to scan and attach a copy of a certificate of release from active duty (DD-214 which is the Department of Defense’s standard report of separation for members of the U.S. Armed Forces that includes the necessary information for the Board to process such requests) or other evidence showing the date and type of discharge to receive expedited review. To date, the Board has not received any other type of evidence in lieu of the DD-214 but includes this possibility to help ensure that applicants have other options for demonstrating they qualify. This information is necessary to determine whether the applicant has provided satisfactory evidence that they have met the requirements for expedited processing per BPC 115.4.

- Item 12: The form asks the applicant whether they already hold a valid license or comparable authority to practice dentistry in another U.S. state or territory, and whether their spouse or domestic partner is an active duty member of the U.S. Armed Forces and is assigned to a duty station in California under official orders. If the applicant answers yes, the form states that their application will receive an expedited review consistent with BPC section 115.5. The question is necessary to determine whether an applicant meets the requirements for expedited review and processing under BPC section 115.5.

The form asks the applicant to provide documentary evidence to support the request including: (1) a certificate of marriage or certified declaration/registration of domestic partnership filed with the Secretary of State or other documentary evidence of legal union with an active-duty member of the Armed Forces; (2) a copy of the applicant's current dental license in another state, district, or territory of the United States; and (3) a copy of the military orders establishing your spouse or partner's duty station in California. These documents are necessary to verify and ensure the applicant meets the statutory requirements for expediting the licensure process by requesting official government documents, licenses and military records to substantiate the information provided to the Board. To date, the Board has not received any other type of evidence in lieu of a certificate of marriage or certified declaration/registration of domestic partnership but includes this possibility of "other documentary evidence" should it be submitted in the future to help ensure that applicants have other options for demonstrating they qualify.

- Item 13: The form asks the applicant to indicate whether (1) the applicant was admitted to the United States as a refugee pursuant to section 1157 of Title 8 of the United States Code; or (2) the applicant was granted asylum by the Secretary of Homeland Security or the Attorney General of the United States pursuant to section 1158 of Title 8 of the United States Code; or, (3) the applicant has a special immigrant visa and was granted a status pursuant to section 1244 of the Public Law 110-181, Public Law 109-163, or section 602(b) of Title VI of division F of Public Law 111-8 [relating to Iraqi and Afghan translators/interpreters of those who worked for or on behalf of the United States government]. These questions are necessary to determine whether the applicant qualifies for expediting of the initial application for refugees, asylees, and holders of special immigrant visas as required by BPC section 135.4(a) 's criteria for expediting these types of applications.

If the applicant answers yes, they are requested to attach official documents commonly issued by federal agencies or the courts for the categories of individuals listed in section 135.4 as evidence of their status as a refugee, asylee, or special immigrant visa holder which includes:

- Form I-94, arrival/departure record, with an admission class code such as "re" (refugee) or "ay" (asylee) or other information designating the person a refugee or asylee.

- Special immigrant visa that includes the “si” or “sq.”
- A permanent resident card (Form I-551), commonly known as a “green card,” with a category designation indicating that the person was admitted as a refugee or asylee.
- An order from a court of competent jurisdiction or other documentary evidence that provides reasonable assurances to the Board that the applicant qualifies for expedited licensure per BPC section 135.4.

These documents are necessary to verify and ensure the applicant meets the statutory requirements for expediting the initial application process. Copies of official government documents will help ensure the accuracy of the information provided by the applicants to the Board.

- Statement before Item 14: The form states: Facilities and Equipment Requirements - All equipment should be maintained, tested, and inspected according to the manufacturers’ specifications. In an office where anesthesia services are to be provided pediatric patients, the required equipment, medication, and resuscitative capabilities shall be appropriately sized for a pediatric population. This statement is necessary to educate the applicant regarding the legal requirements applicable to facilities and equipment necessary for a pediatric population in all offices where pediatric minimal sedation is administered.
- Item 14(1): The form asks the applicant whether the facility has an operatory large enough to adequately accommodate the pediatric patient and permit a team consisting of at least three individuals to freely move about the patient. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.9.2(a)(1).
- Item 14(2): The form asks whether the facility has a table or dental chair that permits the patient to be positioned so the attending team can maintain the airway, quickly alter patient position in an emergency, and provide a firm platform for the management of cardiopulmonary resuscitation. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.9.2(a)(2).
- Item 14(3): The form asks whether the facility has a lighting system adequate to permit evaluation of the pediatric patient's skin and mucosal color and a backup lighting system that is battery powered and of sufficient intensity to permit completion of any treatment which may be underway at the time of a general power failure. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.9.2(a)(3).
- Item 14(4): The form asks whether the facility has an appropriate functional suctioning device that permits aspiration of the oral and pharyngeal cavities. a

backup suction device that can function at the time of general power failure must also be available. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.9.2(a)(4).

- Item 14(5): The form asks whether the facility has a positive-pressure oxygen delivery system capable of administering greater than 90% oxygen at a 10 liter/minute flow for at least sixty minutes (650 liter “e” cylinder), even in the event of a general power failure. all equipment must be appropriate for use on and capable of accommodating the pediatric patients being seen at the permit-holder's office.
- Item 14(6): The form asks whether the facility has inhalation sedation equipment, which if used in conjunction with oral sedation, it must have the capacity for delivering 100%, and never less than 25%, oxygen concentration at a flow rate appropriate for a pediatric patient's size and have a fail-safe system. the equipment must be maintained and checked for accuracy at least annually. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.9.2(a)(5).
- Item 14(7): The form asks whether the facility has the listed ancillary equipment maintained in good operating condition. This question is necessary so the board can determine whether the applicant satisfies the requirements set forth in section 1043.3(c)(1)-(4).
- Item 15: This section helps ensure that the applicant meets the Board's recordkeeping requirements for all facilities that administer pediatric minimal sedation contained in section 1043.9.2. by requiring that the applicant answer “yes” or “no” regarding whether they maintain the records specified in subsections (1)-(4).
- Item 15(1): The form requires the applicant to provide information as to an adequate medical history and physical evaluation updated prior to each administration of pediatric minimal sedation. Such records shall include, but are not limited to, an assessment including at least visual examination of the airway, the age, sex, weight, physical status (American Society of Anesthesiologists classification), and rationale for sedation of the pediatric patient and written informed consent of the parent or legal guardian of the pediatric patient. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.9.2(d)(1).
- Item 15(2): The form asks the applicant whether the applicant maintains pediatric minimal sedation records that include baseline vital signs. If obtaining baseline vital signs is prevented by the pediatric patient's physical resistance or emotional condition, the reason or reasons must be documented. The records shall also include intermittent quantitative monitoring and recording of oxygen saturation, heart and respiratory rates, blood pressure as appropriate for specific techniques,

the name, dose and time of administration of all drugs administered including local and inhalation anesthetics, the length of the procedure, any complications of oral sedation, and a statement of the pediatric patient's condition at the time of discharge. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.9.2(d)(2).

- Item 15(3): The form asks whether the applicant maintains documentation that all emergency equipment is checked and maintained to determine operability and safety for the patient consistent with manufacturer's recommendations. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.9.2(d)(3).
- Item 15(4): The form asks whether the applicant maintains documentation that all drugs maintained at the facility are checked at least quarterly for expired drugs and an adequate supply for the patient population served. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.9.2(d)(4).
- Item 16: The form asks the applicant if they have available and readily accessible an emergency kit or cart that includes (a) the necessary and appropriate emergency drugs and size-appropriate equipment to resuscitate a nonbreathing and unconscious pediatric patient and provide continuous support while the pediatric patient is transported to a medical facility; and (b) emergency drugs of the following types: (1) epinephrine; (2) bronchodilator; (3) appropriate drug antagonists; (4) antihistaminic; (5) anticholinergic; (6) anticonvulsant; (7) oxygen; and (8) dextrose or other antihypoglycemic. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1043.9.2(b)(1)-(8).
- Item 17: The form asks if the applicant and at least one staff member are trained in the monitoring and resuscitation of pediatric patients, noting that trained staff are required to be present during the administration of minimal sedation per BPC section 1647.32. This question is necessary so the Board can determine whether the applicant satisfies the requirement set forth in BPC section 1647.32(e), which requires the operating dentist and a minimum of one additional personnel to be trained in the monitoring and resuscitation of pediatric patients and present during the administration of minimal sedation.
- Item 18: The form asks the applicant whether they obtain a written informed consent from the parent or guardian of the minor patient prior to each administration of pediatric minimal sedation. This question is necessary so the Board can determine whether the applicant satisfies the requirement set forth in section 1043.9.2(d)(1).

- Item 19: The form asks the applicant to provide the addresses of all locations where the applicant will administer or order the administration of pediatric minimal sedation. The form notes that all offices shall meet the standards set forth in regulations adopted by the Board at Title 16, California Code of Regulations section 1043.9.2. This question is necessary to inform the applicant of these requirements, identify the locations where administration will occur for the purposes of future investigation and inspection and also so the Board can verify that the legal requirements set forth in section 1043.9.2 are met at each location.
- Certification under penalty of perjury: The form requires the applicant certify under penalty of perjury under the laws of the State of California that the foregoing information, including any attachments, is true and correct by providing a signature and date. The Board relies upon applicants' self-reported information in evaluating applications. This requirement helps ensure that the representations on the form are accurate and made in good faith.
- Information Collection and Access section: The form includes the required notices and disclosures to the applicant for the Board's collection of personal information in compliance with Civil Code section 1798.17.

FORM PMSP-2, CERTIFICATION OF PEDIATRIC MINIMAL SEDATION TRAINING

- Notice to Applicants: The form includes the required notices and disclosures to the applicant for the Board's collection of personal information in compliance with Civil Code section 1798.17. The notice provides the following:
 - This completed form must be submitted to the Dental Board of California (Board) with your application for a pediatric minimal sedation permit as required by Title 16, California Code of Regulations (CCR) section 1043.9.1 or your application may be rejected as incomplete. The information requested on this form is mandatory pursuant to BPC section 1647.32 and Title 16 CCR section 1043.9.1. The information provided will be used to determine qualification for a pediatric minimal sedation permit.

This statement is necessary to provide notice to the applicant that it must be submitted with Form PMSP-1 or the application for a moderate sedation permit may be rejected as incomplete. The form instructs the applicant that the information requested is mandatory. This helps to ensure the applicant completes the application and is processed by staff expeditiously. This information is also required to be provided to affected individuals in accordance with Civil Code section 1798.17, subdivisions (a), (c), (d), and (e), which require the Board to include with this form notice of the following: the name of the agency requesting the information, the authority (statute or regulation) which authorizes maintenance of the information, whether submission of the information is mandatory, and the consequences of not

providing the requested information.

- The information may be provided to other governmental agencies, or in response to a court order, subpoena, or public records request. You have a right of access to records containing personal information unless the records are exempted from disclosure. Individuals may obtain information regarding the location of their records by contacting the Board's Executive Officer at 2005 Evergreen Street, Suite 1550, Sacramento, CA 95815, Executive Officer, 916-263-2300.

This statement is necessary to notify the applicant that the information they provide may be provided to other governmental agencies. This statement is necessary to comply with the Section 1798.17 of the Civil Code which requires the Board to notify the applicant of the uses of their personal information, as well as provide other disclosures in accordance with Civil Code section 1798.17, subdivisions (b), (f), (g) and (h).

- Items 1-3: Items 1-3 seek identifying information about the applicant, including legal name, license number, and name of school/educational institution. These items of information are necessary to verify the applicant's identity and eligibility to ensure accuracy in the processing of the certification and enable the Board to communicate more efficiently with the applicant.
- Item 4: For ease of comprehension in filling out the certification and to increase likelihood of accuracy in the process, the form includes an introduction before the question that notifies the educational institution of the following:

This dentist is applying for a pediatric minimal sedation 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 form directs the educational institution to indicate whether the permit applicant has successfully completed the institution's educational program in minimal sedation that includes either of the following requirements consistent with BPC section 1647.32(c):

- (1) Consists of 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,
- (2) Completion of a CODA-approved residency in pediatric dentistry.

This provides a simple and convenient way for the applicant to show acceptable documentation approved by the Board under the requirements of the Act, and that they have met the training requirements for the pediatric minimal sedation permit. Also, this form provides educational institutions with the information needed to assist their students in completing the requirements for permit issuance. (Bus. & Prof. Code, § 1647.32, subd. (c)(1) and (c)(2).)

- **Certification:** The certification would require an official from the education institution to acknowledge and certify under penalty of perjury under the laws of the State of California, that the information provided on the certification is true and correct, confirm that according to the institution's records the applicant satisfactorily completed the above referenced training at the education institution, the type of program that applicant was enrolled in, the beginning and end date that the applicant was enrolled in the program, and an education program seal. This helps ensure that the information the educational institution provides is truthful and accurate, that the Board meets its obligations to obtain evidence of training for the issuance of this permit in compliance with BPC section 1647.32, and to help ensure minimum standards are met for the protection of the public. In addition, the provision of the personal information of the educational institution, including the school official's name, title, and telephone number would allow the Board to confirm and investigate the accuracy of the representations in the certification and authenticate the information provided.
- **Seal:** The form asks the educational institution to use their seal (if applicable) to ensure that it is the educational institution providing the information. This is necessary so the Board knows that their information comes from the educational institution and is accurate.

The Board proposes to add BPC section 1614 to the Authority section. This is necessary because this statute authorizes the Board to adopt regulations in the subject matter.

The Board proposes to add BPC sections 1647.31 and 1647.32 to the Reference section. This is necessary because this regulation implements, interprets or makes these statutes specific.

Section 1043.9.2. Facility and Equipment Standards.

There are currently no regulatory requirements for a facility in which minimal sedation is administered by dentists to pediatric patients. The Board proposes to add this section to establish such standards for the facility and equipment to help ensure minimum standards are established and maintained in these facilities for the protection of the public.

BPC section 1647.31 provides “a dentist with a pediatric minimal sedation permit shall possess the training, equipment, and supplies to rescue a patient from an unintended deeper level of sedation.” (Bus. & Prof. Code, § 1647.31, subd. (c).) This section is necessary to implement the requirements of section 1647.31 by establishing the standards for facilities and equipment.

Subdivision (a)

The Board proposes to add subdivision (a) to establish the items a facility must possess to remain in compliance with the Board’s requirements. This subdivision is necessary to properly inform the applicant or permit holder and list the items the Board considers to be required, at a minimum, to meet patient health and safety needs.

Subdivision (a)(1)

The Board proposes to add subdivision (a)(1) to require a facility to possess “[a]n operatory large enough to adequately accommodate the pediatric patient and permit a team consisting of at least three individuals to freely move about the patient.”

This is necessary to adopt the existing standard set forth in section 1044.5(a)(1) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article. The Board’s Study notes that these current Board facility requirements are the same for all levels of sedation and anesthesia (see Table 5, page 91) as set forth in section 1044.5. On page 16 of the Study, the following findings were made:

“State laws specify facility requirements such as a treatment room of adequate size to accommodate the patient and three individuals, adequate lighting, a power operated chair or table, suction, a supply of oxygen, and appropriate backup systems to allow completion of a procedure in the event of a power failure. These requirements are relatively uniform for all states the subcommittee reviewed.”

The Study did not recommend any changes to these existing standards. As a result, the Board has determined the existing standards are still sufficient to ensure minimum standards for patient health and safety are met and should be used consistently in offices or facilities regardless of the level of sedation or anesthesia, including facilities that administer minimal sedation for pediatric patients.

Subdivision (a)(2)

The Board proposes to add subdivision (a)(2) to require a facility to possess “[a] table or dental chair that permits the patient to be positioned so the attending team can maintain the airway, quickly alter a patient’s position in an emergency, and provide a firm platform for the management of cardiopulmonary resuscitation.”

This is necessary to adopt the standard set forth in section 1044.5(a)(2) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article. The Board’s Study notes that these current Board facility requirements are the same for all levels of sedation and anesthesia (see Table 5, page 91) as set forth in section 1044.5. On page 16 of the Study, the following findings were made:

“State laws specify facility requirements such as a treatment room of adequate size to accommodate the patient and three individuals, adequate lighting, a power operated chair or table, suction, a supply of oxygen, and appropriate backup systems to allow completion of a procedure in the event of a power failure. These requirements are relatively uniform for all states the subcommittee reviewed.”

The Study did not recommend any changes to these existing standards. As a result, the Board has determined the existing standards are still sufficient to ensure minimum standards for patient health and safety are met and should be used consistently in offices or facilities regardless of the level of sedation or anesthesia, including facilities that administer minimal sedation for pediatric patients.

Subdivision (a)(3)

The Board proposes to add subdivision (a)(3) to require a facility to possess “[a] lighting system adequate to permit evaluation of the pediatric patient’s skin and mucosal color and a backup lighting system that is battery powered and of sufficient intensity to permit completion of any treatment that may be underway at the time of a general power failure.”

This is necessary to adopt the standard set forth in section 1044.5(a)(3) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article. The Board’s Study notes that these current Board facility requirements are the same for all levels of sedation and anesthesia (see Table 5, page 91) as set forth in section 1044.5. On page 16 of the Study, the following findings were made:

“State laws specify facility requirements such as a treatment room of adequate size to accommodate the patient and three individuals, adequate lighting, a power operated chair or table, suction, a supply of oxygen, and appropriate backup systems to allow completion of a procedure in the event of a power failure. These requirements are relatively uniform for all states the subcommittee reviewed.”

The Study did not recommend any changes to these existing standards. As a result, the Board has determined the existing standards are still sufficient to ensure minimum

standards for patient health and safety are met and should be used consistently in offices or facilities regardless of the level of sedation or anesthesia, including facilities that administer minimal sedation for pediatric patients.

Subdivision (a)(4)

The Board proposes to add subdivision (a)(4) to require a facility to possess “[a]n appropriate functional suctioning device that permits aspiration of the oral and pharyngeal cavities. A backup suction device that can function at the time of general power failure must also be available.”

This is necessary to adopt the standard set forth in section 1044.5(a)(4) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article. The Board’s Study notes that these current Board facility requirements are the same for all levels of sedation and anesthesia (see Table 5, page 91) as set forth in section 1044.5. On page 16 of the Study, the following findings were made:

“State laws specify facility requirements such as a treatment room of adequate size to accommodate the patient and three individuals, adequate lighting, a power operated chair or table, suction, a supply of oxygen, and appropriate backup systems to allow completion of a procedure in the event of a power failure. These requirements are relatively uniform for all states the subcommittee reviewed.”

The Study did not recommend any changes to these existing standards. As a result, the Board has determined the existing standards are still sufficient to ensure minimum standards for patient health and safety are met and should be used consistently in offices or facilities regardless of the level of sedation or anesthesia, including facilities that administer minimal sedation for pediatric patients.

Subdivision (a)(5)

The Board proposes to add subdivision (a)(5) to require a facility to possess “[a] positive-pressure oxygen delivery system capable of administering greater than 90% oxygen at a 10 liter/minute flow for at least sixty minutes (650 liter “E” cylinder), even in the event of a general power failure. All equipment must be appropriate for use on and capable of accommodating the pediatric patients being seen at the permit-holder's office.”

This is necessary to adopt the standard set forth in section 1044.5(a)(5) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article. The Board’s Study notes that these current Board facility requirements are the same for all levels of sedation and anesthesia (see Table 5,

page 91) as set forth in section 1044.5. On page 16 of the Study, the following findings were made:

“State laws specify facility requirements such as a treatment room of adequate size to accommodate the patient and three individuals, adequate lighting, a power operated chair or table, suction, a supply of oxygen, and appropriate backup systems to allow completion of a procedure in the event of a power failure. These requirements are relatively uniform for all states the subcommittee reviewed.”

The Study did not recommend any changes to these existing standards. As a result, the Board has determined the existing standards are still sufficient to ensure minimum standards for patient health and safety are met and should be used consistently in offices or facilities regardless of the level of sedation or anesthesia, including facilities that administer minimal sedation for pediatric patients.

Subdivision (a)(6)

The Board proposes to add subdivision (a)(6) to require a facility to possess “[i]nhalation sedation equipment. If used in conjunction with oral sedation, it must have the capacity for delivering 100%, and never less than 25%, oxygen concentration at a flow rate appropriate for a pediatric patient's size and have a fail-safe system. The equipment must be maintained and checked for accuracy at least annually.”

This is necessary to adopt the standard set forth in section 1044.5(a)(6) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article. The Board’s Study notes that these current Board facility requirements are the same for all levels of sedation and anesthesia (see Table 5, page 91) as set forth in section 1044.5. On page 16 of the Study, the following findings were made:

“State laws specify facility requirements such as a treatment room of adequate size to accommodate the patient and three individuals, adequate lighting, a power operated chair or table, suction, a supply of oxygen, and appropriate backup systems to allow completion of a procedure in the event of a power failure. These requirements are relatively uniform for all states the subcommittee reviewed.”

The Study did not recommend any changes to these existing standards. As a result, the Board has determined the existing standards are still sufficient to ensure minimum standards for patient health and safety are met and should be used consistently in offices or facilities regardless of the level of sedation or anesthesia, including facilities that administer minimal sedation for pediatric patients.

Subdivision (b)

The Board proposes to add subdivision (b) to require a facility to possess “[a]n emergency cart or kit available and readily accessible that shall include the necessary and appropriate emergency drugs and size-appropriate equipment to resuscitate a nonbreathing and unconscious pediatric patient and provide continuous support while the pediatric patient is transported to a medical facility” and requires “[e]mergency drugs of the following types shall be available[.]”

This is necessary to adopt the standard set forth in section 1044.5(d) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article. The Board has not adopted “There must be documentation showing that all emergency equipment and drugs are checked and maintained on a prudent and regularly scheduled basis” from subdivision (d) because it has relocated similar provisions in subdivision (d)(3) and (d)(4) of this regulation. The Study indicated that this requirement was generally consistent with professional guidelines and made no recommendations to change this standard (see Table 6, p. 93 and Table 8, p. 101). As a result, the Board has determined the existing standards are still sufficient to ensure minimum standards for patient health and safety are met and should be used consistently in offices or facilities regardless of the level of sedation or anesthesia, including facilities that administer minimal sedation for pediatric patients.

Subdivisions (b)(1) - (b)(8)

The Board proposes to add subdivision (b) to require a facility to possess the emergency drugs listed at subdivisions (b)(1) through (b)(8).

This is necessary to adopt the standard set forth in section 1044.5(d) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article. The Study analyzed the Board’s current emergency drugs requirements (see Table 8, p. 101) and did not recommend altering the current minimum standards. As a result, the Board has determined the existing standards are still sufficient to ensure minimum standards for patient health and safety are met and should be used consistently in offices or facilities regardless of the level of sedation or anesthesia, including facilities that administer minimal sedation for pediatric patients.

Subdivision (c)

The Board proposes to add subdivision (b) to require a facility to possess and maintain the listed ancillary equipment in good operating condition.

This is necessary to adopt the standards set forth in section 1044.5(b) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article. The Board’s current requirements for oral conscious sedation were examined in the Study (see p.105-106 and Table 6 on p. 93). On pages 16 and 17 of the Board’s Study, the committee made the following findings:

State laws generally require the dentist to equip the treatment room with the appropriate patient monitors and to possess the ancillary equipment necessary to provide safe anesthesia and sedation. Required equipment varies depending on the level of sedation, with additional monitors such as the electrocardiogram (ECG), a defibrillator, and capnography [the measurement of carbon dioxide in a patient's exhaled breath over time] usually required for general anesthesia but not for moderate or minimal sedation. California's requirements are consistent with those of other states as well as with the recommendations included in professional association guidelines.

As a result, the Board has determined the existing standards are still sufficient to ensure minimum standards for patient health and safety are met and should be used consistently in offices or facilities regardless of the level of sedation or anesthesia, including facilities that administer minimal sedation for pediatric patients.

Subdivision (c)(1)

The Board proposes to add subdivision (c)(1) to require ancillary equipment to include “[o]ral airways capable of accommodating pediatric patients of all sizes.”

This amendment is necessary to apply the Board's current standards for pediatric patients (termed “oral conscious sedation”) in 1044.5(b)(1) to pediatric minimal sedation for the reasons explained above in subdivision (c). However, the sentence will be worded differently to make it clearer that this standard accommodates “pediatric patients of all sizes” because the size and age of pediatric patients vary and appropriate equipment to accommodate patients treated must be available for use in order to reduce the likelihood of an adverse event associated with sedation.

Subdivision (c)(2)

The Board proposes to add subdivision (c)(2) to require ancillary equipment to include “[a] sphygmomanometer with cuffs of appropriate size for pediatric patients of all sizes.”

This amendment is necessary to apply the Board's current standards for pediatric patients (termed “oral conscious sedation”) in 1044.5(b)(2) to pediatric minimal sedation for the reasons explained above in subdivision (c). However, the sentence will be worded differently to make it clearer that this standard accommodates “pediatric patients of all sizes” because the size and age of patients vary and equipment to accommodate patients treated must be available for use in order to reduce the likelihood of an adverse event associated with sedation.

Subdivision (c)(3)

The Board proposes to add subdivision (c)(3) to require ancillary equipment to include “[a] precordial/pretracheal stethoscope.”

This is necessary to adopt the standard set forth in section 1044.5(b)(3) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article for the reasons set forth above in subdivision (c).

Subdivision (c)(4)

The Board proposes to add subdivision (c)(4) to require ancillary equipment to include “[a] pulse oximeter.”

This is necessary to adopt the standard set forth in section 1044.5(b)(4) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article for the reasons set forth above in subdivision (c).

Subdivision (d)

The Board proposes to add subdivision (d) to establish what records must be maintained by a facility. The Board’s current requirements for records for oral conscious sedation were examined in the Study (see p.105-106 and Table 6 on p. 93). On page 15 of the Board’s Study, the following findings were made:

California law requires a preoperative evaluation for all patients undergoing sedation or anesthesia prior to each administration of sedation or anesthesia. This includes an adequate medical history and a focused physical evaluation recorded and updated as indicated. Records must include but are not limited to the recording of the age, sex, weight, physical status (American Society of Anesthesiologists Classification I-V), medication use, any known or suspected medically compromising conditions, rationale for sedation of the patient, and visual examination of the airway, and, for general anesthesia only, auscultation of the heart and lungs as medically required (CCR Section 1043.3). All other states reviewed have equivalent or lesser requirements.

In addition, on page 17 of the Board’s study, the following findings were made:

State laws specify the records that must be maintained for sedation and anesthesia, including a time dependent record of pulse, blood pressure, oxygen saturation, ECG where appropriate, the doses of medications administered and the time they are given, and any complications.

State law requires an evaluation of the patient by a qualified person prior to discharge, and notation of their condition in the treatment record. California requires this evaluation notation as do most other states.

As a result, the Board has determined the existing standards are still sufficient to ensure minimum standards for patient health and safety are met and should be used consistently in offices or facilities regardless of the level of sedation or anesthesia, including facilities that administer minimal sedation for pediatric patients.

Subdivision (d)(1)

The Board proposes to add subdivision (d)(1) to require a facility to maintain “[a]n adequate medical history and physical evaluation, updated prior to each administration of pediatric minimal sedation. Such records shall include, but are not limited to, an assessment including an evaluation of the airway, the age, sex, weight, physical status (American Society of Anesthesiologists Classification), and rationale for sedation of the pediatric patient and written informed consent of the parent or legal guardian of the pediatric patient.”

This is necessary to adopt the standard set forth in section 1044.5(c)(1) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article for the reasons set forth above in subdivision (d). However, the sentence will be worded differently to make it clearer that this standard applies to “pediatric” patients.

Subdivision (d)(2)

The Board proposes to add subdivision (d)(2) to require a facility to maintain “[p]ediatric minimal sedation records that include baseline vital signs. If obtaining baseline vital signs is prevented by the pediatric patient's physical resistance or emotional condition, the reason or reasons must be documented. The records shall also include intermittent quantitative monitoring and recording of oxygen saturation, heart and respiratory rates, blood pressure as appropriate for specific techniques, the name, dose and time of administration of all drugs administered including local and inhalation anesthetics, the length of the procedure, any complications of oral sedation, and a statement of the pediatric patient's condition at the time of discharge.”

This is necessary to adopt the standard set forth in section 1044.5(c)(2) for oral conscious sedation, which presently applies to adults and pediatric patients, to pediatric minimal sedation in this Article for the reasons set forth above in subdivision (d). However, the sentence will be worded differently to make it clearer that this standard applies to “pediatric” patients.

Subdivision (d)(3)

The Board proposes to add subdivision (d)(3) to require a facility to maintain “[d]ocumentation that all emergency equipment is checked to determine operability and safety for the patient consistent with the manufacturer's recommendations.” This is necessary to ensure minimum standards for maintenance and safe operation of the

equipment and to help ensure that pediatric dental patients under sedation can be appropriately monitored in order to reduce the likelihood of adverse events resulting from sedation. Operating equipment according to manufacturers' recommendations helps ensure overall equipment effectiveness in the event of an emergency for the protection of the public.

Subdivision (d)(4)

The Board proposes to add subdivision (d)(3) to require a facility to maintain “[d]ocumentation that all drugs maintained at the facility are checked at least quarterly for expired drugs and an adequate supply for the patient population served.” This is necessary to ensure that pediatric dental patients under sedation are administered medications that have not expired in order to reduce the likelihood of adverse events and help ensure efficacy of the drugs for public health and safety. Under California’s Pharmacy Law, it is illegal to sell or transfer a dangerous drug (prescription drug) or controlled substance after the beyond use date on the label. (Bus. & Prof. Code, 4169 (a)(4)), and it is unprofessional conduct for a dentist to violate the Pharmacy Law governing the dispensing of dangerous drugs or controlled substances under the Act (see Bus. & Prof. Code, § 1680(m)). The Board has selected a quarterly time frame, that in the Board’s experience, will help ensure that drugs are kept up to date, supply is adequate, and drugs are disposed of or replaced if expired in a timely manner. Setting a minimum standard for documentation may encourage the regulated community’s attention on complying with this requirement and help avoid possible violation of the Pharmacy Law, and by extension, the Act.

Note:

The Board proposes to add BPC section 1614 to the Authority section. This is necessary because this statute authorizes the Board to adopt regulations in the subject matter.

The Board proposes to add BPC sections 1647.30 and 1647.32 to the Reference section. This is necessary because this regulation implements, interprets or makes these statutes specific.

Section 1044. Definitions.

The Board proposes to delete the Article 2.85 of the BPC reference, from the preface of section 1044 as it will be repealed effective January 1, 2022.

Subdivision (a)

The Board proposes to add “outpatient setting” to the definition of “outpatient basis.” “Outpatient setting” is the term defined in Health and Safety Code section 1248 and the Board inadvertently failed to reflect this in the regulation. This amendment is necessary

to add the correct cross-reference to the regulation as the referenced Health and Safety Code sections do use the term “outpatient setting” whereas the Act calls this same concept “outpatient basis”. The word “and” is added here for grammatical reasons, easier comprehension and readability of this sentence.

Subdivision (c)

The Board proposes to delete “under 13 years of age for the oral conscious sedation certificate for minor patients and” from this subdivision because the Act, as amended by SB 501, replaces the current oral conscious sedation permit (OCSP) for minor patients with the pediatric minimal sedation permit. The Board will no longer issue the OCSP for minor patients. (Bus. & Prof. Code, § 1647.35.)

Note:

The Board proposes to delete BPC section 1647.10 from the Reference section. This is necessary because the regulation does not implement, interpret or make these statutes specific but only relates to grandfathering of existing permits.

Section 1044.1. Requirements; Standards.

The Board proposes to amend this section to remove reference to the “Application for Oral Conscious Sedation for Minors Certificate” OCS-1 (Rev. 01/05)” because this form is now superseded by pediatric minimal sedation permit. The Board will remove reference to the “Application for Adult Oral Conscious Sedation Certificate” OCS-3 (Rev. 03/07) because it is being replaced by the Application for Use of Oral Conscious Sedation on Adult Patients” Form OCS-C NEW (05/2021).

The Board deletes “shall be” for clarity in the regulation and adds the word “completed” to help ensure applicants understand that only completed applications will be accepted for processing by the Board.

The Board replaces “conscious” with “moderate” because the Act, as amended by SB 501, repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board deletes “an oral conscious sedation certificate for a minor patient” and “A dentist who only possesses an adult oral conscious sedation certificate may not provide oral conscious sedation to a minor patient.” These amendments are necessary

to avoid confusion and conform to changes in the Act because, effective January 1, 2022, the Board will no longer issue the OCSP for minor patients.

The form referenced in this subdivision would be cumbersome, unduly expensive and otherwise impractical to publish in the California Code of Regulations. The form will be available on the Board's website and from the Board upon request.

FORM OCS-C, APPLICATION FOR USE OF ORAL CONSCIOUS SEDATION ON ADULTS

- Application fee box with notice that application fees are nonrefundable. The Board established a fee of \$459 for the application in section 1021(ae). The application fee is non-refundable because the Board incurs staff hours and resources to review the application, regardless of whether the application is approved or denied. These statements are necessary to provide notice to the applicants of these requirements.
- Instructions:
 - This application must be completed in its entirety or the application may be rejected as incomplete. Attach additional sheets if necessary.

This statement is necessary to provide notice to the applicant that the entirety of the application must be completed, or it will be rejected. It is also necessary to explain that the applicant may attach additional sheets if necessary. This helps to ensure the applicant completes the application and is processed by staff expeditiously.

- Any material misrepresentation of any information on the application is grounds for denial or subsequent revocation of the permit.

This statement is necessary to provide notice to the applicant that any material misrepresentation of any information on the application is grounds for denial or subsequent revocation of the permit. (Bus. & Prof. Code, § 498 ["A board may revoke, suspend, or otherwise restrict a license on the ground that the licensee secured the license by fraud, deceit, or knowing misrepresentation of a material fact or by knowingly omitting to state a material fact."].) This helps to ensure the applicant provides accurate and truthful information to the Board and provides notice to the applicants of these potential grounds for discipline.

- Under BPC sections 31 and 494.5, the State Board of Equalization (BOE) 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 or FTB certified list of top 500 tax delinquencies.

This statement is necessary to provide to an applicant that the application may be denied or permit suspended if the applicant fails to pay state tax obligations. This notice is required by BPC section 31 and is necessary to give proper notice to the applicants of the possible consequences for failure to pay their state tax obligations as set forth in BPC sections 31 and 494.5.

- Item 1: The form requires the applicant to disclose a social security number, or individual taxpayer identification number as required by BPC section 30(a)(1).
- Items 2-9: Items 2-9 seek identifying information about the applicant, including birth date, legal name, mailing address(address of record which may be a p.o. box under the provisions of BPC section 27(a)), primary practice location (physical address), email address (optional), telephone number, fax number (optional), and dental license number. These items of information are necessary to verify the applicant's identity and eligibility (licensee in good standing per BPC section 1647.19(a)) and ensures accuracy in the processing of the application and enable the Board to communicate more efficiently with the applicant.
- Item 10: The form asks the applicant to indicate whether the applicant is currently or has served in the U.S. military as required by BPC section 114.5.
- Item 11: The form asks the applicant whether the applicant is requesting the expediting of the initial application for members of the U.S. Armed Forces who have been honorably discharged. This question is necessary to determine whether an applicant is applying for expedited review and processing as required by BPC section 115.4. The item asks the applicant to scan and attach a copy of a certificate of release from active duty (DD-214 which is the Department of Defense's standard report of separation for members of the U.S. Armed Forces that includes the necessary information for the Board to process such requests) or other evidence showing the date and type of discharge to receive expedited review. To date, the Board has not received any other type of evidence in lieu of the DD-214 but includes this possibility should it be submitted in the future to help ensure that applicants have other options for demonstrating they qualify. This information is necessary to determine whether the applicant has provided satisfactory evidence that they have met the requirements for expedited processing per BPC 115.4.
- Item 12: The form asks the applicant whether they already hold a valid license or comparable authority to practice dentistry in another U.S. state or territory, and whether their spouse or domestic partner is an active duty member of the U.S. Armed Forces and is assigned to a duty station in California under official orders. If the applicant answers yes, the form states that their application will receive an expedited review consistent with BPC section 115.5. The question is necessary to determine whether an applicant meets the requirements for expedited review and processing under BPC section 115.5.

The form asks the applicant to provide documentary evidence to support the request including: (1) a certificate of marriage or certified declaration/registration of domestic partnership filed with the Secretary of State or other documentary evidence of legal union with an active-duty member of the Armed Forces; (2) a copy of the applicant's current dental license in another state, district, or territory of the United States; and (3) a copy of the military orders establishing your spouse or partner's duty station in California. These documents are necessary to verify and ensure the applicant meets the statutory requirements for expediting the licensure process by requesting official government documents, licenses and military records to substantiate the information provided to the Board. To date, the Board has not received any other type of evidence in lieu of a certificate of marriage or certified declaration/registration of domestic partnership but includes this possibility of "other documentary evidence" should it be submitted in the future to help ensure that applicants have other options for demonstrating they qualify.

- Item 13: The form asks the applicant to indicate whether (1) the applicant was admitted to the United States as a refugee pursuant to section 1157 of Title 8 of the United States Code; or (2) the applicant was granted asylum by the Secretary of Homeland Security or the Attorney General of the United States pursuant to section 1158 of Title 8 of the United States Code; or, (3) the applicant has a special immigrant visa and was granted a status pursuant to section 1244 of the Public Law 110-181, Public Law 109-163, or section 602(b) of Title VI of division F of Public Law 111-8 [relating to Iraqi and Afghan translators/interpreters of those who worked for or on behalf of the United States government]. These questions are necessary to determine whether the applicant qualifies for expediting of the initial application for refugees, asylees, and holders of special immigrant visas as required by BPC section 135.4(a)'s criteria for expediting these types of applications.

If the applicant answers yes, they are requested to attach official documents commonly issued by federal agencies or the courts for the categories of individuals listed in section 135.4 as evidence of their status as a refugee, asylee, or special immigrant visa holder which includes:

- Form I-94, arrival/departure record, with an admission class code such as "re" (refugee) or "ay" (asylee) or other information designating the person a refugee or asylee.
- Special immigrant visa that includes the "si" or "sq."
- A permanent resident card (Form I-551), commonly known as a "green card," with a category designation indicating that the person was admitted as a refugee or asylee.
- An order from a court of competent jurisdiction or other documentary evidence that provides reasonable assurances to the Board that the applicant qualifies for expedited licensure per BPC section 135.4.

These documents are necessary to verify and ensure the applicant meets the statutory requirements for expediting the initial application process. Copies of official government documents will help ensure the accuracy of the information provided by the applicants to the Board.

- Statement before Item 14: Section 1044.5 sets forth specified minimum standards applicable to facilities and equipment for all facilities that administer adult oral conscious sedation to patients. The form states: Facilities and Equipment Requirements - All equipment must be maintained, tested, and inspected according to the manufacturers' specifications. This statement is necessary to educate the applicant regarding this standard and the Board's legal requirements applicable to facilities and equipment in section 1044.5 (as proposed to be amended by this section – see rationale below).
- Item 14: The form asks the applicant whether the facility has an operatory large enough to adequately accommodate the patient and permit a team consisting of at least three individuals to freely move about the patient. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1044.5(a)(1).
- Item 15: The form asks whether the facility has a table or dental chair which permits the patient to be positioned so the attending team can maintain the airway, quickly alter patient position in an emergency, and provide a firm platform for the management of cardiopulmonary resuscitation. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1044.5(a)(2).
- Item 16: The form asks whether the facility has a lighting system that is adequate to permit evaluation of the patient's skin and mucosal color and a backup lighting system which is battery powered and of sufficient intensity to permit completion of any treatment underway at the time of general power failure. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1044.5(a)(3).
- Item 17: The form asks whether the facility has a functional suctioning device that permits aspiration of the oral and pharyngeal cavities and a backup suction device that can function at the time of general power failure. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1044.5(a)(4).
- Item 18. A.: The form asks whether the facility has a positive pressure oxygen delivery system capable of administering greater than 90% oxygen at a 10 litre/minute flow for a least sixty minutes (650 litre “e” cylinder) even in the event of a

general power failure. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1044.5(a)(5).

- Item 18. B.: The form asks if all equipment at the facility age-appropriate and capable of accommodating the patients being seen at the permit-holder's office. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1044.5(a)(5).
- Item 19: The form asks whether the facility has inhalation sedation equipment, and if used in conjunction with oral sedation, whether it has the capacity for delivering 100%, and never less than 25%, oxygen concentration at a flow rate appropriate for an age-appropriate patient's size, and has a fail-safe system. If the answer is yes, the form asks whether the equipment maintained and checked for accuracy at least annually. These questions are necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1044.5(a)(6).
- Item 20: The form asks whether the facility has the ancillary equipment set forth in section 1044.5(b)(1) through (4), which includes the following equipment: (1) age appropriate oral airways capable of accommodating patients of all sizes, (2) age appropriate sphygmomanometer with cuffs of appropriate size for patients of all sizes, (3) precordial/pretracheal stethoscope, and (4) pulse oximeter. The question also asks if this equipment is maintained at the facility in good operating condition. These questions are necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1044.5(b)-(1) through (4).
- Question before Item 21: The form asks whether the applicant maintains the records listed in items 22 through 25 to establish whether the applicant meets the minimum recordkeeping standards in section 1044.5.
- Item 22: The form requires the applicant to provide information as to whether the applicant maintains adequate medical history and physical evaluation updated prior to each administration of oral conscious sedation. such records shall include but are not limited to an assessment including at least visual examination of the airway, the age, sex, weight, physical status (American Society of Anesthesiologists classification), and rationale for sedation of the patient as well as 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. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1044.5(c)(1).
- Item 23: The form asks the applicant whether the applicant maintains oral conscious sedation records including baseline vital signs. if obtaining baseline vital signs is prevented by the patient's physical resistance or emotional condition, the reason or reasons must be documented. the records shall also include intermittent quantitative

monitoring and record of oxygen saturation, heart and respiratory rates, blood pressure as appropriate for specific techniques, the name, dose and time of administration of all drugs administered including local and inhalation anesthetics, the length of the procedure, any complications of oral sedation and a statement of the patient's condition at the time of discharge. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1044.5(c)(2).

- Item 24: The form asks whether the applicant maintains documentation showing that all emergency equipment and drugs are checked and maintained on a prudent and regularly scheduled basis. This question is necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1044.5(d).
- Item 25: The form asks whether the applicant has available and readily accessible an emergency kit or cart that includes:
 1. The necessary and appropriate emergency drugs and size-appropriate equipment to resuscitate a nonbreathing and unconscious patient and provide continuous support while the patient is transported to a medical facility; and
 2. Emergency drugs of the following types:
 - Epinephrine
 - Bronchodilator
 - Appropriate drug antagonist
 - Antihistaminic
 - Anticholinergic
 - Anticonvulsant
 - Oxygen
 - Dextrose or other antihypoglycemic

These questions are necessary so the Board can determine whether the applicant satisfies the requirements set forth in section 1044.5(d).

- Item 26: The form asks the applicant to provide the addresses of all locations of practice where the applicant will administer or order the administration of oral conscious sedation and states "All offices shall meet the standards set forth in regulations adopted by the board at Title 16, California Code of Regulations section 1044.5." This question is necessary to inform the applicant of these requirements, identify the locations where administration will occur for the purposes of future investigation and inspection and also so the Board can verify that the legal requirements set forth in section 1044.5 are met at each location. To help ensure the Board receives complete information, the applicant is directed to "if necessary, continue on the back of this page."

- Certification under penalty of perjury: The form requires the applicant certify under penalty of perjury under the laws of the State of California that the foregoing information including attachments, is true and correct by providing a signature and date. The Board relies upon applicants' self-reported information in evaluating applications. This requirement helps ensure that the representations on the form are accurate, truthful and made in good faith.
- Information Collection and Access section: The form includes the required notices and disclosures to the applicant for the Board's collection of personal information in compliance with Civil Code section 1798.17.

Note:

The Board proposes to delete BPC section 1647.10 and 1647.11 from the Reference section. This is necessary because this regulation does not implement, interpret or make these statutes specific.

Section 1044.2. Board Approved Programs.

The Board proposes to add "of the Code" and capitalize "board" for clarity and consistency throughout the regulations.

The Board proposes to delete BPC section 1647.12(b) because this subdivision will be eliminated effective January 1, 2022.

Note:

The Board proposes to delete BPC section 1647.11 and 1647.12 from the Reference section. This is necessary because this regulation does not implement, interpret or make these statutes specific.

Section 1044.3. Board Approved Education.

Subdivision (a)

The Board proposes to delete "minor" because, effective January 1, 2022, the Board will no longer issue the OCSP for minors. (Bus. & Prof. Code, § 1647.35.)

Subdivision (b)

The Board proposes to capitalize "board" for consistency throughout the regulations.

The Board proposes to delete "The program shall be directed solely toward either the administration of oral conscious sedation to adult patients or the administration of oral conscious sedation to minor patients." This is necessary because, effective January 1,

2022, under amendments enacted by SB 501 to the Act, this section will only apply to the administration of oral conscious sedation for adult patients.

Subdivision (b)(1)

The Board proposes to delete “Business and Professions” before “Code” for consistency throughout the regulations.

Subdivision (b)(4)

The Board proposes to replace “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board proposes to delete “and the American Academy of Pediatric Dentistry” as this was a requirement for the oral conscious sedation for minors permit which will be repealed effective January 1, 2022 under amendments to the Act by SB 501.

Note:

The Board proposes to delete BPC section 1647.10 and 1647.12 from the Reference section. This is necessary because this regulation does not implement, interpret or make these statutes specific.

Section 1044.4. Documentation of 10 Cases.

The Board proposes to repeal section 1044.4 because the requirement is outdated and the authorizing section for this regulation will be repealed effective January 1, 2022 along with the other provisions of Article 2.86 under BPC section 1647.17.5. These outdated provisions will be replaced by Article 2.87 of the Act governing pediatric minimal sedation effective January 1, 2022.

BPC section 1647.20 provides that a dentist who desires to administer, or order the administration of, oral conscious sedation for adult patients, who does not hold a general anesthesia permit, does not hold a conscious sedation permit and has not been certified by the board to administer oral conscious sedation to minor patients, must register with the board. Among other requirements, a dentist who has been using oral conscious sedation with the treatment of adult patients must submit documentation of 10 cases of oral conscious sedation satisfactorily performed by the applicant on

adult patients in any three-year period ending no later than December 31, 2005. (Bus. & Prof. Code, § 1647.20, subd. (d).)

Section 1044.5. Facility and Equipment Standards.

The Board proposes to amend the preface to this regulation by adding “All equipment shall be maintained, tested and inspected according to the manufacturers’ specifications.”

This is necessary because equipment can become faulty or expire. In order to safely administer sedation to the consumers of California the Board must ensure that permit holders are maintaining their equipment and the manufacturer can provide the appropriate specifications. Operating equipment according to manufacturers’ specifications helps ensure overall equipment effectiveness in administration for the patient and in the event of an emergency for the protection of the public.

Subdivision (c)(1)

This section will be amended to add “patient’s conservator, or the informed consent of a person authorized to give such consent for the patient” and delete “parent or legal guardian of the patient.”

This is necessary because the Board wishes to broadly provide the categories of person who can provide written consent to more broadly reflect the legal representatives who could be providing consent on behalf of the patient.

The Board adds a “patient’s conservator” because conservators may be appointed may be appointed for a person who is unable to provide properly for his or her personal needs for physical health, food, clothing, or shelter. (Prob. Code, § 1801, subd. (a).) The Board adds a catch-all category for other persons “authorized to give such consent for the patient” to refer to guardians or other persons who are authorized to make healthcare decisions, such as those possessing an advance health care directive. (Prob. Code, § 4701.)

Note:

The Board proposes to delete BPC section 1647.10 and 1647.16 from the Reference section. This is necessary because this regulation does not implement, interpret or make these statutes specific.

Section 1070.8. Approval of Dental Sedation Assistant Permit Courses

Subdivision (a)(3)

The Board proposes to replace “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board proposes to add “deep sedation” because the Board will, pursuant to BPC section 1646.2(a), be issuing a permit which grants the permit the holder the right to administer both general anesthesia and deep sedation. Additionally, BPC section 1750.5 authorizes dental sedation permitholders to monitor patients undergoing moderate sedation, deep sedation, or general anesthesia. (Bus. & Prof. Code, § 1750, subd. (a)(2).) Accordingly, it is necessary for those instructing students to possess expertise in deep sedation.

Subdivision (b)

The Board replaces “subdivisions” with “subsections” for consistency throughout the regulations.

The Board proposes to replace “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board proposes to add “deep sedation” because BPC section 1750.5 authorizes dental sedation permitholders to monitor patients undergoing moderate sedation, deep sedation, or general anesthesia. (Bus. & Prof. Code, § 1750, subd. (a)(2).) Accordingly, it is necessary for clinical instruction to include cases involving deep sedation.

Subdivision (c)(1)

The Board proposes to delete “Cal. Code Regs., Title 16,” delete “Business and Professions,” and add “of the Code” for consistency throughout the regulations.

The Board proposes to replace “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either

alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board proposes to add “deep sedation” because the Board has amended section 1043 to include deep sedation, and subdivision (c)(1) cross-references section 1043.

Subdivision (c)(2)

The Board proposes to delete “Business and Professions,” and add “of the Code” for consistency throughout the regulations.

Subdivision (d)

The Board replaces “subdivisions” with “subsections” for consistency throughout the regulations.

Subdivision (e)(6)

The Board proposes to replace “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

Subdivision (e)(7)

The Board proposes to replace “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board proposes to add “deep sedation” because BPC section 1750.5 authorizes dental sedation permit holders to monitor patients undergoing moderate sedation, deep sedation, or general anesthesia. (Bus. & Prof. Code, § 1750, subd. (a)(2).)

Subdivision (g)(3)

The Board proposes to replace “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

Subdivision (g)(8)

The Board proposes to add “and resuscitation of pediatric patients” to this subdivision because the Act, as amended by SB 501, prescribes this as required training for personnel. (Bus. & Prof. Code, §§ 1647.32, subds. (c)(1) and (2) & 1682, subd. (b).) Therefore, it is necessary to add resuscitation of pediatric patients to the required didactic instruction in this regulation to ensure help ensure competency for future applicants.

Subdivision (i)(2)

The Board proposes to replace “conscious” with “moderate” because SB 501 repeals existing provisions relating to the use of conscious sedation. The bill replaces the term “conscious sedation” with “moderate sedation,” meaning “a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient’s airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.” (Bus. & Prof. Code, § 1647.1; see also, Bus. & Prof. Code, §§ 1647.2 & 1647.3.)

The Board proposes to add “deep sedation” because BPC section 1750.5 authorizes dental sedation permitholders to monitor patients undergoing moderate sedation, deep sedation, or general anesthesia. (Bus. & Prof. Code, § 1750, subd. (a)(2).) Therefore, it is necessary to add deep sedation to this subdivision so didactic instruction includes instruction in deep sedation records.

Subdivision (j)(2), (k)(2), (l)(3), (m)(3), (n)(3)

The Board proposes to make a minor grammatical change and for consistency throughout the regulations to lowercase the “s” in “Section” in the above cited subsections.

Underlying Data:

1. Senate Bill 501 (Chapter 929, Statutes of 2018)

2. Pediatric Anesthesia Study, December 2016
3. Dental Board of California's Fee Workload Cost Analysis (Fee for Application for: General Anesthesia Permit for Dentist, General Anesthesia Permit for Physician and Surgeon, Moderate Sedation Permit, Pediatric Minimal Sedation Permit, Oral Conscious Sedation Permit for Adults, Pediatric Endorsement for General Anesthesia and Moderate Sedation Permits, and Pediatric Minimal Sedation Permit Renewal)
4. DBC Meeting Minutes, May 16-17, 2018
5. DBC Meeting Minutes, May 13-14, 2021
6. Draft Excerpt DBC Meeting Minutes, Agenda and Materials for Item 22 for November 18-19, 2021 meeting

Business Impact:

The Board has made the initial determination that the proposed regulations would not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other States. This initial determination is based on the following facts.

This regulation may have an economic impact on businesses, specifically, the Board's licensees, permit holders and applicants. The proposal would: (1) increase the fee for an application for the general anesthesia permit (for dentist and physician licensees) to \$524, (2) increase the fee for an application for a moderate sedation permit to \$524, (3) set a new fee for an application for pediatric minimal sedation permit at \$459, (4) set a new pediatric minimal sedation permit renewal fee at \$182, (5) increase the fee for an application for adult oral conscious sedation certificate to \$459, (6) set a new fee for the application for pediatric endorsement for general anesthesia permit at \$532; and, (7) set a new fee for the pediatric endorsement for moderate sedation permit at \$532. To the extent these applicants apply for such permits, or licensees opt to renew their licenses and permits, the proposed regulations will impact them.

Licensees who seek to administer general anesthesia and moderate sedation to pediatric patients may incur costs to provide the Board documentation showing completion of required cases at the time of renewal. However, those costs are anticipated to be minimal considering the number of cases required to be documented.

There is no cost to California businesses except for those of dental offices in which deep sedation, general anesthesia, moderate sedation, pediatric minimal sedation, and oral conscious sedation for adult patients is administered. The cost includes application and renewal fees which are minimal in comparison with the income of such individuals. According to online data, the annual salary of a dentist who practices in California averages \$169,000 per year. In addition, these fees represent incremental increases compared with what is currently being charged by the Board for the same services (increases of \$24, \$91, \$532, and \$14).

Economic Impact Assessment:

This regulatory proposal will have the following effects:

- It will not create nor eliminate jobs within the State of California because this proposal will not be of sufficient magnitude to have the effect of creating or eliminating jobs. The Board has made this determination because this proposal pertains to the adoption of new anesthesia or sedation permits and endorsements and would only impact individual applicants who are applying for the permits and/or endorsements. The cost includes application and renewal fees which are minimal in comparison with the income of such individuals. In addition, these fees represent incremental increases compared with what is currently being charged by the Board for the same services (increases of \$24, \$91, \$532, and \$14). The proposed regulation will require permit holders who administer anesthesia and sedation to pediatric patients to document continued competency by completing a minimal number of cases to provide public protection.
- It will not create new business or eliminate existing businesses within the State of California because this proposal will not be of sufficient magnitude to have the effect of creating or eliminating jobs. The Board has made this determination because this proposal pertains to the adoption of new anesthesia/sedation permits and endorsements and would only impact individual applicants who are applying for the permits and/or endorsements. The cost includes application and renewal fees which are minimal in comparison with the income of such individuals. In addition, these fees represent incremental increases compared with what is currently being charged by the Board for the same services (increases of \$24, \$91, \$532, and \$14). The Board does not anticipate that this will create or eliminate existing businesses in which anesthesia or sedation is administered as the cases required to document competency for the renewal of the general anesthesia and moderate sedation permits are minimal.
- It will not affect the expansion of businesses currently doing business within the State of California because this proposal will not be of sufficient magnitude to limit or further the expansion of businesses. The Board has made this determination because this proposal pertains to the adoption of new anesthesia/sedation permits and endorsements and would only impact individual applicants who are applying for the permits and/or endorsements. The cost includes application and renewal fees which are minimal in comparison with the income of such individuals. In addition, these fees represent incremental increases compared with what is currently being charged by the Board for the same services (increases of \$24, \$91, \$532, and \$14). The Board does not anticipate that this will affect the expansion of businesses in which anesthesia or sedation is administered as the cases

required to document competency for the renewal of the general anesthesia and moderate sedation permits are minimal.

- This regulatory proposal affects the health and welfare of California residents because the proposed regulation will further increase the priority of the Board which is the protection of the public. The adoption of the new permits and endorsements ensures that individual applicants will be current and up to date with the latest in sedation and anesthesia process/methods to ensure that they can perform procedures on consumers consistent with minimum standards for safety and care. The proposal will also benefit the health and welfare of California residents by verifying continued competency is maintained by general anesthesia and moderate sedation permit holders.
- This regulatory proposal does not affect worker safety because the regulations pertain to the Board's adoption of new anesthesia/sedation permits and endorsements and would only impact individual applicants who are applying for the permits and/or endorsements and is not related to worker safety.
- This regulatory proposal does not affect the state's environment because the regulations pertain to the Board's adoption of new anesthesia/sedation permits and endorsements, and this proposal is not relevant to the State's environment.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Cost Impacts a Representative Private Person or Business Will Incur:²

The Board has determined that the following individuals may be affected by the proposed changes to the Boards anesthesia and sedation permit program:

Applicants and existing permit holders of the general anesthesia, moderate sedation, pediatric minimal sedation, or oral conscious sedation for adult's permits, and pediatric endorsement for general anesthesia or moderate sedation permit holders that pay initial application and renewal fees.

The following chart displays current fee amounts, proposed fee amounts and the incremental increase these individuals will be required to pay as follows:

² The Board places this information in the initial statement of reasons since it cannot utilize charts in the notice for accessibility reasons.

Dental Board of California SB 501 - Permits and Fee (Current and Proposed) Amounts

Registration and License Type	Current Fee Amount	Proposed Fee Amount	Incremental Change
General Anesthesia Permit (initial)	\$500	\$524	\$24
Moderate Sedation Permit (initial)	\$500	\$524	\$24
Pediatric Minimal Sedation Permit (initial)	\$368	\$459	\$91
Adult Oral Conscious Sedation Certificate (initial)	\$368	\$459	\$91
*Pediatric Endorsement for General Anesthesia Permit (initial)	\$0	\$532	\$532
*Pediatric Endorsement for Moderate Sedation Permit (initial)	\$0	\$532	\$532
Pediatric Minimal Sedation Permit (renewal)	\$168	\$182	\$14

*New

The proposed regulations are anticipated to result in an economic impact to permit holders ranging from approximately \$141,000 to \$447,000 per year and up to \$2.5 million over a ten-year period as follows:

Dental Board of California SB 501 - Applications (Economic Impact)																		
Registration and License Type	Current Fee	Proposed Fee	Incremental Change	Applicants Per Year	Years Ongoing										Total			
					1	2	3	4	5	6	7	8	9	10				
General Anesthesia Permit (initial)	\$500	\$524	\$24	50	50	50	50	50	50	50	50	50	50	50	50	50	450	
				Sub-total:	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$12,000	
Moderate Sedation Permit (initial)	\$500	\$524	\$24	Various	175	459	175	45	45	45	45	45	45	45	45	45	382	
				Sub-total:	\$4,272	\$11,736	\$4,272	\$1,080	\$1,080	\$1,080	\$1,080	\$1,080	\$1,080	\$1,080	\$1,080	\$1,080	\$10,800	
Pediatric Minimal Sedation Permit (initial)	\$368	\$459	\$91	Various	377	1,071	377	60	60	60	60	60	60	60	60	60	1,885	
				Sub-total:	\$34,307	\$37,461	\$34,307	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$204,295	
Adult Oral Conscious Sedation Certificate (initial)	\$368	\$459	\$91	75	75	75	75	75	75	75	75	75	75	75	75	75	684	
				Sub-total:	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$69,160	
Pediatric Endorsement for General Anesthesia Permit (initial)	\$0	\$532	\$532	482	482	507	25	25	25	25	25	25	25	25	25	25	707	
				Sub-total:	\$256,424	\$269,724	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$62,548
Pediatric Endorsement for Moderate Sedation Permit (initial)	\$0	\$532	\$532	Various	83	115	23	23	23	23	23	23	23	23	23	23	286	
				Sub-total:	\$47,348	\$59,584	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$204,820
Pediatric Minimal Sedation Permit (renewal)	\$0	\$182	\$182	Various	0	0	377	1,071	754	1,131	814	1,191	874	1,251	6,308	6,308	6,308	
				Sub-total:	\$0	\$0	\$68,614	\$194,922	\$137,228	\$205,842	\$148,148	\$216,762	\$159,068	\$227,682	\$135,826	\$135,826	\$1,358,266	
				Total Impact:	\$350,467	\$446,621	\$140,845	\$235,114	\$177,420	\$246,034	\$188,340	\$256,954	\$199,260	\$267,874	\$2,508,929			

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State:³

The Board anticipates workload will be greatest in the first two-years of implementation as existing and new applicants transition to the new permit types.

Permit application workload costs are estimated to range from approximately \$141,000 to \$447,000 per year and up to \$2.5 million over a ten-year period as follows:

³ The Board places this information in the initial statement of reasons since it cannot utilize charts in the notice for accessibility reasons.

Dental Board of California SB 501 - Permit Workload (Fiscal Impact)																	
Registration and License Type	Current Fee	Proposed Fee	Incremental Change	Applicants Per Year	Years Ongoing										Total		
					1	2	3	4	5	6	7	8	9	10			
General Anesthesia Permit (initial)	\$500	\$524	\$24	50	50	50	50	50	50	50	50	50	50	50	50	500	
				Sub-total:	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$12,000	
Moderate Sedation Permit (initial)	\$500	\$524	\$24	Various	179	489	179	45	45	45	45	45	45	45	45	1,800	
				Sub-total:	\$4,272	\$11,736	\$4,272	\$1,080	\$1,080	\$1,080	\$1,080	\$1,080	\$1,080	\$1,080	\$1,080	\$27,840	
Pediatric Minimal Sedation Permit (initial)	\$368	\$459	\$91	Various	377	1071	377	60	60	60	60	60	60	60	60	2,245	
				Sub-total:	\$34,307	\$97,461	\$34,307	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$204,295	
Adult Oral Conscious Sedation Certificate (initial)	\$368	\$459	\$91	76	76	76	76	76	76	76	76	76	76	76	76	760	
				Sub-total:	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$69,160	
Pediatric Endorsement for General Anesthesia Permit (initial)	\$0	\$532	\$532	Various	482	807	25	25	25	25	25	25	25	25	25	1,893	
				Sub-total:	\$256,424	\$269,724	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$832,548
Pediatric Endorsement for Moderate Sedation Permit (initial)	\$0	\$532	\$532	Various	39	112	23	23	23	23	23	23	23	23	23	286	
				Sub-total:	\$47,348	\$59,584	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$204,820	
Pediatric Minimal Sedation Permit (renewal)	\$0	\$182	\$182	Various	-	-	377	1071	754	1,131	814	1,191	874	1,251	6,308		
				Sub-total:	\$-	\$-	\$68,614	\$194,922	\$137,228	\$205,842	\$148,148	\$216,762	\$159,068	\$227,682	\$1,358,266		
				Total Impact:	\$350,467	\$446,621	\$140,845	\$235,114	\$177,420	\$246,034	\$188,340	\$256,954	\$193,260	\$267,874	\$2,508,929		

Permit application revenue is estimated to range from approximately \$141,000 to \$447,000 per year and up to \$2.5 million over a ten-year period as follows:

Dental Board of California SB 501 - Permit Revenues (Fiscal Impact)																
Registration and License Type	Current Fee	Proposed Fee	Incremental Change	Applicants Per Year	Years Ongoing										Total	
					1	2	3	4	5	6	7	8	9	10		
General Anesthesia Permit (initial)	\$500	\$524	\$24	50	50	50	50	50	50	50	50	50	50	50	500	
				Sub-total:	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$1,200	\$12,000	
Moderate Sedation Permit (initial)	\$500	\$524	\$24	Various	179	489	179	45	45	45	45	45	45	45	1,800	
				Sub-total:	\$4,272	\$11,736	\$4,272	\$1,080	\$1,080	\$1,080	\$1,080	\$1,080	\$1,080	\$1,080	\$27,840	
Pediatric Minimal Sedation Permit (initial)	\$368	\$459	\$91	Various	377	1071	377	60	60	60	60	60	60	60	2,245	
				Sub-total:	\$34,307	\$97,461	\$34,307	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$5,460	\$204,295	
Adult Oral Conscious Sedation Certificate (initial)	\$368	\$459	\$91	76	76	76	76	76	76	76	76	76	76	76	760	
				Sub-total:	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$6,916	\$69,160	
Pediatric Endorsement for General Anesthesia Permit (initial)	\$0	\$532	\$532	Various	482	807	25	25	25	25	25	25	25	25	1,893	
				Sub-total:	\$256,424	\$269,724	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$13,300	\$832,548
Pediatric Endorsement for Moderate Sedation Permit (initial)	\$0	\$532	\$532	Various	39	112	23	23	23	23	23	23	23	23	286	
				Sub-total:	\$47,348	\$59,584	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$12,236	\$204,820
Pediatric Minimal Sedation Permit (renewal)	\$0	\$182	\$182	Various	-	-	377	1071	754	1,131	814	1,191	874	1,251	6,308	
				Sub-total:	\$-	\$-	\$68,614	\$194,922	\$137,228	\$205,842	\$148,148	\$216,762	\$159,068	\$227,682	\$1,358,266	
				Total Revenues:	\$350,467	\$446,621	\$140,845	\$235,114	\$177,420	\$246,034	\$188,340	\$256,954	\$193,260	\$267,874	\$2,508,929	

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome 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.

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.

Incorporated by Reference:

The following 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)